Primus Standard Audits
Preventive Controls Guidelines

Used in conjunction with the Primus Standard Audits v20.06

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These guidelines help interpret/support the principles, requirements, and expectations of the Primus Standard Audits v20.06, 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 Systems. Furthermore, Azzule Systems accepts no liability for the content of these links.

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

Audit Execution

The audit should be performed using the most recent version of the Primus Standard Audits normative documents.

The Primus Standard Audits Scheme is divided into different audit types. The Guidelines for the facility audits include applicability charts to help determine which questions apply in each audit type.

- **Farm:** A tract of land (not necessarily a "lot" for production purposes), under common management and common water supply, ideally contiguous (if not contiguous, similar risk is demonstrated) and used for agricultural production.
- **Indoor Agriculture:** Where crops are grown in a controlled environment in a temporary or permanent enclosed structure. This does not include shade or hoop houses.
- **Harvest Crew:** A designated group of workers under common supervision, harvesting the same product.
- **Storage & Distribution:** A facility that is only receiving and storing finished goods for further shipment e.g. regional distribution warehouses. Goods may be stored at controlled or ambient temperatures.
- **Cooling and Cold Storage (with or w/out HACCP):** A facility that is receiving and storing finished goods and performing some kind of pre-cooling and/or cooling activities. In this type of facility, no packing or processing activities are being performed.
- **Packinghouse (with or w/out HACCP):** A facility where commodities are sorted and/or sized, may be minimally trimmed (not altered in form), washed or not washed, may have post-harvest treatments

applied (e.g. fungicide, wax, sprout inhibitor) and packed for commercial distribution and use by consumer or retail establishment.

- **Processing with HACCP:** Washing, slicing, dicing, cutting, shredding, peeling, grading, pasteurization, cooking, chilling, juicing, pressing, freezing, packing in modified atmosphere, packed in vacuum packing or any other activity that significantly transforms the product from its original whole state.

Each audit type is divided into sections, related to specific topics. Please note that there may be some generic questions in all audit types that contain descriptions for both GAP and GMP audit types. For those questions and guidance criteria, you should only focus on the type of audit being conducted.

Depending on commodity specific requirements, buyer requirements, and circumstances at the operation, there are optional addendums which may be added on to the audit.

Audit Template Structures

- *Food Safety Management System* - Covers food safety systems
- *GAP and/or GMP Section* - Covers the physical tour of the operation and documentation
- *HACCP* - Covers the HACCP program
- *Preventive Controls* - Covers the Preventive Controls program
- *Additional Questions* - These questions are not part of the overall score of the audit. Please note that these questions will help assess the auditee's readiness to achieve certification against a GFSI recognized scheme.

Scoring System

For each question, 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 are listed in the following table:

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%. The report will include a breakdown of the scores for each section, even if an automatic failure occurs. 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

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 Circumstances 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, threatening behavior towards an auditor, 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. 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.

Change of Audit Service

Once an audit has been started it cannot be converted into a pre-assessment audit. This includes when an automatic failure question has been scored down, as noted above. Vice versa, a pre-assessment audit cannot be converted into a standard audit once the service has begun. The only time a standard audit can be optionally turned into a pre-assessment audit is when the operation is found not to be running on the day of the audit, which can result in the cancellation of the audit (with charges) or the audit can be turned into a pre-assessment (see texts below).

At the opening meeting, an auditor may suggest that the wrong audit template has been chosen and recommend an optimal template for the auditee operation. For example, if a Packinghouse with HACCP Audit is booked but the auditor learns that processed ready-to-eat baby leaf spinach production is occurring on a weekly basis, the auditor will recommend switching to a Processing with HACCP Audit template, if the processing is occurring the day of the audit. If the auditee decides not to use the optimum template that the auditor/Certification Body recommends, the auditor will indicate in the audit scope which processes were not covered by the audit. In the example, this would be “audited packinghouse operation, but did not audit the processed leafy greens operation”. If an auditee does decide to change service requirements, then the auditor will inform the Certification Body as soon as possible.

Audit Agenda

Audit agendas vary, but the normal pattern of events is as follows:

- **Opening Meeting.** Confirm the appointment details, introduce the auditor(s) and auditee team, confirm scope and the day’s agenda.
- **Tour of Operations**. Areas toured depend on the type of operation. A GMP operation might include raw material storage areas, production, finished goods storage, personnel facilities, maintenance, chemical storage, packaging storage and external areas (e.g., where the dumpsters are located). A GAP operation might include the harvest process, chemical storage, growing areas, portable toilets, and greenhouse. The auditor might also interview some workers.
- **Food Safety File Requirements (paperwork section).** Paperwork (documents and records) is reviewed. Please note that the auditor cannot accept documentary evidence after the audit has ended. For example, if a pest control document is missing at the time of the audit and the auditee tries to fax it the next day, it cannot be used to alter the score.
- **HACCP and/or Preventive Controls Section (if relevant)**. The auditor might look at the HACCP and/or PC files in the opening meeting in order to orientate themselves about the site program and CCPs/PCs. Auditor will interview CCP/PC operators.
- **Additional Questions**. Might be covered at any point in the audit, as the topics arise.

- **Auditor "Quiet" Time.** Time required for the auditor to organize notes before delivering the closing meeting.

- **Closing Meeting**. Discuss all findings with the auditee team. Auditors are not able to provide either a final score or pass/fail commentary at the end of the audit due to the high number of questions that are asked in the template and the scoring system that is applied. However, auditors do submit audit reports quickly and auditees should contact the Certification Body if reports have not been received electronically two weeks after the audit has occurred (at the latest).

Documentation Requirements

Operation's Food Safety Systems:

When an operation is 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 Primus Standard Audits 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 Primus Standard Auditees/First-Time Primus Standard 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 Primus Standard 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 Primus Standard 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 Primus Standard 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.

Preventive Controls

Preliminary Steps

1.1.1: Is there a team responsible for the preventive control program at the operation, with a leader assigned, 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 (a preventive control qualified individual), who has successfully completed recognized training in the development and application of risk-based preventive controls training (or is otherwise qualified) should be designated the preventive control coordinator (leader). 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 preventive control qualified 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.
- 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 preventive control program.
- A large company, but only a single individual has been designated to develop the operational preventive control program.
- Two or less meetings have occurred in the last 12 months (for an all year-round operation).

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 (leader).

1.1.2: 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 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.

1.1.3: 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, 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. Product description(s) should define the potential risk associated with the product, materials used and also who the intended consumers 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.
https://www.ifsh.iit.edu/fspca/fspca-materials

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.

1.1.4: 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 final product storage and shipping), so that the hazard analysis can be completed properly. 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).
https://www.ifsh.iit.edu/fspca/fspca-materials
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.

1.1.5: Is there documented evidence that the flow chart(s) has 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 preventive control 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 preventive controls in place. The flow chart(s) is signed and dated by the preventive control 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 (1.2.1). Any inaccuracies in the flow diagram should be scored in 1.1.4.

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

1.2.1: Has a documented hazard analysis for each product 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 potential food safety hazards and determines the hazards requiring a preventive control because they are reasonably likely to cause illness or injury in the absence of control. There should be a detailed, documented hazard analysis for each product group (including ingredients) process flow in order to prove that a proper hazard analysis was conducted. Note, similar products (e.g. similar in formulation, have similar processing steps and are prepared and packaged in a similar manner) may be grouped. 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), 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. 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.

The hazard identification process should consider preliminary information collected while developing the product description, condition, function and design of facility and equipment, likelihood of hazards being present in the finished product, external information (scientific papers, epidemiological studies, historical data for similar products, etc.), information from applicable government or industry food safety guidance documents. 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), more than one hazard may be controlled by a specified control measure and not all potential hazards require a preventive control. 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.
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm
https://www.ifsh.iit.edu/fspca/fspca-materials

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.

1.2.2: Where risk-based preventive controls are identified have they been developed using plans and/or procedures to control identified hazard(s) are they appropriate and consistent with current scientific understanding?
Total compliance (15 points): 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). Preventive controls may include process preventive controls, food allergen preventive controls, sanitation preventive controls, and supply chain program as well as other preventive controls.
The 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.

1.2.3: Is the preventive control program (as part of the Preventive Control Plan re-analysis) reviewed when significant changes are made (raw materials, packaging, suppliers, product, process, construction, recurring deviations, new scientific information, etc.) and at least once every 3 years?

Total compliance (10 points). The preventive controls should be reviewed by the preventive controls team when significant changes are made e.g. raw materials, packaging, suppliers, product, process, construction, new equipment, recurring deviations, new scientific information, new distribution or consumer handling practices, etc., including the hazard analysis, to ensure that the program is up to date and working properly. Re-analysis should occur at a frequency that ensures the preventive control plan is being followed continuously and at least every 3 years. 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 including the product descriptions, process flows, hazard analyses, preventive control decisions, preventive control recording, customer complaints, equipment calibration, record review, trend analysis data 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 a significant change.
- A review did not take place after an emerging issue took place with a similar product in the industry.
- No record of workers involved being informed of preventive control review outcomes.

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

1.2.4: Do the process preventive controls have critical limits supported by relevant validation documentation, and do other preventive controls have parameters, values and targets (where relevant)?

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, 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 process 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, 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.
Other non-process preventive controls do not control a specific processing action, and how a facility manages their system and its complexity will determine whether they are considered preventive controls or pre-requisite programs. Some examples include segregation of allergenic materials and effective cleaning as essential elements of an allergen management program; personnel practices and hygienic zoning as sanitation controls; using approved suppliers. Validation of non-process preventive controls is not required; however it may be considered under certain circumstances e.g. when major changes are made to a product or process.

Minor deficiency (10 points) if:
- Single/isolated instance(s) of omissions or incorrect CL validation details for process preventive controls.
- Single/isolated instance(s) of errors or omissions in non-process preventive control details.

Major deficiency (5 points) if:
- Numerous instances of omissions or incorrect CL validation details for process preventive controls.
- Numerous instances of errors or omissions in non-process preventive control details.

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

1.2.5: 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. Monitoring applies not only to process preventive controls but also to allergen, sanitation and supply chain preventive controls as appropriate to the food safety program. 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.

1.2.6: 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): Validation is applying scientific concepts and demonstrating that following the plan will control the identified hazards. 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. Validation is required for most process controls when hazards requiring a preventive control are identified. Validation is ideally done before the plan is implemented. Where relevant, other preventive controls types e.g. sanitation-related preventive controls (e.g. how long processing line can run between cleaning, allergen controls) should be supported by validation work and all 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.
- Validation was not done within the first 90 calendar days of production, there is appropriate justification from PCQI for a longer timeframe

Non-compliance (0 points) if:

- Validation was not done within the first 90 calendar days of production, there is no appropriate justification.
- No validation work has been performed.
- Changes in the process or product that may impact the effectiveness of the product has not resulted in a revalidation.

1.2.7: 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. If preventive control records are not being completed properly, this may be an indication that the tasks have not been assigned correctly. The responsibility should be clearly indicated on the preventive control 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 preventive control. All records and documents associated with monitoring preventive controls should be signed by the person(s) doing the monitoring, either physically or electronically.

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.

1.2.8: 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 (10 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 (7 points) if:
- Single/isolated instance(s) of errors and omissions within the preventive control SOPs.

Major deficiency (3 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.

1.2.9: 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): Corrective actions are procedures that must be taken if preventive 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 procedures to follow when there is a loss of control (deviation) of a preventive control appropriate to the nature of the hazard and preventive control. The procedures should include details regarding how to handle affected products (if necessary). Requirements vary for process, food allergen, sanitation and supply chain program preventive controls. For example, many sanitation preventive control deviations can be effectively managed through use of corrections (action is taken in a timely manner to identify and correct a minor problem that does not directly impact product safety) such as identifying a food contact surface that was not properly cleaned and re-cleaning it prior to production. The corrective action details for a process preventive control 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 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 process preventive control has been brought under control and require that a review is conducted in order to prevent a recurrence of the situation. Corrective actions may include reanalyzing the preventive control plan (1.2.3) to determine whether modifications are required.

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.

1.2.10: 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 and operating limit (if applicable) for process preventive controls, 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.

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.
- 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 preventive control 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:
- 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.

1.2.11: Have verification procedures and schedules been developed for the preventive controls?
Total compliance (15 points): Verification is an important component of supply-chain, sanitation, allergen and process preventive controls. Routine verification is an ongoing process after monitoring to provide evidence that the plan is being properly implemented and operating as intended. 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 (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 preventive controls where verification details have not been noted.

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

1.2.12: 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:
- One or more key operators have not been trained.
- 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

1.3.1: 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. Electronic records should be checked to ensure that the correct version is being used. Document control issues specific to the preventive control plan are scored here.

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.

1.3.2: 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. 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 does not match what is noted in the preventive control program.
- 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 does not match what is noted in the preventive control program.
- Numerous instances of issues with how records are being filled out.

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

1.3.3: 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, parameters, 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:
- One instance where the workers are lacking in basic knowledge about preventive controls.
- One instance 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:
- More than one instance where the workers are lacking in basic knowledge about preventive controls.
- More than one instance 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.

1.3.4: 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.

1.3.5: 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. This may include root cause analysis. 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 written procedure (1.2.9).

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 written procedure.

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 written procedure.

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 written procedure.

1.3.6: Are the records associated with preventive controls reviewed and signed off by a preventive controls qualified individual or trained designate (second signatory)?
Total compliance (10 points): Preventive control records should be reviewed, dated and signed off by the designated person(s) responsible i.e. preventive controls qualified individual-PCQI or trained designate within 7 working days of the original preventive control 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. The sign offs should be done by a PCQI or trained designate

e.g. 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 during the record review corrective actions must be taken and documented (1.3.5).

Minor deficiency (7 points) if:

- Single/isolated instance(s) of preventive control records not reviewed, dated and signed off within 7 working days by a PCQI or trained designate.

Major deficiency (3 points) if:

- Numerous instances of preventive control records not reviewed, dated and signed off within 7 working days by a PCQI or trained designate.

Non-compliance (0 points) if:

- Systematic failure for preventive control records to be reviewed, dated and signed off as required.