PACKAGING V14.09

AUDIT SCORING GUIDELINES

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The PrimusLabs Packaging 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) involved. Auditors should interpret the questions and conformance criteria in different situations, with food safety and risk minimization being the key concerns.

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

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

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

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

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

Useful websites that help further investigate food safety requirements include:

FDA “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”
http://www.fda.gov/downloads/food/guidancecomplianceregulatoryinformation/guidancedocuments/produceandplanproducts/ucm169112.pdf
2013 FDA Food Code
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf
Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance
http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/fooddefense/ucm083075.htm
Guidance on Inspection of Firms Producing Food Products Susceptible to Contamination with Allergenic Ingredients http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074944.htm
USDA/FDA Food Safety Information Center, http://www.usda.gov/wps/portal/usda/usdahome?navid=food-safety

Packaging Audit

- Operations that handle and store food contact packaging such as cardboard boxes or cartons, clam shells, bags, etc. This does not include packaging manufacturers.

Audit Template Structure

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

The following is the scoring system used for the PrimusLabs GMP audits:

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

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

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

Automatic Failure

There are four questions in the facility audits, 1.1.1, 1.2.7, 1.8.1, and 1.8.4, that if down scored will lead to an automatic failure and an overall score of 0%. The report will include a breakdown of the scores for each section (summary chart), even if an automatic failure question is scored down. **On being immediately informed of the automatic failure by the auditor during the audit, the auditee has the option to have the auditor continue to complete the audit or to have the audit halt at that point (all charges will apply).**

Special Circumstances

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

Audit Termination

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

Change of Audit Service

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

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

Packaging Selection

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

Facility Audit Agenda

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

- **Opening Meeting**. Confirm the appointment details, introduce the auditor(s) and auditee team, confirm scope and the day's agenda.
- **Tour of Operations**. Areas toured depend of the type of facility, but might include personnel facilities, maintenance, chemical storage, packaging storage and external areas (e.g., where the dumpsters are located). The auditor might interview some operators.
- **Food Safety File (paperwork section)**. New auditees should have at least three months' worth of paperwork available. Please note that the auditor cannot accept documentary evidence after the audit has ended. For example, if a pest control document is missing at the time of the audit and the auditee tries to fax it the next day, it cannot be used to alter the score.
- **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.
- **Additional Questions**. Might be covered at any point in the audit, as the topics arise.
- **Auditor "Quiet" Time**. Time required for the auditor to organize notes before delivering the closing meeting.
- **Closing Meeting**. Discuss findings with the auditee team. Auditors are not able to provide either a final score or pass/fail commentary at the end of the audit due to the high number of questions that are asked in the template and the scoring system that is applied. However, auditors do submit audit reports quickly and auditees should contact PrimusLabs if reports have not been received electronically two weeks after the audit has occurred (at the latest).

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

PrimusLabs Documentation Requirements

New Facility Auditees/First Time Facility Auditees

- **In operation for more than three consecutive months** – auditee should have at least three months of documentation available for review. If the facility has less than three months of most of their documentation available for review, a pre-assessment audit is strongly advised. If the

auditee has less than three months of most of their documentation available for review and decides to have a regular audit, they should be aware that they **cannot receive full conformance for paperwork questions related to monitoring and that the down score will be based on the amount of paperwork available**.

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

Existing Facility Auditees

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

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

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

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

Visual versus Verbal Confirmation

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

How to Use Point Assignment Guidelines

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

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

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

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Point Assignment Guidelines

Good Manufacturing Practices - Section 1 (Facility Tour)

Management Systems

1.1.1 There was no significant threat to the safety of the product that may be considered critical and warrants an automatic failure? Explain any "no" response. ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.
Visual Confirmation. Total conformance (15 points): No observation of any issue that the auditor considers a significant threat to the safety of the product. Issues covered by this question are critical food safety situations that might not be considered in the audit template questions and conformance criteria. Alternatively, there may be question and conformance criteria that cover the topic of the issue within the audit, but the situation discovered warrants an automatic failure as opposed to a point down score; the auditor will note the issue in this question.

Specific directions for pest and other adulteration (direct observation of contamination and/or adulteration of material) are covered in 1.2.7, 1.8.1 and 1.8.4. This question is intended for other issues that may not be covered by those questions. Scoring reverts back to this question where the auditor must detail their concern. If the auditor spots an issue that is a serious threat to food safety (as opposed to a pre-requisite) and corrective actions are not being implemented, issue may also be scored here.

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

Automatic Failure (0 points) if:
- **There is a significant threat to the safety of the product**.

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Storage Areas & Packaging Materials

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

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

All chemical containers should have legible content labels, including chemicals that have been decanted from master containers into smaller containers. Where chemicals are stored, adequate liquid containment (spill controls) techniques need to be employed (e.g., via secondary containment, absorbent materials, angled sealed floors, spill kits, etc.). Chemical storage should be designed to help contain spills and leaking containers. Empty containers should be stored and disposed of safely. Liquids should not be stored above powders.

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

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

Non-conformance (0 points) if:

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

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

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

apart from non-food grade items to eliminate confusion between types. Grease guns should indicate which are for food grade greases and which are for non-food grade use. Non-food grade material use, where required, should not be used in food contact areas and should only 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 storage areas (unless stored securely, with access to entrusted personnel only).

Potentially useful websites:
NSF International: Nonfood Compounds http://info.nsf.org/USDA/psnclistings.asp
http://www.codexalimentarius.org/input/download/standards/3/CXS_150e.pdf
http://pods.dasnr.okstate.edu/docushare/dsweb/Get/Document-963/FAPC-116web.pdf

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

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

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

1.2.3 Is packaging stored to prevent cross contamination?
Visual confirmation. Total conformance (15 points): All packaging should be stored off the ground (i.e., on racks, pallets, shelves, etc.). Materials should be properly protected during storage to prevent contamination. Packaging materials should be stored separately from other items to prevent potential cross contamination. When separate room storage is not possible, the auditor should assess the risks especially with respect to cross contamination.

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

Major deficiency (5 points) if:
- Numerous instances of packaging materials not protected properly.
- Numerous instances of packaging materials stored directly on the ground.

Non-conformance (0 points) if:
- Systematic storage of packaging materials directly on the ground.
- **Any signs of material adulteration from poor storage practices – see 1.2.7, automatic failure due to product contamination.**

1.2.4 Is the storage area completely enclosed?
Visual confirmation. Total conformance (10 points): To protect the packaging materials from the elements and pests, it is necessary to keep the storage area enclosed and pest proof. Main doors should be kept closed, unless in use. Food contact packaging should not be stored outside. Non-food contact packaging (e.g., cardboard outers) should be stored inside if possible. If some non-food contact packaging is stored

outside, then this outside storage area should be included in the pest control program. Outside stored non-food materials should be covered with a waterproof and dust proof shroud (often made of plastic material).

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

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

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

1.2.5 Is the facility's use restricted to the storage of packaging materials?

Visual confirmation. Total conformance (5 points): Only packaging material and related items are stored in the facility's storage areas. Sanitation chemicals and maintenance equipment storage should have their own dedicated storage areas away from packaging and related items.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of storage of unrelated items in areas that are used for storing packaging materials.

Major deficiency (1 point) if:
- Numerous instances of storage of unrelated items in areas that are used for storing packaging materials.

Non-conformance (0 points) if:
- Systematic storage of unrelated items in areas that are used for storing packaging materials.

1.2.6 Are rejected or on hold materials clearly identified and separated from other materials?

Visual confirmation. Total conformance (10 points): All packaging that is being rejected or is awaiting final disposition (on hold) should be stored in a designated hold area, in a way that avoids accidental use of these materials (unless they have been cleared for use). The rejected or on hold items should be tagged as such. The tagged material should not be commingled with other goods in such a way that their disposition is not clear. It is "ideal" that there also be records of items placed on hold (e.g., an on hold/disposition log with item status, date, reason and responsible person for status designation) available for review (scored in 2.4.4).

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

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

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

1.2.7 Is food contact packaging within accepted tolerances and free from adulteration? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.
Visual confirmation. Total conformance (15 points): Food contact packaging and food contact surfaces should be free from adulteration and/or gross contamination (21 CFR 110.3g). If legislation exists, then the contamination should be viewed against this legislation. Adulteration would include any physical, chemical or biological contamination, including bodily fluids. This question is designed to allow an auditor to halt an audit when finding gross contamination issues (note that pests are covered by 1.8.1). Examples might include glass, trash/litter, motor oil on packaging materials, etc. Where an issue is observed by an operator in the normal process, auditor should observe the actions of the operator before scoring. Auditors should use their discretion and decide whether the frequency of the contamination warrants an automatic failure.
Examples include pieces of glass, one piece of rodent bait, paint on packaging, flakes of rust, etc. Is the issue systematic or a one-off issue?

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

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

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

Automatic Failure (0 points) if:
- **Numerous incidences of adulteration of material.**
- **There is a single gross incidence of evidence of adulteration of packaging material.**

1.2.8 Are all storage areas clean, especially the racking structures, lights, ceilings, floor areas by the walls and other hard to reach areas?
Visual confirmation. Total conformance (10 points): All storage areas should be clean and well ventilated and protected from condensation, sewage, dust, dirt, toxic chemicals or other contaminants. Ledges should be free of debris and clean. Stored packaging should be clean and free from dust, debris and out of place of 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 packaging with dust, debris, etc.
- Single/isolated instance(s) of dirty lights/light covers.

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

Non-conformance (0 points) if:

- Storage areas are very dirty – little or no evidence of cleaning occurring.
- Systematic failure to maintain lights/light covers in a clean condition.

1.2.9 Are packaging materials properly marked with rotation codes (receipt dates, manufacture dates, etc.)?

Visual confirmation. Total conformance (5 points): All materials should be properly marked with receipt dates and/or tracking information (e.g., 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 packaging.
- Packaging missing receipt dates and/or tracking information.

Major deficiency (1 point) if:
- Numerous instances of missing receipt dates and/or tracking information on packaging.

Non-conformance (0 points) if:
- There are no receipt dates and/or tracking information on packaging.

1.2.10 Are packaging materials rotated using FIFO policy?

Visual/verbal confirmation. Total conformance (5 points): All materials are rotated using First in First Out (FIFO) policy to ensure items are used in the correct order they are received (this does not apply where rotation is dictated by the initial quality inspection). Packaging rotation might be affected by market forces. Having a “Just In Time” ordering policy and thereby having very limited stock volumes, is acceptable as a replacement for FIFO if it can be proven (e.g., the auditor can see that hardly any stock is maintained). “Just In Time” ordering policy does not replace the need to tag materials as per question 1.2.9.

Minor deficiency (3 points) if:
- Single/isolated instance(s) where materials are not rotated using FIFO policy.
- Packaging is not being rotated using FIFO policy.

Major deficiency (1 point) if:
- Numerous instances where materials are not rotated using FIFO policy.

Non-conformance (0 points) if:
- Systematic failure to use FIFO policy on materials.

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Operational Practices

1.3.1 Does the process flow, facility layout, employee control, utensil, internal vehicle use, etc., ensure that packaging material is not contaminated during storage?
Visual Confirmation. Total conformance (15 Points): There should be plenty of space and separation to help avoid cross contamination issues. Utensils, cleaning implements, internal vehicles, etc. should not be allowed to be vectors for cross contamination.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of employee/utensil/internal vehicle cross contamination.

Major deficiency (5 points) if:
- Numerous instances of employee/utensil cross contamination.

Non-conformance (0 points) if:
- Systematic instances/issues with employee and/or utensil cross contamination.

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

Minor deficiency (10 points) if:
- Single/isolated instance(s) of possible overhead contamination.

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

Non-conformance (0 points) if:
- No protective devices have been installed to eliminate potential contamination.
- **Any observation of direct contamination of materials, the score should revert back to 1.2.7.**

1.3.3 Is all re-work handled correctly?
Visual/verbal confirmation. Total conformance (10 points): Re-work practices should adhere to all required GMP's.
All re-work should be handled correctly:
- Packaging items are opened (if applicable) with clean knives.
- Employees should have washed their hands and (ideally) if company policy, wear clean gloves i.e. should follow company GMP rules for hand sanitation.
- The traceback details are transferred correctly.

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

Minor deficiency (7 points) if:
- One of the items above is not being followed.

Major deficiency (3 points) if:
- Two items above are not being followed.

Non-conformance (0 points) if:

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

1.3.4 Are packaging materials examined before use?

Visual confirmation. Total conformance (5 points): Packaging materials are examined for damage, insect or rodent infestation, foreign materials, tampering evidences (e.g., broken seals, etc.) before use. Visual inspection is acceptable.

Minor deficiency (3 points) if:
- Single packaging material is not examined prior to use.

Major deficiency (1 point) if:
- Numerous packaging materials are not being examined prior to use.

Non-conformance (0 points) if:
- No packaging materials are examined before use.

1.3.5 Does product coding clearly link to supplier(s) of incoming materials? (Auditor performs a live traceback test to verify documentation reviewed for 2.4.1.)

Visual confirmation. Total conformance (10 points): Incoming packaging materials should have traceable lot codes at receipt which follow the item through storage. Auditor should choose a stored product lot code and have auditee demonstrate how the code traces back to material supplier(s). The system being used should match the written traceability system (2.4.1).

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

Major deficiency (3 points) if:
- Single/isolated instance(s) of either incorrect or missing elements or inadequate lot identifiers of the coding system that either limits or stops efficient trace back to the material supplier.

Non-conformance (0 points) if:
- Numerous instances of either incorrect or missing elements or inadequate lot identifiers of the coding system that either limits or stops efficient trace back to the material supplier.

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

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

Potentially Useful Website:
United States Department of Labor 29 CFR 1910.141(c)(1)(i): Toilet Facilities
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf
http://www.dir.ca.gov/title8/3366.html

Minor deficiency (10 points) if:
- Only about 75% of needed hand washing stations are present.
- Single/isolated instance(s) of hand washing stations not in working order .
- Only cold water is available at one or more stations.
- Single/isolated instance(s) of soap with a lingering fragrance being used.

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

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

1.3.7 Are toilet facilities adequate in number and location and are they adequately stocked (e.g. toilet paper, soap, disposable towels, trash cans, etc.)?

Visual confirmation. Total conformance (15 points): Toilet facilities are adequate in number and location:
- Toilet facilities should be located within a reasonable distance from the employees' workstation.
- Toilet facilities should be readily available to male and female employees. The number of facilities provided for each sex should be based on the number of employees of that sex.
- Where there are single-occupancy rooms, separate toilet rooms for each sex are not required (sufficient toilets available).
- There should be sufficient toilets for the employees:

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

- Urinals for male employees should not make up more than 1/3 of the total male toilets provided.
- Each individual toilet facility should be able to be locked from inside.
- Each toilet facility should be maintained, well lighted and ventilated to outside air.
- In the toilet room, the floor and sidewalls should be watertight. The sidewalls should be watertight to a height of at least five inches.
- The floors, walls, ceiling, partitions and doors of all toilet rooms should be made of a finish that can be cleaned easily.
- Doors should not open directly into areas where material is exposed to airborne contamination, i.e., storage areas. Use of double doors or having a positive airflow system is accepted. In older operations, where doors to restrooms are not located in the amenity area or office area, the doors should be kept closed at all times e.g. use a spring loaded door.
- Toilet paper should be available to each person and stored in such a way as to prevent contamination.

- Adequate trash disposal should be available within restrooms.

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

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

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

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

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

1.3.8 Are secondary hand sanitation stations e.g. touch-free dispensers adequate in number and location? Are the stations maintained properly?
Visual confirmation. Total conformance (5 points): Secondary hand sanitation (hand dips, gels or sprays) does not replace hand washing requirements (lack surfactant qualities). Secondary hand sanitation stations should be conveniently located in traffic zones but should not be obstructive. Hand dips (if used) should contain a USDA approved food grade sanitizer at a determined concentration. Refer to hand sanitizer manufacturer label for dilutions. Hand dips should be regularly monitored (recorded anti-microbial strength checks) to ensure their effectiveness with corrective actions recorded (e.g., dip solution replenishment and anti-microbial additions). Hand gel and spray stations should be well stocked with a sanitizer approved for direct hand to food contact (e.g., USDA approved or national equivalent) and regularly monitored (recorded checks) to ensure availability with corrective actions recorded (e.g., pack replenishment). Use of a refill alert type dispenser is ideal practice. Dispensers should be located a sufficient distance from packaging to prevent accidental material contamination. The auditor should check that gel pack type stations are stocked and have the auditee check the strength of anti-microbial chemicals in hand dips while touring the facility. Records are scored in 2.9.1. N/A if secondary hand sanitation stations are not in use.

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

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

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

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

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

Visual confirmation. Total conformance (5 points): Single service containers are used for their intended purpose only (food contact use, not to hold nuts, bolts, trash or other miscellaneous items) and should not be re-used. Returnable plastic containers (RPCs) (e.g., CHEP, IFCO) should be treated like single service containers and only used with designated material. If a single service container is used for any other reason than the storage and distribution of designated material, 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-conformance (0 points) if:
- Systematic miss-use of single services container, used for other than intended purpose.
- **Any observation of direct contamination of packaging materials, the score reverts back to 1.2.7.**

1.3.10 Are all re-usable containers clean and clearly designated for the specific purpose such that cross contamination is prevented?

Visual confirmation. Total conformance (10 points): Bins, boxes, hoppers, barrels, baskets, etc. used for the storage of packaging materials should be kept in a clean state. The storage of these items should ensure that they remain clean and uncontaminated (e.g., covered clean). In-house re-usable containers should be labeled or color-coded so that their designated purpose can be easily identified. Returnable plastic containers (RPCs) (e.g., CHEP, IFCO) should be treated like single service containers and only used for product (score in 1.3.9). If the trash container is the only re-used container on site and is a specific and unique design, so that it cannot be mistaken for another use, then should not be down scored.

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

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

Non-conformance (0 points) if:

- Systematic failure to not clean food storage containers.
- There is no cleaning program for the containers.
- Systematic lack of control with respect to storage of clean food contact storage containers.
- Re-usable containers are used for multiple purposes without the containers being labeled or color-coded.
- **Any observation of direct contamination of packaging materials, the score should revert back to 1.2.7.**

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Employee Practices

1.4.1 Are employees washing and sanitizing their hands before starting work each day, after using the restroom, after breaks and whenever hands may be contaminated?

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

Potentially useful website:
A "Safe Hands" Hand Wash Program,
http://www.fda.gov/food/guidanceregulation/retailfoodprotection/industryandregulatoryassistanceandtrainingresources/ucm135577.htm

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

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

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

1.4.2 Are employees' fingernails clean, short and free of nail polish?

Visual Confirmation. Total conformance (5 points): Fingernails can harbor dirt and debris and can be a source of cross contamination. Therefore, nails should be clean and short to reduce the risk of cross contamination. Fingernail polish and false nails should not be worn, even when gloves are worn. Use of fingernail brushes might assist in nail cleaning, however, care should be taken to ensure that these brushes are kept clean and regularly replaced or they might they become a cross contamination vector.

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

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

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

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

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

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

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

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

Non-compliance (0 points) if:

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

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

Visual confirmation. Total conformance (5 points). First aid kit(s) should be adequately supplied to reflect the kinds of injuries that occur (including any chemicals stored on-site) and should be stored in an area where they are readily available for emergency access. Date-coded materials should be within dates of expiration. Bandages used in storage facilities should be easy to detect. Gloves should be worn over all band aids on hands. Auditors should verify by checking the first-aid kit(s).

Minor deficiency (3 points) if:

- Single/isolated instance(s) of first aid kit(s) not having adequate supplies, supplies out-of-date or kit not readily accessible.

Major deficiency (2 points) if:

- Numerous instances of first aid kit(s) not having adequate supplies, supplies out-of-date or kit not readily accessible.

Non-conformance (0 points) if:

- Bandages are not available.
- Systematic failure to provide first aid kit(s) with adequate supplies, supplies out-of-date or kit not readily accessible.

1.4.5 Are employees wearing effective hair restraints?

Visual Confirmation. Total conformance (10 points): Employees (includes maintenance employees and visitors) should be wearing appropriate hair restraints (hairnets, beard nets and moustache covers, where appropriate) that fully contain all hair.

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

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

Minor deficiency (7 points) if:

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

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

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

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

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

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

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

1.4.7 Do employees remove protective outer garments e.g. gloves when on break, before using the toilets and when going home at the end of their shift?
Visual confirmation. Total conformance (5 points): When worn, protective outer garments (e.g., gloves) are to be removed when employees leave the work area (when they go to the restroom, break room, outside, smoking breaks, etc.). Hairnet removal when leaving the work area is not mandated by this audit.

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

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

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

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

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

Major deficiency (1 point) if:

- Numerous instances are observed of non-conformance to the above.

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

1.4.9 Employees personal items are not being stored in the material storage areas?
Visual confirmation. Total conformance (5 points): Employees should have a designated area for storing personal items such as coats, shoes, purses, medication, etc. Lockers or cubbies are desirable. Areas set aside for employee personal items should be far enough away from stored packaging material and equipment 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 storage areas.

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

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

1.4.10 Is smoking, eating, chewing and drinking confined to designated areas; spitting is prohibited in all areas?
Visual confirmation. Total conformance (10 points): Smoking, chewing tobacco, chewing gum, drinking and eating is permitted in designated areas that are away from storage areas. Spitting should be prohibited in all areas. Smoking should not be permitted in eating and drinking areas. Potable water should be provided in all places of employment for drinking, following local and national laws. Portable drinking water dispensers should be designed, constructed and maintained in a sanitary condition, capable of being closed, and equipped with a tap. The water should be dispensed in single-use drinking cups or by fountains. Common drinking cups and other common utensils are prohibited. Check work areas refuse containers and look in out of sight areas. If food consumption areas are designated within facility offices or maintenance areas, then the control of cross contamination, GMPs and access to hand washing facilities should be considered.

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

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

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

Non-conformance (0 points) if:

- Systematic consumption of food and beverages outside of designated areas.
- No temperature control storage of break time food.
- Systematic evidence of smoking outside the designated area.
- Systematic evidence of using chewing tobacco in storage areas.
- Designated area lacks access to a hand wash station.
- Systematic non-conformance to the above criteria.
- **Any observation of direct contamination of packaging materials, the score should revert back to 1.2.7.**

1.4.11 Are all items removed from garment (shirt, blouse, etc.) top pockets?

Visual confirmation. Total conformance (3 points): Observations show that there are no items stored in employees' shirts and blouse top pockets. Ideally, top pockets are sewn up or non-existent. Remember to also check maintenance employees in the storage 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 or blouse top pocket.

Major deficiency (1 point) if:

- Numerous instances of items observed in shirt or blouse top pockets.

Non-conformance (0 points) if:

- Systematic use of shirt or blouse top pockets.

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Equipment

1.5.1 Are food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g. tape, string, cardboard, etc.)?
Visual confirmation. Total conformance (15 points): Packaging 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 packaging.

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

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

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

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

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

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

1.5.3 Does equipment design and condition (e.g. smooth surfaces, smooth weld seams, non-toxic materials, no wood or other absorbent materials) facilitate effective cleaning and maintenance?
Visual confirmation. Total conformance (15 points): Equipment should be made of appropriate materials for current use that can be easily cleaned (smooth, non-porous, non- toxic, no dead spots) and maintained in an acceptable condition. Equipment should be designed to allow access to all areas and there should be no debris trapping areas that cannot be easily cleaned, including hollow structures on

supports, rollers, racks, etc. There should be no metal-to-metal contact that results in grinding and, therefore, potential metal contamination. There should be no “bobbly”, debris trapping welds that are hard to clean. Equipment should be mounted off the floor at least 6 inches (15 cm) to allow for cleaning.

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

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

Non-conformance (0 points) if:

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

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Equipment Cleaning

1.6.1 Are food contact equipment surfaces clean?

Visual confirmation. Total conformance (15 points): All equipment surfaces that make contact with material should be kept in a clean condition to avoid cross contamination. The auditor must clearly point out any issues to the auditee. Food debris, bio films, excessive dust, etc., should be cleaned off equipment and facility surfaces in order to reduce overall facility bio-burden.

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

Minor deficiency (10 points) if:

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

Major deficiency (5 points) if:

- Numerous instances of food contact surfaces that are unclean.
- Some equipment is not cleaned after final shift.

Non-conformance (0 points) if:

- Systematic observations of food contact surfaces that are unclean.
- Equipment is not cleaned after final shift.
- **Any observation of direct contamination of packaging material, revert back to Q 1.2.7, automatic failure.**

1.6.2 Are non-food contact equipment surfaces clean?

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of non-food contact surfaces that are unclean.
- Some equipment is not cleaned after final shift.

Non-conformance (0 points) if:

- Systematic observations of non-food contact surfaces that are unclean.
- Equipment is not cleaned after final shift.

1.6.3 During cleaning, is packaging protected from contamination?

Visual confirmation. Total conformance (15 points): 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. Not applicable if cleaning practices are not observed.

Minor deficiency (10 points) if:

- Single/isolated instance(s) of cleaning activities having the potential for re-contaminating previously cleaned equipment (e.g., cleaning the floor after sanitizing equipment and observing splash back occurring). Packaging is protected.

Major deficiency (5 points) if:

- Single instance of activities having the potential for contaminating packaging. Packaging is not adequately protected, including splash back. Auditor should be careful to check that no contamination has occurred (consult non-conformance texts).
- Numerous instances of cleaning activities having the potential for re-contaminating previously cleaned equipment (e.g., cleaning the floor after sanitizing equipment and observing splash back occurring). Packaging is protected.

Non-conformance (0 points) if:

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

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

Visual Confirmation. Total conformance (5 points): All fan guards (cooling units and general ventilation) in the facility are clean. There is no build-up of dust or other materials on the fan guards. Check the ceiling in front of the cooling unit for black deposits and signs of cleaning issues. Check and see if there is evidence of cooler unit debris on the floor or 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 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 packaging.
- A single instance where cooling unit debris is noted above packaging, but there is no contamination of food contact packaging.

Non-conformance (0 points) if:

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

1.6.5 Is stored equipment that is not used on a daily basis stored in a clean condition with food-contact surfaces protected and/or are they retained on the cleaning schedules in some manner, even though they are not in use?

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

Minor deficiency (7 points) if:

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

Major deficiency (3 point) if:

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

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

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

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

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

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

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

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

Visual Confirmation. Total conformance (3 points): Tools that are used for repairing equipment in the storage areas should be appropriately stored to ensure they do not pose a risk of direct or indirect contamination. When in storage areas, they should be clean, free of corrosion and in good working order, i.e. fit for their intended use. Special attention should be focused on those tools that are resident in tool boxes, within storage areas, tools in the maintenance areas that are ready to be taken into storage areas, or are used in the maintenance area on equipment that will be going into the storage areas. Sometimes, a maintenance shop might have tools that are used exclusively on external trucks and farm equipment. The auditor should avoid scoring these kinds of tools.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of unclean and/or corroded maintenance tools used on food equipment.
- Single/isolated instance(s) of maintenance tools being stored inappropriately.

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

Non-conformance (0 points) if:
- Systematic failure to ensure that maintenance tools are clean and/or corrosion free.
- Systematic failures to ensure maintenance tools are stored appropriately.

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

Visual Confirmation. Total conformance (5 points): Excess lubricants and greases are removed from equipment and there are no observations of leakage or drips. Where drive motors are mounted over packaging zones, catch pans should be installed, and where needed, with drainage via hosing to the floor. Cranes, chains and pulley equipment above lines are potential areas where excessive grease might be an issue. Key consideration should be given to where lubricants and greases can leak onto food

contact surfaces. Lubrication should be frequent and use small amounts of lubricant, as opposed to large amounts of lubricant used on an infrequent basis. Food grade lube should be used where required (see questions in 1.2), but food grade materials are still only for incidental contact and all precautions should be taken in order to prevent these from contaminating the food contact surfaces.

Minor deficiency (3 points) if:

- Single/isolated instance (s) of excess lubricants or grease on equipment (no packaging material 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 packaging material hazard).
- Numerous instances of unprotected motors, axles, pumps, etc.

Non-conformance (0 points) if:

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

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General Cleaning

1.7.1 Are spills cleaned up immediately?

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-conformance (0 points) if:

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

1.7.2 Are waste and garbage frequently removed from storage areas?

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

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of waste/garbage removal issues, which do not pose a risk to packaging material and/or equipment.
- Single instance where waste has an off odor, has attracted flies and/or is exhibiting mold growth.

Non-conformance (0 points) if:

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

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

Visual Confirmation. Total conformance (5 points):

- All floor drains, including covers and internal channels are clean, and free of decayed/old material.
- All floor drains are free of odors.
- There is no overflow or excessive standing water in the floor drains.
- Water from refrigeration drip pans is drained and disposed of away from packaging and food contact surfaces.
- Drains should have smooth walls and bases that allow free flow of water without catching debris, and also aid cleaning of the drains.

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

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

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

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

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

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

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

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

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

1.7.5 Are plastic strip curtains maintained in a good condition, kept clean and mounted so that the tips are not touching the floor?

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

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

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

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

1.7.6 Does personal protection equipment (PPE) for the sanitation crew meet label requirements of chemicals used; is it in good condition and stored to prevent cross contamination to packaging?

Visual Confirmation. Total conformance (3 points): Safety equipment (Personal Protective Equipment (PPE)) is provided for the sanitation crew. The supplied safety equipment should meet all the

requirements as shown on the chemical labels of the cleaning agents that are used. Safety equipment storage is organized and segregated from packaging material to prevent contamination. Safety equipment is stored separately, away from personal clothing. Access to sanitation equipment should be restricted to trained employees. Safety equipment should be stored securely to prevent unauthorized use. Safety equipment is in good repair.

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

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

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

1.7.7 Is cleaning equipment maintained clean and stored properly?

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

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

Major deficiency (3 points) if:
- Numerous instances of the issues mentioned above.
- Numerous instances of cleaning equipment that is being stored in a way that may represent a risk for packaging materials or equipment.
- Numerous cleaning materials unavailable.

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

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

Visual Confirmation. Total conformance (10 points): Cleaning equipment should be “area specific”. Coding should prevent cross contamination. Separation of restroom (toilet facility), outdoor, maintenance and storage 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 storage area (e.g., equipment used on the floor versus equipment used on the machinery).

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

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

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

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

Visual Confirmation. Total conformance (5 points): Steel wool is avoided for use as cleaning equipment. Cleaning utensils used are constructed to prevent potential contamination of packaging material (e.g., without straw bristles, metal bristles, etc.). Ideally, brightly colored plastic bristles are used. Avoid anything that flakes, is made of pervious materials, is a similar color to the packaging material, corrodes or might damage the equipment or facility.

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

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

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

1.7.10 Are toilet facilities and hand-washing stations clean?

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

- Toilet facilities have a drainage installation that allows the waste to be flushed and disposed properly.
- Toilet facility (including hand washing stations) fixtures are in good operating condition and clean.
- Cleaning and sanitizing frequency is at least daily.
- No offensive odors are evident.
- No soiled toilet tissue either on the floor or in trash cans.
- Trash cans are available for hand wash paper towels.
- Hand washing stations are properly plumbed to drainage system.
- Hand washing stations are clean and not blocked.

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

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

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

1.7.11 Are employee break facilities clean, including microwaves and refrigerators? No rotting or out of date foodstuffs?

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

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

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

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

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

Visual confirmation. Total conformance (5 points): Inspection of the facility shows that the maintenance shop is kept clean and organized. Sanitation practices include the periodic cleaning of this area in order to avoid pest harborage conditions that may contaminate the packaging material 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 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 storage areas and a minor potential for cross contamination exists.

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

1.7.13 Are internal transport vehicles (e.g. forklifts, bobcats, pallet jacks, trolleys, floor cleaners, etc.) clean, do not emit toxic fumes and being used in a sanitary manner?
Visual confirmation. Total conformance (5 points) if:
- Vehicles and equipment used for moving packaging throughout and within the facility are clean, well maintained, and do not transport goods outside the facility (unless cleaned and sanitized before re-entering). Open dock areas are accepted as being within the facility in this instance.
- Internal transport vehicles (forklifts, bobcats (or similar type vehicle)), pallet jacks, trolley, floor cleaners, etc.) used to transport packaging 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 packaging to reduce health risk and possible tainting of food contact surfaces.
- 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.

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

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

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

1.7.14 Are shipping trucks clean and in good condition?
Visual confirmation. Total conformance (5 points). Trucks and/or trailers (including in-house delivery and shuttle trucks) used to transport prodcut 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 material 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 packaging material.

Non-conformance (0 points) if:

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

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Pest Control

1.8.1 Are packaging supplies free of insects/rodents/birds/reptiles/mammals or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.
Visual Confirmation. Total conformance (15 points): Packaging supplies are free from evidence or the presence of insects/rodents/birds/reptiles/mammals (humans, dogs, etc.). See 1.8.2 for potential indications of pest presence.

Automatic Failure (0 points) if:
- **There is a single incidence of direct contamination of packaging.**

1.8.2 Are facility and storage areas free of insects/rodents/birds/reptiles/mammals or any evidence of them?
Visual confirmation. Total conformance (15 points): All areas are free of recurring/existing internal pest activity. Specifically there should be:
- No recurring/existing rodent activity and/or bird nesting observed around the interior perimeter or the facility.
- No evidence of animals observed inside the facility such as cats, dogs, deer, etc., including tracks and animal damage.
- No evidence of feces/pellets.
- No evidence of pests including insects, spiders/webbing, rodents, lizards, ants or birds in the facility.
- No evidence of gnawed bags/sacs or rodents on stored stock or numerous excreta on the floor/shelves of any storage area.
- No decomposed rodent(s) or other animals (frogs, lizards, etc.) in traps. The interior traps should be checked often and the dead rodent(s) or other animals removed.

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

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

Minor deficiency (10 points) if:
- Single/isolated instance(s) of pest activity noted on the interior of the facility, which does not pose an immediate threat of packaging material contamination.
- Single/isolated instance(s) of feces/pellets noted in the interior of the facility, which does not pose an immediate threat of packaging material contamination.
- Single “fresh” rodent found in an internal trap.

Major deficiency (5 points) if:
- Numerous instances of pest activity (including feces/pellets) noted in the interior of the facility, which does not pose an immediate threat of packaging material contamination.
- Pest activity (including fecal matter), which has the potential for contaminating packaging material.
- Two to three instances of “fresh” rodents found in internal traps.

Non-conformance (0 points) if:
- One sighting (including feces/pellets) which has the potential for packaging material 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 packaging contact qualifies as an automatic failure under 1.8.1.**

1.8.3 Is the area outside the facility free of evidence of pest activity?

Visual Confirmation. Total conformance (10 points): All areas should be free of recurring/existing external pest activity. Specifically there should be:

- No recurring/existing rodent or animal (e.g. dogs, humans, etc.) activity/spoors (significant burrows, trails, feces, tracks) in active areas within operation's property perimeter. For example, storage (packaging, bone yards), outbuildings (e.g. shade structures), etc.
- No bird nesting/activity observed around the exterior perimeter of the facility or external storage/outbuildings (e.g., pallets, trailers/containers, bone yards, etc.).
- No decomposed rodent(s) or other animals (frogs, lizards, etc.) in bait stations or along perimeter.

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-conformance (0 points) if:

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

1.8.4 Does the operation have a pest control program? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.

Visual confirmation. Total conformance (15 points): The operation has a proactive pest control program (in-house or contracted) to control rodents (also insects, reptiles and birds where necessary) and prevent infestation.

Automatic Failure (0 points) if:

- **The operation does not have a proactive pest control program**.

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

1.8.5 Are pest control devices (inc. rodent traps and insect light traps) located away from all packaging? Poisonous rodent bait traps are not used within the facility?

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

- Poisonous bait stations and other pesticides should only be used outside the facility.
- There should be no domestic fly sprays used within the storage areas.
- Block bait as opposed to grain and pellet bait should be used (except for the external use of National Organic Program approved materials).
- If used, insect light traps (ILTs), electrical fly killers (EFKs) or pheromone traps should be regularly cleaned out (kept free from a build-up of insects and debris). Sticky type ILTs should be monitored at least monthly and the sticky board replaced if ineffective. ILTs that use sticking as opposed to zapping methods (EFKs) are preferred.
- If used, insect light traps or electric fly killers should not be placed above or in close proximity (10 feet, 3 meters) to food contact surfaces, equipment, or packaging material. Electric fly killers or insect light traps should not be located above dock doors (due to potential forklift damage) or in front of doorways (so attracting insects into the facility). Hallways or dock areas where packaging material passes through are exempt from these distances, as long as packaging material does not stop or is not stored in hallway or dock.
- If used, insect light trap bulbs should be replaced at least every 12 months (this should be recorded), or as more frequently if directed by manufacturers.
- No fly swatters should be evident in storage areas.
- No bait should be found outside of bait stations.
- If necessary (e.g., in facilities with high dust levels) where glue boards may not be practical, multiple-catch traps may be **supplemented** with snap traps inside stations. Snap traps should not use allergen containing baits (e.g., peanut butter). Any supplemental snap traps inside stations should be checked at least weekly and checks recorded (1.8.6).
- Any indoor use of chemicals (e.g., knock down sprays) should be done without contaminating packaging material and equipment (see the next bullet point regarding poisonous rodent baits). All applications should be recorded properly (scored 2.7.3), detailing where and when the application occurred and any special methods used to avoid contamination. All applications should be made by experienced, licensed operators following any and all legal requirements and best practices.
- The use of poisonous rodent bait within the facility should not occur. If this use is required, then the area that is being trapped should have all the packaging removed prior to the use of the poisonous baits.
- Care should be taken to avoid placing bait traps in close proximity to outside storage areas for packaging materials.

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

Minor deficiency: (7 points) if:
- Single/isolated instance(s) of improperly positioning or maintaining electrical fly traps or insect light traps.
- Single/isolated instance(s) of a fly swatter found in 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 storage areas (including chemical/sanitation storage).
- Snap traps being used outside the operation, not contained in trap boxes, not presenting risk to packaging and are lacking weekly inspection logs.
- Single/isolated instance(s) of any other issues noted on the conformance criteria.

Major deficiency (3 points) if:
- Numerous instances of improperly positioning or maintaining electrical fly traps or insect light traps.
- Numerous instances of fly swatters found in storage area.
- Numerous instances of grain or pellet bait being used in an outside bait station (external trap).
- More than one can of fly spray (or other insecticide) found in the storage areas (including chemical/sanitation storage).
- Single instance of bait/poison found inside the facility (inside of a trap).
- Single instance of bait/poison found outside of a trap, outside the facility.

- Single/isolated instances (up to three snap traps) being used inside the operation, not contained in trap boxes and are lacking weekly inspection logs.
- Snap traps using allergenic bait.
- Numerous instance(s) of any other issues noted on the conformance criteria.

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

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

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

Local regulations may require exceptions/differences to above guidelines. At all times, local regulations should be met but if the audit system requirements are more stringent, these should also be adhered to. Some contractors use barcode systems that automatically check to see if all traps are monitored on a scheduled visit.

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

Major deficiency (1 point) if:

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

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

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

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

http://www.epa.gov/oppsrrd1/reregistration/rodenticides/finalriskdecision.htm
http://www.npmapestworld.org/documents/Foodplantstandards2010_000.pdf
http://www.npmapestworld.org/docs/ePestWorld/50%20Foot%20Document%20Clarification%20to%20Bell%20%283%2020%2012%29%28Signed%291.pdf

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

- No exterior traps.

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

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

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

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

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

1.8.9 Are all pest control devices properly installed and secured?
Visual Confirmation. Total conformance (5 points): Bait stations should be secured to minimize movement of the device and be tamper resistant. Bait stations should be secured with a ground rod, chain, cable or wire, or glued to the wall/ground, or secured with a patio stone (wall signs are required if using patio stones) to prevent the bait from being removed by shaking, being washed away, etc. Bait stations should be tamper resistant through the use of screws, latches, locks, or by other effective means. Note that only traps containing bait are required to be secured. Multiple-catch traps used indoors are not required to be secured to the ground. Auditee may use metal “sleeves” or similar solutions to prevent displacement, crushing by forklifts, etc. Live traps should be positioned so that the openings are parallel with and closest to the wall. Glue boards should be inside a device (e.g., trap box, PVC pipe, etc.) following manufacturer’s recommendations rather than loose on the floor. Auditor discretion applies to traps placed on curbs.

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

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

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

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Buildings and Grounds

1.9.1 Are signs supporting GMPs posted appropriately?

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

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

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

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

- Numerous instances of required signs not being in position.

Non-conformance (0 points) if:

- Systematic failure to place signs in the required positions.

1.9.2 Are all lights in the facility that could potentially contaminate packaging shielded, coated or otherwise shatter resistant to protect packaging from contamination in the event of breakage?

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

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

Minor deficiency (10 points) if:

- Single/isolated instance(s) of unprotected glass in an area that could potentially contaminate packaging equipment or 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 packaging equipment or materials.
- Single instance of a broken light found within the facility.

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

1.9.3 Has the facility eliminated or controlled any potential metal, glass or plastic contamination issues?
Visual confirmation. Total conformance (15 points): No metal, glass or plastic issues noted (excluding issues noted under specific questions already noted within this audit). This question is designed to allow the auditor to underline potential foreign material contaminants to the auditee that are not covered by other more specific questions within the audit. Examples include: pins in sign boards within the facility, using "snappable" blades instead of one piece blades, noting broken and brittle plastic issues on re-useable totes and finding uncontrolled glass items like coffee pots, computer screens, clock faces, eye glasses, pens/pencils behind ear, office window glass, etc. in storage areas. Plastic coated shatterproof light bulbs are also acceptable without further protection. Auditors should take precaution not to bring glass items into the facility during inspections. If a glass item cannot be replaced immediately or glass is necessary (e.g., a high pressure gauge), then the use of a glass register might be considered (see question in 2.3.2).

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 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 storage areas, but are not accounted for on the glass register.
- Single instance of a broken glass item found within the facility.

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

1.9.4 Has the facility eliminated the use of wooden items or surfaces?
Visual confirmation. Total conformance (5 points) if:
- Walkways, storage containers, ladders, platforms, broom/mop handles, etc. should not have wooden parts.
- Wood pallets should be acceptable as long as they are not fragmenting, look clean and are dry.
- Ideal practice would be to use a slip-sheet between packaging and pallet.
- "Wet facilities and high humidity facilities" should not be constructed of wooden walls or ceilings.
- Use of wood tables or similar food contact equipment should be scored under 1.5.2.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of utensils/equipment with wood parts in use in the facility.
- Single/isolated instance(s) of structural items (e.g., walls/floors/platforms constructed of wood in wet and/or high humidity facilities).

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

Non-conformance (0 Point) if:

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

1.9.5 Is there adequate lighting in the storage areas?

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

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

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

Non-conformance (0 points) if:
- Any critical area that does not have lighting, such as dock areas, warehousing of packaging.

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

Visual confirmation. Total conformance (10 points): The ventilation system (cooling and heating) should be sufficient to control condensation, mold, dust, odors and vapors so that conditions do not exist where packaging materials may be contaminated. Ventilation equipment is balanced to provide an adequate air exchange rate to prevent condensation on walls, ceilings or other surfaces in the storage areas.

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

Where condensation has formed to such an extent on surfaces (that are not being cleaned and sanitized) that packaging materials may become or are becoming contaminated, the condensation is considered be an adulterant (scoring reverts to Q 1.2.7), and creating insanitary conditions.

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

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

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

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

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

Visual confirmation. Total conformance (10 points): The floor surfaces in the facility should be suitable for the type of operation being conducted. The floor should be constructed in such a manner that it may be adequately cleaned and kept in good repair. Floor surfaces in all areas should be smooth, without deep cracks or seams, durable, non-absorbent and easily cleanable. Cracks should not trap debris or water. Some hairline floor cracking is allowed, but should be easy to keep clean and not trap debris. Check for concrete breakdown (exposed aggregate, where flooring is exposed to concentrations of different chemicals (e.g., chemical stores). Assess areas where concrete is broken down and see if there is standing water and debris. Floors should not have low areas that can allow pools of water to form. Pay special attention to areas that have a lot of forklift traffic.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-conformance (0 points) if:

- Systematic failure to keep floors in good state of repair and in clean condition.
- Systematic failure to prevent standing water.
- **Direct contamination of food packaging materials due to poor maintenance or sanitation of floors. Auditor should consider reverting back to Q 1.2.7, the automatic adulteration failure question.**

1.9.8 Are the floor drains where they are needed for drainage and cleanup?

Visual confirmation. Total conformance (5 points): Drains should be constructed in such a manner that they provide adequate drainage in all areas where floors are subject to flood-type. Discharge water from sinks should not run directly onto the floor. Not applicable in dry facilities with no drains.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of an area(s) having insufficient number of drains.
- Single/isolated instance(s) of an area(s) having blocked or overflowing drains.

Major deficiency (1 point) if:

- Numerous instances of an areas having insufficient number of drains.
- Numerous instances of an areas having blocked or overflowing drains.

Non-conformance (0 points) if:

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

1.9.9 Are doors to the outside pest proof?

Visual Confirmation. Total conformance (5 points): All doors to the outside should be designed and properly fitted out to prevent the ingress of rodents and insects into the facility. Doors should have no gaps greater than approximately 1/8 inch (3 mm). If doors have screens, the openings should be no

greater than 1/8 inch (3 mm). Gaps are often at the bottom of doors and also at the top of roller doors. Air curtains are acceptable, provided they are operating properly. Personnel doors to the outside should be loaded so that they close properly. Rule of thumb is that if you can see daylight gaps, then further investigation is required. If doors to storage are kept open, with no protection (e.g. air curtain, screen, etc.), they cannot be considered pest proof (scored in 1.2.4).

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

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

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

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

Visual confirmation. Total Conformance (5 points): Where dock doors are fitted with buffers, the buffers should seal against trucks and be in good condition. Trucks backed onto the dock should seal properly in order to avoid pest entry in the shipping area and within the truck. Dock door seals ensure that packaging is not exposed to the elements and help prevent pest entry. N/A if no buffers fitted.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a poorly maintained dock buffer.

Major deficiency (1 point) if:
- Numerous instances of poorly maintained dock buffers.

Non-conformance (0 points) if:
- All dock buffers inspected were poorly maintained.

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

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

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

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

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

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

Minor deficiency (3 points) if:
- Single/isolated instance(s) of an exterior wall having holes or deep cracks that could harbor pests/allow pest entry.
- Single/isolated instance(s) of an exterior wall having uncapped pipes, unprotected vents or wire mesh screens greater than 1/8 inch (3mm).

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

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

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

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

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

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

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

Minor deficiency (3 points) if:

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

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

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

1.9.15 Is an 18"(46 cm) internal wall perimeter being maintained within the facility, with adequate access to these wall perimeters thereby allowing inspection and cleaning?
Visual confirmation. Total conformance (5 points): All storage areas should maintain an approximately 18" (46 cm) distance between the stored items and all walls i.e. enough room to access and inspect. This space is necessary to prevent harborage of pests, to allow proper monitoring of pest activity (inspection gap) and for employees to perform their cleaning duties. If you have access and can carry out an inspection, then the space is adequate. Staging areas are not required to conform to these requirements. Auditee should ensure that proper and safe access routes to check the wall floor perimeters are available.

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

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

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

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

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

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

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

1.9.17 Are control measures being implemented for the storage of pallets, equipment, tires, etc. (e.g. out of the mud, pipe ends capped, stacked to prevent pest harborage, away from building perimeter)?
Visual confirmation. Total conformance (5 points): Outdoor storage of equipment is acceptable provided that it is stored in a manner that will prevent the harborage of pests. Pipes should have the ends capped.

Equipment on pallets should not have direct contact with the dirt. All items stored should be at least 4 inches (10 cm) above the dirt. Equipment should be neatly stacked. The equipment stock levels should be reviewed regularly in order to avoid building up a store of obsolete equipment. Outside equipment stores should be checked as part of the pest control program, looking for evidence of rodent harborage. Equipment, tires, pallet storage, etc., should be at least 24 inches (61 cm) away from the building perimeter.

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

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

Major deficiency (1 point) if:
- Numerous instances of improper storage of equipment.
- Outside equipment storage is not being checked as part of the pest control program.

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

1.9.18 Are pallets inspected to separate and replace dirty or broken pallets?

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

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

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

1.9.19 Is the area around the dumpster/cull truck/trash area clean?

Visual confirmation. Total conformance (3 points): The area around the dumpster/cull truck/trash area should be maintained in a clean condition. There should not be any spillage on the ground. There should not be any standing water or liquid seepage around the dumpster/cull truck/trash area and there should not be any foul odor present. The dumpster/cull truck/trash area should be cleaned on a regular basis.

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

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

- Visible liquid leakage from the dumpster(s)/cull truck/trash area.

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

1.9.20 Are outside garbage receptacles and dumpsters kept covered or closed?
Visual confirmation. Total conformance (5 points): All dumpsters and garbage receptacles should have a cover and be kept covered to prevent the attraction of insects, rodents and other pests. Fine mesh lids are acceptable. Just having the lids is not acceptable i.e. when not in use, the dumpsters and garbage receptacles should be closed. Dumpsters that are only used for dry non-food waste (e.g., paper, cardboard, etc.), are exempt.

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

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

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

1.9.21 Are all water lines protected against back siphonage?
Verbal and visual confirmation. Total conformance (5 points): Main water lines entering the facility should be fitted with back-flow protection for the incoming water (no matter what source). Individual water lines within the facility should be fitted with backflow protection where needed (e.g., on hose pipes, inlets to tanks, etc.). The auditor should look for check valves and air gaps. Water drawn back into the main water system can contaminate fresh water. Where facility has a current certificate of inspection on file (scored under 2.8.9), auditor should still look for issues within the facility (e.g., dead end on water lines, hoses on the floor, etc.) that may be an issue. Where the site does waste treatment, check for dedicated back flow between waste treatment and site.

Potentially useful websites:
http://water.epa.gov/infrastructure/drinkingwater/pws/crossconnectioncontrol/crossconnectioncontrol_manual.cfm
http://water.epa.gov/drink/

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

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

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

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Food Safety File Requirements - Section 2 (Documentation)

Management Systems

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

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

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

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

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

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

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

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

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

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

2.1.3 Is there a designated person responsible for the food safety program?

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

Non-conformance (0 points) if:

- No-one is in charge of food safety programs, including food safety document control and verification of sanitation activities.
- **Auditor should consider whether to score an automatic failure under 1.1.1.**

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

Visual Confirmation. Total conformance (5 points): There should be an active food safety committee, responsible for the strategic maintenance and development of the auditee's food safety plan. 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., an operations meeting, etc.). Meetings should occur at least quarterly. This question is not applicable to small family size companies (less than 20 employees).

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

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

Non-conformance (0 points) if:

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

Control of Documents and Records

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

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

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the procedure.

Non-conformance (0 points) if:

- There is no written procedure

2.2.2 Are all records stored for a minimum period of 24 months?
Visual confirmation (5 points): Food safety related records **(documents and/or electronic files)** should be retained for auditing purposes and in case there are legal issues, customer queries, etc. All monitoring and process control records should be held for a minimum of 24 months. Any records required by law to be kept longer than two years should be kept for the legally mandated period. Any records should be kept at least for the duration of the shelf life of the product.
http://www.fda.gov/food/guidanceregulation/fsma/ucm247548.htm

Minor deficiency (3 points) if:

- Single/isolated instance(s) of records not being retained for the required length of time (two years unless legally longer storage is required).

Major deficiency (1 point) if:

- Numerous instances of records not being retained for the required length of time (two years unless legally longer storage is required).

Non-conformance (0 points) if:

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

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

should be single-lined through (and initialed by the person making the change) so that the original information is still legible, avoiding the use of corrective fluid. Any evidence of records being falsified is a non-conformance (e.g., records already filled out for the next day).
21 CFR Part 11: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11

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

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

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

General File Requirements

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

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

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

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

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

Non-conformance (0 points) if:

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

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

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

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

Minor deficiency (3 Points) if:

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

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

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

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

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

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

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

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

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Traceability

2.4.1 Is there a documented account that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?
Visual confirmation. Total conformance (10 points): A written document (narrative) should be available for review, either within the recall program or as a separate document that shows the facility traceability system. **This may be a text explanation or a flow chart.** The system should be able to show that it can trace back to the supplier(s) of materials and also show that the system can trace forward and indicate which customer(s) received products. This is usually accomplished by lot coding materials throughout a process and recording these lot codes at different points in the process. The traceability system should be evident when touring the facility and also when checking paperwork. The written traceability system should match the system that is being used in the storage facility. Recording batches of packaging is required for some products where packaging recalls might occur (e.g., modified atmosphere packaging, etc.). Recording packaging batches is not required for packaging that is not usually the cause of a recall (e.g., cardboard boxes).

The tracking system must meet the requirements for "one step back, one step forward" as per the FDA requirements. Any national, local or importing country legal requirements should be followed.

Potentially useful websites:
http://www.fda.gov/OHRMS/DOCKETS/98fr/04-26929.htm,
http://www.fda.gov/downloads/iceci/compliancemanuals/regulatoryProceduresManual/UCM074312.pdf
http://www.fda.gov/regulatoryinformation/legislation/ucm148797.htm

Minor deficiency (7 points) if:
- Single/isolated instance(s) of the written traceback system not reflecting what is happening in the storage 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).

Major deficiency (3 points) if:
- Numerous instances of the written traceback system not reflecting what is happening in the storage facility.
- Numerous instances of clarity issues in the traceability explanation (text or flow chart).
- Single/isolated instance(s) of either incorrect or missing elements of the traceability system that either limits or stops efficient trace back or trace forward of the packaging.

Non-conformance (0 points) if:
- Systematic failure of the written traceback system to reflect what is happening in the storage facility.
- Numerous instances of either incorrect or missing elements of the traceability system that either limits or stops efficient trace back or trace forward of the packaging.
- No written down traceability system.

2.4.2 Does the facility have a documented recall program including: procedures, recall team roles, their contact details, external contact listings and (in the USA) an explanation of different recall classes?
Visual confirmation. Total conformance (15 points): A written current recall program should be available for review. Documentation should include basic procedures and responsibilities, current facility contact listing with alternates and out of hour's numbers. Contact listings for customers and suppliers should also be part of the recall program, although these might be viewed as confidential (if so, then these listings must at least be referred to in the recall program). Listings should be reviewed regularly. In the USA (or when importing), an explanation of recall classes (Class I, II, III) should be in the recall program. Ideally, contact numbers for attorneys, media specialists (for getting the recall information to the various press outlets), local enforcement officials (e.g., State and City Health Boards) are a good idea (these are optional and should not cause a down score if missing).

Potentially useful websites:
FDA Recall Policy, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7&showFR=1

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

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

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

2.4.3 Is testing of recall procedures (including trace back) performed and documented at least once every six months? Can the company identify where affected product was sent?
Visual confirmation. Total conformance (10 points): A "mock" recall should be performed and documented at least twice in the last 12 months (approximately six month intervals) to show a trace (one step forward, one step back) of the food contact packaging material. Operations with less than six consecutive months of operation should have at least one mock recall per season. Documentation should indicate the date and time the mock recall was initiated, the material chosen, the mock scenario (reason for needing a mock recall), amount of product produced, affected lot ID's (date code(s), lot code(s), etc.), amount located, percent located, time product was located and time mock recall was completed. Scenario should be varied to provide experience in a range of conditions. Some examples include customer complaints for foreign materials, detecting issues such as pathogens, pesticide residues, etc. Recall/trace documentation should support the scenario. Checks should be carried out to ensure that contact details exist for the affected customers. Documentation should also include any "lessons learned" from the process i.e. an evaluation of how the mock recall procedure went and what improvements the auditee could identify to improve their recall process (e.g., speed up the process, improve tracking system, etc.). Documentation should state "Mock Recall", especially the document that shows the scenario, so that at a later date, no one is confused as to whether this was a mock or a real recall. Auditors should remember that mock traceback and recall will vary considerably depending on the scenario chosen. Recalls should be completed within two hours with 100% of chosen product located. Mock recalls might note that product had been 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 packaging material was not located.
- A few gaps noted in the logic of the traceback documentation.
- Not noting "lessons learned" from mock recall exercise (if there are any).
- Total time to complete mock recall took longer than 2 hours but not more than 3 hours.
- There has been only one documented mock recall or trace in the last 12 months.

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

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

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

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

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

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

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

2.4.5 Is there a documented system for dealing with food safety complaints/feedback from consumers and buyers along with records and company responses, including corrective actions?
Visual Confirmation: Total conformance (5 points): There is a documented procedure detailing how to handle client's (buyer and/or consumer) food safety complaints and feedback. It is important to keep the complaints and feedback related records on file to support company policy/procedure. The policy and records should include (where applicable):
- Date/Time of complaint/rejection,
- Who made the complaint,
- Contact information,
- Product description,
- Where the product was purchased,
- Amount of product,
- Product code/date,
- Nature of complaint,
- Corrective actions,
- Corrective actions taken to prevent reoccurrence.

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

Minor Deficiency (3 points) if:

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

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

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

Supplier Control

2.5.1 Are there written specifications for packaging materials and sanitation chemicals?

Visual confirmation. Total conformance (3 points): There should be current written specifications for packaging materials and sanitation chemicals.

This question is only relevant where the company buys “XYZ” to then use/store and sell. Not applicable if acting as a third party storage operation (i.e. have no say in purchase of packaging materials).

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

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

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

2.5.2 Are there written specifications for finished goods?

Visual confirmation. Total conformance (3 points): There should be current written specifications developed by the customer and/or company for finished goods (i.e. finished product specifications). Where relevant, the specification may include the following information: product name, quantity, product code, description, bar code, etc. Specifications should be available to relevant staff. Auditor should check that specifications are being followed and where the specification requires product testing, auditor will verify that testing requirements are being followed as required.

This question is only relevant where the company buys “XYZ” to then use/store and sell. Not applicable if acting as a third party storage operation (i.e. have no say in the purchase of finished goods).

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

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

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

2.5.3 Is there a list of approved suppliers of packaging materials and sanitation chemicals?

Visual confirmation (5 points): There should be a list of approved suppliers of packaging and sanitation chemicals. All packaging are purchased from approved suppliers. Where exceptions are made (e.g., market conditions), approval from management should be documented.

This question is only relevant where the company buys “XYZ” to then use/store and sell. Not applicable if acting as a third party storage operation (i.e. have no say in purchase of packaging items).

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

- Single/isolated instance(s) of purchasing exceptions made (i.e. not of list of approved suppliers) without management approval.

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

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

2.5.4 Is there a written procedure for approval and continued monitoring of suppliers of packaging materials and sanitation chemicals?

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

This question is only relevant where the company buys “XYZ” to then use/store and sell. Not applicable if acting as a third party storage operation (i.e. have no say in purchase of packaging materials).

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

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

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

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

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

This question is only relevant where the company buys “XYZ” to then use/store and sell. Not applicable if acting as a third party storage operation (i.e. have no say in purchase of packaging items).

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

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

Non-conformance (0 points) if:

- No records.
- Failure to maintain records.

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Chemicals

2.6.1 Are copies of all Materials Safety Data Sheets (detergents, sanitizers, pesticides, etc.) on file and fully accessible at all times with clear indexes?

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

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

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

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

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

2.6.2 Are there copies of specimen labels for chemicals used, where the full label is not immediately accessible e.g. rodent chemicals, product sanitizers?

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

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

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

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

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

Visual confirmation. Total conformance (3 points): Chemical usage logs and/or chemical inventories should be on file. Chemicals within the scope of this question are to be limited to cleaners and sanitizers i.e. sanitation chemicals and food contact chemicals, such as chlorine for hydrocoolers, etc. The inventory should take into account the arrival of new stocks and any discrepancies should be explained. Minimum frequency for inventory checks should be monthly.

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

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

Non-conformance (0 points) if:

- No chemical usage logs/inventories are on file.

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Pest Control

2.7.1 Is there a documented pest control program, including a copy of the contract with the extermination company (if used), Pest Control Operator license(s) (if baits are used) and insurance documents?
Visual confirmation. Total conformance (15 points): There should be a documented pest control program in place detailing scope of the program, target pests and frequency of checks. If performed in-house, the pest-control operators or equivalent should be registered, licensed or have documented formal training (if regulation does not require certification or registration). Note that the persons training and/or license should specify structural pest control or equivalent. Any substitute operator's license credentials should also be on file. If the service is contracted, the pest control contract service/company should be licensed in structural pest control, insured and the contract should be documented (quoting the scope of the program, types of pests it covers and frequency of visits). Insurance document should ideally name the auditee as "additional insured". When licensing legislation does not apply (e.g., in certain countries), there should be evidence of on-going training. Auditors should check documentation for expiry dates.

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

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

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

2.7.2 Is there a schematic drawing of the facility showing numbered locations of all traps and bait stations, both inside and outside the facility?
Visual confirmation. Total conformance (10 points): Schematic drawing or trap map is on file, current and details internal and external traps. All devices (e.g., tin cats, Ketch-Alls, bait stations, glue boards, insect light traps, electronic fly killer units, etc.) should be numbered and clearly identified on the map. The numbers should match what is out in the facility. Ideally, the map should be dated, since placement will vary over time.

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

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

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

2.7.3 Are service reports created for pest control checks detailing inspection records, application records, and corrective actions of issues noted(in-house and/or contract)?
Visual confirmation. Total conformance (10 points): Service reports from the contract pest control company should be available for review if pest control is contracted out. In-house inspection records should be available for review if pest control is conducted in-house. Records should include services performed, date of service**,** chemicals used (see below), signs of activity and corrective actions, trend reports. Match operator signature on

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

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

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:

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

Non-conformance (0 points) if:

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

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Internal and External Inspections

2.8.1 Are there written procedures for handling regulatory inspections?

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

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

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

Non-conformance (0 points) if:

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

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

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

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point) if:

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

Non-conformance (0 points) if:

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

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

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

- Inspection frequency. Frequency depends on type and size of operation (auditor's discretion). It is ideal to have a monthly frequency, but at least a quarterly frequency.
- Entire facility (inside and out) should be included.
- Who conducted the inspection.
- Documented findings.

- Note corrective actions (including completion date).

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

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

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

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

2.8.4 Is there a program for periodic inspections of food safety system records e.g. pest control records, sanitation records, maintenance records, etc.?

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

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

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

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

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

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

2.8.5 Is there a daily pre-operation inspection log?

Visual confirmation. Total conformance (5 points): Packaging storage is inspected daily before operation begins. This should be a start-up check of all potential issues, not a repeat of the daily sanitation completion record which is covered in 2.10.6.
The daily pre-operational check should include:

- Examination of equipment to verify cleanliness
- General housekeeping of storage areas
- Checking that personnel meet the GMP requirements
- Corrective actions in the case of non-conformance

Basically, a last minute quick check that all is well and the daily operations can start. Pre-operational system design can vary.

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point) if:

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

Non-conformance (0 points) if:

- No records.
- Failure to maintain records.

2.8.6 Does the facility have incoming packaging material inspection data?

Visual confirmation. Total conformance (5 points): Incoming goods should be inspected for visible issues (e.g., decay, foreign materials (contamination), odor, damage and labeling issues) and any other safety/food security related issues. Packaging is ideally checked routinely, but records can be maintained by exception (e.g., as deviation incidents and recorded as unusual occurrences). This is an acceptable practice where issues are rare.

This question is only relevant where the company sells product. This question is not applicable if acting as a third party storage operation as long as the client(s) utilizing the auditee's service have provided a letter/agreement releasing the auditee from the responsibility of inspecting incoming materials.

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point) if:

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

Non-conformance (0 points) if:

- No records.
- Failure to maintain records.

2.8.7 Are there inspection logs on incoming trailers for rodents and insects, cleanliness and holes?

Visual confirmation. Total conformance (10 points): There should be written records (separate log or on bill of lading, etc.) of trailer (a.k.a. truck body, lorry body) inspections. Designated personnel should be responsible for inspecting the incoming vehicles and checking/documenting the following:

- Interior is clean, odor free, pest free and in good condition i.e. free of damage.
- Records of rejections and any corrective actions (where relevant).

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

Minor Deficiency (7 points) if:

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

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

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

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

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

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

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

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

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

Minor deficiency (2 points) if:
- Last inspection and certification was done over a year ago, but not greater than 18 months ago.

Major deficiency (1 point) if:
- Last inspection and certification was done over a year ago, but not greater than 24 months ago.

Non-conformance (0 points) if:

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

Process Control

2.9.1 Are there stock check and replenishment records for gel and spray stations?

Visual confirmation. Total conformance (3 points): Where hand gel or spray stations using prepared solutions are used, there should be monitoring logs indicating stations are regularly checked to confirm units are stocked and operational.

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

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

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

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Maintenance & Sanitation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Master sanitation schedule should include what is to be cleaned and when:
- List of areas, equipment, internal transport vehicles, in-house delivery trucks, etc.
- Frequency of cleaning (daily, weekly, monthly, quarterly, annually, etc.)

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

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

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

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

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

- Detailed cleaning and sanitation methods following the standard order:
  1. Dry clean (note equipment used)
  2. Rinse (note equipment used)
  3. Clean (note equipment used
  4. Rinse (note equipment used)
  5. Sanitize (note equipment used and dwell time)
  6. Rinse (if label requires)
- Special instructions with respect to cleaning
- Assigned responsibility for each task.
- Logs/records of cleaning
- Verification procedures (visual, microbial) and acceptance criteria

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

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

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

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

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

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

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

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

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

2.10.7 Are there records showing verification of cleaning chemical concentrations?

Visual confirmation. Total conformance (5 points): Where cleaning and sanitizing chemicals are mixed on-site, there should be records of verification of the anti-microbial concentrations. The strength of cleaning chemicals

should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction based test, test probe, ORP meter or as recommended by disinfectant supplier). Solutions that are too weak will be ineffective, while those too strong may be harmful to employees, product or equipment. Methods include, dip sticks, test strip papers, conductivity meters, titration, color comparison methods (e.g., tintometers, etc.). Frequency of checks should correspond with the SSOP, but at least at mixing and then at a frequency that ensures the availability of the anti-microbial is adequate while the cleaning operation is being done. Corrective actions should also be recorded. Not applicable where pre-mixed chemicals are bought and used.

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

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

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

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

2.10.8 Is there a log indicating that floor drains are cleaned on a regular basis?
Visual confirmation. Total conformance (5 points): There is a log that indicates that floor drains are cleaned on a daily basis in wet facilities, and a minimum of weekly for dry facilities (up to auditor discretion).

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

Major deficiency (1 point) if:
- Sanitation schedule or log does not indicate that floors and drains are cleaned, but sanitary condition of floor and drains is checked every day on the pre-operation inspection.
- Numerous instances of incomplete records or omissions.

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

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Personnel

2.11.1 Are there records of new employee food safety (GMP) orientation training (with topics covered and attendees) and are new employees required to sign the company's food safety hygiene and health policy?

Visual confirmation. Total conformance (10 points): The company has logs of GMP orientation (new hire) training with the topics covered, trainer name and materials used and given to new hires. Training should be given prior to new hires starting to work. Materials to be given to new hires after training should be in the relevant language(s) and cover personal hygiene and GMP rules including hand washing, no false nails or nail polish, eating/drinking, smoking, specific clothing rules, etc. Food safety training should be given to all employees working in the storage areas, including temporary employees and agency employees. New employees should be requested to read (in the relevant language), confirm they understand and agree to abide by the company's food safety policy rules regarding personal hygiene/GMPs and health requirements (e.g., they are free from diseases that might be a food safety cross contamination risk). A copy of the signed food safety policy should be kept on file and a copy given to the employee.

Minor Deficiency (7 points) if:

- Single/isolated instance(s) of errors and omissions in the records or food safety hygiene and health policy.
- Up to three points missing off the GMP requirements listing.
- Training materials and/or food safety policy are not in the relevant language(s).
- Training occurring, but relevant materials are not being given to the trainee after the training.
- Training occurs, not before starting to work, but within the first week.
- Single/isolated instance(s) of employees not being trained or not signing a document stating that they will comply with the operations' personal hygiene and health policies.

Major Deficiency (3 point) if:

- Numerous instances of errors and omissions in the records or food safety hygiene and health policy.
- Over three points missing off the GMP requirements listing (or GMP listing does not exist).
- Numerous cases of employees not signing a document stating that they will comply with the operations' personal hygiene and health policies.
- Training occurs, not before starting to work, but within the first month.
- Numerous instances of employees not being trained.

Non-conformance (0 points) if:

- No records of training or employees not being trained.
- No specific orientation given or given after the employee has been working for more than one month.
- Failure to maintain records.
- The company does not have a document for employees to sign stating that they will comply with the operations' personal hygiene and health policies.
- Systematic failure of employees to sign a log stating that they will comply with the operations' personal hygiene and health policies.

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

Visual confirmation. Total conformance (10 points): The auditee should have logs of ongoing food safety educational training with clearly defined food safety topic(s) covered, trainer(s) and material(s) used/given. There should be logs of employees who have attended each session. Food safety training might be part of other training events (e.g., part of occupational training). Some kind of food safety training of employees should occur on at least a quarterly basis, but ideally monthly. Full annual food safety refresher training sessions are encouraged but do not replace the ongoing more frequent training unless a short season facility (e.g., less than 3 months duration). Ongoing training might focus on key areas (e.g., hand washing, eating and drinking etc.) and maybe note issues found in recent internal and external audits (e.g., wearing beard nets, jewelry issues).

Minor Deficiency (7 points) if:

- Single/isolated instance(s) of logs having errors or incomplete information (e.g., missing one of the following: training topic, trainer or material information).
- Training has occurred but on a few occasions full attendance logs have not been kept and/or not all personnel were covered.

Major Deficiency (3 points) if:
- Numerous instances of logs having errors or incomplete information (e.g., missing one of the following: training topic, trainer or material information).
- Training has occurred but on many occasions full attendance logs have not been maintained.
- Some key topics (e.g., hand washing), have been omitted from the training.
- Only annual refresher training has occurred and the operation runs for more than 3 months of the year.

Non-conformance (0 points)
- Failure to maintain records. No records of training.
- Many major topics have been omitted from the training program (e.g., hand washing, eating/drinking rules, jewelry policy, etc.).

2.11.3 Are there written procedures in place that require packaging handlers to report any cuts or grazes and/or if they are suffering any illnesses that might be a contamination risk to the products being produced? (Verbal confirmation accepted.)
Visual and verbal confirmation. Total conformance (3 points): There should be documented procedures that are communicated to packaging handlers, requiring them to report any cuts, grazes and/or any illnesses that might be a food safety cross contamination risk. The procedures should indicate to whom the packaging handlers should report, how the issue is recorded and appropriate actions to be taken for a particular issue. Auditee records may be viewed as confidential and therefore a verbal confirmation should be gained.

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

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

Non-conformance (0 points) if:
- There is not a documented procedure in place.
- A procedure is in place but it has not been communicated to packaging handlers.

2.11.4 Is there a documented training program with training logs for the sanitation employees including best practices and chemical use details?
Visual Confirmation. Total conformance (5 points): Sanitation training should ensure that the employees understand the importance of proper sanitation; cleaning efficacy, how to use the cleaning chemicals and how to understand Sanitation Standard Operating Procedures. Training would also ideally include worker safety issues, (e.g., use of personal protective equipment, accident prevention, what to do in case of an accident, procedures for avoiding electrical hazards when cleaning, etc.). Recorded training should occur at least on a 12 month basis.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of logs having errors or incomplete information (e.g., missing one of the following: training topic, trainer or material information).
- Training has occurred but on a few occasions full attendance logs have not been kept and/or not all personnel were covered.

Major Deficiency (1 point) if:
- Numerous instances of logs having errors or incomplete information (e.g., missing one of the following: training topic, trainer or material information).
- Training has occurred but full attendance logs have not been maintained on many occasions.

Non-conformance (0 points)
- No records or no training has occurred.
- Failure to maintain records.

2.11.5 Are visitors and contractors required to sign a log stating that they will comply with the operations' personal hygiene and health policies?
Visual confirmation. Total conformance (3 points): All visitors and contractors should sign to say that they will abide by the company rules regarding personal hygiene/GMPs (e.g., hair nets, clothing, hand washing, jewelry, eating, drinking, smoking, etc.) and health requirements (i.e. they are free from diseases that might be a food safety cross contamination risk). The rules and policies should be clearly stated in relevant languages. This requirement may be included in the visitor sign in/out book (3.2.5).

Minor deficiency (2 points) if:
- Single/isolated instance(s) of visitor(s) and contractor(s) not signing a log stating that they will comply with the operations' personal hygiene and health policies.

Major deficiency (1 point) if:
- Numerous instances of visitors and contractors not signing a log stating that they will comply with the operations' personal hygiene and health policies.
- Policy is not in the relevant language(s) of the visitors/contractors.

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

2.11.6 Is there an employee non-conformance/disciplinary action procedure? (Verbal confirmation accepted.)
Verbal Confirmation. Total conformance (3 points): The auditee should have a record for employee non-conformance and corrective actions detailed. Auditee records might be viewed as confidential and therefore a verbal confirmation should be gained. There might be a tier system, which includes verbal and written disciplinary actions. There might be immediate termination for gross misconduct.

Minor Deficiency (2 points) if:
- Option for minor down score exists, but at present, no known good examples exist.

Major Deficiency (1 point) if:
- Disciplinary system is not used for GMP violations.

Non-conformance (0 points)
- No records or no disciplinary system.

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Testing

Potentially useful websites:
CDC Disease Information, http://www.cdc.gov/diseasesconditions/
FDA Bad Bug Book, http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf
EPA Drinking Water Standards, http://www.epa.gov/safewater/mcl.html#mcls
USDA, Water Quality Information Center, http://wqic.nal.usda.gov/

2.12.1 Are there routine microbiological tests on water used in the facility (sampled from within the facility)?

Visual confirmation. Total conformance (10 points): There should be microbiological tests on water used in the facility on a routine basis to assure it meets the US EPA (http://www.epa.gov/safewater/mcl.html#mcls) microbiological requirements of potable water). Testing frequency should be related to the risk assessment of the operation:

- Minimum frequency is at least every six months.

Water samples should be taken from the within the facility to account for the sites piping, holding tanks, etc. City water samples http://www.epa.gov/safewater/dwinfo/index.html are still good information to have, but if there is no site sample, then this question should be scored major. Results of water sample testing for total coliforms and/or *E. coli* should meet the US EPA drinking water **microbiological** specification http://www.epa.gov/safewater/mcl.html#mcls. If out of specification results are detected, then full details of corrective actions should be noted.

Potentially useful websites:
http://nepis.epa.gov/Exe/ZyPDF.cgi/P100EEXN.PDF?Dockey=P100EEXN.PDF
http://www.access.gpo.gov/nara/cfr/waisidx_02/40cfr141_02.html
http://edocket.access.gpo.gov/cfr_2003/julqtr/pdf/40cfr141.63.pdf
http://edocket.access.gpo.gov/cfr_2002/julqtr/40cfr141.63.htm

Minor deficiency (7 points) if:

- Single instance of water testing not occurring at the right frequency.

Major deficiency (3 points) if:

- Only water testing records available are from the City Water Board.
- More than one instance of water testing not occurring at the right frequency.

Non-conformance (0 points) if:

- No microbiological test results are available.
- Last test was done over 12 months ago.
- Single out of specification microbiological test result without proper corrective action documentation. **Auditor should consider reverting to Q 1.1.1, the general automatic failure question.**

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Control of Storage & Distribution

2.13.1 Are there sanitary condition logs for shipping trucks (cleanliness, trailer condition, odor, etc.)?
Visual confirmation. Total conformance (10 points): There should be sanitary condition logs for shipping trucks detailing cleanliness and/or any off-odors. Corrective actions should be detailed. This may be indicated on bill of lading. Truck cleaning certificates are acceptable for the sanitation section of the question, but these should be for each load for brokered trucks and on a regular frequency for in-house trucks. Even with certificates, the trucks should be checked for cleanliness.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors, incomplete or missing logs.
- Single/isolated instance(s) of an issue noted without corrective actions detailed.

Major deficiency (3 points) if:
- Numerous instances of errors, incomplete or missing logs.
- Numerous instances of issues noted without corrective actions detailed.

Non-conformance (0 points) if:
- No sanitary condition logs are on file.
- Systematic evidence of failure to record sanitary condition of trucks.

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Food Defense - Section 4

The food defense section of the audit is scored as a separate percentage to the overall food safety score on the default audit report system. Certain buyers do demand that the food defense and food safety scores are combined to show a single audit score.
The following Food Defense section is based in part on the FDA/CFSAN — Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance. Key elements of this guidance have been included in this audit. For full details of this guidance go to http://www.agri.state.id.us/Categories/InspectionsExams/Documents/secguid6.pdf. FSIS has also created a self-assessment guideline for food processors titled "Food Security Guidelines for Food Processors". These guidelines are available at: http://www.fsis.usda.gov/Oa/topics/SecurityGuide.pdf. The associated self-assessment checklist is available at: http://www.fsis.usda.gov/shared/PDF/Self_Assessment_Checklist_Food_Security.pdf.

The checklist facilitates the process of evaluating an operation's Food Defense status. It addresses all aspects of Food Defense, including plan management, interior to exterior physical security, receiving, storage and shipping, utilities and personnel.

Other potentially useful websites:
FDA Food Security Preventive Measures Guidance,
http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/fooddefense/ucm083075.htm
FSIS Food Security Guidance, http://www.fsis.usda.gov/Oa/topics/SecurityGuide.pdf

Physical Security

3.1.1 Are the facility external areas and vulnerable points (i.e. those that are not permanently locked) surrounded by security fencing?

Visual Confirmation. Total conformance (5 points): Where there is external storage and/or vulnerable (not kept locked) entry points, the facility should be surrounded by a continuous security fence. The fence should be designed to exclude intruders (e.g., height (6ft or greater), thick gauge wire and topped off with barbwire). The facility might use a brick wall perimeter and the top of the wall has barbed wire or some other deterrent. Where there is no external storage and doors are permanently locked, score as N/A.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of damaged fencing observed.
- Single/isolated instance(s) of exposed external areas of the facility lacking fencing.

Major deficiency (1 point) if:
- Fence in place, but not a proper security fence (e.g., not high enough to prevent entry).
- Numerous instances of damaged fencing observed.
- Numerous instances of exposed external areas of the facility lacking fencing.

Non-conformance (0 points) if:
- No perimeter fencing.

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

Visual and Verbal confirmation. Total conformance (10 points): The facility should have security systems in place to prevent intruders, deter intruders and ideally alert the employees to the presence of intruders. These include swipe cards, key locks, pass codes on punch pads, biometrics like palm readers, other technologies and a combination of different systems. Security systems should be used correctly and part of facility discipline. The facility should be locked when not in use (e.g., overnight if there is no nightshift). Consideration should also be given to locking down areas of the facility when these areas are not being used continuously and entry could occur undetected (e.g., an external packaging store that is visited infrequently). Auditors should not score down in busy areas, that are not kept secured (e.g., locked during the day when in operation).

Minor deficiency (7 points) if:

- Single/isolated instance(s) of entry door(s) not properly controlled by a security system (e.g., key lock, alarm sensor, etc.).
- Single/isolated instance(s) of areas that are not locked up in the day and are not frequently being visited by employees.

Major deficiency (3 points) if:

- Numerous instances of entry doors not properly controlled by a security system (e.g., key lock, alarm sensor, etc.).
- Numerous instances of areas that are not locked up in the day and are not frequently being visited by employees.
- No system for controlling swipe cards and/or number combination locks.

Non-conformance (0 points) if:

- No locks on doors.
- Swipe card systems and/or number combination locks in place, but not working and there are no other locking systems.

3.1.3 Are chemicals such as chlorine, citric acid, fungicides and sanitation chemicals stored within secured areas with controlled access?

Visual confirmation. Total conformance (5 points): All chemical materials are stored inside or within a secure area with restricted access. This is usually a chemical store with access restricted to specific personnel within the company. Chemical materials include sanitation chemicals, product-washing chemicals, etc. Empty containers should also be stored securely until they are either collected or disposed of properly.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of improperly stored chemicals.
- Single/isolated instance(s) of poor security controls with respect to restricted access to chemical stores.

Major deficiency (1 point) if:

- Numerous instances of improperly stored chemicals.
- Numerous instances of poor security controls with respect to restricted access to chemical stores.

Non-conformance (0 points) if:

- There is no designated restricted access chemical storage area.
- There are no restrictions for accessing the chemical stores.

3.1.4 Are packaging material (cartons, wrap film, fruit cups, etc.) storage areas secure, i.e. within the secure compound?

Visual confirmation. Total conformance (5 points): Packaging items should be stored inside a facility or within a secure compound (e.g., a fenced area) (note that this is different conformance criteria relative to the questions in 1.3). If stored outside within a secure compound, there should be protection against potential tampering and contamination (e.g., store away from the fence line) and also ensure that the materials are protected from contamination (e.g., with shrouds).

Minor deficiency (3 points) if:

- Single/isolated instance(s) of packaging being stored within a secure compound, but not under cover (e.g., a shroud) (therefore exposed to contamination).
- Packaging is stored within a secure compound, but close to a perimeter fence (therefore potential for contaminant to be applied from outside the perimeter fence).

Major deficiency (1 point) if:

- Numerous instances of packaging being stored within a secure compound, but not under cover (e.g., a shroud) (therefore exposed to contamination).

- Majority of packaging is stored inside or within a secure compound, but some occasionally temporary storage of packaging is occurring outside the secure areas.

Non-conformance (0 points) if:
- Packaging is routinely stored outside secure storage areas.

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Employee Security

3.2.1 Are background checks conducted on all personnel with special attention to employees who have access to sensitive areas and/or control of sensitive processes (verbal confirmation accepted)?
Verbal confirmation. Total conformance (5 points): Checks such as social security numbers, INS details, interviewing, previous job references, etc. Privacy laws might limit how much investigating a company can carry out and also limit how much documentation an auditor is allowed to look at, hence verbal confirmation is acceptable. While felony checks are ideal and, if they are occurring, this should be noted in the audit commentary. If felony checks are not being carried out, this is not justification for a down score at present.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of employees not receiving basic background checks (social security, INS, etc.).
- Supervisory/management positions are not being checked with respect to previous positions.

Major deficiency (1 point) if:
- Numerous instances of employees receiving basic background checks (social security, INS, etc.).

Non-conformance (0 points) if:
- No checks of any employees are occurring.

3.2.2 Employee personal items are not being stored in the material storage areas?
Visual confirmation. Total conformance (5 points): Employees should have a designated area for storing personal items, such as coats, shoes, purses, etc. Lockers are desirable. Areas set aside for employee personal items should be far enough away from packaging materials and equipment to prevent contamination and avoid food security risks. Please note that this question is the same as what is found in 1.4.9. 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 storage areas.

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

No points (0 points) if:
- Systematic failure to prevent personal belongings, personal food, etc. being taken into the storage areas.

3.2.3 Are employees issued non-reproducible identification e.g. badges, company ID cards, etc.?
Visual confirmation. Total conformance (5 points): Employees should have personal identifications that link them to the company. The ID's should have the employee's number, photo and position within the organization. Time cards with photo identification are acceptable. The ID cards, if worn on the outer garments, should be firmly attached so as not to be a food safety hazard. If stored on one's person, this is also acceptable i.e. the ID card can be provided if challenged (if stored in pockets, etc., hand sanitation would be required after showing the ID card, prior to handling product). Control of the ID card, especially with respect to employees leaving the operation should be maintained. All employees should have ID's, including management and agency labor. Agency labor might have agency ID cards (which are checked on arrival). Companies with less than 20 employees are not expected to have an ID system.

Minor deficiency (3 points) if:
- ID's have been issued to all employees, but these do not include photos.
- Single/isolated instance(s) of employees not having ID cards.

Major deficiency (1 point) if:
- Numerous instances of employees not having ID cards.
- Lack of controls over ID cards when employees leave the operation.

Non-conformance (0 points) if:

- Employees are not supplied identification cards.

3.2.4 Are visitors (including contractors) also required to be issued with identification e.g. badges, high visibility visitor apparel, etc.?

Visual confirmation. Total conformance (5 points): All visitors, including contractors, should be provided with identification (e.g., badges that are valid only for the time that these visitors are on site). The identification cards should be collected when the visitors leave the site. Badge issue and return should be recorded (e.g., in the visitors sign in book). Ideally each badge should have a unique number and this number is recorded in the logbook. The ID cards if worn on the outer garments should be firmly attached so as not to be a food safety hazard. If stored on one's person, this is also acceptable i.e. the ID card can be provided if challenged (if stored in pockets etc., hand sanitation would be required after showing the ID card, prior to handling product). Issue of unique high visibility vests or bump hats marked with "visitor" to visitors with issue and return recorded (e.g., as part of sign in /sign out process) are also acceptable. Companies with less than 20 employees are exempt from this requirement, score as N/A.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of visitor(s) and contractor(s) who have not been supplied company ID badges or other identification (must specify).
- Single/isolated instance(s) of visitor ID badge(s) or other identification (must specify) issue and return not being recorded (e.g., as part of the sign in and sign book process).

Major deficiency (1 point) if:

- Numerous instances of visitors and contractors who have not been supplied company ID badges or other identification (must specify).
- Numerous instances of visitor ID badges or other identification (must specify) issue and return not being recorded (e.g., as part of the sign in and sign book process).

Non-conformance (0 points) if:

- Visitors (and contractors) are not supplied ID badges or other identification.

3.2.5 Are visitors (including contractors) required to "sign in" and "sign out" in a visitors logbook?

Visual confirmation. Total conformance (5 points): Facility should have a logbook that visitors and subcontractors should be required to sign in and out of (including date, time, reason for visit, visitor's host and employer name). Contractors, whether long term or short term, should also be covered by the site security procedures. If a contractor is going to be on site frequently or for a long time period, the auditee can grant a permanent ID card status. Special attention should be focused on those visitors who do not have to report to the front reception offices (e.g., contracted maintenance employees).

Minor deficiency (3 points) if:

- Single/isolated instance(s) of visitor(s) and contractor(s) not signing in.
- Single/isolated instance(s) of visitor(s) and contractor(s) not signing out.

Major deficiency (1 point) if:

- Numerous instances of visitors and contractors not signing in.
- Numerous instance(s) of visitors and contractors not signing out.

Non-conformance (0 points) if:

- Visitor/contractor sign in and sign out logbook is not being used or does not exist.

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Transport Security

3.3.1 Does the company make use of sealed and/or locked trailers on inbound loads (excluding open flatbed trucks)?

Verbal confirmation. Total conformance (3 points): Inbound trailers i.e. deliveries to the auditee of packaging materials should be fitted with seals and/or locks in order to maintain security. Seal numbers should be recorded if seals are used. Seals are difficult to demand from material suppliers, if the auditee is not ordering full loads of material. Open flatbed trucks cannot be sealed or locked, therefore mark N/A.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of inbound trailers not being sealed and/or locked.
- Single/isolated instance(s) of seal numbers not being recorded (where seals are being used).

Major deficiency (1 point) if:

- Numerous instances of inbound trailers not being sealed and/or locked.
- Numerous instances of seal numbers not being recorded (where seals are being used).

Non-conformance (0 points) if:

- Inbound trailers are not sealed and/or locked.
- Seal numbers are not being recorded (where seals are being used).

3.3.2 Does the company make use of sealed and/or locked trailers on outbound loads?

Verbal confirmation. Total conformance (3 points): Outbound trailers (shipping) of packaging should be fitted with seals and/or locks in order to maintain security. Seal numbers should be recorded if seals are used. Seals are difficult to use if the shipping trailer is making multiple drops. Where the auditee has no decision in the choice of trucking company i.e. the trailers are booked by the buyers (not by the auditee), it might not be possible for the auditee to enforce trailer locking or sealing policy. In these cases, this question should be scored N/A.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of outbound trailers not being sealed and/or locked.
- Single/isolated instance(s) of seal numbers not being recorded (where seals are being used).

Major deficiency (1 point) if:

- Numerous instances of outbound trailers not being sealed and/or locked.
- Numerous instances of seal numbers not being recorded (where seals are being used).

Non-conformance (0 points) if:

- Trailers are not sealed and/or locked.
- Seal numbers are not being recorded (where seals are being used).

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Water Supply Security

Potentially use website:
EPA Water Security, http://water.epa.gov/infrastructure/watersecurity/
http://www.epa.gov/watersecurity/pubs/water_security_handbook_rptb.pdf

3.4.1 Are potable and non-potable water supplies clearly identified?

Visual confirmation. Total conformance (3 points): Water lines should be clearly identified if water is used for any particular process (e.g., fire suppression) and there is more than one source or type of water on site. The aim is to ensure that anyone can tell what water source or type of water is within a pipe or coming out of a tap. Examples of methods used include color-coded pipes, labeled pipes, signs on taps, etc. Where there is only one type of water source used on site, this question should be scored N/A.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of water pipes, taps etc., not indicating potability status where there is more than one water source/type being used on the site.

Major deficiency (1 point) if:

- Numerous instances of water pipes, taps, etc., not indicating potability status where there is more than one water source/type being used on the site.

Non-conformance (0 points) if:

- None of the water pipes, taps, etc. indicate their potability status where there is more than one water source/type being used on the site.

3.4.2 Are tamper evident/tamper resistant systems (e.g. tamper tags) in place where appropriate?

Visual confirmation. Total conformance (3 points): Where appropriate (e.g. incoming water supply), water valves should be fitted with tamper evident or tamper resistant systems. For example, the main incoming water valve could be fitted with a tamper evident chain (sacrificial link), that has to be broken if the valve is opened or closed. Other examples of tamper evident systems may include tamper tags/seals, padlocks, valve chains, zip ties on valves, cage, etc.

Potentially useful website:
EPA Valve Lockout Devices, http://www.epa.gov/watersecurity/pubs/water_security_handbook_rptb.pdf

Minor deficiency (2 points) if:

- Single/isolated instance(s) of incoming water valves not fitted with tamper evident systems.

Major deficiency (1 point) if:

- Numerous instances of incoming water valves not fitted with tamper evident systems.

Non-conformance (0 points) if:

- None of the incoming water valves are fitted with tamper evident systems.

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Food Defense Systems

3.5.1 Does the company have a documented food defense policy based on the risks associated with the operation?

Visual confirmation. Total conformance (10 points): The company should have a documented food defense policy that outlines the operation security controls. These should include policies covering personnel, visitors, contractors, packaging material receipt, trucks (incoming and outbound), etc., i.e. any relevant food security risk. There might also be a requirement to ensure that suppliers have proper food defense programs. Documented operational risk management (ORM) systems are acceptable, if they show the controls that have been implemented for the food defense risks that have been identified.

Minor deficiency (7 points) if:

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

Major deficiency (3 point) if:

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

Non-conformance (0 points) if:

- Food defense policies have not been documented.

3.5.2 Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?

Visual confirmation. Total conformance (3 points): The company should have a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies. This information may be found as part of the recall plan.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of errors or omissions in the list.
- The list is has not been updated in more than a year (less than two years).

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the list.
- The list has not been updated in more than two years.

Non-conformance (0 points) if:

- A list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies has not been documented.

3.5.3 Are all personnel required to undergo training on food defense issues and are training records kept?

Visual confirmation. Total conformance (5 points): Employees should attend either external or in-house training on food security/defense requirements at least every 12 months. Records should be kept (showing topics and attendance). Training might include checking materials, facility security, handling visitors, etc. Training might also include formal operational risk management evaluation. All employees should be trained, but the depth and level might vary depending on the employee's role within the auditee company.

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the food defense training topics covered.
- Numerous instances of errors or omissions in the food defense training attendance records.

- Numerous instance(s) of employees not being trained with respect to food defense.

Non-conformance (0 points) if:
- Employees are not trained with respect to food defense requirements.
- No records of the food defense training.

3.5.4 Is there a log of who has access to sensitive areas e.g. a listing of key holders for access to areas like chemical stores?

Visual confirmation. Total conformance (3 points): In order to track who has been granted access to sensitive areas and to maintain information about the whereabouts of keys, a documented log should be maintained. For example, the chemical stores should have restricted access and there should be a log of who has access to this area. In many cases, this will be a listing of key holders, however, some operations might use pass codes, palm readers and other technologies. Special attention should be employed when employees leave or move positions within a company (e.g., pass codes should be changed, keys returned and records should be updated). The auditor can challenge the systems (e.g., asking to see key holders keys).

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the logs showing who has access to sensitive areas.
- Single/isolated instance(s) of employee(s) who should have access to restricted areas, unable to prove that they have this access (e.g., a lost key).
- Single/isolated instance(s) of employee(s) who should not have access to restricted areas that have access i.e. having a key that they should not have, knowing a secure pass code.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the logs showing who has access to sensitive areas.
- Numerous instances of employees who should have access to restricted areas, unable to prove that they have this access (e.g., a lost key).
- Numerous instances of employees who should not have access to restricted areas that have access i.e. having a key that they should not have, knowing a secure pass code.

Non-conformance (0 points) if:
- Logs showing who has access to sensitive areas do not exist.
- Pass codes to restricted areas have been publicly displayed in some way.

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Additional Questions (Not Part of Overall Food Safety Percentage) – Section 6

These questions are answered Full, Minor Deficiency, Major Deficiency or Non-conformance. These questions do not affect either the Food Safety or Food Defense scores in this audit version v14.09, but will most likely be added in the next versions of the audit as part of the food safety section, where they will be scored.

4.1.1 Is there a written procedure requiring transportation vehicles be dedicated to produce and related packaging material, and that animals, animal products or other materials that may be a source of contamination are not allowed to be transported?

Visual confirmation. Total conformance (5 points): There should be a written procedure in place that prohibits the transportation of trash, animals, raw animal products or other materials that may be a source of contamination with pathogens in vehicles that transport packaging.

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the procedure.

Non-conformance (0 points) if:

- There is no written procedure.

4.1.2 Is there a documented food safety plan covering site and facility?

Visual confirmation. Total conformance (10 points): The operation should have a facility-specific documented food safety plan meeting requirements of the FDA Food Safety Modernization Act (FSMA).This includes:

- A hazard analysis that identifies and evaluates known or reasonably foreseeable hazards for packaging at the facility. Analysis justifies conclusions reached, including any conclusion that no hazards are likely.
- Preventative controls required are identified and implemented to provide assurances that hazards that are reasonably likely to occur will be significantly minimized or prevented.
- Monitoring procedures documenting preventive controls are consistently performed.
- Corrective actions to correct problems and minimize the likelihood of re-occurrence, evaluate the food for safety and prevent affected food from entering commerce where necessary.
- Verification to ensure preventive controls are consistently implemented and are effective.
- Recall plan detailing steps to be taken, and assigned responsibilities.

The plan should be signed and dated, and updated at least every three years, or whenever significant changes are made in the operation.

Potentially useful websites:
http://www.fda.gov/food/guidanceregulation/fsma/ucm247548.htm
http://www.fda.gov/Food/guidanceregulation/FSMA/ucm334114.htm
http://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm

Minor deficiency (7 Points) if:

- Plan lacks an element listed above.
- Single/isolated instance(s) of errors or omissions in the plan.
- Single/isolated instance(s) of errors or omissions in records (e.g., corrective actions).

Major deficiency (3 points) if:

- Plan lacks more than one element noted above.
- Numerous instances of errors or omissions in the plan.
- Numerous instances of errors or omissions in records (e.g., corrective actions).
- Failure to update plan every three years, or whenever a significant change in operations has been made.

Non-conformance (0 points) if:

- No plan exists.

- Systematic failures to keep records and/or corrective actions.

4.1.3 Is there a documented business continuity and disaster recovery plan?

Visual confirmation. Total conformance (5 points): Business continuity and disaster recovery (BC&DR) planning are documented processes to help organizations prepare for disruptive events that may impact the ability of the auditee to assure the safety of the food product. Disruptive events may include natural and man-made hazards such as a hurricane or earthquake, a computer virus attack, tampering or even a power outage. Business continuity planning should be orientated to how to continue doing business until recovery is accomplished, whilst disaster recovery should be orientated to recovery after a disruptive event.

The business continuity and disaster recovery plan should list and identify a crisis management team who represent the departments to handle and resolve any critical situations that may occur. Team should meet at least every 12 months (with documented minutes) to review, test and verify the plan. This question is not applicable to small family size companies (less than 20 persons).

The plan should include:

- Current list of team members with office and after hour contact details.
- Contact details for regulatory agencies, corporate personnel, clients, suppliers and other key contacts (e.g., trade association, media representative, consultants, legal team, etc.).
- Written responsibilities for each team member, including contacting regulatory officials, law enforcement, media, etc.
- Documented training for team members on crisis management procedures and responses.
- Written plans for handling critical situations to assure that food contact packaging materials are protected and there are plans for alternate product supply to the customer(s).
- Requirement that QA management determine the status of any food contact packaging materials involved in a critical situation. Evaluation and release to be documented.

Potentially useful websites:
http://www.fda.gov/food/guidanceregulation/fsma/ucm247548.htm
http://www.unitedfresh.org/assets/food_safety/FDA_Food_Safety_Modernization_Act_White_Paper_January_2011.pdf

Minor deficiency (3 Points) if:
- Plan lacks an element listed above.
- Single/isolated instance(s) of errors or omissions in the plan details.
- Single/isolated instance(s) of errors or omissions in records (e.g., evaluation and release).

Major deficiency (1 point) if:
- Plan lacks more than one element noted above.
- Numerous instances of errors or omissions in the plan details.
- Numerous instances of errors or omissions in records (e.g., evaluation and release).
- Failure to meet every 12 months to evaluate the plan.

Non-conformance (0 points) if:
- No plan exists.
- Systematic failures to keep records.

4.1.4 Does the facility have documented evidence to ensure that any food safety hazards relevant to waste water treatments (e.g. settling ponds, land applications, etc.) are controlled?

Visual confirmation. Total conformance (10 points): All national and local laws pertaining to on-site water treatment systems should be followed and this should be documented. There should be applicable permits on file and evidence of regulatory and/or third party inspections or copies of any exemptions. This question only pertains to open water collection areas: settling ponds, land applications. This question is not applicable if there are no on-site wastewater treatments. Not applicable to septic systems or sewer systems.
http://www.p2pays.org/ref%5C05/04874.pdf

http://www.epa.gov/watersecurity/pubs/water_security_handbook_rptb.pdf
http://water.epa.gov/aboutow/owm/upload/2005_08_19_primer.pdf

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the records

Non-conformance (0 points) if:

- There are no records showing conformance to national and local laws pertaining to on-site water treatment systems (where applicable).

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