

PrimusGFS Audit
Preventive Controls
(Module 7) Guidelines

Used in conjunction with the PrimusGFS v3.1 audit

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These guidelines help interpret/support the principles, requirements and expectations of the PrimusGFS v3.1 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 is a modified excerpt from the PrimusGFS General Regulations v3.1. 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 points	1 points
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 systematic deficiencies against the question and/or compliance criteria (severe or non-severe issues).
Not applicable	The requirement described in the question is not applicable for the operation being audited. Justification should be provided in the auditor's comments. Be aware that there are some questions that do not allow a non-applicable response.

Automatic Failure

There are some questions that if down scored will lead to an automatic failure and an overall score of 0% 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).

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 conformance for paperwork questions relating to monitoring and that the down score will be based on the amount of paperwork available**.

- **In short season operations that operate for less than three consecutive months throughout the year** - auditee should have at least three months of documentation (i.e. records of monitoring, training, meetings, etc.) available for review (this may include last season's documentation). Where an operation does not have three months of records available (e.g., they are in operation for one month out of the year), the auditee should have at least the previous season's records available for review. If the auditee has less than three months of 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).	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 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.

Module 7: Preventive Controls
Preliminary Steps

7.01.01: Is there a team responsible for the preventive control program at the operation, with a leader assigned, if applicable, for the development, implementation and on-going maintenance of the preventive control program?
Total compliance (10 points): There should be a formally identified group of people in charge of development and maintenance of the preventive control 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, consultants, trade association, universities, extension office, etc. One member of the team, should be designated the preventive control coordinator. Where a consultant has been designated the preventive control coordinator, it should be evident that they are present at all meetings and actively involved in the program. The preventive control team should meet at least quarterly (ideally monthly). If the company is too small (less than 20 people) to have a preventive control team, there should still be one individual designated as the preventive control coordinator. That individual is responsible for the implementation of the preventive control program along with any changes and updates to the preventive control 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 preventive control program.
- A large company, but only a single individual has been designated to develop the operational preventive control program.

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

7.01.02: Is there documented evidence that the preventive control team members have been trained on preventive control program development?
Total compliance (15 points): The preventive control coordinator should have a certificate of a formal Preventive Control Qualified Individual training from a recognized organization, institution or trainer. Management and preventive control team members should have thorough training (in-house or external) given by someone who has gone to a formal Preventive Control Qualified Individual training. Records of training should be kept and also certificates, where relevant.

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

Major deficiency (5 points) if:
- Preventive control coordinator has not completed a formal Preventive Control Qualified Individual training course.
- Numerous instances of omissions or incorrect data in the records.

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

7.01.03: 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, is it RTE, etc., by the consumer and reflect the label of the product (unit packed product). Product description(s) should define and indicate details regarding whether the item is perishable or long life, if there are any special storage requirements and any important food safety characteristics (e.g., pH, water activity). 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, 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.
- 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.

7.01.04: 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 preventive control plan. The flow chart should show each step of the process(es) under control of the operation (from receiving through to shipping), 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. All inputs should be included, 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. 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:
- Systematic 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.

7.01.05: Is there documented evidence that the flow chart(s) been verified on-site?
Total compliance (10 points): Flow diagrams should be verified on-site and signed and dated by the preventive control coordinator to confirm it reflects the process at different moments and there are no missing steps. Insufficient detail, missing steps, etc., will undermine the hazard analysis process. Any inaccuracies in the flow diagram should be scored in 7.01.04.

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 Preventive Controls Program

7.02.01: 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?
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. 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 food safety hazards that may be reasonably expected to occur in terms of specific biological, chemical (including radiological), physical, and economically motivated hazards, as well as the control measures for each. Preventive controls, such as process, allergens, sanitization, and supply chain should be identified for the identified hazards. 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.

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. 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.

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.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 systematic 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.

7.02.02: Have preventive control decisions been made with documented relevant validation justifications and where preventive control(s) are implemented in a specific processing step, have they been developed using plans and/or procedures to control the identified hazard(s)?
Total compliance (15 points): The preventive control decisions should be properly justified with supporting documents and evidence. The preventive controls defined in the hazard analysis should be developed to define, in detail, the parameters involved, and monitoring requirements to control the hazard(s). Types of preventive controls: process, allergen, sanitation, and supply chain.
The process preventive controls should be created from the documented hazard analysis i.e. there should be a logical documented approach (such as utilizing a decision tree) showing why the process was deemed a preventive control or not.

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

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

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

7.02.03: Have processing steps that are deemed preventive controls been identified i.e. steps that significantly minimize or prevent food safety hazards? Informational gathering. If answer is YES, continue with next question. If answer is NO, the rest of "Module 7 Preventive Controls" is not applicable.
Total points (0). The identification of preventive controls in the process requires development of the criteria with adequate detail, defined parameters and the execution of the necessary activities in the production line. Types of preventive controls: process, allergen, sanitation and supply-chain. If preventive controls have been identified, the rest of this module should be completed. The preventive controls should be created from the documented hazard analysis, i.e. there should be a logical documented approach showing why the process was deemed a preventive control or not. Preventive controls 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 preventive control 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 preventive controls (and the auditor is in agreement), no further preventive control program development is required, and the rest of the module is not applicable.
For facility operations, the organization will determine the need for a preventive control 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 preventive control program,

even if no preventive controls are identified, then the auditor will complete the preventive controls module of this audit as a verification of the preventive control 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

7.02.04: Do the process preventive controls have critical limits, and other preventive controls have parameters Do the process preventive controls have critical limits, supported by relevant validation documentation, and other preventive controls have parameters, values and targets (where relevant) supported by relevant validation documentation?
Total confirmation (15 points): Process preventive controls should have critical limit parameters (which are supported by validation documentation), showing that the parameters are scientifically derived and meet any relevant legal requirements. Critical limits (CL'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 the size/type of test pieces used, or with an anti-microbial, the minimum concentration required should be stated. Other CLs may include temperature parameters, pH, flow rates, dwell times, etc.

All preventive controls should be supported by validation documentation showing that the critical limits (CL) 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, 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 CL validation details.

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

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

7.02.05: Have monitoring requirements and frequencies been determined and documented for the preventive controls?
Total compliance (15 points): There should be determined and documented monitoring requirements and frequencies for the preventive controls. The plans/charts and/or procedures should document the monitoring requirements including detailing the actions necessary (observations or measurements) to ensure whether a preventive control is under control. Where monitoring is not continuous, the type and frequency of monitoring should be sufficient to ensure the preventive control is under control. Frequency should be specified; "as needed" is not accepted as a stated frequency. Monitoring activities will vary between preventive control types. The requirements i.e. what is to be done, should be specified on the preventive control program.

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 preventive control (where there are multiple preventive controls) is lacking monitoring requirements or frequency details.

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

7.02.06: Are there documents that show validation work for the process preventive controls and was this validation work performed by or overseen by a Preventive Control Qualified Individual?
Total compliance (10 points): Process preventive controls should have documented validation work performed or overseen by a qualified individual. The validation work could include peer reviewed scientific literature, legislative documentation, trade association guidance, in-plant observations and testing, etc. Where useful and relevant, other preventive controls types e.g. sanitation preventive controls should be supported by validation work dated within 90 days of starting production.

Minor deficiency (7 points) if:
- Single/isolated instance(s) of an omission in the validation work.

Major deficiency (3 points) if:
- Numerous instances of an omission in the validation work.
- Validation work was not overseen by a Preventive Control Qualified Individual.

Non-compliance (0 points) if:
- No validation work has been performed.

7.02.07: Do the preventive control plans, charts and/or procedures indicate that specific responsibilities have been assigned for the monitoring, recording and corrective action implementation?
Total compliance (10 points). Specific responsibilities should be assigned for the monitoring, recording and corrective action implementation of each preventive control to ensure compliance.

Minor deficiency (7 points) if:
- Single/isolated instance of a responsibility not being assigned.

Major deficiency (3 points) if:
- Numerous instances of a responsibility not being assigned.

Non-compliance (0 points) if:
- No responsibilities have been assigned.
- Systematic failure to assign responsibilities.

7.02.08: Have standard operating procedures (SOPs) been created for the monitoring process(es) of the preventive controls, including those in plan or chart format (e.g., process preventive controls)?
Total compliance (5 points): Clear and simple standard operating instructions (SOPs) should be written for each preventive control monitoring process(es). These SOPs should expand the preventive control monitoring activities in detail in the form of work instructions, and match what is written in the preventive control 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 preventive control SOPs.

Major deficiency (1 point) if:
- Numerous instances of errors and omissions within the preventive control SOPs.
- Single instance of a preventive control SOP not being created in a system where there are multiple preventive controls.

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

7.02.09: Have corrective action procedures been established for the preventive controls, including a detailed action plan for operators to follow if out of specification situations are observed (loss of control/deviation) and plans to adjust the process back into control?
Total compliance (15 points): There should be a documented, detailed plan with procedures to follow when there is a loss of control (deviation) of a preventive control. The procedures should include details regarding how to handle affected products (if necessary). The corrective action details should note the critical 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 preventive control 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 preventive control 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 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.
- Systematic errors in corrective action plan details.

7.02.10: Have recording templates (recording forms) been developed for monitoring the preventive controls?
Total compliance (15 points): Monitoring record templates should be designed to record the monitoring of preventive controls that have been identified. The records should match the details as noted in the preventive control plan and have preventive controls identified by name and number, what is being measured, the frequency of the measurement, the critical limit, the operating limit, the responsible person(s) or team and the corrective action(s) required in the case of measurements not in compliance. Monitoring recording requirements vary depending on preventive control type. Recording forms should have a specific document code as part of the document control program (1.02.01). The records ideally show the preventive control parameters (not a scoring issue).

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 preventive control plan i.e. information or requirements on the recording template that does not match what is noted in the plan.

Major deficiency (5 points) if:
- Numerous instances of a record(s) having been developed but do not match the details in the preventive control 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 preventive control plan i.e. information or requirements on the recording template that does not match what is noted in the plan.
- Single instance where a preventive control has been created but a record for the monitoring data has not been developed.

7.02.11: Have verification procedures and schedules been developed for the preventive controls?
Total compliance (10 points): Verification activities related to each preventive control in the preventive control program should be clearly detailed and documented. Examples of verification include preventive control monitoring and corrective action record reviews, testing associated with preventive controls, equipment inspection associated with preventive controls, 2nd and 3rd party supplier audits, testing related to raw materials, internal audits, equipment calibration and accuracy, etc. Verification activities should include a verification of the preventive control monitoring records by a Preventive Control Qualified Individual trained supervisor or manager, checking that the monitoring records have been completed in a proper and timely manner and including any corrective action work. Note, a worker cannot verify their own work. Verification information might help improve and develop the preventive control 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 preventive control, a process flow, a hazard analysis step, etc.). Where verification activities have found that preventive controls were not performing as required, there should be records that show that this prompted a review of the relevant part of the preventive control program.

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

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

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

7.02.12: Are the preventive controls (as part of the Food Safety Plan re-analysis) reviewed when operational changes are made (facility, process, equipment, ingredients, packaging etc.) and at least once every 3 years?
Total compliance (10 points). The preventive controls should be reviewed by the preventive controls team when operational changes are made and at least every 3 years, including the product descriptions, process flows, hazard analyses, preventive control decisions, preventive control recording and worker training, to ensure that the program is up to date and working properly. Where emerging issues, such as recalls, an outbreak, new research, etc., are relevant to the products and processes at hand, consideration of a preventive controls 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 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 preventive controls team should inform workers involved of the review outcomes.

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

Major deficiency (3 points) if:
- Numerous instances of omissions in the review.
- A review was performed within more than three but less than four years.
- A review did not take place after an emerging issue took place with a similar crop in the industry.

Non-compliance (0 points) if:
- No review has occurred.

7.02.13: Is there documented evidence that all plant workers have attended a preventive control training, including training for workers directly involved with preventive controls?
Total compliance (10 points): All site workers should receive basic preventive control overview training i.e. what are preventive controls, and what are the preventive controls on site. Basic training might form part of the new hire orientation package. Workers should be specially trained for their function(s) and include the operations they are responsible for. Senior management should also receive training (preventive controls 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 preventive controls 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 preventive controls (but all key operators and majority of workers have been trained).
- Senior management has not received preventive control training.
- Single/isolated instance(s) of omissions or incorrect data in the records.

Major deficiency (3 points) if:
- Workers 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 Preventive Controls Program

7.03.01: Do all of the documents noted in the preventive control plan accurately reflect plan requirements for the preventive controls?
Total compliance (15 points): All documents noted in the preventive control plans, charts, and procedures should be in place for preventive controls (where relevant), for example process preventive controls. Records should reflect the plan requirements. Check current logs against the preventive control 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 if the forms were revised, are the revised forms being used by the workers. Usually this is monitoring logs, but if logs are mentioned in the verification section of the CCPs, these should also 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 preventive control log in place, but the “version” of the log in use is different from that in the preventive control plan i.e. the details are different or there are omissions.
- Single instance of a document that does not accurately reflect plan requirements.

Major deficiency (5 points) if:
- Numerous instances of preventive control logs in place, but the “versions” of the logs in use are different from those in the preventive control plan i.e. the details are different or there are omissions.
- Numerous instances of a document that does not accurately reflect plan requirements.

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

7.03.02: Are the preventive control monitoring activities and frequencies in compliance with the preventive control plans, charts, and procedures?
Total compliance (15 points): Preventive control monitoring activities and frequencies are in compliance with what is written in the preventive control plans, charts, and procedures. Check current logs against the preventive control program. Auditor should carefully check the monitoring frequencies – allow some slight variations (minutes either way of the target frequency). The critical limits should exactly match those mentioned on the preventive control program. 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 records does not match what is noted in the preventive control program.

Major deficiency (5 points) if:
- Numerous instances where information or requirements on the records does not match what is noted in the preventive control program.

Non-compliance (0 points) if:
- Systematic failure to have information or requirements on the records matching what is noted in the preventive control program.
- Single instance where a preventive control has been created but monitoring data has not been recorded.

7.03.03: Do workers directly involved with preventive control operations understand basic preventive control principles and their role in monitoring preventive controls?
Total compliance (10 points): Individuals should understand the basics of a preventive control program and how it applies to their operations. Individuals should have a good understanding of the details of the preventive controls that they are directly involved with, including procedures, critical limits in the case of process preventive controls and corrective action procedures. 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 worker says versus what is written in the preventive control documentation and the preventive control monitoring logs.

Minor deficiency (7 points) if:
- Single/isolated instance(s) where the workers are lacking in basic knowledge about preventive controls.
- Single/isolated instance(s) where the workers are not able to explain correctly, details about the preventive controls they are monitoring e.g. what to do if the critical limits are exceeded.

Major deficiency (3 points) if:
- Numerous instances where the workers are lacking in basic knowledge about preventive controls.
- Numerous instances where the workers are not able to explain correctly, details about the preventive controls they are monitoring e.g. what to do if the critical limits are exceeded.

Non-compliance (0 points) if:
- Systematic failure of the interviewed worker to show basic knowledge about preventive controls.

- Systematic failure of the interviewed workers to be able to explain correctly, details about the preventive controls they are monitoring e.g. what to do if the critical limits are exceeded.

7.03.04: Are preventive control associated records signed off (or initialed) by the workers who are carrying out and recording the preventive control activities?
Total compliance (15 points): All preventive control 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 preventive control record(s) not signed off by operator(s).

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

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

7.03.05: Is there a deviation record detailing documented corrective actions when a deviation or deficiency of a preventive control occurs?
Total compliance (15 points): Corrective actions should be detailed in writing when a deviation or deficiency occurs against a preventive control. The preventive control deviations should be noted on a deviation record (or similar form, as noted in the preventive control program), 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 preventive control program.

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 preventive control program.

Major deficiency (5 points) if:
- Single instance of preventive control critical 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 preventive control program.

Non-compliance (0 points) if:
- More than one instance of preventive control critical 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 preventive control program.

7.03.06: Are the records associated with preventive controls reviewed and signed off by the quality control supervisor and/or management (second signatory)?
Total compliance (10 points): Preventive control records should be reviewed and signed off by the designated person(s) responsible (i.e. qualified individual for preventive controls) within 7 calendar days of the original preventive control monitoring activity occurring. 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 preventive control 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 preventive control program 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 preventive control records not reviewed and signed off within 7 days by the quality control supervisor or manager (second signatory).
- Single/isolated instance(s) of the preventive control records being signed off by the second signatory

Major deficiency (3 points) if:

- Numerous instances of preventive control records not reviewed and signed off within 7 days by the quality control supervisor or manager (second signatory).
- Numerous instances of the preventive control 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 preventive control records to be reviewed and signed off.
- Systematic errors on the preventive control records that are being signed off by the second signatory.