PrimusGFS Audit

HACCP

(Module 3) Guidelines

Used in conjunction with PrimusGFS V1.6 audit

Edition v1.4, July 2013

PrimusGFS (owned by Azzule Systems, LLC)
2520 Skyway Drive, Suite B
Santa Maria, CA 93455

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Module 3 – HACCP

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These guidelines help interpret/support the principles, requirements and expectations of the PrimusGFS v1.6 Modules 1, 2 and 3 as noted in the Scheme normative documents. These guidelines are not 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, 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/compliance than those included in the audit scheme system.

Website links shown in this document are there to aid understanding and provide assistance. These links are not a sign of endorsement by 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 actual audit templates http://www.primusgfs.com/Documentation/Documentation.aspx. 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 V 1.6. 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/Documentation/Documentation.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.

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 Auditor 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 to answer Non-applicable.

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 to answer Non-applicable.

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.
These questions have been defined as automatic failure because they represent high risk situations where any deficiency on them represents a sign of an immediate potential food safety risk. These questions are identified with the phrase: "ANY DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE".
The applicant should be immediately informed of the automatic failure by the auditor during the audit.

Documentation Requirements

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 facility has less than three months of most of their documentation available for review a pre-assessment audit is strongly advised. If the auditee has less than three months of most of their documentation available for review and decides to have a regular audit, they should be aware that they **cannot receive full conformance for paperwork questions 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 at least three months of documentation and documentation at least since the last 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 three consecutive months of records**	**Records since last audit**

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 into 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:

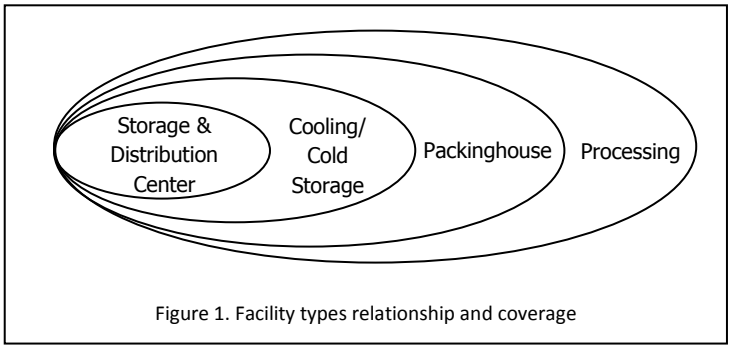

Figure 1. Facility types relationship and coverage

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 another type of operation named “Harvesting”.

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

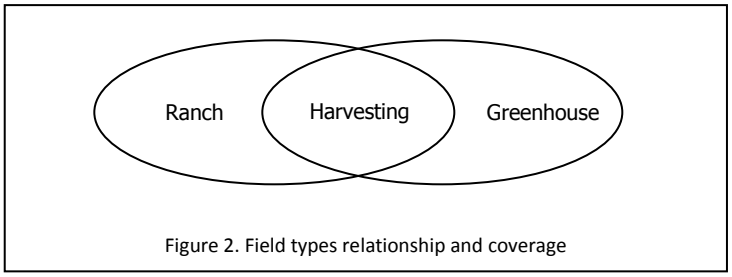

Figure 2. Field types relationship and coverage

Greenhouse
A greenhouse is defined as a building constructed of glass or plastic, for the cultivation of plants under controlled environmental conditions. 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, manual development or self-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 3

Applicability of HACCP

3.01.01: Is there need of a HACCP system to be developed and implemented in the operation? Only a Yes or No answer is allowed. If Yes, go to 3.02.01.

Total points (0). The need for a Hazard Analysis Critical Control Point (HACCP) system to be implemented for a specific operation should be determined by performing a hazard analysis of all steps of each process. A HACCP program may be required by legal requirements, by industry practice, by the organization and/or by contracts with specific companies or company policies. A HACCP program is required when the operation is minimally processing or altering in form the nature of the product by peeling, coring, slicing, shredding, chopping, juicing, freezing, roasting, etc. prior to packaging for use by consumer or retailer (e.g. pre-cut salad mixes, sliced apples, etc.). This also includes sprout operations and leafy greens (iceberg lettuce, romaine lettuce, green leaf lettuce, red leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage (green, red and savoy), kale, arugula and chard).
http://www.caleafygreens.ca.gov/food-safety-practices
http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/
http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ucm218750.htm

3.01.02: If the company has determined that a HACCP system is not needed for the operation, is there a documented hazard analysis of all steps of each process showing that all hazards can be controlled through the implementation of prerequisite programs negating the need to develop and implement a complete HACCP system? If Yes, the rest of the HACCP Module is not applicable. ANY DOWN SCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THE MODULE.

Total points (15): For facility operations where there is no preparation, manufacturing or processing of food but only handling (including washed product, product that is cooled or maintained cooled, etc.), the organization will determine the need for a HACCP system by performing a documented hazard analysis of all steps of each process. Examples of specific biological hazards include *Listeria monocytogenes, Salmonella* spp*.,* Enterohaemorrhagic *E. coli* (EHEC), Shiga toxin-producing *E. coli* (STEC), *Cryptosporidium parvum, Cyclospora cayetanensis*; chemical hazards include mycotoxins, pesticide residues, sanitation chemicals, lubricants, allergens; physical hazards include stones, metal, glass, and brittle plastic. If the hazard analysis shows that all hazards can be controlled, eliminated or reduced to an acceptable level through the implementation of prerequisite requirements (such as current Good Manufacturing Practices (cGMP) like personal hygiene, supplier control, cleaning/sanitation), there is no need to develop and implement a complete HACCP system; in this case, the rest of the HACCP module questions will be not applicable. If however, there is a step where pre-requisite programs may not be sufficient to prevent or eliminate a food safety hazard or reduce it to an acceptable level then there must be additional control measures, including the establishment of a critical control point identified within a properly designed and implemented HACCP plan. In this case the rest of the HACCP module questions are applicable. If an auditee decides to complete a HACCP program, whether or not CCP's are identified, whether or not the audit criteria for requiring a HACCP are met, then the auditor will complete the HACCP module of this audit as a verification of the HACCP program.

The written hazard analysis should determine whether there are food hazards that are reasonably likely to occur and identify measures that can be applied to control those hazards. HACCP principles should be applied and documented in order to prove that a proper hazard analysis was conducted:

- Assemble HACCP team
- Describe product
- Identify intended use

- Construct flow diagram of all steps in the operation for a specific product
- On-site confirmation of flow diagram
- List all potential hazards (specific physical, chemical and biological hazards) associated with each step, conduct a hazard analysis, and measures to control identified hazards.
- The hazard analysis should include the likelihood of the hazard and severity of the hazard's adverse health effect(s). Consider all production/process steps carefully e.g., receiving, dump tanks, brush bed systems, recycled wash systems (including hydro-vacuum coolers, ice injectors, flume washers, etc.), single line wash systems, ice manufacturing, inputs including packaging and post-harvest treatments, etc.

Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

http://www.fda.gov/food/foodsafety/HazardAnalysisCriticalControlPointsHACCP/ucm114868.htm
http://www.fao.org/docrep/005/Y1579E/y1579e03.htm
http://www.fda.gov/downloads/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/UCM297627.pdf

Management Support of HACCP

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

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

Minor deficiency (10 points) if:
- Team has been put together but lacks key representation e.g. maintenance.
- No one person has been designated the project leader.

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

Non-compliance (0 points) if:
- The HACCP team or the individual assigned to manage the HACCP program has not kept the program updated.
- There is no HACCP team or HACCP Coordinator.

3.02.02: Does the plant have formal recorded HACCP training for all employees (especially CCP operators and management)?

Total compliance (10 points): The HACCP coordinator and other key employees should be formally HACCP trained i.e. certification from a HACCP training course accredited by the International HACCP Alliance or equivalent (e.g. university provided courses) providing a minimum of 2 days training. Management, QA and Critical Control Point (CCP) monitoring and verification employees should have thorough HACCP training (in-house or external) given by someone who has HACCP experience and has

attended an accredited International HACCP Alliance course (or equivalent). CCP operators should be specially trained for their function(s). All other site employees should receive basic overview training i.e. what is HACCP, the 7 principles and what are the CCPs on site. Basic training might form part of the new hire orientation package. Senior management should receive training (HACCP requires "buy in" from all levels). Records of training should be kept and also certificates where relevant. All employees should be trained to understand the principles of HACCP and the plan implemented in the facility. Training should be scheduled on a regular basis and documented. The training should be tailored to the people and their positions within the company.
http://www.haccpalliance.org/sub/index.html

Minor deficiency (7 points) if:
- Not all plant employees are trained in HACCP (but all key operators and majority of employees have been trained).
- Senior management has not received HACCP training.
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major deficiency (3 point) if:
- HACCP coordinator has not completed a certified HACCP training course.
- CCP operators have not been trained in their specific functions.
- Numerous instances of omissions or incorrect data in the records.

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

3.02.03: Are changes in the process, equipment, ingredients etc., causing timely reviews of HACCP systems, including hazard analysis, CCP decisions, CCP records and staff training?

Total compliance (10 points): When any changes are made to the process, equipment, ingredients, etc., all HACCP systems should be reviewed and the HACCP coordinator should inform all employees involved. Re-training or educational sessions may be necessary. Look for evidence of plan change, review of hazard analysis, CCP decisions, CCP records and check to see if key operators were informed/retrained. All changes should be dated. If no changes have occurred, quiz the auditee how they would communicate the changes, if they happened in the future. Records of any re-training should be available.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of omissions or incorrect data in the records.
- Single/isolated instance(s) of required employees e.g. CCP operators, supervisors etc. not being informed about changes to the HACCP plan.

Major deficiency (3 point) if:
- Numerous instances of omissions or incorrect data in the records.
- Numerous instances of required employees e.g. CCP operators, supervisors etc. not being informed about changes to the HACCP plan.

Non-compliance (0 points) if:
- Changes to the process, equipment, ingredients, etc., have taken place but there has been no review of HACCP systems.
- HACCP plan has been changed and none of the required employees were informed.
- Re-training records have not been maintained.

3.02.04: Is the plant conducting self-audits of the HACCP program?

Total compliance (10 points). At a minimum, self-audits of the HACCP program should be done on at least once within last 12 months. Self-audits should ensure that the process flow, hazard analysis and HACCP chart reflect reality and ensure that the program has captured any changes to the process. Whenever changes are made to the program i.e. new equipment added to the facility, new critical control points added to the plan, new limits added, new packaging is required, etc., then the plan needs to be re-evaluated by a self-audit to make sure it is working properly (see 3.02.03). HACCP program reviews should also take into account the latest guidelines, legal changes, issues arising from other audits and any other information gained about the production process. Self-audits help verify the effectiveness of the HACCP program, identify deficiencies and help improve the program. Self-audits should be fully documented even if no changes are located. If issues are found, there should be detailed corrective action records. Audit records should include the date, personnel involved, areas that were checked, findings and corrective actions (where necessary).

Minor deficiency (7 points) if:
- Single/isolated instance(s) of the self-audit(s) having omissions or incorrect data.
- Self -audit occurred in the last 18 months as opposed to the last 12 months.

Major deficiency (3 point) if:
- Numerous instances of the self-audit(s) having omissions or incorrect data.
- Changes to the HACCP plan have been made but the self-audit had not been conducted.
- Self-audit occurred in the last 24 months as opposed to the last 12 months.

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

3.02.05: Have standard operating procedures (SOPs) been created for the monitoring process of the HACCP system, which would include how to carry out the monitoring activities?

Total compliance (10 points): Clear and simple standard operating instructions should be written for each CCP monitoring process – this expands in detail the CCP monitoring in the form of work instructions. These SOPs must match what is written in the HACCP plan. These SOPs can be used for training and as reference tools. This question only occurs in audits that have the HACCP module attached. Where no CCPs have been identified then this question should be scored N/A.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors and omissions within the CCP SOPs.

Major deficiency (3 point) if:
- Numerous instances of errors and omissions within the CCP SOPs.
- Single instance of a CCP SOP not being created in a system where there are multiple CCPs.

Non-compliance (0 points) if:
- CCP SOP(s) has/have not been created.
- CCP SOP(s) do not reflect at all the reality of what is being performed in the operation.

3.02.06: Is there a person or group responsible for all the records generated through the monitoring activities of the HACCP plan?
Total compliance (5 points): An individual (or group) should be assigned the responsibility of receiving HACCP records and making sure that the records are stored in a secure place. There should be

adequate plans made to ensure records are collated and managed if an assigned individual is unable to perform their duties e.g. on vacation, sick leave etc.

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

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

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

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

Minor deficiency (3 points) if:
- Single/isolated instance(s) of records not being organized and easy to retrieve.

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

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

3.02.08: Are there security measures to insure against HACCP monitoring activity record loss?

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

Minor deficiency (3 points) if:
- Records kept in cabinet or room but in an open area, where access is not always controlled.

Major deficiency (1 point) if:
- File cabinet(s) or room does not have locks.
- Documents are kept on computer but lacking data management controls e.g. not recording changes to documents, limited editing access, etc.
- No back-up drives for files stored electronically.

Non-compliance (0 points) if:
- No procedures in place to insure against record loss.
- Documents kept on computer but there are no password controls.

- Records have been lost.

Development of the Written HACCP Plan

3.03.01: Does a product description exist for each product produced? Do they contain the products intended use, materials and raw ingredients, and who the intended consumer is?

Total compliance (10 points): Product description(s) should clearly indicate the item(s) intended use i.e. does it need washing, peeling, cooking prior to consumption, etc., by the consumer, reflect the label of the product (unit packed product). Product description should define and indicate details regarding whether the item is perishable or long life and if there are any special storage requirements. Product descriptions should define the potential risk associated with the product, materials used and also who the intended customers are (general public, restricted to certain sectors, e.g. people not suffering from a certain allergy, diabetic issues etc.). The product description can be generic if the products and processes are similar. Where the products and/or processes are not similar to each other specific product descriptions are required.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions on the product descriptions(s).

Major deficiency (3 point) if:
- Numerous instances of errors or omissions on the product descriptions(s).
- In an operation with multiple products/processes that are not similar, a few of product descriptions are not available, but the majority are available

Non-compliance (0 points) if:
- No product descriptions exist.
- Systematic errors or omissions on the product description(s).
- In an operation with multiple products/processes that are not similar, many of product descriptions are not available.

3.03.02: Has the process been flow charted? Is the flow chart in sufficient detail to completely describe the process or product manufacturing steps?

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

Minor deficiency (10 points) if:
- Single/isolated instance(s) of errors or omissions on the process flow chart(s).

Major deficiency (5 point) if:
- Numerous instances of errors or omissions on the process flow chart(s).
- In an operation with multiple products/process that are not similar, a few of the flow charts are not available, but the majority are available

Non-compliance (0 points) if:
- Systematic errors on the flow chart(s).
- No process flow chart(s).

- In an operation with multiple products/process that are not similar, many of the flow charts are not available.

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

Total compliance (15 points): A hazard analysis identifies and evaluates hazards, and determines if control measures are in place to prevent, eliminate or reduce the food safety hazard to an acceptable level. A detailed hazard analysis for each process flow should have been conducted and **documented**. At each step of the process, the hazard analysis should look at the significance of any potential food safety hazards that the process might create usually in terms of specific biological, chemical and physical issues. Note that the identified hazards must be specified in detail, i.e. "metal contamination" as opposed to "physical", "*Salmonella* spp, Enterohaemorrhagic *E. coli* (EHEC), *Listeria monocytogenes*" as opposed to "biological". The controls for each hazard should be noted on this chart. The hazard analysis should indicate if an adequate control step for this potential risk exists further down the process.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of errors or omissions on the hazard analysis chart(s).

Major deficiency (5 point) if:
- Numerous instance(s) of errors or omissions on the hazard analysis chart(s)
- In an operation with multiple products/processes that are not similar, a few of hazard analysis charts are not available, but the majority are available

Non-compliance (0 points) if:
- Multiple systematic errors on the hazard analysis chart(s).
- No process hazard analysis chart(s).
- In an operation with multiple products/processes that are not similar, many of hazard analysis charts are not available.

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

Total compliance (15 points): Critical Control Points (CCPs) should have been developed to control hazards identified in the hazard analysis step if any are deemed to be found to be CCPs by the HACCP team after deliberating the hazards identified. CCPs should be developed with adequate detail and defined parameters.
The CCP's should be created from the documented hazard analysis i.e. there should be a logical documented approach showing why the process was deemed a CCP or not. CCP's are often steps that if not controlled will lead to a food safety issue and also there is no step further down the process that controls the issue. A CCP should be controllable and the controls should be able to eliminate or reduce the risk to acceptable "safe" levels. It is possible to find that an auditee has carried out a proper hazard analysis and found no CCPs.

Minor deficiency (10 points) if:
- Single fault in the logic of one CCP decision.
- Single CCP developed that does not meet the criteria for a CCP.

Major deficiency (5 point) if:
- More than one fault in the logic of the CCP decisions.
- More than one CCP developed that does not meet the criteria for a CCP.
- One (where there are multiple) CCP has been omitted.

Non-compliance (0 points) if:
- No CCP's have been developed in the hazard analysis step even though clearly CCPs did exist.

- More than one CCP has been omitted in a plan where there should be multiple CCPs.
- A single CCP has been omitted in a plan where there is a single CCP.

3.02.05: Have monitoring requirements and frequencies been determined for the CCPs?

Total compliance (15 points): Monitoring requirements and frequencies should have been determined for the CCPs. Frequency should be specified; “as needed” is not accepted as a stated frequency. The requirements i.e. what is to be done should be specified on the HACCP chart. Requirements should include the critical control limits (CCL’s) i.e. the maximum and/or minimum parameters of what is being monitored e.g. with a metal detector, the sensitivity of the detector setting should be stated and size/type of test pieces used, or with an anti-microbial the minimum concentration required should be stated. Other CCLs may include temperature parameters, pH, flow rates, dwell times, etc.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of omissions or errors in the monitoring requirements.
- Single/isolated instance(s) of omissions or errors in the frequency details.

Major deficiency (5 point) if:
- Numerous instances of omissions or errors in the monitoring requirements.
- Numerous instances of omissions or errors in the frequency details.
- A single CCP (where there are multiple CCP’s) is lacking monitoring requirements or frequency details.

Non-compliance (0 points) if:
- More than one CCP is lacking monitoring requirements or frequency details where there are multiple CCP’s in a plan.
- A single CCP is lacking monitoring requirements or frequency details in a plan where there is a single CCP.

3.03.06: Are identified CCP critical control limits supported by validation document?

Total confirmation (5 points): All CCP's should be supported by validation documentation showing that the critical control limits (CCL) are scientifically derived and meet any relevant legal requirements. Where publicly available validation is not available, the auditee should have performed validation studies to support their stated critical control limits. For example, ORP limits for chlorinated recycled water systems could be stated in research papers and State documentation e.g. Leafy Greens Marketing Agreement. Another example, metal detection limits could be supported by validation studies that show that smallest test probes possible were used and meet the FDA guidelines http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-425.htm .

Minor deficiency (3 points) if:
- Single/isolated instance(s) of omissions or incorrect CCL validation details.

Major deficiency (1 point) if:
- Numerous instances of omissions or incorrect CCL validation details.

Non-compliance (0 points) if:
- There is no documentation to support CCP critical control limits.
- Systematic omissions or incorrect CCL validation details.

3.03.07: Is there a clear detailed action plan for operators to follow if the limits are exceeded? Does it describe plans to adjust the process back into control and withhold out of compliance products if necessary?

Total compliance (15 points): The corrective action details should note the critical control limit issue that has occurred, what corrective actions were carried out, including what happened to potentially affected product and also how the process was "repaired" or "amended" in order to get the process back to the required control level. The HACCP plan corrective action sections should state where the corrective action details are to be recorded. Where required, preventative measures should also be recorded.

Minor deficiency (10 points) if:
- Any one of the above criteria is missing in the corrective action plan details.
- Single/isolated instance(s) of omission or errors in the corrective action details.

Major deficiency (5 point) if:
- Two of the above criteria are missing in the corrective action plan details.
- Numerous instances of omission or errors in the corrective action details.

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

3.03.08: Have recording templates (recording forms) been developed for monitoring the CCPs?

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

Minor deficiency (7 points) if:
- Single/isolated instance(s) of a record(s) having been developed but does/do not match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.

Major deficiency (3 point) if:
- Numerous instances of a record(s) having been developed but do not match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.

Non-compliance (0 points) if:
- Systematic failure of record(s) that have been developed to match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.
- Single instance where a CCP has been created but a record for the monitoring data has not been developed.

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

Total compliance (10 points): Specific responsibilities should be assigned for the monitoring, recording and corrective actions of each CCP. If CCP records are not being completed properly, this may be an indication that the CCPs have not been assigned correctly. The responsibility should be clearly indicated on the HACCP chart by at least naming the function e.g. QA Department, who are responsible for monitoring, recording and executing corrective action related to an individual CCP.

Minor deficiency (7 points) if:

- Single instance of a CCP not being assigned (to either a person or group), where there are multiple CCPs.

Major deficiency (3 point) if:
- Numerous instances of a CCP not being assigned (to either a person or group), where there are multiple CCPs.

Non-compliance (0 points) if:
- No CCPs have been assigned to either a person or group.

3.03.10: Have verification plans and schedules been developed for each CCP?

Visual confirmation. Total compliance (10 points): Verification activities related to each CCP on the HACCP chart should be clearly detailed. Verification activities should include a verification of the CCP monitoring records by a HACCP trained supervisor or manager, checking that the CCP monitoring records have been completed in a proper and timely manner and including any corrective action work. Note, a CCP operator cannot verify their own work. Verification activities might include microbial testing, customer complaints and any other information that CCPs might help generate. Verification information might help improve and develop the HACCP program, but should show that the plan is being implemented correctly, is controlling the risk to an acceptable level (or eliminating the risk) and where this is not the case, this should be indicated on the verification paperwork along with corrective action details (e.g. reviewing a CCP, a process flow, a hazard analysis step, etc.).

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors or omissions in the verification details on the plan.

Major deficiency (3 point) if:
- Numerous instances of errors or omissions in the verification details on the plan
- Single instance in a plan with multiple CCPs where verification details have not been noted.

Non-compliance (0 points) if:
- No verification plans have been developed for any CCP.

Execution of the HACCP plan on the Plant Floor

3.04.01: Are all of the documents noted in the HACCP plan in place for real time monitoring of the CCPs?

Total compliance (15 points): All documents noted in the HACCP plan should be in place for real time monitoring of the CCP(s). Check current logs against the HACCP plan. Check to see if the right version of the log is being used i.e. if the plan was updated and new parameters were chosen and the forms were revised, are the revised forms being used by the CCP operators. Usually this is monitoring logs, but if logs are mentioned in the verification section of the CCPs, these also must be checked. Electronic records should be checked to ensure that the correct version is being used.

Minor deficiency (10 points) if:
- Single instance of a CCP log in place, but the “version” of the log in use is different from that in the HACCP plan i.e. the details are different or there are omissions.

Major deficiency (5 point) if:
- Numerous instances of CCP logs in place, but the “versions” of the logs in use are different from those in the HACCP plan i.e. the details are different or there are omissions.

Non-compliance (0 points) if:
- Systematic failure to control the “versions” of the CCP logs being used.

- Single CCP monitoring requirement not being recorded.

3.04.02: Are the CCP monitoring activities and frequencies in compliance with the plan?

Total compliance (15 points): CCP monitoring activities and frequencies are in compliance with the plan. Check current logs against the HACCP plan. Auditor should carefully check the monitoring frequencies – allow some slight variations (minutes either way of the target frequency). The critical control limits should exactly match those mentioned on the HACCP plan. Note that if a monitoring test is done more frequently than stated, it is not necessarily a fault (i.e. point loss) if "it is in the spirit" of the plan.

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

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

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

3.04.03: Do CCP operators understand basic HACCP principles and their role in monitoring CCPs? (Interview operators to verify).

Total compliance (15 points): CCP operators should be aware of basic HACCP principles, specifically CCPs in their areas and their responsibilities for taking appropriate action should the limits be exceeded. This can be determined through casual employee interview, with the approval of the audit host. The visual part of this confirmation is matching what the CCP operator says versus what is written in the HACCP documentation and also what is written in the CCP monitoring logs.

Minor deficiency (10 points) if:
- Single/isolated instance(s) where the CCP operator(s) are lacking in basic knowledge about HACCP principles.
- Single/isolated instance(s) where the CCP operator(s) are not able explain correctly, details about the CCP's they are monitoring e.g. what to do if the critical control points are exceeded.

Major deficiency (5 point) if:
- Numerous instances where the CCP operators are lacking in basic knowledge about HACCP principles.
- Numerous instances where the CCP operators are not able explain correctly, details about the CCP's they are monitoring e.g. what to do if the critical control points are exceeded.

Non-compliance (0 points) if:
- Systematic failure of the interviewed CCP operator to show basic knowledge about HACCP principle.
- Systematic failure of the interviewed CCP operators to be able to explain correctly, details about the CCP's they are monitoring e.g. what to do if the critical control points are exceeded.

3.04.04: Are CCP monitoring records signed off (or initialed) by the operator(s) who are carrying out and recording the CCP check?

Total compliance (10 points): Each CCP check should be signed off by the CCP operator carrying out the check. Full signatures (with printed name if signature is not legible), initials and electronic signatures are

acceptable. If initials are used, care should be taken to ensure that there is no confusion between two individuals who have the same initials e.g. by using middle initials as well.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of CCP record(s) not signed off by operator(s).

Major deficiency (3 point) if:
- Numerous instances of CCP record(s) not signed off by operator(s).

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

3.04.05: Are corrective actions detailed in writing when the failure of a CCP occurs?

Visual Confirmation. Total compliance (15 points): Corrective actions should be detailed in writing when the failure of a CCP occurs. The CCP failures should be noted in the correct records (as noted in the HACCP plan), should detail what has happened, what was done to correct the issue and if there were any preventative actions. Records should indicate what happened to any affected product and also detail how the process was rectified. The corrective action details should match what is described in the HACCP plan.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of corrective action(s) being recorded, but lacking some details.
- Single/isolated instance(s) of corrective action(s) being recorded, but not meeting the requirements as noted in the HACCP plan.

Major deficiency (5 point) if:
- Single instance of CCP critical control limit breach not being recorded and/or corrective actions not being recorded.
- Numerous instances of corrective action(s) being recorded, but lacking some details.
- Numerous instances of corrective action(s) being recorded, but not meeting the requirements as noted in the HACCP plan.

Non-compliance (0 points) if:
- More than one instance of CCP critical control limit breach not being recorded and/or corrective actions not being recorded.
- Systematic failure to properly record corrective action details or the details recorded in no way meet what is required by the HACCP plan.

3.04.06: Are the CCP records reviewed and signed off daily by the quality control supervisor and/or management?

Visual Confirmation. Total compliance (10 points): CCP records should be reviewed and signed off daily by the quality control supervisor or manager (second signatory). This should be a separate signature to that of the CCP operator. The individual signing off these should check the records e.g. dates, production lines, monitoring results, frequencies, corrective actions, use of correct forms, etc., since their signature is basically stating that everything is in order relative to the written HACCP plan and associated documents. If discrepancies are found, then the sign off signatory should note the issues and corrective actions that are then taken.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of CCP records not reviewed and signed off daily by the quality control supervisor or manager (second signatory).

- Single/isolated instance(s) of the CCP records being signed off by the second signatory but there are issues with the records that have not been highlighted.

Major deficiency (3 point) if:
- Numerous instances of CCP records not reviewed and signed off daily by the quality control supervisor or manager (second signatory).
- Numerous instances of the CCP records being signed off by the second signatory but there are issues with the records that have not been highlighted.

Non-compliance (0 points) if:
- Systematic failure for CCP records to be reviewed and signed off.
- Systematic errors on the CCP records that are being signed off by the second signatory.

Verification of the HACCP Plan

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

Total compliance (10 points): Verification, monitoring, feedback and other ongoing HACCP information should be discussed at management level meetings with records of what was discussed and who attended these meetings. These meetings notes should be kept on file and available for review. These meetings should occur at least quarterly, but ideally monthly. These meetings can be combined with other topic e.g. pre-requisite food safety topics, like sanitation, pest control etc. If the company is too small to have a HACCP group (less than 20 people), the designated HACCP coordinator will be responsible for the HACCP program.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of errors and omissions in the meeting logs, e.g. not noting who was attending the meeting.
- Single/isolated instances(s) of meetings not being held at the minimum specified frequency.

Major deficiency (3 point) if:
- Numerous instances of errors and omissions in the meeting logs, e.g. not noting who was attending the meeting.
- Numerous instances of meetings not being held at the minimum specified frequency.

Non-compliance (0 points) if:
- Meeting reviewing the HACCP progress are not occurring or are not being documented.

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

Total compliance (10 points): Independent (from the operational employees) audits of the HACCP program should occur at least every 12 months e.g. third party audits, etc. Records of these HACCP system audits, and corrective actions should be available for review. The audit report must state that HACCP is included in the scope and the audit must review all the key HACCP details (HACCP development, implementation, monitoring and self-auditing of plan and associated records).

Minor deficiency (7 points) if:
- Last external HACCP audit was over 12 months ago, but no greater than 18 months ago.

Major deficiency (3 point) if:
- Last external HACCP audit was over 18 months ago, but no greater than 24 month ago.

Non-compliance (0 points) if:

- Last external HACCP audit was over 24 months ago.