Primus Standard Audits
GMP Cooling & Cold Storage
with HACCP Guidelines

Used in conjunction with the Primus Standard Audits v20.06

Primus Standard Audits (owned by Azzule Systems, LLC)
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Table of Contents

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These guidelines help interpret/support the principles, requirements, and expectations of the Primus Standard Audits v20.06, as noted in the Scheme normative documents. These guidelines are neither exhaustive nor exclusive and detail minimum requirements only by means of statements related to audit questions and expectations. There will be variations in applicability to an operation based on the process(es) and commodities involved. Auditors and auditees should interpret the questions and criteria in different situations, with the food safety and risk minimization being the key concerns.

The operation's practices, policies and procedures should be pertinent to the situation at hand and be able to stand up to any challenge by an auditor or other relevant interested party (including law enforcement). Where laws, customer requirements and specifications, 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 compliance than those included in the audit scheme.

Website links shown in this document are there to aid understanding and provide assistance by way of example (link listings are not exhaustive). These links are not a sign of endorsement by Azzule Systems. Furthermore, Azzule Systems accepts no liability for the content of these links.

Please be aware that there is additional information on the Primus Standard Audits website including the audit checklist templates. The Primus Standard Audits website also has access to the official Primus Standard Audits General Regulations, which explain the overall scheme scoring systems and other details of the scheme.

Audit Execution

The audit should be performed using the most recent version of the Primus Standard Audits normative documents.

The Primus Standard Audits Scheme is divided into different audit types. The Guidelines for the facility audits include applicability charts to help determine which questions apply in each audit type.

- **Farm:** A tract of land (not necessarily a "lot" for production purposes), under common management and common water supply, ideally contiguous (if not contiguous, similar risk is demonstrated) and used for agricultural production.
- **Indoor Agriculture:** Where crops are grown in a controlled environment in a temporary or permanent enclosed structure. This does not include shade or hoop houses.
- **Harvest Crew:** A designated group of workers under common supervision, harvesting the same product.
- **Storage & Distribution:** A facility that is only receiving and storing finished goods for further shipment e.g. regional distribution warehouses. Goods may be stored at controlled or ambient temperatures.
- **Cooling and Cold Storage (with or w/out HACCP):** A facility that is receiving and storing finished goods and performing some kind of pre-cooling and/or cooling activities. In this type of facility, no packing or processing activities are being performed.
- **Packinghouse (with or w/out HACCP):** A facility where commodities are sorted and/or sized, may be minimally trimmed (not altered in form), washed or not washed, may have post-harvest treatments applied (e.g. fungicide, wax, sprout inhibitor) and packed for commercial distribution and use by consumer or retail establishment.

- **Processing with HACCP:** Washing, slicing, dicing, cutting, shredding, peeling, grading, pasteurization, cooking, chilling, juicing, pressing, freezing, packing in modified atmosphere, packed in vacuum packing or any other activity that significantly transforms the product from its original whole state.

Each audit type is divided into sections, related to specific topics. Please note that there may be some generic questions in all audit types that contain descriptions for both GAP and GMP audit types. For those questions and guidance criteria, you should only focus on the type of audit being conducted.

Depending on commodity specific requirements, buyer requirements, and circumstances at the operation, there are optional addendums which may be added on to the audit.

Audit Template Structures

- *Food Safety Management System* - Covers food safety systems
- *GAP and/or GMP Section* - Covers the physical tour of the operation and documentation
- *HACCP* - Covers the HACCP program
- *Preventive Controls* - Covers the Preventive Controls program
- *Additional Questions* - These questions are not part of the overall score of the audit. Please note that these questions will help assess the auditee's readiness to achieve certification against a GFSI recognized scheme.

Scoring System

For each question, the amount of deficiencies and the associated risks have to be considered to assign the severity of the finding, which can be Minor Deficiency, Major Deficiency and Non-Compliance. When no deficiencies are found, a Total Compliance is given. The possible points for the questions are listed in the following table:

Detailed compliance requirements are noted for each question throughout this document, but some general statements are described below. These statements are superseded by the specific question compliance criteria and users should be aware that some questions do not follow the general statements below (e.g., automatic failure questions).

Compliance for Questions	
Answer	**Criteria Used**
Total compliance	To meet the question and/or compliance criteria in full.
Minor deficiency	To have minor deficiencies against the question and/or compliance criteria. To have single or isolated non-severe deficiencies (usually up to three) against the question and/or compliance criteria. To have covered most of the question compliance criteria, but not all.
Major deficiency	To have major deficiencies against the question and/or compliance criteria. To have numerous non-severe deficiencies (usually more than three) against the question and/or compliance criteria. To have single or isolated severe deficiencies against the question and/or compliance criteria. To have covered some of the question compliance criteria, but not most of it.
Non-compliance	To have not met the question and/or compliance criteria requirements at all. Having fundamental deficiencies against the question and/or compliance criteria (severe or non-severe issues).
Not applicable	The requirement described in the question is not applicable for the operation being audited. Justification should be provided in the auditor's comments. Be aware that there are some questions that do not allow a non-applicable response.

Automatic Failure

There are some questions 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, even if an automatic failure occurs. On being immediately informed of the automatic failure by the auditor during the audit, the auditee has the option to have the auditor continue the audit or to have the audit halt at that point (all charges will apply).

Special Circumstances

Please also note, that under special circumstances and upon finding serious food safety risks, a "not certified" decision can be given. The auditee should be immediately informed of the automatic failure by the auditor during the audit. The auditee has the option to have the auditor continue the audit or to have the audit halt at that point (all charges will apply).

There are other Special Circumstances that are not technical in nature. Examples of these include detection of deliberate illegal activities, such as deliberate mislabeling, discovery of falsified records, attempting to bribe an auditor, threatening behavior towards an auditor, etc. Please refer to the General Regulations for further details.

Audit Termination

Once an audit has been started, should the auditee wish to stop the audit for any reason, the auditor will complete the report for as many questions as they were able to verify. If an audit is terminated early,

questions that the auditor was unable to verify will be marked as a non-compliance and will receive a score of zero. For questions unable to be verified, the auditor will indicate that 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 created on the database and 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 above. Vice versa, a pre-assessment audit cannot be converted into a standard audit once the service has begun. The only time a standard audit can be optionally turned into a pre-assessment audit is when the operation is found not to be running on the day of the audit, which can result in the cancellation of the audit (with charges) or the audit can be turned into a pre-assessment (see texts below).

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

Audit Agenda

Audit agendas 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 on the type of operation. A GMP operation might include raw material storage areas, production, finished goods storage, personnel facilities, maintenance, chemical storage, packaging storage and external areas (e.g., where the dumpsters are located). A GAP operation might include the harvest process, chemical storage, growing areas, portable toilets, and greenhouse. The auditor might also interview some workers.

- **Food Safety File Requirements (paperwork section).** Paperwork (documents and records) is reviewed. Please note that the auditor cannot accept documentary evidence after the audit has ended. For example, if a pest control document is missing at the time of the audit and the auditee tries to fax it the next day, it cannot be used to alter the score.

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

- **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 all 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 the Certification Body if reports have not been received electronically two weeks after the audit has occurred (at the latest).

Documentation Requirements

Operation's Food Safety Systems:

When an operation is being audited, the auditor is checking the systems (SOP's, policies, etc.) and the implementation of these systems throughout the visual inspection.

While auditees often create and implement their own systems, they can also use systems that have been created by other entities, for example, their customers' technical manager, their consultants, etc., or a combination of resources. The organization can create their own SOPs, or in other instances, can utilize SOP templates provided by other entities. As long as the systems meet the requirements of the Primus Standard Audits questions and expectations and these systems are being implemented properly, the auditee should receive full points for their efforts. The auditee is responsible for ensuring that the systems they use are reviewed, maintained and up-to-date. If the auditor detects any inconsistency, it will result in a down score.

New Primus Standard Auditees/First-Time Primus Standard Auditees

In operations that operate for more than three consecutive months throughout the year – auditee should have at least three months of documentation (i.e. records of monitoring, training, meetings, etc.) available for review. If the auditee 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 scheduled audit, they should be aware that they **cannot receive full conformance for paperwork questions relating to monitoring and that the down score will be based on the amount of paperwork available**.

- **In short season operations that operate for less than three consecutive months throughout the year** - auditee should have at least three months of documentation (i.e. records of monitoring, training, meetings, etc.) available for review (this may include last season's documentation). Where an operation does not have three months of records available (e.g., they are in operation for one month out of the year), the 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 scheduled audit, they should be aware that they **may not receive full conformance for paperwork questions relating to monitoring and that the down score will be based on the amount of paperwork available**.

Existing Primus Standard Auditees

- **In operations that operate for more than three consecutive months throughout the year** – auditee should have documentation available from the date of the prior audit.
- **In short season operations that operate for less than three consecutive months throughout the year** – auditee should have at least three months of documentation and documentation at least since the last audit (which includes the last season). Where an operation does not have three months of records available (e.g. they are in operation for one month out of the year), the auditee should have at least the previous season's records available for review.

	Operates <three months/year	Operates >three months/year
New Primus Standard Auditee	Three months of records (may include last season's records). Where an operation does not have three months of records available (e.g., they are in operation for one month out of the year), the auditee	Three months of records (may include last season's records).

	should have at least the previous season's records available for review.	
Existing Primus Standard Auditee	Records at least since the last audit (or longer) to meet the minimum requirement of three consecutive months of records.	Records since the last audit.

Visual versus Verbal Confirmation

Visual confirmation is the default method of auditing, whether on the visual inspection portion or the paperwork section. Scores and comments are assumed to have been visually confirmed, unless stated otherwise. 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 report for that specific question.

How to Use Point Assignment Guidelines

The following sections of this guidance manual are designed to help auditors 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 to 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 their Certification Body and Azzule Systems, LLC in a separate note, so that this can be reviewed for future versions of the manual.)

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

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

Section 1: Good Manufacturing Requirements

General

1.1.1: Was the operation free from any significant threat to the safety of the product that may be considered critical and warrants an automatic failure? Explain. ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE AUDIT.
Total compliance (15 points): There should be no observation of any issue that the auditor considers a significant threat to the safety of the product. Issues covered by this question are critical food safety situations that might not be considered in the audit template questions and conformance criteria. Alternatively, there may be question and conformance criteria that cover the topic of the issue within the audit, but the situation discovered warrants an automatic failure as opposed to a point down score; the auditor will note the issue in this question. Specific directions for pest and other adulteration (direct observation of product contamination and/or adulteration) are covered in 1.3.1, 1.3.2, 1.3.5 and 1.4.5. This question is intended for other issues that may not be covered by those questions. Scoring reverts back to this question where the auditor must detail their concern. If the auditor spots an issue that is a serious threat to food safety (as opposed to a pre-requisite) and corrective actions are not being implemented, issue may also be scored here.
https://www.fda.gov/regulatory-information/federal-food-drug-and-cosmetic-act-fdc-act/fdc-act-chapter-iv-food

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

General GMP

1.2.1: Are all cleaning and maintenance chemicals (pesticides, sanitizers, detergents, lubricants, etc.) stored securely, safely and are they labeled correctly?
Total compliance (15 points): Chemicals are stored in a designated (with a sign), secure (locked) area, away from food and packaging materials and separated from the production areas. Storage area is maintained clean and sanitary. Access to chemicals needs to be controlled, so that only workers who understand the risks involved and have been trained properly are allowed to access these chemicals.

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

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 an enclosed, 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.
- Numerous instances of chemicals being used without proper attention to chemical spillage.

Non-compliance (0 points) if:

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

1.2.2: Are "food grade" and "non-food grade" chemicals used appropriately, according to the label and stored in a controlled manner?
Total compliance (10 points): Food grade chemicals, including lubricants, greases, etc., are used in all product/packaging contact areas. All chemicals applied should be approved by the prevailing authority (e.g., US: EPA/FDA, Canada: CFIA/Environment Canada, Chile: SAG/Ministerio de Salud, Mexico: COFEPRIS) for their designated use and used according to label instructions. Only food grade lubricants should be used anywhere near product and packaging materials. Food grade chemicals should be stored apart from non-food grade items to eliminate confusion between types, and adequately labeled. Non-food grade chemicals also include cleaning chemicals and paint, for example use of domestic polishes which are not intended for food contact surfaces and have strong fragrances should not be used on food contact surfaces; office cleaning materials, restroom cleaning material, truck cleaning materials should be stored separately from production cleaning materials. Grease guns and containers should indicate which are for food grade greases and which are for non-food grade use. Non-food grade material use, where required should not be used in food contact areas and be entrusted to workers who know how to use the chemicals to avoid contamination issues. Non-food grade materials should not be found in the production/storage areas (unless stored securely, with access to entrusted workers only). Chemicals should be used according to label instructions e.g. following correct dilutions, only food grade salt should be used in ice injectors, H1 designation on lubricants, etc. Food grade lubricants/oils should be used on air compressors if compressed air is used in direct contact with food, food contact surfaces and interior of surface of packaging. Any chlorine bleach that is used for making a sanitizing solution, whether for equipment or raw produce, must be of sufficient purity to be categorized as a “food grade” substance. Some commercially available household chlorine bleaches contain fragrances, thickeners and/or other additives 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.”

NSF International: Nonfood Compounds
http://info.nsf.org/USDA/PSNCListings.asp
http://pods.dasnr.okstate.edu/docushare/dsweb/Get/Document-963/FAPC-116web.pdf

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

Major deficiency (3 point) if:
- Numerous instances of commingling of non-food grade with food grade chemicals.

- Numerous instances of grease guns not coded for food grade/non-food grade materials.
- Numerous instances of non-food grade materials found/used in the production/storage areas.
- Numerous instances of a chemical(s) being used contrary to label.

Non-compliance (0 points) if:
- No attempt to split non-food grade from food grade materials.
- Widespread use of non-food grade materials found/used in the production/storage areas.
- Widespread use of a chemical(s) used contrary to label.
- **Evidence of the use of a non-food grade that has caused product contamination – revert to 1.4.5, automatic failure.**

1.2.3: Are signs supporting GMPs posted appropriately?
Total compliance (10 points): Signs for proper GMP's need to be posted visibly and in the language of the workers (picture signs are allowed) to remind them of proper practices. Signs should be posted in the following areas:
- Before entering areas that require hair nets and smocks (PPE), including production and storage areas.
- Before areas that prohibit food consumption, drinking, tobacco products, chewing gum.
- Bathrooms and break-room(s) should have hand-washing signs as reminders to wash hands before eating, returning to work, after using the toilet.

Signage reminding workers and visitors of GMP rules around the site are very useful (but should not cause down score) such as additional PPE rules, hand dip/gel use (where relevant), not allowing personal items in the production areas, etc.

Minor deficiency (7 points) if:
- The signs are not in the workers' language (visuals are acceptable)
- Single/isolated instance(s) of required signs not being in position.

Major deficiency (3 points) if:
- Numerous instances of required signs not being in position.

Non-compliance (0 points) if:
- Fundamental failure to place signs in the required positions.

1.2.4: Are the necessary food defense controls implemented in the operation?
Total compliance (10 points): The operation should have implemented the necessary controls for preventing intentional contamination of the product and high-risk areas. These measures should be based on the risk associated with the operation, as detailed in the food defense plan (2.8.1). Some high-risk areas of the facility include: personnel, visitors, contractors, computers, raw material receipt (raw materials, product and packaging), trucks (incoming and outbound), water sources, storage areas for product, materials, chemicals, production areas, shipping areas, etc.

FSIS has 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
https://www.fsis.usda.gov/wps/wcm/connect/53b140bf-8eca-41e6-95ef-6209f48c4371/Warehouse_Center_Checklist_2.pdf?MOD=AJPERES

FDA Food Security Preventive Measures Guidance
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-security-preventive-measures-guidance-food-producers-processors-and
FDA Guidance for Industry,
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/

Minor deficiency (7 points) if:
- Single/isolated instance(s) is observed of an area lacking necessary food defense controls, based on the risks associated with the operation.

Major deficiency (3 points) if:
- Numerous instances are observed of areas lacking necessary food defense controls, based on the risks associated with the operation.

Non-compliance (0 points) if:
- Systematic non-conformance to implement necessary food defense controls, based on the risks associated with the operation.

Pest Control

1.3.1: Are products or ingredients free of pests (e.g. insects, rodents, birds, reptiles, mammals) or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.
Total compliance (15 points): Raw materials, work in progress, ingredients, finished goods are free from evidence or the infestation of **pests (e.g. insects, rodents, birds, reptiles, mammals).** See 1.3.3 for reference to potential indications of pest presence.

Automatic Failure (0 points) if:
- **There is a single incidence of direct contamination on or in products or ingredients**.

1.3.2: Are packaging supplies free of pests (e.g. insects, rodents, birds, reptiles, mammals) or any evidence of them? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.
Total compliance (15 points): Packaging supplies are free from evidence or the presence of **pests (e.g. insects, rodents, birds, reptiles, mammals).** See 1.3.3 for reference for potential indications of pest presence.

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

1.3.3: Are plant and storage areas free of pests (e.g. insects, rodents, birds, reptiles, mammals), or any evidence of them?
Total compliance (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 scored accordingly. Insects should be at a minimal level on glue boards. The facility should have additional glue boards for replacement/change out.

Pests of Homes, Structures, People, Pets - UC Pest Notes,
http://www.ipm.ucdavis.edu/PMG/menu.house.html

National Pest Management Standards, Pest Management Standards for Food Plants
http://npmapestworld.org/default/assets/File/2016%20Pest%20Management%20Standards%20for%20Food%20Processing-Electronic.pdf

Minor deficiency (10 points) if:
- Single/isolated instance(s) of pest activity noted on the interior of the facility, which does not pose an immediate threat of product contamination.
- Single/isolated instance(s) of feces/pellets noted in the interior of the facility, which does not pose an immediate threat of product contamination.
- Single "fresh" pest 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 do not pose an immediate threat of product contamination.
- Two to three instances of "fresh" rodents found in internal traps.

Non-compliance (0 points) if:

- One sighting (including feces/pellets) which has the potential for product contamination.
- Evidence of live animals observed inside the facility.
- Decomposed rodent(s) in trap(s).
- More than three "fresh" rodents found in internal traps.
- **Any observation of contaminated ingredient, product or packaging contact. (This qualifies as an automatic failure under 1.3.1 and 1.3.2).**

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

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

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

Major deficiency (3 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-compliance (0 points) if:
- Evidence of significant (infestation level) rodent activity (burrows, trails, feces, tracks, animal spoor)
- Significant bird activity in traffic zones.
- More than one decomposed rodent or other animals (frogs, lizards, etc.) in external traps or along perimeter.
- **Any observation of contaminated ingredient, product or packaging contact qualifies as an automatic failure under 1.3.1 and 1.3.2.**

1.3.5: Is there an effective pest control program in place? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.
Total compliance (15 points): There should be an effective, proactive pest control program (in-house or contracted) to control rodents (also insects, reptiles and birds where necessary) and prevent infestation.

Potentially useful website:
National Pest Management Standards, Pest Management Standards for Food Plants
http://npmapestworld.org/default/assets/File/2016%20Pest%20Management%20Standards%20for%20Food%20Processing-Electronic.pdf

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

1.3.6: Are pest control devices located away from exposed raw materials, work-in-progress, ingredients (including water and ice), finished goods and packaging, and poisonous rodent bait stations are not used within the facility?
Total compliance (10 points): Pest control devices should be located away from exposed food products, packaging materials, or equipment to prevent any physical or microbial contamination. Poisonous rodent bait traps should not be located within the facility. Care should be taken to place pest control devices in such a manner that they do not pose a threat of contaminating product, packaging or raw materials. This includes the following restrictions:
- Poisonous bait stations and other pesticides should only be used outside the facility.
- There should be no domestic fly sprays used within the production and storage areas.
- Block bait as opposed to grain and pellet bait should be used (except for the external use of National Organic Program approved materials).
- If used, insect light traps (ILTs), electrical fly killers (EFKs) or pheromone traps should be regularly cleaned out (kept free from a build-up of insects and debris). Sticky type ILTs should be monitored at least monthly and the sticky board replaced if ineffective. ILTs that use sticking as opposed to zapping methods (EFKs) are preferred.
- If used, insect light traps or electric fly killers should not be placed above or in close proximity (10 feet, 3 meters) to product, food contact surfaces, equipment, or packaging material. Electric fly killers or insect light traps should not be located above dock doors (due to potential forklift damage) or in front of doorways (so attracting insects into the facility). Hallways or dock areas where product passes through are exempt from these distances, as long as product does not stop or is not stored in hallway or dock.
- If used, insect light trap bulbs should be replaced at least every 12 months (this should be recorded), or as more frequently if directed by manufacturers.
- No fly swatters should be evident in production or storage areas.
- No bait should be found outside of bait stations.
- If used, snap traps should be placed inside a trap box and should not use allergen containing baits (e.g., peanut butter). Any snap traps inside stations should be checked at least weekly and checks recorded (scored in 1.3.7).
- Any indoor use of chemicals e.g. knock down sprays should be done without contaminating food, packaging, and equipment (see the next bullet point regarding poisonous rodent baits). All applications should be recorded properly (scored in 2.10.3), detailing where and when the application

occurred and any special methods used to avoid contamination. All applications should be made by experienced, licensed operators following any and all legal requirements and best practices.
- The use of poisonous rodent bait within the facility should not occur. If this use is required, then the area that is being trapped should have all the product and packaging removed prior to the use of the poisonous baits.

Minor deficiency: (7 points) if:
- Single/isolated instance(s) of improperly positioning or maintaining electrical fly traps or insect light traps.
- Single/isolated instance(s) of a fly swatter found in production or storage area.
- Single/isolated instance(s) of grain or pellet baits being used in an outside bait station (external trap).
- Single can of fly spray (or other insecticide) found in the production/storage areas (including chemical/sanitation storage).
- Single/isolated instance (up to three snap traps) of snap traps being used outside a trap box (not presenting risk to product or packaging).
- Single/isolated instance(s) of any other issues noted on the compliance criteria.

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

Non-compliance (0 points) if:
- More than one instance of bait/poison inside the facility (inside of a trap).
- Single instance of bait/poison inside the facility (outside of a trap).
- More than one instance of bait/poison found outside of a trap, outside the facility.
- More than one major deficiency.
- Systematic use of snap traps outside of trap boxes.
- **Any observation of contamination of product or product contact material (this qualifies for an automatic failure and applies under 1.3.1 and/or 1.3.2.**

1.3.7: Are pest control devices maintained in a clean and intact condition and marked as monitored (or bar code scanned) on a regular basis?
Total compliance (5 points): All pest control devices should be maintained clean, in working order and replaced when damaged in order to accomplish their intended use. Date of inspections should be posted on the devices as well as kept on file (unless barcode scanned). This included any in-house service inspections.
The following criteria should be 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 2.10.1).
- 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 at least monthly – these checks to be recorded.
- Internal multiple-catch devices should be checked at least weekly – these checks to be recorded.
- Any snap traps used should be inside stations and should be checked at least weekly – these checks to be recorded.

Local regulations may require exceptions/differences to above guidelines. At all times, local regulations should be met but if the audit system requirements are more stringent, these should also be adhered 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 traps, bait stations and glue boards not working properly or adequately maintained (check cards, cleanliness, etc.)
- Single/isolated instance(s) of unsecured bait inside bait stations.
- Single/isolated instance(s) of bait stations having moldy bait.
- Single/isolated instance(s) of any other issues noted on the compliance criteria.

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

Non-compliance (0 points) if:
- Fundamental failure to maintain the pest control devices.
- Fundamental failure to monitor the pest control devices.

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

Total compliance (5 points): The distance between traps should be determined based on the activity and the needs of the operation. As a ***guide*** (i.e. not expecting the use of tape measures) to number and placement of 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. Spacing might be affected by the structure, storage and types of activities occurring.
- Snap traps in stations may be used if necessary in certain areas e.g., in areas with high dust levels (e.g., potatoes, onions), covered breezeways or box mezzanines where large traps or glue boards are not practical. Snap traps in stations should be positioned between 20 to 40 feet (6 to 12 meters) intervals though spacing may be affected by the structure, storage and types of activities occurring.
- Inside the facility, traps should be placed within 6 feet (about 2 meters) of both sides of all outside exit/entry doors. This includes either side of the pedestrian doors. Effort should be made to avoid placing traps on curbing.
- Trapping inside Cold Storage and Cooler operations is mandatory. Trapping inside cold rooms within packinghouse and processors is recommended, but it is left to the auditor's discretion to review the

risks (doors that open to the outside, proofing issues, potential for rodents to be harbored in the materials being stored).
- Bait stations or multiple-catch traps should be positioned between 50-100 feet (15-30 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 meters) of structures. This may impact fence line/property boundary baiting i.e. bait stations must be within 100 feet (30 meters) of buildings and at 50-100 feet (15-30 m) intervals. If an exterior fence line/property perimeter program is utilized at distances greater than 100 feet (30 m) from buildings, then non-bait traps (e.g. multiple-catch traps) should be positioned at 50-100 feet (15-30 m) intervals along perimeter. Auditor should check label for bait and ensure compliance to distance requirements on label.
- Outside packaging and any outside food storage should be protected by an adequate number of pest control devices.

https://www.epa.gov/rodenticides/restrictions-rodenticide-products#types
http://npmapestworld.org/default/assets/File/2016%20Pest%20Management%20Standards%20for%20Food%20Processing-Electronic.pdf

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

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

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

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

Minor deficiency (3 points) if:
- Single/isolated instance(s) of 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-compliance (0 points) if:
- None of the devices are numbered.

1.3.10: Are all pest control devices effective and bait stations secured?
Total compliance (5 points): All traps should be correctly orientated with openings parallel with and closest to wall. Bait stations should be secured to minimize movement of the device and be tamper resistant, and only block bait (no pellets) should be used (scored under 1.3.6). 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, washed away, etc. Bait stations should be tamper resistant through the use of screws, latches, locks, or by other effective means. Note – only traps containing bait are required to be secured. Live 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. Glue boards should be inside a device (e.g. trap box, PVC pipe, etc.) rather than loose on the floor. Auditor discretion applies to traps placed on curbing.

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

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

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

Storage Areas & Packaging Materials

1.4.1: Does the facility layout ensure separation of ingredients (including ice), products, and packaging stored to prevent cross contamination (this includes iced product pallets stored above pallets of product without adequate protection as well as any allergen cross contamination issues)?
Total compliance (15 points): All raw materials, products and packaging should be stored off the ground (i.e. on racks, pallets, shelves, etc.). Materials should be properly protected during storage to prevent contamination (e.g., away from chemicals, battery chargers, etc.). Raw materials, finished product and packaging materials should be stored in separate areas to prevent cross contamination. When separate room storage is not possible, the auditor should assess the risks, especially with respect to cross contamination. When assessing raw contamination of finished goods, the auditor should assess the level of risk e.g. how "processed" are the finished goods, what kind of packaging is used etc. Raw unprocessed items should not be able to contaminate finished washed/processed items. Packaging storage, especially dust from cardboard storage should not contaminate produce items. If mixed food items are stored on site then there should be controls to prevent contamination issues e.g. raw eggs should not be stored above raw produce, glass items should be kept in a separated area and always stored near ground level. Wet product is not stored above other product (e.g. product from a different lot, dry product) – this especially important where iced product is being stored in conditions where the ice is thawing and dripping; any sign of product contamination is an automatic failure (1.4.5) – auditor discretion applies.

Ice should be manufactured, stored and handled in a manner that eliminates contamination issues; attention to ice tools and how salt for ice making is being stored and handled. Condensate is scored in 1.5.2.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of products or packaging materials stored on the floor or not protected properly.
- Single instance of a pallet or boxes/bags of finished product stored too close to raw product or ingredients.
- Single instance of ice/water dripping from above pallet onto unprotected product underneath but with no signs of product adulteration.
- Single instance of improper ice storage or handling practices.

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

Non-compliance (0 points) if:
- Different food items being stored together in a way that poses a cross contamination risk.
- Widespread storage of product or packaging materials directly on the ground.
- Numerous instances of raw product or ingredients and bagged/boxed finished product stored in the same room without adequate segregation; high risk raw and processed finished goods cross contaminating.
- More than three instances of ice/water dripping from above pallet onto unprotected product underneath but with no signs of product adulteration.
- More than three instances of improper ice storage or handling practices.
- **Any signs of product adulteration from poor storage practices – see 1.4.5, automatic failure due to product contamination.**

1.4.2: Is the storage area completely enclosed?
Total compliance (10 points): To protect the product and packaging materials from the elements and pests, it is necessary to keep the storage area enclosed and pest proof. Main doors should be kept closed unless in use. Food contact packaging should not be stored outside (including RPCs if used as primary packaging). 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). Yards or dock areas where product passes through (e.g., to and from a hydrocooler) are exempt, as long as the product is being transferred and is not actually being stored. Auditor discretion applies.

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

Major deficiency (3 points) if:
- Open areas in the ceiling/roof.
- Food contact packaging is stored outside (even if covered with shroud).

- Non-food contact packaging stored outside but not included in the pest control program and/or is not shrouded.
- Numerous instances of doors left open.
- Storage area is open on one to three sides.

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

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

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

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

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

1.4.4: Are rejected or on hold materials clearly identified and separated from other materials?
Total compliance (10 points): All raw materials, work in progress, ingredients, finished goods or packaging that are being rejected or are awaiting final disposition (on hold) should be stored in a designated hold area, in a way that avoids accidental use of these materials in the production process (unless they have been cleared for use). The rejected or on hold items should be tagged as such, with a date showing when the product was placed on hold/rejected and the reason for being on hold/rejected and the name of the person who put the product on hold. The tagged product should not be commingled with other goods in such a way that their disposition is not clear. There should also be records of items placed on hold (e.g. an on hold/disposition log) available for review (scored in 3.5.3). N/A if rejected or on hold materials are not observed.

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

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

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

1.4.5: Are raw products, work in progress, ingredients (including water and ice), finished goods and food contact packaging within accepted tolerances for spoilage and free from adulteration? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.

Total compliance (15 points): Raw products, work in progress, ingredients, finished goods, food contact packaging and food contact surfaces should be free from spoilage, adulteration and/or gross contamination (21 CFR 110.3g). If legislation exists, then the contamination should be viewed against this legislation (e.g., USDA Grading Standards often include decay tolerances). Spoilage and adulteration would include any physical, chemical or biological contamination including blood and bodily fluids. Measures should be taken to prevent any known or reasonably foreseeable hazard (e.g., Clostridium botulinum in mushrooms, low-acid fruit juices, honey, garlic and herb infused oils). Other examples might include glass, trash/litter, motor oil in products, pesticides, etc. This question is designed to allow an auditor to halt an audit when finding gross contamination issues (note pests are covered by 1.3.1 and 1.3.2). Where an issue is observed by an operator in the normal process, auditor should observe the actions of the operator before scoring. Auditors should use their discretion and decide whether the frequency of the contamination warrants an automatic failure.
Examples include pieces of glass, one piece of rodent bait, paint on product or packaging, flakes of rust, etc. Is the issue widespread or a one-off issue? There is no adulteration of ice permitted. Water used for ice for product cooling should be potable. Ensure that ice production and storage areas are inspected. Water directly sourced from rivers, canals, ponds, etc., (i.e. surface water) used to cool, wash, make ice or other product contact use without proper treatment i.e. filtration and/or anti-microbial treatment and proper testing (see 2.14.4) is not considered potable (US EPA drinking water **microbiological** specification (chemical criteria also, if appropriate) https://www.epa.gov/dwstandardsregulations and for the purposes of this audit is considered to be adulterated. Use of waste process discharge water from a surface source (e.g. discharged into a pond then re-used as process water) should not be considered suitable for product contact use and for the purposes of this audit is considered to be adulterated.

CPG Sec. 555.425 Foods, Adulteration Involving hard or Sharp Foreign Objects, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555425-foods-adulteration-involving-hard-or-sharp-foreign-objects
US FDA/CFSAN Defect Levels Handbook, The Food Defect Action Levels http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/sanitationtransportation/ucm056174.htm
US EPA Water Quality Standards for Coastal and Great Lakes Recreation Waters https://www.epa.gov/beach-tech/final-water-quality-standards-bacteria-rule-coastal-and-great-lakes-recreation-waters

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

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

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

1.4.6: Are all storage areas clean, especially the racking structures, lights, ceilings, floor areas by the walls and other hard to reach areas?
Total compliance (10 points): All storage areas should be clean and well ventilated and protected from condensation, sewage, dust, dirt, toxic chemicals or other contaminants. Ledges should be free of debris and clean. Stored products and packaging should be clean and free from dust, debris and out of place materials, etc. Inside light covers should be clean, free of algae, insects and excessive dirt. Pay special attention to the corners of the stores, girder areas, racking structures and spaces between walls and racking structures.

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

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

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

1.4.7: Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) properly marked with rotation codes (receipt dates, manufacture dates, etc.)?
Total compliance (5 points): All materials should be properly marked with receipt dates and/or tracking information (lot numbers, code dating) for traceability/recall and stock rotation purposes. Finished product coding should consider any specific customer requirements (e.g., as per customer specifications, customer expectation requirements). This coding should be understood by all workers, in order to ensure FIFO and effective traceback/recall procedures. Coding on raw and finished product should also consider any local or national laws where they exist.

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

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

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

1.4.8: Are materials (commodities, packaging, ingredients, processing aids, work in progress, etc.) rotated using FIFO policy?
Total compliance (5 points): All materials should be rotated using FIFO (First In First Out) policy to ensure items are used in the correct order they are received and within their allocated shelf-life (this does not apply to commodities that undergo ripening treatments or where rotation is dictated by the initial quality inspection). Materials should be clearly marked or labeled with some kind of rotation coding that is understood by all staff, in order to ensure FIFO and effective traceback/recall procedures. 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 1.4.7.

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

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

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

1.4.9: Are storage areas at the appropriate temperatures for the specific products being stored?
Total compliance (10 points). All products should be stored at the correct temperatures. Products should be stored in separate chambers if they require different optimum storage temperatures. Check the area/chamber thermometers and thermostats and compare the reading against the types of products being stored in the area. Holding temperatures in refrigerated storage rooms should not exceed 41 ^{0}F (5 ^{0}C) for microbiologically sensitive raw materials, ingredients or products including an animal food that is raw or heat treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation.

FDA Food Code 2017: Chapter 1 – Purpose and Definitions https://www.fda.gov/food/fda-food-code/food-code-2017

Minor deficiency (7 points) if:
- Single/isolated instance(s) of product being stored in areas which are set at the wrong temperature.

Major deficiency (3 points) if:
- Numerous instances of product being stored in areas which are set at the wrong temperature.

Non-compliance (0 points) if:
- Fundamental failure to store products at the right temperatures.
- Storage room temperature regimes are incompatible with the types of products being stored.

Operational Practices

1.5.1: Does the process flow, facility layout, worker control, utensil control, internal vehicle use, etc. ensure that finished (processed) products are not contaminated by raw (unprocessed) products?
Total compliance (15 Points): Incoming raw materials should not be a source of contamination to work-in-progress and/or finished goods. Raw products should not come into contact with processed products, especially processed products that have been washed, cut or thermally treated. In some cases, a physical barrier between production and storage areas might be required – this will depend on the type of product being produced and the items being stored. For example, cardboard should not be stored in a fresh-cut-processing area. Another example would be storing raw material near where finished fresh-cut product is being stored. There should be plenty of space and separation to help avoid cross contamination issues. Workers who handle raw products should not then handle finished/processed goods without first ensuring that they are free of raw material contaminants. This should include hand washing, glove change etc., but might also include changing into a new set of garments; ideally workers should be dedicated to handling raw or finished/processed goods, but not both within a shift. Utensils, cleaning implements, internal vehicles etc. should not be allowed to be vectors for cross contamination; ideally dedicated coded equipment should be provided for raw and processed goods. Failing this, there should be equipment sanitation steps between uses. Anti-microbial washes (often found in fresh cut operations) are not kill steps with respect to products, though they do reduce microbial loading when properly maintained. Refer to 1.9.3 for drainage flow and discharge.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of worker/utensil/internal vehicle cross contamination.
- Minor process issues where processed materials come into the same area raw materials, but the two products do not touch in any way, i.e. no potential risk of cross contamination.

- Some potential space issues where the process flow is being forced to bring finished and raw material into close proximity.
- Production areas are not sufficiently separated from storage areas. There is not a threat of product or packaging contamination.

Major deficiency (5 points) if:
- Numerous instances of worker/utensil cross contamination.
- Serious process flow issues where raw material can potentially cross contaminate finished goods.
- Numerous space issues where the process flow is being forced to bring finished and raw material into close proximity.
- Production areas are not sufficiently separated from storage areas. There may be a threat to product or packaging.

Non-compliance (0 points) if:
- Widespread instances/issues with worker and/or utensil cross contamination.
- Process flow issues are observed to result in product raw/finished goods cross contamination.
- Production areas are sufficiently not separated from storage areas. There may be a threat to product or packaging from a serious food safety threatening contaminant.

1.5.2: Are all exposed materials (product, packaging, etc.) protected from overhead contamination (e.g. ladders, motors, condensation, lubricants, walkways, loose panels, degrading insulation, etc.)?
Total compliance (15 points): Ceilings and/or any overhead fixtures above lines and storage are free from condensation or dust. Ladders or walkways (catwalks) above exposed product or packaging material have kick plates at least 3.5 inches (8 cm) high and are covered in some way that protects the product underneath. Drips or condensate (e.g., from roof, fixtures, ducts, pipes, etc.) should not contaminate food, food contact surfaces or packaging material. Adequate measures should be in place to protect from condensate. Condensate is scored in 1.10.5.

OSHA: CFR 29 Part 1910k(1)(iii)
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9721

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

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

Non-compliance (0 points) if:
- No protective devices have been installed to eliminate potential contamination.
- **Any observation of direct contamination of raw materials, work in progress, finished product, ingredient or packaging materials. In this case the score reverts back to 1.4.5.**

1.5.3: Are production areas completely enclosed?
Total compliance (15 points): Production areas should all be enclosed (walls and roof) with doors either closed or pest protected in some way (e.g., strip curtains, air curtains, speed doors, etc.). Walls can be solid, fine mesh or any other pest proof material, with openings that should be no greater than 1/8 inch (3 mm). Dust and pest proof wall materials are required for processing operations. Production should also be physically separated from storage areas.

Minor deficiency (10 points) if:
- Single incident of an open door being left open that is not meshed or fitted with air curtain.

Major deficiency (5 points) if:
- Numerous incidents of open doors that are being left open and not meshed or fitted with air curtain.

- One or more open walls (with no proofing), but with a proper roof and floor.

Non-compliance (0 points): if one of the following:
- Production area is outside or in an open sided building.
- No roofing (either with or without open walls).

1.5.4: Are production areas clean and well maintained; especially lights, ducts, fans, floor areas by the walls and equipment, and other hard to reach areas?
Total compliance (15 points): Production areas should be maintained in a clean and sanitary state. Auditors should check the ceilings, lights, corners, against walls and alongside equipment (look up, look down, look all around). This question is designed to capture any hygiene issues that are not covered by specific issues noted in other questions. This question is the sister question to 1.4.6 which asks about storage area hygiene. Auditors should carefully note which areas are dirty when down scoring in this question. This question is not applicable in the Storage and Distribution audits, or in the Cooling and Cold Storage audits.

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

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

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

1.5.5: Is all re-work / re-packaging handled correctly?
Total compliance (10 points): Re-work includes product that has come directly from the end of the line or where possible, product that has been returned from a customer (but is still in good quality). Re-work possibilities will vary from product to product. Re-work areas in coolers should adhere to all required GMP's. In a cooler or storage and distribution center where the re-packing is routine i.e. a regular activity (more than once per week) as opposed to an occasional unscheduled event, then a packinghouse audit template should be used.
All re-work should be handled correctly:
- Whole products undergoing re-packing should be in new final boxes and not be commingled with products from other producers and/or lots. Re-use of boxes in tomato, citrus, etc. re-pack operations is permitted only if product is re-packed into a container from the same lot of product and that the container is clean, sanitary and properly labeled. Any misuse of single use containers is scored in 1.5.15.
- Packaging items are opened with clean knives.
- Workers emptying packaging should have washed their hands and (ideally) if company policy, wear clean gloves i.e. should follow company GMP rules for hand sanitation.
- Re-work area is separated from the main production line.
- Product is collected in a clearly designated container before being transferred back to the processing line; ideally product should go through the washing step again.
- Outside of packaging does not touch the re-work product as it is being emptied.
- The traceback details are transferred correctly.

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

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

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

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

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

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

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

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

1.5.7: Are finished products coded (carton and unit packaging) for the day of production?
Total compliance (5 points): All products are appropriately labeled, identified and possess lot numbers and/or date coding information that can be used for traceback and recall purposes. If required by buyer or legal requirements, packaging labelling should include information about recommended storage conditions and usage. On bulk product, the coding should be identified on the carton or RPC tag; on bagged, clamshells and other pre-packs, the coding should be on the pack itself and also the cartons. Auditee should have records linking the code(s) used to date of production/packing (see 2.7.1). Auditor should check that product specifications (2.6.3) are being followed as required regarding date coding. For example, some buyers do not consider Julian date codes to be “readable” and require unencoded date information on the packaging e.g. pack date, sell-by date, use-by date information.

21 CFR Parts 1 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1) and 11 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11)
US Bioterrorism Act
https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm122876.htm
Produce Traceability Initiative http://www.producetraceability.org/

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a product not having accurate or readable lot or date code information.
- Single/isolated instance(s) of date coding not matching specification requirements.
- Single/isolated instance(s) of codes on unit packs not matching codes on cartons.
- Bags not being coded, but the cartons are coded, and the business is majority bulk packing as opposed to pre-packing (e.g. bags).

Major deficiency (1 point) if:
- Numerous products not having accurate or readable lot or date code information.
- Numerous instances of date coding not matching specification requirements.
- Numerous instances of codes of unit packs not matching codes on cartons.
- Bags not being coded, but the cartons are coded and the business only packs small amounts of bulk product as opposed to pre-packing (e.g. bags).
- Coding pallets only.

Non-compliance (0 points) if:

- No product lot coding and/or code dating either on bags, pre-pack or cartons on the majority of lines.
- Fundamental failure for date coding to meet required specifications.

1.5.8: Are foreign material control methods (e.g. metal detectors, metal traps, magnets, visual inspection, x-ray machines, etc.) in place and regularly tested (where relevant) to ensure proper operation?

Total compliance (10 points): Foreign material control method(s) are in place where needed. These systems should be frequently checked (recorded) to ensure that they are working correctly with a functioning rejection device (e.g., belt, air jet, etc.). Discovery of foreign material issues should be recorded along with relevant corrective actions (might be recorded in the NUOCA Log). Where necessary, foreign material control systems should be tested to ensure they are operating properly. The frequency and types of testing are established in a written program and the frequency is adhered to by QA personnel and documented. Foreign material controls include detectors, traps, visual, sieves, filters and magnets. Also check that the rejection system/mechanism is being tested as well e.g. rejection arm timing, alarm system, etc. Continuous visual inspection is acceptable for whole products. Metal detection should be used for all products that have been cut/sliced i.e. processed. Metal detectors should be tested at least hourly, including pre-start, at a product change, at a lot change/end of production run. At least ferrous, non-ferrous and stainless steel (usually 316) test pieces should be used separately to test the metal detectors – other specific metal test pieces should be considered if the plant equipment is made out of other materials. Where available, customer specifications should be used. Test pieces should be placed as close to the aperture center as possible; embedding test pieces in the product is an ideal method. Discovery of foreign material issues should be recorded along with relevant corrective actions. The auditor should have the auditee check metal detector(s) sensitivity while touring the facility.

OSU Metal Detectors for Food Processing,
http://pods.dasnr.okstate.edu/docushare/dsweb/Get/Document-964/FAPC-105web.pdf
A Guide to Metal Detection in the Food Manufacturing Industry https://www.loma.com/en-US/Industry-Guides/Guide-to-Metal-Detection-in-the-Food-Industry

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

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

Non-compliance (0 points) if:
- Majority of processing/packing line in operation missing a form of foreign material control method if there are more than three processing/packing lines in operation.
- No foreign material control methods are in place (cut product).
- No established program that specifies the frequency of device testing is in place.
- No established testing methodologies.
- Testing frequency for metal detectors is not at least every four hours.

- No detectors operating properly. If only one detector is used and it is malfunctioning, score non-compliance.
- Not using three of the required test pieces (metal detection).

1.5.9: Does the facility use the appropriate test strips, test kits or test probes for verifying the concentrations of anti-microbial chemicals (product contact water, terminal sanitizers, dip stations, etc.) being used, are they in operational condition and are they being used correctly?
Total compliance (15 points): The strength of anti-microbial chemicals (product and cleaning) should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, ORP meter or as recommended by disinfectant supplier). Any water treatment at source (e.g. well, canal) should be monitored. Solutions that are too weak will be ineffective, while those too strong may be harmful to workers or product. Where necessary, pH of solutions should also be checked. Methods include, dip sticks, test strip papers, conductivity meters, titration, color comparison methods e.g. tintometers, etc. All test solutions/strips should be within date code, appropriate for the concentrations used and stored correctly (especially light and temperature sensitive materials). If the ORP meter controls the pumps that are injecting the anti-microbial and/or buffer, there should be an independent other method (e.g., test trip papers, titration) in order to verify injector readings. Probe sensors need periodic cleaning and calibration and may become temporarily saturated by over-injection of anti-microbial or buffer. The auditor should have the auditee check the strength of anti-microbial chemicals while touring the facility.
Potentially useful websites:
http://postharvest.ucdavis.edu/files/260798.pdf
http://anrcatalog.ucanr.edu/pdf/8149.pdf
http://ucfoodsafety.ucdavis.edu/files/26414.pdf

Minor deficiency (10 points) if:
- Single/isolated instance(s) of a method not being used correctly.
- Single/isolated instance(s) of a testing procedure being used that is not appropriate for the concentration and/or sanitizer in use.
- Single/isolated instance(s) of out of date verifying chemicals being used.

Major deficiency (5 points) if:
- Numerous instances of a method not being used correctly.
- Numerous instances of a testing procedure being used that is not appropriate for the concentration and/or chemical in use.
- Numerous instances of out of date verifying chemicals being used.
- ORP meter used to control pumps injecting anti-microbial and or/buffer without an independent probe or other method to verify readings.

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

1.5.10: Are hand washing stations adequate in number and appropriately located for worker access and monitoring usage?
Total compliance (15 points): To ensure efficient worker flow, there should be a minimum of one hand wash station for every ten people and should be available to all workers and visitors. Hand washing stations should be located at access to production areas in processing and packinghouse audits and in, or immediately adjacent to toilet facilities. Within close proximity of/at toilet facilities and lunchroom is acceptable for other facility audits.

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

Minor deficiency (10 points) if:

- Only about 75% of needed hand washing stations are present.
- There are no hand washing stations located in visible production entry areas (processing and packinghouse only) where the worker hand washing practices can be monitored.

Major deficiency (5 points) if:
- Only about 50% of needed hand washing stations are present.

Non-compliance (0 points) if:
- Hand washing stations are inadequate in both number and location (less than 25% of the needed hand washing stations are provided).

1.5.11: Are hand washing stations in working order, have water of suitable temperature and pressure, adequately stocked (e.g. disposable towels, unscented soap, etc.) and restricted to hand washing purposes only?

Total compliance (15 points): Hand washing facilities should be used only for hand washing (no storage, food handling, etc.), have water of suitable temperature and pressure and be maintained in good working order with proper drainage. Hand washing stations should be properly stocked with liquid unscented/non-perfumed, neutral or antiseptic 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; hot air driers are acceptable if properly located (hot air driers should not be located within production areas since they create aerosols). There should be an adequate stock of soap and paper towels. Hand washing stations should be maintained in good working order with proper drainage and warm water (> 100 ^{o}F, 38 ^{o}C) available for use. Discharge water from sinks should not run directly onto the floor. Care should be taken to ensure that hand wash water temperatures are not too hot when using pre-set mixer faucets (taps). Hands-free operations are an optimum system for food establishments. Cleanliness of hand wash stations is scored in 1.9.10.

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

Minor deficiency (10 points) if:
- Single/isolated instance(s) of hand washing stations not in working order.
- Only cold water is available at hand washing stations.
- Single/isolated instance of water being too hot.
- Single/isolated instance(s) of water pressure not being adequate.
- Single/isolated instance(s) of soap with a lingering fragrance being used.
- Single instance of hand washing station being used for another purpose.

Major deficiency (5 points) if:
- Numerous instances of hand washing stations not in working order.
- Numerous instances of water pressure not being adequate.
- Numerous instances or widespread use of soap with a lingering fragrance being used.
- Using terry cloth re-useable towels or roller towels.
- No paper towels are provided or hot air driers are located within production areas.
- Numerous instances of hand washing stations without warm water available or where water is too hot.
- More than one instance of a hand washing station being used for another purpose.

Non-compliance (0 points) if:
- No soap is provided.
- There are no functioning hand wash stations.
- **Any observation of direct gross widespread contamination of product, ingredient or packaging materials (revert back to Q 1.4.5, automatic failure).**

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

Total compliance (15 points): Toilet facilities should be available to all workers and visitors, and are adequate in number and location:

- Toilet facilities should be located within a reasonable distance from the workers' workstation.
- Toilet facilities should be readily available to male and female workers. The number of facilities provided for each sex should be based on the number of workers 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 workers. Please use this table as a guide:

Number of workers	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 workers

- Where toilet facilities will not be used by women, urinals may be provided instead of toilets, except that the number of toilets in such cases should not be reduced to less than 2/3 of the minimum specified.
- Each individual toilet facility should be able to be locked from inside.
- Each toilet facility should be maintained, well lighted and ventilated to outside air.
- In the toilet room, the floor and sidewalls should be watertight. The sidewalls should be watertight to a height of at least five inches.
- The floors, walls, ceiling, partitions and doors of all toilet rooms should be made of a finish that can be cleaned easily.
- Doors should not open directly into areas where food is exposed to airborne contamination, i.e. storage, processing and packing areas. Use of double doors or having a positive airflow system is accepted
- Toilet paper should be available to each person and stored in such a way as to prevent contamination.
- Adequate trash disposal should be available within restrooms.

Restrooms should have hand washing facilities with:

- Unscented/non-perfumed, neutral or antiseptic 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 (> 100F, 38^{o}C) available for use.
- If hand washing stations within toilet facilities are the only stations provided, then requirements for 1.5.11 apply.
- Cleanliness of toilet facilities is scored in 1.9.10.

United States Department of Labor 29 CFR 1910.141(c)(1)(i): Toilet Facilities
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790
21 CFR Part 110.37: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=110.37

Minor deficiency (10 points) if:

- One of the above criteria is not met.
- Operation has door(s) opening into the production areas, i.e. not located in the amenity area or office area and are self-closing (e.g., use a spring-loaded door).

Major deficiency (5 points) if:

- Two of the above criteria are not met.
- Operation has door(s) opening into the production areas, i.e. not located in the amenity area or office area and are not self-closing (e.g., use a spring-loaded door).

Non-compliance (0 points) if:
- Failure to provide sufficient or adequate restroom facilities.
- Three of the above criteria are not met.
- **Any observation of direct gross widespread contamination of product, ingredient or packaging materials (revert back to Q 1.4.5, automatic failure).**

1.5.13: Are secondary hand sanitation stations (e.g., touch-free dispensers) adequate in number and location, and are the stations maintained properly?
Total compliance (5 points): In processing, packing and repackaging areas, the use of (non-perfumed) secondary hand sanitation stations is the last activity a worker performs before taking their position on the line. Secondary hand sanitation is required for fresh-cut operations and for operations producing items that may be "ready-to-eat" (e.g., herbs, stone fruit, tomatoes, citrus, edible flowers, etc.). Note that citrus peel is often used in drinks, used for zesting, etc. Secondary hand sanitation (hand dips, gels or sprays) does not replace hand washing requirements (lack surfactant qualities). Secondary hand sanitation stations should be unscented/non-perfumed, have 60% to 95% ethanol or isopropanol (benzalkonium chloride is also acceptable) and conveniently located in traffic zones but should not be obstructive. Hand dips (if used) should contain a 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 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 production line to prevent accidental product contamination. The auditor should check that gel pack type stations are stocked and have the auditee check the strength of anti-microbial chemicals in hand dips while touring the facility. Records are scored in 2.11.5.

https://www.fda.gov/news-events/press-announcements/fda-issues-final-rule-safety-and-effectiveness-consumer-hand-sanitizers
http://www.qualityassurancemag.com/qa0612-proper-hand-sanitation-practices.aspx
https://www.cdc.gov/handwashing/index.html
https://nelsonjameson.com/learn/sanitation-maintenance/hand-hygiene/
https://www.fda.gov/food/guidanceregulation/retailfoodprotection/industryandregulatoryassistanceandtrainingresources/ucm113827.htm

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

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

Non-compliance (0 points) if:
- There are no secondary hand sanitation stations where needed or all are empty.

- All hand dips checked found containing under-strength solutions.

1.5.14: Are foot baths, foamers or dry powdered sanitizing stations adequate in number and location, and are the stations maintained properly?
Total compliance (3 points): Foot (boot) stations (foot dip mats, baths, sprays) should be located in areas when crossing into a "clean" zone from an area of potential contamination (e.g., from outside into the packing zone, from raw storage into packing, from bathrooms into processing, etc.). Foot dips are required in processing operations. They are not required in packinghouses but may be considered as an additional control. Foot dips should contain a food grade sanitizer at a determined concentration. Refer to sanitizer manufacturer label for dilutions. Foot dips should be regularly monitored for volume and concentration (recorded anti-microbial strength checks) and the dip solution regularly changed to ensure their effectiveness with corrective actions recorded (e.g. dip solution replenishment and anti-microbial additions). Dry products should be EPA registered and applied as per the label instructions (label dosage directions should be followed for EPA registered floor sanitizers) and regular renewal should be monitored. The auditor should have the auditee check the strength of anti-microbial chemicals while touring the facility. Records are scored in 2.11.5. Workers should be using the foot dips as they enter the processing areas.

http://www.foodsafetymagazine.com/magazine-archive1/december-2004january-2005/the-dos-and-donts-of-food-plant-personal-hygiene-practices/
http://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2011/sanitizers-and-disinfectants-the-chemicals-of-prevention/
http://www.foodqualityandsafety.com/article/dry-floor-products-wont-slip-up/2/
21 CFR 178.1010: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=178.1010

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

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

Non-compliance (0 points) if:
- No foot dip stations where needed.
- All foot dips checked being found to contain under strength solutions or volume not maintained.
- All workers avoiding using the foot dips.

1.5.15: Are single service containers used for their intended purpose only so that potential cross contamination is prevented?
Total compliance (5 points): Single service containers are used for their intended purpose only (food contact use, not to hold nuts, bolts, trash or other miscellaneous items) and should not be re-used. Reuse of boxes in tomato, citrus, etc. re-pack operations should be permitted only if product is re-packed into a container from the same lot of product and that the container is clean, sanitary and properly labeled. Returnable plastic containers (RPCs) (e.g., CHEP, IFCO) should be treated like single service container and only used for product. If a single service container is used for any other reason than the storage and distribution of food, it should be clearly differentiated as such (e.g., painted another color and labeled).

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

Major deficiency (1 point) if:

- Numerous instance(s) of single service container used for other than intended purpose.
- More than one instance of product repacked into a container from another lot.

Non-compliance (0 points) if:
- Widespread miss-use of single services container used for other than intended purpose.
- Numerous instances or widespread use of containers being used from different lots for repack.

1.5.16: Are re-usable containers cleanable and clearly designated for the specific purpose (trash, raw product, finished product, re-work, ice, etc.) such that cross contamination is prevented?
Total compliance (5 points): All re-usable containers should be able to be cleaned (smooth, non-porous, non-toxic) or used with a clean liner to protect against contamination. Bins, boxes, hoppers, barrels, baskets, etc. used for the storage of raw materials, work in progress, ingredients, finished goods or packaging should be kept in a clean state. In-house re-usable containers should be identifiable (color-coded or labeled in the language understood by the workers) so that their designated purpose can be easily known. Returnable plastic containers (RPCs) (e.g., CHEP, IFCO) should be treated like single service containers and only used for product (score in 1.5.15). If the trash container is the only re-used container on site and is a specific and unique design, so that it cannot be mistaken for another use, then it should not be down scored.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a dirty re-usable container (there is no direct product contamination).
- Single/isolated instance(s) of inferior materials e.g. porous material construction, wood, non-food grade materials).
- Single/isolated instance(s) of a re-usable container not labeled or color-coded.

Major deficiency (1 point) if:
- Numerous instances of dirty re-usable containers (there is no direct product contamination).
- Numerous instances of inferior materials e.g. porous material construction, wood, non-food grade materials).
- Numerous instances of re-usable containers not properly labeled or color-coded.

Non-compliance (0 points) if:
- Condition and/or design of re-usable containers will not allow for effective cleaning under normal conditions.
- Re-usable containers are used for multiple purposes without the containers being labeled or color-coded.
- **Any observation of direct contamination of product, ingredients or packaging material – revert to 1.4.5, automatic failure.**

1.5.17: Are devices used to measure, regulate or control temperature, pH, acidity, water activity, and other conditions that affect food safety, working properly and adequately maintained?
Total compliance (3 points): All pieces of food safety measuring equipment are working properly and where necessary calibrated. Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency of testing. Devices include thermometers, pH meters, ORP meters, ATP testing systems, etc. Metal detectors are scored in 1.5.8. Measurement methods for anti-microbials are scored in 1.5.9. The auditor should challenge some equipment by checking (or having the auditee) check the calibration of the equipment, especially if the auditor thinks the equipment might be faulty or the auditee is unsure of the equipment calibration status. Examples would include using an ice slurry for thermometers, a temperature standard thermometer, known pH solutions for a pH probe, calibration kit/positive control for ATP meters, etc. Be sure that all calibration solutions (where used) are within “Use By” date.

Thermometer Calibration http://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2003/a-simple-introduction-to-thermometry-and-basic-calibration/

Minor deficiency (2 points) if:
- Single/isolated instance(s) of piece(s) of equipment found not to be working properly or out of calibration.
- Single/isolated instance(s) of a calibration solution in use that is past its expiration date.

Major deficiency (1 point) if:
- Numerous pieces of equipment found not to be working properly or out of calibration.
- Numerous instances of calibration solutions in use that are past their expiration dates.

Non-compliance (0 points) if:
- All equipment checked was found not to be working properly or out of calibration.
- All calibration solutions found to be past their expiration dates.

Worker Practices

1.6.1: Are workers washing and sanitizing their hands before starting work each day, after using the restroom, after breaks, before putting on gloves and whenever hands may be contaminated?
Total compliance (15 points): Worker conformance to hand washing and sanitizing procedures should be assessed, as washing hands is the first step in avoiding food contamination. Workers should be observed washing their hands prior to beginning work, after breaks, after using the toilet, before putting on gloves, and whenever hands may have become a source of contamination (e.g., after eating, after using a handkerchief or tissue, smoking, drinking, etc.). Auditors are expected to view hand washing disciplines – in operations where hand washing stations are not visible, this means watching worker movements after breaks (are they using the toilet facility hand wash stations); are there signs of soap and paper towel use? Hand washing is a critical part of the food suppliers' food safety program – this should be stressed to the auditee.

Potentially useful website:
A "Safe Hands" Hand Wash Program, https://www.cdc.gov/handwashing/index.html

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

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

Non-compliance (0 points) if:
- Majority of or fundamental failure of workers to comply with hand washing policies.

1.6.2: Are workers' fingernails clean, short and free of nail polish?
Total compliance (5 points): Fingernails can harbor dirt and debris and can be a source of cross contamination. Therefore, nails should be clean and short to reduce the risk of cross contamination. Fingernail polish and false nails 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 (sections 2-302.11)
https://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-compliance (0 points) if:
- Fundamental failure to ensure that fingernails are short and clean.
- Fundamental failure to ensure that fingernail polish and/or false fingernails are not worn.

1.6.3: Are workers who are working directly or indirectly with food, free from signs of boils, sores, open wounds and are not exhibiting signs of foodborne illness?
Total compliance (10 points): Workers who have exposed boils, sores, exposed infected wounds, foodborne illness or any other source of abnormal microbial contamination should not be allowed to work in contact with the product, packaging or food contact surfaces. Workers 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 (7 points) if:
- There is no minor deficiency category for this question

Major deficiency (3 points) if:
- There is no major deficiency category for this question.

Non-compliance (0 points) if:
- One or more workers are observed working in contact with food, food contact surfaces or packaging that 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.

1.6.4: Are workers wearing effective hair restraints that contain all hair?
Total compliance (5 points): Workers (includes maintenance workers and visitors) should be wearing appropriate hair restraints (hairnets, beard nets and moustache covers where appropriate) that fully contain all hair. Wearing effective hair restraints (i.e. hair nets, beard nets), is required in all operations where product is exposed, including with products that require cooking prior to consumption. Hair restraints are not required when there is no exposed product (e.g. cross docking, storage and distribution center).
Baseball caps and head coverings are allowed in packinghouses, only if they are clean and worn with a hair net covering them that is clearly visible and a hair net restrains all hair. Bobby pins, hairgrips should not be worn outside hair nets. Long hair should be tied back for safety reasons, using a band of some type (not metal clips or pins). Hair restraints should a) stop hair falling onto the product and b) prevent workers from touching their hair and then the product.

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

Minor deficiency (3 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 (1 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-compliance (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 workers.

1.6.5: Is jewelry confined to a plain wedding band and watches are not worn?
Total compliance (5 points): Workers are not observed wearing jewelry (including earrings, ear gauges, necklaces, bracelets, rings with stones, rings or studs in nose, lip and eyebrow, watches) in the facility. Plain wedding bands are the only exception. Other examples of foreign items that may be a source of foreign material contamination include studs, false eye lashes, eye lash extensions, etc.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a worker observed wearing jewelry or watches or any other personal item that may be a foreign contaminant.

Major deficiency (1 point) if:
- Numerous instances of workers observed wearing jewelry or watches or any other personal item that may be a foreign contaminant.

Non-compliance (0 points) if:
- Majority of workers wearing jewelry or watches or any other personal item that may be a foreign contaminant i.e. jewelry policy does not exist and/or jewelry policy exists but is not being implemented.

1.6.6: Are all workers wearing protective outer garments suitable for the operation (e.g., appropriate clean clothes, smocks, aprons, sleeves, non-latex gloves)?
Total compliance (10 points): If the operation has taken a decision to establish an outer garment policy based on risks this should consider the following: customer requirements, national and local legal requirements, potential cross contamination and foreign material risks, etc. Suitable protective outer garments are required for workers handling processed products, washed packinghouse products (after the washing step) that are potentially ready-to-eat (e.g., tomatoes, leafy greens, etc.), and in packinghouses that overwrap product (e.g., washed whole potatoes). Outer garments include where applicable: smocks, aprons, sleeves, gloves, etc. For example, smocks worn in processing operations, aprons (minimum) in packinghouses after wash step and where product is being overwrapped. Sleeves are required to prevent product contact with clothing. Provided items should be laundered in-house or by contract laundering agency. Individual workers should not take garments home for cleaning. Where items are laundered in-house the auditee should have documented SOP and GMP rules about how these garments are cleaned. If workers sleeves come into contact with washed ready-to-eat products, then protective waterproof sleeve covers should be used. Glove policy should be clear to workers – auditors will establish policy before making scoring decisions and note this policy for the audit report. Gloves are not allowed to replace hand-washing requirements. Gloves should be changed after break periods, using toilet facilities, any activity other than handling of food items or when gloves are soiled, torn or otherwise contaminated. If re-useable gloves are used, then they should be made of material that can be readily cleaned and sanitized, clean gloves should be issued at least daily and as needed throughout the day and stored properly in-between uses. Gloves should not be taken home for cleaning. Where gloves are used they should be non-latex (e.g. vinyl, nitrile, etc.). This includes gloves in first-aid kits.
Where dedicated protective clothing is not required/worn, it must be clear that outer street clothes are clean and not a potential source of contamination. Workers should not wear personal clothes with sequins, pom-poms, fur, etc. No sleeveless tops without an over garment.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of outer garments or gloves being taken home.
- Single/isolated instance(s) of gloves not being replaced when contaminated.
- Single/isolated instance(s) of protective garments not being worn where required (processed products, after wash step in packinghouse).
- Single/isolated instance(s) of outer clothing not clean or being a potential source of contamination.

Major deficiency (3 point) if:
- Numerous instances of outer garments or gloves being taken home.
- Numerous instances of gloves not being replaced when contaminated.
- Numerous instances of protective garments not being worn where required (processed products, after wash step in packinghouse).
- Numerous instance(s) of outer clothing not clean or being a potential source of contamination.

Non-compliance (0 points) if:
- An outer garment policy is **not** established.
- Fundamental failure to replace gloves when contaminated.
- Fundamental failure to wear protective garments where required (processed products, after wash step in packinghouse).
- Fundamental failure to wear clean outer clothing or of clothing being a potential source of contamination.
- Widespread non-compliance to the above and/or company policy.

1.6.7: Do workers remove protective outer garments (e.g., smocks, aprons, sleeves, and gloves) when on break, before using the toilets and when going home at the end of their shift?
Total compliance (5 points): When worn, protective clothing (e.g., aprons, smocks, sleeves, and gloves) should be removed when workers leave the work area (e.g., when they go to the toilet facility, lunchroom, outside, etc.). Workers cannot smoke, eat, go outside the building or use the restroom while wearing these garments. 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-compliance to the above

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

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

1.6.8: Is there a designated area for workers to leave protective outer garments (e.g., smocks, aprons, sleeves, and gloves) when on break and before using the toilets?
Total compliance (5 points): There should be a designated area for workers to leave protective clothing when they are worn (e.g., aprons, smocks, sleeves and gloves). Workers are observed using the designated area when they leave the work area (e.g., when they go to the toilet facility, lunchroom, outside, etc.). Workers 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 worker clothing or any other area that might be a risk to the outer garments. Garments should not be left touching product, packaging or food contact surfaces.

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

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

Non-compliance (0 points) if:

- There is not a designated area for workers to leave aprons, sleeves and gloves when on a break.
- There is a designated area; however, no workers use this area.
- Any of the items are observed being placed on the floor.
- Widespread non-compliance to the above.

1.6.9: Are worker personal items being stored appropriately (i.e. not in the production or material storage area)?
Total compliance (5 points): Workers should have a designated area for storing personal items such as coats, shoes, purses, medication, phones, etc. Areas set aside for workers' personal items should be far enough away from stored raw or finished products, packaging materials, processing equipment or processing lines to prevent contamination and avoid food security risks. Lockers or cubbies are ideal if maintained properly, mounted off the floor and with sloping tops and located outside production and storage areas. Wire, see-through lockers are ideal.

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

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

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

1.6.10: Is smoking, eating, chewing and drinking confined to designated areas, and spitting is prohibited in all areas?
Total compliance (5 points): Smoking, chewing tobacco, chewing gum, drinking and eating is permitted in designated areas that are away from production and storage areas. Spitting should be prohibited in all areas. Smoking should not be permitted in eating and drinking areas. Drinking is not permitted near the production line. Check work areas refuse containers and look in out of sight areas. If food consumption areas are designated within production offices or maintenance areas then the control of cross contamination, GMPs and access to hand washing facilities should be considered.

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 (3 points) if:
- Single/isolated instance(s) are observed of non-compliance to the above (includes evidence of smoking, eating, spitting, 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 (1 point) if:
- Numerous instances are observed of non-compliance to the above (includes evidence of smoking, eating, spitting, chewing gum, improper storage of break time food or drinking containers in interior refuse containers).
- No designated smoking area (unless the site has a non-smoking policy).
- Numerous instances of designated area not meeting appropriate GMP standards.

Non-compliance (0 points) if:
- Widespread consumption of food and beverages outside of designated areas.
- No temperature control storage of break time food.

- Widespread evidence of smoking outside the designated area.
- Widespread evidence of using chewing tobacco in production and storage areas.
- Designated area lacks access to a hand wash station.
- Widespread non-compliance to the above criteria.

1.6.11: Is fresh potable drinking water readily accessible to workers?
Total compliance (10 points): Fresh potable water meeting the quality standards for drinking water should be provided in all places of employment for drinking, following local and national laws. The term "potable" meaning that the water is of drinking water quality (e.g., the EPA Drinking Water Standard or equivalent). Auditors should verbally verify the source of the water at the time of the audit. 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. If there is evidence (i.e. visual observation or documentation) the water is coming from a questionable source, the auditor should review water quality test results.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of an unclean water container being used.

Major deficiency (3 points) if:
- Numerous instances of an unclean water containers being used.

Non-compliance (0 points) if:
- There is no water provided.
- The water provided is not potable.

1.6.12: Are all items removed from garment (shirt, blouse, etc.) top pockets, and unsecured items are not worn (e.g., pens, glasses on top of head, Bluetooth devices, etc.)?
Total compliance (3 points): There should be no items stored in workers' shirt, blouse and smock top pockets. Ideally, top pockets are sewn up or non-existent. Remember to also check maintenance workers in the production area. Special exception allowed for security identification tags, as long as they are securely fastened to the person and/or below the waist.

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

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

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

1.6.13: Are first aid kits adequately stocked and readily available in the facility, and are blue band aids used?
Total compliance (5 points): First aid kit(s) should be adequately supplied to reflect the kinds of injuries that occur (including any chemicals stored on-site) and should be stored in an area where they are readily available for emergency access. Date-coded materials should be within dates of expiration. Bandages used in food facilities should be blue in color for easy visual detection with a metal strip behind the wound pad for detection on lines with metal detectors, and ideally waterproof. In facilities that handle only whole product, blue bandages without a metal strip are acceptable (inclusion of a metal strip is preferred). For facilities handling products that may be perceived as blue e.g. blueberries, use of band aids that are not

blue are permitted if of a color contrasting to product and equipment. 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 instance of a facility with metal detection in place having blue bandages without a metal strip.
- Single instance of a facility without metal detection (whole or boxed products) not having blue bandages.
- Single/isolated instance(s) of first aid kit(s) not having adequate supplies, supplies out-of-date or kit not readily accessible.

Major deficiency (1 point) if:
- More than one instance of a facility with metal detection in place using blue bandages without a metal strip.
- More than one instance of a facility without metal detection in place (whole or boxed products) not having blue bandages.
- Numerous instances of first aid kit(s) not having adequate supplies, supplies out-of-date or kit not readily accessible.

Non-compliance (0 points) if:
- Blue bandages with a metal strip are not available in a facility with metal detection.
- Blue bandages are not available in a facility without metal detection.
- Fundamental failure to provide first aid kit(s) with adequate supplies, supplies out-of-date or kit not readily accessible.

Equipment

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

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

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

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

Non-compliance (0 points) if:
- Inspection shows numerous areas of flaking paint, rust or other unhygienic materials, which may pose a threat to product or packing contamination.
- **Any observation of direct gross widespread contamination of product, ingredient or packaging materials (revert back to Q 1.4.5, automatic failure).**

1.7.2: Are non-food contact equipment surfaces free of flaking paint, corrosion, rust and other unhygienic materials (e.g., tape, string, cardboard, etc.)?
Total compliance (10 points): Non-food contact surfaces should be free from any potential source of contamination such as flaking paint, corrosion, rust and/or other unhygienic materials (e.g., tape, string, cardboard, etc.). The surface should be made of smooth material that can be cleaned and sanitized easily. Where possible, equipment framework is not penetrated by bolts or studs.

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

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

Non-compliance (0 points) if:
- Widespread evidence of rusting, flaking paint, use of unhygienic materials e.g. tape.
- **Any observation of direct gross widespread contamination of product, ingredient or packaging materials (revert back to Q 1.4.5, automatic failure).**

1.7.3: Does food contact equipment design, placement, and condition (e.g., smooth surfaces, smooth weld seams, non-toxic materials, corrosion-resistant, no wood or other absorbent materials) facilitate effective cleaning and maintenance?
Total compliance (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 and adjacent wall areas should be accessible.

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-compliance (0 points) if:
- Condition and/or design of equipment will not allow for effective cleaning under normal conditions.
- Widespread proof of poor design and installation making it difficult to access equipment and/or surroundings for cleaning.
- Widespread poor welding, rough surfaces, poorly designed equipment that traps debris.

1.7.4: Are thermometers (independent of thermostat probes) present in all coolers and freezers?
Total compliance (5 points): Independent thermometers or temperature recorders should be present in all coolers and freezers and placed to accurately record temperature. Thermometers should be separated from the thermostat probes, since there is always a chance that the thermostat system might go down and/or the probes themselves might be incorrect. If multiple probes are in a room with a system able to

detect an out-of-calibration, broken or down probe and able to see the other probes in the room are in working order then this is also acceptable. Not applicable if cooler and/or freezers are not used.

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

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

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

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

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

Major deficiency (3 points) if:
- Numerous (more than 3) unshielded glass stem thermometers observed.

Non-compliance (0 points) if:
- Single instance of a mercury thermometer.
- Single instance of broken glass or glass/mercury thermometer is observed.
- **Any observation of direct contamination of product, ingredients or packaging material – revert to 1.4.5, automatic failure.**

Equipment Cleaning

1.8.1: Are food contact equipment surfaces clean?
Total compliance (15 points): All equipment surfaces that come into contact with product (zone 1) should be kept in a clean condition to avoid cross contamination. If the line is already running, check the line surfaces; does the debris look fresh or old? The auditor must clearly point out any issues to the auditee. Food debris, bio films, excessive dust, etc., should be cleaned off equipment and facility surfaces in order to reduce the overall facility bio-burden.

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

Minor deficiency (10 points) if:
- Single/isolated instance(s) of food contact surface that is unclean.

Major deficiency (5 points) if:
- Numerous instances of food contact surfaces that are unclean.
- Some equipment is not cleaned after the production has ceased for that run time e.g. after final shift.

Non-compliance (0 points) if:
- Widespread observations of food contact surfaces that are unclean.

- Equipment is not cleaned after the production has ceased for that run time e.g. after final shift.

1.8.2: Are non-food contact equipment surfaces clean?
Total compliance (10 points): All equipment surfaces that do not make contact with product (zones 2, 3) 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 non-food contact equipment and facility surfaces in order to reduce the overall facility bio-burden.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of a non-food contact surface that is unclean.

Major deficiency (3 points) if:
- Numerous instances of non-food contact surfaces that are unclean.
- Some equipment is not cleaned after the production has ceased for that run time e.g. after final shift.

Non-compliance (0 points) if:
- Widespread observations of non-food contact surfaces that are unclean.
- Equipment is not cleaned after the production has ceased for that run time e.g. after final shift.

1.8.3: Are items (totes, bins, etc.) that are used to hold or store product clean?
Total compliance (10 points): Bins, boxes, hoppers, barrels, baskets, etc. used for the storage of product, or ingredients should be kept in a clean state. Cleaning type and frequency should be determined based on the products and processes involved (cross reference with Master Sanitation Schedule). The storage of these items should ensure that they remain clean and uncontaminated (e.g., covered clean).

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) of a product storage container that is clean but is being stored in an area where it might be contaminated and then used, e.g. a centrifuge barrel stored under an overhead production line, without proper protection.

Major deficiency (3 points) if:
- Numerous instances of dirty product storage containers (there is no direct product contamination).
- Numerous product storage containers, which are clean, but being stored in an area where they might be contaminated and then used, e.g. centrifuge barrels stored under an overhead production line, without proper protection.

Non-compliance (0 points) if:
- Fundamental failure to clean food storage containers.
- There is no cleaning program for the containers.
- Widespread lack of control with respect to storage of clean food storage containers.

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

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

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

Non-compliance (0 points) if:
- Any observation of direct contamination of product, ingredients or packaging materials that adulterates the product with a cleaning chemical or contaminates product with splash back. **The auditor should observe and see if the auditee takes corrective actions (without prompting). If no action is taken and the contamination is severe e.g. not just water, but say cleaning chemical and water, then the auditor should consider using the 1.4.5 adulteration option and scoring an automatic failure.**

1.8.5: Are cooling units, including coils in coolers and freezers, clean and free of aged, dirty ice?
Total compliance (5 points): All coils in coolers and freezers should be clean. There should be no build-up of dust, mold or other airborne contaminants (a good flashlight is useful). Not applicable if there are no cooling units on site. There should be no colored ice/dirty ice build-up. Water from refrigeration drip pans is drained and disposed of away from product and product contact surfaces (score in 1.9.3).

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

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

Non-compliance (0 points) if:
- All coils that are observed are unclean.
- Ice build-up on all coils that appears to be old (dirty or off colored).
- **Any observation of direct contamination of product, ingredient or packaging materials – reverts back to Q 1.4.5.**

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

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

Major deficiency (1 point) if:

- Numerous instances of fan guards that are unclean and/or evidence of issues with the ceilings and pipe fittings in front of the chiller units. Fans are not located above uncovered product, ingredients or packaging.

- A single instance where cooling unit debris is noted above finished product and/or packaging, but there is no contamination of food materials or food contact packaging.

Non-compliance (0 points) if:
- Consistent failure to maintain clean fan guards and ceilings/pipe work in front of the fan guards.
- More than one instance where cooling unit debris is noted on finished product and/or packaging but there is no contamination of food materials or food contact packaging.
- Any evidence of cooling unit debris noted directly contaminating food materials or food contact packaging. **The auditor should consider whether this is adulteration and whether to apply Q 1.4.5 and score an automatic failure.**

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

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

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

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

1.8.8: Are all utensils, hoses, and other items not being used, stored clean and in a manner to prevent contamination?
Total compliance (10 points): All utensils, hoses and other items not being used are stored clean and in a manner to prevent contamination (off ground, dedicated areas, etc.). Hoses should be stored coiled, off the floor and ideally used in such a manner that ground contact is avoided.

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

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

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

1.8.9: Are maintenance tools that are used in the production and storage areas of the facility clean, sanitary and corrosion free?
Total compliance (3 points): Tools that are used for repairing equipment in the production and storage areas should be clean, free of corrosion and in good working order i.e. fit for their intended use. They

should be stored appropriately to ensure they do not pose a risk of direct or indirect contamination when in production and storage areas, Special attention should be focused on those tools that are resident in tool boxes, within production areas, tools in the maintenance areas that are ready to be taken into production areas, or are used in the maintenance area on equipment that will be going into the production and storage areas. Sometimes a maintenance shop might have tools that are used exclusively on external trucks and farm equipment; the auditor should avoid scoring these kinds of tools.

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

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

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

1.8.10: Are excess lubricants and grease removed from the equipment and are lubricant catch pans fitted where needed?
Total compliance (5 points): Excess lubricants and greases are removed from equipment and there are no observations of leakage or drips. Where drive motors are mounted over product or packaging zones catch pans should be installed and where needed, with drainage via hosing to the floor. Cranes, chains and pulley equipment above lines are potential areas where excessive grease might be an issue. Key consideration should be given to where lubricants and greases can leak onto product and product contact surfaces. Lubrication should be frequent and using small amounts of lubricant, as opposed to large amounts of lubricant used on an infrequent basis. Food grade lubricant should be used where required (see question 1.2.2), but food grade materials are still only for incidental contact and all precautions should be taken in order to prevent these from contaminating the product and product contact surfaces.

Minor deficiency (3 points) if:
- Single/isolated instance (s) of excess lubricants or grease on equipment (no product hazard).
- Single/isolated instance(s) of unprotected motor, axle, pump etc.

Major deficiency (1 point) if:
- Numerous instances of excess lubricants or grease on equipment (no product hazard).
- Numerous instances of unprotected motors, pumps axles etc.

Non-compliance (0 points) if:
- Fundamental failure to protect pumps, motors, axles etc.
- **Observation of serious direct contamination of product, ingredient or packaging materials with a food grade material – auditor should revert back to question 1.4.5, automatic failure.**
- **Any observation of direct contamination of product, ingredient or packaging materials with a non-food grade material – auditor should revert back to question 1.4.5, automatic failure.**

General Cleaning

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

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:
- Numerous instances of cleaning issues related to spills.
- Single/isolated instance(s) of spills that may pose the potential risk of contamination for product, materials, and/or product contact surfaces.
- Single/isolated instance(s) of spills exhibiting mold growth or an off odor i.e. that have not been cleaned up for some time.

Non-compliance (0 points) if:
- Numerous instances exhibiting mold growth or an off odor i.e. that have not been cleaned up for some time.
- Numerous instances of spills that may lead to potential product, materials, and/or product contamination.

1.9.2: Are waste and garbage frequently removed from production and storage areas?
Total compliance (5 points): Cleaning practices include the frequent removal of garbage and waste from all areas to assure that acceptable levels of sanitation are maintained and prevent the attraction of pests. Garbage containers are included in a regular cleaning schedule, in order to prevent them from developing odors, flies, bacterial growth, etc.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a waste/garbage removal issue, which does not pose a risk to product, material and/or equipment.

Major deficiency (1 point) if:
- Numerous instances of waste/garbage removal issues, which do not pose a risk to product, material and/or equipment.
- Single instance where waste has an off odor; attracted flies (unless in mushroom or onion facility) and or is exhibiting mold growth.

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

1.9.3: Do floor drains flow in a manner that prevents contamination (e.g., from high to low risk areas, from high risk directly to drain system), are they covered, appear clean, free from odors and are well maintained?
Total compliance (5 points):
- All facility floor drains, including covers and internal channels are clean, and free of decayed/old material.
- Drains flow from high risk to low risk areas, from high risk directly to drain system
- All facility floor drains are free of odors.
- There is no overflow or excessive standing water in the floor drains.
- Drains in processing plants, packinghouses with washing steps and high humidity coolers should be cleaned daily. Daily drain cleaning should also occur at coolers that use hydro-vacuum, dry vacuum, ice injectors, and humidifiers, where storage areas are often wet and/or humid, and also any coolers that while not having this sort of cooling equipment, do store products at high humidity.
- Drains should have smooth walls and bases that allow free flow of water without catching debris, and also aid cleaning of the drains.
- Water from refrigeration drip pans is drained and disposed of away from product and product contact surfaces.

Where possible, auditor should request floor drain covers to be removed for inspection. Use a flashlight to illuminate the bottom of deep drains.

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

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

Non-compliance (0 points) if:
- Fundamental failure to maintain the facility floor drains in a clean condition.
- **Drains are plugged and overflowing and providing a condition that may contaminate the product, equipment or packaging materials. Auditor should consider reverting back to question 1.4.5 if product/packaging looks like it is has widespread contamination.**

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

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

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

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

1.9.5: Are plastic strip curtains maintained in good condition, kept clean and mounted so that the tips are not touching the floor?
Total compliance (5 points): All facility plastic strip curtains are clean, free of mold/mildew, black discoloration, free of off-odors, etc. Broken strips are replaced when damaged. Strip curtains should be installed so that the tips are just off the ground (prevents contamination and also is not a forklift safety issue). Strip tips should not touch exposed food products when they pass through the strip curtains – this issue can be scored under 1.5.2, the generic question regarding exposed materials. 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.
- Single/isolated instance(s) of strip curtains mounted touching the floor.

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

Non-compliance (0 points) if:
- Fundamental failure to maintain strip curtains in a good condition.
- Fundamental failure to mount strip curtains off the floor.

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

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

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

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

1.9.7: Is cleaning equipment maintained clean and stored properly?
Total compliance (5 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 uses. Cleaning equipment should be stored away from the food and operational areas in a designated storage area. Cleaning equipment is stored to prevent it becoming a source of cross contamination for the product, materials, packing equipment, and in general, for the complete operation. Brooms, mops, etc., should be stored off the floor and “head down” in order to avoid them being contaminated by any accidental spills and prevent them from being harborage areas for pests and ensure debris does not contaminate the handle. Squeegees actively being used for cleaning and condensate control operations 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 (3 points) if:
- Single/isolated instance(s) of the issues mentioned above.
- Single/isolated instance(s) of cleaning equipment that is kept in areas where it may represent a potential risk to contaminate product, materials or equipment.
- Single/isolated instance(s) of cleaning materials temporarily unavailable.

Major deficiency (1 point) if:
- Numerous instances of the issues mentioned above.
- Numerous instances of cleaning equipment that is being stored in a way that may represent a risk for product, materials or equipment.
- Numerous cleaning materials unavailable.

Non-compliance (0 points) if:

- Fundamental failure to properly store cleaning equipment.
- Very poor availability of cleaning materials.
- Any instance of cleaning tool dips not at the correct dilution and part of the sanitizer monitoring system.

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

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

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

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

1.9.9: Are all items used for sanitation appropriate for their designated purpose (e.g., no steel wool, metal bristles, etc.)?
Total compliance (5 points): Steel wool is avoided for use as cleaning equipment. Cleaning utensils used are constructed to prevent potential contamination of product (e.g. without straw bristles, metal bristles, etc.). Ideally brightly colored plastic bristles are used. Avoid anything that flakes, is made of pervious materials, is a similar color to the products, corrodes or might damage the equipment or facility. Where cloths are used for cleaning purposes, there should be a procedure in place for laundering or disposal after use.

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

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

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

1.9.10: Are toilet facilities and hand washing stations clean?
Total compliance (15 points): Toilet facilities and hand-washing stations are maintained in a sanitary condition:
- Toilet facilities have a drainage installation that allows the waste to be flushed and disposed properly.
- Toilet facility (including hand washing stations) fixtures are in good operating condition and clean.
- 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-compliance to above requirements.
- Single/isolated instance(s) of soiled toilet tissues being placed in trash can.

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

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

1.9.11: Are worker break facilities clean, including microwaves and refrigerators, and no rotting or out of date foodstuffs?
Total compliance (5 points): Inspection shows that the worker break areas are kept in a sanitary condition and pose no threat of contamination to production or storage areas. Sanitation practices include the periodic cleaning of these areas (includes inside microwaves, inside and behind refrigerators, behind, under and on top of all vending machines, tables, chairs, tops of lockers, etc.) to assure that acceptable levels of sanitation are maintained to prevent potential pest harborage that may affect the product. Temperature sensitive food should be kept in refrigerators, 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 of 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 worker 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 worker break areas.
- Numerous instances of out of code product in vending machines.
- Numerous instances of foodstuffs being stored at the wrong temperature.

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

1.9.12: Is the maintenance shop organized, with equipment and spares stored in a neat and tidy fashion?
Total compliance (5 points): Inspection of the facility shows that the maintenance shop is kept clean and organized. Sanitation practices include the periodic cleaning of this area in order to avoid pest harborage conditions that may contaminate the product, materials or equipment. Shop should employ a “clean as you go” policy with respect to metal filings and chips which are generated when metalworking. Shops should not be located near or in production and product and packaging storage areas, in order to avoid foreign material contamination. Shops that have small break areas, should follow all the usual GMP rules to prevent cross contamination i.e. a segregated area away from equipment, tools and machinery being

worked on, hand washing after breaks and care should be taken not to contravene the facility glass policy – any issues with the break area would be scored down under the question about break areas.

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

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

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

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

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

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

Non-compliance (0 points) if:
- Fundamental failure to maintain the transport vehicles in a clean and sanitary condition.
- Widespread use of gasoline or diesel-powered vehicles in food areas.
- Multiple instances of failure to maintain the transport vehicles in a sanitary condition that may lead to potential product contamination.
- **The auditor should consider whether the issue is adulteration and should be applied to Q 1.4.5 and scored as an automatic failure.**

1.9.14: Are shipping trucks clean and in good condition?

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

Minor deficiency (3 points) if:
- Single/isolated instance(s) of improperly maintained shipping truck.

Major deficiency (1 point) if:
- Numerous instances of shipping trucks that are not maintained under acceptable sanitary conditions.
- A single instance of shipping truck in an unacceptable sanitary condition, which may contaminate the product.

Non-compliance (0 points) if:
- Fundamental failure to maintain shipping trucks in a clean and sanitary condition.
- Multiple instances of cases where the failure on maintaining the shipping trucks in sanitary conditions may lead to potential product contamination.
- **Any observation of direct contamination of product, ingredient or packaging materials (except condensate). In this case the score reverts back to 1.4.5, automatic failure question.**

Buildings and Grounds

1.10.1: Are all lights in the facility that could potentially contaminate raw materials, work in progress, ingredients (including ice), finished goods, equipment or packaging shielded, coated or otherwise shatter resistant to protect product from contamination in the event of breakage?
Total compliance (15 points): All glass lights in the facility that can potentially contaminate finished products, raw materials, equipment, or packaging should be shielded, coated or otherwise shatter-resistant to protect product from contamination in the event of a breakage. This includes, but is not limited to items such as light bulbs, emergency lights, windows, truck loading lights (dock lamps), insect light trap lights, forklift lights, lights in bathrooms or maintenance shops that open into the production area, etc. End piece fittings on tube lights should be secure. Precautions should be taken to prevent glass contamination in the event of glass breakage. Windows and computer monitors in packing areas should be covered with a plastic film to prevent shatter. Inside light covers should be clean, free of algae, insects and excessive dirt (scored under 1.4.6, 1.5.4).

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

Minor deficiency (10 points) if:
- Single/isolated instance(s) of unprotected glass in an area that could potentially contaminate finished product, raw materials, processing/packaging equipment, or packaging materials.
- Observed missing end piece tube light fittings.

Major deficiency (5 points) if:
- Numerous instances of unprotected glass in an area that could potentially contaminate finished product, raw materials, processing/packaging equipment, or packaging materials.
- Single instance of a broken light found within the facility.

Non-compliance (0 points) if:

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

1.10.2: Has the operation eliminated or adequately controlled any potential metal, glass or brittle plastic contamination issues?
Total compliance (10 points): No metal, glass or plastic issues noted (excluding issues noted under specific questions already noted within this audit). This question is designed to allow the auditor to underline potential foreign material contaminants to the auditee that are not covered by other more specific questions within the audit. Examples include: pins in sign boards within the facility, using "snappable" blades instead of one-piece blades, noting broken and brittle plastic issues on re-useable totes and finding uncontrolled glass items like coffee pots, computer screens, clock faces, eye glasses, office window glass, brittle plastic from any source, staples, etc. in production areas. Plastic coated shatterproof light bulbs are also acceptable without further protection. Auditors should take precaution not to bring glass items into the facility during inspections. If a glass or brittle plastic item cannot be replaced immediately or glass is necessary, e.g. a high-pressure gauge, then use of a glass register might be considered, see question in 2.12.12.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of potential foreign material contaminants observed.
- Single/isolated instance(s) of glass or brittle plastic item noted in the production/storage areas, but is not accounted for on the glass register.

Major deficiency (3 points) if:
- Numerous instances of potential foreign material contaminants observed.
- Numerous glass or brittle plastic items noted in the production/storage areas, but are not accounted for on the glass register.
- Single instance of a broken glass or brittle plastic item found within the facility.

Non-compliance (0 points) if:

- Fundamental failure to control potential foreign objects on site.
- More than one instance of a broken glass or brittle plastic item found within the facility.
- **Any incident of direct product contamination with a foreign material like glass, metal or plastic constitutes a health hazard and is viewed as adulteration. Revert to Q 1.4.5.**

1.10.3: Has the facility eliminated the use of wooden items or surfaces?
Total compliance (5 points) if:
- Walkways, storage containers, ladders, platforms, broom/mop handles, utensil handles, etc. should not have wooden parts.
- Wood pallets should be acceptable as long as they are of not fragmenting, look clean and are dry. Wooden pallets should never directly touch product.
- Wooden bins for potatoes, onions and other items that require cooking (or some other kill step) prior to consumption or have an inedible skin should be allowed if they are not fragmenting and they are clean and in a good condition. Repairing of wooden bins should be recorded as part of the maintenance records; see maintenance document questions 2.12.1 to 2.12.3. Plastic storage bins are preferred.
- Wooden mushroom growing trays should be allowed in mushroom operations, as long as they are clean and not fragmenting. Mushrooms destined for consumption should not be touching the wooden trays.
- "Wet areas and high humidity areas" should not be constructed of wooden walls, floors or ceilings.
- Use of wood tables or similar food contact equipment should be scored under 1.7.3.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of utensils/equipment with wood parts in use in the facility.
- Using wooden bins (that are not fragmenting and are clean and generally in good condition) for potentially ready-to-eat items like apples, stone fruit, citrus, melons, etc.
- Single/isolated instance(s) of structural items e.g. walls/floors/platforms constructed of wood in "wet" and/or high humidity areas.

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

Non-compliance (0 Point) if:
- Majority of structural items e.g. walls/floors/platforms constructed of wood in “wet” and/or high humidity areas.

1.10.4: Is there adequate lighting in the production and storage areas?
Total compliance (5 points): Adequate lighting should be made available in all areas where inspection operations and inspections are occurring. This includes all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned, maintenance areas, restrooms, etc. The lighting should be strong enough to allow workers to see clearly so that they can conduct their work in an unobstructed manner. The color of lighting should be such that it does not hide dirt, decay, etc.

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

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

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

1.10.5: Is ventilation adequate to control dust, condensation, odors and vapors?
Total compliance (10 points): The ventilation system (cooling and heating) should be sufficient to control condensation, mold, dust, odors and vapors so that conditions do not exist where raw materials, work in progress, ingredients or packaging materials may be contaminated or tainted. Ventilation equipment is balanced to provide an adequate air exchange rate to prevent condensation on walls, ceilings or other surfaces in production areas. Ideally, positive air pressure is employed in processing operations.
Where condensation is not adequately controlled by ventilation or is considered inevitable, action should be taken to ensure raw materials, work in progress, ingredients, finished products or packaging materials are not located below areas where condensate may drip. Where this is not possible facilities should control such condensation by cleaning and sanitizing the surfaces as often as needed in accordance with the facility’s SSOPs.
Where condensation has formed to such an extent on surfaces (that are not being cleaned and sanitized) that raw materials, work in progress, ingredients, finished product or packaging materials may become or are becoming contaminated the condensation is considered to be an adulterant (scoring reverts to Q 1.4.5), and creating insanitary conditions. For example, heavily beaded condensation drips from a ceiling of a processing area that is not regularly cleaned and sanitized in accordance with the facility’s SSOPs. Another example, condensate from a cooler ceiling drips onto exposed product, condensate from refrigeration unit surfaces (which have not been cleaned and sanitized) drips onto exposed product or onto product boxes.

http://www.qualityassurancemag.com/article/cleaning-sanitation-condensation-mitigation/
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf
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-compliance (0 points) if:
- Numerous instances of potential product contamination by dust, condensation or objectionable and/or tainting odor.
- **Direct contamination of raw materials, work in progress, ingredients, finished goods, food contact packaging or food contact surfaces by dust or condensation. Auditor should consider reverting to Q 1.4.5, the automatic failure adulteration question.**

1.10.6: Are floor surfaces in good condition, with no standing water, no debris trapping cracks and are they easy to clean?
Total compliance (10 points): The floor surfaces in the facility should be suitable for the type of operation being conducted. The floor should be constructed in such a manner that it may be adequately cleaned and kept in good repair. Floors surfaces in all areas should be smooth without deep cracks or seams; durable, non-absorbent, easily cleanable, and resistant to wear and corrosion. Cracks should not trap debris or water. Some hairline floor cracking is allowed, but should be easy to keep clean and not trapping debris. Check for concrete breakdown (exposed aggregate, where flooring is exposed to concentrations of different chemicals e.g. near wash lines, chemical stores etc.). Assess areas where concrete has 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 traffic flow (foot and forklift).

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

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

Non-compliance (0 points) if:
- Fundamental failure to keep floors in good state of repair and in clean condition.
- Fundamental failure to prevent standing water.
- **Direct contamination of food product, food packaging materials, or food processing equipment due to poor maintenance or sanitation of floors. Auditor should consider reverting to Q. 1.4.5, the automatic adulteration failure question.**

1.10.7: Are the floor drains where they are needed for drainage and cleanup?
Total compliance (5 points): Drains should be constructed and located in such a manner that they provide adequate drainage in all areas where floors are subject to flood-type cleaning or where normal operations release or discharge water or other liquid waste on the floor. Drains should flow from processed to raw to avoid contamination in processing plants. Facilities that are washing product should have adequate drainage. Discharge water from sinks should not run directly onto the floor. Not applicable in dry facilities with no drains.

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 where drain(s) are improperly located.

Major deficiency (1 point) if:
- Numerous instances of an areas having insufficient number of drains.
- Numerous instance(s) of an area where drains are improperly located.

Non-compliance (0 points) if:
- An entire area lacking drains.
- Drains are predominately located in unsuitable areas.

1.10.8: Are closed doors, and windows to the outside pest-proof?
Total compliance (10 points): All doors, windows, louvers and screens 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, windows or louvers have screens, the openings should be no greater than 1/8 inch (3 mm). Gaps are often at bottom of doors and at the top of roller doors. Air curtains are acceptable, provided they are operating properly. Personnel doors to the outside should be loaded so that they close properly. Rule of thumb is that if you can see daylight gaps, then further investigation is required. If doors are maintained open during production with no protection (e.g. air curtain, screen, etc.) they cannot be considered pest proof (scored in 1.4.2/1.5.3.). Dock doors are scored under 1.10.10.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of there being a gap greater than1/8 inch (3 mm).
- Single/isolated instance(s) of personnel doors not closing properly or improper mesh size (where screens are used).
- Single/isolated instance(s) of an air curtain not operating properly.

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

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

1.10.9: In temperature controlled environments, are docks enclosed and dock doors fitted with buffers/shelters to seal against trucks?
Total Compliance (5 points): This question should be scored for operations that are handling time/temperature control for safety items. In operations where goods are not time/temperature control for safety, then this question is only scored if the docks are enclosed and dock door buffers are fitted.

Examples of time/temperature control for safety food includes an animal food that is raw or heat treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation. Product assessment is required for food where because of pH or Aw or the interaction of pH and Aw the growth or toxin formation of pathogenic microorganisms are reasonably likely to occur. Refer to Food Code.

FDA Food Code 2017: Chapter 1 – Purpose and Definitions https://www.fda.gov/media/110822/download
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=117.206

Minor deficiency (3 points) if:
- Operation handling temperature-sensitive goods that do not use a dock buffer system (or equivalent temperature management system). Counter measures in place.

Major deficiency (1 point) if:
- Operation handling temperature-sensitive goods that do not use a dock buffer system (or equivalent temperature management system). Limited counter measure in place.

Non-compliance (0 points) if:
- Operation handling temperature-sensitive goods that do not use a dock buffer system (or equivalent temperature management system). No counter measures in place.
- Operation handling temperature-sensitive goods does not have an enclosed, temperature-controlled dock.

1.10.10: Are dock load levelers and buffers/shelters maintained in a good condition, pest proof and debris free?
Total compliance (3 points): This question is only scored where dock load levelers and buffers/shelters are fitted. Dock levelers are cleaned, pest free and in good repair. Product debris can attract pests to the area. Dock buffer seals should be in good condition. Trucks backed onto the dock should seal properly in order to avoid pest entry and maintain temperature control in the shipping area and within the truck. Dock door seals ensure that the product is not exposed to the elements and help prevent pest entry. Auditor should inspect under the plates when touring the outside of the facility.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of improperly maintained load levelers or buffers/shelters.
- Single/isolated instance(s) of a load levelers or buffers/shelters not proofed properly against pest entry e.g. fitted with rubber strips.

Major deficiency (1 point) if:
- Numerous instances of improperly maintained load levelers or buffers/shelters.
- Numerous instances of load levelers or buffers/shelters not proofed properly against pest entry e.g. fitted with rubber strips.

Non-compliance (0 points) if:
- Systematically observation of improperly maintained load levelers or buffers/shelters.

1.10.11: Are exterior walls free of holes to exclude pests, and are pipes, vents, and air ducts designed and protected in order to prevent pest entry (e.g., by using fine mesh)?
Total compliance (5 points): Exterior walls should be maintained. They should be free of holes and deep cracks that could harbor pests. All pipes on the exterior walls should have caps, mesh screens etc., to prevent rodents and other 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) to limit insect entry.

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

Major deficiency (1 point) if:

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

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

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

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

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

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

1.10.13: Is an 18" (46 cm) internal wall perimeter being maintained within the facility, with adequate access to these wall perimeters, thereby allowing inspection and cleaning?
Total compliance (5 points): All storage areas should maintain 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, and to allow proper monitoring of pest activity (inspection gap) and for workers to perform cleaning and maintenance. 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-compliance (0 points) if:
- Fundamental failure to maintain required inspection perimeters or clearance.

1.10.14: Is the exterior area immediately outside the facility, including roads, yards and parking areas, free of litter, weeds and standing water?
Total compliance (5 points): Facility grounds should be maintained in a clean and orderly condition to prevent attraction of insects, rodents and other pests. Weeds and grass should be maintained in order to help avoid pest harborage. There should be no excessive standing water and/or foul-smelling odors. If there is a designated smoking area outside, then there should a disposal can for cigarette butts – butts should not be found on the ground. Car parking areas should be free from litter, butts, etc., especially if

workers are using their cars at break times. When locating a suitable designated smoking area, auditees should consider the need for hand washing prior to returning to the work place.

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

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

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

1.10.15: Are control measures being implemented for the outside storage of equipment, pallets, equipment, tires, etc. (i.e. out of the mud, pipe ends capped, stacked to prevent pest harborage, away from the building perimeter)?
Total compliance (5 points): Outdoor storage of equipment is acceptable provided that it is stored in a manner that will prevent the harborage of pests. Pipes should have the ends capped. Equipment on pallets should not have direct contact with the dirt. All items stored should be at least 4 inches (10 cm) above the ground. 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.

National Pest Management Standards, Pest Management Standards for Food Plants
http://npmapestworld.org/default/assets/File/2016%20Pest%20Management%20Standards%20for%20Food%20Processing-Electronic.pdf

Minor deficiency (3 points) if:
- Single/isolated instance(s) of equipment not stored properly.
- Excessive storage of old obsolete equipment.

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

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

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

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

Major deficiency (1 point) if:
- Numerous instances of broken or dirty pallets in use for raw or packaged product.

- Numerous instances of broken and dirty pallets being stored together with pallets in good condition.

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

1.10.17: Is the area around the dumpster/cull truck/trash area clean?
Total compliance (3 points): The dumpster/cull truck/trash area should be located away from facility entrances, where traffic flow may be a source of cross contamination. The area around the dumpster/cull truck/trash area should be maintained in a clean condition. There should not be any spillage on the ground. There should not be any standing water or liquid seepage around the dumpster/cull truck/trash area and there should not be any foul odor present. The dumpster/cull truck/trash area should be cleaned on a regular basis (cross reference with Master Sanitation Schedule).

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

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

Non-compliance (0 points) if:
- Evidence of old trash and spillage around the dumpster/cull truck/trash area, indicating that spills are not cleaned up as they happen.
- Evidence of insects or other pests in or around dumpster/cull truck/trash area.
- Dumpster/cull/trash area is in an area where traffic flow is a potential source of cross contamination.

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

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 covers and are covered, but some are lacking covers.

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

1.10.19: Are all water lines protected against back siphonage?
Total compliance (5 points): Main water lines entering the facility should be fitted with back-flow protection for the incoming water (no matter what source). Individual water lines within the facility should be fitted with backflow protection where needed e.g. on hose pipes, inlets to tanks, etc. The auditor should look for check valves, air gaps and also look for inlet pipes that are submerged below the wash tank fill lines. Water drawn back to into the mains water system can contaminate fresh water. Where facility has a current certificate of inspection on file (scored under 2.4.5), auditor should still look for issues within the facility (inlet pipes below wash tank fill lines, dead end on water lines, hoses not in water tanks or on floor, etc.) that may be an issue. Where the site does waste treatment, check for dedicated back flow between waste treatment and site.

http://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-compliance (0 points) if:
- Facility officials do not know if there is back flow protection.
- Documentation of back flow protection will be scored under 2.4.5.
- There is no primary mains water backflow protection.
- Waste discharge lacks back flow protection.

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

https://www.osha.gov/Publications/laboratory/OSHA3404laboratory-safety-guidance.pdf

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

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

Non-compliance (0 points): if one of the following:
- Laboratory is not sufficiently separated from production and/or storage areas. There may be a threat to product or packaging from a serious food safety threatening contaminant.
- Pathogen analyses are being done on-site without adequate precautions.

Section 2: Food Safety File Requirements

Management System

2.1.1: Is the operation registered as a food handling establishment?
Total compliance (10 points): There is documentation from relevant state, federal or recognized country authority indicating the facility is registered or permitted as a food handling establishment. The registration details should match the operation details, for example, address information. This may be the appropriate State or country registration documentation or documentation of the FDA registration requirement of the federal Bioterrorism Act. If the operation is exempt from registration requirements, auditee should have written documentation to show this.
https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions

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

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

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

2.1.2: Is there a documented food safety policy detailing the company's commitment to food safety?
Total compliance (5 points): There should be a clear documented food safety policy statement and detailed objectives reflecting the company's ongoing commitment to meet the food safety needs of its products that is dated and signed (by senior management). The policy should include statements and objectives 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 a public area and in the language understood by the workers. The policy may take the form of a "mission statement" provided it meets the requirements detailed above.

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 workers.
- Policy is not posted in a public place.

Non-compliance (0 points) if:
- No policy exists.

2.1.3: Is there a designated person responsible for the operation's food safety program?
Total compliance (10 points): There should be a designated person(s) in charge of the operation's food safety program, including food safety document control and verification of food safety activities and be independent of production (does not apply to operations of less than 20 workers). They should have

documented formal training or trained by someone that has the documented formal credentials. This training should meet all state and federal requirements e.g. operations covered under US FDA FSMS must have at least one responsible person who has completed training at least equivalent to that under a standardized curriculum recognized by the FDA.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors and omissions in the records showing person/persons in charge of the operation's food safety program training and/or their relevant experience in food safety.
- Designated person is not independent of production.

Major deficiency (3 points) if:
- Numerous instance(s) of errors and omissions in the records showing person/persons in charge of the operation's food safety program training and/or their relevant experience in food safety.

Non-compliance (0 points) if:
- Fundamental failure to document person/persons in charge of the operation's food safety program training and/or their relevant experience in food safety.
- No-one is in charge of food safety programs, including food safety document control and verification of sanitation activities.

2.1.4: Is there an organizational chart showing all management and workers who are involved in food safety related activities and documentation (job descriptions) detailing their food safety responsibilities?
Total compliance (10 points): There should be an organizational chart showing positions and reporting structure of workers whose activities affect food safety within the company. Chart is dated and signed by management to indicate it is correct and current. Job functions and responsibilities related to food safety should also be documented. Suitable alternates should be indicated or reference document indicating this information. For very small companies, an individual worker may cover many jobs.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions on the organizational structure chart or responsibilities.
- A document is not dated and/or signed.

Major deficiency (3 points) if:
- Numerous instances of errors or omissions on the organizational structure chart or responsibilities.

Non-compliance (0 points) if:
- Fundamental errors on the organizational structure chart or responsibilities.
- No process organizational structure chart or responsibilities.

2.1.5: Is there a food safety committee and are there logs of food safety meetings with topics covered and attendees?
Total compliance (5 points): There should be an active food safety committee, responsible for the strategic maintenance and development of the operation's food safety plan. If an operation has a HACCP plan, the HACCP team may also look after the food safety issues. The company should be keeping logs and minutes/notes of meetings addressing food safety topics. These meetings might be dedicated to food safety or may be part of another regular meeting, e.g. a production meeting, HACCP meeting, etc. These records should demonstrate Senior Management involvement in the Food Safety program - for example show management attendance, minutes copied to management and, missing members are indicated on records. Meetings should occur at least quarterly during the season of operation. Where the operation has less than three months of records available (new, short season operations) there should still be at least one meeting available for review – score minor deficiency; if no records score non-compliance. Refer to "New PrimusGFS Auditees/First-Time PrimusGFS Auditees" section.

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 (including Senior Management).
- Only three meeting have occurred in the last 12 months (for an all year-round operation)
- Signed attendance is not kept (attendee names only).

Major deficiency (1 point) if:
- Numerous instances of errors and omissions in the meeting logs e.g. not noting who was attending the meeting (including Senior Management).
- Two or less meetings have occurred in the last 12 months (for an all year-round operation)

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

Control of Documents and Records

2.2.1: Is there a written document control procedure (including document control register/record) describing how documents will be maintained, updated and replaced?
Total compliance (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, forms (record templates), other work instructions, raw material and finished product specifications, etc.
The document control procedure should specify:
- Who is responsible for document control (i.e. making sure documents are updated and securely stored).
- How documents are to be written, coded and approved.
- How documents are updated, and amendments are approved (e.g. how paper versions are approved, computer records password protected, etc.).
- How changes are identified and recorded (e.g. date, issue number, different colored text or font, change history document etc.).
- How the inadvertent use of obsolete documents is prevented.
- Register/record listing all documents used, when issued, when updated and current revision status.

If using an electronic record keeping system, the procedure should cover the above, plus how electronic records are managed to control access, how changes to records are controlled, including who has edit rights and how electronic records are secured; i.e. back-up system.

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-compliance (0 points) if:
- There is no written procedure

2.2.2: Is there a documented and implemented procedure that requires all records to be stored for a minimum period of 24 months (or greater if legally required) or for at least the shelf life of the product if it is greater than 24 months?
Total compliance (5 points): There should be a written procedure in place requiring that all records are retained for auditing purposes, in case where there are legal issues, customer queries, etc. All monitoring and process control records should be held for a minimum of 24 months, regardless of the production

item's shelf-life. For Good Agricultural Practices (GAP) growing area records include all cultivation records; for GAP harvest crew records include harvesting related records. Any records required by law to be kept longer than 24 months should be kept for the legally mandated period. Any records pertaining to long life product should be kept at least for the duration of the shelf life of the product. Ideally (not part of the audit scoring), some records that might go to prove the long-term food safety performance of the operation should be retained for as long as possible, for example internal and third-party audit records and corrective actions.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of procedure and/or process control records not being required to be or retained for the required length of time (two years unless legally longer storage is required, or the product has a longer shelf life than 24 months).

Major deficiency (1 point) if:
- Numerous instances of procedure and/or process control records not being required to be or retained for the required length of time (one year unless legally longer storage is required, or the product has a longer shelf life than 24 months).

Non-compliance (0 points) if:
- Process control records are kept less than 24 months.
- Process control records are kept less than the required time mandated by law for a particular product.
- Process control records are kept for less than the shelf life of the product.

2.2.3: Are both paper and electronic food safety related documents and records created, edited, stored and handled in a secure manner?
Total compliance (5 points): Both paper and electronic food safety documentation that are part of the food safety program (e.g. procedures, policies, training records, testing results, monitoring records, etc.) should be created, edited, stored and handled in a secure manner that deters theft and prevents tampering when not in use. For example, the system might be the locking up of all manuals and recording logs at night in the QA Lab., when the operation is not running. There might also be rules for storing records in a secure archive room. Where computer systems are used to store SOPs records, etc., there should also be security measures including access control (password protection). The electronic records and documents should also be "backed-up" in some way e.g. stored in two locations, so that if one location breakdowns or is damaged, the data is not lost. Paper files should be written in ink, not pencil and if changes are made to records after initial entry, changes should be clearly legible and tracked, and no use of correction fluid. When electronic records are amended, they should show what was amended, by whom and when (editing history). Electronic records should be storable in the database, available for immediate retrieval when needed (see 2.2.4) and have secure digital signature (including and date and time (where appropriate)) capabilities. All records should be legible and accurate.
The system should include appropriate electronic security and comply with the relevant electronic regulatory record-keeping requirements, e.g. FDA (21CFR117.305, 21CFR11) and/or national equivalents.

FDA Electronic Records Guidance:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=117.305

Minor deficiency (3 points) if:
- Single/isolated instance(s) of hard copy documents and records not being created, edited, stored and handled securely.
- Single/isolated instance(s) of electronic documents and records not being created, edited, stored and handled securely.
- Single/isolated instances of electronic records lacking digital signature capabilities.

Major deficiency (1 point) if:

- Numerous instances of hard copy documents and records not being created, edited, stored and handled securely.
- Numerous instances of electronic documents and records not being created, edited, stored and handled securely.
- Numerous instances electronic documents and records lacking digital signature capabilities.
- Electronic documents and records are not being backed-up.

Non-compliance (0 points) if:
- Hard copy documents and records are not stored securely.
- Electronic documents and records are not being stored securely.
- No control over creating or editing of hard copy and/or computerized records.
- Widespread failure to use electronic signatures and/or software lacks secure electronic signature capability.

2.2.4: Are records maintained in an organized and retrievable manner?
Total compliance (3 points): All food safety records and documents should be maintained in a designated area where they can be retrieved readily. These records should be well organized, and should be accessible, even if the operation is seasonal. This will aid in the detection of issues, the isolation of problems, and the identification of trends and retrieval of information. Binders or file system is acceptable. System might be by date or together in a single file for a particular record. It may be that data is kept on computer. Data on computers must be easily retrievable.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of records and/or documents not being organized and easy to retrieve.

Major deficiency (1 point) if:
- Numerous instances of records and/or documents not being organized and easy to retrieve.

Non-compliance (0 points) if:
- No organization of records and/or documents.
- Many missing records and/or documents.

Procedures and Corrective Actions

2.3.1: Is there a written and standardized procedure for creating Standard Operating Procedures (SOPs) and their content?
Total compliance (5 points): There should be a written document that describes how to write Standard Operating Procedures (SOPs) for food safety activities related to good agricultural practices and/or good manufacturing practices that when followed, help prevent food safety hazards from occurring. SOPs should include a date and document number or reference code and detail:
- what is to be done,
- how it is done,
- how often,
- by whom,
- what recordings are required and
- any immediate corrective action procedures to perform when there are any deficiencies.

These SOPs can be used for training and as reference tools. There should be clear evidence that this system is being followed, based on SOPs reviewed. SOPs should follow the organization's document control systems, especially proper version management (see Control of Documents and Records).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors and/or omissions within the document.
- Single/isolated instance(s) of SOPs not having the required format.

Major deficiency (1 point) if:
- Numerous instances of errors and omissions within the document.
- Numerous instances of SOPs not having the required format.

Non-compliance (0 points) if:
- A document describing how to write standard operating procedures has not been created.
- Widespread evidence that SOPs are not written following the standardized procedure.

2.3.2: Are the written procedures available to relevant users and is a master copy maintained in a central file?

Total compliance (5 points): The written procedures (SOPs) should be available to the users and other interested parties involved in performing the activities described in the procedures. A master copy of all SOPs and associated recording forms should be assembled and stored as a reference. SOPs should be used by the relevant workers (e.g., QA workers, production, sanitation, etc.). SOPs can be used for training and for reference. The number of copies of SOPs depends on the size of the company and the types of processes involved. In the event of electronic SOPs, access should be allowed to all relevant workers, however, there should be controls in place to prevent unauthorized editing. A master copy of all SOPs and associated recording forms should be assembled and stored as a reference.

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

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

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

2.3.3: Is there an incident reporting system, also known as a Notice(s) of Unusual Occurrence and Corrective Actions Log (NUOCA)?

Total compliance (5 points): The company has a log or report for recording infrequent and/or unusual events that impact food safety such as deviations, incidents, process failures, unusual occurrences, etc. For example, 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, often called a NUOCA log (Notice(s) of Unusual Occurrence and Corrective Action Log), helps avoid creating multiple logs for events that do not occur very often. If product testing is performed (microbiological, heavy metal, pesticides, dioxins, aflatoxins, etc.), and there are out of specification results, there should be a NUOCA. Useful to consider recording issues that might or might not temporarily affect production e.g. loss of power, blocked drains, weather damage, earthquakes, flooding by heavy rainfall, evidence of human intrusion during non-working hours in or around the growing area, etc., since at a later date, if there are product issues, these events might be of significance.

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

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

Non-compliance (0 points)

- No records.
- Failure to maintain records.

Internal and External Inspections

2.4.1: Are there written procedures for handling regulatory inspections?
Total compliance (3 points): Written procedures for handling regulatory inspections are available for workers to follow when regulatory agencies inspect the operation. Regulatory agencies could be Health Departments, State enforcement organizations, etc. (e.g., US: USDA/FDA, Canada: CFIA, Chile: Ministerio de Agricultura/SAG, Mexico: SAGARPA). The procedures should include at a minimum, rules for always accompanying inspections, identified meeting space, rules on taking samples and taking photographs, how to follow-up after the inspection, corrective action requirements, etc. This policy should be communicated to key personnel including the receptionists, field staff and crew supervisors. Inspection policies must not contravene bio-terrorism laws and restrict access to documents that have been covered by these laws.

https://www.fda.gov/iceci/inspections/iom/default.htm

Minor deficiency (2 points) if:
- If one of the above elements of the policy is missing.
- If the receptionist(s) has/have not been briefed properly.

Major deficiency (1 point) if:
- If two or more elements of the policy are missing.

Non-compliance (0 points) if:
- A written procedure for handling regulatory inspections is not available for review.

2.4.2: Are there records of regulatory inspections and/or contracted inspections, company responses and corrective actions, if any?
Total compliance (5 points): Reports of previous inspections are on file and any deficiencies noted have been responded to (date of response, action taken, and signature of responsible person (if applicable)). Inspections include regulatory (e.g., Federal and State) and third-party audits. This question is not applicable if there have been no regulatory or third-party inspections in the past year. Evidence of corrective actions (and their follow-up) 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.

https://www.fda.gov/ICECI/Inspections/ucm256377.htm

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of corrective actions not being recorded.
- A single audit inspection report is missing in the last year.

Major Deficiency (1 point) if:
- Numerous instances of corrective actions not being recorded.
- More than one audit inspection report is missing in the last year.

Non-compliance (0 points) if:
- There are no records of previous inspections and corrective actions taken although there have been more than two inspections in the last year.
- If a previous inspection indicated an observation of contaminated ingredient, product or food contact packaging and there are no documented corrective actions.

2.4.3: Are there documented calibration and/or accuracy verification procedures for measuring and monitoring devices used in the operations that are related to the safety of the product?
Total compliance (10 points): The equipment used should be identified (i.e. catalog, roster, list) and there are documented procedures for the calibration for measuring and monitoring devices used in the operation. Regular calibration ensures correct and accurate operation of equipment used for measuring and monitoring processes related to food safety and/or verification of ingredient label requirements (e.g. for weight or volume of ingredients). Scales/weight or volume measuring devices should have verification of accuracy and/or calibration regularly to ensure correct and accurate operation where relevant to food safety.

For GAP, this covers items such as fertilizer and pesticide application equipment, pesticide measuring equipment (e.g. scales), ORP and pH meters, and other equipment related to the safety of the product. Pesticides application equipment (e.g. sprayers), and corresponding measuring equipment (e.g. scales, cups) should be verified and when required calibrated (or replaced) regularly to ensure correct and accurate operation. Calibration and/or verification procedures should describe frequency, method and the acceptable range of variation (when applicable). Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency.

For GMP, this includes equipment used for measuring and monitoring processes (handheld and automated) related to food safety e.g. ATP testing systems, thermometers, metal detectors, ORP meters, flow meters and pH meters.

Calibration procedures should describe the frequency of testing, the testing method and the acceptable range of variation. Procedures should require that all test solutions/strips are within date code, appropriate for the concentrations used and stored correctly (especially light and temperature sensitive materials). Corrective actions should be detailed when applicable. Legal requirements, manufacturer recommendations, best practice and experience of equipment drift help to determine the frequency. Both internal (where the company checks the equipment for themselves) and external (where equipment is sent away, or an outside specialist company comes on site and checks the equipment in situ) calibrations should be documented and on file. Proof of calibration includes records, invoices and on machines labels. Where an external service is used, procedures, licenses and/or certifications are acceptable.

https://www.pubs.ext.vt.edu/content/dam/pubs_ext_vt_edu/424/424-100/PDF_part16.pdf
http://www.ugaurbanag.com/content/calibrating-your-spreader

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

Major Deficiency (3 points) if:
- Numerous instances of omissions in the procedure(s).
- Numerous instances of pieces/sets of equipment omitted from the procedure(s).

Non-compliance (0 points) if:
- No procedure

2.4.4: Are calibration and/or accuracy verification records maintained and are they consistent with the requirements outlined in the SOP(s) for instruments and measuring devices requiring calibration?
Total compliance (5 points). Calibration and/or accuracy verification records should be available for all applicable equipment and should consider at least equipment identification, date, frequency of testing, testing method, result (variation), and corrective actions. Both internal (where the company checks the equipment for themselves) and external (where equipment is sent away, or an outside specialist company comes on site and checks the equipment in situ) calibrations should be documented and on file. Proof of

calibration includes records, invoices and on machines labels. Where an external service is used, procedures, licenses and/or certifications are acceptable.

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

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

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

2.4.5: Is there a current certificate of inspection (or similar record) for backflow prevention assemblies on water lines into the facility?
Total compliance (3 points): There should be a backflow prevention device on main water lines entering the facility and backflow prevention devices on individual water lines within production areas. A trained inspector (e.g., appropriately certified plumber) should verify the principle backflow prevention system annually (unless there is a stated expiration on the certificate). Certificate should indicate name of tester, their certificate number, location information for assembly, type of assembly, pressure across check valve(s), relief valve pressure and whether unit passed or failed the test. 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. This question is not applicable if the facility has no water supply. If the valve type is one that cannot be inspected or tested, then the auditee should have documentation supporting this on–site e.g. valve manufacturer's documentation.

http://www.abpa.org/?page=Tester_Cert
http://www.usc.edu/dept/fccchr/

Minor deficiency (2 points) if:
- Last inspection and certification was done over a year ago, but not greater than 18 months ago.
- Single/isolated instance(s) of omissions or incorrect data in the inspection certificate documentation.

Major deficiency (1 point) if:
- Last inspection and certification was done over a year ago, but not greater than 24 months ago.
- Numerous instances of omissions or incorrect data in the inspection certificate documentation.

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

Release of Items/Product

2.5.1: Is there a documented procedure for handling on hold and rejected items?
Total compliance (5 points): A documented procedure exists that explains how products (including raw materials, packaging, work in progress, finished product, etc.) that have either been rejected or placed on hold should be handled, including the release of the on hold/rejected items. Procedure should explain how returned items and items for donation are handled (where relevant).

For harvested product in the field and the facility, the procedure should identify who (position/title) is authorized to determine the disposition of materials that are placed on hold and include details on how the affected item(s) is/are separated from other lots in terms of tagging systems (e.g., date showing when the item was placed on hold/rejected, the reason for being on hold/rejected and the name of the person who put the item on hold (details may be recorded electronically as long as products are clearly tagged))

and any other physical separation needed to ensure that affected items are not commingled with other goods in such a way that their disposition is not clear.

For the pre-harvest materials, procedures should include how the affected product is indicated in the field (e.g., cordoned off, any buffer zones used, how these details are recorded, etc.).
Procedure requires authorized personnel should sign (with date and time) a "release" for any item placed on hold or rejected, detailing actions taken (e.g., disposition, re-work, food bank, tilled back into the ground, etc.).

Minor deficiency (3 points) if:
- Single part of the procedure is omitted.
- Single/isolated instance(s) of the procedure not being applied in the field, production and/or storage areas.

Major deficiency (1 point) if:
- Procedure missing more than one part, but SOP exists.
- Numerous instances of the procedure not being applied in the field, production and/or storage areas.

Non-compliance (0 points) if:
- No procedure.
- Procedure created bears no resemblance to what is being applied in the field, production and/or storage areas.

2.5.2: Is there a documented procedure for dealing with customer and buyer food safety complaints/feedback, along with records and company responses, including corrective actions?
Total compliance (10 points): There is a documented procedure detailing how to handle food safety and food quality complaints and feedback. Food quality issues are relevant if they have the potential to also be food safety issues. It is important to keep the complaints and feedback related records on file to support company procedure. The procedure and records should include (where applicable):

- Date/Time of complaint/rejection,
- Who made the complaint/gave feedback,
- Contact information,
- Product description,
- Where the product was purchased,
- Amount of product,
- Product code/date,
- Nature of complaint/feedback,
- Corrective actions,
- Corrective actions taken to prevent reoccurrence.

Where appropriate, a trend analysis of food safety feedback should be performed to assist with the development of corrective actions.

Complaints and feedback information, along with any corrective actions that are taken or associated with the operation should be available for review. For example, a blue colored Band Aid in a product could have come from either a facility or a harvest crew so details of the issue(s) should be sent to both facility and harvesting company. Ideally (not part of the audit scoring) foreign material issues should include photographs of the issue found (where possible). 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 5 in a month) complaints, a degree of analysis and review is expected to determine if trends are present.

Where a corporate office/sales department or other parties handle the incoming food safety related complaints, the operation is still required to have a documented procedure including how complaints/feedback are communicated to the operation and how they are managed internally (e.g. investigation, root cause, corrective action, communication, etc.).

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.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of omissions and incorrect data in the records including corrective actions.
- More than 10 complaints/rejections received, but no trend analysis or review carried out.

Major Deficiency (3 points) if:
- Numerous instances of omissions and incorrect data in the records including corrective actions.

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

Supplier Monitoring/Control

2.6.1: Is there a written procedure detailing how suppliers and service providers are evaluated, and approved and include the ongoing verification activities including monitoring?
Total compliance (10 points): There is a written procedure detailing how suppliers and service providers (e.g. raw materials, propagation materials, fertilizers, crop protection products, ingredients, processing aids, primary packaging items) are evaluated, approved and monitored. The procedure for evaluation, approval and on-going verification, including monitoring of suppliers, on-site service providers and outsourced service providers should include the indicators to be considered for decision making (including food safety hazards), exceptions and the elements the providers should comply with to make sure they meet the defined specifications. This procedure should include monitoring requirements in order to remain approved, and methods for suspending and un-approving suppliers and service providers. The procedure should also detail what is needed (minimum requirements) in the case of working with a supplier in an exceptional situation (e.g. market conditions, emergency situation) that has not yet been approved including ensuring approval from named management is justified and documented.
U.S. importers under the FDA's Rule Foreign Supplier Verification Programs should ensure requirements of rule are included in this procedure.
As a minimum, the procedure should detail the following where relevant:
- Agreed specifications
- Letters of guarantee
- Methods of evaluating approved suppliers and service providers (including second and third party audit requirements where relevant, at least for raw materials and primary packaging
- Methods of approving approved suppliers and service providers
- Methods and frequency of monitoring approved suppliers and service providers
- Methods of reviewing approved supplier and service providers performance and status (including removal of approved status)

Minor deficiency (7 points) if:
- If one of the above elements of the procedure is missing.

Major deficiency (3 point) if:
- If two or more elements of the procedure are missing.

Non-compliance (0 points) if:
- A written procedure detailing the selection, evaluation, approval and monitoring process of approved suppliers is not available for review.

2.6.2: Is there a list of approved suppliers and service providers?
Total compliance (10 points): There is a list of approved suppliers of materials and services. All incoming agricultural inputs, ingredients, products, materials (including primary packaging) and services that relate

to food safety (e.g., contract crop protection sprayers, pest control, chemical suppliers, water and waste utilities, RPC rental, transport, laboratory testing, maintenance and sanitation services) are purchased from &/or provided by approved suppliers.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions in the records.
- Single/isolated instance(s) of purchasing exceptions made (i.e. not from list of approved suppliers) without management approval.

Major deficiency (3 point) if:
- Numerous instances of errors or omissions in the records.
- Numerous instances of purchasing exceptions made (i.e. not from list of approved suppliers) without management approval.

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

2.6.3: Are there current written food safety related specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services?

Total compliance (10 points): A specification is an explicit set of food safety requirements or criteria to be met (e.g., indicating what an item is made of, contract details). Specifications are accurate, acceptable and ensure conformance with relevant customer and legislative requirements. There are written, detailed, up-to-date specifications for all incoming products, ingredients, materials (including primary packaging), services provided on-site, and outsourced services (including when exceptions will be allowed) that have an effect on food safety, addressing the required Good Agricultural and/or Good Manufacturing Practices. Documented specifications are easily accessible to users and there is a documented procedure for review, amendment and approval of all specifications. Government registration and/or label information (e.g. EPA) for crop protection and processing aid products is acceptable in lieu of an actual specification provided there is evidence products are used according to label instructions. Specifications should be reviewed on at least an annual basis and there should be at least the following specifications available to review (where applicable):
- seeds (e.g. lettuce or leafy greens, sprouts, microgreens)
- transplants,
- fertilizer/crop protection materials/adjuvants,
- ingredients (e.g. product raw materials, ice),
- processing aids (e.g. anti-microbials, buffers, post-harvest fungicides),
- primary packaging materials (material/components manufactured with),
- other materials with potential for direct product contact based on risk assessment, for example labels in direct contact with product,
- On-site and outsourced services (e.g., contract crop protection sprayers, pest control, chemical suppliers, water and waste utilities, RPC rental, transport, laboratory testing, maintenance and sanitation services) provided.

Note that contracted auditee operations such as co-packers, harvest crews, etc., that use materials or services that are supplied and/or selected by their customers, i.e. not purchased by the auditee should still have copies of specifications for the item provided. For example, a harvest crew that has some or all of their primary packaging provided by their contracting customer should obtain a copy of the up-to-date specification(s) from the customer.

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

Major Deficiency (3 point) if:

- Numerous instances of errors or omissions in the records.

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

2.6.4: Does the organization have documented evidence to ensure that all incoming products, ingredients, materials, services provided on-site, and outsourced service suppliers comply with the approval requirements and that all supplier verification activities (including monitoring) are being followed, as defined in the supplier approval procedure?
Total compliance (15 points): The organization has relevant information from approved suppliers to ensure that they are complying with the established supplier/service provider approval procedures, contracts, specifications, customer and regulatory requirements and best practice guidelines. This applies to agricultural inputs, raw material, primary packaging, processing aids and other ingredients suppliers, products and services suppliers. Supplier verification documents should demonstrate that the ongoing approval requirements detailed in 2.6.1 are being met (e.g., third party audits, certificates of analysis, reviews of supplier records, etc.).
The evidence may include (as applicable):

- Verification that packaging material is suitable for its intended purpose. e.g., current 3rd party audit certificate (ideally GFSI standard or equivalent) for all primary/food contact packaging by the manufacture. Ideally, a tests/analysis confirming no chemical migration to food contents if there is history of past occurrences.
- Current (within last 12 months) second and/or third-party audit certificates that includes the scope of certification for suppliers of product and ingredients.
- Letters of guarantee for agricultural inputs, product raw material, processing aids, and other ingredients and service suppliers that are purchased. Letters of guarantee (also certificate of conformance) should indicate that the items supplied meet any and all legal standards, best practice guidelines and agreed specifications. Letters of guarantee should be current (within last 12 months) or indicate they are “on-going”. Letters of guarantee for products are not required if own product e.g. “in-house grown” is being packed, although certificates for auditing are worth noting.
- U.S. Importers under the FDA’s Rule Foreign Supplier Verification Programs should have documented evidence that foreign suppliers follow requirements to verify that imported food meets U.S. safety standards.

Note that contracted auditee operations such as co-packers, harvest crews, etc., that use materials or services that are supplied and/or selected by their customers, i.e. not purchased by the auditee should still have copies of the documents noted in this question, for example, third party audits. For example, in the case of a harvest crew company that has some or all of their packaging provided by their contracting customer, the harvest crew should obtain copies of the relevant packaging supplier documents such as third-party audits from their contracting customer

Minor Deficiency (10 points) if:
- Single/isolated instance(s) of errors or omissions in the records.

Major Deficiency (5 points) if:
- Numerous instances of errors or omissions in the records.

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

Traceability and Recall

2.7.1: Is there a document that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?
Total compliance (10 points): The tracking system is shown in writing or in the form of a flow diagram and demonstrate the product tracking system that is used by the operation. The system should be able to show that it can trace back to the supplier(s) of materials, packaging, ingredients, processing aids, work-in-progress, etc., and show that the system can trace forward and indicate which customer(s) received products. This is usually accomplished by lot coding materials throughout a process and recording these lot codes at different points in the process. The traceability system should be in evidence when touring the operation and also when checking paperwork. The auditor should choose a finished product lot code to test the traceability system and have the auditee demonstrate how the code traces back to raw material supplier(s) and traces forward to the customer(s). The traceability system should include any product, ingredient, packaging and/or service related to the food safety that is outsourced.
The written traceability system should match the system that is being used in the field or production facility (as applicable). Recording batches of packaging is required for some products where packaging recalls might occur e.g. modified atmosphere packaging, juice bottles, etc. Recording packaging batches is not required for packaging that is not usually the cause of recall e.g. cardboard boxes. Cooling/Cold Storage & Storage and Distribution auditees that operate in a third-party capacity for their clients might have their own traceability system or have adopted their client(s'). Growers may have access to customer traceback system or create their own tracking seed/transplant to field/block code, input dates (water, fertilizer, pesticides) to harvest dates and onto facility. While either route is acceptable, if the individual client(s') traceability systems are used then the auditor will check each individual traceability system on site. Cooling/Cold Storage & Storage and Distribution operations should have a system that can traceback from outgoing lots back through their process to the incoming lots.

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

http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm#SEC201

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

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

Non-compliance (0 points) if:
- Fundamental failure of the written traceback system to reflect what is happening in the production facility.
- Numerous instances of either incorrect or missing elements of the traceability system that either limits or stops efficient tracing back or tracing forward of the production process. For example, not recording which lot codes are going to which customer thereby requiring that all customers are contacted in the case of a recall. The production step not properly recording what raw material lots are processed on a certain day.

- No written down traceability system.

2.7.2: Does the organization have a documented recall program including procedures, recall team roles and contact details, external contact listings, requirement for recall effectiveness checks, explanation of different recall classes and handling of recalled product?
Total compliance (15 points): To facilitate an efficient recall there should be a written procedure describing how to perform a product recall, recall team details (contact details, alternates, roles and responsibilities), referral to customer and supplier contact details, explanations of relevant laws e.g. product withdrawal, class of recalls (if USA is production or destination country), etc.
Documentation should include basic procedures and responsibilities, current facility contact listing with alternates and out of hour's numbers. Contact listings for customers and suppliers should also be part of the recall program, although these might be viewed as confidential (if so, then these listings must at least be referred to in the recall program). Listings should be reviewed regularly. An explanation of recall classes (Classes I, II, and III in the USA) should be in the recall program. Ideally contact details for the Certification Body, 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).

Auditees that operate in a third-party capacity e.g. contract copacker, storage operations, might not have supplier and customer contact details, but they should have their client(s) details as part of their recall program. Auditees that operate in a third-party capacity have the option of creating their own recall program or using those provided by their clients. If latter option is used, then the auditor will check each individual recall program on site. Growers may create their own recall program or be using their customer's recall system. If the latter option is used, then the auditor will check each individual recall program on site.

Potentially useful websites:
FDA Industry Guidance for Recalls, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls

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

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

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

2.7.3: Is testing of recall procedures (including trace back) performed and documented at least every six months and the company can demonstrate the ability to trace materials (one step forward, one step back) effectively?
Total compliance (10 points): Testing of recall procedures should be performed at least every six months. (For short season crops where the operation runs 6 months or less throughout the year, only one mock recall is required.) Where two mock recalls per year are required, one of the mock recalls should include the primary packaging as part of the exercise (not required for operations not using or handling primary packaging). The steps taken to conduct the mock recall, as well as the records utilized to demonstrate the program, are effective and should be consistent with the scenario identified. Documentation should indicate the date and time the mock recall was initiated, the product or material chosen, the scenario, amount of product produced, affected lot ID's (date code(s), lot code(s), etc.), amount located, percent located, time product was located and time mock recall was completed. Scenario should be varied to provide experience in a range of conditions; some examples include customer complaints for foreign materials, test results (buyer, government, in-house) detecting issues such as pathogens, pesticide residues, etc. Mock recall documentation should include copies of documentation that support the traceback scenario from the affected finished good lot through to the production run(s) affected and therefore showing if other lots are affected and which other customers might have received affected lot(s).

Checks should be carried out to ensure that contact details exist for the affected customers. Documentation should also include any "lessons learned" from the mock recall process. GAP related organizations (for example (farm and crew)) operations may create a mock scenario where they receive information from a client indicating there is a problem that warrants a recall. An alternate GAP mock scenario is that the grower is informed of a problem with an input that may warrant a recall e.g. some form of crop contamination. They should show how they know which lots were affected and the associated records of agricultural inputs, they should also be able to show who the field was harvested by and where the harvest crops were sent to. If an Organization (for example, a grower) opts to use a customer's recall program to meet the requirements of this question then the Organization can also use a valid mock recall from the customer that shows that the recall system has been properly tested. This mock recall would only cover the relationship between the Organization and the customer who has provided the mock recall example.

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 culled and rejected in some situations. Auditees are not expected to call or otherwise contact any suppliers or customers when carrying out mock recalls. If a live (real) recall has occurred in the last year, then this can be used to meet the requirements of this question, but the documentation details noted above should be in place.

Minor deficiency (7 points) if:
- Three or less elements of the mock recall are missing (e.g., supporting documentation, primary packaging material)
- Five percent or less of product was not located.
- A few gaps noted in the logic of the traceback documentation
- Not noting "lessons learned" from mock recall exercise (if there are any)
- Total time to complete mock recall took longer than 2 hours but not more than 3 hours.

Major deficiency (3 points) if:
- Four or more elements of the mock recall are missing (e.g., supporting documentation, primary packaging material)
- Mock recall scenario is not varied to provide experience in a range of conditions
- More than five percent of product was not located.
- Lacking documentation that proves how the traceback and recall system identified all affected items and customers.
- Total time to complete mock recall took more than 3 hours.
- Only one mock recall was performed in the prior 12 months.

Non-compliance (0 points) if:
- Mock recall has not been performed within the prior 12 months.
- Mock recall was initiated, but could not be completed

Food Defense

2.8.1: Does the company have a documented food defense plan based on the risks associated with the operation?
Total compliance (5 points): The operation should have a documented food defense plan that outlines the organization's security controls based on a written vulnerability assessment of risks associated with the operations. This plan should include Good Agricultural Practices and/or Good Manufacturing Practices, as well as a written risk/vulnerability assessment, and controls for the identified risks.

The document should include relevant food defense risks such as building access, personnel, visitors, contractors, computers, raw material receipt (raw materials, product and packaging), trucks (incoming and

outbound), water sources, storage areas for product, materials, chemicals, production areas, shipping areas, etc. There may also be a requirement to ensure that suppliers have proper food defense programs. The food defense plan creation should also meet any national or local regulations (including management oversight and approval. Based on this assessment, the operation should create monitoring, corrective action and verification procedures (where appropriate). These procedures should note the recording requirements of the food defense plan. The plan should be reviewed at least once every 12 months.

Additional resources:
https://www.fsis.usda.gov/wps/wcm/connect/9fb1c725-4aae-4e06-b56e-217e0fc08f43/Self_Assessment_Checklist_Food_Security.pdf?MOD=AJPERES
https://www.fda.gov/food/food-defense-tools-educational-materials/food-defense-plan-builder

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or omissions in the risk assessment or food defense plan.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the risk assessment or food defense plan.

Non-compliance (0 points) if:
- Food defense plan has not been documented.
- There is no risk assessment.

2.8.2: Is there a current list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies?
Total compliance (3 points): The operation should have a current list of emergency contact phone numbers available 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 has not been updated in more than a year (less than two years).

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the list.
- The list has not been updated in more than two years.

Non-compliance (0 points) if:
- A list of emergency contact phone numbers for management, law enforcement and appropriate regulatory agencies has not been documented.

2.8.3: Are visitors and contractors to the company operations required to adhere to food defense procedures?
Total compliance (3 points): All visitors and contractors should be required to abide by the operation's food defense policies, including wearing appropriate identification. The rules and policies should be clearly stated in relevant languages. This requirement may be evidenced by signing a log on arrival at the operation, where the requirements are available for review, where they are agreeing to meet the company visitor and contractor food defense requirements.

Minor deficiency (2 points) if:
- Single/isolated instance(s) that visitor(s) and contractor(s) are not being required to comply with the operations' food defense policies.

Major deficiency (1 point) if:

- Numerous instances of visitors and contractors not being required to comply with the operations' food defense policies.
- Policy is not in the relevant language(s) of the visitors/contractors.

Non-compliance (0 points) if:
- The company does not have evidence of a requirement for visitors and contractors to comply with the operations' food defense policies.
- Fundamental failure of visitors and contractors not being required to comply with the operations' food defense policies.

Chemical Files

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

CDMS Label / SDS Information, http://www.cdms.net/manuf/manuf.asp
SDS Databases, http://info.nsf.org/USDA/Listings.asp?Company=N04391

Minor deficiency (3 points) if:
- SDS 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 SDS's for a chemical that is currently being used.
- Limited access to SDS's for workers using the chemicals.

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

Non-compliance (0 points) if:
- No SDS are on file.

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

Minor deficiency (3 points) if:

- Single/isolated instance(s) of missing specimen label(s) for a decanted chemical(s) that is/are currently being used.

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

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

2.9.3: Are there chemical inventory logs for chemicals, including pesticides, fertilizers and cleaning and sanitizing chemicals?
Total compliance (3 points): Chemical inventories should be on file. Chemicals within the scope of this question include pesticides, fertilizers, cleaners and sanitizers i.e. sanitation chemicals and food contact chemicals, such as chlorine for water flumes, hydrocoolers, etc., and any post-harvest chemicals (e.g., fungicides, wax, ethylene). This also applies to fertilizers that are used in sprout operations. Primary information in the product inventory includes: the product or chemical names, container volumes, number on hand, and location of containers. Inventory by storage area/type of chemical is optimal. The inventory should take into account the arrival of new stocks and any discrepancies should be explained. Minimum frequency for inventory checks should be monthly and a copy should be maintained separate from the chemical storage location(s).

Minor deficiency (2 points) if:
- Single/isolated instance(s) of missing chemical usage logs and/or inventories.
- Single/isolated instance(s) of omission(s) or error(s) in the chemical usage logs and/or inventories.
- Single/isolated instance(s) of new deliveries not being accounted for.
- Single/isolated instance(s) of minimum inventory frequency not being maintained (if usage logs are not being utilized).

Major deficiency (1 point) if:
- Numerous instances of missing chemical usage logs/inventories.
- Numerous instances of omissions or errors in the chemical usage logs and/or inventories.
- Numerous instances of new deliveries not being accounted for.
- Numerous instances of minimum inventory frequency not being maintained (if usage logs are not being utilized).

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

2.9.4: Are there specific Standard Operating Procedures (SOPs) for the monitoring/ testing and changing of recirculated and batch water systems (e.g., dump tanks, flumes, hydrovacuums, hydrocoolers, etc.) and testing of single pass water systems?
Total compliance (10 points): Water systems should have specific SOPs that describe the process of changing the water, performing and recording anti-microbial sanitizer strength testing (including parameters, testing frequency, methodology and corrective action requirements), and methods and monitoring procedures for measuring build-up of organic material (turbidity) in recirculated and batch water systems and monitoring the water temperature and pH (if applicable). Water should be changed when it is dirty or when switching products. There should be documentation that validates the water changing frequency and water testing frequency. Minimum frequency for water changing is at least daily; records of changes are kept. Water may be used for longer if a validated regeneration system (e.g., a water pasteurization/filtration system) is being used. The water temperature should be appropriate for the products and processes being performed. For single pass water systems, there should be a specific SOP that describe the performing and recording anti-microbial sanitizer strength testing (including parameters, testing frequency, methodology and corrective action requirements). Measuring total chlorine is not viewed

as acceptable for recycled water systems. Single pass systems must have a stated anti-microbial level. For chlorine, the criteria should be ≥10ppm free chlorine. Other anti-microbials include peracetic acid, etc. This question is not applicable in dry operations.

https://www.canr.msu.edu/news/turbidity_in_post_harvest_wash_water_monitor_and_change_when_needed
Gomez-Lopez, V.M., Lannoo A.S., Gil, M.I. Allende, A., 2014. Minimum free chlorine residual level required for the inactivation of *Escherichia coli* O157:H7 and trihalomethane generation during dynamic washing of fresh-cut spinach. Food Control 42, 132-138.
Haute, S.V., Luo, Y., Bolten, S., Gu, G., Nuo, X., 2020. Survival of *Salmonella enterica* and shifts in the culturable mesophilic aerobic bacterial community as impacted by tomato wash water particulate size and chlorine treatment. Food Microbiology 90, 103070.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions within the SOPs for water changing/testing relating to water and ice systems.
- Single/isolated instance(s) of errors or omissions in the validation documentation for water changing and testing relating to water and ice systems.

Major deficiency (3 points) if:
- Numerous instances of errors or omissions within the SOPs for water changing/testing relating to water and ice systems.
- Numerous instances of errors or omissions in the validation documentation for water changing and testing relating to water and ice systems.

Non-compliance (0 points) if:
- SOPs for water changing/testing relating to water and ice systems do not exist.
- SOPs do not address the frequency of water changing and/or testing.
- Water changing is occurring less than daily and there is not a validated regeneration system used.
- There is no validation documentation for water changing frequency and/or water testing frequency.

Pest Control Documentation

2.10.1: Is there a documented pest control program, detailing the scope of the program, target pests and frequency of checks, including a copy of the contract with the extermination company (if used), Pest Control Operator license(s)/training (if baits are used), and insurance documents?
Total compliance (15 points): There should be a documented pest control program in place detailing scope of the program, target pests and frequency of checks. The program should include requirements for at least an annual pest control survey based on preventive IPM practices of interior and exterior areas. If performed in-house, the pest-control operators or equivalent should be registered, licensed or have documented formal training (if regulation does not require certification or registration). Note that the person's training and/or license should specify structural pest control or equivalent or have documentation to show that license includes structural pest control training if not specified on license. 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 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, such as evidence of the training and/or license for one pest control operator.
- Numerous omissions in the written program.

Non-compliance (0 points):
- More than two pieces of documentation are not in place or are not current.
- There is no documented pest control program.
- Written program does not resemble what is happening in practice at all.
- There is no evidence of the training and/or license of the pest control operator(s).

2.10.2: Is there a schematic drawing/plan of the facility, showing numbered locations of all pest monitoring devices (e.g., rodent traps, bait stations, insect light traps, etc.) both inside and outside the facility?
Total compliance (10 points): A schematic drawing or trap map is on file, current and details internal and external traps. All devices (e.g., tin cats, Ketch-Alls, bait stations, glue boards, insect light traps, electronic fly killer units, etc.) should be numbered and clearly identified on the map. The numbers should match what is in the facility. The document should be accurate, dated and should show the type of device.

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

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

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

2.10.3: Are service reports records including IPM observations, created for pest control checks detailing inspection records, application records, and corrective actions of issues noted (in-house and/or contract)?
Total compliance (10 points): Service reports from the contract pest control company should be available for review if pest control is contracted out. In-house inspection records should be available for review if pest control is conducted in-house. Records should include services performed, date of service, chemicals used (see below), signs of activity with corrective actions, and trend reports. Match Pest Control Operator (PCO) signature on service logs with licenses/certificates on file. Records should show when electric fly killing unit bulbs are changed. Where the contracted pest control has left their client details of an issue or a recommendation (e.g., excessive gap at the bottom of a door), then the client should acknowledge the issue(s) and note corrective action completion(s) where relevant. Specimen labels and SDS sheets for chemicals used are scored under section 2.9.1.
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

- Corrective actions
- Trend reports

National Pest Management Standards, Pest Management Standards for Food Plants
http://npmapestworld.org/default/assets/File/2016%20Pest%20Management%20Standards%20for%20Food%20Processing-Electronic.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-compliance (0 points) if:
- No service reports.
- Fundamental failure to maintain service reports.
- Fundamental failure to record chemical use details.
- Fundamental failure to complete corrective actions.
- There are no records of IPM survey observations within the last 12 months

Operation Monitoring Records

2.11.1: Are there inspection records for incoming goods (e.g., raw materials, ingredients and packing materials)?
Total compliance (5 points): There should be records showing incoming materials are being received as per documented procedures and from approved suppliers. Incoming goods should be inspected for visible issues (e.g., decay, pests, foreign materials (contamination), odor, damage, tampering, and labeling issues), any other safety/food security related issues, and to ensure that the materials are appropriate for use. Packaging should be checked routinely and records can be maintained by exception, where issues are rare (e.g., as deviation incidents and recorded as unusual occurrences). Inspection data for products are not required if “own product” (e.g., in-house grown commodity), is being packed.

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

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

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

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

2.11.2: Are there inspection logs on incoming trailers (and other forms of transport) for rodents and insects, cleanliness, holes and temperature control of the trailer (for food requiring temperature control for safety and/or as required per buyer specifications)?
Total compliance (10 points): There should be written records (separate log or on bill of lading, etc.) of trailer (a.k.a. truck body, lorry body) inspections. Designated personnel should be responsible for inspecting the incoming vehicles, following any special documented instructions and specifications communicated by the shipper/supplier of the materials, 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 where relevant any corrective actions.
- Inspection records when receiving food materials that are temperature controlled for safety reasons should show that the transport temperature control equipment was working properly, temperature settings were set correctly, product was received at the required temperature and that were no signs of temperature abuse in transit.

Not applicable if flatbeds are used. Truck cleaning certificates are acceptable as sanitation completion records for in-house trucks in question 2.12.4 and 2.12.6 but do not replace the inspection log requirements of this question. Packaging supply trucks can be recorded by exception and are 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-compliance (0 points) if:

- No records.
- Failure to maintain records.

2.11.3: Are there records for the necessary process monitoring activities (e.g., pH, water temperature vs. product temperature, metal detection, X-ray, labeling, heating processes, reduction/kill step processes, postharvest pesticides (e.g. fungicides), control of water activity, drying, etc.) showing, for example, the monitoring frequencies, results and where necessary the corrective actions?
Total compliance (10 points): There should be appropriate logs in use for all process monitoring activities, including postharvest treatments. Processes include sterilizing, irradiating, pasteurizing, cooking, blanching, freezing, refrigerating, controlling pH, or controlling aw. Any process and/or chemicals used should meet existing legal requirements (including residue levels), used as per label requirements and meet export requirements (as applicable). These may be combined on a single log or on multiple logs. The records should show process control parameters are being met and detail corrective actions when the process is outside the established limits. Corrective actions to also include root cause analysis and preventive actions (where relevant). If monitoring is not continuous, then the amount or frequency of monitoring should be sufficient to verify the process is in control; **auditee should be able to support monitoring frequency being used**. Any issues with monitoring frequency for metal detection is scored in Q 1.5.8. Where produce is immersed in water and has been shown to be susceptible to microbial infiltration from water, the water temperature differentials during immersion should be controlled in accordance with current regulation, industry guidelines or best practices. For example, for tomatoes FDACS, USDA and the University of Florida-GAPs require postharvest water to be maintained at temperatures 10ºF (5.6ºC) or higher above the fruit pulp temperature, and water temperature should be monitored at least hourly.

Note, product washing, metal detection, etc., are often detailed further in the HACCP and/or Preventive Controls questions.

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

Major Deficiency (3 points) if:

- Numerous instances of omissions or incorrect data in the records and corrective action details.
- Numerous omissions or errors in the frequency of monitoring.
- Numerous instances of incorrect parameters being monitored.
- No supporting documentation of the monitoring frequency being used.

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

2.11.4: Are there records (with corrective actions) that show anti-microbial (e.g., free chlorine, ORP, peroxyacetic acid) strength testing of product contact water and ice solutions prior to start up and throughout the production runs?
Total compliance (10 points): Product contact water and ice production systems using anti-microbial agents e.g. hypochlorite (chlorine), aqueous chlorine dioxide, peroxyacetic acid (PAA), ozone should have records showing that the strengths of the solutions are within parameters. Recycled/reused water systems (for example, flumes, wash tanks, ice injectors, hydrovacuums, etc.) and single pass systems (e.g., spray bars) should be using an approved anti-microbial. Recirculated/batch water systems should be checked by measuring the "free anti-microbial" as opposed to bound microbial e.g. testing for free chlorine as opposed to total chlorine; pH should also be measured (2.11.3) when using chlorine. In single pass systems it is acceptable to measure total chlorine (as per legislation). See links below for data and research on threshold levels for free and total chlorine, chlorine dioxide, ORP, peroxyacetic acid (PAA) and pH level parameters. Other anti-microbials e.g. ozone, electrolyzed water, etc., should meet manufacturer recommendations (**auditee should have proof of parameter derivation**) and be approved for use in wash water. Frequency of checks should be relative to the stability of the system, but at least pre-start, then at a frequency that ensures the availability of the anti-microbial is adequate while the system is running. As a minimum guide, a fresh-cut facility should be checked every 30 minutes, whereas whole washed product water anti-microbial levels should be checked hourly. Corrective actions should also be recorded. These steps may be covered in a HACCP plan (sanitizing of flume water). Any water treatment (e.g. chlorine, reverse osmosis, UV light, active carbon) at the source (e.g. well, canal) should be monitored and records available. Where out of specification results are recorded, there should be corrective action records, including root cause analysis and preventive actions (where relevant).

Journal of Food Protection, Vol. 74, No. 3, 2011, Pages 352–358
http://edocket.access.gpo.gov/cfr_2009/aprqtr/pdf/21cfr173.315.pdf
http://archive.onfarmfoodsafety.org/wp-content/uploads/2011/05/Chlorination-of-Water-for-Fluming-and-Cleaning-Fresh-Fruits-and-Vegetables-and-Cleaning-Equipment.pdf
UC Davis, http://ucce.ucdavis.edu/files/datastore/234-406.pdf
UC Davis, http://ucanr.edu/sites/GAP/news/Water_Disinfection/
https://lgma.ca.gov/news/metrics
https://producesafetyalliance.cornell.edu/resources/general-resource-listing/

Minor deficiency (7 points) if:
- Single/isolated instance(s) of records showing solution strength out of parameters without adequate documented corrective actions.
- Single/isolated instance(s) of errors or omission in the records.

- Single/isolated instance(s) of total chlorine being recorded when free chlorine should have been recorded e.g. in chlorinated recycled water systems
- Single/isolated instance(s) of checks not carried out at the required frequencies.

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

Non-compliance (0 points) if:
- Water/ice testing is not being recorded.
- Recorded solution strengths consistently out of parameters i.e. an unstable system (even if documented corrective actions exist).
- Fundamental errors and omissions in the records.
- Total chlorine has been recorded throughout the system, when free chlorine should have been recorded e.g. in chlorinated recycled water systems.
- Frequencies of checks consistently do not meet requirements of prior to start up and throughout the production runs.
- No evidence of water anti-microbial parameters has been stated/ incorrect parameters being used.
- Single pass water system is in use without anti-microbial being used. **The auditor should consider whether to apply Q 1.4.5 and score an automatic failure in view of the risk of cross contamination.**
- Recycled/reused water system is in use without an anti-microbial being used. **The auditor should consider whether to apply Q 1.4.5 and score an automatic failure in view of the risk of cross contamination.**

2.11.5: Are there records (with corrective actions) that show anti-microbial strength testing of hand/foot/tool dip stations, and are there stock check and replenishment records for gel and spray stations?
Total compliance (3 points): The company should have a log sheet for evaluating the hand and/or foot and/or tool dip (where appropriate) stations solution strength at mixing and at a frequency sufficient to ensure adequate anti-microbial strength throughout the day. The log sheet should include target anti-microbial concentration (ppm) and frequency of verification. The figures recorded must match the type and graduation of the testing system being used. An omission would include where an out of spec concentration is recorded but there is no record of corrective actions. Foot dips are required in processing audit operations (see 1.5.14). Any operation with hand, foot or tool dips is required to keep monitoring records (uncontrolled dips are a hazard). Where hand gel or spray stations using prepared solutions are used, there should be monitoring logs indicating stations are regularly checked to confirm units are stocked and operational.

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

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

Non-compliance (0 points) if:

- No records.
- Failure to maintain records

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

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

Minor deficiency (2 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the records

Non-compliance (0 points) if:

- There are no records for tool accountability.
- Production hand tools do not remain under the control of the company e.g. taken home by workers.

2.11.7: Is there a pre-operation inspection log?

Total compliance (10 points): Food handling departments are inspected before operation begins. Where an operation has multiple shifts, there should be pre-operational inspections for each shift. This should be a start-up check of all potential issues not a repeat of the daily sanitation completion record which is covered in 2.12.6.

The daily pre-operational check should include:

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

Basically, a last minute quick check that all is well and the production can start. Use of rapid testing, e.g., ATP measuring equipment, is something an auditor should note in the comments and if used, auditor must check to ensure that the results and corrective actions are being recorded correctly (see question 2.12.11).

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.
- Persistent repetition of corrective action without long-term solution.

Non-compliance (0 points) if:

- No records.
- Failure to maintain records.

2.11.8: Is there documented evidence of the internal audits performed, detailing findings and corrective actions?

Total compliance (15 points): There should be records of the internal audits performed at each operation, with the frequency defined in the internal audit program. Frequency depends on the type and size of the operation; auditor's discretion applies. Processing plants should have at least a monthly frequency. Packinghouses, coolers and storage operation ideally have a monthly frequency, but at least a quarterly frequency. Food safety documentation should be audited at least quarterly.

The records should include the date of the audit, name of the internal auditor, justification for the answers, (not just checked √ or all Y/N), detail any deficiencies found and the corrective action(s) taken. An audit checklist (ideally PSA) should be used that covers all areas of the PSA audit, including production area, storage, worker amenities, external areas, worker practices, production processes, documentation, etc. No down score if another audit checklist is used, as long as all areas are covered. See 4.4.1 regarding internal audit program requirements.

Minor Deficiency (10 points) if:
- Single/isolated instance(s) of follow up/corrective actions not noted.
- Single/isolated instance(s) of incomplete answers or missing records.
- Single/isolated instance(s) of areas/issues missing on the inspection.

Major Deficiency (5 points) if:
- Numerous instances of follow up/corrective actions not noted.
- Numerous instances of incomplete answers 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.

Non-compliance (0 points) if:
- Fundamental failure to maintain records.
- Fundamental failure to complete inspection records with detailed responses.
- No documented internal audits have been performed.

Maintenance & Sanitation Files

2.12.1: Does the facility have a preventative maintenance program and a documented schedule?
Total compliance (10 points): There should be a formal preventative maintenance program for the whole operation, including production and ancillary equipment, facility structure and fittings. Equipment includes for example, production line equipment, cooling equipment, compressed air equipment, water treatment equipment, etc. The maintenance program should have a schedule showing routine inspections, lubrications, part replacements etc. at appropriate frequencies (daily, weekly, monthly, etc.). There should be preventative maintenance completion records. All records are kept on file and organized in an easily retrievable manner (including any database systems). In complex operations (e.g. juice processors), auditor can choose specific pieces of equipment to check the planned maintenance schedules and completion records for the chosen pieces of equipment. Use of predictive maintenance systems are also acceptable for this question.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions in program,
- Single/isolated instance(s) of pieces of equipment missed off the schedule.

Major deficiency (3 points) if:
- Numerous instances of errors or omissions in program.
- Numerous instances of pieces of equipment missed off the schedule.

Non-compliance (0 points) if:
- No program.

- Fundamental failure to maintain records.

2.12.2: Are there logs of maintenance work and repairs and are they signed off when work is completed?
Total compliance (10 points): There should be a log for repairs/ maintenance service orders/ work orders and completion of work. This log may include: date/ time, targeted equipment/ area, reason for service required, who is requesting, who is being informed, observations; date & signature when repair is completed. Logs are kept on file in an easily retrievable manner.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of incomplete records.

Major deficiency (3 points) if:
- Numerous instances of incomplete records.

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

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

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

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

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

2.12.4: Is there a written cleaning schedule (Master Sanitation Schedule) that shows what and where is to be cleaned and how often?
Total compliance (10 points): The company should have a master sanitation program that covers the entire area of the facility including equipment (e.g., production equipment (food contact and non-food contact), pallet jacks, fork lifts, carts, floor scrubbers, trash cans, cooling equipment (evaporators, cooling coils, drip pans, etc.), lift trucks and company owned trailers, etc.). The schedule should state what is to be cleaned and when (how often). Areas should include where applicable, processing, packing, product storage, dry storage, maintenance areas, 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 on equipment. Note that all cleaning mentioned

on the schedule should be covered somewhere in the cleaning procedures and also on the sanitation logs. Schedule should be kept on file in an easily retrievable manner.

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

See the Preventive Controls Addendum regarding sanitation preventive controls (where relevant).

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

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

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

2.12.5: Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the facility and all equipment?
Total compliance (10 points): There should be written cleaning and sanitation procedures for all equipment (food contact, non-food contact, cooling equipment, etc.), areas (floors, walls, overheads, etc.), internal transport vehicles and in-house owned trailers that should be cleaned and sanitized on a regularly scheduled basis, based on written Sanitation Standard Operating Procedures (SSOPs). There should be SSOPs covering the cleaning and sanitizing operations noted in the master sanitation schedule. SSOPs should also be created for dry cleaning operations (where applicable). This includes production line equipment (named equipment and equipment parts and surfaces), floors, walls, light covers, pipes, ceilings, evaporators, cooling coils, drip pans, drains, drain lines and reservoirs, internal transport equipment (e.g. forklifts, Bobcats where scoops come into contact with ingredients such as ice, pallet jacks, trolleys, floor cleaners, etc.). In-house delivery and shuttle trucks should be included in sanitation schedules, have SSOPs and cleaning records. A surface cannot be properly sanitized unless it is effectively cleaned. Use of a sanitizer is required unless there are justified exceptions that are fully documented. Procedures should respect the label (e.g. rinse/no-rinse, sanitizers, dwell time, etc.) and match operations noted on the master sanitation schedule (2.12.4). These procedures should include:
- Responsibility for cleaning with cleaning methods
- Item/area to be cleaned
- Frequency of cleaning
- Safety precautions (tag outs, worker safety with respect to chemicals, etc.)
- Chemical (name, dilution and water temperature requirements, 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, including solution temperature, water pressure, dwell times, any disassembly/reassembly instructions and cleaning verification procedures
- 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

- Responsible person
- Logs/records of cleaning and responsibility for verification
- Verification procedures (visual, ATP, microbial) and acceptance criteria

https://porkgateway.org/resource/industry-guidelines-to-prevent-contamination-from-listeria-monocytogenes/

See the Preventive Controls Addendum regarding sanitation preventive controls (where relevant).

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

2.12.6: Are cleaning and sanitation logs on file that show what was done, when and by who?
Total compliance (10 points): The company has sanitation logs that cover all areas of the facility (e.g., production areas, storage areas, break areas, restrooms, maintenance, etc.), detailing walls, floors, overhead and all equipment (e.g., production equipment (food contact and non-food contact), pallet jacks, forklifts, carts, floor scrubbers, trash cans, cooling equipment, lift trucks, company owned trailers, etc.). Logs are kept on file in an easily retrievable manner. The logs should be cross-checked against the master sanitation program (2.12.4). Logs of infrequent cleaning should be checked. Logs should include:
- Date
- List of areas/equipment that were cleaned and sanitized
- The individual accountable who signed-off for each task completed
- Verification of task completed
- Any deviations against the set SSOPs

Minor deficiency (7 points) if:
- Single/isolated instance(s) of incomplete records, discrepancies against the master sanitation schedule or other omissions.

Major deficiency (3 points) if:
- Numerous instances of incomplete records, discrepancies against the master sanitation schedule or other omissions.
- Missing infrequent cleaning logs.

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

2.12.7: Are there records showing verification of cleaning and sanitizing chemical concentrations?
Total compliance (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, or as recommended by disinfectant supplier). Solutions that are too weak will be ineffective, while

those too strong may be harmful to workers, 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. N/A if no mixing is taking place on-site e.g. where pre-mixed chemicals are bought and used.

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

Major deficiency (1 point) if:
- Numerous instances of incomplete records.

Non-compliance (0 points) if:
- No records.
- Fundamental failure to maintain records.

2.12.8: Are there documented procedures and completion records for clean-in-place (CIP) activities (e.g., cleaning re-circulating water systems such as washing flumes, ice injectors, hydrocoolers, chilled water systems, ice makers, etc.), where applicable?
Total compliance (10 points). Where operations utilize clean-in-place (CIP)* e.g. as part of the process of cleaning re-circulated flume system pipes and pumps, there should be detailed procedures in place. CIP activities should be monitored to ensure CIP process is effective and not a source of contamination to product. The CIP procedure should be detailed and include:
- Identity of equipment to be cleaned
- Frequency of cleaning
- Safety precautions (tag outs, personnel safety with respect to chemicals, etc.)
- Chemical name, dilution requirements and concentration testing
- 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, including water pressure, solution temperature, dwell times, etc.
- Detailed cleaning and sanitation methods following the standard order:
  1. Dry clean (note equipment used)
  2. Rinse (note equipment used)
  3. Clean (note equipment used, any dwell times)
  4. Rinse (note equipment used)
  5. Sanitize (note equipment used and any dwell times)
  6. Rinse (if label requires)
- Special instructions with respect to cleaning
- Assigned responsibility for each task
- Logs/records of cleaning
- Verification procedures (visual, ATP, microbial) and acceptance criteria.
- Required temperatures for chemical dilutions used
- Required flow rates and dwell/cycle times for the CIP process
- Specific details on how re-circulated chemicals are drained and rinsed out of the CIP system (so avoiding contamination issues)

The chemical label details, equipment manufacturer's instructions and company safety rules are to be followed. Records of CIP cleaning should be maintained.
*Clean In Place (CIP) – an equipment cleaning procedure that occurs with all the equipment left "in place" and a cleaning program of some kind occurs. This procedure is sometimes part of larger procedure where equipment is partially cleaned in some way while still assembled and then broken down for a deeper

clean before being assembled again and then “flushed” through (clean in place) by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse and sanitizing solution onto or over equipment surfaces that require cleaning. CIP does not include the cleaning of equipment such as band saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a CIP system.
https://www.fda.gov/media/110822/download
http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf

Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors and omissions within the SSOPs.
- Single/isolated instance(s) of omission(s) in procedure or records for a piece of equipment or facility area.

Major deficiency (3 points) if:
- Numerous instances of errors and omissions within the SSOPs.
- Numerous instances of omissions in procedure or records for a piece of equipment or facility area.

Non-compliance (0 points) if:
- No written procedures have been developed.
- There are no records.
- Procedures exist but they do not reflect what actually occurs.

2.12.9: Are there sanitation logs on file indicating that floor drains are cleaned on a regular basis (minimum daily in wet and fresh-cut production areas)?
Total compliance (10 points): There is a log that indicates that floor drains are cleaned on a daily basis in wet storage and production areas. Auditors should use their discretion when auditing dry facilities, but the minimum drain cleaning frequency should be weekly.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of incomplete records or omissions.

Major deficiency (3 points) if:
- Sanitation schedule or log does not indicate that floors drains are cleaned; but sanitary condition of floor and drains is checked every day on the pre-operation inspection.
- Numerous instances of incomplete records or omissions.

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

2.12.10: Are there records showing cooling units are maintenance serviced and cleaned at least every 12 months or more frequently as required?
Total compliance (10 points): Records should be available to verify that the cooling units are serviced and cleaned on a scheduled basis. Records might include in-house sanitation records, maintenance records and/or contractor records/invoices. Note contracts, invoices etc., must clearly state the services provided as per any other record. A cleaning and servicing at least once in the last 12 months is a minimum requirement, but usually frequency is higher, especially in high humidity/wet operations and also with chiller units that are known to become dirty at a faster rate than others, e.g. next to open doors.

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

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

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

2.12.11: Is there a routine program and written procedure to verify sanitation effectiveness using rapid post sanitation checks (e.g., ATP measurements, allergen specific proteins)?
Total compliance (15 points): Rapid post sanitation checks (e.g., ATP (adenosine tri phosphate)) testing provides an instant indication of the hygiene status of product contact surfaces after cleaning and/or prior to start up by measuring the ATP from food residues, bacteria, yeast, mold - either living or dead (i.e. all organic matter) so giving a measure of cleaning effectiveness. There should be a procedure detailing sampling strategy, standardized sampling technique including location of sample and time of sampling and there should be pass/fail parameters. The detection of non-specific ATP provides a reliable quick indicator of cleaning efficiency and hygienic status (therefore a good pre-operational tool) but for the purpose of this audit, it is not a replacement for specific microbiological testing or for ensuring that the allergen specific proteins have been removed from a production surface. This question application is similar to that laid out in 2.14.1 and operations may choose to include ATP under 2.14.1 documentation. If there are no food contact surfaces, or products/processes are deemed not applicable using the 2.14.1 criteria, then N/A may be scored. Procedures for use should be documented, validated for use with product being run, in line with any manufacturer recommendations and should detail sampling strategy, standardized sampling technique, including location of sample and time of sampling, and there should be clear threshold parameters. Records of routine testing (at least daily in processing operations and weekly in others) and corrective actions should be maintained.

http://www.foodqualityandsafety.com/article/atp-bioluminescence-moves-mainstream/

Minor deficiency (10 points) if:
- Single/isolated instance(s) of equipment being missed off the swabbing schedule, incorrect frequency.
- Single/isolated instance(s) of a record or records showing high counts relative to threshold but no corrective action documentation.
- Single/isolated instance(s) of errors or omissions in the procedure.

Major deficiency (5 points) if:
- Numerous instances of equipment being missed off the swabbing schedule, incorrect frequency.
- Testing is sporadic and not on a scheduled basis.
- Numerous records showing high counts relative to threshold but there are no corrective actions documented.
- Numerous instances of errors or omissions in the procedure.

Non-compliance (0 points) if:
- There are no records of equipment ATP testing.
- There is no procedure for sampling strategy, technique or threshold limits.

2.12.12: Is there a documented glass and brittle plastic management procedure (including company glass and brittle plastic policy, glass breakage procedure and where necessary a glass register)?
Total compliance (10 points). There should be a written glass and brittle plastic policy and procedure, which should state:
- Where glass and brittle plastic is prohibited and where glass and brittle plastic is allowed.
- Policy should state how workers should report missing or broken spectacles or contact lenses and to whom they report the issue.
- If certain glass and brittle plastic 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 GMP e.g. allowing glass drinking bottles into production areas, unprotected glass light bulbs. Glass register items should be checked on a routine basis (at least monthly) to ensure they are not damaged/cracked etc. Checks should be documented.
- Glass breakage procedure including requiring recording what happened, recording what happens to potentially affected product, recording future preventative actions and especially where to record the incident details e.g. in the NUOCA log.
- Clean-up procedure after glass or brittle plastic breakage should indicate what equipment to use and include boot and tool checks/decontamination procedures to ensure broken glass or brittle plastic is not unintentionally transported out of the area.
- A no glass policy in production, storage or maintenance areas should be the target.

Minor deficiency (7 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 (3 points) 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-compliance (0 points) if:
- No policy exists
- There has been a glass breakage, but no records exist.
- Fundamental failures to check glass register items on a routine basis.

Worker Documentation

2.13.1: Are there records of new worker food safety (GMP) orientation training (with topics covered and attendees) and are all workers required to sign the company's food safety hygiene and health policy?
Total compliance (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 (including workers in departments such as production, storage, sanitation, maintenance, sales team, etc.) in the language understood by the workers. Materials to be given to new hires after training should be in the relevant language(s) and cover key GMP rules including hand washing, eating/drinking, smoking, specific clothing rules, cosmetic use rules, foreign material issues (including jewelry, no sequins, studs, false finger nails, finger nail polish, false eyelashes, eyelash extensions, badges, etc.), cuts/wounds and illness rules, etc. Food safety training should be given to all workers working in the production and storage areas; this includes temporary workers and agency workers. All workers 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 worker. Training provided and associated records should meet local and national regulations.

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 occurring, not before starting to work but within the first week.

- Single/isolated instance(s) of workers not being trained or not signing a document stating that they will comply with the operations' personal hygiene and health policies

Major Deficiency (3 points) 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 workers not signing a document stating that they will comply with the operations' personal hygiene and health policies.
- Training occurring, not before starting to work but within the first month.
- Numerous instances of workers not being trained.

Non-compliance (0 points) if:
- No records of training or workers not being trained.
- No specific orientation given or given after the worker has been working for more than one month.
- Failure to maintain records.
- The company does not have a document for workers to sign stating that they will comply with the operations' personal hygiene and health policies.
- Fundamental failure of workers to sign a log stating that they will comply with the operations' personal hygiene and health policies.

2.13.2: Are there logs of ongoing worker food safety education training, including topics covered, attendees, etc.?

Total compliance (10 points): The auditee should have logs of ongoing food safety educational training with clearly defined food safety topic(s) covered, trainer(s) and trainer details, who has been trained, and material(s) used/given. There should be logs of workers 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 workers 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, foreign material control, etc., maybe note issues found in recent internal and external audits (e.g., wearing beard nets, jewelry issues). Workers should also be trained on any new practices and/or procedures and when any new information on best practices becomes available. There should be records of training with date of training, clearly defined topic(s) covered, trainer(s), material(s) used/given and the names and signatures of workers trained. Training provided and associated records should meet local and national regulations.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of logs having errors or incomplete information e.g. missing one of the following: training topic, trainer or material information.
- Training has occurred but on a few occasions full attendance logs have not been kept and/or not all personnel were covered.

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

Non-compliance (0 points) if:
- 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.

2.13.3: Is there a documented training program with training logs for the sanitation workers, including best practices and chemical use details?
Total compliance (5 points): Sanitation training should ensure that the workers understand the importance of proper sanitation, cleaning efficacy, how to use the cleaning chemicals and how to understand Sanitation Standard Operating Procedures. A job shadowing training program is ideally in place for new sanitation workers with sign-off of tasks recorded. Unless sanitation workers attend regular food safety trainings (scored under 2.13.1 and 2.13.2), sanitation training should also include elements of food safety training pertinent to sanitation operations (e.g., hand washing, restroom use, foreign material, etc.). (Cross reference with 4.1.1 requirements). Training logs should have a clearly defined topic(s) covered, trainer(s) and material(s) used/given. 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 isolated instances full attendance logs have not been kept and/or not all workers 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 on numerous instances full attendance logs have not been maintained.

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

2.13.4: Are there written and communicated procedures in place that require food handlers to report any cuts or grazes and/or if they are suffering any illnesses that might be a contamination risk to the products being produced, and include return to work requirements? (In countries with health privacy/confidentiality laws, e.g., USA, auditors should check procedure/policy but not the actual records).
Total compliance (10 points): There should be documented procedures that are communicated (e.g., worker signature on a training log) to food handlers, requiring them to report any cuts, grazes and/or any illnesses that might be a food safety cross contamination risk. The procedures should indicate return to work requirements for affected workers: to whom the food handlers should report, how the issue is recorded and appropriate actions to be taken for a particular issue. Auditors should not request to review records where countries have laws covering privacy/confidentiality of health records, and therefore, a verbal confirmation that records are kept should be gained.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions in procedure.
- Single/isolated instance(s) of evidence that workers are unaware of the procedure requirements

Major deficiency (3 points) if:
- Numerous instances of errors or omissions in the procedure.
- Numerous instances of workers being unaware of procedure requirements

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

2.13.5: Are there worker food safety non-conformance records and associated corrective actions (including retraining records)?
Total compliance (3 points): A worker non-conformance should be recorded when workers are found not following food safety requirements. The auditee should have a record for worker non-compliance, corrective actions and evidence that retraining has occurred (where relevant). Auditee records might be viewed as confidential, and therefore, a verbal confirmation should be gained. There might be a tier system, which includes re-training, verbal and written disciplinary actions and allowance for immediate termination for gross misconduct.

Minor Deficiency (2 points) if:
- Single/isolated instance(s) of follow up/corrective actions not noted.

Major Deficiency (1 point) if:
- Numerous instances of follow up/corrective actions not noted.

Non-compliance (0 points) if:
- No records or fundamental failure to record follow up/corrective actions.

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

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.
- Single/isolated instance(s) of errors or omissions in personal hygiene and health requirements

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.
- Numerous instances of errors or omissions in personal hygiene and health requirements

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

Testing

2.14.1: Is there a written risk-based, scientifically valid microbiological testing program that may include pathogen testing, and details program design (zonal approach, food contact/non-food contact surfaces, spent sprout irrigation water, test & hold, water, ice, etc.), rationale for organisms tested for, procedures for sampling and testing (surfaces, water, product, ingredients, etc.), timing and frequency of testing, the testing methodology, the lab that performs the tests, and acceptable results/threshold levels for each organism?

Total compliance (15 points). A written risk-based, scientifically valid microbiological testing program has been developed and is used to verify the effectiveness of cleaning and sanitization programs and/or meet customer or other specific requirements. A microbiological testing program can be used to verify that appropriate controls such as GMPs and sanitation programs are in place and working properly.
The operation's program should be recorded and include:

- design and scope, such as the zonal approach, food or non-food contact, spent irrigation water, test & hold, water, ice, product, ingredients, etc.
- rationale for organisms chosen to be tested for
- procedures for sampling and testing (i.e. surfaces, water, product, ingredients, etc.)
- timing and frequency of testing
- the testing methodology
- the lab that performs the testing
- acceptable results/threshold levels for each organism tested
- any hold and release (test and hold) activities

The "Environmental Monitoring Program Sampling & Testing Guide" chart (Appendix I) outlines the minimum environmental and water/ice sampling and testing frequency expected based on product and processes. See specific questions below for expectations regarding other types of testing (compressed air, spent sprout irrigation water, product, raw ingredients, etc.).
Rational for sampling and testing frequency: The testing should be performed on sample sites that are chosen based upon microbial risk to the facility's environment and potential for microbial product contamination. Each process should be evaluated in order to identify the actual and potential sources of contamination. The number of samples routinely taken in each site location will vary depending on the classification of the area's risk (i.e., raw or processed product area), design, amount and complexity of equipment and process, and the layout of the handling environment. Site locations should be reassessed and updated based on test results obtained.
The records should show evidence that an appropriate number of sampling sites were tested (see 2.14.3-2.14.7). There may be some overlap with HACCP and/or Preventive Control topics.
Testing results should be recorded, including the organism tested for, the testing methodology, lab that performed the test, details of the sampling sites, when the test occurred and the results (including units of measure). If any issues are detected, corrective actions should be recorded (see 2.14.8).
Reference:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-control-listeria-monocytogenes-ready-eat-foods
https://info.unitedfresh.org/hubfs/Food%20Safety%20Pubs/FINAL-UFPA-Listeria-Guidance5.pdf
https://www.fsis.usda.gov/wps/wcm/connect/fc73c914-baec-47ca-a8be-564559b2f3b3/37d_IM_Common_Pathogens.pdf?MOD=AJPERES

Minor compliance (10 points) if:

- Single/isolated instance(s) of a missing component to the program.
- Single/isolated instance(s) of an integral part of facility ~~the~~ design and/or process being excluded from the program.

Major compliance (5 points) if:

- Numerous instances of missing components to the program.
- Numerous instances of an integral part of facility design and/or process being excluded from the program.

Non-compliance (0 points) if:

- No written risk-based, scientifically valid microbiological testing program.
- Fundamental failure to include relevant features of the facility and/or process into the program.

2.14.2: Are there written risk-based corrective action procedures for when unacceptable test results are received, that describe the steps to be taken, assign responsibility for taking those steps, and steps to ensure the cause is identified (e.g., root cause analysis) and corrected to minimize the potential for product contamination?

Total compliance (10 points). There should be written corrective action procedures detailing actions to take when unacceptable results are received, based on the risk that contamination could result in contaminated food and consumer illness that describe the steps to be taken, assign responsibility for taking those steps, and steps to ensure the cause is identified (e.g., root cause analysis) and corrected to minimize the potential for product contamination. This may include root cause analysis, intensified sampling and testing, review of SOPs, sanitation and maintenance programs, etc.

Minor deficiency (7 points):
- Single instance of a missing component in the corrective action procedures.

Major deficiency (3 points):
- More than one of missing components in the corrective action procedures.

Non-compliance (0 points):
- No corrective action procedures.
- Corrective action procedures are inadequate.

2.14.3: Are there records of environmental microbiological test results and does testing meet the program requirements?
Total compliance (15 points). Testing should be recorded, including organism tested for, the testing methodology, lab that performed the test, details of the sampling sites, when the test occurred and the results (including units of measure). If any issues are detected, corrective actions should be recorded (see 2.14.8). Testing should meet written program requirements (2.14.1), including zonal approach, food contact/non-food contact surfaces, spent sprout irrigation water, test & hold, water, ice, etc.

Minor compliance (10 points) if:
- Single/isolated instance(s) of a missing test record.
- Single/isolated instance(s) of missing details from the test records.
- Single/isolated instance(s) of environmental testing not occurring at the right frequency.

Major compliance (5 points) if:
- Numerous instances of missing test records.
- Numerous instances of missing details from the test records.
- Numerous instances of testing not occurring at the right frequency or testing is sporadic and not on a scheduled basis.

Non-compliance (0 points) if:
- No testing.
- Fundamental failure to include all of the required recording details in the testing records.

2.14.4: Are there records of microbiological tests on water used in the facility (sampled from within the facility) and does the testing meet the program requirements?
Total compliance (15 points): There should be microbiological tests on water used in the facility on a routine basis to assure it meets the microbiological requirements of potable water. Testing frequency should be related to the risk assessment of the production. Testing should meet written program requirements (2.14.1).
- Processors of ready-to-eat products (e.g., baby leaf spinach, sliced apples, etc.) should test at least monthly.
- Facilities that have water coming into contact with product (excluding products to be cooked (e.g., potatoes)) i.e. wash steps, hydrocooling, etc. should test at least quarterly.
- Otherwise, minimum frequency is at least every 12 months.

If there is any doubt whether a product is consumed raw i.e. not cooked (e.g. cranberries, Brussels sprouts, asparagus, in-shell nuts, etc.), then it is assumed that raw consumption does occur and testing frequency is applicable. Water samples should be taken from the within the facility to account for the sites piping, holding tanks, etc. City water samples http://www.epa.gov/safewater/dwinfo/index.html are still

good information to have, but if there is no site sample, then this question should be scored major. Results of water testing for total coliforms and *E. coli* should meet the US EPA drinking water **microbiological** specification. If out of specification results are detected, then full details of corrective actions should be noted.
Where industry schemes e.g. Leafy Greens Marketing Agreement (LGMA) or specific legislative requirements are higher than audit requirements, the higher requirements should be followed and will be scored against. For example, LGMA rules require one sample per water source, collected and tested for generic *E. coli* prior to use if >60 days since last test of the water source. Additional samples should be collected and tested at least monthly during use. Refer to http://www.caleafygreens.ca.gov/ for additional information.

https://www.epa.gov/dwstandardsregulations
http://www.gpo.gov/fdsys/pkg/CFR-2011-title40-vol23/pdf/CFR-2011-title40-vol23-part141.pdf

Minor deficiency (10 points) if:
- Single instance of water testing not occurring at the right frequency.

Major deficiency (5 points) if:
- Only water testing records available are from the City Water Board (if using municipal water supply).
- More than one instance of water testing not occurring at the right frequency.

Non-compliance (0 points) if:
- No microbiological test results are available.
- Last test was done over 12 months ago.

2.14.5: Are there records of microbiological tests on ice used in the facility (either produced in-house or purchased) and does testing meet the program requirements?
Total compliance (15 points): There should be routine microbiological tests on ice used in the facility. Testing frequency should be related to the risk assessment of the production. Testing should meet written program requirements (2.14.1).
- Processors of ready-to-eat products that use ice in their process should test at least monthly.
- Facilities that have ice coming into contact with product (excluding products to be cooked) (e.g., ice injectors, top icing, etc.) should test at least quarterly.
- Otherwise, minimum frequency is at least every 12 months.

If there is any doubt whether a product is consumed raw i.e. not cooked (e.g. cranberries, Brussels sprouts, asparagus, in-shell nuts, etc.), then it is assumed that raw consumption does occur and testing frequency is applicable. Ice samples should be taken from actual ice used to account for the sites piping, holding tanks, ice making equipment and ice storage, etc. Results of ice testing for total coliforms and *E.*coli should meet the US EPA drinking water **microbiological** specification. If out of specification results are detected, then full details of corrective actions should be noted.

If an auditee is procuring ice from an outside vendor, the above requirements are still valid and the auditee should obtain testing results in order to gain full credit for this question, although some points will be awarded for letters of guarantee.

Where industry schemes e.g. Leafy Green Marketing Agreement (LGMA) or specific legislative requirements are higher than the audit requirements, these industry scheme and legal requirements should be followed and will be scored against.

Minor deficiency (10 points) if:
- Single instance of ice testing not occurring at the right frequency.

Major deficiency (5 points) if:
- Only water testing records available are from the City Water Board (if using municipal water supply).
- More than one instance of water testing not occurring at the right frequency.

- Only a current (dated within last 12 months) letter of guarantee (for externally supplied ice) is available.

Non-compliance (0 points) if:
- No microbiological test results are available.
- Last test was done over 12 months ago.
- Ice is used from an outside source but there is no current (dated within last 12 months) letter of guarantee (and no ice micro test).

2.14.6: Are there records of tests performed on compressed air or other mechanically introduced gases that is used directly on food and food contact surfaces and does testing meet the program requirements?

Total Compliance (5 points): Compressed air used in direct contact with product, product food contact areas and the interior surface of packaging should be free of contaminants (e.g., particulates, oil, etc.). Often compressors employ high efficiency filters with a very small mesh size to protect against contamination (which should be part of the equipment preventative maintenance, see 2.12.1) and be fitted as close to point of use as possible. There should be routine microbiological tests on air used in the facility. Testing should be based on a documented risk assessment and controls in place (e.g., use of the air/gas, risk to the product/food contact surfaces and type of process/product). At a minimum, testing should occur once every 12 months. Testing may include microbiological (e.g., indicator organisms) and moisture content if there is risk to the product, dry operations using compressed air. Testing should meet written program requirements (2.14.1) and be based on risk of the product and process.

Potentially useful websites:
http://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2014/food-safety-insider-rapid-micro-solutions/compressed-air-an-overlooked-source-of-contamination-in-the-food-industry/
http://www.airbestpractices.com/standards/food-grade-air
http://www.airbestpractices.com/industries/food/three-types-food-industry-compressed-air-systems
http://www.iso.org/iso/catalogue_detail.htm?csnumber=31385

Minor Deficiency (3 points) if:
- Single instance of testing not occurring at the right frequency.

Major Deficiency (1 point) if:

- More than one instance of testing not occurring at the right frequency.

Non-compliance (0 points) if:

  - No records.
- Testing has not been performed within the past 12 months.

2.14.7: Are there records of other tests (e.g., spent sprout irrigation water, product, raw ingredients, etc.) that are performed for any reason (e.g., customer requirements, best practice, regulatory requirements) and does testing meet program requirements?
Total compliance (15 points). Testing should be recorded, including organism tested for, the testing methodology, lab that performed the test, details of the sampling sites, when the test occurred, the results (including units of measure). Product testing may include microbiological, allergens, heavy metals, pesticide MRLs, dioxins, aflatoxins and other natural toxins, etc. Testing should meet written program requirements (2.14.1) and any legal requirements.

Minor deficiency (10 points):

- Single/isolated instance(s) of testing not occurring at the right frequency.

Major deficiency (5 points):
- Numerous instances of testing not occurring at the right frequency.

Non-compliance (0 points):
- No test results are available.

2.14.8: Are there records of corrective actions taken after unsuitable testing results that describe the steps taken, responsibility for taking those steps, and actions taken to ensure that the cause of contamination has been identified and corrected?
Total compliance (15 points). There should be documented evidence that corrective actions have been taken when required and were adequate for the specific situation.

Minor deficiency (10 points):
- Single/isolated instance(s) of corrective action records missing details.

Major deficiency (5 points):
- Numerous instances of corrective action records missing details.

Non-compliance (0 points):
- No corrective actions were performed.
- Corrective actions were not recorded.
- **A single out of specification test result without proper corrective actions, the auditor should consider production adulteration potential see 1.4.5, automatic failure due to product contamination.**

Temperature Controlled Storage & Distribution Logs

2.15.1: Are there records of final product temperature checks for temperature sensitive product?
Total compliance (10 points): There should be records which show actual product final temperatures after processing and/or prior to dispatch for temperature sensitive goods (air temperature recordings are not acceptable for this question – see 2.15.3). Examples of temperature sensitive products include an animal food that is raw or heat treated; a plant food that is heat-treated or consists of seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation. Refer to Food Code.

FDA Food Code 2017: Chapter 1 – Purpose and Definitions https://www.fda.gov/media/110822/download
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=117.206

Temperature requirements of customers and organizations that are coordinating the shipping of the finished products should be considered. Records should show that product is not shipped above temperature requirements (in-house specifications, buyer specifications, best practice requirements or legal requirements). Corrective and preventive actions and should be recorded (where relevant).

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

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

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

2.15.2: Are there temperature logs for the production area (if refrigerated)?
Total compliance (5 points): There should be temperature logs or recording thermometer printouts on file. Not applicable if the production area is not refrigerated. The issue of using an independent probe, separate from the thermostat probes and systems is covered under 1.7.4. Corrective and preventive actions should be recorded (where relevant).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or incomplete records, including corrective actions.

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

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

2.15.3: Are there temperature logs for storage rooms?
Total compliance (5 points): There should be temperature logs or recording thermometer printouts on file. Holding temperatures in refrigerated storage rooms should not exceed 41°F (5°C) for microbiologically sensitive raw materials, ingredients or products including an animal food that is raw or heat treated; a plant food that it heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens*, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation. Not applicable if products are held at controlled high ambient temperature e.g. whole tomatoes, bananas, etc. The issue of using an independent probe, separate from the thermostat probes and systems is covered under 1.7.4. Corrective and preventive actions should be recorded (where relevant).
* Leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard; does not include herbs such as cilantro or parsley. Lettuce and other leafy greens cut from their root in the field with no other processing are considered raw agricultural commodities and are not included in the definition of “cut leafy greens” and are therefore not considered a potentially hazardous food requiring time/temperature control for safety (PHF/TCS) food, as defined and applied in the 2017 Food Code.
https://www.fda.gov/media/110822/download
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=117.206

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or incomplete records, including corrective actions.
- Single/isolated instance(s) of temperatures exceeding 41°F (5°C) for microbiologically sensitive raw materials, ingredients or products.

Major deficiency (1 point) if:
- Numerous instances of errors or incomplete records, including corrective actions.
- Numerous instances of temperatures exceeding 41°F (5°C) for microbiologically sensitive raw materials, ingredients or products.

Non-compliance (0 points) if:

- No temperature logs are on file (and the storage room is refrigerated).
- Records show temperatures consistently exceed 41°F (5°C) for microbiologically sensitive raw materials, ingredients or products.

2.15.4: Are there records of shipping truck trailer (or other transportation systems) temperature checks, indicating the truck trailer temperature settings and that the truck trailer was pre-cooled prior to loading?
Total compliance (5 points). Truck trailers (or other transportation system, e.g. railway carriages) should be checked to ensure they are pre-cooled when transporting temperature sensitive products, and the truck trailer refrigeration unit set point should be recorded. There should be specific set temperature requirements for each product.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a missing record.

Major deficiency (1 point) if:
- Numerous instances of missing records.

Non-compliance (0 points) if:
- No records.
- Fundamental failure to maintain records.

2.15.5: Are there sanitary condition logs for shipping truck trailers (or other transportation systems)?
Total compliance (5 points). Truck trailers (or other transportation systems, e.g., railway carriages) should be checked for their sanitary condition and records maintained.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a missing record.

Major deficiency (1 point) if:
- Numerous instances of missing records.

Non-compliance (0 points) if:
- No records.
- Fundamental failure to maintain records.

Allergen Control

2.16.1: Are there no allergen risks handled or stored within production and storage areas?
Total compliance (0 points): If the production process includes the handling of allergen containing materials, then the allergen questions below should be completed (applicability of some questions will vary depending on variables, such as process steps and how allergen containing materials are handled). Also, the allergen hazards should form part of the HACCP and/or Preventive Controls programs). The key concerning allergens (a.k.a. major 8) in the U.S. are Wheat, Eggs, Milk, Soybeans, Crustaceans (Shellfish), Peanuts, Tree Nuts and Fish. Auditors and auditees should review legislation to see if the country of production or countries being exported to have different allergen listings e.g. mustard, celery and sesame. Other sensitive ingredients that would need investigating further are Sulfites and Artificial Color FDC №. 5. (See the Appendix III for allergen reference per country.) If there is no allergen handling on site then mark this question "Yes", state an explanation and mark the rest of the allergen questions as N/A (with a statement referring back to this question e.g. N/A, see question 2.16.1). This question is not designed to cover allergen containing items found in break room vending machines, personal break food stuffs etc., but ideally auditees should make their workers aware of the potential issues, especially when carrying out hand washing training.

Potentially useful websites:

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/default.htm
http://www.foodallergy.org
https://www.fda.gov/industry/fda-basics-industry/section-201qq-act-defines-term-major-food-allergen-include-tree-nuts-addition-three-examples

Non-compliance (0 points) if:
- Allergens are handled or stored within production and/or storage areas.

2.16.2: Has a documented allergen management plan been developed?
Total compliance (5 points): An allergen management plan has been developed and documented. The plan gives an overview of the operation's management of allergen control from product development, raw material procurement (supplier management), goods receiving, raw material storage, production, finished goods storage through to shipping. The plan should cover areas, such as how raw material supplier allergen risks are evaluated/mitigated, on-site labeling, sanitation, labeling, worker training, etc. The plan should include an up to date list of allergens handled on site. Some facets of the allergen plan are audited in the rest of the questions in this section.
https://www.fsis.usda.gov/wps/wcm/connect/f9cbb0e9-6b4d-4132-ae27-53e0b52e840e/Allergens-Ingredients.pdf?MOD=AJPERES
Minor deficiency (3 points) if:
- Policy lacks a key element.
- Single/isolated instance(s) of errors or omissions in the plan.
- Allergen list is missing one allergen handled on site.

Major deficiency (1 point) if:
- Plan lacks more than one key element.
- Numerous instances of errors or omissions in the plan.
- Allergen list is missing two allergens handled on site.

Non-compliance (0 points) if:
- No plan exists.
- Allergen list is not current and/or does not reflect allergens being handled on site.

2.16.3: Are there adequate storage controls (e.g., separation, identification, etc.) that ensure that allergens are not contaminating other raw materials?
Total compliance (5 points): Allergen materials and allergen containing materials should be stored in a manner that avoids cross contaminating all other materials. Allergenic ingredients and products should be physically separated from other materials, separate storage areas are ideal and allergens should never be stored above food products, other than those containing the exact same allergens. Where segregated storage is not possible, store like-allergens (e.g., milk and whey) together. Allergens should be tagged as usual (rotation and lot coding), and should also be identified as allergens (e.g., tagged or color-coded).

Minor deficiency (3 points) if:
- Single instance of improper allergen storage or handling practices.
- Single instance of allergenic items not labeled as allergens.

Major deficiency (1 point) if:
- Isolated instances (no more than three) of improper allergen storing or handling practices or where there is not adequate physical separation and demarcation within the room.
- More than one but less than three instances of allergens not labeled as such.

Non-compliance (0 points) if:
- Allergens being stored together with other items in a way that poses a cross contamination risk.

- Numerous instances of improper allergen storing or handling practices or where there is not adequate physical separation and demarcation within the room.

2.16.4: Is there a dedicated allergen production line or adequate clean down and production procedures that prevent allergen cross contamination?
Total compliance (5 points): Ideally facilities have dedicated equipment and production line(s) for allergen containing ingredients. If no separate production line is being used then procedures should be written so as to prevent allergen cross contamination (e.g., schedule production of non-allergenic items before items with allergens, add allergenic ingredients as late in the process as possible, schedule sanitation immediately after production of foods containing allergens). Some allergen testing kits (where available for the particular allergen) are also used in order to check the sanitation after an allergen has been used in a product. Where allergen dust is considered a risk, practices, such as keeping ingredient bins covered, consideration of ventilation flows, etc., should be considered.

Allergens should not come into contact with non-allergenic products, especially processed products that have been washed, cut or thermally treated. There should be plenty of space and separation to help avoid cross contamination issues. Workers who handle allergen products should not then handle non-allergen products without first ensuring that they are free of allergen contaminants. This should include hand washing, glove change etc., but might also include changing into a new set of garments; ideally workers should be dedicated to allergen or non-allergen goods, but not both within a shift. Utensils, cleaning implements, internal vehicles etc. should not be allowed to be vectors for cross contamination; ideally dedicated coded equipment and storage areas should be provided for allergen and non-allergen goods. Where dedicated utensils and equipment are not possible, items must be cleaned prior to use for non-allergenic materials.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of worker/utensil/internal vehicle allergen cross contamination.
- Minor process issues where allergenic materials come into the same area as non-allergenic materials, but the two products do not touch in any way, i.e. no potential risk of cross contamination.
- Some potential space issues where the process flow is being forced to bring allergenic and non-allergenic material into close proximity.

Major deficiency (1 point) if:
- Numerous instances of worker/utensil allergen cross contamination.
- Serious process flow issues where allergenic material can potentially cross contaminate non-allergenic goods.
- Numerous space issues where the process flow is being forced to bring allergenic and non-allergenic material into close proximity.

Non-compliance (0 points) if:
- Widespread instances/issues with worker and/or utensil allergen cross contamination.
- Process flow issues are observed to result in allergen/non-allergenic goods cross contamination

2.16.5: Are utensils and work in progress storage containers identified in order to prevent allergen cross contamination?
Total compliance (5 points): Utensils, such as shovels, paddles, knives, maintenance tools, etc. should be coded in order to differentiate between items associated with producing allergen containing products and products that do not contain allergens. Where dedicated utensils and equipment are not possible, items must be cleaned prior to use for non-allergenic materials. Sanitation equipment (e.g., cleaning pads, mops, brushes etc.) should also be coded and separated, between equipment destined to be used on allergen containing products/processes and non-allergen containing products/processes. Product holding bins, including re-work bins, should be coded in a similar fashion i.e. a separate set of bins for the allergen containing product, this includes rework bins.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of utensils or work in progress storage containers not identified (tagged or color-coded) to differentiate between items associated with producing allergen containing products and products that do not contain allergens

Major deficiency (1 point) if:
- Numerous instances of utensils or work in progress storage containers not identified (tagged or color-coded) differentiate between items associated with producing allergen containing products and products that do not contain allergens.
- Items are commingled with other goods in such a way that their status is unclear and a potential misuse might occur.

Non-compliance (0 points) if:
- Utensils or work in progress storage containers are not clearly separated and identified.

2.16.6: Does re-work handling take into account the issues associated with allergen containing products?
Total compliance (5 points): Re-work of allergen containing products needs to be strictly controlled. Allergen re-work product should be clearly labeled. Allergen re-work should be stored separately from non-allergen re-work, raw materials and product. Allergen re-work should only be used when a similar allergen containing product is being packed/processed. Even the outside of allergen containing condiment packs might be a risk to the foodstuff (e.g., romaine lettuce), that a condiment pack was touching and therefore this foodstuff (e.g., romaine lettuce) should only be re-used for the allergen containing product. Like all re-work, traceability should be maintained, meaning that the use of re-work materials is being properly recorded.

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

Minor deficiency (3 points) if:
- Single/isolated instance(s) of an issue with re-work handling.

Major deficiency (1 point) if:
- Numerous instances of issues with re-work handling.

Non-compliance (0 points) if:
- Widespread issues observed in handling how re-work is done.

2.16.7: Are workers trained with respect to allergen risks and the facility allergen cross contamination controls (including hand washing between production runs) and are there records of this allergen training?
Total compliance (5 points): Workers should be aware of the Allergen Management Plan (2.16.2) including what allergens are, the effects of allergens on allergy sufferers, the actual allergens handled on site and the facility controls to prevent allergen cross contamination. Training should include personnel practices (e.g., hand washing, changing protective garments and gloves, etc.) when moving around the production area between allergen and non-allergen handling. Key operators, including warehouse workers, production workers, label designers, etc. should receive specific training for the risk involved. Training should be ongoing and recorded for both new and existing workers.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of errors and omissions in the records.
- Training materials are not in the relevant language(s).
- Training occurring but relevant materials are not being given to the trainee after the training.
- Training occurring, not before starting to work but within the first week.
- Single/isolated instance(s) of workers not being trained.

Major Deficiency (1 point) if:
- Numerous instances of errors and omissions in the records.
- Training occurring, not before starting to work but within the first month.
- Failure to communicate the Allergen Management Plan to workers.
- Numerous instances of workers not being trained.

Non-compliance (0 points) if:
- No records that workers are being trained regarding allergens.
- No specific allergen orientation training given or given after the worker has been working for more than one month.
- Failure to maintain records.

2.16.8: Are worker practices adequate and being followed to protect against allergen cross-contact and against contamination of food?
Total compliance (5 points). Worker practices should be adequate to ensure that necessary precautions are being followed to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with allergenic substances. Some practices may include unique color-code designation for PPE, utensils and supplies, designated process and personnel flow.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of a worker not following trained procedure.

Major Deficiency (1 point) if:
- Numerous instances of workers not following trained procedure.

Non-compliance (0 points) if:
- Fundamental failure of workers to follow procedures in which they were trained.
- Fundamental failure of workers to prevent cross-contamination issues.

2.16.9: Are all products manufactured on site labeled correctly with respect to allergens?
Total compliance (5 points): Allergen containing products should clearly show on the label the allergens that are associated with the product and meet any laws in the country of production and consumption. The correct label should be on the product. If the allergens form part of condiment inclusion packs, these allergens should still be indicated on the main product label. If an operation is producing allergen containing products that will be used as an ingredient by a subsequent manufacturer, the documentation that goes with the product should underline the allergen contents and also ideally the bag and cartons should indicate the allergen contained within the product. If non-allergen containing products are produced on a site where allergens are used, the management should consider the chance of allergen cross contamination and if satisfactory controls to prevent such contamination are in place. If there are any doubts about the adequacy of these controls (GMPs), etc., then the management should have considered using a “may contain” (or a similar clause) on the non-allergy containing products (this is a last resort and should not replace proper GMPs). Labeling should follow the national and local labeling laws.

Potentially useful website:
http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/default.htm

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

Major deficiency (1 point) if:
- Numerous instances of missing allergen information on commodities, packaging, ingredients, processing aids, work in progress, etc.

Non-compliance (0 points) if:
- There is no allergen information on commodities, packaging, ingredients, processing aids, work in progress, etc.

Section 3: HACCP

Preliminary Steps

3.1.1: Is there a team with an assigned leader, responsible for the HACCP program at the operation, and the development, implementation and on-going maintenance of the HACCP system?
Total compliance (10 points): There should be a formally identified group of people in charge of development and maintenance of the Hazard Analysis Critical Control Point (HACCP) program along with their corresponding responsibilities. The group should be comprised of individuals from different areas of the company such as top management, quality management, production, maintenance, sanitation, QC, etc. Consider including resources from outside e.g. suppliers, buyers, consultants, trade association, universities, extension office, etc. One member of the team should be designated the HACCP Coordinator (leader). Where a consultant has been designated the HACCP coordinator, it should be evident that they are present at all meetings and actively involved in the program. The HACCP team should meet at least quarterly (ideally monthly). If the company is too small (less than 20 people) to have a HACCP team, there should still be one individual designated as the HACCP coordinator. That individual is responsible for the implementation of the HACCP program along with any changes and updates to the HACCP program.

Minor deficiency (7 points) if:
- Team has been put together but lacks key representation e.g. maintenance.
- Only three meetings have occurred in the last 12 months (for an all year-round operation)

Major deficiency (3 points) if:
- The team or individual is assigned but does not meet regularly to review the HACCP program.
- A large company, but only a single individual has been designated to develop the operational HACCP plan.
- Two or less meetings have occurred in the last 12 months (for an all year-round operation).

Non-compliance (0 points) if:
- The HACCP team or the individual assigned to manage the HACCP program has not kept the program updated.
- There is no HACCP team or designated HACCP Coordinator.

3.1.2: Is there documented evidence that the HACCP team members have been trained on HACCP principles?
Total compliance (15 points): The HACCP Coordinator should have a certificate of formal HACCP training from a recognized organization, institution or trainer i.e. certification from a HACCP training course accredited by the International HACCP Alliance or equivalent (e.g. university provided courses) providing formal training, taken within the last 5 years. Preventive Control Qualified Individual (PCQI) training can also be accepted, as long as it is equivalent to the International HACCP Alliance training (covers the 7 Codex Alimentarius HACCP principles and the 12 HACCP implementation steps). Management and HACCP team members should have thorough HACCP training (in-house or external within the last 5 years) given by someone who has HACCP experience and has attended an accredited International HACCP Alliance course (or equivalent). Records of training should be kept and also certificates, where relevant. http://www.haccpalliance.org/sub/index.html

Minor deficiency (10 points) if:
- The majority but not all HACCP team members are trained in HACCP .

- Management has not received HACCP training.
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major deficiency (5 points) if:
- HACCP Coordinator has not completed a certified HACCP training course within the last 5 years.
- Numerous instances of omissions or incorrect data in the records.

Non-compliance (0 points) if:
- No formal training records for HACCP team members.

3.1.3: Does a product description exist for the products produced?
Total compliance (10 points): Product description(s) should clearly describe the product and its distribution and be used to determine if specific controls are important throughout the distribution chain. The description should indicate the product(s) name, type(s) of packaging, shelf-life and method of storage and distribution. Information should include intended use i.e. does it need washing, peeling, cooking prior to consumption, is it RTE, etc., by the consumer, and reflect the label of the product (unit packed product). Intended use should include any potential for abuse or misuse of the produce (e.g. eating raw when product is intended to be cooked). Product description(s) should list all ingredients including allergens, define and indicate details regarding whether the item is perishable or long life, if there are any special storage and distribution requirements and any important food safety characteristics that can influence the growth of pathogens (e.g., pH, water activity), and labeling requirements. Product description(s) should define the potential risk associated with the product, materials used and also who the intended customers are (general public, restricted to certain sectors, e.g. people not suffering from a certain allergy, diabetic issues, other at-risk groups, etc.). The product description can be generic if the products and processes are similar. Where the products and/or processes are not similar to each other, specific product descriptions are required.

Minor deficiency (7 points) if:

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

Major deficiency (3 points) if:
- Numerous instances of errors or omissions on the product descriptions(s).
- In an operation with multiple products/processes that are not similar, a single product description is not available, but the majority are available

Non-compliance (0 points) if:
- No product descriptions exist.
- Fundamental errors or omissions on the product description(s).
- In an operation with multiple products/processes that are not similar, more than one product description is not available.

3.1.4: Has the process(es) been flow charted in sufficient detail to completely describe the process or product handling/processing steps?
Total compliance (10 points). There should be process flow charts for each HACCP plan. The flow chart should show each step of the process(es) under control of the operation (from receiving through to final storage and shipping), so that the hazard analysis can be completed properly. The flow chart should indicate the raw materials, ingredients and materials used in all preparation steps, all equipment used, blending steps, processing steps, rework, by-products, returned products and products destined for further processing, packaging materials (carton and unit packaging) and packaging equipment. All inputs should be included, such as packaging, water source (e.g. city or well), ice, anti-microbials, fungicides, etc. Each step should show any holding times, temperature regimes, etc. Each step should show any holding times, temperature regimes, etc., at appropriate process steps. For example, a step termed “packing” in an apple packinghouse is incorrect since it omits to detail many of the processes, e.g. dump

tanks, selections, recirculated product wash/rinse steps, single-pass wash/rinse steps, waxers, fungicide, drying, packing the boxes and coding. In operations with multiple products but similar processes, a single process flow may be used. Where there are multiple products but with different processes then individual process flows are required. Diagram should show re-work processes and when product is diverted to be used for other purposes. Process flows can be augmented by written process descriptions (where helpful).

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions on the process flow chart(s).

Major deficiency (3 points) if:
- Numerous instances of errors or omissions on the process flow chart(s).
- In an operation with multiple products/process that are not similar, a few of the flow charts are not available, but the majority are available

Non-compliance (0 points) if:
- Fundamental errors on the flow chart(s).
- No process flow chart(s).
- In an operation with multiple products/processes that are not similar, many of the flow charts are not available.

3.1.5: Is there documented evidence that the flow chart(s) been verified on-site?
Total compliance (10 points): The steps in the flow chart are used to organize the hazard analysis. Flow diagrams should be verified on-site by the food safety team and the team should make any changes required to the flow diagram. Any significant changes to the process must be accurately reflected in the flow diagram and evaluated to determine if the changes have an impact on the hazards analysis and CCPs in place. The flow chart(s) is signed and dated by the HACCP coordinator to confirm it reflects the process at different moments in time (auditor should confirm how and when flow chart(s) were verified) and there are no missing steps. Insufficient detail, missing steps, etc., will undermine the hazard analysis process (3.2.1). Any inaccuracies in the flow diagram should be scored in 3.1.4.

Minor deficiency (7 points) if:
- Single instance of a flow chart not being verified.

Major deficiency (3 points) if:
- More than one instance of a flow chart not verified.

Non-compliance (0 points) if:
- Flow charts have not been verified.

Development of the HACCP Plan

3.2.1: Has a documented hazard analysis for the processes been conducted, showing the various types of hazards, their likelihood of occurrence, their associated severity and their control measures? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.
Total compliance (15 points): A hazard analysis identifies and evaluates potential food safety hazards and determines if control measures are in place to prevent, eliminate or reduce the food safety hazard to an acceptable level. There should be a detailed, documented hazard analysis for each process flow in order to prove that a proper hazard analysis was conducted. Note, if there are errors in the process flow, it is likely there will also be errors in the hazard analysis. At each step of the process, from raw material receipt and storage, through processing and packing, storage and distribution the hazard analysis should look at the severity and likelihood of all potential (known or reasonably foreseeable) food safety hazards that may be reasonably expected to occur in terms of specific biological, chemical (including radiological), physical, and economically motivated hazards, as well as the control measures for each. Preventive

controls, such as process, allergens, sanitization, and supply chain should be identified for the identified hazards. Any potentially RTE products must include an evaluation of specific environmental pathogens related to ingredients/products. Research previous outbreaks and issues associated with the ingredients/products to help identify specific risks with ingredients/products used. Examples of specific biological hazards (bacteria, viruses, parasites and pathogens) include Listeria monocytogenes, Salmonella spp., Enterohaemorrhagic E. coli (EHEC), Shiga toxin-producing E. coli (STEC), Cryptosporidium parvum, Cyclospora cayetanensis; chemical hazards include mycotoxins, pesticide residues, sanitation chemicals, lubricants, allergens, natural toxins, unapproved additives; physical hazards include extraneous matter that may cause choking or other injury e.g. stones, metal, glass, and brittle plastic; radiological hazards include local environmental issues (e.g. refer to Water Management District reports); economically motivated hazards including product substitutions, fillers, etc. Evaluation should include all ingredients, equipment, processing steps (e.g., receiving, dump tanks, brush bed systems, recycled wash systems including hydro-vacuum coolers, ice injectors, flume washers, etc., single line wash systems, ice manufacturing), inputs including packaging materials and post-harvest treatments, sanitation and employee hygiene, etc.

Each step identified in the process flow diagram should be assessed in the hazard analysis. Justifications should be documented when identifying significant and non-significant hazards. Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure. The hazard analysis should indicate if an adequate control step for this potential risk exists further down the process. The hazard analysis should be reviewed when changes occur affecting the product description and/or the process flow. The hazard analysis for all products must be written, regardless of its outcome.
http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm

Minor deficiency (10 points) if:
- Single/isolated instance(s) of errors or omissions on the hazard analysis chart(s).

Major deficiency (5 points) if:
- Numerous instance(s) of errors or omissions on the hazard analysis chart(s)

Non-compliance (and an automatic failure of this module) (0 points) if:
- Multiple fundamental errors on the hazard analysis chart(s).
- In an operation with multiple products/processes that are not similar, one or more hazard analysis charts are not available.

3.2.2: Have CCP decisions been made with documented justifications and where CCPs are implemented in a specific processing step, have they been developed to control the identified hazard(s)?
Total compliance (15 points): CCP decisions should be properly justified with supporting documents and evidence. The CCPs identified in the hazard analysis should be developed to define, in detail, the parameters involved, and monitoring requirements to control the hazard(s).
The CCPs should be created from the documented hazard analysis i.e. *there should be a logical documented approach (such as utilizing a CCP decision tree) showing why the process was deemed a CCP or not*. CCPs are often steps that if not controlled will lead to a food safety issue and also there is no step further down the process that controls the issue. A CCP should be controllable and the controls should be able to eliminate or reduce the risk to acceptable “safe” levels.

Minor deficiency (10 points) if:
- Single fault in the logic or justification of one CCP decision.
- Single CCP developed that does not meet the criteria for a CCP.

Major deficiency (5 points) if:

- More than one fault in the logic or justification of the CCP decisions.
- More than one CCP developed that does not meet the criteria for a CCP.
- One (where there are multiple) CCP has been omitted.

Non-compliance (0 points) if:
- No CCPs have been developed in the hazard analysis step even though clearly CCPs did exist.
- More than one CCP has been omitted in a plan where there should be multiple CCPs.
- A single CCP has been omitted in a plan where there is a single CCP.

3.2.3: Is the HACCP system verified when operational changes are made and at least once every 12 months?
Total compliance (10 points). The HACCP system should be reviewed by the HACCP team when significant changes are made e.g. raw materials, packaging, suppliers, product, process, construction, new equipment, recurring deviations, new scientific information, new distribution or consumer practices, etc., including the hazard analyses, to ensure that the program is up to date and working properly. HACCP system review should occur at a frequency that ensures the HACCP Plan is being followed continuously and at least every 12 months. Where emerging issues, such as recalls, an outbreak, new research, etc., are relevant to the products and processes at hand, consideration of a HACCP review should occur. Documented re-training or educational sessions may be necessary. The review should include a written record which demonstrates each of the elements of the plan including the product descriptions, process flows, hazard analyses, CCP decisions, CCP recording, customer complaints, equipment calibration, record review, trend analysis data, etc., have been reviewed, verified as being accurate/appropriate and there should be a change record included in the plan to track changes over time. The HACCP team should inform workers involved of the review outcomes.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of a change made without being documented.
- Single/isolated instance(s) of omissions in the review.

Major deficiency (3 points) if:
- Numerous instances of a change made without being documented.
- Numerous instances of omissions in the review.
- No record of workers involved being informed of HACCP review outcomes.
- Verification did not take place in the last 12 months but did take place in the last 18 months.

Non-compliance (0 points) if:
- No verification activities are being performed.
- There is no documented record of review.

3.2.4: Have critical control point (CCP) processing steps been identified that eliminate or reduce food safety hazards to an acceptable level? Informational gathering. If answer is YES, continue with next question. If answer is NO, the rest of section 3 is not applicable.
Total points (0). The identification of a CCP in the process requires development of the criteria with adequate detail, defined parameters and the execution of the necessary activities in the production line. If CCPs have been identified, the rest of this module should be completed. The CCPs should be created from the documented hazard analysis, i.e. there should be a logical documented approach showing why the process was deemed a CCP or not. CCPs are often steps that if not controlled will lead to a food safety issue, and also, there is no step further down the process that controls the issue. A CCP should be controllable and the controls should be able to eliminate or reduce the risk to acceptable “safe” levels. Where the operation determined that there are no CCPs (and the auditor is in agreement), no further HACCP development is required, and the rest of the module is not applicable.

For facility operations, the organization will determine the need for a HACCP program by performing a documented hazard analysis for all steps of each process. Examples of specific biological hazards include *Listeria monocytogenes, Salmonella* spp., Enterohaemorrhagic *E. coli* (EHEC), Shiga toxin-producing *E. coli* (STEC), *Cryptosporidium parvum, Cyclospora cayetanensis*; chemical hazards include mycotoxins, pesticide residues, sanitation chemicals, lubricants, allergens; physical hazards include stones, metal, glass, and brittle plastic. If an auditee decides to complete a HACCP program, even if no CCPs are identified, then the auditor will complete the HACCP module of this audit as a verification of the HACCP program.

http://www.caleafygreens.ca.gov/food-safety-practices
http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm082751.htm

3.2.5: Have CCP critical control limits been established and are they supported by relevant validation documentation?

Total confirmation (15 points): A critical control limit (CCL) represents the dividing line used to judge whether a CCP is under control or not. Each Critical Control Point should have one or more critical control limits for each identified hazard. Critical control limits (CCL's) i.e. the maximum and/or minimum parameters of what is being monitored e.g. with a metal detector, the sensitivity of the detector setting should be stated along with the size/type of test pieces used, or with an anti-microbial the minimum concentration required should be stated. Other CCLs may include temperature, time, pH, water activity, flow rates, line speed, dwell times, etc. More stringent "operating limits" may be useful during production to minimize failure to meet a critical limit.
All CCPs should be supported by validation documentation showing that the critical control limits (CCL) are scientifically derived and meet any relevant legal requirements. Validation could take the form of publicly available legislative documents, industry best practice documents, peer reviewed research papers, on site validation studies, etc., or a mix of different validation sources. Where publicly available validation is not available, the auditee should have performed validation studies to support their stated critical control limits. For example, free chlorine limits for chlorinated recycled water systems could be stated in research papers and State documentation (e.g., Leafy Greens Marketing Agreement). Another example, metal detection limits could be supported by validation studies that show that smallest test probes possible were used and meet the FDA guidelines

Minor deficiency (10 points) if:
- Single/isolated instance(s) of omissions or incorrect CCL validation details.

Major deficiency (5 points) if:
- Numerous instances of omissions or incorrect CCL validation details.

Non-compliance (0 points) if:
- There is no documentation to support CCP critical control limits.
- Validation documentation provided does not support the CCP critical control limits.
- Widespread omissions or incorrect CCL validation details.

3.2.6: Have monitoring requirements and frequencies been determined and documented for the CCPs?
Total compliance (15 points): There should be determined and documented monitoring requirements and frequencies for the CCPs. Where monitoring is not continuous, the type and frequency of monitoring should be sufficient to ensure the CCP is under control. Frequency should be specified; "as needed" is not accepted as a stated frequency. Requirements should include the critical control limits (CCL's) i.e. the maximum and/or minimum parameters of what is being monitored e.g. with a metal detector, the sensitivity of the detector setting should be stated and size/type of test pieces used, or with an anti-

microbial the minimum concentration required should be stated. Other CCLs may include temperature parameters, pH, flow rates, dwell time, etc. The requirements i.e. what is to be done should be specified on the HACCP plan.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of omissions or errors in the monitoring requirements.
- Single/isolated instance(s) of omissions or errors in the frequency details.

Major deficiency (5 points) if:
- Numerous instances of omissions or errors in the monitoring requirements.
- Numerous instances of omissions or errors in the frequency details.
- A single CCP (where there are multiple CCPs) is lacking monitoring requirements or frequency details.

Non-compliance (0 points) if:
- More than one CCP is lacking monitoring requirements or frequency details where there are multiple CCPs in a plan.
- A single CCP is lacking monitoring requirements or frequency details in a plan where there is a single CCP.

3.2.7: Have specific responsibilities been assigned for the monitoring, recording and corrective action implementation of each CCP?
Total compliance (10 points): Specific responsibilities should be assigned for the monitoring, recording and corrective action implementation of each CCP to ensure compliance. If CCP records are not being completed properly, this may be an indication that the CCPs have not been assigned correctly. The responsibility should be clearly indicated on the HACCP plan by at least naming the function e.g. QA Technician or trained designate, who is responsible for monitoring, recording and executing corrective action related to an individual CCP. All records and documents associated with monitoring CCPs should be signed by the person(s) doing the monitoring, either physically or electronically.

Minor deficiency (7 points) if:
- Single instance of a CCP not being assigned (to either a person or group), where there are multiple CCPs.

Major deficiency (3 points) if:
- Numerous instances of a CCP not being assigned (to either a person or group), where there are multiple CCPs.

Non-compliance (0 points) if:
- No CCPs have been assigned to either a person or group.

3.2.8: Have standard operating procedures (SOPs) been created for the monitoring process(es) of the CCPs, which would include how to carry out the monitoring activities?
Total compliance (10 points): Clear and simple standard operating instructions (SOPs) should be written for each CCP monitoring process(es). These SOPs should expand the CCP monitoring activities in detail in the form of work instructions, and match what is written in the HACCP plan. These SOPs can be used for training and as reference tools.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors and omissions within the CCP SOPs.

Major deficiency (3 point) if:
- Numerous instances of errors and omissions within the CCP SOPs.
- Single instance of a CCP SOP not being created in a system where there are multiple CCPs.

Non-compliance (0 points) if:
- CCP SOP(s) has/have not been created.
- CCP SOP(s) do not reflect at all the reality of what is being performed in the operation.

3.2.9: Have corrective action procedures been established for the CCPs, including a detailed action plan for operators to follow if the critical control limits are not met (loss of control/deviation) and plans to adjust the process back into control?
Total compliance (15 points): Corrective actions are procedures that must be taken if critical controls are not properly implemented (e.g. there is a deviation from a critical limit) and unsafe product may have been produced. There should be a documented, detailed plan with written procedures to follow when there is a loss of control (deviation) of a CCP appropriate to the nature of the hazard. The procedures should include details regarding how to handle affected products (if necessary). The corrective action details should note the critical control limit issue that occurred, what corrective actions were carried out, including what happened to potentially affected product and also how the process was "repaired" or "amended" in order to get the process back to the required control level. The HACCP plan corrective action sections should state where the corrective action details are to be recorded and details should match the written corrective action procedures. Where appropriate, preventative measures should also be required to reduce the likelihood the problem with recur. This may include root cause analysis. Corrective actions should ensure that the CCP has been brought under control and require that a review is conducted in order to prevent a recurrence of the situation. Corrective actions may require review of the HACCP system (3.2.3) to determine if modifications are required. Corrective action records are scored under 3.3.5.

Minor deficiency (10 points) if:
- Any one of the above criteria is missing in the corrective action plan details.
- Single/isolated instance(s) of omission or errors in the corrective action details.

Major deficiency (5 points) if:
- Two of the above criteria are missing in the corrective action plan details.
- Numerous instances of omission or errors in the corrective action details.

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

3.2.10: Have recording templates (recording forms) been developed for monitoring the CCPs?
Total compliance (15 points): Monitoring record templates should be designed to record the monitoring of the CCPs that have been identified. The records should match the details as noted in the HACCP Plan and have CCPs identified by name and number, what is being measured, the frequency of the measurement, the critical control limit, the operating limit (if applicable), the responsible person(s) or team and the corrective action(s) required in the case of measurements not in compliance. Recording forms should have a specific document code as part of the document control program (2.2.1).

Minor deficiency (10 points) if:
- Single/isolated instance(s) of a record(s) having been developed but does/do not match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.
- Single instance of recording forms lacking required details.

Major deficiency (5 points) if:
- Numerous instances of a record(s) having been developed but do not match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.
- More than one instance of recording forms lacking required details.

Non-compliance (0 points) if:
- Fundamental failure of record(s) that have been developed to match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.
- Single instance where a CCP has been created but a record for the monitoring data has not been developed.

3.2.11: Have verification plans and schedules been developed for each CCP?
Total compliance (15 points): Verification activities related to each CCP on the HACCP plan should be clearly detailed and documented. Verification activities should include a verification of the CCP monitoring records by a HACCP trained supervisor or manager, checking that the CCP monitoring records have been completed in a proper and timely manner and including any corrective action work. Note, a CCP operator cannot verify their own work. Verification activities verify that the HACCP plan is being implemented correctly, and might include microbial testing, customer complaints, equipment calibration, blade checks, visually observing a CCP operator, date checks of reagent expiration dates and any other information that CCPs might help generate. Verification information might help improve and develop the HACCP program, but should show that the plan is being implemented correctly, is controlling the risk to an acceptable level (or eliminating the risk) and where this is not the case, this should be indicated on the verification paperwork along with corrective action details (e.g., reviewing a CCP, a process flow, a hazard analysis step, etc.). Where verification activities have found that CCPs were not performing as required, there should be records that show that this prompted a review of the relevant part of the HACCP Plan.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of errors or omissions in the verification details on the plan.

Major deficiency (5 points) if:
- Numerous instances of errors or omissions in the verification details on the plan
- Single instance in a plan with multiple CCPs where verification details have not been noted.

Non-compliance (0 points) if:
- No verification plans have been developed for any CCP.

3.2.12: Is there documented evidence that all plant workers have attended a HACCP training, including training for CCP operators?
Total compliance (10 points): All site workers should receive basic HACCP overview training i.e. what is HACCP, the 7 principles, and what are the CCPs on site. Basic training might form part of the new hire orientation package. CCP operators should be specifically trained for their function(s) and include the operations they are responsible for. Senior management should also receive training (HACCP requires “buy in” from all levels). Records of training should be kept and also certificates where relevant. All workers should be trained to understand the principles of HACCP and the plan implemented in the facility. Training should be scheduled on a regular basis and documented. The training should be tailored to the people and their positions within the company. HACCP team member training is scored under 3.1.2.

Minor deficiency (7 points) if:
- Not all plant workers are trained in HACCP (but all key operators and majority of workers have been trained).
- Senior management has not received HACCP training.
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major deficiency (3 points) if:
- One or more CCP operators have not been trained in their specific functions.
- Numerous instances of omissions or incorrect data in the records.

Non-compliance (0 points) if:

- No formal training session developed for workers.
- No records of training being maintained.
- Fundamental failure to train all workers.

Execution of the HACCP Plan on the Plant Floor

3.3.1: Do all of the documents noted in the HACCP Plan accurately reflect plan requirements for the CCPs?
Total compliance (15 points): All documents noted in the HACCP plan should be in place for monitoring of the CCP(s). Check current logs against the HACCP plan and check that document version codes match. Check to see if the right version of the log is being used i.e. if the plan was updated and new parameters were chosen and the forms were revised, are the revised forms being used by the CCP operators. Usually this is monitoring logs, but if logs are mentioned in the verification section of the CCPs, these should also be checked. Electronic records should be checked to ensure that the correct version is being used. Document control issues specific to the HACCP plan are scored here.

Minor deficiency (10 points) if:
- Single instance of a CCP log in place, but the "version" of the log in use is different from that in the HACCP plan i.e. the details are different or there are omissions.
- Single instance of a document that does not accurately reflect plan requirements.

Major deficiency (5 points) if:
- Numerous instances of CCP logs in place, but the "versions" of the logs in use are different from those in the HACCP plan i.e. the details are different or there are omissions.
- Numerous instances of documents that do not accurately reflect plan requirements.

Non-compliance (0 points) if:
- Fundamental failure to control the "versions" of the CCP logs being used.
- Fundamental failure to control the HACCP Plan documents.

3.3.2: Are the CCP monitoring activities and frequencies in compliance with the HACCP Plan and CCP SOPs?
Total compliance (15 points): CCP monitoring activities and frequencies are in compliance with what is written in the HACCP Plan and CCP SOPs. Check current logs against the HACCP plan. Auditor should carefully check the monitoring frequencies – allow some slight variations (minutes either way of the target frequency). The critical control limits should exactly match those mentioned on the HACCP plan. Note that if a monitoring test is done more frequently than stated, it is not necessarily a fault (i.e. point loss) if it is "in the spirit" of the plan. The records should show actual values or observations, be accurate and legible, be real-time recording and have adequate detail.

Minor deficiency (10 points) if:
- Single/isolated instance(s) where information or requirements on the records do not match what is noted in the HACCP plan.
- Single/isolated instance(s) of issues with how records are being filled out.

Major deficiency (5 points) if:
- Numerous instances where information or requirements on the records do not match what is noted in the HACCP plan.
- Numerous instances of issues with how records are being filled out.

Non-compliance (0 points) if:
- Fundamental failure to have information or requirements on the records matching what is noted in the HACCP plan.
- Records are consistently being filled out incorrectly.

- Single instance where a CCP has been created but monitoring data has not been recorded.

3.3.3: Do CCP operators understand basic HACCP principles and their role in monitoring CCPs?
Total compliance (10 points): CCP operators should understand basic HACCP principles, specifically CCPs in their areas and their responsibilities for taking appropriate action should the limits be exceeded. This can be determined through casual worker interview, with the approval of the audit host. The visual part of this confirmation is matching what the CCP operator says versus what is written in the HACCP documentation and also what is written in the CCP monitoring logs.

Minor deficiency (7 points) if:
- One instance where the CCP operator(s) are lacking in basic knowledge about HACCP principles.
- One instance where the CCP operator(s) are not able to explain correctly, details about the CCPs they are monitoring e.g. what to do if the critical control limits are exceeded.

Major deficiency (3 points) if:
- More than one instance where the CCP operators are lacking in basic knowledge about HACCP principles.
- More than one instance where the CCP operators are not able explain correctly, details about the CCPs they are monitoring e.g. what to do if the critical control limits are exceeded.

Non-compliance (0 points) if:
- Fundamental failure of the interviewed CCP operator to show basic knowledge about HACCP principle.
- Fundamental failure of the interviewed CCP operators to be able to explain correctly, details about the CCPs they are monitoring e.g. what to do if the critical control limits are exceeded.

3.3.4: Are CCP monitoring records signed off (or initialed) by the operator(s) who are carrying out and recording the CCP check?
Total compliance (15 points): All CCP monitoring records and documents should be legibly signed off by the person(s) doing the monitoring. Full signatures (with printed name if signature is not legible), initials and electronic signatures are acceptable. If initials are used, care should be taken to ensure that there is no confusion between two individuals who have the same initials e.g. by using middle initials as well.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of CCP record(s) not signed off by operator(s).

Major deficiency (5 points) if:
- Numerous instances of CCP record(s) not signed off by operator(s).

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

3.3.5: Is there a deviation record detailing documented corrective actions when a deviation/loss of control of a CCP occurs (a critical control limit is exceeded)?
Total compliance (15 points): Corrective actions should be detailed in writing when a deviation/loss of control of a CCP occurs as per procedure in 3.2.8). The CCP deviations should be noted on a deviation record (or similar form, as noted in the HACCP plan), should detail what has happened, what was done to correct the issue and any preventative actions taken to prevent reoccurrence. Records should indicate what happened to any affected product and also detail how the process was rectified. The corrective action details should match what is described in the HACCP plan.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of corrective action(s) being recorded, but are lacking some details.

- Single/isolated instance(s) of corrective action(s) being recorded, but not meeting the requirements as noted in the HACCP plan.

Major deficiency (5 points) if:
- Single instance of CCP critical control limit breach not being recorded and/or corrective actions not being recorded.
- Numerous instances of corrective action(s) being recorded, but are lacking some details.
- Numerous instances of corrective action(s) being recorded, but not meeting the requirements as noted in the HACCP plan.

Non-compliance (0 points) if:
- More than one instance of CCP critical control limit breach not being recorded and/or corrective actions not being recorded.
- Fundamental failure to properly record corrective action details or the details recorded in no way meet what is required by the HACCP plan.

3.3.6: Are the CCP records reviewed and signed off by the quality control supervisor and/or management (second signatory)?
Total compliance (10 points): CCP records should be reviewed, dated and signed off within 36 hours of the original CCP monitoring activity occurring. Ideally records are reviewed prior to release of product to prevent potential recall and unintended consequences should a deviation be found during record review. Allowance may be made for operations that are not running daily (auditor discretion applies). The sign offs should be done by the quality control supervisor or manager (second signatory). This should be a separate signature to that of the CCP operator. The individual signing off should check the records (e.g. dates, production lines, monitoring results, frequencies, corrective actions, use of correct forms, etc.), since their signature is basically stating that everything is in order relative to the written HACCP plan and associated documents. If discrepancies are found during the record review corrective actions must be taken and documented (3.3.5).

Minor deficiency (7 points) if:
- Single/isolated instance(s) of CCP records not reviewed, dated and signed off within 36 hours by the quality control supervisor or manager (second signatory).
- Single/isolated instance(s) of the CCP records being signed off by the second signatory but there are issues with the records that have not been highlighted.

Major deficiency (3 points) if:
- Numerous instances of CCP records not reviewed, dated and signed off within 36 hours by the quality control supervisor or manager (second signatory).
- Numerous instances of the CCP records being signed off by the second signatory but there are issues with the records that have not been highlighted.

Non-compliance (0 points) if:
- Fundamental failure for CCP records to be reviewed, dated and signed off.
- Fundamental errors on the CCP records that are being signed off by the second signatory.

Section 4: Additional Questions (Not Part of Overall Food Safety Percentage)

Management System

4.1.1: Is there a training management system in place that shows what types of trainings are required for various job roles of specific workers, including who has been trained, when they were trained, which trainings they still need to take, and a training schedule?

Total compliance (5 points). The company has a system in place (e.g. training matrix) that shows what types of trainings are required for various job roles that affect food safety, who has been trained, when they were trained, which trainings they still need to take, and a training schedule. This question is related to the organizational chart and job role descriptions. Training records required under specific questions will be reviewed in the applicable section(s).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of trainings for a job role being omitted from the system.

Major deficiency (1 point) if:
- Numerous instances of trainings for job roles being omitted from the system.

Non-compliance (0 points) if:
- There is no training management system.
- There is a training management system, but it does not reflect how workers are actually being trained.

4.1.2: Is there documented management verification review of the entire food safety management system at least every 12 months, including an evaluation of resources, and are there records of changes made?

Total compliance (10 points): There is documented verification of the entire food safety management system at planned intervals (minimum 12 month intervals) and reviewed by senior management (e.g. signatures, meeting minutes) to ensure its continuing suitability, adequacy and effectiveness, and that they are continuing to support and invest in adequate food safety resources (e.g., equipment, services, supplies, personnel training, worker staffing levels, customer requirements/specifications, etc.). The documented review should meet any national or local legislative requirements. The review should include an analysis of the effectiveness of key food safety programs and that they are implemented correctly. Based on effectiveness, changes to the system are documented. The review should show if the system is being implemented correctly and determine the need for changes to the system. Where changes are required, this should be indicated on the verification paperwork along with corrective action details. If applicable, HACCP verification should be performed as well. Both activities can be performed together or separately. Changes made in programs should be reflected in the report. Records of all verifications activities, reasons for amending documents, validations and changes should be available for review.

- Internal Audits
- External Audits (2nd Party and 3rd Party)
- Other audits/visits (official)
- Analysis of feedback/complaints and recalls (where applicable)
- Review of incidents including unusual occurrences, foreign material issues, pest control issues, microbial testing results, food defense, food fraud, etc.
- Review and updates to operation's objectives
- Review of organizational chart
- Document control activities including updates, changes or new SOPs, customer specification issues
- HACCP/PC verification
- Sanitation
- Pest control
- Approved supplier/service provider programs
- Worker training review
- Facility and equipment maintenance
- Other food safety managements system related activities

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions in the verification activities.
- Single/isolated instances of key programs not evaluated for effectiveness
- It has been more than 12 months since management verification but less than 18 months.

Major deficiency (3 points) if:
- Numerous instances of errors or omissions in the verification activities.
- Numerous key programs such as pest control, supplier control or sanitation operating procedures not evaluated for effectiveness
- It has been more than 18 months since management verification (but less than 24 months).
- No proof of senior management review.

Non-compliance (0 points) if:
- Widespread errors or omissions in the verification activities.
- Most key food safety programs not evaluated for effectiveness
- It has been more than 24 months since management verification.

4.1.3: Where specific industry guidelines or best practices exist for the crop and/or product, does the operation have a current copy of the document?
Total compliance (3 points). There is a current copy of any specific industry guidelines for the crop and/or product available for review (electronic copies are accepted). Some examples include the Produce Safety Rule, FSMA Seven Rules including Foreign Supplier Verification Programs, Sanitary Transportation of Human and Animal Food, the Leafy Green Marketing Agreement (LGMA), California Cantaloupe Program, Tomato Good Agricultural Practices (T-GAP), Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Herbs, Food Safety Best Practices Guide for the Growing and Handling of Mexican Papaya, etc. Not applicable if no specific industry guidelines or best practices exist for the crop and/or product or activity.
Reference:

FSMA: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#guidance
FDA Produce & Plant Products Guidance Documents & Regulatory Information:
https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/default.htm
Center of Produce Safety Resources: https://www.centerforproducesafety.org/resources.php
Penn State Mushroom Resources: https://plantpath.psu.edu/facilities/mushroom/resources

Minor deficiency (2 points) if:
- Missing one copy of specific industry guidelines of best practices where more than one crop or product is handled.

Major deficiency (1 point) if:
- There is a copy of the best practices, but it is not the current version.
- Missing more than one copy of specific industry guidelines or best practices where more than one crop or product is handled.

Non-compliance (0 points) if:
- Specific industry guidelines or best practices exist for the crop/crop group being audited, but the operation does not have a copy.

Control of Documents and Records

4.2.1: Are all records and test results that can have an impact on the food safety program verified by a qualified person independent of the individual(s) completing the records?
Total compliance (5 points): Records and test results should be reviewed, signed off and dated by a qualified person within seven (7) days. The verifier is independent of the individual completing the record(s), understands the purpose of the verification and understands what they need to review on the

record(s) before they sign (i.e. PCQI qualification, evidence of training, etc.). Examples of monitoring records may include composting records, CCPs, sanitizer, pH, water turbidity, cleaning and sanitation, etc. If any issues are detected, corrective actions should be recorded.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of records and/or test results not being reviewed and signed off by a qualified person within 7 days (second signatory).
- Single/isolated instance(s) of records and/or test results being signed off by a qualified person but there are issues with the records that have not been highlighted.

Major deficiency (1 point) if:
- Numerous instances of records and/or test results not being reviewed and signed off by a qualified person within 7 days (second signatory).
- Numerous instances of the records and/or test results being signed off by a qualified person but there are issues with the records that have not been highlighted.

Non-conformance (0 points) if:
- Fundamental failure for records and/or test results to be reviewed and signed off by a qualified person within 7 days (second signatory).
- Fundamental errors on the records and/or test results that are being signed off by a qualified person.
- The verifier is not independent of the individual(s) completing the records.

Procedures and Corrective Actions

4.3.1: Is there a documented corrective action procedure that describes the basic requirements for handling all non-conformances affecting food safety?
Total compliance (5 points): The corrective action procedure should outline how the company manages corrective actions including preventative actions and follow-up validation to ensure corrective action taken has solved the problem. Records of the corrective action activities and their follow-up should be kept on file (omission of corrective actions is scored under specific questions in later modules).
Corrective action procedure should include:
- the review of the non-conformance
- the determination of the cause(s)
- the establishment of an action plan to address such non-conformances and prevent future occurrences (preventive action plan)
- the implementation of corrective actions and preventive actions
- the follow-up validation to ensure actions taken have solved the problem

Auditees may consider the option of using root cause analysis method when trying to determine the cause of a non-conformance or trend of non-conformances.

Minor deficiency (3 points) if:
- Single instance of an error or omission in the information within the corrective action procedure.
- Single instance of corrective action procedure missing a key element from list above.

Major deficiency (1 point) if:
- More than one instance of errors or omissions in the information within the corrective action procedure.
- More than one instance of corrective action procedure missing a key element from list above.

Non-compliance (0 points) if:
- Numerous errors or omissions in the corrective action procedure.
- Corrective action procedures have not been developed.

Internal and External Inspections

4.4.1: Is there a documented procedure for how internal audits are to be performed at the operations, including frequency and covering all processes impacting food safety and the related documents and records?

Total compliance (10 points): Self-auditing (self-diagnostics) is a key part of an operation's food safety program. A written procedure for internal audits should be created for each operation (farm, indoor agriculture, harvest crew, or facility) in order to proactively ensure safe food production. The internal audits procedure should include the checklist used for the internal audits, cover the inspection of sites, the practices in place, the related documents required, the records generated, the frequency of the internal audits, and identification of the person(s) or position(s) responsible for conducting the internal audits. Procedure should include the verification of the practices and the related documents and any corrective actions taken. Self-audits should be fully documented even if no changes are located. If issues are found, there should be detailed corrective action records. Audit records should include the date, personnel involved, areas that were checked, findings and corrective actions (where necessary). Recording systems (documentation) for food safety related topics should be audited at least quarterly (frequency could increase or decrease depending on production seasonality) to ensure that they are being completed properly (e.g., using the correct log, correct frequencies, recording results correctly, recording corrective actions, etc.). The food safety management system is audited every 12 months. The internal audit records are assessed in specific records questions. Inspection should include:

- Inspection frequency depends on type and size of operation but as a minimum:
- Food safety management system: at least every 12 months.
- Food safety documentation: at least quarterly.
- Facility: Processing plants should have at least a monthly frequency. Packinghouses, coolers and storage operation ideally have a monthly frequency, but at least a quarterly frequency. Entire facility (inside and out) should be included.
- HACCP: self-audits of the HACCP program should have been done at least once within last 12 months to ensure that the process flow, hazard analysis and HACCP plan reflect reality and ensure that the program has captured any changes to the process. Whenever changes are made to the program i.e. new equipment added to the facility, new critical control points added to the plan, new limits added, new packaging is required, etc., then the plan needs to be re-evaluated by a self-audit to make sure it is working properly. HACCP program reviews should also take into account the latest guidelines, legal changes, issues arising from other audits and any other information gained about the production process. Self-audits help verify the effectiveness of the HACCP program, identify deficiencies and help improve the program.
- Preventative Controls: self-audit of the program at least every three years to ensure product descriptions, process flows, hazard analyses, preventative control decisions, preventative control recording and worker training reflect reality and ensure the program has captured any changes to the process. Whenever changes are made to the program and where emerging issues may be relevant to the product and processes, then the plan needs to be re-evaluated by a self-audit to make sure it is working properly.

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.
- Single instance of self-audit not being required at least at the minimum frequency.

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.
- Changes to the HACCP plan have been made but the self-audit had not been conducted.

- Numerous instances of areas/issues missing on the inspection program.
- More than one instance of a self-audit not being required at least at the minimum frequency.

Non-compliance (0 points) if:
- Fundamental failure to record self-audits properly.
- Self-audits are not being conducted.
- Numerous instances of self-audits not being required at least at the minimum frequency.

Release of Items/Product

4.5.1: Is there a documented product release procedure available?
Total compliance (5 points): Product release procedures are needed when the product is approved for shipment or harvest (they do not indicate the release of a product that has been placed on hold). Product release procedures assure that a lot is only released for shipment (sale) when the lot meets agreed standards, such as order requirements (e.g. specification) and/or meets agreed testing requirements (e.g. results confirmed negative or within limits results from testing, etc.). This includes crops approved for harvest and crop harvest where harvested product is directly packed in the final packaging unit during harvest (e.g., mushrooms, berries, individually wrapped lettuce) or there is in-field processing/semi-processing. Products should not be released for harvest or shipment without assuring that all food safety evaluations have been completed. Designated personnel are responsible for signing off. Sign off may be part of harvest record, bill of lading, etc. Procedures should be properly documented, implemented and pertinent records retained. Procedures should take into account any specific customer requirements, for example, testing requirements. N/A for organization's that only have authority over the growing activities and operation(s), and not the harvesting activities.

Minor deficiency (3 points) if:
- Single part of the procedure is omitted.
- Single/isolated instance(s) of the procedure not being applied in the field, production and/or storage areas.

Major deficiency (1 point) if:
- Procedure missing more than one part, but SOP exists.
- Numerous instances of the procedure not being applied in the field, production and/or storage areas.

Non-compliance (0 points) if:
- No procedure.
- Procedure created bears no resemblance to what is being applied in the field, production and/or storage areas.

4.5.2: Are there records of product releases kept on file?
Total compliance (5 points): Records showing product releases should be available for review. Product release records are needed to document when the product is approved for shipment or harvest (they do not indicate the release of a product that has been placed on hold). Authorized personnel should sign a "release" for product. Sign off may be part of harvest record, bill of lading, etc. Records should be available demonstrating the sign off for the "release" of all product shipped. N/A for organization's that only have authority over the growing activities and operation(s), and not the harvesting activities.

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

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

Non-compliance (0 points) if:

- Failure to have signed records of product release.

4.5.3: Are there records of the handling of on hold and rejected items kept on file?
Total compliance (5 points): Records of items placed on hold or rejected (e.g. an on hold/disposition log) should be available for review and should be kept to provide information about any item (raw materials, packaging, work in progress, finished product, etc.) that is rejected or put on hold. Records should show date when the item was placed on hold/rejected, amount of product affected, the reason for being on hold/rejected, the name of the person who put the product on hold and any other actions taken to ensure that affected product is not commingled with other goods in such a way that their disposition is not clear. Authorized personnel should sign (with date and time) a "release" for any item placed on hold or rejected, detailing actions taken e.g. disposition, re-work, food bank, tilled back into the ground, etc. Disposition records for products placed on hold or rejected should be maintained and available for review where applicable. Where required by law, certificates of destruction should be kept for review.

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

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

Non-compliance (0 points) if:
- There is no record of on hold or rejected materials.

Supplier Monitoring/Control

4.6.1: Where food safety related testing is being performed by external laboratory service providers, are these licensed and/or accredited laboratories (e.g., ISO 17025 or equivalent, national and local regulations, etc.)?
Total compliance (5 points): All food safety relevant tests and/or analyses that are performed by external laboratories (e.g., water, pesticide residue and microbial) should be done by laboratories with current licenses and/or accreditations for the methods used. These can be ISO 17025 or equivalent, National Regulations or State Department approvals in the country of production. Documented evidence of these licenses and/or accreditations should be available indicating the scope of the license/accreditation/what analyses the laboratory is accredited to perform, what standard/code it is accredited to, who accredited the laboratory and date of expiration. Auditor should confirm that the laboratory has the appropriate licenses and/or accreditations for the analyses being done i.e. product testing, water testing, pesticide residue testing, etc. Letters of guarantee from the laboratory are not acceptable and proficiency testing (while useful supporting information) does not replace the requirement for laboratory licensing and/or accreditation.

Minor Deficiency (3 points) if:
- Single instance of an omission or incorrect data in the documentation.

Major Deficiency (1 point) if:
- More than one instance of omissions or incorrect data in the documentation.

Non-compliance (0 points) if:
- No documentation.
- Using a non-licensed or accredited laboratory.
- License/accreditation of testing laboratory has expired.

Food Defense

4.7.1: Is there a written food fraud vulnerability assessment (FFVA) and protection plan for all types of fraud, including all incoming and outgoing products?
Total compliance (3 points). There should be a vulnerability assessment and comprehensive protection plan for all types of food fraud. This includes economically motivated hazards, economically motivated food safety hazards, adulterant substances, mislabeling, theft, tampering, simulation, diversion or gray market, intellectual property rights and counterfeiting. An example of a food fraud scenario that may occur at an operation is when suppliers provide products/materials that do not match their required specifications (e.g. unapproved chemicals, non-food grade packaging material, product substitution).

Additional resources:
https://www.pwc.com/gx/en/services/food-supply-integrity-services/food-fraud-vulnerability-assessment.html
https://www.federalregister.gov/documents/2015/09/17/2015-21920/current-good-manufacturing-practicehazard-analysis-and-risk-based-preventive-controls-for-human
https://www.ssafe-food.org/
https://www.mygfsi.com/component/k2/item/89-http-www-mygfsi-com-files-technical-documents-201805-food-fraud-technical-document-final-pdf.html
https://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2018/is-that-a-beet-or-a-banana-unwrapping-food-fraud-in-the-produce-industry/
https://www.foodsafetymagazine.com/magazine-archive1/februarymarch-2017/food-fraud-vulnerability-assessment-and-prefilter-for-fsma-gfsi-and-sox-requirements/

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

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

Non-compliance (0 points) if:
- There is no vulnerability assessment.
- Fundamental failure to review food fraud types for the assessment.

4.7.2: Are records associated with the food defense plan and its procedures being maintained, including monitoring, corrective action and verification records (where appropriate)?
Total compliance (5 points). The records required in the food defense plan should be maintained, in accordance with the details of the plan (2.8.1) and its associated procedures. These records are also subject to the document control and records requirements of this audit.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors or omissions in the records.
- Single/isolated instance(s) of records not being maintained as per plan.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions in the records.
- Numerous instances of records not being maintained as per plan.

Non-compliance (0 points) if:
- There are no available records.
- Fundamental failure to maintain records as per plan.

Site

4.8.1: Is there a site plan showing the facility location, adjacent sites, roads, water sources, storm water, wastewater and other relevant features?
Total compliance (5 points). There should be a site map or similar document (photograph, drawing) that accurately shows the facility building(s), location of permanent water fixtures (well, mains) and water systems, including any holding tanks and water captured for re-use. Storm water, wastewater, septic systems, effluent lagoons or ponds, surface water bodies are also identified.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a missing feature.

Major deficiency (1 point) if:
- Numerous instances of missing features.

Non-compliance (0 points) if:
- There is no site plan.
- The site plan does not represent the actual features of the facility.

4.8.2: Is there a facility floor plan showing the layout of the building, production areas, storage areas, water sources and fixtures, layout of equipment and traffic flow patterns?
Total compliance (5 points). There should be a facility floor plan (map, drawing) indicating production areas, storage areas, water fixtures and drainage, layout of equipment and traffic flow patterns of equipment and workers. The flow pattern for food products, waste material, workers and equipment should prevent raw materials and waste from coming in contact with the finished product. Flow is ideally in one direction and follows a logical sequence from raw material handling to finished product storage.
Minor deficiency (3 points) if:
- Single/isolated instance(s) of a missing feature.

Major deficiency (1 point) if:
- Numerous instances of missing features.

Non-compliance (0 points) if:
- There is no floor plan.
- The floor plan does not represent the actual features of the facility.

4.8.3: Has a documented risk assessment been performed to ensure that any food safety hazards relevant to facility location and adjacent land use are identified and controlled?
Total compliance (10 points): There should be a documented risk assessment for the facility to identify and control any food safety hazards relevant to facility location and adjacent land use e.g. animal activity, industrial activity, water characteristics, waste water treatment sites (settling ponds, land applications, etc.) or any other potential sources of contamination. All national and local laws pertaining to land use and on-site water treatment systems should be followed. Where necessary, for wastewater treatment areas, there should be applicable permits on file and evidence of regulatory and/or third-party inspections. The risk assessment should be reviewed at least annually and when a significant facility location/adjacent land change occurs.

A detailed risk assessment should be conducted and **documented**.
One approach:
i) Identify hazards.
ii) Determine who may be harmed and how
iii) Evaluate the risks and decide on actions to control the risks
iv) Document findings and implement actions
v) Review and update assessment as necessary

http://www.fsc.go.jp/sonota/foodsafety_riskanalysis.pdf
http://water.epa.gov/infrastructure/watersecurity/
http://water.epa.gov/infrastructure/sustain/upload/2009_05_26_waterinfrastructures_tools_si_watereum_primerforeffectiveutilities.pdf

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions on the risk analysis

Major deficiency (3 points) if:
- Numerous instance(s) of errors or omissions on the risk analysis

Non-compliance (0 points) if:
- Multiple fundamental errors on the risk analysis
- No documented risk analysis

Operational Monitoring Records

4.9.1: Are there records of visual monitoring and/or testing and changing of recirculated and batch water systems (e.g., dump tanks, flumes, hydrovacuums, hydrocoolers, etc.), for build-up of organic material (turbidity)?
Total compliance (5 points). There should be records of visual monitoring and/or testing and changing of recirculated and batch water systems during production. Water should be changed when it is dirty and when switching products. Frequency is at least daily. Water may be used for longer if a validated regeneration system (e.g., a water pasteurization/filtration system) is being used.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.
- Single/isolated instance(s) of monitoring not taking place on a consistent basis.

Major deficiency (1 point) if:
- Numerous instances of omissions or incorrect data in the records.
- Numerous instances of monitoring not taking place on a consistent basis.

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

Maintenance and Sanitation files

4.10.1: Are there records showing filters in air conditioning, evaporative coolers, ventilation and air filtration units are regularly cleaned and replaced?
Total compliance (5 points). Records should be made available to verify that filters in air conditioning, evaporative coolers, ventilation and air filtration units are regularly cleaned and/or replaced. Records might include in-house sanitation records, maintenance records and/or contractor records/invoices.

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

Major compliance (1 point) if:
- Numerous instances of incomplete records or omissions.

Non-compliance (0 points) if:
- No records.

- Fundamental failure to maintain records.

Testing

4.11.1: Where food safety related testing is being done in-house, is there a laboratory quality assurance manual with validated testing methods and protocols, evidence of training related to sample collection and testing protocols, and relevant records of results?
Total compliance (10 points). There should be documented evidence that the in-house laboratory is using the correct methods for testing (e.g., validation) and have established protocols to detect errors and to initiate corrective actions. There are records showing that workers handling samples have been trained on proper sample collection and testing protocols. An accredited laboratory should be used when testing is conducted to comply with specific regulatory (e.g. FDA) testing requirements applied to address an identified or suspected food safety problem (e.g. sprout spent irrigation water).

Minor deficiency (7 points):
- Single/isolated instance(s) of missing test records.
- Single/isolated instance(s) of missing training records.

Major deficiency (3 points):

- Numerous instances of missing test records.
- Numerous instances of missing training records.

Non-compliance (0 points):
- No established laboratory quality assurance manual.
- The established protocols are not being followed.
- There is no validation material to justify the testing methods being used.
- Fundamental failure to maintain test records.

Temperature Controlled Storage & Distribution Logs

4.12.1: Is there a documented procedure for checking truck trailer temperature prior to shipping?
Total compliance (5 points). There should be a documented procedure to check truck trailer temperature prior to shipment. Where relevant, requirements from the organization that has contracted the carrier should be followed, including the use of time temperature recording devices.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of not having a completed procedure.

Major deficiency (1 point) if:
- Numerous instances of not having a completed procedure.

Non-compliance (0 points) if:
- There is no documented procedure.

4.12.2: Is there a documented procedure for reviewing the sanitary condition of truck trailers that will transport the product?
Total compliance (5 points). Truck trailers (or other transportation system, e.g. railway carriages) should be checked for their sanitary condition and records maintained. Attributes checked should include cleanliness, trailer fitness for intended use (design and construction materials), issues from previous loads, pest free, odor free, load segregation, etc. There should be a documented procedure to cover this

check. Where relevant, requirements from the organization that has contracted the carrier should be followed.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of not having a completed procedure.

Major deficiency (1 point) if:

- Numerous instances of not having a completed procedure.

Non-compliance (0 points) if:

- There is no documented procedure.