PrimusGFS Audit

HACCP

(Module 3) Guidelines

Used in conjunction with PrimusGFS V2.1-2c audit
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PrimusGFS (owned by Azzule Systems, LLC)
3030 Industrial Parkway
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 v2.1-2 Modules 1, 2 and 3 as noted in the Scheme normative documents. These guidelines are not exhaustive or 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 compliance/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 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 an 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 an 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 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 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 three consecutive months of records	Records since last audit

Visual versus Verbal Confirmation

Visual confirmation is the default method of auditing, whether on the visual inspection portion or the paperwork section. Scores and comments are assumed to have been visually confirmed, unless 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 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:

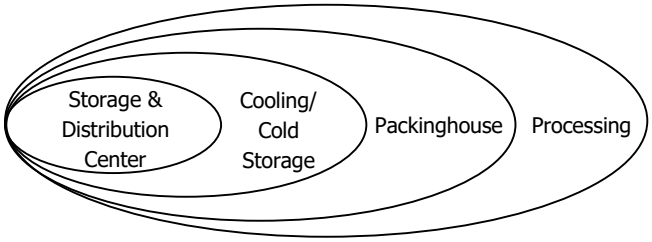

Figure 1. Facility types relationship and coverage

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 3

Preliminary Steps

3.01.01: Is there a team responsible for HACCP program at the operation, with a leader assigned and if applicable, for the development, implementation and on-going maintenance of the HACCP system?

Total compliance (10 points): There should be a formally identified group of people in charge of development and maintenance of the Hazard Analysis Critical Control Point (HACCP) program along with their corresponding responsibilities. Ideally, the group should be comprised of individuals from different areas of the company such as top management, quality management, production, maintenance, sanitation, QC, etc. Consider including resources from outside e.g. suppliers, buyers, consultant, trade association, university, extension office, 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 team, there should still be one individual designated as the HACCP coordinator. That individual is responsible for the implementation of the HACCP program along with any changes and updates to the HACCP program.

Minor deficiency (7 points) if:
- Team has been put together but lacks key representation e.g. maintenance.

Major deficiency (3 points) if:
- The team or individual is assigned but does not meet regularly to review the HACCP program.
- A large company, but only a single individual has been designated to develop the operational HACCP plan.

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.

3.01.02: Is there documented evidence that the HACCP team members have been trained on HACCP principles?

Total compliance (10 points): The HACCP coordinator should have a certificate of formal HACCP training from a recognized organization, institution or trainer i.e. certification from a HACCP training course accredited by the International HACCP Alliance or equivalent (e.g. university provided courses) providing a minimum of 2 days or 16 hours training, taken within the last 5 years. Management and HACCP team members 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). Records of training should be kept and also certificates where relevant.
http://www.haccpalliance.org/sub/index.html

Minor deficiency (7 points) if:
- Not all HACCP team members are trained in HACCP (but all key operators and majority of team members have been trained).
- 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.
- Numerous instances of omissions or incorrect data in the records.

Non-compliance (0 points) if:

- No formal training records for HACCP team members.
- No records of training being maintained.

3.01.03: Does a product description exist for the products produced?

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 single product description is 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, more than one product description is not available.

3.01.04: Has the process(es) been flow charted in sufficient detail to completely describe the process or product handling/processing steps and has the flow chart been verified?

Total compliance (15 points Process flow charts should have been created for each HACCP plan. The flow chart should show each step of the process(es) under control of the operation, so that the hazard analysis can be completed properly. The flow chart should indicate the raw materials, ingredients and materials used in all preparation steps, all equipment used, blending steps, processing steps, rework, returned products and products destined for further processing, packaging materials (carton and unit packaging) and packaging equipment. Be sure to include all inputs such as packaging, water source (e.g. city or well), ice, anti-microbials, etc. Each step should show any holding times, temperature regimes and tagging. For example, a step termed “packing” in an apple packinghouse is incorrect since it omits to detail many of the processes, e.g. dump tanks, selections, recirculated product wash/rinse steps, single-pass wash/rinse steps, waxers (with fungicide), drying, packing the boxes and coding. In operations with multiple products but similar processes, a single process flow may be used. Where there are multiple products but with different processes then individual process flows are required. Flow diagram should be verified on-site to ensure it reflects the process; insufficient detail, missing steps, etc., will undermine the hazard analysis process.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of errors or omissions on the process flow chart(s).
- Single instance of a flow chart not being verified.

Major deficiency (5 point) if:
- Numerous instances of errors or omissions on the process flow chart(s).
- More than one instance of a flow chart not verified.

- 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).
- Flow charts have not been verified.
- No process flow chart(s).
- In an operation with multiple products/processes that are not similar, many of the flow charts are not available.

Development of the HACCP Plan

3.02.01: Has a documented hazard analysis for the process been conducted, showing the various types of hazard, their likelihood of occurrence and their associated severity? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.
Total compliance (15 points): A hazard analysis identifies and evaluates 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 in order to prove that a proper hazard analysis was conducted. Note, if there are errors in the process flow it is likely there will also be errors in the hazard analysis. At each step of the process, from raw material receipt and storage, through processing and packing, storage and distribution the hazard analysis should look at the severity and likelihood of all potential food safety hazards that may be reasonably expected to occur in terms of specific biological, chemical and physical or other issues. 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. Evaluation should include all ingredients, equipment, processing steps (e.g., receiving, dump tanks, brush bed systems, recycled wash systems including hydro-vacuum coolers, ice injectors, flume washers, etc., single line wash systems, ice manufacturing), and inputs including packaging materials and post-harvest treatments, etc.

Justifications should be documented when identifying significant and non-significant hazards. Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure. The hazard analysis should indicate if an adequate control step for this potential risk exists further down the process. The hazard analysis should be reviewed when changes occur affecting the product description and/or the process flow.

http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm

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

Major deficiency (5 point) if:
- Numerous instance(s) of errors or omissions on the hazard analysis chart(s)

Non-compliance (and an automatic failure of this module) (0 points) if:
- Multiple systematic errors on the hazard analysis chart(s).
- One or more hazard analysis chart(s) have not been created for the process flow(s).
- In an operation with multiple products/processes that are not similar, one or more hazard analysis chart are not available.

3.02.02: Have CCPs been developed? If answer is YES, continue with next question. If answer is NO, the rest of "Module 3 HACCP" is not applicable. If the auditor detects that one or more CCPs have been omitted, then the auditor should score a Zero Point, Non-Compliance under 3.02.01. If the auditor thinks that CCPs have been added that should be omitted, then the auditor should note the issue under 3.02.03.

Total points (0). The identification of a CCP in the process requires development of the criteria with adequate detail, defined parameters and the execution of the necessary activities in the production line. The rest of this module should be completed. 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.
Where the operation determined that there are no CCPs (and the auditor is in agreement), no further HACCP development is required and the rest of the module is not applicable.

For facility operations, the organization will determine the need for a HACCP program by performing a documented hazard analysis for all steps of each process. Examples of specific biological hazards include *Listeria monocytogenes, Salmonella* spp*.,* Enterohaemorrhagic *E. coli* (EHEC), Shiga toxin-producing *E. coli* (STEC), *Cryptosporidium parvum, Cyclospora cayetanensis*; chemical hazards include mycotoxins, pesticide residues, sanitation chemicals, lubricants, allergens; physical hazards include stones, metal, glass, and brittle plastic. If an auditee decides to complete a HACCP program, even if no CCP's are identified, then the auditor will complete the HACCP module of this audit as a verification of the HACCP program.

http://www.caleafygreens.ca.gov/food-safety-practices
http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm082751.htm

3.02.03: Have CCP decisions been made with documented justifications and where CCPs are noted have they been developed to control the hazards identified in the hazard analysis step?

Total compliance (15 points): CCP decisions should be properly justified with supporting documents and evidence. The CCPs defined in the hazard analysis should be developed to define in detail the parameters involved, and monitoring requirements to control the hazard(s).
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.

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

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

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

3.02.04: Have CCP critical control limits been established with support of relevant sources of information or by validation documentation?

Total confirmation (15 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

Minor deficiency (10 points) if:

- Single/isolated instance(s) of omissions or incorrect CCL validation details.

Major deficiency (5point) 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.

3.02.05: 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. Where monitoring is not continuous, the type and frequency of monitoring should be sufficient to ensure the CCP is under control. Frequency should be specified; “as needed” is not accepted as a stated frequency. 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.

3.02.06: 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 Technician, who are responsible for monitoring, recording and executing corrective action related to an individual CCP. All records and documents associated with monitoring CCPs should be signed by the person(s) doing the monitoring, either physically or electronically.

Minor deficiency (7 points) if:
- Single instance of a CCP not being assigned (to either a person or group), where there are multiple CCPs.

Major deficiency (3 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.

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

Total compliance (5 points): Clear and simple standard operating instructions (SOPs) 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.

Minor deficiency (3 points) if:
- Single/isolated instance(s) of errors and omissions within the CCP SOPs.

Major deficiency (1 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.

3.02.08: Have corrective action procedures for the CCPs been established, including a detailed action plan for operators to follow if the limits are not met and plans to adjust the process back into control?

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. Corrective actions should ensure that the CCP has been brought under control and require that a review is conducted in order to prevent a recurrence of the situation.

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.
- Systematic errors in corrective action plan details.

3.02.09: 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 and have CCPs identified by name and number, what is being measured, the frequency of the measurement, the critical control limit, the operating limit, the responsible person(s) or team and the corrective action(s) required in the case of measurements not in compliance. Recording forms should have a specific document code as part of the document control program (1.02.01). 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.

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

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.

3.02.11: 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 workers 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 workers 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 workers 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 workers were informed.
- Re-training records have not been maintained.

3.02.12: Is there evidence recorded for HACCP training to all plant workers, including training for CCP operators?

Total compliance (10 points): All site workers should receive basic HACCP overview training i.e. what is HACCP, the 7 principles, and what are the CCPs on site. Basic training might form part of the new hire orientation package. CCP operators should be specially trained for their function(s) and include the operations they are responsible for. Senior management should also receive training (HACCP requires “buy in” from all levels). Records of training should be kept and also certificates where relevant. All workers should be trained to understand the principles of HACCP and the plan implemented in the facility. Training should be scheduled on a regular basis and documented. The training should be tailored to the people and their positions within the company.

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

Major deficiency (3 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 workers.
- No records of training being maintained.

Execution of the HACCP plan on the Plant Floor

3.03.01: 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 and check that document version codes match. Check to see if the right version of the log is being used i.e. if the plan was updated and new parameters were chosen and the forms were revised, are the revised forms being used by the CCP operators. Usually this is monitoring logs, but if logs are mentioned in the verification section of the CCPs, these 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.

3.03.02: 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) where information or requirements on the recording template does not match what is noted in the HACCP plan.

Major deficiency (5 point) if:

- Numerous instances where information or requirements on the recording template does not match what is noted in the HACCP plan.

Non-compliance (0 points) if:

- Systematic failure to have information or requirements on the recording template matching what is noted in the HACCP plan.

Single instance where a CCP has been created but a record for the monitoring data has not been developed.

3.03.03: 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 worker interview, with the approval of the audit host. The visual part of this confirmation is matching what the CCP operator says versus what is written in the HACCP documentation and also what is written in the CCP monitoring logs.

Minor deficiency (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.

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

Total compliance (15 points): All CCP monitoring records and documents should be signed off by the person(s) doing the monitoring. Full signatures (with printed name if signature is not legible), initials and electronic signatures are acceptable. If initials are used, care should be taken to ensure that there is no confusion between two individuals who have the same initials e.g. by using middle initials as well.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of CCP record(s) not signed off by operator(s).

Major deficiency (5 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.

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

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 taken to prevent reoccurrence. Records should indicate what happened to any affected product and also detail how the process was rectified. The corrective action details should match what is described in the HACCP plan.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of corrective action(s) being recorded, but 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.

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

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.

3.03.07: Is any other CCP verification performed (apart from daily record verification) according to the HACCP Plan?

Total conformance (10 points): CCP verification steps as per the HACCP plan should be completed and records maintained. The plan might include microbiological testing, customer feedback, equipment calibration, etc. Where verification activities have found that CCPs were not performing as required there should be records that show that this has prompted a review of the relevant part of the HACCP program. For example, metal contamination complaints, where metal detection is a CCP should prompt a review of the metal detection operation (metal detection performance, types of metal being scanned for, detection sensitivity (CCL's), worker performance and training).

Minor deficiency (7 points) if:

- Single/isolated instance(s) of CCP verification activity not being performed as per plan.

Major deficiency (3 point) if:

- Numerous instances of CCP verification activities not being performed as per plan.

Non-conformance (0 points) if:

- Systematic failure to implement verification plan.