PrimusGFS Audit
Food Safety Management Systems
(Module 1) Guidelines

Used in conjunction with PrimusGFS V2.1-2c audit
Edition v1.1, 27 June 2017
Mandatory as of 1 August 2017

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These guidelines help interpret/support the principles, requirements and expectations of the PrimusGFS v2.1-2 Food Safety Management Section (Module 1) as noted in the Scheme normative documents. These guidelines are neither exhaustive nor exclusive and detail minimum requirements only by means of statements related to audit questions and expectations. There will be variations in applicability to an operation based on the process(es) and commodities involved. Auditors and auditees should interpret the questions and criteria in different situations, with the food safety and risk minimization being the key concerns.

The operation practices, policies and procedures should be pertinent to the situation at hand and be able to stand up to any challenge by an auditor or other relevant interested party (including law enforcement). Where laws, customer requirements and specifications, commodity specific guidelines and/or best practice recommendations exist and are derived from a reputable source these practices and parameters should be followed if they present a higher level of conformance/compliance than those included in the audit scheme system.

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

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

The following is a modified excerpt from PrimusGFS General Regulations v2.1-2. It is provided here as an introduction to the audit notes. For full and current text please refer to the most recent version of PrimusGFS General Regulations at http://www.primusgfs.com/documents.aspx.

Audit Execution

The audit should be performed using the most recent version of the PrimusGFS normative documents. The PrimusGFS Standard is divided into three Modules:

- Module 1 - Food Safety Management System
- Module 2 - GAP and/or GMP options
- Module 3 - HACCP program

Each Module is divided into sections, related to the specific Module and each section includes questions that detail the requirements for the specific section.

Please note, with all operations it is imperative that the facility is running product i.e. processing, packing, cooling (whatever functions are usually occurring as on a "normal" day) and that a normal compliment of personnel are on site when the audit occurs in order for the auditor to complete a valid assessment.

Scoring System

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

Module 1	Module 2		Module 3
Food Safety Management System	GAP Option	GMP Option	HACCP
Possible answers: • Total Compliance • Minor Deficiency • Major Deficiency • Non Compliance • Non Applicable	Possible answers: • Yes • No • Not Applicable	Possible answers: • Total Compliance • Minor Deficiency • Major Deficiency • Non Compliance • Non Applicable	Possible answers: • Total Compliance • Minor Deficiency • Major Deficiency • Non Compliance • Non Applicable

For questions in Module 1, Module 2 – GMP option and Module 3, 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. Some general statements for the scoring decision are described in the table below. These statements are superseded by the criteria described in the question's expectations and users should be aware that some questions do not follow these general statements e.g. automatic failure questions.
The possible answers to the questions in each Module are listed in the following table:

Scoring system for questions in Module 1, Module 2 – GMP option and Module 3				
Possible answer	**Possible Points for the question**			
Total compliance	15 points	10 points	5 points	3 points
Minor deficiency	10 points	7 points	3 points	2 points
Major deficiency	5 points	3 points	1 points	1 points
Non-compliance	0 points	0 points	0 points	0 points
Not applicable	0 points	0 points	0 points	0 points

For questions in Module 2 GAP option, the scoring system is described in the table below:

Scoring system for questions in Module 2 – GAP option								
Possible answer	**Possible Points for the question**							
Total compliance (may be Yes or No)	20 points	15 points	10 points	7 points	5 points	3 points	2 points	0 points
Non-compliance (may be Yes or No)	0 points	0 points	0 points	0 points	0 points	0 points	0 points	0 points
Not applicable	0 points	0 points	0 points	0 points	0 points	0 points	0 points	0 points

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

Compliance for questions in Module 1, Module 2 – GMP option and Module 3	
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 the not applicable response.

For questions in Module 2 – GAP option, if deficiencies for the question and/or the applicable expectations for that question are found, assign the answer to each question as described below in the general statement of the table. These statements are superseded by the criteria described in the question's expectations and applicants and users should be aware that some questions do not follow these general statements e.g. automatic failure questions

Compliance for questions in Module 2 – GAP option	
Answer	**Criteria used**
Total compliance (can be Yes or No, depending on the question)	To meet the question and/or compliance criteria in full. This is when the answer Yes or No is the same as the "earning points answer".
Non-compliance (can be Yes or No, depending on the question)	The question or compliance criteria has not been fully met. This is when the answer Yes or No is NOT the same as the "earning points answer".
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 the not applicable response.

Automatic Failure

There are some questions that if down scored will lead to an automatic failure and an overall score of 0% for the corresponding Module. On being immediately informed of the automatic failure by the auditor during the audit, the auditee has the option to have the auditor continue to complete the audit or to have the audit halt at that point (all charges will apply).

Special Circumstances For Not Certifying

Please also note, that under special circumstances and upon finding serious food safety risks a "not certified" decision can be attributed. 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 and complete the audit or to have the audit halt at that point (all charges will apply).

There are other Special Circumstance that are not technical in nature, examples of these include detection of deliberate illegal activities like deliberate mislabeling, discovery of falsified records, attempting to bribe an auditor/CB officer, threatening behavior towards an auditor/CB officer, etc.

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. PrimusGFS audits cannot be converted into a pre-assessment audit once the audit has been started. If an audit is terminated early then questions that the auditor was unable to verify, will be marked as non-compliance and receive a score of zero. For questions unable to be verified the auditor will indicate the audit was terminated at the request of the auditee before the auditor could verify whether or not the audit conformed to the

compliance criteria of the question. A report will be created on the database and issued and all charges will apply.

Documentation Requirements

Organization's Food Safety Systems:

When an Organization and its associated Operations are being audited the auditor is checking the systems (SOP's, policies etc. in Module 1 FSMS) and the implementation of these systems (Module 2).

While usually auditees often create and implement their own systems, they can also use systems that have been created by other entities, for example, their customers technical manager, their consultants etc or a combination of resources.

For example, an Organization may opt to create their own SOP's, in other instances utilize SOP's templates provided by other entities. As long as the systems meet the requirements of the PrimusGFS 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 Auditees/First Time Auditees

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

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

Existing Auditees

- **In operation for more than three consecutive months** – auditee should have documentation available from the date of the prior audit.

- **Short season operation, in operation for less than three consecutive months** – 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. 1 month of operation per year) auditee should have at least the previous season's records available for review.

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

	three consecutive months of records	

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 otherwise stated. Verbal confirmation should be the exception to the rule and, if auditing properly, these should be rarely used. If a verbal confirmation is accepted, the auditor should write this in the comments section of the question.

How to Use Point Assignment Guidelines

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

In order to be consistent with the voluntary nature of requesting a third party audit, and in order not to 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.

Glossary

Agricultural Inputs
Materials used in the production of crops including seeds, transplants, rootstock, cuttings, fertilizers, crop protection products, adjuvants, growth promoters, predator additions, irrigation water and any other material inputs to the growing process.

Cooling Cold Storage
This type of facility is where they are not only receiving and storing finished goods but performing some kind of pre-cooling and/or cooling activities. In this type of facility, no packing or processing activities are being performed, if so, a different type of facility operation shall be used. A Cooling Cold Storage facility covers the activities involved in the Storage & Distribution Center type.

Facility operation
A handling operation carried out in one or several buildings where product is being handled. The type of Facility operation can be classified as: “Storage & Distribution Center”, “Cooling Cold Storage”, “Packinghouse” or “Processing”.

The following image describes the scope of each one of the facility types described in this certification scheme:

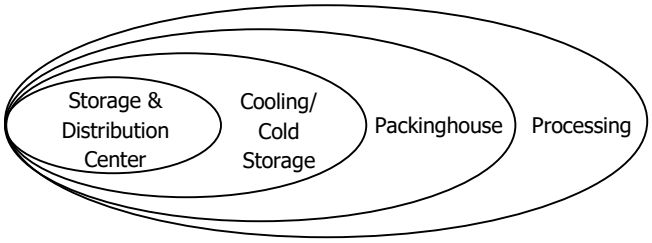

Figure 1. Facility types relationship and coverage

Auditees should not apply for multiple GMP audits of different operation types at the same address, unless there is different ownership.

Field operation
A growing operation carried out in an open or in a covered area for the production of fresh produce for human consumption. The type of Field operation can be classified as: “Ranch” or “Greenhouse”, they can both include or not include a “Harvest Crew”. In addition, standalone “Harvest Crew” audits can also be performed that do not need to be performed in conjunction with a “Ranch” or “Greenhouse” audit.

Greenhouse
A greenhouse is defined as a temporary or permanent enclosed structure where crops are grown in a controlled environment. Does not include shade or hoop houses. Product grown under this type of operation is marketed as “Greenhouse grown”.

Harvest Crew
A "harvest crew" is defined as a crew of harvest personnel under common management.

Packinghouse
This type of facility is where whole commodities are sorted and/or sized, may be minimally trimmed (not altered in form), washed or not washed, possible post-harvest fungicide treatments applied (e.g. wax treatments) and packed for commercial distribution and use by consumer or retail establishment. In this type of facility, no processing activities are being performed, if so, a different type of facility operation shall be used. A Packinghouse facility covers the activities involved in the Storage & Distribution Center and Cooling/Cold Storage facilities.

Processing
This type of facility is where whole commodities are minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing, prior to being packaged for use by the consumer or a retail establishment (e.g., pre-cut, packaged, ready-to-eat salad mixes). In this type of facility, processing activities are being performed, if not, a different type of facility operation shall be used. A Processing facility covers the activities involved in the Storage & Distribution Center, Cooling/Cold Storage and Packinghouse facilities.

Ranch
A "ranch" is defined as a parcel of ground (not necessarily a "lot" for production purposes) with the following characteristics: common management, common water supply and contiguous grounds. For the purpose of farm or ranch audits, a ranch or farm is defined as contiguous ground that is under common management.

Storage & Distribution Center
This type of facility is where they are only receiving and storing finished goods for further shipment e.g. regional distribution warehouses.
In this type of facility, no cooling, packing or processing activities are being performed, if so, a different type of facility operation shall be used.

Module 1

Management System

1.01.01: **Is there a Food Safety Manual or other documented food safety management system covering the scope of business included in this audit and procedures/instructions for all food safety processes?**

Total compliance (5 points): The Food Safety Manual is appropriate for the scope to be covered by the audit and include documented policies, standards, procedures* etc., and/or specific reference to them. The Food Safety Manual should be available to relevant workers. A food safety plan may also be used to cover the requirements of this question, as long as it also covers the points noted below.

The Manual should include or reference (actual documents may be located in another manual):

1. The company's food safety policy
2. Organizational chart
3. List of products
4. Pre-requisite programs
5. Product descriptions, process flows, hazard analysis, etc., and where relevant, details of critical control points including monitoring and corrective action details.
6. Forms used in implementation of food safety management system (actual records may be located elsewhere e.g. another manual).
7. Verification activities such as internal audits, testing, complaints analysis and validation work where application.

* Standard operating procedures (SOPs) are scored in 1.03.01 and 1.03.02.

Minor deficiency (3 points) if:

- If one of the above elements is missing.

Major deficiency (1 point) if:

- If two or more elements are missing.

Non-compliance (0 points) if:

- A written Food Safety Manual (or equivalent) is not available for review.

1.01.02: Is there a documented food safety policy detailing the company's commitment to food safety?

Total compliance (5 points): There should be a dated, signed (by senior management) documented food safety policy statement reflecting the organization's ongoing commitment to providing a safe product. 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. 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.
- Systematic failures to keep records and or corrective actions.

1.01.03: Is there an organizational chart of all workers who have food safety related activities?

Total compliance (3 points): There should be an organizational chart showing positions and reporting structure of workers whose activities affect food safety within the company. Chart is dated to indicate it is correct and current. Job functions and responsibilities related to food safety should also be documented. Alternates should be indicated or reference document indicating this information. For very small companies, an individual worker may cover many jobs. Document should be dated and reflect current status.

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions on the organizational structure chart or responsibilities.
- A document is not dated.

Major deficiency (1 point) if:
- Numerous instances of errors or omissions on the organizational structure chart or responsibilities.
- More than one document is not dated.

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

1.01.04: 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 operations food safety plan. If an operation has a HACCP plan, the HACCP team may also look after the food safety issues. The company should be keeping logs and minutes/notes of meetings addressing food safety topics. These meetings might be dedicated to food safety or may be part of another regular meeting, e.g. a production meeting, HACCP meeting, etc. These records should demonstrate Senior Management involvement in the Food Safety program for example show management attendance, minutes copied to management and, missing members are indicated on records. Meetings should occur at least quarterly during the season of operation. Where the operation has less than three months of records available there should be at least one meeting available for review – score minor deficiency; if no records score non-compliance.

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.

1.01.05: Is there documented management verification of the entire food safety management system at least every 12 months?

Total compliance (5 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. 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 verifications activities, reasons for amending documents, validations and changes should be available for review.

- Internal Audits
- External Audits (2nd Party and 3rd Party)
- Analysis of feedback/complaints and recalls (where applicable)
- Review and updates to operation's objectives
- Review of organizational chart
- Updates, changes or new SOPs
- HACCP verification
- Other food safety managements system related activities

Minor deficiency (3 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 (1 point) 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:

- Systematic 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.

1.01.06: Is there a documented analysis detailing resources required to implement and improve the food safety management system processes with documented commitment from senior management to provide these resources?

Total compliance (5 points): There should be documented evidence that management is aware of the requirements of the food safety program including (as a minimum) an analysis of the resources required and provided for. This could include:

- Personnel training requirements, especially food safety related training for all levels of the company. Analysis should show what training is required for the different roles (machine operators, sorters, harvesters, sanitation, QA, etc.), sometimes called training needs analysis. Are the training activities planned for and occurring.
- Worker staffing levels to help ensure food safety functions are properly resourced), This includes the allowance of worker absentees (covering training days, sickness, vacations, etc.).

Considerations such as increases in production, shift patterns and changes in the process flow might need to be included.
- Job roles and descriptions are published (see under 1.01.03) and available for workers.
- Equipment and services (e.g., providing computers and food safety testing equipment, such as thermometers, sanitizer test kits, sanitation services, calibration services, etc.).
- Meeting customer requirements/specifications (e.g., micro testing, test and hold programs, etc.).
- A document from Senior Management demonstrating a commitment to continually support and invest in adequate food safety resources (e.g., training, equipment, staffing levels, etc.).

The documentation could take the form of a checklist of questions related to food safety resources. Documentation could be part of a review (e.g., a Management Review), or could take the form of a policy/procedure regarding providing food safety resources which is reviewed on at least a 12 month basis.

Minor deficiency (3 points) if:
- If one of the above elements is missing.

Major deficiency (1 point) if:
- If two or more elements are missing.
- There is no evidence of management commitment.

Non-compliance (0 points) if:
- Documented evidence is not available for review.

Control of Documents and Records

1.02.01: Is there a written document control procedure describing how documents will be maintained, updated and replaced?

Total conformance (3 points): There should be a record of all documents used, when they were issued and updated with the current revision status to help avoid using obsolete documents. Documents 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 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.

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

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

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

1.02.02: Are all records stored for a minimum period of 12 months or for at least the shelf life of product if greater than a year?

Total compliance (5 points): 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 one year 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 one year should be kept the legally mandated period. Any records pertaining to long life product should be kept at least for the duration of the shelf life of the product. 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 (one year unless legally longer storage is required or the product has a longer shelf life than 12 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 12 months).

Non-compliance (0 points) if:

- Process control records are kept less than 12 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.

1.02.03: Are food safety related documents and records stored and handled in a secure manner?

Total compliance (3 points): Food safety documentation e.g. SOP's, records, etc. including procedures, policies, programs, training records, testing results, monitoring records and tracebacks should be stored in a secure manner that deters theft and prevents tampering, when not in use. For example, the system might be the locking up of all manuals and recording logs at night in the QA Lab., when the operation is not running. There might also be rules for storing records in a secure archive room. Where computer systems are used to store SOP's records, etc., there should also be security measures including access control (password protection). The computerized records and documents should also be "backed-up" in some way e.g. stored in two locations, so that if one location breakdowns or is damaged, the data is not lost. 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 no use of correction fluid. Electronic records should show editing history.

Minor deficiency (2 points) if:

- Single/isolated instance(s) of hard copy documents and records not being stored securely.
- Single/isolated instance(s) of computerized documents and records not being stored securely.
- Single/isolated instance(s) of hard copy and/or computerized records not being updated properly.

Major deficiency (1 point) if:

- Numerous instances of hard copy documents and records not being stored securely.
- Numerous instances of computerized documents and records not being stored securely.
- Computerized documents and records are not being backed-up.
- Numerous instance(s) of hard copy and/or computerized records not being updated properly.

Non-conformance (0 points) if:

- Hard copy documents and records are not stored securely.
- Computerized documents and records are not being stored securely.

- No control over editing of hard copy and/or computerized records.

1.02.04: Are the records maintained in an organized and retrievable manner?

Total compliance (3 points): All food safety records should be maintained in a designated area where they can be retrieved readily. These records should be well organized. This will aid in the detection of issues, trends and retrievable 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 not being organized and easy to retrieve.

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

Non-conformance (0 points) if:
- No organization of records.
- Many missing records.

Procedures and Corrective Actions

1.03.01: Are there documented instructions for the creation of Standard Operating Procedures?

Total compliance (5 points): There should be written document that describes how to write Standard Operating Procedures (SOPs) for food safety activities and good manufacturing practices that when followed, help prevent food safety hazards from occurring. The SOP's should detail:

- what is to be done,
- how it is done,
- how often,
- by whom,
- what recordings are required and
- any corrective action procedures to perform when there are any deficiencies.

These SOPs can be used for training and as reference tools. SOPs should follow the organizations 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 omissions within the document.

Major deficiency (1 point) if:

- Numerous instances of errors and omissions within the document.

Non-conformance (0 points) if:

- A document describing how to write standard operating procedures has not been created.

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

Total conformance (5 points): The written procedures (SOPs) should be available to the users and any other interested parties. A master copy of all SOP's and associated recording forms should be collated in order to create (an) SOP Manual(s), sometimes called a Quality Manual. SOP's should be used by the relevant workers, e.g. QA workers, production, sanitation, etc. SOP's can be used for training and for reference. The number of copies of SOP's depends on the size of the company and the types of processes involved. In the event of electronic SOP's, access should be allowed to all relevant workers, however there should be controls in place to prevent unauthorized editing. Ideally (not part of the audit scoring) a manual with current copies of required recording forms (often referred to in SOP's) is available to users and a master copy maintained in a central file.

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-conformance (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.

1.03.03: Is there a corrective action procedure that describes the requirements for handling deficiencies affecting food safety and prevention of future occurrences?

Total compliance (5 points): Written procedures include the corrective actions to be taken in case of any deficiency affecting food safety is identified. Records of the corrective action activities and their follow-up should be kept on file (omission of corrective actions is scored under specific questions in Module 2 of the audit).

Corrective action procedure should include:

- the review of the non-conformance
- the determination of the causes
- the establishment of an action plan 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.

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

Total conformance (5 points): The company has a log or report for recording infrequent and/or unusual events 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, etc., since at a later date, if there are product issues, these events might be of significance.

Minor Deficiency (3 points) if:

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

Major Deficiency (1 point)

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

Non-conformance (0 points)

- No records.
- Failure to maintain records.

Internal and External Inspections

1.04.01: Is there a documented program for internal audits to be performed at the operations, covering all processes impacting food safety and related documents and records?

Total compliance (3 points): Self-auditing (self-diagnostics) is a key part of an operation's food safety program. A program for internal audits should be created for each operation (field or facility) in order to proactively ensure safe food production. The internal audits should cover the inspection of sites, the practices in place, the related documents required and the records generated. The program should include the checklist used for the internal audits, the frequency of the internal audits and identification of the person(s) responsible for conducting the internal audits. Program 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 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.

Inspection should include:

- Inspection frequency depends on type and size of operation but as a minimum:
  - Field (GAP option): at least a pre-season assessment and a full GAP self-assessment during harvest season should be on file covering growing and harvesting operations. More frequent inspections may be necessary depending on the type of crop, field location and associated risk pressures .These factors will also affect the need for pre-harvest inspections. Fields, storage, harvesting and associated paperwork should be included.
  - Facility (GMP option): Processing plants should have at least a monthly frequency. Packinghouses, coolers and storage operation ideally have a monthly frequency, but at least a quarterly frequency. Entire facility (inside and out) should be included.
  - HACCP: self-audits of the HACCP program should have been done at least once within last 12 months to ensure that the process flow, hazard analysis and HACCP chart reflect reality and ensure that the program has captured any changes to the process. Whenever changes are made to the program i.e. new equipment added to the facility, new critical control points added to the plan, new limits added, new packaging is required, etc., then the plan needs to be re-evaluated by a self-audit to make sure it is working properly (3.02.11). HACCP program reviews should also take into account the latest guidelines, legal changes, issues arising from other audits and any other information gained about the production process. Self-audits help verify the effectiveness of the HACCP program, identify deficiencies and help improve the program.
- Who conducted the inspection
- Documented findings
- Corrective actions (including completion date)

Minor Deficiency (2 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 occurring at least at the minimum frequency.

Major Deficiency (1 point) if:

- Numerous instances of follow up/corrective actions not noted.

- Numerous instances of incomplete or missing records.
- Inspection frequency is not adequate relative to the type of business and the number of issues that require monitoring.
- 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 occurring at least at the minimum frequency.

Non-conformance (0 points) if:

- Systematic failure to record self-audits properly.
- Self-audits are not being conducted.
- Numerous instances of self-audits not being done at least at the minimum frequency.

1.04.02: 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 FDA, USDA, Health Department, State enforcement organizations, etc. The procedures should include at a minimum rules for always accompanying inspections, rules on taking samples and taking photographs. 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.

http://www.fda.gov/ICECI/Inspections/IOM/ucm122531.htm#5.3.4

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.

1.04.03: 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). Inspections include regulatory (e.g. Federal and State) and third party audits. Auditors are requested not to look at second party audits, since sometimes they include confidential quality and product development information. This question is not applicable if there have been no regulatory or third party inspections in the past year. 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.

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.

1.04.04: Are there documented calibration procedures for measuring and monitoring devices used in the operations that are related to the safety of the product?

Total compliance (10 points): There are documented policies and/or procedures for the calibration for measuring and monitoring devices used in the operation. Regular calibration ensures correct and accurate operation.

For the farm (GAP option), this covers items such as fertilizer and crop protection application equipment, crop protection measuring equipment (e.g. scales), ORP and pH meters, and other equipment related to the safety of the product.

For the facility (GMP option) this includes equipment used for measuring and monitoring processes (hand held and automated) related to food safety e.g. thermometers, metal detectors, ORP meters, flow meters and pH meters.

Equipment is calibrated regularly to ensure correct and accurate operation. Calibration procedures should describe the frequency of testing, the testing method and the acceptable range of variation. 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. Hand application of fertilizers is not recommended as it is difficult to assure an even distribution of fertilizer or crop protection product. If done however, it is important to choose a pace that is easy to maintain and duplicate

http://pubs.ext.vt.edu/436/436-048/PDF_64-68Calibration.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 omissions or incorrect data in the records.
- Single/isolated instance(s) of piece/set of equipment omitted from the scheme.

Major Deficiency (3 points) if:

- Numerous instances of omissions in the procedure(s).
- Numerous instances of omissions or incorrect data in the records.
- Numerous instances of pieces/sets of equipment omitted from the scheme.

Non compliance (0 points) if:

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

Rejection and Release of Product

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

Total compliance (5 points): A documented procedure exists that explains how products (including ingredients and packaging) should be handled, that have either been rejected or placed on hold, including the release of the on hold/rejected product.

For harvested product in the field and the facility, the procedure should include details on how the affected product lot(s) is/are separated from other lots in terms of tagging systems e.g. date showing when the product was placed on hold/rejected, the reason for being on hold/rejected and the name of the person who put the product on hold (details may be recorded electronically as long as products are clearly tagged) and any other physical separation to ensure that affected product is not commingled with other goods in such a way that their disposition is not clear.

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 bares no resemblance to what is being applied in the field, production and/or storage areas.

1.05.02: Are there records of the handling of on hold or rejected products 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. Records should show date when the product was placed on hold/rejected, 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-conformance (0 points) if:
- There is no record of on hold or rejected materials.

1.05.03: Is there a documented product release procedure available?

Total compliance (5 points): 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.). Products should not be released for 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. Note: this procedure is not referring to the release of product placed on hold or rejected, but for the release of all product that is shipped.

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

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

1.05.04: Are there records of product releases kept on file?

Total compliance (5 points): Records showing product releases should be available for review. 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.

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

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

Non-conformance (0 points) if:
- There is no record of on hold or rejected materials.

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

Total compliance (10 points): There is a documented policy/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 policy/procedure. The policy 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.

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.
If a corporate office/sales department or other parties handle the incoming food safety related complaints then these should be communicated to relevant personnel.
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 100 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 Control

1.06.01: Are there current written food safety related specifications for all raw products, ingredients, materials and services purchased?

Total compliance (5 points): A specification is an explicit set of requirements or criteria to be met. Specifications are accurate, acceptable and ensure conformance with relevant customer and legislative requirements. There are documented specifications for all products, ingredients, materials and services purchased or provided that have an effect on product 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,

- services (contract sprayers, pest control, chemical suppliers, water and waste utilities, transport, maintenance and sanitation services) purchased/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 omissions or incorrect data in the records.

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

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

1.06.02: Is there a written procedure detailing how suppliers are evaluated, approved and monitored?

Total compliance (5 points): There is a written procedure detailing how service providers and suppliers (e.g. raw materials, propagation materials, fertilizers, crop protection products, ingredients, processing aids, packaging items) are evaluated, approved and monitored. This procedure includes methods of removal of approved suppliers. An approved supplier list should be maintained along with any inspections and audits of approved suppliers.

As a minimum the procedure should detail the following where relevant:
- Agreed specifications
- Letters of guarantee
- Methods of evaluating approved suppliers (including third party audit requirements where relevant)
- Methods of approving approved suppliers
- Methods and frequency of monitoring approved suppliers
- Methods of reviewing approved supplier performance and status (including removal of approved status)

Minor deficiency (3 points) if:
- If one of the above elements of the procedure is missing.

Major deficiency (1 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.

1.06.03: Is there a list of approved suppliers?

Total compliance (5 points): There is a list of approved suppliers of materials and services. All agricultural inputs, ingredients, products, materials and services that relate to food safety are purchased from &/or provided by approved suppliers; where exceptions are made (e.g. market conditions, emergency situations) approval from management is 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.

1.06.04: Does the organization have documented evidence to ensure that all products, ingredients or materials and services suppliers comply with the approval requirements and that they are being monitored as defined in the procedure?

Total compliance (15 points): The organization has relevant information from approved suppliers to ensure that they are complying with the established 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.

There should be:
- A list of raw material (e.g. seeds, transplants, products) and packaging specifications (includes methods and responsibility for developing and approving specifications).
- Validation that packaging material is suitable for its intended purpose (e.g. certificate of conformance for all food contact packaging, tests/analysis confirming no chemical migration to food contents).
- Verification that all customer requirements (if applicable) are being met.

The auditee should have on file current (within last 12 months) third party audit certificates and audit reports for suppliers of product, ingredients and packaging. The auditee should also have 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. Pay special attention for letters of guarantee/certifications/audit reports for imported goods.

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 omissions or incorrect data in the records.

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

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

1.06.05: If the organization is outsourcing any processes that may affect food safety are there control procedures over such processes?

Total compliance (15 points): Where the organization is outsourcing any process that may have an effect on food safety, the process(es) is/are identified, documented and monitored to make sure they are conducted in such a way that the raw materials (including packaging), production/process flows, equipment, facility/growing area and finished product, are not compromised are and following established applicable good practices. Examples of outsourced processes that require coverage in a procedure include agency labor for production, sanitation services, pest control, pre and post-harvest chemical applications, maintenance services, co-packing, etc. This outsourcing may supplement in-house operations or completely replace in-house operations. Note that question 1.06.01 asks for specification regarding services, while this question is asking for SOP's for dealing with outsourced services.

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

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

Non compliance (0 points) if:
- No procedures.
- Procedures are inadequate to ensure product safety.
- No records.
- Failure to maintain records.

1.06.06: If tests and/or analysis within the scope of food safety are performed by external laboratories, are they licensed/accredited laboratories (e.g. ISO 17025 or equivalent, National Regulations, State Department, 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.

Traceability and Recall

1.07.01: Is there a documented account that indicates how the company product tracking system works, thereby enabling trace back and trace forward to occur in the event of a potential recall issue?

Total compliance (10 points): The tracking system is shown in writing or in the form of a flow diagram. 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 also show that the system can trace forward and indicate which customer(s) received products. This is usually accomplished by lot coding materials throughout a process and recording these lot codes at different points in the process. The traceability system should be in evidence when touring the operation and also when checking paperwork. The written traceability system should match the system that is being used in the operation. 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/OHRMS/DOCKETS/98fr/04-26929.htm,
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:

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

1.07.02: Does the organization have a documented recall program including procedures, recall team roles and contact details, external contact listings, explanation of different types of recall classes?

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:-
ORA Recall Guidelines, http://www.fda.gov/ora/conformance_ref/recalls/ggp_recall.htm

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

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

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

1.07.03: Is testing of recall procedures (including trace back) performed and documented at least every six months? Can the company identify where affected product was sent?

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.) Documentation should indicate the date and time the mock recall was initiated, the product chosen, the scenario, amount of product produced, affected lot ID's (date code(s), lot code(s),

etc.), amount located, 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 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. For facility audits only, a mock recall needs to be conducted at the time of the audit. GAP related organizations (for example (ranch and crew)) operations may create a mock scenario where they are receive information from a client indicating there is a problem that warrants a recall, another alternation 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
- Five percent or less of product was not located.
- A few gaps noted in the logic of the traceback documentation
- Not noting "lessons learned" from mock recall exercise (if there are any)
- Total time to complete mock recall took longer than 2 hours but not more than 3 hours.

Major deficiency (3 points) if:
- Four or more elements of the mock recall are missing
- More than five percent of product was not located.
- Lacking documentation that proves how the traceback and recall system identified all affected items and customers.
- Total time to complete mock recall took more than 3 hours.
- 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

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

Total conformance (5 points): The operation should have a documented food defense policy that outlines the organization's security controls based on the risk associated with the operations. This policy should include Good Agricultural Practices and/or Good Manufacturing Practices as applicable.
The document should include relevant food defense risks such as personnel, visitors, contractors, raw material receipt (raw materials, product and packaging), trucks (incoming and outbound), etc. There may also be a requirement to ensure that suppliers have proper food defense programs. Documented operational risk management (ORM) systems are acceptable if they show the controls that have been implemented for the food defense risks that have been identified.

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

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

Non-conformance (0 points) if:
- Food defense policies have not been documented.

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

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

Minor deficiency (2 points) if:
- Single/isolated instance(s) of errors or omissions in the list.
- The list is has not been updated in more than a year (less than two years).

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

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

1.08.03: Are visitors to the company operations required to adhere to food defense policies?

Total conformance (3 points): All visitors and contractors should be required to abide by the operation's rules 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.

Minor deficiency (3 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-conformance (0 points) if:

- The company does not have evidence of a requirement for visitors and contractors to comply with the operations' food defense policies.
- Systematic failure of visitors and contractors not being required to comply with the operations' food defense policies.