Primus Standard Audits

Harvest Crew

Interpretation Guidelines

Used in conjunction with the Primus Standard Audits v20.06

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These guidelines are written to 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 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/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 included 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 without 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 without 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 certification programs.

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 systematic 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 still 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 a standard certification 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 certification audit once the service has begun. The only time a standard certification 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 processing is observed on the day of the audit. If the auditee decides not to use the 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 above 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 (documentation 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. The documentation may also be inspected via a Desk Review, which is an off-site review of required documentation submitted by the auditee. The auditor will still verify documentation while on-site. Please see the General Regulations and Certification Body specific guidelines for more information about a Desk Review.

- **HACCP and/or Preventive Controls (PC) 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 (e.g. 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 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 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 should have at least the previous season's records available for review.	Three months of records (may include last season's records).
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: Food Safety Management System

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 relevant questions. 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.**

Control of Documents and Records

1.2.1: 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 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 process control records not being retained for the required length of time (two years unless legally longer storage is required, or the product has a longer shelf life than 24 months).

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

1.2.2: 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 SOP's 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 1.2.3) 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 stored 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 editing of hard copy and/or computerized records.
- Widespread failure to use electronic signatures and/or software lacks secure electronic signature capability.

1.2.3: 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.

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

1.3.1: 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

1.4.1: 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.

Traceability and Recall

1.5.1: 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 demonstrates 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.

1.5.2: 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.

1.5.3: 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 is effective, should be consistent with the scenario identified. Documentation should indicate the date and time the mock recall was initiated, the product or material chosen, the scenario, amount of product produced, affected lot ID's (date code(s), lot code(s), etc.), amount located, 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

1.6.1: 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.

1.6.2: 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.

Section 2: Harvest Crew

General

2.1.1: Is there a designated person responsible for the operation's food safety program?
Total compliance (10 points): There should be a designated person/persons responsible for the operation's food safety program that has been trained accordingly. They should have documented formal training or be trained by someone that has formal credentials that are documented. 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's training and/or their relevant experience in food safety.

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's training and/or their relevant experience in food safety.

Non-compliance (0 points) if:
- Failure to document person/persons in charge of the operation's food safety program's 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.

2.1.2: Does the operation have a written food safety hygiene and health policy covering at least worker and visitor hygiene and health, infants and toddlers, animal presence in growing and storage areas, fecal matter, dropped product, blood and bodily fluids?
Total compliance (15 points): There should be a written food safety policy regarding worker and visitor personal hygiene, GAPs and health requirements. The policy should cover the rules related to hygiene and health (e.g., hand washing, eating/drinking, smoking, specific clothing rules, foreign material issues (including jewelry), cuts/wounds, illness rules, etc.), what to do in the case of evidence of animals and/or fecal matter in the growing and/or storage areas (e.g., product disposal, buffer zones, equipment cleaning), and what to do in the case of dropped product (discard), and if the product comes into contact with blood or other bodily fluids (destroy all product). All workers and visitors should be issued a list of rules in the relevant languages and confirm by signing that they understand and agree to abide by.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of errors and omissions in the food safety hygiene and health policy.
- Up to three key points missing off the worker and visitor personal hygiene, GAPs and health requirements listing.
- Single/isolated instance(s) of workers or visitors not signing a document stating that they will comply with the operations' personal hygiene and healthy policy.

Major deficiency (5 points) if:
- Numerous instances of errors and omissions in the food safety hygiene and health policy.
- Over three key points missing off the visitor personal hygiene, GAPs and health requirements listing.
- Numerous cases of workers or visitors not signing a document stating that they will comply with the operations' personal hygiene and healthy policy.

Non-compliance (0 points) if:
- Failure to maintain records.

- The company does not have a document for workers and visitors to sign stating that they will comply with the operations' personal hygiene and health policies.
- Fundamental failure of workers and/or visitors to sign a document stating that they will comply with the operations' personal hygiene and health policies.

Inspection

2.2.1: 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 for each of the harvesting operations, with the frequency defined in the internal audit program. Frequency depends on type of harvesting activity and associated risk pressures but should be at least quarterly. The records should include the crew name/identification, date of the audit, name of the internal auditor, justification for answers (not just checked √ or all Y/N), details of any deficiencies found and the corrective actions taken. An audit checklist (ideally Primus Standard Audits) should be used that covers all areas of the Primus Standard audit, including worker hygiene, harvest practices, on-site storage, documentation, etc. No down score if another audit checklist is used, as long as all areas are covered. See 3.4.1 regarding internal audit schedule.
Frequency Details for Farm, Indoor Agriculture and Harvest Crew: at least a pre-season growing area assessment and a full GAP self-assessment during harvest season covering growing and harvesting operations should be on file. If growing and harvest activities are under the same organizational authority the self-assessment should be on file covering both growing and harvesting and conducted during the harvest season. A harvesting company not under the authority of a grower should have self-assessments on file during harvest season covering each type of harvest process utilized for the crew(s), i.e. crew can harvest product in-field semi-processing and bulk/final packing in the field. A more frequent self-assessment frequency should be used depending on the crop type, farm or indoor agriculture location, any associated risk pressures, and/or if required by any national, local or importing country legal requirements, or customer requirements. These factors will also affect the need for pre-harvest inspections. Farm(s), indoor agriculture growing area(s), storage, harvesting, worker and visitor hygiene, agricultural water sources, training program, etc., and all associated paperwork should be included.

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 records with detailed responses.
- No documented internal audits have been performed.

2.2.2: Are there records of pre-harvest inspections and do they show that the current block (or coded area) is cleared for harvest? If there are no pre-harvest inspections, go to 2.2.3.
Total compliance (5 points): A pre-harvest block inspection should have been performed and if harvesting is occurring, it should show if there are any harvesting restrictions, etc. (e.g. evidence of animal intrusion, standing water in the harvest area, changes in weather conditions or weather events, pesticide application

events). The harvest crew might not have a copy of the actual inspection, but they should have a document indicating which blocks have been inspected and cleared for harvest. Inspections should typically occur within 7 days of harvest, Auditor should use discretion if inspections are occurring more than 7 days prior to harvest. If there are no pre-harvest inspections, go to 2.2.3.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of incomplete or missing records.
- Single/isolated instance(s) of inspection occurring more than 7 days prior to harvest.

Major Deficiency (1 point) if:
- Numerous instances of incomplete or missing records.
- Numerous instances of inspections occurring more than 7 days prior to harvest.

Non-compliance (0 points) if:
- No documented pre-harvest inspections have been performed.
- No evidence that the current block being harvested had been cleared for harvest.

2.2.2a: Where pre-harvest inspections have discovered issues, have buffer zones been clearly identified and at the time of the audit, are those buffer zones being respected?
Total compliance (15 points): Where pre-harvest inspections have discovered issues (e.g., flooding, animal intrusion issues), have the buffer zones been implemented (e.g., 30ft (9.1m) from flooded areas, 5ft (1.5m) from evidence of pest activity - use larger buffer zones if national and local laws are more stringent. Not applicable if no issues have been found.

Minor Deficiency (10 points) if:
- Single/isolated instance(s) of an issue being detected, and no corrective actions being performed prior to harvest.
- Single/isolated instance(s) of incomplete or missing records.

Major Deficiency (5 points) if:
- Numerous instances of issues being detected, and no corrective actions being performed prior to harvest.
- Numerous instances of incomplete or missing records.

Non-compliance (0 points) if:
- Fundamental failure to perform corrective actions.
- A single instance of a serious issue detected during the pre-harvest inspection and no corrective actions were performed prior to harvest.

2.2.3: Is there a pre-operation inspection log?
Total compliance (10 points): Pre-operation inspections should identify potential problems with the harvesting operation, including equipment hygiene, tool hygiene, worker hygiene and issues in the harvest area. These inspections and corrective actions should be recorded. Use of ATP is an ideal practice and if used, should be recorded properly along with any required corrective actions.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of incomplete or missing records.
- Single/isolated instance(s) of a hygiene section missing from the pre-operation inspections.

Major Deficiency (3 points) if:
- Numerous instances of incomplete or missing records.
- Numerous instances of hygiene sections missing from the pre-operation inspections.

Non-compliance (0 points) if:

- Fundamental failure to perform pre-operation inspections prior to starting the shift.
- No documented pre-operation inspections have been performed.

Training

2.3.1: Is there a food safety hygiene training program covering new and existing workers and are there records of these training events?

Total compliance (15 points): There should be a formal training program to inform all workers (including temporary, part-time, seasonal and contracted) of the current policies and procedures and requirements of the company regarding hygiene. Trainings should be in the language understood by the workers, and training type and intensity should reflect the risks associated with the products/processes. Frequency should be at the start of the season, before starting work, and then some topics covered at least quarterly, but ideally monthly. Full annual food safety refresher training sessions are encouraged but do not replace the ongoing more frequent training. Training material covering the content of the company policies and requirements regarding food safety and hygiene (2.1.2) and training should include the basic food safety and hygiene topics (e.g. toilet use, hand washing, protective clothing (where applicable), recognizing and reporting injury and illness, blood and other bodily fluids, jewelry, dropped product, animal intrusion, food consumption/taking breaks, foreign material requirements, food defense, etc.), the importance of recognizing and detecting food safety and/or hygiene issues with co-workers and visitors, and all food safety or hygiene issues for which they are responsible (e.g. recognizing contaminated produce that should not be harvested, inspecting harvest containers and equipment for contamination issues), correcting problems and reporting problems to a supervisor. 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.

Minor Deficiency (10 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 workers were covered.
- Training materials are not in the relevant language(s).
- Training occurring, not before starting to work but within the first week.
- Single/isolated instance(s) of workers not being trained

Major Deficiency (5 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.
- Up to three key topics e.g. hand washing, reporting injury/illness, blood and other bodily fluids, jewelry, dropped produce, animal intrusion, etc., have been omitted from the training.
- Only annual refresher training has occurred, and the operation runs for more than 3 months of the year.
- Training occurring, not before starting to work but within the first month.
- Numerous instances of workers not being trained.

Non-compliance (0 points) if:

- Failure to maintain records.
- No records of training or workers not being trained.
- More than three key topics e.g. hand washing, reporting injury/illness, blood and other bodily fluids, jewelry, dropped produce, animal intrusion, etc., have been omitted from the training program
- No specific orientation given or given after the worker has been working for more than one month.

2.3.2: 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. Unless sanitation workers attend regular food safety trainings, sanitation training should also include elements of food safety training pertinent to sanitation operations (e.g., hand washing, restroom use, foreign material etc.). Training logs should have a clearly defined topic(s) covered, trainer(s) and material(s) used/given. Training would also ideally include worker safety issues (e.g., use of personal protective equipment, accident prevention, what to do in case of an accident, procedures for avoiding electrical hazards when cleaning, etc.). Recorded training should occur at least on a 12-month basis.

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

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

2.3.3: 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 return to work requirements? (In countries with health privacy/confidentiality laws, e.g. USA, auditors can 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 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.

2.3.4: 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:
- Option for minor down score exists but as present no known good examples exist.

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

Non-compliance (0 points) if:
- No records or no disciplinary system.

Harvest Worker Hygiene

2.4.1: Are toilet facilities adequate in number and location? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.
Total compliance (15 points): Toilet facilities should be available to all workers and visitors, while work is actively occurring. At least one toilet per 20 workers should be provided, or if more stringent, as per prevailing national/ local guidelines. Toilet facility placement should be within ¼ mile or 5 minutes walking distance of where workers are located, or if more stringent, as per prevailing national/ local guidelines. A 5-minute drive is not acceptable, while farm work is actively occurring with groups of three or more workers. Where there are two or less workers present (e.g., spray activities, irrigation check) and workers have transportation that is immediately available to toilets within a 5-minute drive, it is acceptable to score as total compliance.
United States Department of Labor 1928 Title Field Sanitation
https://www.osha.gov/laws-regs/regulations/standardnumber/1928/1928.110

Minor deficiency (10 points) if:
- The toilet facilities are not within ¼ mile or 5 minutes walking distance for crews of three or more.
- The toilet facilities are not within a 5-minute driving distance for crews of two or less.

Major deficiency (5 points) if:
- The operation is not meeting the 1 toilet per 20 workers criteria.

Automatic Failure (0 points) if:
- **There are insufficient or inadequate toilet facilities.**

2.4.1a: Are toilet facilities in a suitable location to prevent contamination to product, packaging, equipment, and growing areas?
Total compliance (15 points): Placement of toilet facilities should be in a suitable location to prevent contamination to product, packaging, equipment, water sources, and growing areas. Consideration should be given when portable units are used that they are not situated too close to the edge of the crop. If pit toilets are used, consider proximity to crop and water sources.

Minor deficiency (10 points) if:
- Option for minor down score exists but at present, no known good examples exist.

Major deficiency (5 points) if:
- Toilet facilities pose a potential risk to product, packaging and equipment areas.

Non-compliance (0 points) if:
- Toilet facilities are located too close to the growing area or water source.

2.4.1b: Are toilets designed and maintained to prevent contamination (e.g., free from leaks and cracks)?
Total compliance (5 points): Toilets should be free from cracks and leaks and any waste holding tanks from toilets must be designed and maintained properly to prevent contamination. Waste holding tanks should be free of leaks, cracks and constructed of durable materials (e.g., plastic) that will not degrade or decompose (no wood). Note: pit toilets cannot be considered to be properly designed to prevent contamination.

Minor deficiency (3 points) if:
- Single observation of one the catch basin(s) not designed or maintained improperly.

Major deficiency (1 point) if:
- More than one observation of the catch basin(s) designed or maintained improperly.

Non-compliance (0 points) if:
- Catch basin(s) poses a risk of contamination to the growing area, product, packaging, and equipment, such as observing leaks or being improperly constructed.

2.4.1c: Are toilets constructed of materials that are easy to clean?
Total compliance (3 points): Toilet facilities should be constructed of non-porous materials that are easy to clean and sanitize. The floors, walls, ceiling, partitions and doors should be made of a finish that can be easily cleaned. Each toilet should be maintained and ventilated to outside air, and the floor and sidewalls should be watertight.

Minor Deficiency (2 points) if:
- Single/isolated instance of toilets not being constructed of non-porous materials.
- Single/isolated instance of floor and sidewalls not being watertight.

Major Deficiency (1 point) if:
- Numerous instances of toilets not being constructed of non-porous materials.
- Numerous instances of floor and sidewalls not being watertight.

Non-compliance (0 points) if:
- Toilets are not constructed of non-porous materials.

2.4.1d: Are the toilet materials constructed of a light color allowing easy evaluation of cleaning performance?
Total compliance (3 points): Toilets should be constructed of materials light in color, allowing easy evaluation of cleaning performance.

Minor Deficiency (2 points) if:
- Single/isolated instance of toilets not being constructed of light materials.

Major Deficiency (1 point) if:
- Numerous instances of toilets not being constructed of light materials.

Non-compliance (0 points) if:
- Toilets are not constructed of light materials.

2.4.1e: Are toilets supplied with toilet paper and is the toilet paper maintained properly (e.g., toilet paper rolls **are not stored on the floor or in the urinals)?**
Total compliance (5 points): Toilet paper should be provided in a suitable holder in each toilet facility. Toilet paper should be maintained properly (e.g., toilet paper rolls are not stored on the floor, sink or in the urinals).

Minor Deficiency (3 points) if:

- Single/isolated instance of toilet paper rolls not being maintained properly (e.g., stored on the floor, sink or in the urinals).

Major Deficiency (1 point) if:
- Numerous instances of toilet paper rolls not being maintained properly (e.g., stored on the floor, sink or in the urinals).
- One of the toilet facilities is out of toilet paper and has not been restocked.

Non-compliance (0 points) if:
- There was no toilet paper available at the time of the audit.

2.4.1f: Where used, is there a documented procedure for emptying the waste holding tanks in a hygienic manner and also in a way that prevents product, packaging, equipment, water systems and growing area contamination?

Total compliance (5 points): If toilets have waste holding tanks, they should be emptied, pumped, and cleaned in a manner to avoid contamination to product, packaging, equipment, water systems and growing area(s). Equipment used in emptying/pumping must be in good working order. A documented procedure should exist and should include a response plan for major leaks or spills, as well as indicating where pumped waste is disposed of and requiring communication to the designated person(s) responsible for the food safety program regarding the actions taken when a major leak or spill occurred.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of incomplete or missing details in the procedure.

Major Deficiency (1 point) if:
- Numerous instances of incomplete or missing details in the procedure.

Non-compliance (0 points) if:
- There is no documented procedure.

2.4.1g: Are the toilet facilities and hand washing stations clean and are there records showing toilet cleaning, servicing and stocking is occurring regularly?

Total compliance (10 points): Toilet facilities should be cleaned and sanitized on a regular basis. Servicing records (either contracted or in-house) should be available for review showing toilet cleaning, servicing and stocking is occurring regularly. Soiled tissue should be flushed down the toilet/placed in the holding tank (not be placed in trash cans and/or on the floor).
- Toilet facility (including hand washing stations) fixtures are in good operating condition and clean.
- Cleaning and sanitizing are occurring on a regular basis.
- 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 clean and not blocked.

Minor deficiency (7 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 (3 points) if:
- Numerous instances of non-compliance to the above requirements.
- Widespread observation of soiled toilet tissues being placed in trash cans.

Non-compliance (0 points) if:
- Failure to properly maintain areas.
- Single instance of soiled toilet tissues being left on the floor of the toilet facility.
- No cleaning and service records available.

2.4.2: Is the harvesting area free from any evidence of human fecal contamination? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.
Total compliance (15 points): There should be no evidence of human fecal contamination in the harvesting area, area being harvested, packaging area, equipment area, or in any other area that would cause a contamination issue. If this question is answered No, an automatic failure of the audit will result.

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:
- **Any observation of human fecal matter in the harvesting area.**

2.4.3: Is hand washing signage posted appropriately?
Total compliance (5 points): Toilet facilities should have hand washing signs as a reminder to wash hands before and after eating, returning to work and after using the toilet. Signs need to be posted visibly and in the language of the workers (visual signs are allowed). The visuals or signs should be permanent and placed in key areas where workers can easily see them.

Minor deficiency (3 points) if:
- Single/isolated instance of signage not being permanent.
- Single/isolated instance of signage not being in the language of the workers.
- Single/isolated instance of signage not posted visibly.

Major deficiency (1 point) if:
- Numerous instances of signage not being permanent.
- Numerous instances of signage not being in the language of the workers.
- Numerous instances of signage not posted visibly.

Non-compliance (0 points) if:
- There is no signage.

2.4.4: Are hand washing stations adequate in number and appropriately located for worker access and monitoring usage? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.
Total compliance (15 points): An adequate number of hand washing stations, in working order, should be provided to ensure efficient worker flow (1 per 20 people on site), and be available to all workers and visitors. Hands free is an optimum system. Hand washing stations should be visible and located within close proximity of toilet facilities and 1/4 mile or 5 minutes walking distance of where workers are located.

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

Minor deficiency (10 points) if:
- Only about 75% of needed hand washing stations are present.

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

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

- **There are no functioning hand wash stations.**

2.4.4a: Are the hand wash stations designed and maintained properly (e.g., ability to capture or control rinse water to prevent contamination onto product, packaging, and growing area, free of clogged drains, etc.)?
Total compliance (5 points): Hand wash stations should be free of clogged drains, designed and maintained properly to capture or control rinse water that could cause contamination onto product, packaging, equipment and growing area(s).

Minor Deficiency (3 points) if:
- Single/isolated instance of hand wash stations not draining properly.

Major Deficiency (1 point) if:
- Numerous instances of hand wash stations not draining properly.

Non-compliance (0 points) if:
- Systematic failure for hand wash stations to drain properly.
- Fundamental failure for hand wash stations not containing a system to catch the rinse water.

2.4.4b: Are hand wash stations clearly visible (e.g., situated outside the toilet facility) and easily accessible to workers?
Total compliance (5 points): Hand wash stations should be clearly visible (i.e. situated outside the toilet facility) in order to verify hand washing activities, and easily accessible to workers.

Minor Deficiency (3 points) if:
- Single/isolated instance of a hand wash station located inside a toilet facility.

Major Deficiency (1 point) if:
- Numerous instances of hand wash stations located inside the toilet facilities.

Non-compliance (0 points) if:
- All hand wash stations are located inside the toilet facilities.

2.4.4c: Are hand wash stations adequately stocked with unscented soap and paper towels?
Total compliance (5 points): All hand washing facilities should be properly stocked with liquid unscented/non-perfumed, neutral or antiseptic soap. Single use paper towels should be used, and units should be properly located. There should be an adequate stock of soap and paper towels.

Minor Deficiency (3 points) if:
- Single/isolated instance of a hand wash station out of soap and/or paper towels.

Major Deficiency (1 point) if:
- Numerous instances of hand wash stations out of soap and/or paper towels.

Non-compliance (0 points) if:
- There is no soap and/or paper towels available to workers.

2.4.4d: In the event of running out of toilet materials (e.g., water, soap, toilet tissue, paper towels), are there extra supplies readily available so that toilets can be restocked quickly?
Total compliance (5 points): Extra stocks of fresh water, soap, toilet paper and paper towels, etc., should be readily available in the event that replenishment is needed while harvesting is occurring.

Minor Deficiency (3 points) if:
- Single/isolated instance of extra supplies missing.

Major Deficiency (1 point) if:
- Numerous instances of extra supplies missing.

Non-compliance (0 points) if:
- No extra supplies were available.

2.4.5: Are total coliforms (TC) and generic *E. coli* tests conducted on the water used for hand washing at the required and/or expected frequency?
Total compliance (15 points): Total coliforms (TC) and generic *E. coli* testing should occur on a routine basis. All water sources used for hand washing throughout the harvesting season should be tested. One sample per water source should be collected and tested prior to use and then at least quarterly, ideally monthly. Water samples should be taken from as close to the point of use as is practical. At least one sample per distribution system is required. If there are multiple sampling points in a distribution system, then samples should be taken from a different location each test (randomize or rotate locations).
https://extension.psu.edu/coliform-bacteria
https://www.govinfo.gov/content/pkg/CFR-2011-title40-vol23/pdf/CFR-2011-title40-vol23-part141.pdf
https://www.epa.gov/dwstandardsregulations

Minor deficiency (10 points) if:
- Single instance of water testing not occurring at the right frequency.
- Sample was not taken from the closest practical point of use.

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

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

2.4.5a: Do written procedures (SOPs) exist covering proper sampling protocols, which include where samples should be taken and how samples should be identified?
Total compliance (10 points): There should be a documented procedure in place detailing how water samples are to be taken, including stating how samples should be identified i.e. clearly naming the location that the sample was taken, identifying the hand wash station, the water source and the date.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of incomplete or missing details in the procedure.

Major Deficiency (3 points) if:
- Numerous instances of incomplete or missing details in the procedure.

Non-compliance (0 points) if:
- There is no documented procedure.

2.4.5b: Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?
Total compliance (10 points): Written procedures (SOPs) should exist covering corrective measures, not only for the discovery of unsuitable or abnormal water testing results, but also as a preparation on how to handle such findings.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of incomplete or missing details in the procedure.

Major Deficiency (3 points) if:

- Numerous instances of incomplete or missing details in the procedure.

Non-compliance (0 points) if:
- There is no documented procedure.

2.4.5c: If unsuitable or abnormal results have been detected, have documented corrective measures been performed?
Total compliance (15 points): For total coliforms (TC) and generic *E. coli*, there should be negative or < detection limit (MPN or CFU/100mL). Where thresholds have been exceeded, there should be recorded corrective actions, including investigations and water retests.

Minor Deficiency (10 points) if:
- Single/isolated instance(s) of records showing abnormal test results for total coliforms without adequate documented corrective actions.

Major Deficiency (5 points) if:
- Numerous instances of records showing abnormal test results for total coliforms without adequate documented corrective actions.

Non-compliance (0 points) if:
- No corrective actions have been performed.

A single out of specification result for generic *E. coli* without proper corrective actions.

2.4.6: 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. 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.

2.4.7: Are secondary hand sanitation stations (e.g., hand dips, gels or spray stations) adequate in number and location, and are the stations maintained properly?
Total compliance (5 points): Secondary hand sanitation is required for items that may be "ready-to-eat" (e.g., herbs, stone fruit, tomatoes, citrus, edible flowers, etc.). Secondary hand sanitizers are optional for root vegetable crops or a commodity that requires cooking prior to eating. Secondary hand sanitation (hand dips, gels or sprays) does not replace hand washing requirements (lack surfactant qualities). Secondary hand sanitation stations should be non-perfumed/unscented, have 60% to 95% ethanol or isopropanol (benzalkonium chloride is also acceptable) and should be located near hand washing and other easily accessible areas. Hand gel / spray stations should be well stocked and tested regularly to ensure they are at the required strength - checks should be recorded. Strength checks do not need to be performed for commercially purchased sanitizers that have been purchased already mixed.

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.

Major deficiency (1 point) if:
- Numerous instances of hand secondary hand sanitation stations not in place or being empty.
- Numerous instances of hand dips containing under-strength solutions.
- Numerous instances of dispensers not properly located.
- 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.

2.4.8: Is it evident that corrective actions are taken when workers fail to comply with hand washing guidelines?
Total compliance (5 points): It should be evident that corrective actions are taken by a supervisor in charge when workers fail to comply with hand washing requirements.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of corrective actions not being taken.

Major deficiency (1 point) if:
- Numerous instances of corrective actions not being taken.

Non-compliance (0 points) if:
- Corrective actions are not taken.

2.4.9: 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 for this question.

Major deficiency (3 points) if:
- There is no major deficiency 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.

2.4.10: 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 growing area. Plain wedding bands are the only exception. Other examples of foreign items that may be a source of foreign material contamination include studs, false fingernails and finger nail polish, false eye lashes, eye lash extensions and badges, 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.

2.4.11: Are worker personal items being stored appropriately (i.e. not in the growing areas or material storage areas)?
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 growing area(s) and material storage area(s) to prevent contamination and avoid food security risks.

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

Major deficiency (1 point) if:
- Numerous instances of personal belongings, personal food, etc. being found in the growing or material storage area(s).

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

2.4.12: 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 growing and storage areas. Spitting should be prohibited in all areas. Smoking should not be permitted in eating and drinking areas.
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 refuse containers located in the growing area).
- Single/isolated instance(s) of designated area not meeting appropriate GAP 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 refuse containers located in the growing area).
- No designated smoking area (unless the site has a non-smoking policy).
- Numerous instances of designated area not meeting appropriate GAP standards.

Non-compliance (0 points) if:
- Widespread consumption of food and beverages outside of designated areas.
- Widespread evidence of smoking outside the designated area.
- Widespread evidence of using chewing tobacco in growing and storage areas.
- Designated area lacks access to a hand wash station.
- Widespread non-compliance to the above criteria.

2.4.13: Are workers wearing effective hair restraints that contain all hair?
Total compliance (5 points): If the operation requires the use of hair nets, the harvest workers should be wearing appropriate hair nets that restrain all hair. Baseball caps and head coverings are allowed in the harvesting area only if they are clean and worn with a clearly visible hair net that restrains all hair (where operation requires use of hair nets).
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 workers observed not wearing an appropriate hair restraint or not wearing them properly.

Major deficiency (1 point) if:
- Numerous instances of workers observed not wearing an appropriate hair restraint or not wearing them properly.

Non-compliance (0 points) if:
- Hairnets and/or beard-nets are not available for workers.

2.4.14: 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. Items in pockets and otherwise unsecured have the potential to fall into the product. Ideally, top pockets are sewn up or non-existent.

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.

2.4.15: Are all workers wearing protective outer garments suitable for the operation (e.g., appropriate clean clothes, smocks, aprons, sleeves and 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. Outer garments include where applicable: smocks, aprons, sleeves, non-latex gloves, etc. Suitable clothing is required for workers handling products that are potentially ready-to-eat (e.g., tomatoes, leafy greens, etc.). Items should be laundered in-house or by contract laundering agency. Individual workers should not take protective outer garments home for cleaning. Where items are laundered in-house the auditee should have documented

SOP and GAP rules about how these garments are cleaned. 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.), intact and appropriate for purpose. 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. Foot protection should also be considered where it could lead to contamination of the product (e.g., during watermelon harvest where workers stand inside harvest bins/trailers/buses); auditor discretion applies.

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.
- Single/isolated instance(s) of outer clothing not clean or being a potential source of contamination including use of latex gloves.

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.
- Numerous instance(s) of outer clothing not clean or being a potential source of contamination including use of latex gloves.

Non-compliance (0 points) if:
- Widespread failure to replace gloves when contaminated.
- Widespread failure to wear protective garments where required.
- Widespread non-compliance to the above and/or company policy.
- Widespread failure to wear clean outer clothing or of clothing being a potential source of contamination including use of latex gloves.

2.4.16: 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, break areas, etc.). Workers cannot smoke, eat, 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.

2.4.16a: 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 toilet?

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, break areas, etc.). Workers should not leave protective outer garments on equipment or packaging materials. Designated area should not be within the toilet facilities, break area, 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.
- Widespread non-compliance to the above.

2.4.17: 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 and placed in locations readily accessible to all workers on-site to prevent dehydration. Water should be suitably cool and in sufficient amounts, taking into account the air temperature, humidity and the nature of the work performed, to meet the needs of all workers. 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. If water containers are used, they should be maintained in a clean condition, free from residues and contamination to ensure workers are not adversely affected by contaminated water from unclean containers. 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.

2.4.17a: Are single use cups provided (unless a drinking fountain is used) and made available near the drinking water?
Total compliance (5 points): Single use cups should be provided so that cross contamination issues are avoided from person to person. Examples include single-use paper cups, drinking fountains, etc.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of single-use cups missing from one of the water containers.

Major deficiency (1 point) if:
- Numerous instances of single-use cups missing from the water containers.
- A drinking fountain is being used but is not in a sanitary condition.

Non-compliance (0 points) if:
- Single-use cups are not provided for the water containers.

2.4.18: Are first aid kits adequately stocked and readily available?

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. Gloves should be worn over all band aids on hands. Auditors should verify by checking the first-aid kit(s).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of first aid kit(s) not having adequate supplies, supplies out-of-date or kit not readily accessible.

Major deficiency (1 point) if:
- 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:
- Fundamental failure to provide first aid kit(s) with adequate supplies, supplies out-of-date or kit not readily accessible.

2.4.19: Are all commodities that come in contact with blood and/or other bodily fluids destroyed? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.
Total compliance (15 points): Any commodity that comes into contact with blood and/or other bodily fluids must be destroyed. If this occurs during the time of inspection, auditor must witness that product is destroyed.

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:
- **A single incidence of a commodity coming into contact with blood and/or other bodily fluids without being destroyed.**

2.4.20: Are there adequate trash cans placed in suitable locations?
Total compliance (5 points): There should be adequate measures for trash disposal so that the growing, harvesting and storage areas are not contaminated. Containers (e.g., dumpsters, cans) should be available and placed in suitable locations for the disposal of waste and trash.

Minor deficiency (3 points) if:
- Single/isolated instance of containers not being maintained.

Major deficiency (1 point) if:
- Numerous instances of containers not being maintained.

Non-compliance (0 points) if:
- Fundamental failure to maintain containers to protect against potential contamination of the crop.

2.4.21: Are any potential foreign material issues (e.g., metal, glass, plastic) controlled?
Total compliance (5 points): There should be no foreign material issues that are or could be potential risks to the product. Examples include, but are not limited to, glass bottles, unprotected lights on equipment, staples on wooden crates, hair pins, using “snappable” blades instead of one-piece blades, broken and brittle plastic issues on re-useable totes.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of a foreign material issue.

Major deficiency (1 point) if:
- Numerous instances of foreign material issues.

Non-compliance (0 points) if:
- Fundamental failure to prevent against foreign material issues.

Harvest Practices

2.5.1: Is the harvest area free from animal presence and/or animal activity (wild or domestic)? If yes, go to 2.5.2.
Total compliance (15 points): Animals can represent potential contamination to the harvesting area, to the crop, to the field equipment, etc., and therefore, should not be present in the operations. Evidence of animal presence can include tracks, fecal matter, feathers, etc.

Minor deficiency (10 points) if:
- Single/isolated instance of evidence of animal presence and/or animal activity.

Major deficiency (5 points) if:
- Numerous instances of evidence of animal presence and/or animal activity.

Non-compliance (0 points) if:
- Fundamental failure to prevent animal presence and/or animal activity in the harvesting area.

2.5.1a: Is the harvest area free from any evidence of animal fecal matter? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.
Total compliance (15 points): Fecal matter is a potential contaminant to the product being grown. Produce that has come into direct contact with fecal matter is not to be harvested. A "no harvest zone" of approximately 5ft (1.5 m) radius should be implemented unless or until adequate mitigation measures have been considered. If evidence of fecal matter is found, a food safety risk assessment should be conducted by a qualified worker and include appropriate corrective and preventative actions. Consideration of the maturity stage and type of crop involved is required. Any evidence of human fecal matter in the growing area is an automatic failure and scored under 2.4.2.

Minor deficiency (10 points) if:
- Single instance of fecal matter found in the audited area and a food safety risk assessment was implemented correctly.
- A “no harvest zone” is implemented, but the radius is less than 5ft.

Major deficiency (5 points) if:
- More than one instance of fecal matter found in the audited area and a food safety risk assessment was implemented correctly.
- Any instance of fecal matter is found in the audited area and a “no harvest zone” was not implemented.
- Any instance of fecal matter is found, and a food safety assessment is not conducted.

Automatic Failure (0 points) if:
- **Any observation of widespread animal fecal contamination in the audited area is an automatic failure.**
- **Any observation of any human fecal matter in the audited area is an automatic failure. Score under 2.4.2.**

2.5.2: Is the harvest area free from evidence of infants or toddlers?

Total compliance (10 points): Infants and toddlers can represent potential contamination to the growing area, to the crop, to packaging and should not be present in the operations, including chemical or equipment storage areas.

Minor deficiency (7 points) if:
- Single/isolated instance or evidence of infants or toddlers in the harvesting area.

Major deficiency (3 points) if:
- Numerous instances or evidence of infants or toddlers in the harvesting area.

Non-compliance (0 points) if:
- Fundamental failure to keep infants or toddlers out of the harvesting area.

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

Total compliance (15 points): Chemicals located on-site are required to be stored in a well vented, designated (with a sign), secure (locked) area. Storage area is maintained clean. 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. The chemical storage area should be located away from any growing areas, raw materials, packaging & finished food products, water sources and living areas. Spill controls should be in place for opened in use containers. All chemical containers should be off the floor, 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. Empty containers should be stored and disposed of safely. All federal and state or local laws and regulations for pesticides storage should be considered. Empty pesticide containers should be kept in a secured storage area until they can be recycled or disposed of properly. If containers cannot be refilled, reconditioned, recycled or returned to the manufacturer, they should be crushed, broken or punctured to make them unusable. Containers should be disposed of in accordance with label directions and with federal and state or local laws and regulations. Pesticide containers designed to be returned and refilled should not be reused or tampered with.
Where pesticide storage is not located on-site auditor discretion applies on question applicability.

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 instances of chemicals being used without proper attention to chemical spillage.

Non-compliance (0 points) if:

- Failure to properly store chemicals.
- 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 are evident that have not been cleaned up.

2.5.4: Are "food grade" and "non-food grade" chemicals used appropriately, according to label and stored in a controlled manner (not commingled)?

Total compliance (10 points): Food grade chemicals, including lubricants, greases, etc., are used in all product/packaging contact areas. All chemicals applied by the harvesting operation(s) should be approved by the prevailing authority (e.g., US: EPA/FDA, Canada: CFIA/Health Canada, Chile: SAG, 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. 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 growing/storage areas (unless stored securely, with access to entrusted workers only). Chemicals should be used according to label instructions e.g. following correct dilutions, H1 designation on lubricants, etc. Any chlorine bleach that is used for making a sanitizing solution, 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 a chemical being used contrary to label.

Major deficiency (3 points) 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 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 a chemical(s) used contrary to label.

2.5.5: Are there records of microbial testing for water used for postharvest product contact (e.g., washing, re-hydrating) and product contact surfaces (e.g., cleaning grading packing tables and harvest tools) showing that there is no detectable total coliforms and generic *E. coli* in the water?

Total compliance (15 points): All water sources that are used for postharvest contact with the edible portion of a crop (e.g., washing, re-hydrating) and product contact surfaces (e.g., cleaning grading or packing tables and harvest tools) should be tested on a routine basis. One sample per water source should be collected and tested prior to use and then at least quarterly thereafter, or at a frequency relative to the associated

risks. For commodities under the Leafy Greens Marketing Agreement, one sample per water source should be collected and tested prior to use if >60 days since the last test of the water source. Additional samples shall be collected at intervals of no less than 18 hrs. and at least monthly during use. Results of water testing for total coliforms and *E. coli* should meet the US EPA drinking water microbiological specification. For total coliforms and generic *E. coli*, there should be negative or < detection limit (MPN or CFU/100mL). If out of specification results are detected, then full details of corrective actions should be noted, including investigations and water retests.

https://extension.psu.edu/coliform-bacteria
https://safewater.zendesk.com/hc/en-us/sections/202366208-Total-Coliforms
https://www.govinfo.gov/content/pkg/CFR-2011-title40-vol23/pdf/CFR-2011-title40-vol23-part141.pdf
https://www.epa.gov/dwstandardsregulations

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

Major deficiency (5 points) if:
- More than one instances of testing of a water source not occurring at the required frequency

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

2.5.5a: Do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?
Total compliance (10 points): Written procedures (SOPs) should exist covering corrective measures not only for the discovery of unsuitable or abnormal water results, but also as a preparation on how to handle such findings.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of incomplete or missing details in the procedure.

Major Deficiency (3 points) if:
- Numerous instances of incomplete or missing details in the procedure.

Non-compliance (0 points) if:
- There is no documented procedure.

2.5.5b: If unsuitable or abnormal results have been detected, have documented corrective measures been performed?
Total compliance (15 points): For total coliforms and generic *E. coli*, there should be negative or < detection limit (MPN or CFU/100mL). Where thresholds have been exceeded, there should be recorded corrective actions, including investigations, water retests and if required, crop testing (*E. coli* O157:H7 and Salmonella < detection limits or Negative-zero tolerance).

Minor Deficiency (10 points) if:
- Single instance of records showing abnormal test results without adequate documented corrective actions.

Major Deficiency (5 points) if:
- More than one instance of records showing abnormal test results without adequate documented corrective actions.

Non-compliance (0 points) if:
- No corrective actions have been performed.

2.5.6: Is the product harvested and transported to a facility for additional handling and/or final packing?
Total points 0: Information gathering question. This question refers to product that is harvested in the field and then taken to a facility for additional handling and/or packing.

2.5.7: Is the product packed in the final packing unit in the field? If no, go to 2.5.8.
Total points 0: Information gathering question. This question refers to product packed in the field that is in the final unit for shipping (i.e. clamshell, wrapped products, carton boxes, etc.), that usually bypasses any selection packing lines in a facility i.e. goes to a cooling process as opposed to a packing line.

2.5.7a: Is packing material (e.g. cartons, bags, clamshells, sacks, RPCs) intended for carrying product used for that purpose only?
Total compliance (5 points): All containers intended for product 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. If a product container is used for any other reason than the storage of product, it should be clearly differentiated as such (e.g., painted another color and labeled).

Minor deficiency (3 points) if:
- Single/isolated instance(s) of single service container used for other than intended purpose.

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

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

2.5.7b: Is packaging material inspected prior to use and is product and packaging material free from handling contamination and exposure to ground?
Total compliance (10 points): Avoid stacking soiled bins on top of each other if the bottom of the bin has had direct contact with soil. Product and packing materials used in the harvesting process should be placed with protection underneath and handled in a manner to eliminate contamination from the ground or from inappropriate human handling, which includes commodities where it is industry practice to place the products on the ground after harvest (e.g., celery, asparagus). Crops down scored for exposure to the ground do not include root crops that are grown underground (e.g., carrots, potatoes, onions, garlic, etc.) or crops that are grown on the ground. Handling contamination could also be caused by using cloths or towels to remove dirt and/or debris from product. Automatic failure question 2.5.8 should be used when observing evidence of product or packaging foreign material, hazardous materials or adulteration issues.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of packaging coming in direct contact with the ground.
- Single/isolated instance(s) of packaging material not being inspected prior to use.
- Single/isolated instance(s) of handling contamination from use of cloths or towels used on product.

Major Deficiency (3 points) if:
- Numerous instances of packaging coming in direct contact with the ground.
- Numerous instances of packaging material not being inspected prior to use.
- Numerous instances of handling contamination from use of cloths or towels used on product.

Non-compliance (0 points) if:
- No inspections of packaging material are being performed prior to use.
- Fundamental failure to keep packaging from directly contacting the ground.
- Widespread use of cloths or towels to remove dirt/debris from product.
- **Any signs of product adulteration from poor handling practices – see 2.5.8, automatic failure due to product contamination**.

2.5.7c: If packing material is left in the field unattended, is it stored secured and protected?
Total compliance (5 points): All containers, cartons, packing material should be stored in a protected area to reduce the risk of contamination and tampering that can occur if packing material is left in the field unattended.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of packaging not being stored secure and protected.

Major Deficiency (1 point) if:
- Numerous instances of packaging not being stored secure and protected.

Non-compliance (0 points) if:
- Fundamental failure to store packaging in a secured and protected manner.

2.5.8: Is the crop, harvested product, ingredients (including water), food contact packaging and food contact surfaces 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): The crop, harvested product, ingredients (including water), 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). Other examples might include glass, trash/litter, motor oil in products, etc. This question is designed to allow an auditor to halt an audit when finding gross contamination issues. 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?

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 product.**
- **There is a single gross incidence of evidence of unacceptable limits of spoilage or adulteration in the crop, harvested product, ingredients (including water), food contact packaging or food contact surfaces.**

2.5.9: Are grading and packing surfaces, carts, ladders and other harvest aids used? If No, go to 2.5.10

Total points 0: Information gathering question. This refers to food contact surfaces used to grade, inspect, re-pack, or pack product (e.g., picking carts, grading tables, mushroom grading platforms, ladders, etc.).

2.5.9a: Does the design and condition of the grading and packing surfaces (e.g., e.g., smooth, non-porous, non-toxic, corrosion resistant, no wood, no fabric) facilitate effective cleaning and maintenance?

Total compliance (10 points): Grading and packing surfaces should be made of materials suitable for food contact that can be easily cleaned, sanitized and maintained. Equipment should be designed to allow access and easy cleaning (including hollow structures on supports, rollers, racks, etc.), with no hard to get to (debris catching) areas. Surfaces that are porous, trap debris, or are badly damaged should be replaced. Wood, for example, is porous and can trap moisture. Welds should be smooth and not "bobbly".

Minor deficiency (7 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 (3 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 poor welding, rough surfaces, poorly designed equipment that traps debris.

2.5.9b: Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the grading and packing surfaces that include the frequency of cleaning and sanitizing, and the procedures used including chemical use details?

Total compliance (5 points): Food contact surfaces used to grade, inspect, re-pack, or pack product (e.g., picking carts, grading tables, ladders, etc.) should be cleaned and sanitized on a regularly scheduled basis, based on written Sanitation Standard Operating Procedures (SSOPs). The program should state the frequency of cleaning and sanitizing, detail what, who, how and when, including chemical details (name, dilution/strength), and cleaning verification procedures.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of information missing from the SSOPs.

Major deficiency (1 point) if:

- Numerous instances of information missing from the SSOPs.

Non-compliance (0 points) if:

- There are no documented SSOPs.

2.5.9c: Are cleaning and sanitation logs on file for grading and packing surfaces that show what was done, when, by who and detail strength testing of anti-microbial solution used to sanitize surfaces?

Total compliance (10 points): Sanitation logs should include: date, list of areas/equipment that were cleaned and sanitized, sanitizer strength tests, and the individual accountable who signed-off for each task completed.

Minor deficiency (7 points) if:

- Single/isolated instance(s) of incomplete records, discrepancies against the SSOPs or other omissions.

Major deficiency (3 points) if:
- Numerous instances of incomplete records, discrepancies against the SSOPs or other omissions.

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

2.5.10: Are re-useable containers (e.g. buckets, field totes, lugs, RPCs, bins) used in the harvesting operation? If No, go to 2.5.11.
Total points 0: Information gathering question. This refers to any re-useable containers used in the harvesting operation (e.g., buckets, field totes, lugs, RPCs, bins, gondolas, etc.) used in the harvesting operation.

2.5.10a: Does the design and condition of re-useable containers (e.g., smooth, non-porous, non-toxic, corrosion resistant, no wood, no fabric) facilitate effective cleaning and maintenance?
Total compliance (10 points): All re-useable containers (totes, bins, buckets, etc.) should be made of easy to clean, smooth seamed, non-absorbent materials that do not flake or oxidize. Efforts should be made to eliminate wooden surfaces because of its porous nature. Where wood containers are used, they should be in a state of good repair and covered by a documented repair program.

Minor deficiency (7 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 (3 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 poor welding, rough surfaces, poorly designed equipment that traps debris.

2.5.10b: Are reusable containers free from any handling contamination?
Total compliance (10 points): Reusable containers used in the harvesting process should be managed to eliminate contamination from inappropriate handling practices. Handling contamination could also be caused using cloths or towels to remove dirt and/or debris from packaging. Avoid stacking soiled bins on top of each other if the bottom of the bin has had direct contact with soil.

Minor Deficiency (7 points) if:
- Single/isolated instance(s) of inappropriate handling practices.

Major Deficiency (3 points) if:
- Numerous instances of inappropriate handling practices.

Non-compliance (0 points) if:
- Widespread failure to prevent handling contamination.

2.5.10c: Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the reusable containers that includes the frequency of cleaning and sanitizing, and the procedures used including chemical use details?
Total compliance (5 points): Re-usable containers should be cleaned and sanitized on a regularly scheduled basis, based on written Sanitation Standard Operating Procedures (SSOPs). The program should state the frequency of cleaning and sanitizing, detail what, who, how and when, including chemical details (name, dilution/strength), and cleaning verification procedures.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of information missing from the SSOPs .

Major deficiency (1 point) if:
- Numerous instances of information missing from the SSOPs .

Non-compliance (0 points) if:
- There are no documented SSOPs .

2.5.10d Are cleaning and sanitation logs on file for reusable containers that show what was done, when, by who and detail strength testing of anti-microbial solution used to sanitize surfaces?
Total compliance (10 points): Sanitation logs should include: date, list of areas/equipment that were cleaned and sanitized, sanitizer strength tests, and the individual accountable who signed-off for each task completed. Where cleaning & sanitizing is handled by a 3rd party (packinghouse, contract RPC company) auditee is expected to provide evidence of cleaning & sanitizing activities.

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

Major deficiency (3 points) if:
- Numerous instances of incomplete records, discrepancies against the SSOPs or other omissions.

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

2.5.11: Are tools (e.g. knives, clippers, scissors, etc.) used in harvesting? If No, go to 2.5.12.
Total points 0: Information gathering question. This refers to harvest tools (e.g. knives, clippers, scissors, etc.) used in harvesting.

2.5.11a: Does the design and condition of harvest tools (e.g., smooth surfaces, smooth weld seams, nontoxic materials, no wood, no fabric) facilitate effective cleaning and maintenance?
Total compliance (10 points): To prevent foreign contamination issues, harvest tools (e.g., knives, coring rings, etc.) should be constructed of easy to clean materials. Tools should be shard free, and smooth seamed so that they do not have the ability to flake or oxidize.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of “bobbly” welds, rough surfaces, poorly designed tools that trap debris.
- Single/isolated instance(s) of tools where cleaning is made difficult.
- Single/isolated instance(s) of inferior materials (e.g. porous material construction, wood, non-food grade materials).

Major deficiency (3 point) if:
- Numerous instances of “bobbly” welds, rough surfaces, poorly designed tools that trap debris.
- Numerous instances of tools 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 tools will not allow for effective cleaning under normal conditions.
- Widespread poor welding, rough surfaces, poorly designed tools that trap debris.

2.5.11b: Are harvest tools free from exposure to the ground and/or any handling contamination?
Total compliance (5 points): Harvest tools (e.g., knives, clippers, scissors, coring rings, holsters, etc.) should be free from exposure to the ground and/or any handling contamination.

Minor Deficiency (3 points) if:
- Single/isolated instance(s) of handling contamination (e.g., exposure to the ground).

Major Deficiency (1 point) if:
- Numerous instances of handling contamination (e.g., exposure to the ground).

Non-compliance (0 points) if:
- Widespread failure to prevent handling contamination.

2.5.11c: Is there a tool accountability, storage and control program for knives and similar cutting hand tools used in the harvest area when not in use?
Total compliance (5 points): There should be an accountability, storage and control program in place for knives and similar cutting hand tools to identify potential product contamination. Tool accountability should include the inspection of the cutting surfaces for wear and tear, as well as a tool inventory check at the start and end of each shift. Workers should not take tools, such as knives, from the work area and should be required to use knife scabbards that can easily be cleaned i.e. non-porous. Leather scabbards should not be used.

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

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

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).

2.5.11d: Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for harvest tools that includes the frequency of cleaning and sanitizing, and the procedures used including chemical use details?
Total compliance (5 points): Harvest tools should be cleaned and sanitized on a regularly scheduled basis, based on written Sanitation Standard Operating Procedures (SSOPs). The program should state the frequency of cleaning and sanitizing, detail what, who, how and when, including chemical details (name, dilution/strength), and cleaning verification procedures.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of information missing from the SSOPs .

Major deficiency (1 point) if:
- Numerous instances of information missing from the SSOPs .

Non-compliance (0 points) if:
- There are no documented SSOPs .

2.5.11e Are cleaning and sanitation logs on file for harvest tools that show what was done, when, by who and detail strength testing of anti-microbial solution used to sanitize surfaces?
Total compliance (10 points): Sanitation logs should include: date, list of areas/equipment that were cleaned and sanitized, sanitizer strength tests, and the individual accountable who signed-off for each task completed.

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

Major deficiency (3 points) if:
- Numerous instances of incomplete records, discrepancies against the SSOPs or other omissions.

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

2.5.11f: Are harvesting tool dips being maintained properly in terms of anti-microbial solution strength and are records of the solution checks being maintained? AUDITORS SHOULD REQUIRE A TEST AT THE TIME OF THE AUDIT.
Total compliance (5 points): There should be records to show that the tool dip solutions (e.g. knife dips) are being maintained on a regular basis. The strength of the sanitizers should be checked on a regular basis (e.g., hourly) and recorded, with a minimum strength for a chlorinated system of ≥10 ppm free chlorine. All test solutions/strips should be within date code, appropriate for the concentrations used and stored correctly (especially light and temperature sensitive materials). Total chlorine does not measure the "available chlorine" after the tool dip has started to be used. AUDITORS ARE INSTRUCTED TO REQUIRE A TEST AT THE TIME OF THE AUDIT.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of strength tests not being performed at the required frequency.
- Single/isolated instance(s) of missing or incomplete records.
- Single/isolated instance(s) of corrective actions not being performed.
- Single/isolated instance(s) of testing not being done correctly.

Major deficiency (1 point) if:
- Numerous instances of strength tests not being performed at the required frequency.
- Numerous instances of missing or incomplete records.
- Numerous instances of corrective actions not being performed.
- Numerous instances of testing not being done correctly.

Non-compliance (0 points) if:
- There is no strength testing being performed or widespread failure to perform tests correctly.
- Fundamental failure to maintain records.
- Corrective actions are not being performed.

2.5.12: Is machinery used in the harvesting process? If No, go to 2.5.13.
Total points 0: Information gathering question. This includes equipment with the potential to affect product (e.g., conveyor belts, mechanical harvesting units, field packing rigs, coring rigs and any "in-field" processing rigs, school buses, live-bottom trailers, and tractors/trucks pulling in-field equipment). Please note that there are some more specific questions for coring rigs and any "in-field" processing rigs in a later section.

2.5.12a: 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): Food contact surfaces on equipment should be free of flaking paint corrosion, rust, and/or unhygienic materials, as they can pose foreign material and/or microbiological hazards. Food

contact surfaces should be made of non-toxic, non-porous materials. Surfaces should be maintained in good condition.

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 2.5.8, automatic failure).**

2.5.12b: Are food contact equipment surfaces clean?
Total compliance (15 points): Unsanitary food contact surfaces can directly lead to contamination of the product. All equipment surfaces that make contact with product should be kept in a clean condition to avoid cross contamination. Food debris, bio films, excessive dust, etc., should be cleaned off equipment.

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, 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 harvesting operation 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 harvesting operation has ceased for that run time e.g. after final shift.

2.5.12c: 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 2.5.8, automatic failure).**

2.5.12d: Are non-food contact equipment surfaces clean?
Total compliance (10 points): Unsanitary non-food contact surfaces can indirectly lead to contamination of the product. All equipment surfaces that do not make contact with product should be kept in a clean condition to avoid cross contamination. Food debris, bio films, excessive dust, etc., should be cleaned off non-food contact equipment.

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, etc.

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 harvesting operation has ceased for that run time e.g. after final shift.

2.5.12e: Does the design and condition of the equipment (e.g., e.g., smooth, non-porous, non-toxic, corrosion resistant, no wood, no fabric) facilitate effective cleaning, sanitation and maintenance?
Total compliance (10 points): Equipment should be made of appropriate materials that can be easily cleaned and maintained, that are not porous or toxic and can withstand the cleaning process. Equipment should be designed to allow access and easy cleaning (including hollow structures on supports, rollers, racks, etc.), with no hard to get to (debris catching) areas. Surfaces that are porous, trap debris, badly damaged should be replaced. Wood, for example, is porous and can trap moisture. Welds should be smooth and not "bobbly".

Minor deficiency (7 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 (3 point) 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 poor welding, rough surfaces, poorly designed equipment that traps debris.

2.5.12f: Is equipment designed and used properly to minimize product contamination (e.g. drip pans utilized, dedicated tractor pathways)?
Total compliance (5 points): Overhead contamination from materials such as hydraulic fluid can result in product and packaging contamination, and therefore, equipment should be fitted with catch pans. Dedicated tractor pathways should also be used to minimize product contamination.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of possible overhead contamination.

Major deficiency (1 point) if:
- Numerous instances of possible overhead contamination.

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

2.5.12g: Are all glass issues on harvesting machines, in-field trucks, and tractors protected in some manner?
Total compliance (3 points): Glass located on the harvesting machinery (e.g., lights, night lights) that may pose a threat of contamination onto product, packaging, and re-useable containers should be protected. Machinery includes tractors and other equipment that may come into contact with product. There should be no evidence of cracked lenses.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of unprotected glass.

Major deficiency (1 point) if:
- Numerous instances of unprotected glass.

Non-compliance (0 points) if:
- Widespread failure to control glass on harvesting machines, in-field trucks and/or tractors.
- More than one instance of a broken glass item found during the audit.

2.5.12h: Are all platforms above product, packaging, or food contact surfaces (e.g., belts) on the harvest machinery and in-field trucks fitted with protection to prevent product contamination?
Total compliance (3 points): Overhead contamination of exposed product areas can result in microbiological, chemical and/or physical contamination. Measures should be taken to eliminate or reduce potential contamination by fitting protection on equipment above exposed product, food contact surfaces, and belts.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of possible overhead contamination.

Major deficiency (1 point) if:
- Numerous instances of possible overhead contamination.

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

2.5.12i: Are there written cleaning and sanitation procedures (Sanitation Standard Operating Procedures) for the harvest equipment that includes the frequency of cleaning and sanitizing, the procedures used including chemical use details?
Total compliance (5 points): Harvest equipment should be cleaned and sanitized on a regularly scheduled basis, based on written Sanitation Standard Operating Procedures (SSOPs). The program should state the frequency of cleaning and sanitizing, detail what, who, how and when, including chemical details (name, dilution/strength), and cleaning verification procedures. Frequency should reflect the type of machinery,

type of harvesting practice and the risk associated with the crop involved. This includes water tanks used for post-harvest water use. For "in-field" processing, clean and core, etc., at least daily cleaning should be performed.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of information missing from the cleaning program.

Major deficiency (1 point) if:
- Numerous instances of information missing from the cleaning program.

Non-compliance (0 points) if:
- There is no documented cleaning program.

2.5.12j Are cleaning and sanitation logs on file for harvest equipment that show what was done, when, by who and detail strength testing of anti-microbial solution used to sanitize surfaces?
Total compliance (10 points): Sanitation logs should include: date, list of areas/equipment that were cleaned and sanitized, sanitizer strength tests, and the individual accountable who signed-off for each task completed.

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

Major deficiency (3 points) if:
- Numerous instances of incomplete records, discrepancies against the SSOPs or other omissions.

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

2.5.12k: Is there written documentation showing that only food grade lubricants are used on the critical parts of the harvesting machinery that have the potential to contaminate product?
Total compliance (3 points): In order to prevent or reduce contamination to product/packaging, food grade lubricants (i.e. incidental food contact compounds or H1 materials) should be used on critical areas of the equipment where product exposure exists. Proof must be available that food grade lubricants are being used.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of missing or incomplete evidence.

Major deficiency (1 point) if:
- Numerous instances of missing or incomplete evidence.

Non-compliance (0 points) if:
- There is no documented evidence that food grade lubricants are being used on the critical parts of the harvest machinery.

2.5.13: Is water used directly on product contact (e.g. re-hydration, core in field)? If No, go to 2.5.14.
Total points 0: Information gathering question. This refers to water that is used directly on product contact. Examples may include but are not limited to re-hydration, core in field.

2.5.13a: Are there specific Standard Operating Procedures (SOPs) for the monitoring of anti-microbial parameters in single-pass and recirculated/batch water systems and changing of recirculated and batch water systems (e.g., dump tanks) and for monitoring water temperature?
Total compliance (10 points): There should be specific SOPs describing the process of performing and recording anti-microbial strength testing in water systems, changing the recirculated/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. 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.
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 and testing.
- Single/isolated instance(s) of errors or omissions in the validation documentation for water changing and testing.

Major deficiency (3 points) if:
- Numerous instances of errors or omissions within the SOP's for water changing and testing.
- Numerous instances of errors or omissions in the validation documentation for water changing and testing.

Non-compliance (0 points) if:
- SOPs for water changing and testing do not exist.
- SOPs do not address the frequency of water changing and/or testing.
- There is no validation documentation for water changing frequency and/or water testing frequency.

2.5.13b: Are there records (with corrective actions) that show anti-microbial (e.g., free chlorine, peroxyacetic acid) strength testing of wash water prior to start up and throughout the run?
Total compliance (10 points): Water systems using anti-microbial agents should have records showing that the strength of the solution is within stated parameters. For "single pass" systems, this should be every batch of anti-microbial solution that is mixed. Recirculated/batch water systems should be checked hourly by measuring the "free anti-microbial" as opposed to bound microbial (e.g., testing for free chlorine as opposed to total chlorine). Water systems using chlorine should have records showing the pH is controlled. Where out of specification results are recorded, there should be corrective action records, including root cause analysis and preventive actions (where relevant).

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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/food-safety-program

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 would have more been suitable e.g. in chlorinated recycled water systems
- Single/isolated instance(s) of checks not carried out at the required frequencies.

Major deficiency (3 points) if:
- Numerous instances of records showing solution strength out of parameters without adequate documented corrective actions.
- Numerous instances of errors or omission in the records.
- Numerous instances of total chlorine being recorded when free chlorine would have more been suitable e.g. in chlorinated recycled water systems.
- Numerous instances of checks not carried out at the required frequencies.

Non-compliance (0 points) if:
- Water testing is not being recorded.
- Widespread observation of recorded solution strengths out of parameters i.e. an unstable system (even if documented corrective actions exist).
- Widespread 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.
- Widespread observation of frequencies of checks not meeting requirements of prior to start up and throughout the production runs.
- Single pass water system is in use without anti-microbial being used. The auditor should consider whether to apply 2.5.8 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 2.5.8 and score an automatic failure in view of the risk of cross contamination.

2.5.13c: Are there records of visual monitoring, testing and changing of recirculated and batch water systems (e.g., dump tanks) and water temperature checks (where relevant)?
Total compliance (5 points): There should be records of visual monitoring, testing and changing of recirculated and batch water systems and water temperature checks (where relevant) during use. Water should be changed when it is dirty and when switching products. Frequency of water changing 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.

2.5.13d: Does the operation use the appropriate test strips, test kits or test probes for verifying the concentrations of anti-microbial chemicals (e.g., postharvest product contact water, dip stations, etc.), are they in operational condition and are they being used correctly?
Total compliance (15 points): The strength (concentration, pH, etc.) of anti-microbial chemicals should be checked using an appropriate method for the anti-microbial in use (e.g., chemical reaction-based test, test probe, ORP meter or as recommended by the disinfectant supplier). Any water treatment at the 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 during the audit.

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:
- Chemical concentrations are not monitored.
- Equipment to monitor anti-microbial chemical concentrations is not available or is not being used correctly.

2.5.14: Is the harvested product "in-field processed" or "in-field semi-processed" (e.g., core in field, top & tail, florets)? If No, go to 2.5.15.
Total points 0: Information gathering question. "In-field processed" products are subject to all the questions in this audit and these extra requirements below. "In-field processed" usually refers to product having multiple cut surfaces created in the field (e.g., coring in field, topping & tailing, florets).

2.5.14a: Where harvested product is "in-field processed" or "in-field semi-processed," does the process flow, machine layout, worker control, utensil control, etc. ensure that processed products are not contaminated by unprocessed products?
Total compliance (5 points): The design, worker management, utensil management and general practice should avoid contact between processed and unprocessed product, contact surfaces and tools.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of worker/utensil/machine layout cross contamination.
- Minor process issues where processed materials come into the same area as raw materials, but the two products do not touch in any way, i.e. no potential risk of cross contamination.
- Some potential space issues where the process flow is being forced to bring finished and raw material into close proximity.

Major deficiency (1 point) 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.

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.

2.5.14b: Are all plastic bin liners closed immediately after harvest to avoid contamination of the harvested product?
Total compliance (3 points): All plastic bin liners should be closed immediately and appropriately secured after harvest to avoid product contamination.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of a bin liner not being closed immediately after harvest.

Major deficiency (1 point) if:
- Numerous instances of bin liners not being closed immediately after harvest.

Non-compliance (0 points) if:
- Widespread failure to close bin liners immediately after harvest.

2.5.15: Are there any post-harvest treatments performed to the product in the fields? If No, go to 2.6.1.
Total points 0: Information gathering question. This refers to any post-harvest treatments taking place in the field (e.g. blueberries packed in the field with sodium metabisulphite pads, tables grapes packed in the field treated/gassed with sulfur dioxide, etc.).

2.5.15a: Are there up-to-date records of all post-harvest pesticides applied in the field to the harvested products? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.
Total compliance (15 points): The growing operation should follow a post-harvest pesticide application record keeping program that at least includes the following: date of application, product identity (e.g. Lot or batch number/code), brand/product name, EPA registration number (or country of production equivalent registration information), active ingredient, amount applied (rate/dosage), applicator identification, application equipment identification "and/or" type of treatment, and target pest/disease. Information may be recorded on separate documents providing all information is available and consistent.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of missing required information (e.g. missing target pest, applicator identification, equipment identification or type of treatment, etc.)

Major deficiency (5 points) if:
- Numerous instances of missing required information (e.g. missing target pest, applicator identification, equipment identification or type of treatment, etc.)

Automatic Failure (0 points) if:
- **Any failure to record critical required information. (e.g. brand/product name, date, amount applied, product identity, etc.)**
- **Fundamental failure to record required information.**

2.5.15b: Are all pesticides applied post-harvest authorized/registered by the authority/government of the country of production? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.
Total compliance (15 points): Application records show all post-harvest pesticides applied are officially registered by the country of production for the target crop (e.g. EPA in the US, COFEPRIS in Mexico, SAG in Chile, Pest Management Regulatory Agency (PMRA) in Canada).

In countries where there is approval for its use, this is acceptable when operated by the government and considers as a minimum the target crop, pesticide trade name and active ingredient, formulation, dosage, pre-harvest intervals and target pest(s) or in cases where the government authorizes an active ingredient but not a trade name, there must be evidence of compliance with the MRLs of the destination countries for the applied "authorized" active ingredient (see 2.5.15d)
When pesticide product registration/authorization information does not exist for the target crop in the country of production or there are not enough products registered/authorized to control a pest or disease (partial registration/authorization), extrapolation is possible if that practice is allowed by the country of production (e.g. in Mexico "Anexo Técnico 1. Requisitos Generales para la Certificación y Reconocimiento de Sistemas de Riesgos de Contaminación (SRRC) Buen Uso y Manejo de Plaguicidas (BUMP) o Buenas Prácticas Agrícolas en la Actividad de Cosecha (BPCo) durante la producción primaria de vegetales – Section 12.3 should be considered. ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.

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 single incidence of pesticides being used without being registered or authorized by the country of production government.**

2.5.15c: Are all pesticides applied post-harvest used as recommended/directed in the label? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.
Total compliance (15 points): Application records should show all post-harvest pesticides are applied in accordance with label directions and any federal, state or local regulation.

In operations applying post-harvest pesticides “authorized” by the government, where use directions are not in the label, application records should show “authorization program” use/applications directions are followed.

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 single incidence of pesticides being used without following label directions.**

2.5.15d: Where products are destined for export, is there information for post-harvest pesticide Maximum Residue Limits (MRLs) compliance considering, country of destination, target crop(s) and active ingredients applied?
Total compliance (15 points): Where products are destined for export, the operation should have documented evidence about the MRL requirements for each country of destination for each post-harvest pesticide (active ingredient) applied. If there is no MRL defined by the country of destination for any active ingredient applied, the operation shall have documented evidence of the applicable regulations in that country (e.g. default MRL, Codex Alimentarius, non-detectable, etc.). In the case where the MRLs have been standardized or harmonized for a group of countries (i.e. European Union) it is acceptable that the operation demonstrate compliance by referencing the "list" of MRLs issued from the formal body that represents those countries for this purpose.

This question is Not Applicable if the product is only sold in the country of production (domestic market).

Minor deficiency (10 points) if:
- Single/isolated instance(s) of missing required information (e.g. missing MRL information for an active ingredient)

Major deficiency (5 points) if:
- Numerous instances of missing required information (e.g. missing MRL information for 3 or more active ingredient)

Non-Compliance (0 points) if:
- There is no MRL information for the destination countries (or widespread missing information)

2.5.15e: Where products are destined for export, is there evidence that Maximum Residue Levels (MRL's), of the intended markets are met? ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.
Total compliance (15 points): Maximum Residue Limits (MRLs) analysis should be performed when the MRL of the destination countries are lower (stricter) than the country of production. MRL test results and records should demonstrate that products/crops meet MRL regulations in those intended markets and any non-conforming product is diverted from those markets.

The auditor should review MRL laboratory reports to ensure MRL entry requirements are met for the country of destination or the applicable regulation in the country of destination when there is no MRL set for any active ingredient, (e.g. the Codex Alimentarius Commission, default MRL, under the limit of detection [LOD], etc.) MRL laboratory reports shall be traceable to the operation and consider at least the active ingredients applied post-harvest.
Other alternative or complementary methods to demonstrate MRL compliance for an active ingredient include:

i) Documented analysis of degradation curves and corresponding dosage and/or pre-harvest interval modifications. Degradation curves used as reference should be issued/provided by the manufacturer of the pesticide or country of production government and correspond to the degradation of the pesticide active ingredient in the agroclimatic zone where the Plant Protection Product was applied.
ii) Industry guidelines (e.g. "Agenda de Pesticidas" From ASOEX Chile).

Following a procedure for when and where to pull samples for MRL testing based on risk considering factors such as active ingredients applied, timing of the application and harvest, pre-harvest intervals, dosage, etc., is an ideal practice.

This question is Not Applicable if the product is only sold in the country of production (domestic market).

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 single incidence of an active ingredient with an exceeded MRL.**
- **There is no evidence of MRL compliance for any active ingredient applied.**
- **Evidence provided is not sufficient to support MRL compliance**

2.5.15f: Is there a documented procedure for the post-harvest pesticide applications, considering mixing and loading, applying, and equipment cleaning?

Total compliance (15 points): There should be a documented procedure describing how to mix and load post-harvest pesticides, how to apply post-harvest pesticides and how to rinse and clean post-harvest pesticide application equipment. The procedure should include adhering to the product label.
Mixing and loading procedures should require activity to be in a well-ventilated, well-lit area away from unprotected people, food and other items that might be contaminated.
Application procedures should include information about the necessary Personal Protective Equipment (PPE), re-entry intervals, excessive winds, posting of treated areas, etc.
Equipment cleaning procedures should include measuring devices, mixing containers, application equipment (e.g. spray bar), rinseable containers, etc., and should address: rinsing empty equipment immediately to prevent residues from drying and becoming difficult to remove, and adding the rinsate (water from rinsing containers or equipment) to spray tanks as part of the pesticide mixing process.

If any of these practices are observed during the inspection, it should be evident that the procedures are being followed.

This procedure could be partially applicable or non-applicable depending the type of post-harvest treatment used (e.g. SO_2 Generator pads do not require mixing/loading instructions)

Minor deficiency (10 points) if:
- Single/isolated instance(s) of an error or omission in the procedure or practice.

Major deficiency (5 points) if:
- Numerous instances of an error or omission in the procedure or practice.

Non-Compliance (0 points) if:
- Widespread errors or omissions in the procedure or practice.
- There is no procedure.

2.5.15g: Is there documentation that shows the individual(s) making decisions for post-harvest pesticide applications is competent?
Total compliance (15 points): Current valid certificates, licenses, or another form of proof of training recognized by prevailing national/local standards and guidelines should be available for the individual(s) making decisions on post-harvest pesticide applications (e.g., choice of pesticides, application rates, etc.)

Minor deficiency (10 points) if:
- Single/isolated instance(s) of missing documentation.

Major deficiency (5 points) if:
- Single/isolated instance of a proof of training/certificate/license being out of date.
- Numerous instances of missing documentation.

Non-compliance (0 points) if:
- There is no documentation for the individual(s) making the decision.

2.5.15h: Is there documentation that shows that individuals who handle post-harvest pesticide materials are trained and are under the supervision of a trained person?
Total compliance (15 points): All workers who handle pesticides must have current certificates, licenses, or other forms of proof of training (recognized by prevailing national/local standards and guidelines) qualifying them to do so independently or they must have proof of training and be under the supervision of a worker who can do so independently.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of missing training documentation.

Major deficiency (5 points) if:

- Numerous instances of missing training documentation.
- Worker who is not qualified to handle pesticide materials independently has training but no supervision

Non-compliance (0 points) if:
- There is no documentation showing training for individuals handling pesticides materials.
- There is no documentation for the supervising person

Transportation and Tracking

2.6.1: Are the vehicles loading and transporting fresh produce from field to facility limited to this function only, maintained in proper condition, and adequate for the purpose?
Total compliance (5 points): Vehicles loading and transporting product (e.g., forklifts, trucks) should be limited to this function only and should be adequate for transporting produce i.e. part of the sanitation program, maintained clean and not allowed to be a vector of cross contamination. Vehicles should be in a good state of repair, clean, odor free, free from personal items, and free from chemical and microbiological contamination. If loads are tied down, tarps, belts, ropes, etc., should also be in good working order, without contamination risk to product.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of unsanitary conditions.
- Single/isolated instance(s) of an issue with a transport vehicle.

Major deficiency (1 point) if:
- Numerous instances of unsanitary conditions.
- Numerous instances of issues with transport vehicle(s).

Non-compliance (0 points) if:
- Fundamental failure to maintain the transport vehicles in a clean and sanitary condition.
- Multiple instances of cases where the failure to maintain the transport vehicles in a sanitary condition may lead to potential product contamination.
- Fundamental failure to maintain transport vehicles in good repair, in good working order and/or to prevent contamination risk to the product.

2.6.2: Is there a system in place to track product from the farm? If No, go to 2.7.1.
Total compliance (10 points): There should be a tracking system in place to ensure that product can be traced back to each exact growing location and harvest date (e.g., grower identification, farm identification, block, harvesting date, etc.).

Minor deficiency (7 points) if:
- Single/isolated instance(s) of missing required information on commodities i.e. growing location or harvest information.

Major deficiency (3 point) if:
- Numerous instances of missing required information on commodities i.e. growing location of harvest information.

Non-compliance (0 points) if:
- There is no tracking information on commodities.

2.6.2a: If product is being packed in the field, are the cartons, boxes, RPCs or any other packaging material used, identified with the harvesting date and growing location information? This question does not apply for raw material/bulk product destined for further handling in a packinghouse or processing facility.

Total compliance (10 points): For finished goods packed in the field, there should be date coding on each external package, as cartons, boxes, reusable plastic containers or any other. The information should be enough to identify the date of harvest and the exact location of where the product was grown. This question is not applicable for raw material/bulk product destined for further handling in a packinghouse or processing facility.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of missing or incomplete tracking information on the packaging.

Major deficiency (3 points) if:
- Numerous instances of missing or incomplete tracking information on the packaging.

Non-compliance (0 points) if:
- Widespread failure to label packaging with complete tracking information.
- There is no labeling taking place on packaging.

2.6.2b: If product is being packed in the field and individual packing units are used (e.g., clamshells, bags, baskets or others), are these individual units identified with the harvesting date and growing location information on them? This question does not apply for raw material/bulk product destined for further handling in a packinghouse or processing facility.
Total compliance (10 points): For finished goods packed in the field, there should be date coding on each individual unit package, as clamshells, bags, baskets or others. The information should be enough to identify the date of harvest and the exact location of where the product was grown. This question is not-applicable for raw material/bulk product destined for further handling in a packinghouse or processing facility.
https://www.producetraceability.org/documents/Best_Practices_Case_Label-_010312_FINAL.pdf

Minor deficiency (7 points) if:
- Single/isolated instance(s) of missing or incomplete tracking information on the individual unit package.

Major deficiency (3 points) if:
- Numerous instances of missing or incomplete tracking information on the individual unit package.

Non-compliance (0 points) if:
- Widespread failure to label individual unit package with complete tracking information.
- There is no labeling taking place on the individual unit packages.

On-site Storage

2.7.1: Is there an on-site storage for items and/or equipment used in the harvesting process (e.g., packing material, cartons, clamshells, re-usable containers, disinfectants, grading/packing tables, RPCs, harvesting equipment, etc.)?
Total points 0: Information gathering question. This question refers to an on-site storage for items and/or equipment used in the harvesting process (e.g., packing material, cartons, clamshells, re-usable containers, disinfectants, grading/packing tables, RPCs, harvesting equipment, etc.).

2.7.1a: Is on-site storage for items and/or equipment used in the harvesting process (e.g., packing material, cartons, clamshells, re-usable containers, disinfectants, grading/packing tables, RPCs, harvesting equipment, etc.) clean and secure?
Total compliance (10 points): On-site storage (including inside vehicle storage) for items and/or equipment used in the harvesting process should be secure, clean, and maintained properly to reduce pest and foreign material contamination.

Minor deficiency (7 points) if:
- Single/isolated instance of unclean and/or unsecure storage areas.

Major deficiency (3 points) if:
- Numerous instances storage of unclean and/or unsecure storage areas.

Non-compliance (0 points) if:
- Fundamental failure to maintain a clean and secure storage area.

2.7.2: Are packaging, containers, and harvesting equipment stored to prevent cross contamination (this includes RPCs, cartons, clamshells, bins, and other harvesting type of containers that are single use or reusable, etc.)?
Total compliance (5 points): Packaging, containers, etc., should be stored away from farm chemicals, sanitizers, fertilizers, etc. All packaging materials should be stored off the ground (i.e. on racks, pallets, shelves, etc.). Cartons and other packing materials should be properly protected during storage to prevent contamination.

Minor deficiency (3 points) if:
- Single/isolated instance of improper storage.

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

Non-compliance (0 points) if:
- Fundamental failure to prevent cross contamination during storage.

2.7.3: Are there cleaning logs for the storage area(s)?
Total compliance (5 points): All storage areas should have a sanitation program in place and there should be records of the cleaning and sanitation activities performed, including areas cleaned, dates and person performing the activity.

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

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

Non-compliance (0 points) if:
- Fundamental failure to keep records.
- There are no records.
- There is no sanitation program in place.

2.7.4: Is there a documented and effective pest control program in place for fixed location storage areas?
Total compliance (15 points): There should be a documented and effective, proactive pest control program (in-house or contracted) to control rodents (also insects, reptiles and birds where necessary) and prevent infestation in all fixed (permanent/dropped in place) storage areas. There should be a written scope of the program, indicating target pests and frequency of checks.

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

Minor deficiency (10 points) if:
- Single/isolated omission(s) in the written program.

Major deficiency (5 points) if:
- Numerous omissions in the written program.

Non-compliance (0 points) if:
- There is no pest control program in place for fixed location storage area(s).
- There is no documented pest control program.
- Written program does not resemble what is happening in practice at all.

2.7.4a: Are pest control devices located away from items and/or equipment used in the harvesting process (e.g., packing material, cartons, clamshells, re-usable containers, disinfectants, grading/packing tables, RPCs, harvesting equipment, etc.), and poisonous bait stations are not used inside the storage areas?

Total compliance (5 points): Pest control devices should be located away from items or equipment with food contact surfaces to prevent any physical or microbial contamination. Poisonous bait stations should not be used inside any storage areas.

Care should be taken to place pest control devices in such a manner that they do not pose a threat of contaminating product, packing or raw materials. This includes the following restrictions:
- There should be no domestic fly sprays used within the storage areas.
- Block bait as opposed to grain and pellet bait should be used (except for the external use of National Organic Program approved materials).
- If used, insect light traps (ILTs), electrical fly killers (EFKs) or pheromone traps should be regularly cleaned out (kept free from a build-up of insects and debris). Sticky type ILTs should be monitored at least monthly and the sticky board replaced if ineffective. ILTs that use sticking as opposed to zapping methods (EFKs) are preferred.
- If used, insect light traps or electric fly killers should not be placed above or in close proximity (10 feet, 3 meters) to product, food contact surfaces, equipment, or packaging material.
- 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 the 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.
- The use of poisonous rodent bait within storage areas (buildings) 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: (3 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 growing 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 growing/storage areas (including chemical/sanitation storage).
- Snap traps being used outside the operation (not presenting risk to product or packaging) and are lacking weekly inspection logs or being used for routine monitoring (as opposed to short term eradication).
- Single/isolated instance(s) of any other issues noted on the compliance criteria.

Major deficiency (1 point) if:
- Numerous instances of improperly positioning or maintaining electrical fly traps or insect light traps.
- Numerous instances fly swatters found in growing 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 growing/storage areas (including chemical/sanitation storage).

- Single instance of bait/poison found outside of a trap.
- Snap traps being used for a short-term eradication process with weekly inspection logs but 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 found outside of a trap.
- More than one major deficiency.
- Numerous (more than three snap traps) being used inside the operation and are lacking weekly inspection logs or being used for routine monitoring (as opposed to short term eradication).

2.7.4b: 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.
- 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 weekly – these checks to be recorded.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of inspections occurring less than the required frequency.
- Single/isolated instance(s) of traps, bait stations and glue boards not working properly or adequately maintained (check cards, cleanliness, etc.)
- Single/isolated instance(s) of unsecured bait inside bait stations.
- Single/isolated instance(s) of bait stations having moldy bait.

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

Non-compliance (0 points) if:
- More than one instance of bait/poison found outside of a trap.
- More than one major deficiency.

2.7.4c: Are pest control devices adequate in number and location?
Total compliance (5 points): The location of the traps should be based on a risk assessment of the storage area and surrounding area.
- 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 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 activities occurring.
- Inside the storage area, 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.
- 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.

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.
- Single/isolated instance(s) of the traps not matching what was determined from the risk assessment.

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.
- Numerous instances of the traps not matching what was determined from the risk assessment.

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.
- Traps not located in numerous areas that should be trapped.
- There is no risk assessment.

2.7.4d: If storage areas are fully enclosed, are measures taken to prevent pest entry?
Total compliance (5 points): Fully enclosed storage buildings should have measures in place to prevent pest entry (i.e. pest proof doors, screened openings, etc.). Main doors should be kept closed unless in use.

Minor deficiency (3 points) if:

- Single/isolated instance(s) of doors left open.
- Single/isolated instance(s) of a damaged pest proof door, screened opening or any other preventive measure taken.

Major deficiency (1 point) if:
- Numerous instances of doors left open.
- Numerous instances of damaged pest proof doors, screened openings or any other preventive measures taken.

Non-compliance (0 points) if:
- Widespread failure to prevent pest entry.

2.7.4e: 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 wall signs (that state the trap number and also that they are trap identifier signs).

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

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

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

2.7.4f: 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 walls. 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 2.8.4a). 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:

- Widespread failure to secure bait stations.

2.7.4g: Is there a schematic drawing/plan of the storage area showing numbered locations of all pest monitoring devices, both inside and outside the storage area?
Total compliance (5 points): A schematic drawing or trap map is on file, current and details internal and external traps. All devices should be numbered and clearly identified on the map. Map numbers should match physical placements. The document should be accurate, dated and should show the type of device.

Minor deficiency (3 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 (1 point) 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.

2.7.4h: Are service reports created for pest control checks detailing inspection records, application records, and corrective actions of issues noted (in-house and/or contracted)?
Total compliance (5 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. 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 (3 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 (1 point) 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.
- Widespread failure to maintain service reports.
- Widespread failure to record chemical use details.

Section 3: Additional Questions (Not Part of Overall Food Safety Percentage)

Management System

3.1.1: 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 organization'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.

3.1.2: 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 signed and dated 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:
- Widespread errors on the organizational structure chart or responsibilities.
- No process organizational structure chart or responsibilities.

3.1.3: 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. 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, 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 Primus Standard Auditees/First-Time Primus Standard 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)

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.

3.1.4: 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.

3.1.5: 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 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. Records of all verification 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.

3.1.6: 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, etc. Not applicable if no specific industry guidelines or best practices exist for the crop and/or product or activity.

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

3.2.1: 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

3.2.2: 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. PSA qualification, evidence of training, etc.). Examples of monitoring records may include composting records, 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.
- 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 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-compliance (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).
- Widespread errors on the records and/or test results that are being signed off a qualified person.
- The verifier is not independent of the individual(s) completing the records.

Procedures and Corrective Actions

3.3.1: 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 require detailing:

- what is to be done,
- how it is done,
- how often,
- by whom,
- what recordings are required and
- any 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.

3.3.2: 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 SOP's and associated recording forms should be assembled and stored as a reference. SOP's 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 SOP's, 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 SOP's not being made available to relevant workers.
- Single/isolated instance(s) of SOP's and recording forms being omitted from the Master SOP file (SOP Manual).

Major deficiency (1 point) if:

- Numerous instances of some SOP's not being made available to relevant workers.
- Numerous instances of SOP's and recording forms being omitted from the Master SOP file (SOP Manual).

Non-compliance (0 points) if:

- SOP's are not accessible to relevant workers.
- A master file (SOP Manual) containing the SOP's and recording forms that are being used, has not been created.

3.3.3: Is there a documented corrective action procedure that describes the required 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.

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

3.4.1: 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 on a routine basis to ensure that they are being completed properly (e.g., using the correct log, correct frequencies, recording results correctly, recording corrective actions, etc.). This includes the food safety management system. 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.
- Farm, Indoor Agriculture and Harvest Crew: at least a pre-season growing area assessment and a full GAP self-assessment during harvest season covering growing and harvesting operations should be on file. If growing and harvest activities are under the same organizational authority the self-assessment should be on file covering both growing and harvesting and conducted during the harvest season. A harvesting company not under the authority of a grower should have self-assessments on file during harvest season covering each type of harvest process utilized for the crew(s), i.e. crew can harvest product in-field semi-processing and bulk/final packing in the field. A more frequent self-assessment frequency should be used depending on the crop type, farm or indoor agriculture location, any associated risk pressures, and/or if required by any national, local or importing country legal requirements, or customer requirements. These factors will also affect the need for pre-harvest inspections. Farm(s), indoor agriculture growing area(s), storage, harvesting, worker and visitor hygiene, agricultural water sources, training program, etc., and all associated paperwork should be included.

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.

3.4.2: 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.

3.4.3: 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, 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. Where service providers are used (e.g., calibration of pesticide application equipment when applications are performed by an external service provider) score calibration requirements under section 3.6.

For GMP, this includes equipment used for measuring and monitoring processes (hand held 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

3.4.4: 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.

Release of Items/Product

3.5.1: 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. Not applicable for organizations 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.

3.5.2: 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. Not applicable 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.

3.5.3: 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.

3.5.4: 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.

3.5.5: 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

3.6.1: 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, packaging items) are evaluated, approved and monitored. The procedure for evaluation (including hazard analysis and supplier control of hazards, where applicable), 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.

3.6.2: Is there a list of approved suppliers and service providers?

Total compliance (5 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. Where exceptions are made (e.g., market conditions, emergency situations), approval from management is justified and documented.

Minor deficiency (3 points) if:

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

Major deficiency (1 point) if:

- Numerous instances of errors or omissions in the records.
- Numerous instances of purchasing exceptions made (i.e. not 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.

3.6.3: 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 (5 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),
- 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 packaging provided by their contracting customer should obtain a copy of the up-to-date specification(s) from the customer.

Minor Deficiency (3 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:

- No records.
- Failure to maintain records.

3.6.4: 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, regulatory requirements and best practice guidelines. This applies to agricultural inputs, raw material, packaging, processing aids and other ingredients suppliers, products and services suppliers. Supplier verification documents should demonstrate that the ongoing approval requirements

detailed in 3.6.1 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.

3.6.5: 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)
- More than one instance of omissions or incorrect data in the documentation.

Non-compliance (points)
- No documentation.
- Using a non-licensed or accredited laboratory.
- License/accreditation of testing laboratory has expired.

Food Defense

3.7.1: 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
http://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.

3.7.2: 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 plan should be reviewed at least once every 12 months.

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.

Risk/vulnerability assessment templates can be found at:
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.

3.7.3: 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 (3.7.2) 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.