PACKINGHOUSE WITH HACCP
AUDIT SCORING GUIDELINES

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Used in conjunction with v08.06 facility audits.

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The PrimusLabs.com Facility 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 compliance criteria in different situations, with the 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.

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

Please be aware that there is additional information on the PrimusLabs.com website including the actual audit templates, web based audit entry system http://www.primuslabs.com/rs/documents.aspx.

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

1st Party Auditors, e.g. used by 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, PrimusLabs.com employed auditors, PrimusLabs.com subcontracted auditors and any affiliated auditors who are using the PrimusLabs.com templates.

Useful websites that help further investigate food safety requirements include:-

FDA "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables"
http://vm.cfsan.fda.gov/%7Edms/prodguid.html%20
Current Good Manufacturing Practices (GMPs) regulations 21 CFR 100-169
http://www.cfsan.fda.gov/~lrd/cfr110.htmlFood Code 2005 edition http://www.cfsan.fda.gov/~dms/fc05-toc.html
Guidence for Industry Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance http://vm.cfsan.fda.gov/~dms/secguid.html
Guidance on Inspection of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients http://www.fda.gov/ora/inspect_ref/igs/Allergy_Inspection_Guide.htm
USDA/FDA Food Safety Information Center,
http://foodsafety.nal.usda.gov/nal_display/index.php?info_center=16&tax_level=1
California Leafy Green Handler Market Agreement GAP Metrics
http://www.caleafygreens.ca.gov/members/resources.asp

Audit Template Definitions, Audit Structures and Scoring Systems

There are currently seven facility audit templates covering the supply chain: -

- **Cooling and Cold Storage Audit.**
  This audit is designed to be used for facilities that are receiving goods directly from the fields, orchards etc. after harvest. If there is any packing, repacking, grading etc. occurring on site, then a Packinghouse Audit should be used.
- **Cooling and Cold Storage with HACCP Audit.**
  Some buyers are requesting facilities to create and maintain HACCP Systems for their products. PrimusLabs.com offers its Cooling and Cold Storage, Packinghouse and Processing Audits with a HACCP Audit section added onto the standard version. This audit is designed to be used for facilities that are receiving goods directly from the fields, orchards etc. after harvest. If there is any packing, repacking, grading etc. occurring on site, then a Packinghouse Audit should be used.
- **Packinghouse Audit.**
  This audit should be used for any operation that is storing (cold or ambient temps), grading, packing, repacking, washing whole produce etc. If the item is being sliced, shredded, dried, juiced etc., then a Processing Audit should be used.
- **Packinghouse with HACCP Audit.**
  Some buyers are requesting facilities to create and maintain HACCP Systems for their products. PrimusLabs.com offers its Cooling and Cold Storage, Packinghouse and Processing Audits with a HACCP Audit section added onto the standard version.
- **Processing Audit.**
  This audit should be used for any operation that is storing (cold or ambient temps), washing and slicing, shredding, drying, juicing etc. any item i.e. any "further processed" items.
- **Processing with HACCP Audit.**
  Some buyers are requesting facilities to create and maintain HACCP Systems for their products. PrimusLabs.com offers its Cooling and Cold Storage, Packinghouse and Processing Audits with a HACCP Audit section added onto the standard version.
- **Storage and Distribution.**
  This audit is designed to be used on facilities that are receiving and storing finished goods e.g. regional distribution warehouses. If there is any packing, repacking, grading etc. occurring on site, then a Packinghouse Audit should be used.

Audit Template Structures

- *GMP Section*, covering the physical tour of the facility
- *Food Safety File*, covering 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 Security 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*. Yes/No questions that do not form part of the main audit at present and are not scored.
- *New Questions*. These are scored individually and are not part of the overall audit score. Please note that these questions are 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.com facility audits:

Point System (Weighting) for Individual Questions				
Possible Question Points	Full compliance	Minor Deficiency	Major Deficiency	Non-compliance
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 compliance have to be looked at individually and scored according to the severity of the deficiency, the number of deficiencies and the associated risks. Detailed compliance requirements are noted in this Point Assignment Guidelines, but some general statements are described below. These statements are superseded by the compliance criteria and users should be aware that some questions do not follow the general statements below e.g. automatic failure questions.

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

Automatic Failure

There are four questions in the facility audits, 1.2.1, 1.2.2, 1.2.5 and 1.3.5, 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 and complete the audit or to have the audit halt at that point (all charges will apply).**

Once an audit has been started it cannot be converted into a pre-assessment audit. This includes when an automatic failure question as 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; the audit can either be cancelled (with charges) or turned into a pre-assessment (see texts below).

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 contacts, 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 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 i.e. in operation less than three months of the year). Please note that the auditor cannot accept documentary evidence after the audit has ended e.g. if on the audit, a pest control document is missing 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 him or herself 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. These questions are scored.
- **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 collate 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. Auditors however do expedite audit reports very quickly and auditees should contact PrimusLabs.com 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 (what ever functions are usually occurring as on a "normal" day) and that a normal compliment 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.

If the facility has less than three months of most of their paperwork available for review and is not a short season crop packing facility (in operation for less than three months of the year) a pre-assessment audit is strongly advised. If the auditee has less than three months of most of their paperwork available for review and decides to have a regular audit, they should be aware that they cannot receive full compliance for paperwork questions relating to monitoring and that the downscore will be based on amount of paperwork available. Short season operations should have previous season's records available for auditor review.

For further information about the facility audit process and booking facility audits please go to http://www.primuslabs.com/docs/PrimusLabsAuditBookingWebpageRev10101707.pdf

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 confirmations should be the exception to the rule and if auditing properly, these should be rarely used. If a verbal confirmation is accepted, then the auditor should write this in the comments on 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 far 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 has to 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.com 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 "shoulds" – these can be scored. In some questions, the term "ideally" maybe used; these statements cannot be scored against, but give the auditee an opportunity for improvement.

Notes in "red" are where the questions and/or compliance criteria have been changed significantly. 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, which 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

General Food Safety

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

Non-compliance (0 points) if:
- No-one is in charge of food safety programs including verification of sanitation activities.

1.1.2 Are all chemicals (pesticides, sanitizers, detergents, lubricants, etc.) stored securely, safely and are they labeled correctly?
Visual confirmation. Total compliance (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 labels of contents; this includes 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 (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. Liquid 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-compliance (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.

1.1.3 Are "food grade" and "non-food grade" chemicals handled and stored in a controlled manner?
Visual/Records confirmation. Total compliance (10 points): Food grade chemicals, including lubricants, greases, etc., are used in all product/packing contact areas. Food grade chemicals should be stored apart from non-food grade items to eliminate confusion between types. 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; office cleaning materials, restroom cleaning material, truck cleaning materials should be stored separately from production cleaning materials. 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 website:-
NSF International: Nonfood Compounds
http://www.nsf.org/business/nonfood_compounds/index.asp?program=NonFoodComReg

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.

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.

Non-compliance (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.
- **Evidence of the use of a non-food grade that has caused product contamination – revert to 1.3.5, automatic failure.**

1.1.4 Are signs supporting GMPs posted appropriately?
Visual Confirmation. Total compliance (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/beard restraints and smocks.
- Before areas that prohibit food, tobacco products, chewing gum.
- Bathrooms and break-room(s) should have hand-washing signs as reminders to wash hands before returning to work.

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/nal_display/index.php?info_center=14&tax_level=3&tax_subject=231&topic_id=1198&level3_id=5075

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-compliance (0 points) if:

- Systematic failure to place signs in the required positions.

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Pest Control

1.2.1 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 compliance (15 points): Products and ingredients are free from evidence or the presence of insects/rodents/birds/reptiles/mammals (humans, dogs, etc.). See 1.2.3 for reference potential indications of pest presence.

Automatic Failure (0 points) if:

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

1.2.2 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 compliance (15 points): Packaging supplies are free from evidence or the presence of insects/rodents/birds/reptiles/mammals (humans, dogs, etc.). See 1.2.3 for reference potential indications of pest presence.

Automatic Failure (0 points) if:

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

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

Visual confirmation. Total compliance (10 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 live animals observed inside the facility such as cats, dogs, deer, etc.
- 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/menu.house.html

Minor deficiency (7 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 (3 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-compliance (0 points) if:
- One active sighting 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. (This qualifies as an automatic failure under 1.2.1 and 1.2.2)**

1.2.4 Is the area outside the facility free of evidence of pest activity?
Visual Confirmation. Total compliance (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 e.g. 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 point) 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-compliance (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 1.2.1 and 1.2.2.**

1.2.5 Does the operation have a pest control program?
Visual confirmation. Total compliance (15 points): The operation has a pest control program (in-house or contracted)**. ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.**

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

1.2.6 Are pest control devices (inc. rodent traps and electrical fly killers) located away from exposed food products? Poisonous rodent bait traps are not used within the facility?
Visual Confirmation. Total compliance (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, packing or raw materials. This includes the following restrictions:
- 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, electrical fly killers (EFK), insect light traps or pheromone traps should be regularly cleaned out (kept free from a build-up of insects and debris). Ideally electrical fly killers that use sticking as opposed to zapping methods are preferred.
- If used, electric fly killers or insect light traps should be at least 10 feet (3 meters) from product, equipment, or packaging material. Electric fly killers or insect light traps should not be located above dock doors (due to potential forklift damage and also attracting insects into the facility). Hallways where product passes through are exempt from these distances, as long as product does not stop or is not stored in hallway.
- If used, insect trap bulbs to should be replaced at least annually (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.
- Snaps traps can only be used when monitoring traps e.g. tin traps show that there is a serious problem and eradication steps are required. Snap traps should be checked daily (and recorded). Snap traps should not use allergen containing baits e.g. peanut butter. Snaps traps are only allowed as a short term emergency eradication solution since they present several risks.
- 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, 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.

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 presenting risk to product or packaging) and are lacking daily inspection logs or being used for routine monitoring (as opposed to short term eradication).

Major deficiency (3 points) if:

- Numerous instances of improperly positioning or maintaining electrical fly traps or insect light traps.
- Numerous instances fly swatters found in production or storage area.
- Numerous instances of grain or pellet baits 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 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 and are lacking daily inspection logs or being used for routine monitoring (as opposed to short term eradication).
- Snap traps being used for a short term eradication process with daily inspection logs but using an allergenic bait.

Non-compliance (0 points) if:
- More than one instance of bait/poison inside the facility (inside of a trap).
- Single instance of bait/poison 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 and are lacking daily inspection logs or being used for routine monitoring (as opposed to short term eradication).
- **Any observation of contamination of product or product contact material (this qualifies for an automatic failure and applies under 1.3.5).**

1.2.7 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 compliance (5 points): The following criteria are met:
- If non-toxic glue boards are used, they should be 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.
- Bait and other poisons should be controlled and applied by a licensed applicator (see 2.4.1).
- 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.
- Pest control devices should be checked at least monthly (checking more frequently is an ideal situation) – these checks to be recorded.

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 too. 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 traps, bait stations and glue boards not working properly or adequately maintained (check cards, cleanliness, etc)
- Single/isolated instance(s) of unsecured bait inside bait stations.
- Single/isolated instance(s) of bait stations having moldy bait.

Major deficiency (1 point) if:
- Numerous instances of traps, bait stations or glue boards not working properly or adequately maintained (check cards, cleanliness, etc)
- Numerous instances of unsecured bait inside bait station.
- Numerous instances of bait stations having moldy bait.

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

1.2.8 Are interior, exterior of the building perimeter and land perimeter pest control devices adequate in number and location?

Visual Confirmation. Total compliance (5 points): As a ***guid****e* (i.e. not expecting the use of tape measures) to number and placement of traps and bait stations:
- Traps should be positioned between 20 to 40 feet (6 to 12 meters) intervals around the inside perimeter of all rooms. Spacing might be affected by the structure, storage and types activities occurring.
- 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 Cold Storage and Cooler 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 live traps should be positioned between 50 to 100 feet (15 to 30.5 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 or live traps should be positioned between 100 to 200 feet (30.5 to 61 meters) intervals along the fencing or boundary of the facility property, except where there is a public access. *Auditor discretion applies to "fence line" perimeter pest control devices i.e. consider terrain – paved parking or field or grassland and historical pest activity to determine whether traps are adequate in number and location.*
- Outside packaging storage should be protected by an adequate number of pest control devices.

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).

- No exterior traps.

Non-compliance (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).

1.2.9 Are all pest control devices identified by a number or other code (barcode)?
Visual Confirmation. Total compliance (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 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:
- Numerous instances of the devices not labeled.
- The devices are marked on the map but the devices themselves are not numbered or the numbering sequence is incorrect.

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

1.2.10 Are all pest control devices properly installed and secured?
Visual Confirmation. Total compliance (5 points): Bait stations should be secured to minimize movement of the device and be tamper resistant. Bait stations should be secured with either a ground rod or a chain, or glued to the wall/ground, or secured with patio blocks (wall signs are required if using patio blocks). Bait stations should be tamper resistant through the use of screws, latches, locks, or by other effective means. Live traps used indoors are not required to be secured to the ground as this may affect sanitation crew activities, etc; ideally auditee makes use of 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. Effort should be made to avoid placing traps on curbing.

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

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Storage Areas & Packaging Materials

1.3.1. 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 compliance (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 contaminating 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 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; attention to ice tools and how salt for ice making is being stored and handled

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-compliance (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 1.3.5, automatic failure due to product contamination.**

1.3.2. Is the storage area completely enclosed?

Visual confirmation. Total compliance (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). This question is now in all audit templates.

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 compliance (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.

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

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

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

1.3.4. Are rejected or on hold materials clearly identified and separated from other materials?
Visual confirmation. Total compliance (10 points): All products that are being rejected or are awaiting final disposition (on hold) should be stored 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, with a date showing when the product was placed on hold/rejected and the reason for being on hold/rejected and the name of the person who put the product on hold. The tagged product should not be commingled with other goods in such a way that their disposition is not clear. Ideally have a designated hold area and disposition logs.

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 (with the required label tag details).

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 (with the required label tag details).
- 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-compliance (0 points) if:
- Rejected or on hold products are not clearly separated and identified.

1.3.5. Are products, ingredients (including ice) and food contact packaging within accepted tolerances for spoilage or adulteration? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.

Visual confirmation. Total compliance (15 points): Products, raw materials, ingredients and food contact surfaces such as packaging should 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 or adulteration would include any physical, chemical or biological contamination. This question is designed to allow an auditor to halt an audit when finding gross contamination issues (note pests are covered by 1.2.1 and 1.2.2). Examples might include glass, trash/litter, oil in products. 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.

Potentially useful websites:-
FDA/ORA compliance Policy Guide 555.425, http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-425.htm
US FDA/CFSAN Defect Action Level Handbook, http://www.cfsan.fda.gov/~dms/dalbook.html#CHPT3

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 products, packaging or ingredients, including ice.**

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

Visual confirmation. Total compliance (10 points): All storage areas should be clean and well ventilated and protected from condensation, sewage, dust, dirt, toxic chemicals or other contaminants. Ledges 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, and/or ceilings being dirty.
- Numerous instances of ingredients and packaging with dust, debris, etc.
- Numerous instances of dirty lights/light covers.

Non-compliance (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.

1.3.7 Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) properly marked with rotation codes (receipt dates, manufacture dates, etc.)?

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

1.3.8 Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) rotated using FIFO policy?

Visual/verbal confirmation. Total compliance (5 points): All materials are rotated using FIFO (First in First Out) 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 1.3.7.

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-compliance (0 points) if:

- Systematic failure to use FIFO policy on commodities, packaging, ingredients, processing aids, work in progress, etc.

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Operational Practices

1.4.1 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 compliance (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 3 inches high and are covered in some way that protects the product underneath.

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-compliance (0 points) if:
- No protective devices have been installed to eliminate potential contamination.
- Condensate/water is continuously dripping onto the process line, product or packaging.
- **Any observation of direct contamination of product, ingredient or packaging materials (except condensate). In this case the score reverts back to 1.3.5.**

1.4.2 Are packing and/or processing areas completely enclosed?

Visual confirmation. Total compliance (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 e.g. strip curtains, air curtains, speed doors, etc. Walls can be solid, fine mesh or any other pest proof material. 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 meshed or fitted with air curtain.
- One or more open walls (with no proofing), but with a proper roof and floor.

Non-compliance (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).

1.4.3 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 compliance (15 points): Production areas should be maintained in a clean and sanitary state. Auditors 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 1.3.6 which asks about storage area hygiene. Auditors should carefully note which areas are dirty when down scoring in this question. This question does not occur in the Storage and Distribution audits, or in the Cooling and Cold Storage audits.

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-compliance (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.

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

Visual/verbal confirmation. Total compliance (10 points): Rework 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). Rework possibilities will vary from product to product. Re-work areas in coolers should adhere to all required GMP's. In a cooler where the re-packing is a daily routine event, then a packinghouse audit template should be used. All re-work should be handled correctly:
- 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.

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-compliance (0 points) if:
- Three or more of the items above are not being followed.

1.4.5 Are raw ingredients examined before use?

Visual confirmation. Total compliance (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-compliance (0 points) if:
- No raw materials are examined before use.

1.4.6 Are finished products coded (carton and unit packaging) for the day of production?
Visual confirmation. Total compliance (10 points): All products are appropriately labeled, identified and possess lot numbers and/or code dating information. 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.

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 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 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-compliance (0 points) if:
- No product lot coding either on bags, pre-pack or cartons on the majority of lines.

1.4.7 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 compliance (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 2.5 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. 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. If possible the auditor should have the auditee check metal detector(s) sensitivity while touring the facility.

Potentially useful websites:-
OSU Metal Detectors For Food Processing, http://osuextra.okstate.edu/pdfs/FAPC-105web.pdf

METTLER TOLEDO Safeline, http://us.mt.com/mt/filters/products-applications_Product-Inspection_Safeline-Contaminant-Detection/Safeline-Metaldetection-X-ray_FilterHierarchy-ProductFamily_1148578324890.jsp?als=safelineus&cnty=US

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 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 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-compliance (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-compliance.
- Not using three of the required test pieces (metal detection).

1.4.8 Does the facility have 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 compliance (10 points): The strength of anti-microbial chemicals (product and cleaning) should be checked using an appropriate method e.g. chemical reaction based test, test probe, ORP or as recommended by disinfectant supplier.. 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 paper, 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 possible the auditor should have the auditee check the strength of anti-microbial chemicals while touring the facility.

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 sanitizer 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.

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

1.4.9 Are hand washing stations adequate in number, appropriate in location, in working order, have warm water and adequately stocked (e.g. disposable towels, soap, etc.)?

Visual confirmation. Total compliance (15 points): To ensure efficient employee flow there should be a minimum of one hand wash station for every 10 people. Hand washing stations should be located at access to production areas in processing and packinghouse audits; within close proximity of toilet facilities area and lunchroom area is acceptable for other facility audits. Hand washing stations should be properly stocked with 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; hot air driers are acceptable if properly located (hot air driers should not be located within production areas since they create aerosols). There should 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. 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 1.8.10.

Minor deficiency (10 points) if:
- Only about 50% of needed hand washing stations are present.
- Single/isolated instance(s) of hand washing stations not in working order
- Only about 50% of hand washing stations have warm water or where water is too hot.
- 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 25% of needed hand washing stations are present.
- Numerous instances of hand washing stations not in working order.
- Only about 25% of hand washing stations have warm water or where water is too hot.
- Only cold water is available at hand washing stations.
- 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-compliance (0 points) if:
- 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.
- No soap is provided.

1.4.10 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 compliance (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.
- There should be one toilet for every 15 employees (toilets being available to employees).
- 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.

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 1.4.9 apply.
- Cleanliness of toilet facilities is scored in 1.8.10.

Minor deficiency (10 points) if:

- One of the above criteria is not met.
- Only about 50% of required toilets are present.

Major deficiency (5 points) if:

- Two of the above criteria are not met.
- Only about 25% of required toilets are present.

Non-compliance (0 points) if:

- Less than 25% of the required toilets are provided
- Failure to provide sufficient or adequate restroom facilities.
- Three of the above criteria are not met.

1.4.11 Are secondary hand sanitation stations e.g. hand dip, gel or spray stations adequate in number and location? Are the stations maintained properly?

Visual confirmation. Total compliance (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 – common chemicals include iodine (20-25 ppm), chlorine (150-200 ppm total chlorine) and quaternary ammonium (150-200 ppm). 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; use of a refill alert type dispenser is ideal practice. See the applicability chart.

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.

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.

Non-compliance (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.

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

Visual confirmation. Total compliance (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 reused. Reuse of boxes in tomato, citrus, etc. re-pack operations should be permitted only if there are measures in place to re-inspect the containers, FIFO rotate and correct box transfer procedures in place. Returnable plastic containers, e.g. CHEP, IFCO, should be treated like single service container and only used for product. If a single service container is used for any other reason that 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.

Major deficiency (1 point) if:
- Numerous instance(s) of single service container used for other than intended purpose.

Non-compliance (0 points) if:
- Systematic miss-use of single services container, used for other than intended purpose.

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

Visual confirmation. Total compliance (5 points): In-house re-usable containers should be labeled or color-coded so that their designated purpose can be easily identified. 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 (3 points) if:
- Single/isolated instance(s) of a re-usable container not labeled or color-coded.

Major deficiency (1 point) if:
- Numerous instances of re-usable containers not properly labeled or color-coded.

Non-compliance (0 points) if:

- Re-usable containers are used for multiple purposes without the containers being labeled or color-coded.

1.4.14 Are food safety measuring devices working properly?

Visual confirmation. Total compliance (3 points). All pieces of food safety measuring equipment are working properly and where necessary calibrated. Devices include thermometers, pH probes, ATP testing systems, etc. 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 anice 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-compliance (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.

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Employee Practices

1.5.1 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 compliance (15 points): Employee compliance to hand washing and sanitizing procedures should be assessed. Employees are observed washing their hands before starting work each day, after using the restroom and after breaks. Hand sanitizing applicability is linked to the question on secondary hand sanitation in section 1.4. 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); are there 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.hi-tm.com/Documents/Handwash-FL99.html

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

1.5.2 Are employees' fingernails clean, short and if gloves are not used, free of nail polish?

Visual Confirmation. Total compliance (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 can be worn if using gloves that are in good repair. 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, http://www.cfsan.fda.gov/~acrobat/fc05-2.pdf (section 2-302.11)

Minor deficiency (3 points) if:
- Single/isolated instance(s) of dirty and/or long fingernails.
- Single/isolated instance(s) of fingernail polish being worn (without intact gloves).
- Single/isolated instance(s) of false fingernails being worn (without intact gloves).

Major deficiency (1 point) if:
- Numerous instances of dirty and/or long fingernails.
- Numerous instances of fingernail polish being worn (without intact gloves).
- Numerous instances of false fingernails being worn (without intact gloves).

Non-compliance (0 points) if:
- Systematic failure to ensure that fingernails are short and clean.
- Systematic failure to ensure that fingernail polish and false fingernails are not worn (without intact gloves).

1.5.3 Are employees with boils, sores, infected wounds or exhibiting signs of foodborne illness excluded from operations involving direct and indirect food contact?

Visual confirmation. Total compliance (10 points): Employees who have exposed boils, sores, exposed infected wounds, food borne sickness 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 latex or plastic gloves. Ideally blue colored Band-Aids are to be encouraged (ideally versions that incorporate blue metal strips in order to aid discovery).

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.

1.5.4 Are employees wearing hairnets (or similar hair restraints) and beard-nets?

Visual Confirmation. Total compliance (5 points): Employees (includes maintenance employees and visitors) should be wearing hairnets (or similar hair restraints) and beard-nets. For the purposes of this audit, hairnets (or similar hair restraints) are not necessary in operations with products that require cooking prior to consumption e.g. potatoes and/or outer layer of commodity (rind, peel, skin, etc.) is not consumed or used as a food item in any way e.g. “dry” onions, avocados, etc. (hair restraint of some type is best practice).

Handlers of items that may be “ready-to-eat” e.g. green onions, stone fruit, tomatoes, citrus, etc., should wear hairnets (or similar hair restraints). Note that citrus peel is often used in drinks, used for zesting, etc. Baseball caps are allowed in packinghouses as long as they are clean and worn in a way such that the fringe hair is protected. Bobby pins, hairgrips should not be worn outside hair restraints. Long hair should be tied back for safety reasons, using a band of some type (not metal clips or pins). Hair restraint (baseball caps, hairnets, mop caps) should a) stop hair falling onto the product and b) prevent employees from touching their hair and then the product. See the applicability chart.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of personnel observed not wearing a hairnet (or similar type of hair restraint) or beard-net (when applicable), or not wearing them properly.
- Single/isolated instance(s) of personnel wearing bobby pins/hair grips on the outside of hair restraints.

Major deficiency (1 point) if:

- Numerous instances of personnel observed not wearing a hairnet (or similar type of hair restraints) or beard-net (when applicable), or not wearing them properly.
- Numerous instances of personnel wearing bobby pins/hair grips on the outside of hair restraints.

Non-compliance (0 points) if:

- The practice of wearing hairnets (or similar type of hair restraints) and/or beard-nets is not enforced in an operation requiring them.
- Hairnets and/or beard-nets are not available for employees

1.5.5 Is jewelry confined to a plain wedding band?

Visual Confirmation. Total compliance (3 points): Employees are not observed wearing jewelry (earrings, necklaces, bracelets, rings with stones) or 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-compliance (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.

1.5.6. Are all employees wearing outer garments suitable for the operation (e.g. smocks, aprons, sleeves and gloves)?

Visual confirmation. Total compliance (5 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. For processors, garments should be laundered in house or by contract laundering agency. For packinghouses, ideally employees should not take garments home for cleaning, but if this allowed, the auditee should have documented GMP rules about how these garments should be cleaned. If workers sleeves come into contact with washed ready-to-eat products then protective 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. If re-useable gloves are used, then they need to be cleaned and stored properly in-between uses. Soiled or torn items should be replaced when necessary. Employees should not wear personal clothes with sequins, pom-poms, etc; ideally no sleeveless tops without an over garment. See the applicability chart.

Minor deficiency (3 points) if:
- Single/isolated instance(s) are observed of non-compliances to the above and/or company policy.

Major deficiency (1 point) if:
- Numerous instances are observed of non-compliance to the above and/or company policy

Non-compliance (0 points) if: (one of the following is found)
- An outer garment policy is **not** established
- Systematic non-compliance to the above and/or company policy.

1.5.7. 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 compliance (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.).

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

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

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

1.5.8. 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 compliance (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 outer garments on floors, work tables, equipment or packaging materials. Designated area should not be within the toilet facilities 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-compliance to the above

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

Non-compliance (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.

1.5.9. Is smoking, eating, chewing and drinking confined to designated areas?

Visual confirmation. Total compliance (10 points): Smoking, chewing tobacco, chewing gum and eating is permitted in designated areas that are away from production and storage areas. Only water is allowed to be consumed near the line, under controlled conditions where water consumption does not affect the product. Ideal situation is the installation of water fountains, but clear plastic screw top water bottles are allowed (not the sport bottle style pop tops, where the tops are handled after consumption (cross contamination.)).
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.

Minor deficiency (7 points) if:
- Single/isolated instance(s) are observed of non-compliance to the above (includes evidence of smoking, eating, use of pop top 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-compliance to the above (includes evidence of smoking, eating, use of pop top 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-compliance (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-compliance to the above criteria.

1.5.10. Are all items removed from shirt or blouse top pockets?
Visual confirmation. Total compliance (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-compliance (0 points) if:
- Systematic use of shirts, blouse or smock top pockets.

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Equipment

1.6.1. Are food contact surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?

Visual confirmation. Total compliance (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. 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-compliance (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 1.3.5, automatic failure).**

1.6.2. Are non-food contact surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?

Visual confirmation. Total compliance (10 points): Non-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 be cleaned and sanitized easily.

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-compliance (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 1.3.5, automatic failure).**

1.6.3. Does equipment design and condition (e.g. smooth surfaces, smooth weld seams, non-toxic materials, no wood) facilitate effective cleaning and maintenance?

Visual confirmation. Total compliance (15 points): Equipment should be made of appropriate materials that can be easily cleaned (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. 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.

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-compliance (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.

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

Visual confirmation. Total compliance (5 points): Independent thermometers or temperature recorders should be present in all coolers and freezers. Non-applicable if no coolers and/or freezers are not used. 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, broken or down probe and able to see the other probes in the room are in working order then this is also acceptable.
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-compliance (0 points) if:
- No thermometers present in coolers or freezers.

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

Visual confirmation. Total compliance (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; mercury thermometers should be disposed of safely at a hazardous waste collection site. Where an operation is thermally processing e.g. canning, juicing etc. and requires a high degree of accuracy, use of "certified probes" e.g. NIST Certificated http://www.drillspot.com/products/336240/Fluke_53-2_NIST_Hand_Held_Thermometer is recommended.

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-compliance (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 to 1.3.5, automatic failure.**

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Equipment Cleaning

1.7.1. Are food contact surfaces clean?

Visual confirmation. Total compliance (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.

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 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-compliance (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.

1.7.2. Are non-food contact surfaces clean?

Visual confirmation. Total compliance (10 points): All non-food contact equipment surfaces should be kept in a clean condition to prevent potential 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.

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-compliance (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.

1.7.3. Are items (barrels, bins, etc.) that are used to hold or store product clean?

Visual confirmation. Total compliance (10 points): Bins, boxes, hoppers, barrels, baskets, etc. used for the storage of product, or ingredients should be kept in a clean state. The storage of these items should ensure that they remain clean and uncontaminated e.g. covered.

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.

Major deficiency (3 points) if:
- Numerous instances of dirty product storage containers (there is no direct product contamination).
- Numerous product storage containers, which are clean, but 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.

Non-compliance (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.

1.7.4 During cleaning are foods and packaging protected?

Visual confirmation. Total compliance (15 points): Products, ingredients and packaging should be protected or removed from the area during cleaning. 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.

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-compliance 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-compliance (0 points) if:
- Any observation of direct contamination of product, ingredients or packaging materials that adulterates the product with a cleaning chemical or contaminates 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 1.3.5 adulteration option and scoring an automatic failure.**

1.7.5 Are cooling units including coils in coolers and freezers clean and free of aged, dirty ice?

Visual Confirmation. Total compliance (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). Not applicable if there are no cooling units on site. There should be no colored ice/dirty ice build up.

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-compliance (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 – reverts back to Q 1.3.5.**

1.7.6 Are all fan guards in the facility dust-free and the ceiling in front of the fans free of excessive black deposits?

Visual Confirmation. Total compliance (5 points): All fan guards (cooling units and general ventilation) 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-compliance (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 1.3.5 and score an automatic failure.**

1.7.7 Is stored clean 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 use?

Visual Confirmation. Total compliance (10 points): All equipment that is not used on a daily basis should be stored clean, with food-contact surfaces protected. 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 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 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-compliance (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.

1.7.8 Are all utensils, hoses and other items not being used stored clean and in a manner to prevent contamination?

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

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

Visual Confirmation. Total compliance (3 points): Tools that are used for repairing equipment in the production and storage areas 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 tools used on food equipment.

Major deficiency (1 point) if:
- Numerous instances of unclean and/or corroded tools used on food equipment.

Non-compliance (0 points) if:
- Systematic failure to ensure that tools are clean and/or corrosion free.

1.7.10 Are excess lubricants and grease removed from the equipment?

Visual Confirmation. Total compliance (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 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 using 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 1.1), 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, pumps axles etc.

Non-compliance (0 points) if:

- **Observation of serious direct contamination of product, ingredient or packaging materials with a food grade material – auditor should consider reverting back to question 1.3.5, automatic failure.**
- **Any observation of direct contamination of product, ingredient or packaging materials with a non-food grade material – auditor should revert back to 1.3.5, automatic failure.**
- Systematic failure to protect pumps, motors, axles etc.

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General Cleaning

1.8.1 Are spills cleaned up immediately?
Verbal & visual confirmation. Total compliance (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.

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-compliance (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.

1.8.2 Are waste and garbage frequently removed from production and storage areas?
Verbal & visual confirmation. Total compliance (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; attracted flies (unless in mushroom or onion facility) and or is exhibiting mold growth.

Non-compliance (0 points) if:
- Failure on maintaining the facility areas free of waste and garbage.
- Numerous instances where waste has an off odor; attracted flies (unless mushroom or onion facility) and or is exhibiting mold growth.

1.8.3 Do floor drains appear clean, free from odors and well maintained?
Visual Confirmation. Total compliance (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.

- Drains in processing plants, packinghouses with washing 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.

If necessary and where possible, request floor drain covers to be removed for inspection. 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-compliance (0 points) if:
- Systematic failure to maintain the facility floor drains in a clean condition.

1.8.4 Do high level areas including overhead pipes, ducts, fans, etc., appear clean?

Visual & verbal confirmation. Total compliance (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). Look for stains and other issues with respect to the use of false ceilings if used.

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

1.8.5 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 compliance (5 points): All facility plastic strip curtains are clean, free of mold/mildew, black discoloration free of 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 section 1.4 (1.4.2 in the Processing Audits Templates and 1.4.1 in all other templates). 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-compliance (0 points) if:
- Systematic failure to maintain strip curtains in a good condition.

1.8.6 Is safety equipment for the sanitation crew adequate, in good condition and stored to prevent cross contamination to ingredients, packaging or product?

Visual Confirmation. Total compliance (3 points): Safety equipment (Personal Protective Equipment (PPE)) is provided for the sanitation crew. The safety equipment supplied 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. 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.
- Single/isolated instance(s) where safety equipment 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.
- Numerous instances where safety equipment does not appear to have been cleaned prior to storage.
- Numerous instances of the safety equipment not being in good repair.
- Numerous instances of safety equipment not being supplied to employees

Non-compliance (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.

1.8.7 Is cleaning equipment available and stored properly?

Visual confirmation. Total compliance (5 points): Cleaning equipment should be stored away from the food and operational areas in a designated storage area. Cleaning equipment is stored to prevent it becoming a source of cross contamination for the product, materials, packing equipment, and in general, for the complete operation. Brooms, mops etc., should be stored off the floor in order to avoid them being contaminated by any accidental spills and prevent them from being harborage areas for pests. Access to sanitation equipment should be restricted to trained employees. There should be an adequate supply of cleaning equipment (as per procedures employed). Equipment used for different types of cleaning should not be stored touching each other (see next question).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of the issues mentioned above.
- Single/isolated instance(s) of cleaning equipment that is kept 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 (1 point) 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-compliance (0 points) if:
- Systematic failure to properly store cleaning equipment.
- Very poor availability of cleaning materials.

1.8.8 Is cleaning equipment identified in order to prevent potential cross contamination issues e.g. production, maintenance, outside, restroom equipment?

Visual Confirmation. Total compliance (5 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 (3 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 (1 point) if:
- Numerous instances of color not being applied properly.
- Numerous instances of materials not being coded.

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

1.8.9 Are all items used for sanitation appropriate for their designated purpose? (no steel wool, metal bristles, etc)

Visual Confirmation. Total compliance (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.

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

1.8.10 Are toilet facilities and hand-washing stations clean?

Visual confirmation. Total compliance (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.
- No offensive odors are evident.
- No soiled toilet tissue either on the floor or in trash cans.
- Trashcans 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 (10points) if:
- Single/isolated instance(s) of non-conformance to above requirements.
- Single/isolated instance(s) of soiled toilet tissues being placed in trashcan.

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

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

1.8.11 Are employee locker and lunchroom facilities clean, including microwaves and refrigerators? No rotting or out of date foodstuffs?

Visual confirmation. Total compliance (5 points): Inspection shows that the employee locker and lunchroom areas are kept in a sanitary condition. Sanitation practices include the periodic cleaning of these areas (includes inside microwaves, inside and behind refrigerators, behind and on top of all vending machines, tops of lockers) 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.

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

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

1.8.12. Is the maintenance shop organized - i.e. equipment and spares stored in a neat and tidy fashion?

Visual confirmation. Total compliance (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-compliance (0 points) if:
- Failure in maintaining the maintenance shop in a clean condition.
- Shop is located in production/storage areas and a major potential for cross contamination exists.

1.8.13 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 compliance (5 points) if:
- 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-compliance (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.

1.8.14 Are shipping trucks clean and in good condition?

Visual confirmation. Total compliance (5 points). Trucks and/or trailers 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-compliance (0 points) if:

- Systematic failure to maintain shipping trucks in a clean and sanitary condition.
- Multiple instances of cases where the failure on maintaining 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). In this case the score reverts back to 1.3.5.**

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Buildings and Grounds

1.9.1 Are all lights above products, product storage areas, packaging storage areas and maintenance shops intact and protected?

Visual confirmation. Total compliance (15 points): All glass lights in the facility that can contaminate finished products, raw materials, equipment, or packaging should be shielded to protect from product 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), electronic fly killer lights, forklift lights, etc. End piece fittings might be necessary on tube lights. 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.

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-compliance (0 points) if:

- Majority of lights are not protected.
- More than one instance of broken lights found within the facility.

1.9.2 Has the facility eliminated or controlled any potential metal, glass or plastic contamination issues?

Visual confirmation. Total compliance (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, 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 use of a glass register might be considered, see question in 2.1.

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.

Non-compliance (0 points) if:

- Systematic failure to control potential foreign objects on site.

- **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 1.3.5.**

1.9.3 Has the facility eliminated the use of wooden items or surfaces?

Visual confirmation. Total compliance (5 points) if:

- Tools, 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 of 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 1.6.3.

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, etc.
- Single/isolated instance(s) of structural items e.g. walls/floors constructed of wood in "wet" 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 constructed of wood in "wet" facilities.

Non-compliance (0 Point) if:

- Majority of structural items e.g. walls/floors constructed of wood in "wet" facilities.

1.9.4 Is there adequate lighting in the production and storage areas?

Visual confirmation. Total compliance (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-compliance (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.

1.9.5 Is ventilation adequate to remove dust, steam, and odors?

Visual confirmation. Total compliance (3 points): The facility should have a good ventilation system that will minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate (taint) product, ingredients or packaging materials. There should not be dust or condensation present in areas that can contaminate product or processing equipment or packaging supplies. Ventilation equipment is maintained to provide an adequate air exchange rate. Ideally positive air pressure should be employed in processing operations where deemed useful.

Minor deficiency (2 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-compliance (0 points) if:
- **Direct contamination of food products, food processing equipment or packaging supplies by dust or condensation. Auditor should consider reverting to Q 1.3.5, the automatic failure adulteration question.**
- Numerous instances of potential product contamination by dust, condensation or objectionable and/or tainting odor.

1.9.6 Are floor surfaces in good condition, with no standing water, no debris trapping cracks and are they easy to clean?

Visual confirmation. Total compliance (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. Floors should be smooth without deep cracks or seams. Cracks should not trap debris. Some hairline floor cracking is allowed, but should be easy to keep clean and not trapping 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 as 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-compliance (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 to Q. 1.3.5, the automatic adulteration failure question.**

1.9.7 Are the floor drains where they are needed for drainage and cleanup?
Visual confirmation. Total compliance (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 product washing should have adequate drainage.

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-compliance (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 question 1.3.5 if product/packaging looks like it is being systematically contaminated.**

1.9.8 Are doors to the outside pest proof?
Visual Confirmation. Total compliance (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 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.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a door having a gap greater than1/8 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.
- Single instance of a door maintained open without additional protection (e.g. air curtain, screen, etc.)

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.
- More than one instance of a door maintained open without additional protection (e.g air curtain, screen, etc.)

Non-compliance (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.
- Systematic observation of doors maintained open without additional protection (e.g. air curtain, screen, etc.).

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

Visual confirmation. Total Compliance (3 points): In cold stores, coolers and packinghouses this question is only applicable if the facility is fitted with raised dock doors, levelers and buffers. This question should be scored for processors who are handling temperature-controlled items. In a processing audit where goods are not temperature controlled, then this question is only scored if the raised dock doors, levelers and buffers are fitted. Dock 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.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of a poorly maintained dock buffer.
- Processing site producing temperature controlled goods that does not use 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.
- Processing site producing temperature controlled goods that does not use a dock buffer system (or equivalent temperature management system). Limited counter measure in place.

Non-compliance (0 points) if:

- All dock buffers inspected were poorly maintained.
- Processing site producing temperature controlled goods that does not use a dock buffer system (or equivalent temperature management system). No counter measures in place.

1.9.10 Are dock load levelers and shelters maintained in a good condition, pest proof and debris free?

Visual Confirmation. Total compliance (3 points): This question is only scored where raised dock doors are fitted. Dock levelers are cleaned, 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 – 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-compliance (0 points) if:

- Systematically observing improperly maintained shipping docks and levelers.

1.9.11 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 compliance (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-compliance (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.

1.9.12 Are interior walls and ceilings free of cracks and crevices to prevent insect's harborage and allow proper sanitation?

Visual confirmation. Total compliance (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 – with heat and water, this becomes an ideal breeding ground for microbes.

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-compliance (0 points) if:
- Walls not maintained in an acceptable condition.

1.9.13 Employee personal items are not being stored in the production and material storage areas?

Visual confirmation. Total compliance (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.

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

1.9.14 Is an 18"(46cm) internal wall perimeter being maintained within the facility, with adequate access to these wall perimeters thereby allowing inspection and cleaning?

Visual confirmation. Total compliance (5 points): All storage areas should maintain an 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, and 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.

Major deficiency (1 point) if:

- Numerous incidences of areas not maintaining required inspection perimeters or clearance i.e. not accessible for inspection.

Non-compliance (0 points) if:

- Systematic failure to maintain required inspection perimeters or clearance.

1.9.15 Is exterior area immediately outside the facility free of litter, weeds and standing water?

Visual confirmation. Total compliance (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 designated smoking area outside, then there should a disposal can for cigarette butts – 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-compliance (0 points) if:

- Grounds are not maintained.

1.9.16 Are control measures being implemented for the storage of pallets, equipment, tires, etc. (e.g. out of the mud, stacked to prevent pest harborage, away from building perimeter)?

Visual confirmation. Total compliance (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 away from the building perimeter.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of equipment not stored properly.
- 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-compliance (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.

1.9.17 Are pallets inspected to separate and replace dirty or broken pallets?
Visual confirmation. Total compliance (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-compliance (0 points) if:
- Systematic failure to separate dirty or broken pallets from good pallets.

1.9.18 Is the area around the dumpster/cull truck/trash area clean?
Visual confirmation. Total compliance (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/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-compliance (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.

1.9.19 Are outside garbage receptacles and dumpsters kept covered or closed?
Visual confirmation. Total compliance (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-compliance (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.

1.9.20 Are all water lines protected against back siphonage?

Verbal and visual confirmation. Total compliance (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 to into the mains water system can contaminate fresh water. Where facility has a current certificate of inspection on file (scored under 6.1.4), auditor should still look for issues within the facility (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.
http://www.epa.gov/safewater/crossconnection.html
http://www.epa.gov/nrmrl/pubs/625r00008/html/625R00008.htm
http://www.epa.gov/nrmrl/pubs/625r00008/625R00008totaldocument.pdf

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-compliance (0 points) if:
- Facility officials do not know if there is back flow protection.
- Documentation of back flow protection will be scored under 6.1.4.
- There is no primary mains water backflow protection.
- Waste discharge lacks back flow protection.

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Food Safety File Requirements - Section 2

General File Requirements

2.1.1 Are there written procedures for handling regulatory inspections?

Visual confirmation. Total compliance (3 points): Procedures are written for employees to follow when regulatory agencies inspect the facilities. Regulatory agencies could be FDA, USDA, OSHA, Health Department, etc and State enforcement organizations. The procedures should include at a minimum rules for accompanying inspections, sampling protocol i.e. duplicate samples and a photo taking protocol. 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 elements of the policy are missing.

Non-compliance (0 points) if:

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

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

Visual Confirmation. Total compliance (5 points). There should be a written glass policy and procedure, which should state: -

- Where glass is prohibited and where glass is allowed.
- If certain glass items are allowed, then a glass register should exist. Note 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 GMP e.g. allowing glass drinking bottles into production areas. Glass register items should be checked on a routine basis to ensure they are not damaged/cracked etc.
- Glass breakage procedure including requiring recording what happened, recording what happens to potentially affected product, recording future preventative actions and especially where to record the incident details e.g. in the NUOCA log.
- Clean-up procedure after glass breakage including boot and tool checks 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.

Major deficiency (1 point) if:

- Policy lacks more than one element noted above.
- Numerous instances where glass breakage details are not being recorded properly

Non-compliance (0 points) if:

- No policy exists
- There has been a glass breakage but no records exist.

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

Visual Confirmation. Total compliance (5 points): 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 to be 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 2.2.4, changing and testing of water and ice systems in question 2.3.4. 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 a written SOP for the following important tasks (if applicable):

- Goods receiving
- Temperature control (where applicable)
- Foreign material control e.g. metal detection
- Pest control (if done in-house)
- Shipping
- 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-compliance (0 points) if:

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

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

Visual Confirmation. Total compliance (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 the 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-compliance (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

2.2.1 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 compliance (10 points): A written document either within the recall program or as a separate document that shows the facility traceability system should be available for review. Could 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 in evidence 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. Cooler and Cold Storage & Storage and Distribution auditees that operate in a third party capacity for their clients might have their own trace ability 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. Cooler and 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.
http://www.fda.gov/OHRMS/DOCKETS/98fr/04-26929.htm,
http://www.cfsan.fda.gov/~dms/fsbtac23.html,
http://www.cfsan.fda.gov/~dms/ffregui4.html
http://www.cfsan.fda.gov/~dms/fsbtac12.html,

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 tracing back or tracing 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-compliance (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 tracing back or tracing 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.

2.2.2 Does the facility have a documented recall program including: procedures, recall team roles and contact details, external contact listings, explanation of different types (classes) of recalls?

Visual confirmation. Total compliance (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. An explanation of recall classes (Class I, II, III in the USA) 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). Cooler and 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. Coolers and 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://vm.cfsan.fda.gov/~lrd/recall2.html
ORA Recall Guidelines, http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm

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

2.2.3 Is testing of recall procedures (including trace back) performed and documented annually? Can the company identify where affected product was sent?

Visual confirmation. Total compliance (10 points): A "mock" recall should be performed at least annually. Documentation should indicate the date and time the mock recall was initiated, the product chosen, the scenario, amount of product produced, affected lot ID's (date code(s), lot code(s), etc.), amount located, and percent located. Mock recall documentation should include copies of documentation that support the traceback from the affected finished good lot through to the production run(s) affected and therefore showing if other lots are affected and which other customers might have received affected lot(s). Checks should be carried out to ensure that contact details exist for the affected customers. Documentation should also include any "lessons learned" from the process. Documentation should state "Mock Recall", especially the document that shows the scenario, so that 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. 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.

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.

Non-compliance (0 points) if:
- Mock recall has not been performed on an annual basis.
- Mock recall was initiated, but could not be completed

2.2.4 Is there a written procedure for handling on hold or rejected products?

Visual confirmation. Total compliance (10 points): A documented procedure exists that explains how product should be handled, that has either been rejected or placed on hold. The procedure should include details on how the affected product lot(s) is/are separated from other lots in terms of tagging systems (date showing when the product was placed on hold/rejected and the reason for being on hold/rejected and the name of the person who put he product on hold) and any other physical separation to ensure that affected product is 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.

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.

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.

Non-compliance (0 points) if:
- Procedure has not been created.
- Procedure created bares no resemblance to what is being applied in the production and storage areas.

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Chemicals

2.3.1 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 compliance (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 and postharvest pesticides), 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. Ideally have copies of regulatory approvals (where available) on file for cleaners and chemicals (including postharvest pesticides) 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.cfsan.fda.gov/~lrd/foodadd.html

http://www.nsf.org/business/nonfood_compounds/categories.asp?program=NonFoodComReg

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 points) if:

- Numerous instances of missing MSDS's for chemicals that are currently being used.

Non-compliance (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.

2.3.2 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 compliance (5 points): Specimen labels should be available for chemicals (pesticides, cleaning and sanitizing chemicals, postharvest pesticides, 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 at speed. Specimen labels might be kept on file 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.

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-compliance (0 points) if:

- No specimen labels for decanted chemicals being used.

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

Visual confirmation. Total compliance (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. 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-compliance (0 points) if:
- No chemical usage logs/inventories are on file.

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

Visual Confirmation. Total compliance (10 points): Ice and water systems should have specific SOPs which describe the process of changing the water and performing and recording anti-microbial sanitizer strength testing (including parameters, frequency of testing, methodology and corrective action requirements). There should be documentation that validates the water changing frequency and water testing frequency. 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-compliance (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.

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Pest Control

2.4.1. 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 compliance (15 points): There should be a documented pest control program in place detailing scope, target pests and frequency of checks. If performed in-house the pest-control operators or State equivalent should be licensed (if handling chemicals) – note the persons training and license should cover the management of structural pests. Substitute operators license credentials should also be on file. If the service is contracted, the pest control contract service should be licensed, insured and the contract should be documented (quoting scope, types of pests and frequency of visits). 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 where necessary.

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-compliance (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.

2.4.2 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 compliance (10 points): Schematic drawing or trap map is on file, current and details internal and external traps. All devices (e.g. Ketch-Alls, bait stations, glue boards, electronic fly killer units) 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) being missed off the plan.
- Single/isolated instance(s) of trap(s) numbering being incorrect.

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

Non-compliance (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.

2.4.3 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 compliance (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 done in-house. Records should include services performed, date of service**,** chemicals used (including EPA # if in the US), signs of activity and corrective actions. Match PCO signature on service logs with licenses/certificates on file. Records should show when electric fly killing unit 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 completion(s) where relevant. Specimen labels and MSDS sheets for chemicals used are scored under section 2.2.

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-compliance (0 points) if:

- No service reports.
- Systematic failure to maintain service reports including not recording chemicals used.

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Self Inspection

2.5.1. Is there a documented system for dealing with customer complaints and buyer food safety complaints and are rejections on file, along with company responses, including corrective actions?

Visual Confirmation: Total compliance (5 points): The company has a system for dealing with client's (buyer and/or consumer) complaints, which includes (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 should include 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 100 in a year) 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 of complaints and frequencies. 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.

This question is only relevant in the Cooling & Cold Storage and Storage & Distribution audits where the company sells product. Not applicable if acting as a third party storage operation.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of omissions and incorrect data in the records including corrective actions.
- More than 100 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-compliance (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

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

Visual confirmation. Total compliance (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.com 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.com 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-compliance (0 points) if:
- There are no records of previous inspections and corrective actions taken although there have been inspections in the last year.

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

Visual confirmation. Total compliance (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; auditee should be able to support monitoring frequency being used. For tomatoes, to limit potential of infiltration of foodborne pathogens, postharvest immersion water should be maintained at temperatures 10 ºF (5.6ºC) above the incoming fruit pulp temperature; water depth and amount time fruit is submersed should also be monitored. Potentially useful website:-http://www.cfsan.fda.gov/~acrobat/tomatsup.pdf. 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 product washing, metal detection, etc., are 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.

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.

Non compliance (0 points) if:
- No records.
- Monitoring frequency is insufficient to verify the process is in control.
- Failure to maintain records properly.

2.5.4 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 compliance (10 points): Wash water and ice production systems using anti-microbial agents e.g. disinfectants, should have records showing that the strengths of the solutions are within parameters. Recycled 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. Recycled chlorine systems would be expected to have parameters such as ≥1ppm free chlorine and/or ≥650mv ORP (at pH 6.5-7.5). Other anti-microbials e.g. ozone, paracetic acids, etc., should meet manufacturer recommendations (auditee should have proof of parameter derivation). 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. Corrective actions should also be recorded. These steps might be covered in a HACCP plan (sanitizing of flume water).

Potentially useful websites:-
UC Davis, http://ucce.ucdavis.edu/files/datastore/234-406.pdf
UC Davis, http://ucce.ucdavis.edu/files/filelibrary/5359/3843.PDF
UC Davis, http://ucce.ucdavis.edu/files/filelibrary/5453/4369.pdf
UC Davis, http://ucce.ucdavis.edu/freeform/UC_GAPs/documents/Water_Disinfection1890.pdf
http://www.caleafygreens.ca.gov/docs/resources.asp

Minor deficiency (7 points) if:
- Single/isolated instance(s) of records showing solution strength out of parameters.
- 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.
- 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.

Non-compliance (0 points) if:
- Water/ice testing and water changes are not being recorded.
- Recorded solution strengths systematically out of parameters.
- 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 water parameters have been stated.

2.5.5 Is there a hand/foot/tool dip station log?

Visual confirmation. Total compliance (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 1.4.15). Any operation with hand, foot or tool dips is required to keep monitoring records (uncontrolled dips are a hazard).
Minor Deficiency (2 points) if:

- Single/isolated instance(s) of omissions or incorrect data in the records.
- Single/isolated instance(s) of dips being omitted from the logs.

Major Deficiency (1 point) if:

- Numerous instances of omissions or incorrect data in the records.
- Numerous instances of dips being omitted from the logs.

Non compliance (0 points) if:

- No records.
- Failure to maintain records

2.5.6 Is there a daily pre-operation inspection log?
Visual confirmation. Total compliance (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 2.6.6.
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 personnel meet the GMP requirements
- Corrective actions in case of non-compliance.

Basically a last minute quick check that all is well and the production can start. 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.

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 compliance (0 points) if:

- No records.
- Failure to maintain records.

2.5.7 Is there a program for periodic facility/GMP internal (self) inspections and are records maintained detailing corrective actions?
Visual confirmation. Total compliance (10 points): There should be a program for periodic internal (self) inspections. Inspection should include:

- Inspection frequency. Frequency depends on type and size of operation; auditors discretion. 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.
- 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 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-compliance (0 points) if:
- Systematic failure to maintain records.

2.5.8 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 compliance (10 points): Equipment for monitoring processes (hand held and automated) related to food safety e.g. thermometers, metal detectors, ORP meters, flow meters and pH meters are calibrated regularly to ensure correct and accurate operation**.** Calibration procedures should describe the frequency of testing, the testing method and the acceptable range of variation. Corrective actions should be detailed when applicable. Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency of testing. Note 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 and on machines labels.

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 compliance (0 points) if:
- No procedure
- No records
- Failure to maintain records.

2.5.9 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 compliance (5 points): Recording systems for food safety related topics should be audited 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 be at least quarterly.

Self-auditing (self diagnostics) is 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-compliance (0 points) if:
- Systematic failure to maintain records.

2.5.10 Does the facility have incoming goods (products, ingredients and packing materials) inspection data?
Visual confirmation. Total compliance (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 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. Not applicable if acting as a third party storage operation.

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

2.5.11 Does the facility have relevant supplier third party audit certifications, third party audit reports and/or supplier letters of guarantee for product raw material, processing aids and other ingredients?
Visual confirmation. Total compliance (15 points): The auditee should have on file current third party audit certificates, audit reports or letters of guarantee for product raw material, processing aids 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. Letters of guarantee for products are not required if own

product e.g. “in-house grown” 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 Coolingr & 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 (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 compliance (0 points) if:
- No records.
- Failure to maintain records.

2.5.12 Does the facility have relevant supplier third party audit certifications, third party audit reports and/or supplier letters of guarantee for packaging items?
Visual confirmation. Total compliance (15 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. 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 (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 compliance (0 points) if:
- No records.
- Failure to maintain records.

2.5.13 Are there inspection logs on incoming trailers for rodents and insects, cleanliness, holes and temperature control?
Visual confirmation. Total compliance (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 compliance with specified temperatures.
- Records of rejections and where relevant any corrective actions.

Not applicable if flatbeds are used. 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. Packaging supply trucks can be recorded by exception or on the routine monitoring log.

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

2.5.14 Is there a daily incidents report, sometimes called a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA)?

Visual confirmation. Total compliance (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. 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). 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 compliance (0 points)
- No records.
- Failure to maintain records.

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Maintenance & Sanitation

2.6.1 Does the facility have a preventative maintenance program and schedule?
Visual confirmation. Total compliance (10 points): There should be a formal preventative maintenance program. The maintenance program should schedule routine inspections, lubrications, part replacements etc. at appropriate frequencies (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 also choose specific pieces of equipment 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-compliance (0 points) if:
- No program.
- Systematic failure to maintain records.

2.6.2. Is there a log of maintenance work or repairs ordered and is it signed off on work completed?
Visual confirmation. Total compliance (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 & 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-compliance (0 points) if:
- No logs are on file.
- Systematic failure to maintain records.

2.6.3.Are there logs showing that equipment is cleaned and sanitized after maintenance work has been completed?
Visual confirmation. Total compliance (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 compliance (0 points) if:
- No records.
- Failure to maintain records.

2.6.4 Is there a written cleaning schedule (Master Sanitation Schedule) that shows what and where is to be cleaned and how often?

Visual confirmation. Total compliance (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, named equipment and equipment parts and surfaces; include 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 on equipment. Note that all cleaning mentioned on the schedule should be covered somewhere in the cleaning procedures and also on 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, i.e.:
- List of areas, equipment, internal transport vehicles, in-house delivery trucks, etc.
- Frequency of cleaning (daily, weekly, monthly, quarterly, annually, etc.)

Potentially useful website:-
Purdue University Tool Kit, http://www.cfs.purdue.edu/RHIT/foodsafety/Checklists_Cleaning.htm

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 i.e. missed areas/equipment (including internal transport vehicles, in-house delivery trucks) and/or no frequencies being set.

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

2.6.5 Are there written cleaning procedures (Sanitation Standard Operating Procedures) for the facility and all equipment?

Visual confirmation. Total compliance (10 points): There should be written sanitation/cleaning procedures for all equipment and areas. These are also called Sanitation Standard Operating Procedures (SSOP's). Equipment

includes production line equipment and internal transport equipment (e.g. forklifts, 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. Procedures should respect the label (e.g. rinse/no-rinse, dwell time, etc.) and match operations noted on the master sanitation schedule (2.6.4).These procedures should include: -

- Responsiblity for cleaning
- Item/area to be cleaned
- Frequency of cleaning
- Safety precautions (tag outs, personnel safety with respect to chemicals, etc.)
- Chemical (name, dilution and water temperature requirements) and utensils used
- Detailed cleaning /sanitation methods (especially with respect to rinsing off chemical and using terminal sanitizers)
- Special instructions with respect to cleaning
- Responsible person
- Logs/records of cleaning and responsibility for verification

Minor deficiency (7 points) if:

- Up to two of the requirements listed above are missing or incorrect.
- Single/isolated instance(s) of omitted procedure(s) for a piece of equipment, internal transport vehicle or facility area.

Major deficiency (3 points) if:

- Three or more of the above requirements are missing or incorrect.
- Numerous instances of omitted procedures for a piece of equipment, internal transport vehicle or facility area.

Non-compliance (0 points) if:

- No written procedures have been developed.
- Procedures exist but they are not reflecting what actually occurs.

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

Visual confirmation. Total compliance (5 points): The company has sanitation logs that cover the entire area of the facility and equipment. Logs are kept on file in an easily retrievable manner. The logs should be cross-checked against the master sanitation program (2.6.4). 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-compliance (0 points) if:
- No sanitation logs.
- Sanitation logs exist but they are not reflecting what actually occurs.

2.6.7 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 compliance (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 areas 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-compliance (0 points) if:
- There is no written evidence (schedule or log) that floor drains are cleaned.

2.6.8 Are there records showing cooling units are serviced and cleaned at least on an annual basis or more frequently as required?

Visual confirmation. Total compliance (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. Annual is a minimum requirement, but usually frequency is higher, especially in high humidity/wet operations and also maybe 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 compliance (0 points)
- No records.
- Failure to maintain records.

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Personnel

2.7.1 Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?

Visual Confirmation. Total compliance (5 points): There should be an active food safety committee, responsible for the strategic maintenance and development of the operations food safety plan. If an operation has a HACCP plan, the HACCP team might also look after the food safety issues. This question is not applicable to small family size companies (less than 20 full time persons). 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.

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-compliance (0 points) if:

- Food safety committee has not been created.
- The company does not have logs of food safety meetings.

2.7.2 Are there logs of new employee food safety (GMP) orientation training with topics covered and attendees?

Visual confirmation. Total compliance (5 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. Materials to be given to new hires after training should be in the relevant language(s) and cover key GMP rules including hand washing, eating/drinking, smoking, specific clothing rules, etc. Food safety training should be given to all employees working in the production and storage areas, this includes temporary employees and agency employees.

Minor Deficiency (3 points) if:

- Single/isolated instance(s) of errors and omissions in the records.
- Up to three points missing off the GMP requirements listing.
- Training materials and GMP listing are not in the relevant language(s).
- Training occurring but relevant materials are not being given to the trainee after the training.
- Single/isolated instance(s) of employees not being trained.

Major Deficiency (1 point) if:

- Numerous instances of errors and omissions in the records.
- Over three points missing off the GMP requirements listing (or GMP listing does not exist).
- Numerous instances of employees not being trained.

Non-compliance (0 points) if:

- No records of training or employees not being trained.
- Failure to maintain records.

2.7.3 Are there logs of ongoing employee food safety education training with topics covered and attendees?

Visual confirmation. Total compliance (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., 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-compliance (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.

2.7.4 Is there a documented training program with training logs for the sanitation employees including best practices and chemical use details?

Visual Confirmation. Total compliance (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 quarterly basis – auditors not to score down for frequency issues in this current version of the audit.

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 error
- 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.

Non-compliance (0 points)

- No records or no training has occurred.
- Failure to maintain records.

2.7.5. Is there an employee non-compliance/disciplinary action procedure? (verbal confirmation accepted).

Verbal Confirmation. Total compliance (3 points): The auditee should have a record for employee non-compliance 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 as present no known good examples exist.

Major Deficiency (1 point) if:

- Disciplinary system is not used for GMP violations.

Non-compliance (0 points)

- No records or no disciplinary system.

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Microbial Tests

Potentially useful websites :-
CDC Disease Information, http://www.cdc.gov/ncidod/dbmd/diseaseinfo/#E
FDA Bad Bug Book, http://www.cfsan.fda.gov/~mow/intro.html
EPA Drinking Water Standards, http://www.epa.gov/safewater/mcl.html#mcls
USDA, Water Quality Information Center, http://www.nal.usda.gov/wqic/

2.8.1. Are there records of routine equipment microbiological testing?
Visual confirmation. Total compliance (5 points): There should be records of equipment microbiological swab testing, for production and storage facilities that either have a washing step or involves 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) and with edible peel or skin. Note that citrus peel is often used in drinks, used for zesting, etc. This question is not applicable for products that require cooking e.g. potatoes and/or outer layer of commodity (rind, peel, skin, etc.) is not consumed or used as a food item in any way e.g. "dry" onions, avocados, etc; although testing in any operation is encouraged. Testing frequency should be related to the risk assessment of the production involved. For example a fresh-cut facility should be carrying out weekly checks, whereas low risk products e.g. apples, citrus should be checked 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, and frequency of testing. See the applicability chart.

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 but no corrective action documentation.

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 but there are no corrective actions documented.

Non-compliance (0 points) if:
- There are no records of equipment microbiological testing.

2.8.2 Are there records of routine facility environmental testing?
Visual confirmation. Total compliance (5 points): There should be records of facility environmental 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. 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) and with edible peel or skin. Note that citrus peel is often used in drinks, used for zesting, etc. This question is not applicable for products that require cooking e.g. potatoes and/or outer layer of commodity (rind, peel, skin, etc.) is not consumed or used as a food item in any way e.g. "dry" onions, avocados, etc; although testing in any operation is encouraged. Testing frequency should be related to the risk assessment of the production involved. For example a fresh-cut facility should be carrying out weekly checks, whereas low risk products e.g. apples, citrus should be checked 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 and frequency of testing. See the applicability chart.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of environmental testing not occurring at the right frequency.
- Single/isolated instance(s) of a record or records showing high counts but no corrective action documentation.

Major deficiency (1 point) if:
- Numerous instances of environmental testing not occurring at the right frequency or testing is sporadic and not on a scheduled basis.
- Numerous records showing high counts but there are no corrective actions documented.

Non-compliance (0 points) if:
- There are no records of equipment microbiological testing.

2.8.3. Is there at least an annual microbiological test on water used in the facility (sampled from within the facility)?
Visual confirmation. Total compliance (10 points): There should be at least an annual microbiological test on potable water used in the facility. The water sample should be taken from the operation (either by the company itself or the local water company). Water samples taken from the site, account for the sites piping, holding tanks, etc. Facilities using well water should also test at the well. City water samples are still good information to have, but if there is no site sample, then this question should be scored minor. Results of water sample testing 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.

Minor deficiency (7 points) if:
- Only water testing records available are from the City Water Board.
- Last test was done over a year ago, but not greater than 18 months ago.

Major deficiency (3 points) if:
- Last test was done over a year ago, but not greater than 24 months ago.
- Single high count recorded and lacking corrective action documentation.

Non-compliance (0 points) if:
- No microbiological test results are available.
- Last test was done over 24 months ago.
- More than one high count recorded and lacking corrective action documentation.

2.8.4 Is there (at least) an annual microbiological test for in-house produced ice or a letter of guarantee from external suppliers of ice?
Visual confirmation. Total compliance (5 points): There should be at least an annual microbiological test on ice used in the facility if the ice is produced "in-house" by the company. The ice sample should be taken from the operation (either by the company itself or the local water company). Ice samples taken from the site, account for the sites piping, holding tanks, ice making equipment and ice storage, etc. Results of ice sample testing 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. For ice procured from outside sources, there should be a letter of guarantee (either written as an annual letter of guarantee or a continuing letter of guarantee), that at least states that the ice meets all relevant legislation (potability, food safety, etc.). If an ice supplier provides a recent microbiological test of the ice produced, this is also acceptable.

Minor deficiency (3 points):

- In-house or external ice supplier - last ice micro test was done over a year ago, but not greater than 18 months ago.
- Letter of guarantee (for externally supplied ice) is older than one year but less than 18 months old (unless a letter of continuing guarantee and there is no relevant test).

Major deficiency (1 point):

- In-house or external ice supplier - last test ice micro test was done over a year ago, but not greater than 24 months ago.
- Letter of guarantee (for externally supplied ice) is older than one year but less than 24 months old (unless a letter of continuing guarantee and there is no relevant test).
- Single high count recorded and lacking corrective action documentation

Non-compliance (0 points):

- Ice is used from an outside source but there is no letter of guarantee (and no ice micro test).
- In-house or external ice supplier – the last test was done more than 24 months ago.
- More than one high count recorded and lacking corrective action documentation.

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Temperature Controlled Storage & Distribution

2.9.1 Are there temperature logs for the packing/processing room (if refrigerated)?
Visual confirmation. Total compliance (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 1.6.4.

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-compliance (0 points) if:
- No temperature logs are on file (and the processing room is refrigerated).

2.9.2 Are there temperature logs for storage rooms?
Visual confirmation. Total compliance (5 points): There should be temperature logs or recording thermometer printouts on file. Not applicable if there are no chilled storage rooms on site or the products are held at control high ambient temperature e.g. tomatoes, bananas etc. The issue of using an independent probe, separate from the thermostat probes and systems is covered under 1.6.4.

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-compliance (0 points) if:
- No temperature logs are on file (and the storage room is refrigerated)

2.9.3 Are there records of shipping truck temperature checks indicating that the truck was pre-cooled prior to loading?
Visual confirmation. Total compliance (5 points): Refrigerated items should not be loaded on trucks which have not been pre-cooled prior to loading. Records of truck temperature checks (prior to loading) should be available for inspection. Since the air temperature is affected by the dock air temperature (which could be warm in an open dock or cold in an enclosed temperature controlled dock), the test should focus on the truck insulation – a touch test is acceptable, but a probe test is preferred e.g. an infrared surface probe. If temperature issues are noted, then consideration should be given to checking the thermostat settings. 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 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).

Major deficiency (1 point) if:
- Numerous instances of errors, incomplete or missing records (including missing corrective actions).

Non-compliance (0 points) if:

- No temperature logs are on file.

2.9.4 Are there sanitary condition logs for shipping trucks (cleanliness, trailer condition, odor, etc.)?
Visual confirmation. Total compliance (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 regularly 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

Major deficiency (3 points) if:

- Numerous instances of errors, incomplete missing logs

Non-compliance (0 points) if:

- No sanitary condition logs are on file

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HACCP Program – Section 3

Potentially useful websites:-
FDA HACCP Overview, http://www.cfsan.fda.gov/~comm/haccpov.html
Food Safety.gov HACCP site, http://www.foodsafety.gov/~fsg/fsghaccp.html
HACCP Alliance, http://haccpalliance.org

Management Support of HACCP

3.1.1 Is there a team responsible for HACCP development, implementation and on-going maintenance which is chaired by the site HACCP coordinator?

Verbal confirmation. Total compliance (15 points): There should be a group of people responsible for the development and maintenance of the HACCP program. Ideally, the group should be comprised of individuals from different areas of the company such as maintenance, sanitation, QC, etc. One member of the team, should be designated the HACCP Coordinator. If the company is too small (less than 20 people) to have a HACCP group, one individual should be designated as the HACCP coordinator. That individual will be responsible for the implementation and any changes or 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 the project leader.

Major deficiency (5 point) if:
- The team or individual is assigned but does not meet regularly to review the HACCP program.
- A large company, but only a single individual has been designated to develop the operational HACCP Plan.

Non-compliance (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 Does the plant have formal recorded HACCP training for all employees (especially CCP operators and management)?

Visual confirmation. Total compliance (10 points)
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. The HACCP coordinator and maybe some other key employees should either be formally trained e.g. a HACCP Alliance Course and/or are very experienced. Management, QA and CCP Operators should have a thorough HACCP training (in-house or external). CCP operators should be specially trained for their function(s). All other site employees should receive basic overview training i.e. what is HACCP, 7 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.

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-compliance (0 points) if:
- No formal training session developed for employees.
- No records of training being maintained.

3.1.3 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 compliance (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/retrained. All changes should be dated. If no changes have occurred, quiz the auditee how they would communicate the changes, if they happened in the future. Records of any re-training should be available.

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-compliance (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.

3.1.4 Is the plant conducting self-audits of the HACCP program?

Visual confirmation. Total compliance (10 points). At a minimum, self-audits of the HACCP program should be done on a yearly basis. 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. 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 by a self-audit to make sure it is working properly. HACCP program reviews should also 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 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).

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-compliance (0 points) if:
- Systematic failure to record self audits properly.
- Self-audits are not being conducted.
- Self -audit occurred over 24 months ago.

3.1.5 Have standard operating procedures (SOPs) been created for the CCP monitoring processes that include how to carry out the monitoring?

Visual confirmation. Total compliance (10 points): Clear and simple standard operating instructions should be written for each CCP monitoring process – this 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 then 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-compliance (0 points) if:
- CCP SOPs have not been created.

3.1.6 Is there a person or group responsible for the CCP records?

Verbal confirmation. Total compliance (5 points): An individual (or group) should be assigned the responsibility of receiving HACCP records and making sure that the records are stored in a secure place. There should be adequate plans made to ensure records are collated if an assigned individual is unable to perform their duties e.g. on vacation, sick leave etc.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of CCP records not being collated and managed by the nominated group/individuals.

Major deficiency (1 point) if:
- Numerous instances of CCP records not being collated and managed by the nominated group/individuals.
- No plans or back up for individual assigned CCP record responsibilities if he or she is not able to perform their duties e.g. on vacation leave.

Non-compliance (0 points) if:
- No one individual or group is assigned the responsibility of receiving, reviewing and storing CCP records.
- Individual or group not collating and managing CCP records.

3.1.7 Are the CCP records maintained in an organized and retrievable manner?

Visual confirmation. Total compliance (5 points): All HACCP CCP records should be maintained in a designated area where they can be retrieved readily. These records should be well organized. Binders or file system is acceptable. System might be by date with CCPs filed separately (day files) or together in a single file for a particular record. It might be that CCP's data is kept on computer.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of records not being organized and easy to retrieve.

Major deficiency (1 point) if:

- Numerous instances of records not being organized and easy to retrieve.

Non-compliance (0 points) if:

- No organization of records.
- Many missing records.

3.1.8 Are there security measures to insure against CCP record loss?

Visual and verbal confirmation. Total compliance (5 points): All HACCP records should be kept in a secured area. A locked cabinet or locked room is preferred with access to authorized individuals only. If records are maintained on computer, then adequate security precautions should have been implemented, e.g. password protection, read only controls (as opposed to being able to edit) and file history systems (that show if a file was modified and how).

Minor deficiency (3 points) if:

- Records kept in cabinet or room but in an open area, where access is not always controlled.

Major deficiency (1 point) if:

- File cabinet(s) or room does not have locks.
- Documents are kept on computer but lacking data management controls e.g. not recording changes to documents, limited editing access, etc.

Non-compliance (0 points) if:

- No procedures in place to insure against record loss.
- Documents kept on computer but there are no password controls.
- Records have been lost.

3.1.9 Are CCP records held for a minimum of one year (longer if legally required or for long-shelf products?

Visual confirmation. Total compliance (5 points): All HACCP CCP records should be held for a minimum of one year regardless of the production item's shelf life. Any records required by law to be kept longer than one year should be kept 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.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of CCP records not being retained for the required length of time (one year unless legally longer storage is required or the product has a longer shelf life than 1 year).

Major deficiency (1 point) if:

- Numerous instances of CCP records not being retained for the required length of time (one year unless legally longer storage is required or the product has a longer shelf life than 1 year).

Non-compliance (0 points) if:

- CCP records are kept less than one year.
- CCP records are kept less than the required time mandated by law for a particular product.
- CCP records are kept for less than the shelf life of the product.

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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 compliance (10 points): Product description(s) should clearly indicate the item(s) intended use i.e. does it need washing, peeling, cooking, etc., by the consumer. 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 the intended customers are (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 processes are not similar then specific product descriptions are required.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors or omissions on the product descriptions(s).

Major deficiency (3 point) if:

- Numerous instances of errors or omissions on the product descriptions(s).
- In an operation with multiple products/processes that are not similar, a few of product descriptions are not available, but the majority are available

Non-compliance (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, many of product descriptions are 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 compliance (15 points): Process flow charts should have been created. The flow chart should show each step of the process, so that the hazard analysis can be completed properly. Insufficient detail, missing steps etc., will detract from the hazard analysis process. Each step should show any holding times, temperature regimes and tagging. For example, a step termed "packing" in an apple packinghouse is not correct since it omits to detail many of the processes, e.g. dump tanks, selections, washers, waxers (with fungicide), drying, packing the boxes and coding. In operations with multiple products but similar processes, a single process flow could be created. Where there are multiple products but with different processes then individual process flows are required.

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 few of the flow charts are not available, but the majority are available

Non-compliance (0 points) if:

- Systematic errors on the flow chart(s).
- No process flow chart(s).
- In an operation with multiple products/process that are not similar, many of the flow charts are not available.

3.2.3 Has a documented hazard analysis for the process been conducted, showing the various types of hazard and their associated severity?

Visual confirmation. Total compliance (15 points): A detailed hazard analysis for each process flow should have been conducted and **documented**. At each step of the process, the hazard analysis should look at the severity and likelihood of any potential food safety hazards that the process might create usually in terms of biological, chemical and physical issues. The hazard analysis should then decide if an adequate control step for this potential risk exists further down the process (see 3.2.4).

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 few of hazard analysis charts are not available, but the majority are available

Non-compliance (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, many of hazard analysis charts are not available.

3.2.4 Have CCPs been developed to control the hazards identified in the hazard analysis step?

Visual confirmation. Total compliance (15 points): CCPs should have been developed to control hazards identified in the hazard analysis step if any are deemed to be found by the HACCP team after deliberating the hazards identified. CCPs should be developed with adequate detail and defined parameters.
The auditor cannot "question" CCPs unless there is clearly a mistake in the hazard analysis and/or parts of the process were missed in the process flow and hazard analysis work. **Auditors should be very careful when claiming that clear CCP's have been omitted or CCP's have been added in error – an auditor should be absolutely sure that they are right about their assertions (this should be a rare event).**An auditor can also refer to industry templates/texts. The CCP's should be created from the documented hazard analysis i.e. there should be a logical approach showing why the process was deemed a CCP. 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 should be able to eliminate or reduce the risk to acceptable "safe" levels. **It is possible to find that an auditee has carried out a proper hazard analysis and found no CCPs.** In this instance 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-compliance (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.

3.2.5 Have monitoring requirements and frequencies been determined for the CCPs?

Visual confirmation. Total compliance (15 points): Monitoring requirements and frequencies should have been determined for the CCPs. Frequency should be specified; "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 tested 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.

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-compliance (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.

3.2.6 Is there a clear detailed action plan for operators to follow if the 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 compliance (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. Where required, preventative measures should also be recorded.

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-compliance (0 points) if:
- More than two of the above criteria are missing in the corrective action plan details.

3.2.7 Have recording templates (recording forms) been developed for monitoring CCPs?

Visual confirmation. Total compliance (10 points): Monitoring records should have been designed to record the CCPs that have been identified. The records should match the details as noted in the HACCP Plan.
Ideally the record should identify the CCP clearly by the CCP number (not a scoring issue). The records ideally show the CCP parameters (not a scoring issue).

Minor deficiency (7 points) if:

- Single/isolated instance(s) of a record(s) having been developed but does/do not match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.

Major deficiency (3 point) if:

- Numerous instances of a record(s) having been developed but do not match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.

Non-compliance (0 points) if:

- Systematic failure of record(s) that have been developed to match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.
- Single instance where a CCP has been created but a record for the monitoring data has not been developed.

3.2.8 Have specific responsibilities been assigned for the monitoring, recording and corrective action management of each CCP?

Visual confirmation. Total compliance (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 Employees, who are responsible for monitoring, recording and executing corrective action related to an individual CCP.

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-compliance (0 points) if:

- No CCPs have been assigned to either a person or group.

3.2.9 Have verification plans and schedules been developed for each CCP?

Visual confirmation. Total compliance (10 points): Verification activities related to each CCP on the HACCP chart should be clearly detailed. Verification activities might include checking paperwork (CCPs checks), checking signatures, 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 and where this is not the case, this should be indicated on the verification paperwork along with corrective action details.

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-compliance (0 points) if:

- No verification plans have been developed for any CCP.

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Execution of the HACCP Plan on the Plant Floor

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 compliance (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. 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.

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-compliance (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 CCPs monitoring activities and frequencies in compliance with the plan?
Visual Confirmation. Total compliance (15 points): CCP monitoring activities and frequencies are in compliance with the plan. Check current logs against the HACCP plan. Auditor should carefully check the frequencies – allow some slight variations. The critical control limits should match those mentioned on the HACCP plan. Operational limit issues cannot be scored down as critical control limit issues under this question, however can be noted in question 2.5.3 where applicable. 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.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of an activity not in compliance with the plan.
- Single/isolated instance(s) of the frequency of monitoring the CCP(s) not in compliance with the plan.

Major deficiency (5 point) if:
- Numerous instances of activities not monitored in compliance with the plan.
- Numerous instances of the frequency of monitoring the CCP(s) not in compliance with the plan.

Non-compliance (0 points) if:
- There is no formal monitoring of CCPs
- Monitoring of CCPs does not resemble the details noted on the HACCP plan.

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 compliance (15 points): CCP operators should be aware of basic HACCP principles, specifically CCPs in their areas and their responsibilities for taking appropriate action should the limits be exceeded. This can be determined through casual employee interview, 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.

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 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 explain correctly, details about the CCP's they are monitoring e.g. what to do if the critical control points are exceeded.

Non-compliance (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 records free of "correction fluid" (white out), pencil text and erasable ink text? If using computerized records, is there a system that shows CCP records amendments (data history) if the records are changed after initial entry?

Visual Confirmation. Total compliance (5 points): Corrections to CCP records should be made without the use of "correction fluid" ("white-out"). Records should be in permanent ink, not pencil or erasable ink. If corrections are made they should be crossed out (and initialed by the person making the change) so that the original information is still legible. If records are stored on computer, then there should be a way of tracking any amendments to the records i.e. an amendment history with the ability to see what was changed, by whom and when (this allows one to see what value was changed).

Minor deficiency (3 points):
- Single/isolated instance(s) of CCP records found with white-out, pencil or erasable ink.
- Single/isolated instance(s) of CCP records with amendments where the original texts are not legible.
- Single/isolated instance(s) of CCP computer records lacking amendment histories.

Major deficiency (1 point) if:
- Numerous instances of CCP records found with white-out, pencil or erasable ink.
- Numerous instances of CCP records with amendments where the original texts are not legible.
- Numerous instances of computer CCP records lacking amendment histories.

Non-compliance (0 points) if:
- Systematic use of white out, pencil or erasable ink in CCP records.
- Systematic failure to ensure that original texts are legible when amendments have been made to CCP records.
- Systematic failure to record CCP amendment histories when records have been computerized.

3.3.5. Are CCP monitor records signed off (or initialed) by the operator(s) who are carrying out and recording the CCP check?

Visual Confirmation. Total compliance (10 points): Each CCP check should be signed off by the CCP operator carrying out the check. Full signatures, 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.

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-compliance (0 points) if:
- Systematic failure to sign off records.

3.3.6. Are corrective actions detailed in writing when the failure of a CCP occurs?
Visual Confirmation. Total compliance (15 points): Corrective actions should be detailed in writing when the failure of a CCP occurrs. 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. Records should indicate what happened to any affected product and also detail how the process was rectified (as per the requirements of 3.2.6). The corrective action details should match what is described in the HACCP plan.

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-compliance (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.

3.3.7. Are the CCP records reviewed and signed off daily by the quality control supervisor and/or management?
Visual Confirmation. Total compliance (10 points): CCP records should be reviewed and signed off 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 these should check the records e.g. monitoring results, frequencies, 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.

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-compliance (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.

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Verification of the HACCP Plan

3.4.1 Are monitoring and verification information reviewed and discussed at management level meetings?

Visual confirmation. Total compliance (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 meetings 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 topic 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.

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-compliance (0 points) if:

- Meeting reviewing the HACCP progress are not occurring or are not being documented.

3.4.2 Are there independent audits e.g. third party audits of the plant's HACCP program (at least annually)?

Visual confirmation. Total compliance (10 points): Independent (from the operational employees) audits of the HACCP program should occur at least annually e.g. third party audits, second 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. If the last PrimusLabs.com 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.com audit is greater than 12 months, then the rules below must be applied).

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-compliance (0 points) if:

- Last external HACCP audit was over 24 months ago.

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Food Security - Section 4

The food security 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 security and food safety scores are combined to show a single audit score.

Potentially useful websites:-
FDA Guidance, http://www.cfsan.fda.gov/~dms/secguid6.html
PMA Food Security Guidance,
http://www.pma.com/Template.cfm?Section=Food_Security2&CONTENTID=3413&TEMPLATE=/ContentManagement/ContentDisplay.cfm
FDA Food Safety and Terrorism Portal, http://www.cfsan.fda.gov/~dms/fsterr.html
FSIS Food Security Guidance,
http://www.fsis.usda.gov/Food_Security_&_Emergency_Preparedness/Security_Guidelines/index.asp

Facility 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 compliance (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 (maybe 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.

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-compliance (0 points) if:
- No perimeter fencing.

4.1.2 Is access to the facility controlled by swipe cards, locks, alarms or other devices?

Visual and Verbal confirmation. Total compliance (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-compliance (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 compliance (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 compliance 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-compliance (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 compliance (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. 1.1.2 also looks at chemical storage but from a food safety perspective.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of chemicals not properly stored.
- 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-compliance (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 compliance (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 compliance 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-compliance (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 compliance (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-compliance (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 compliance (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 is question is the same found in 1.9.13 – 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 compliance (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-compliance (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 compliance (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 – mark 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-compliance (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 compliance (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-compliance (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 compliance (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-compliance (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 compliance (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-compliance (0 points) if:
- Trailers are not sealed and/or locked.
- Seal numbers are not being recorded (where seals are being used).

4.3.3 Are transportation vehicles (trucks, trailers, rail cars, etc) equipped with a communication device e.g. cell phone, two-way radio?

Verbal confirmation. Total compliance (3 points): Outbound trailers (shipping) of finished goods should be equipped with a communication system e.g. cell phone or two-way radio in order to maintain security. Ideally transportation vehicles are fitted with GPS or similar location devices in order to locate vehicles and loads. 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 a communication system – in these cases this question should be scored N/A.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of outbound trailers not equipped with a communication device e.g. cell phone, two-way radio.

Major deficiency (1 point) if:
- Numerous instances of outbound trailers not equipped with a communication device e.g. cell phone, two-way radio.

Non-compliance (0 points) if:
- Outbound trailers are not equipped with a communication device e.g. cell phone, two-way radio.

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Water Supply Security

Potentially use website:-
EPA Water Security, http://cfpub.epa.gov/safewater/watersecurity/index.cfm

4.4.1 Are potable and non-potable water supplies clearly identified?
Visual confirmation. Total compliance (3 points): Water lines should be clearly identified if water is used for any particular process and there is more than source or type of water on site. Different water sources or types of water might be used for production as opposed to fire suppression for example. The aim is to ensure that any one can tell what water source or type of water is within a pipe or coming out of a tap. Examples of methods used included 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 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 water source/type being used on the site.

Non-compliance (0 points) if:
- None of the water pipes, taps, etc., indicate their potability status where there is more than water source/type being used on the site.

4.4.2 Are tamper evident systems (e.g tamper tags) in place where appropriate?
Visual confirmation. Total compliance (3 points): Where appropriate (e.g. incoming water supply) water valves should be fitted with tamper evident 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.

Potentially useful website:-
EPA Valve Lockout Devices,
http://cfpub.epa.gov/safewater/watersecurity/guide/productguide.cfm?page=valvelockoutdevices
http://cfpub.epa.gov/safewater/watersecurity/guide/index.cfm

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-compliance (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 compliance (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. Back flow prevention might be fitted with 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-compliance (0 points) if:

- No restrictions to sensitive water systems.

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Food Security Systems

4.5.1 Does the company have documented food security policies based on the risks associated with the operation?

Visual confirmation. Total compliance (10 points): The company should have a documented food security 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 security programs. Documented operational risk management (ORM) systems are acceptable if they show the controls that have been implemented for the food security risks that have been identified.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors or omissions in the food security policies.

Major deficiency (3 point) if:

- Numerous instances of errors or omissions in the food security policies.

Non-compliance (0 points) if:

- Food security 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?

Verbal confirmation. Total compliance (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-compliance (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 security issues and are training records kept?

Visual confirmation. Total compliance (10 points): Employees should attend either external or in-house training on food security requirements. 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 (7 points) if:

- Single/isolated instance(s) of errors or omissions in the food security training topics covered.
- Single/isolated instance(s) of errors or omissions in the food security training attendance records.
- Single/isolated instance(s) of employees not being trained with respect to food security.

Major deficiency (3 point) if:
- Numerous instances of errors or omissions in the food security training topics covered.
- Numerous instances of errors or omissions in the food security training attendance records.
- Numerous instance(s) of employees not being trained with respect to food security.

Non-compliance (0 points) if:
- Employees are not trained with respect to food security requirements.
- No records of the food security 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 compliance (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 – 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, having 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, having access i.e. having a key that they should not have, knowing a secure pass code.

Non-compliance (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.

4.5.5 Is there a system to protect the security of food safety documentation and computer systems (including a back-up system for computer safety data)?

Visual confirmation. Total compliance (3 points): Food safety documentation e.g. SOP's, records, etc. including testing results and tracebacks should be stored in a secure manner that deters theft and prevents tampering, when not in use. For example, the system might be the locking up of all manuals and recording logs at night in the QA Lab., when the operation is not running. There might also be rules for storing records in a secure archive room. Where computer systems are used to store SOP's records, etc there should also be security measures including password protections. The computerized records and documents should also be "backed-up" in some way e.g. stored in two locations, so that if one location breakdowns or is damaged, the data is not lost.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of hardcopy documents and records not being stored securely.

- Single/isolated instance(s) of computerized documents and records not being stored securely.
-

Major deficiency (1 point) if:
- Numerous instances of hardcopy documents and records not being stored securely.
- Numerous instances of computerized documents and records not being stored securely.
- Computerized documents and records are not being backed-up.

Non-compliance (0 points) if:
- Hardcopy documents and records are not stored securely.
- Computerized documents and records are not being stored securely.

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

Visual confirmation. Total compliance (3 points): Chemical usage logs and/or chemical inventories should be on file. Chemicals within the scope of this question are limited 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. Minimum frequency for inventory checks should be monthly. This is a repeat of question 2.3.3.

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-compliance (0 points) if:
- No chemical usage logs/inventories are on file.

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Miscellaneous Survey Questions – Section 5

These questions are answered Yes, No or N/A. They do not affect either the Food Safety or Food Security scores.

Employing Minors

5.1.1 Minors (children) are not employed below the National and/or State Legal Minimum Age (verbal confirmation accepted)?

Verbal and visual confirmation. Total compliance (Yes): No under age employees should be employed. If minors are employed, then their employment should meet both Federal and State Laws in terms of types of work and hours spent working. The auditee should have an in-depth knowledge of the local requirements. Auditees should also be following their factory insurer's guidelines. Auditor should note minimum age that company employs. While an auditor can look at policy documentation, insurance requirements etc., auditor must not demand to look at personnel information. This might mean that the auditor has to accept a verbal confirmation (auditor should remember to note this in the commentary text).

5.1.2 If minors are employed, do the records of hours of employment meet National and/or State Laws (both in and out of school time)?

Verbal & visual confirmation. Total compliance (Yes): If the auditee is employing minors, then the hours worked should be below State's maximum allowance. The auditee should be keeping records to prove that these hours are not being exceeded. If Minors are not employed, then this question should be scored N/A (with explanation).

5.1.3 If minors are employed, are they prohibited from doing certain jobs, which are restricted by law?

Verbal & visual confirmation. Total compliance (Yes): If the auditee is employing minors, then the work carried out should be in line with State requirements Minor's are usually restricted to light weight work in safe conditions. If Minors are not employed, then this question should be scored N/A (with explanation).

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Allergens

Potentially useful website:-
FDA ORA Inspection Guidance, http://www.fda.gov/ora/inspect_ref/igs/Allergy_Inspection_Guide.htm

5.2.1 There are no allergen risks handled or stored on site? If N, then complete Allergens Section (next questions).

Visual and verbal confirmation. Total compliance (Yes): 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 8) are Wheat, Eggs, Milk, Soybeans, Crustaceans (Shellfish), Peanuts, Tree Nuts and Fish. Other sensitive ingredients that would need investigating further are Sulfites and Artificial Color FDC Nº. 5. If there is no allergen handling on site then mark this question "Yes", 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 5.2.1). 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.

5.2.2 Are there adequate storage controls (separation, identification etc.) that ensure that allergens are not contaminating other raw materials?

Visual confirmation. Total compliance (Yes): 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 also should be identified as allergens.

5.2.3 Is there a dedicated production line or adequate clean down and production procedures that prevent allergen cross contamination?

Visual and verbal confirmation. Total compliance (Yes): 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. These procedures might include specific order of producing allergen containing products and special sanitation SOP's between allergen and non-allergen production runs. Some allergen testing kits (where available for the particular allergen) are also used in order to check the sanitation after an allergen has been used in a product.

5.2.4 Are utensils and work in progress storage containers identified in order to prevent allergen cross contamination?

Visual and verbal confirmation. Total compliance (Yes): 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, this includes rework bins.

5.2.5 Does re-work handling take into account the issues associated with allergen containing products?

Visual and verbal confirmation. Total compliance (Yes): Rework of allergen containing products needs to be strictly controlled. Allergen rework product should be clearly labeled. Allergen rework should be stored separately to non-allergen rework, raw materials and product. Allergen rework 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 rework, the traceability should be maintained which means that the use of rework materials is being properly recorded.

5.2.6 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 compliance (Yes): 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.

5.2.7 Are all products manufactured on site, labeled correctly with respect to allergens?

Visual and Verbal Confirmation. Total compliance (Yes): Allergen containing products should clearly show on the label the allergens that are associated with the product. If the allergens form part of condiment inclusion packs, these allergens should still be indicated on the main product label. If an operation is producing allergen containing products that will be used as an ingredient by a subsequent manufacturer, the documentation that goes with the product should underline the allergen contents and also ideally the bag and cartons should indicate the allergen contained within the product. If non-allergen containing products are produced on a site where allergens are used, the management should consider the chance of allergen cross contamination and if satisfactory controls to prevent such contamination are in place. If there are any doubts about the adequacy of these controls (GMPs), etc., then the 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.

Potentially useful website:-
FDA FALCP 2004, http://www.cfsan.fda.gov/~dms/alrgact.html

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Country of Origin Labeling

5.3.1 Is the company labeling retail packaging with the correct country of origin? N/A for food service.
Visual confirmation. Total compliance (Yes). 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.

5.3.2 Is the company labeling the finished goods carton with the correct country of origin? N/A for food service.
Visual confirmation. Total compliance (Yes). 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/prepacked 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.

5.3.3 Are there records that support the country of origin labeling e.g., bill of lading, production records, etc?
Visual confirmation. Total compliance (Yes). 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/getfile?dDocName=STELDEV3103377

5.3.4 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 compliance (Yes). 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.

Potentially useful websites:
http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateM&navID=CountryofOriginLabeling&rightNav1=CountryofOriginLabeling&topNav=&leftNav=CommodityAreas&page=CountryOfOriginLabeling&acct=cntryoforgnlbl
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3103388
http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3103377

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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-compliance. These questions do no affect either the Food Safety or Food Security scores in this audit version v08.06, 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 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, etc.)?

Visual confirmation. Total compliance (5 points). Where operations utilize 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 requirements and concentration testing
- 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 (so avoiding contamination issues)

The chemical label details, equipment manufacturers instructions and company safety rules are to be followed. Records of CIP cleaning should be maintained.

Minor deficiency (7 points) if:

- Up to two of the requirements listed above are missing or incorrect.
- Single/isolated instance(s) of omission(s) in procedure or records for a piece of equipment or facility area.

Major deficiency (3 points) if:

- Three or more of the above requirements are missing or incorrect.
- Numerous instances of omissions in procedure or records for a piece of equipment or facility area.

Non-compliance (0 points) if:

- No written procedures have been developed.
- There are no records.
- Procedures exist but they do not reflect what actually occurs.

6.1.2 Is there a tool accountability program for knives and similar hand tools used in the production area?

Visual Confirmation. Total compliance (3 points): There should be an accountability program in place for knives and similar hand tools 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. Question is non-applicable if knives or hand tools are not used.

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-compliance (0 points) if:

- There are no records for tool accountability.

6.1.3 Is there a list of approved commodity/ingredient suppliers?

Visual confirmation (5 points): There should be a list of approved suppliers of commodities and ingredients. All products and ingredients are ideally purchased from approved suppliers; where exceptions are made (e.g. market conditions) approval from management should be documented. Evaluations of vendor facilities by auditee are the ideal; third-party audit reports or certificates are also accepted. This question is only applicable to processing facilities and packinghouse operations.

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

6.1.4 Is there an annual certificate of inspection for the backflow prevention systems on water lines into the facility?

Visual confirmation. Total compliance (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 annually.

Potentially useful sites:
http://www.mindspring.com/~bakflotek/thelaw.htm
http://www.cdph.ca.gov/certlic/drinkingwater/Documents/DWdocuments/BackflowAssemblyApproval-12-28-05.pdf
http://phcc.files.cms-plus.com/Depts/Technical/2006NSPCNonIllustratedWeb.pdf

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-compliance (0 points) if:
- Last inspection and certification was done over 24 months ago.
- No inspection or certification records.

6.1.5 Where gloves are used, are they latex-free (e.g. vinyl, nitrile) or powder-free latex?

Visual confirmation. Total compliance (3 points): For some workers, exposures to latex which binds to the cornstarch in powdered gloves, may result in allergenic reactions. Use non-latex gloves (preferred) or powder-free latex gloves for food preparation, routine housekeeping, general maintenance, etc.

http://www.cdc.gov/Niosh/latexalt.html

Minor deficiency (2 points) if:
- Single/isolated instance(s) of gloves that are not either latex free or powder-free latex.

Major deficiency (1 point) if:
- Numerous instances of gloves that are not either latex free or powder-free latex.

Non-compliance (0 points) if:
- Systematic use of gloves that are not either latex free or powder-free latex.

6.1.6 Are employees required to sign a document stating that they will comply with the operations' personal hygiene, health and occupational safety policies?

Visual confirmation. Total compliance (5 points): All employees should sign a document 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.), health requirements (i.e. they are free from diseases that might be a food safety cross contamination risk) and occupational safety rules. The rules and policies should be clearly stated in relevant languages.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of important omissions in the document.

Major deficiency (1 point) if:
- Numerous instances of important omissions in the document.
- Numerous cases of employees not signing a document stating that they will comply with the operations' personal hygiene, health and occupational safety policies.
- Policy is not in the relevant language(s) of the employees.

Non-compliance (0 points) if:
- The company does not have a document for employees to sign stating that they will comply with the operations' personal hygiene, health and occupational safety policies.
- Systematic failure of visitors and contractors to sign a log stating that they will comply with the operations' personal hygiene, health and occupational safety policies

6.1.7 Are visitors and contractors required to sign a log stating that they will comply with the operations' personal hygiene, health and occupational safety policies?

Visual confirmation. Total compliance (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.), health requirements (i.e. they are free from diseases that might be a food safety cross contamination risk) and occupational safety rules. The rules and policies should be clearly stated in relevant languages. Compare this log with visitor sign in/out book (4.2.5) to confirm compliance.

Minor deficiency (3 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, health and occupational safety 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, health and occupational safety policies.
- Policy is not in the relevant language(s) of the visitors/contractors.

Non-compliance (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, health and occupational safety policies.
- Systematic failure of visitors and contractors to sign a log stating that they will comply with the operations' personal hygiene, health and occupational safety policies

6.1.8 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? (In the US, auditors can check procedure/policy but not actual records).

Visual and verbal confirmation. Total compliance (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 who the food handlers should report, how the issue is recorded and appropriate actions to be taken for a particular issue.

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-compliance (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.

6.1.9 Are all cuts and wounds covered with waterproof detectable blue bandages (Band Aids) that contain a metal strip?

Visual confirmation. Total compliance (5 points): Bandages used in food facilities should be waterproof and blue in color for easy visual detection, with a metal strip behind the wound pad for detection on lines with metal detectors. In facilities that handle only whole product, waterproof blue bandages without a metal strip are acceptable but ideal is for inclusion of a metal strip. Verify by checking the first-aid kit(s).

Minor deficiency (3 points) if:

- Single instance of a facility with metal detection in place using blue bandages without a metal strip.
- Single instance of a facility without metal detection (whole or boxed products) not using blue bandages.

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 using blue bandages.

Non-compliance (0 points) if:

- Waterproof blue bandages with a metal strip are not being used in a facility with metal detection.
- Waterproof blue bandages are not being used in a facility without metal detection.

6.1.10 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 compliance (10 points): All national and local laws pertaining to on-site water treatment systems should be followed; this should be documented. Where necessary there should be applicable

permits on file and evidence of regulatory and/or third party inspections. This question is non-applicable if there are no on-site wastewater treatments.
http://www.p2pays.org/ref%5C05/04874.pdf
http://cfpub.epa.gov/safewater/watersecurity/index.cfm
http://www.environment.tas.gov.au/_downloads/Guidelines%20for%20Fruit%20and%20Veg%20Processing%20Activities.pdf
http://www.epa.gov/owm/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-compliance (0 points) if:
- There are no records showing compliance to national and local laws pertaining to on-site water treatment systems.

6.1.11 Are all records free of "correction fluid" (white out), pencil text and erasable ink text? If using computerized records, is there a system that shows record amendments (data history) if the records are changed after initial entry?

Visual Confirmation. Total compliance (3 points): Corrections to records should be made without the use of "correction fluid" ("white-out"). Records should be in permanent ink, not pencil or erasable ink. If corrections are made they should be crossed out (and initialed by the person making the change) so that the original information is still legible. If records are stored on computer, then there should be a way of tracking any amendments to the records i.e. an amendment history with the ability to see who changed what, and when (this allows one to see what value was changed).

Minor deficiency (2 points):
- Single/isolated instance(s) of records found with white-out, 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 (1 point) if:
- Numerous instances of records found with white-out, 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.

Non-compliance (0 points) if:
- Systematic use of white out, 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.

6.1.12 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) 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/ora/compliance_ref/cpg/cpgfod/cpg555-425.htm.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of omissions or incorrect CCL validation details.

Major deficiency (1 point) if:

- Numerous instances of omissions or incorrect CCL validation details.

Non-compliance (0 points) if:

- There is no documentation to support CCP critical control limits.
- Systematic omissions or incorrect CCL validation details.

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PrimusLabs.com 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 (ready-to-eat)**	Y	Y	Y	Y	Y	Y	Fresh-cut salad
2	**Processing Audit (product requires cooking)**	Y	Y	Y	Y	Y		Frozen blueberries for further processing
3	**Packinghouse Audit (washed, potentially ready-to-eat)**	Y	Y	Y	Y1	Y		Washed whole tomatoes, apples, citrus
4	**Packinghouse Audit (washed, requires cooking &/or outer layer2 not an integral part of product)**	N	N	N	N	N		Washed whole potatoes
5	**Packinghouse Audit (unwashed, potentially ready-to-eat)**	N	N	Y	N	Y		Fresh blueberries, herbs
6	**Packinghouse Audit (unwashed, requires cooking &/or outer layer2 not an integral part of product)**	N	N	N	N	N		Onions
7	**Cooling/Cold Storage Audit (with hydrocoolers, hydrovacs, ice injection)**	Y	Y	N4				Field-packed broccoli
8	**Storage & Distribution Audit**	Y3						

Note

1 In packinghouses that wash product, smocks are a "must" after the wash step but ideally throughout the operation.

2 Outer layer e.g. rind, peel, skin is not eaten or used as an integral part of the product i.e as a food item.

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.

question is not included in this audit

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