PrimusGFS Audit

HACCP

(Module 6) Guidelines

Used in conjunction with the PrimusGFS v3.2 audit

PrimusGFS (owned by Azzule Systems, LLC)
3030 Industrial Parkway
Santa Maria, CA 93455

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These guidelines help interpret/support the principles, requirements and expectations of the PrimusGFS v3.2 Modules 1, 2, 3, 4, 5, 6 and 7 as noted in the Scheme normative documents. These guidelines are neither exhaustive nor exclusive and detail minimum requirements only by means of statements related to audit questions and expectations. There will be variations in applicability to an operation based on the process(es) and commodities involved. Auditors and auditees should interpret the questions and criteria in different situations, with the food safety and risk minimization being the key concerns.

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

Website links shown in this document are there to aid understanding and provide assistance by way of example (link listings are not exhaustive). These links are not a sign of endorsement by Azzule. 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 explain the overall scheme scoring systems and other details of the scheme.

The following text is a modified excerpt from the PrimusGFS General Regulations v3.2. It is provided here as an introduction to the audit notes. For full and current text please refer to the most recent version of the 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 seven Modules:

- Module 1 – Food Safety Management System
- Module 2 – Farm
- Module 3 – Indoor Agriculture
- Module 4 – Harvest Crew
- Module 5 – GMP
- Module 6 – HACCP
- Module 7 – Preventive Controls

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

For all Modules, the amount of deficiencies and the associated risks have to be considered to assign the severity of the finding, which can be Minor Deficiency, Major Deficiency and Non-Compliance. When no

deficiencies are found, a Total Compliance is given. The possible points for the questions in each Module are listed in the following table:

Scoring System for Questions				
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 point	1 point
Non-compliance	0 points	0 points	0 points	0 points
Not applicable	0 points	0 points	0 points	0 points

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

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

Automatic Failure

There are some questions that if down scored will lead to an automatic failure and an overall score of 0% 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 the audit or to have the audit halt at that point (all charges will apply). The auditor should explain the advantages of finishing the audit, including the

ability for the auditee to learn of other potential non-conformances and to show their buyers the status of their food safety system despite the automatic failure issue.

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 given. The auditee should be immediately informed of the automatic failure by the auditor during the audit. The auditee has the option to have the auditor continue the audit or to have the audit halt at that point (all charges will apply).
There are other Special Circumstance that are not technical in nature. Examples of these include detection of deliberate illegal activities, such as deliberate mislabeling, discovery of falsified records, attempting to bribe an auditor/CB personnel, threatening behavior towards an auditor/CB personnel, etc. Please refer to the General Regulations for further details.

Audit Termination

Once an audit has been started, should the auditee wish to stop the audit for any reason, the auditor will complete the report for as many questions as they were able to verify. PrimusGFS audits cannot be converted into a pre-assessment audit once the audit has been started. If an audit is terminated early, questions that the auditor was unable to verify will be marked as a non-compliance and will receive a score of zero. For questions unable to be verified, the auditor will indicate that the audit was terminated at the request of the auditee before the auditor could verify whether or not the audit conformed to the compliance criteria of the question. A report will be created on the database and issued, and all charges will apply.

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.) and the implementation of these systems throughout the visual inspection.

While auditees often create and implement their own systems, they can also use systems that have been created by other entities, for example, their customers' technical manager, their consultants, etc., or a combination of resources. The Organization can create their own SOPs, or in other instances, can utilize SOP templates provided by other entities. As long as the systems meet the requirements of the 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 PrimusGFS Auditees/First-Time PrimusGFS Auditees

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

review. If the auditee has less than three months of most of their documentation available for review and decides to have a regular scheduled audit, they should be aware that they **may not receive full conformance for paperwork questions relating to monitoring and that the down score will be based on the amount of paperwork available**.

Existing PrimusGFS Auditees

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

	Operates <three months/year	Operates >three months/year
New PrimusGFS Auditee	Three months of records (may include last season's records). Where an operation does not have three months of records available (e.g., they are in operation for one month out of the year), the auditee should have at least the previous season's records available for review.	Three months of records (may include last season's records).
Existing PrimusGFS Auditee	Records at least since the last audit (or longer) to meet the minimum requirement of three consecutive months of records.	Records since the last audit.

Visual versus Verbal Confirmation

Visual confirmation is the default method of auditing, whether on the visual inspection portion or the paperwork section. Scores and comments are assumed to have been visually confirmed, unless stated otherwise. Verbal confirmation should be the exception to the rule and, if auditing properly, these should be rarely used. If a verbal confirmation is accepted, the auditor should write this in the comments section of the report for that specific question.

How to Use Point Assignment Guidelines

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

In order to be consistent with the voluntary nature of requesting a third-party audit, and in order not to seem to be a legal document, the requirements within the questions are written as "should" and can be

scored against. In other questions that use the term “ideally”, these statements cannot be scored against, but give the auditee an opportunity for improvement.

Notes in “red” are where the questions and/or compliance 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.

Module 6: HACCP

Preliminary Steps

6.01.01: Is there a team responsible for the HACCP program at the operation, with an assigned leader 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. The group should be comprised of individuals from different areas of the company such as top management, quality management, production, maintenance, sanitation, QC, etc. Consider including resources from outside e.g. suppliers, buyers, consultants, trade association, universities, extension office, etc. One member of the team should be designated the HACCP Coordinator (leader). Where a consultant has been designated the HACCP coordinator, it should be evident that they are present at all meetings and actively involved in the program. The HACCP team should meet at least quarterly (ideally monthly). If the company is too small (less than 20 people) to have a HACCP team, there should still be one individual designated as the HACCP coordinator. That individual is responsible for the implementation of the HACCP program along with any changes and updates to the HACCP program.

Minor deficiency (7 points) if:
- Team has been put together but lacks key representation e.g. maintenance, sanitation.
- Only three meetings have occurred in the last 12 months (for an all year-round operation)

Major deficiency (3 points) if:
- The team or individual is assigned but does not meet regularly to review the HACCP program.
- A large company, but only a single individual has been designated to develop the operational HACCP plan.
- Two or less meetings have occurred in the last 12 months (for an all year-round operation).

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

6.01.02: Is there documented evidence that the HACCP team members have been trained on HACCP principles?
Total compliance (15 points): The HACCP Coordinator should have a certificate of formal HACCP training from a recognized organization, institution or trainer i.e. certification from a HACCP training course accredited by the International HACCP Alliance or equivalent (e.g. university provided courses) providing formal training, taken within the last 5 years. Preventive Control Qualified Individual (PCQI) training can also be accepted, as long as it is equivalent to the International HACCP Alliance training (covers the 7 Codex Alimentarius HACCP principles and the 12 HACCP implementation steps). HACCP team members should have thorough HACCP training (in-house or external within the last 5 years) given by someone who has HACCP experience and has attended an accredited International HACCP Alliance course (or equivalent). Records of training should be kept and certificates, where relevant.
http://www.haccpalliance.org/sub/index.html

Minor deficiency (10 points) if:
- Not all HACCP team members are trained in HACCP (but majority of HACCP team members have been trained).
- Management team members have not received HACCP training.
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major deficiency (5 points) if:

- HACCP Coordinator has not completed a formal certified HACCP training course within the last 5 years.
- Numerous instances of omissions or incorrect data in the records.

Non-compliance (0 points) if:
- No training records for HACCP team members.

6.01.03: Does a product description exist for the products produced?
Total compliance (10 points): Product description(s) should clearly describe the product and its distribution and be used to determine if specific controls are important throughout the distribution chain. The description should indicate the product(s) name, composition (ingredients), type(s) of packaging, shelf-life and method of storage and distribution. Information should include intended use i.e. does it need washing, peeling, cooking prior to consumption, is it RTE, etc., by the consumer, and reflect the label of the product (unit packed product). Intended use should include any potential for abuse or misuse of the produce (e.g. eating raw when product is intended to be cooked). Product description(s) should list all ingredients including allergens, define and indicate details regarding whether the item is perishable or long life, if there are any special storage and distribution requirements and any important food safety characteristics that can influence the growth of pathogens (e.g., pH, water activity), and labeling requirements including allergen information and any other legal requirements. Product description(s) should define the potential risk associated with the product, materials used and also who the intended customers are (general public, restricted to certain sectors, e.g. people not suffering from a certain allergy, diabetic issues, other at-risk groups, etc.). The product description can be generic if the products and processes are similar. Where the products and/or processes are not similar to each other, specific product descriptions are required.

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

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

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

6.01.04: Has the process(es) been flow charted in sufficient detail to completely describe the process or product handling/processing steps?
Total compliance (10 points). There should be process flow charts for each HACCP plan. The flow chart should show each step of the process(es) under control of the operation (from receiving through final storage and shipping), so that the hazard analysis can be completed properly. The flow chart is used to identify any and all steps throughout the process where there is a potential for a food safety hazard to be introduced or for a product safety control to be implemented. The flow chart should indicate all raw materials, ingredients and materials used in all preparation steps, all equipment used, blending steps, processing steps, rework, by-product, returned products and products destined for further processing, packaging materials (carton and unit packaging) and packaging equipment. All inputs should be included, such as packaging, water source (e.g. city or well), ice, anti-microbials, fungicides, etc. Each step should show any holding times, temperature regimes, etc., at appropriate process steps. For example, a step termed “packing” in an apple packinghouse is incorrect since it omits to detail many of the processes, e.g. dump tanks, selections, recirculated product wash/rinse steps, single-pass wash/rinse steps, waxers, fungicide, drying, packing the boxes and coding. In operations with multiple products but similar processes, a single process flow may be used. Where there are multiple products but with different

processes then individual process flows are required. Diagram should show re-work processes and when product is diverted to be used for other purposes. Process flows can be augmented by written process descriptions (where helpful).

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

Major deficiency (3 points) if:
- Numerous instances of errors or omissions on the process flow chart(s).
- In an operation with multiple products/process that are not similar, a few of the flow charts are not available, but the majority are available

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

6.01.05: Is there documented evidence that the flow chart(s) been verified on-site?
Total compliance (10 points): The steps in the flow chart are used to organize the hazard analysis. Flow diagrams should be verified on-site by the food safety team and the team should make any changes required to the flow diagram. Any significant changes to the process must be accurately reflected in the flow diagram and evaluated to determine if the changes have an impact on the hazard analysis and CCPs in place. The flow chart(s) is signed and dated by the HACCP coordinator to confirm it reflects the process at different moments in time (auditor should confirm how and when flow chart(s) were verified) and there are no missing steps. Insufficient detail, missing steps, etc., will undermine the hazard analysis process (6.02.01). Any inaccuracies in the flow diagram should be scored in 6.01.04.

Minor deficiency (7 points) if:
- Single instance of a flow chart not being verified.

Major deficiency (3 points) if:
- More than one instance of a flow chart not verified.

Non-compliance (0 points) if:
- Flow charts have not been verified.

Development of the HACCP Plan

6.02.01: Has a documented hazard analysis for the processes been conducted, showing the various types of hazards, their likelihood of occurrence, their associated severity and their control measures? A ZERO POINT (NON-COMPLIANCE) DOWNSCORE IN THIS QUESTION RESULTS IN AUTOMATIC FAILURE OF THIS AUDIT.
Total compliance (15 points): A hazard analysis identifies and evaluates potential food safety hazards and determines if control measures are in place to prevent, eliminate or reduce the food safety hazard to an acceptable level. There should be a detailed, documented hazard analysis for each process flow in order to prove that a proper hazard analysis was conducted. Note, if there are errors in the process flow, it is likely there will also be errors in the hazard analysis. At each step of the process, from raw material receipt and storage, through processing and packing, storage and distribution, the hazard analysis should look at the severity and likelihood of all potential (known or reasonably foreseeable) food safety hazards that may be reasonably expected to occur in terms of specific biological, chemical (including radiological), and physical hazards, as well as the control measures for each. Operations following US FDA FSMA requirements should also consider economically motivated hazards and preventive controls, such as process, allergens, sanitization, and supply chain controls for the identified hazards. Any potentially RTE products must include an evaluation of specific environmental pathogens related to ingredients/products.

Research previous outbreaks and issues associated with the ingredients/products to help identify specific risks with ingredients/products used. Examples of specific biological hazards (bacteria, viruses, parasites and pathogens) include Listeria monocytogenes, Salmonella spp., Enterohaemorrhagic *E. coli* (EHEC), Shiga toxin-producing *E. coli* (STEC), Cryptosporidium parvum, Cyclospora cayetanensis; chemical hazards include mycotoxins, pesticide residues, sanitation chemicals, lubricants, allergens, natural toxins, unapproved additives; physical hazards include extraneous matter that may cause choking or other injury e.g. stones, metal, glass, and brittle plastic; radiological hazards include local environmental issues (e.g. refer to Water Management District reports); economically motivated hazards including product substitutions, fillers, etc. Evaluation should include all ingredients, equipment, processing steps (e.g., receiving, dump tanks, brush bed systems, recycled wash systems including hydro-vacuum coolers, ice injectors, flume washers, etc., single line wash systems, ice manufacturing), inputs including packaging materials and post-harvest treatments, sanitation and employee hygiene, etc.

Each step identified in the process flow diagram should be assessed in the hazard analysis. Justifications should be documented when identifying significant and non-significant hazards. Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure. Consider pre-requisite programs (PRPs) in place which provide basic environmental and operating conditions necessary for the production of safe, wholesome food and support decisions in the hazard analysis (e.g. pest control programs, allergen control programs, sanitation programs, maintenance programs, microbial testing programs, supplier control program, worker hygiene training, waste management, storage and transportation, etc.). The hazard analysis should indicate if an adequate control step for this potential risk exists further down the process. The hazard analysis should be reviewed when changes occur affecting the product description and/or the process flow. The hazard analysis for all products must be written, regardless of its outcome.
http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm

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

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

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

6.02.02: Have CCP decisions been made with logical, documented justifications and where CCPs are implemented in a specific processing step, have they been developed to control the identified hazard(s)?
Total compliance (15 points): CCP decisions should be properly justified with supporting documents, rationale and evidence. The CCPs identified in the hazard analysis should be developed to define, in detail, the parameters involved, and monitoring requirements to control the hazard(s).
The CCPs should be created from the documented hazard analysis i.e. *there should be a logical documented approach (such as utilizing a CCP decision tree that justifies whether or not there is a step(s) in the process determined to be a CCP(s)*. CCPs are steps that if not controlled will lead to a food safety issue and where there is no step further down the process that controls the risk. A CCP should be controllable and control is essential to prevent or eliminate a food safety hazard or reduce the risk to an acceptable "safe" level. It is possible to find that an auditee has carried out a proper hazard analysis and found no CCPs (see 6.02.04).

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

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

Non-compliance (0 points) if:
- No CCPs have been developed in the hazard analysis step even though clearly CCPs did exist.
- More than one CCP has been omitted in a plan where there should be multiple CCPs.
- A single CCP has been omitted in a plan where there is a single CCP.

6.02.03: Is the HACCP system reviewed when significant changes are made and at least once every 12 months?
Total compliance (10 points). The HACCP system should be reviewed by the HACCP team when significant changes are made e.g. raw materials, new products, labeling requirements (including allergens), packaging, suppliers, product, process, construction, new equipment, recurring deviations, new scientific information, new legal requirements, new distribution or consumer practices, etc., including the hazard analyses, to ensure that the program is up to date and working properly. HACCP system review should occur at a frequency that ensures the HACCP Plan is being followed continuously and at least every 12 months. Where emerging issues, such as recalls, an outbreak, new research, etc., are relevant to the products and processes at hand, consideration of a HACCP review should occur. Documented re-training or educational sessions may be necessary. The review should include a written record which demonstrates each of the elements of the plan including the product descriptions, process flows, hazard analyses, CCP decisions, CCP recording, customer complaints, equipment calibration, record review, trend analysis data, etc., have been reviewed, verified as being accurate/appropriate and there should be a change record included in the plan to track changes over time. The HACCP team should inform workers involved of the review outcomes.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of omissions in the review.

Major deficiency (3 points) if:
- Numerous instances of omissions in the review.
- No record of workers involved being informed of HACCP review outcomes.
- Verification did not take place in the last 12 months but did take place in the last 18 months.

Non-compliance (0 points) if:
- There is no documented record of review.

6.02.04: Have critical control point (CCP) processing steps been identified that eliminate or reduce food safety hazards to an acceptable level? Informational gathering. If answer is YES, continue with next question. If answer is NO, the rest of "Module 6 HACCP" is not applicable.
Total points (0 points). The identification of a CCP in the process requires development of the criteria with adequate detail, defined parameters and the execution of the necessary activities in the production line. If CCPs have been identified, the rest of this module should be completed. The CCPs should be created from the documented hazard analysis, i.e. there should be a logical documented approach showing why the process was deemed a CCP or not. CCPs are often steps that if not controlled will lead to a food safety issue, and also, there is no step further down the process that controls the issue. A CCP should be controllable and the controls should be able to eliminate or reduce the risk to acceptable "safe" levels. Where the operation determined that there are no CCPs (and the auditor is in agreement), no further HACCP development is required, and the rest of the module is not applicable.

For facility operations, the organization will determine the need for a HACCP program by performing a documented hazard analysis for all steps of each process. If an auditee decides to complete a HACCP program, even if no CCPs are identified, then the auditor will complete the HACCP module of this audit as a verification of the HACCP program.

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

6.02.05: Have CCP critical control limits been established and are they supported by relevant validation documentation?

Total compliance (15 points): A critical control limit (CCL) represents the dividing line used to judge whether a CCP is under control or not. Each Critical Control Point should have one or more critical control limits for each identified hazard. Critical control limits (CCL's) i.e. the maximum and/or minimum parameters of what is being monitored e.g. with a metal detector, the sensitivity of the detector setting should be stated along with the size/type of test pieces used, or with an anti-microbial the minimum concentration required should be stated. Other CCLs may include temperature, time, pH, water activity, flow rates, line speed, dwell times, etc. More stringent "operating limits" may be useful during production to minimize failure to meet a critical limit.
All CCPs should be supported by validation documentation showing that the critical control limits (CCL) are scientifically derived and meet any relevant legal requirements. Validation could take the form of publicly available legislative documents, industry best practice documents, peer reviewed research papers, on site validation studies, etc., or a mix of different validation sources. Where publicly available validation is not available, the auditee should have performed validation studies to support their stated critical control limits. For example, free chlorine limits for chlorinated recycled water systems could be stated in research papers and State documentation (e.g., Leafy Greens Marketing Agreement). Another example, metal detection limits could be supported by validation studies that show that smallest test probes possible were used and meet the FDA guidelines

Minor deficiency (10 points) if:
- Single/isolated instance(s) of omissions or incorrect CCL validation details.

Major deficiency (5 points) if:
- Numerous instances of omissions or incorrect CCL validation details.

Non-compliance (0 points) if:
- There is no documentation to support CCP critical control limits.
- Validation documentation provided does not support the CCP control limits.
- Widespread omissions or incorrect CCL validation details.

6.02.06: Have monitoring requirements and frequencies been determined and documented for the CCPs?
Total compliance (15 points): There should be determined and documented monitoring requirements and frequencies for the CCPs. Where monitoring is not continuous, the type and frequency of monitoring should be sufficient to ensure the CCP is under control. Frequency should be specified; "as needed" is not accepted as a stated frequency. Requirements should include the critical control limits (CCL's) i.e. the maximum and/or minimum parameters of what is being monitored e.g. with a metal detector, the sensitivity of the detector setting should be stated and size/type of test pieces used, or with an anti-microbial the minimum concentration required should be stated. Other CCLs may include temperature parameters, pH, flow rates, dwell time, etc. The requirements i.e. what is to be done should be specified on the HACCP plan.

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

Major deficiency (5 points) if:
- Numerous instances of omissions or errors in the monitoring requirements.

- Numerous instances of omissions or errors in the frequency details.
- A single CCP (where there are multiple CCPs) is lacking monitoring requirements or frequency details.

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

6.02.07: Have specific responsibilities been assigned for the monitoring, recording and corrective action implementation of each CCP?
Total compliance (10 points): Specific responsibilities should be assigned for the monitoring, recording and corrective action implementation of each CCP to ensure compliance. If CCP records are not being completed properly, this may be an indication that the CCPs have not been assigned correctly. The responsibility should be clearly indicated on the HACCP plan by at least naming the function e.g. QA Technician or trained designate, who is responsible for monitoring, recording and executing corrective action related to an individual CCP. All records and documents associated with monitoring CCPs should be signed by the person(s) doing the monitoring, either physically or electronically.

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

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

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

6.02.08: Have standard operating procedures (SOPs) been created for the monitoring process(es) of the CCPs, which would include how to carry out the monitoring activities?
Total compliance (10 points): Clear and simple standard operating instructions (SOPs) should be written for each CCP monitoring process(es). These SOPs should expand the CCP monitoring activities in detail in the form of work instructions, and match what is written in the HACCP plan. These SOPs can be used for training and as reference tools.

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

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

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

6.02.09: Have corrective action procedures been established for the CCPs, including a detailed action plan for operators to follow if the critical control limits are not met (loss of control/deviation) and plans to adjust the process back into control?
Total compliance (15 points): Corrective actions are procedures that must be taken if critical controls are not properly implemented (e.g. there is a deviation from a critical limit) and unsafe product may have been produced. There should be a documented, detailed plan with written procedures to follow when

there is a loss of control (deviation) of a CCP appropriate to the nature of the hazard. The procedures should include details regarding how to handle affected products (if necessary). The corrective action details should note the critical control limit issue that occurred, what corrective actions were carried out, including what happened to potentially affected product and also how the process was "repaired" or "amended" in order to get the process back to the required control level. The HACCP plan corrective action sections should state where the corrective action details are to be recorded and details should match the written corrective action procedures. Where appropriate, preventative measures should also be required to reduce the likelihood the problem will recur. This may include root cause analysis.
Corrective actions should ensure that the CCP has been brought under control and require that a review is conducted in order to prevent a recurrence of the situation. Corrective actions may require review of the HACCP system (6.02.03) to determine if modifications are required. Corrective action records are scored under 6.03.06.

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

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

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

6.02.10: Have recording forms been developed for monitoring the CCPs?
Total compliance (15 points): Monitoring record templates should be designed to record the monitoring of the CCPs that have been identified. The records should match the details as noted in the HACCP Plan and have CCPs identified by name and number, what is being measured, the frequency of the measurement, the critical control limit, the operating limit (if applicable), the responsible person(s) or team and the corrective action(s) required in the case of measurements not in compliance. Recording forms should have a specific document and/or version code as part of the document control program (1.02.01).

Minor deficiency (10 points) if:
- Single/isolated instance(s) of a record(s) having been developed but does/do not match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.
- Single instance of recording forms lacking required details.

Major deficiency (5 points) if:
- Numerous instances of a record(s) having been developed but do not match the details in the HACCP plan i.e. information or requirements on the recording template that does not match what is noted in the plan.
- More than one instance of recording forms lacking required details.

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

6.02.11: Have verification plans and schedules been developed for each CCP?
Total compliance (15 points): Verification activities related to each CCP on the HACCP plan should be clearly detailed and documented. Verification activities verify that the HACCP plan is being implemented

correctly, and might include microbial testing, customer complaints, equipment calibration, blade checks, visually observing a CCP operator, date checks of reagent expiration dates and any other information that CCPs might help generate. Verification activities also include a verification of the CCP monitoring records (6.03.05) 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 information might help improve and develop the HACCP program, but should show that the plan is being implemented correctly, is controlling the risk to an acceptable level (or eliminating the risk) and where this is not the case, this should be indicated on the verification paperwork along with corrective action details (e.g., reviewing a CCP, a process flow, a hazard analysis step, etc.). Where verification activities have found that CCPs were not performing as required, there should be records that show that this prompted a review of the relevant part of the HACCP Plan.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of errors or omissions in the verification details on the plan.

Major deficiency (5 points) if:
- Numerous instances of errors or omissions in the verification details on the plan
- Single instance in a plan with multiple CCPs where verification details have not been noted.

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

Execution of the HACCP Plan on the Plant Floor

6.03.01: Is there documented evidence that all plant workers have attended a HACCP training, including specific training for CCP operators?
Total compliance (10 points): All plant workers (excludes office personnel) 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 and be included in the training management program (see 1.01.04). Records of training should be kept and also certificates where relevant. All workers should be trained to understand the principles of HACCP and the plan implemented in the facility. Training should be scheduled on a regular basis and documented. The training should be tailored to the people and their positions within the company. HACCP team member training is scored under 6.01.02.

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

Major deficiency (3 points) if:
- One or more CCP operators has not been trained in their specific functions (but has received basic HACCP training).
- 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.

6.03.02: Do CCP operators understand basic HACCP principles and their role in monitoring CCPs?
Total compliance (10 points): CCP operators should understand basic HACCP principles, specifically CCPs in their areas and their responsibilities for taking appropriate action should the limits be exceeded.

This can be determined through casual worker interview, with the approval of the audit host. The visual part of this confirmation is matching what the CCP operator says versus what is written in the HACCP documentation and also what is written in the CCP monitoring logs.

Minor deficiency (7 points) if:
- One instance where the CCP operator(s) are lacking in basic knowledge about HACCP principles.
- One instance where the CCP operator(s) are not able to explain correctly, details about the CCPs they are monitoring e.g. what to do if the critical control limits are exceeded.

Major deficiency (3 points) if:
- More than one instance where the CCP operators are lacking in basic knowledge about HACCP principles.
- More than one instance where the CCP operators are not able explain correctly, details about the CCPs they are monitoring e.g. what to do if the critical control limits are exceeded.

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

6.03.03: Are the CCP monitoring activities and frequencies in compliance with the HACCP Plan and CCP SOPs?
Total compliance (15 points): CCP monitoring activities and frequencies are in compliance with what is written in the HACCP Plan and CCP SOPs. Check current logs against the HACCP plan. Auditor should carefully check the monitoring frequencies – allow some slight variations (minutes either way of the target frequency). The critical control limits should exactly match those mentioned on the HACCP plan. Note that if a monitoring test is done more frequently than stated, it is not necessarily a fault (i.e. point loss) if it is “in the spirit” of the plan. The records should show actual values or observations, be accurate and legible, be real-time recording and have adequate detail.

Minor deficiency (10 points) if:
- Single/isolated instance(s) where information or requirements on the records do not match what is noted in the HACCP plan.
- Single/isolated instance(s) of issues with how records are being filled out.

Major deficiency (5 points) if:
- Numerous instances where information or requirements on the records do not match what is noted in the HACCP plan.
- Numerous instances of issues with how records are being filled out.

Non-compliance (0 points) if:
- Fundamental failure to have information or requirements on the records matching what is noted in the HACCP plan.
- Records are consistently being filled out incorrectly.
- Single instance where a CCP has been created but monitoring data has not been recorded.

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

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

Major deficiency (5 points) if:
- Numerous instances of CCP record(s) not signed off by operator(s).

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

6.03.05: Are the CCP records reviewed and signed off by the quality control supervisor and/or management (second signatory)?
Total compliance (10 points): CCP records should be reviewed, dated and signed off by a trained, designated person within 36 hours of the original CCP monitoring activity occurring. Ideally records are reviewed prior to release of product to prevent potential recall and unintended consequences should a deviation be found during record review. Allowance may be made for operations that are not running daily (auditor discretion applies). The sign offs should be done by the quality control supervisor or manager (second signatory). This should be a separate signature to that of the CCP operator. The individual signing off should check the records (e.g. dates, production lines, monitoring results, frequencies, corrective actions, use of correct forms, etc.), since their signature is basically stating that everything is in order relative to the written HACCP plan and associated documents. If discrepancies are found during the record review corrective actions must be taken and documented (6.03.06).

Minor deficiency (7 points) if:
- Single/isolated instance(s) of CCP records not reviewed, dated and signed off within 36 hours by the quality control supervisor or manager (second signatory).
- Single/isolated instance(s) of the CCP records being signed off by the second signatory but there are issues with the records that have not been highlighted.

Major deficiency (3 points) if:
- Numerous instances of CCP records not reviewed, dated and signed off within 36 hours by the quality control supervisor or manager (second signatory).
- Numerous instances of the CCP records being signed off by the second signatory but there are issues with the records that have not been highlighted.

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

6.03.06: Is there a deviation record detailing documented corrective actions when a deviation/loss of control of a CCP occurs (a critical control limit is exceeded)?
Total compliance (15 points): Corrective actions should be detailed in writing when a deviation/loss of control of a CCP occurs as per procedure in 6.02.09. The CCP deviations should be noted on a deviation record (or similar form, as noted in the HACCP plan), should detail what has happened, what was done to correct the issue and any preventative actions taken to prevent reoccurrence. Records should indicate what happened to any affected product and also detail how the process was rectified. The corrective action details should match what is described in the HACCP plan.

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

Major deficiency (5 points) if:

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

Non-compliance (0 points) if:

- More than one instance of CCP critical control limit breach not being recorded and/or corrective actions not being recorded.
- Fundamental failure to properly record corrective action details or the details recorded in no way meet what is required by the HACCP plan.

Document Revision History		
Date	Rev.#	Description
2/18/21	0	Initial