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## General Description of Changes to Module 7

1. Changes to question numbers
2. Expanded expectations

**PrimusGFS v3.2 Summary of Changes**

| Section | Q # | v3.1 Question | v3.1 Expectations | v3.1 Interpretation Guideline | New # | v3.2 Question | v3.2 Expectation | v3.2 Interpretation Guideline |
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| 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? | There should be a documented list of the team carrying out the preventive control program in the operation, with one leader or coordinator assigned as responsible. The team should be multidisciplinary and may include people from production, quality, sanitation, maintenance, shipping, procurement, sales, external consultants, etc. The size of the team will depend on the size of the operation and the processes performed. | 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.<br><br>Minor deficiency (7 points) if:<br>• Team has been put together but lacks key representation e.g. maintenance.<br>Major deficiency (3 points) if:<br>• The team or individual is assigned but does not meet regularly to review the preventive control program.<br>• A large company, but only a single individual has been designated to develop the operational preventive control program.<br>Non-compliance (0 points) if:<br>• The preventive control team or the individual assigned to manage the preventive control program has not kept the program updated.<br>• There is no preventive control team or preventive control coordinator. | | No change in v3.2 | There should be a documented list of the team carrying out the preventive control program in the operation, with 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) designated the preventive control coordinator (leader). The team should be multidisciplinary and include people from production, quality, sanitation, maintenance, shipping, procurement, sales, external consultants, etc. The size of the team will depend on the size of the operation and the processes performed. | 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. The group should be multidisciplinary and include 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.<br><br>Minor deficiency (7 points) if:<br>• Team has been put together but lacks key representation e.g. senior management, maintenance, sanitation.<br>• Only three meetings have occurred in the last 12 months (for an all year-round operation)<br>Major deficiency (3 points) if:<br>• The team or individual is assigned but does not meet regularly to review the preventive control program.<br>• A large company, but only a single individual has been designated to develop the operational preventive control program.<br>• Two or less meetings have occurred in the last 12 months (for an all year-round operation).<br>Non-compliance (0 points) if:<br>• The preventive control team or the individual assigned to manage the preventive control program has not kept the program updated.<br>• There is no preventive control team or preventive control coordinator (leader). |
| Preliminary steps | 7.01.02 | Is there documented evidence that the preventive control team members have been trained on preventive control program development? | At least one member of the preventive control team should have a formal Preventive Control Qualified Individual training.The rest of the team should have at least an internal training to make sure they are knowledgeable of the preventive control program development. These trainings should be documented. | Minor deficiency (10 points) if:<br>• 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).<br>• Management has not received preventive control training.<br>• Single/isolated instance(s) of omissions or incorrect data in the records.<br>Major deficiency (5 points) if:<br>• Preventive control coordinator has not completed a formal Preventive Control Qualified Individual training course.<br>• Numerous instances of omissions or incorrect data in the records.<br>Non-compliance (0 points) if:<br>• No formal training records for preventive control team members. | | No change in v3.2 | The preventive control coordinator should have a certificate of a formal Preventive Control Qualified Individual training from a recognized organization, institution or trainer. The rest of the team should have at least an internal training given by someone who has gone to a formal Preventive Control Qualified Individual training to make sure they are knowledgeable of the preventive control program development. These trainings should be documented. | Minor deficiency (10 points) if:<br>• Not all preventive control team members are trained in preventive control principles (but majority of preventive control team members have been trained).<br>• Management team members have not received preventive control training.<br>• Single/isolated instance(s) of omissions or incorrect data in the records.<br>Major deficiency (5 points) if:<br>• Preventive control coordinator has not completed a formal Preventive Control Qualified Individual training course.<br>• Numerous instances of omissions or incorrect data in the records.<br>Non-compliance (0 points) if:<br>• No formal training records for preventive control team members. |
| Preliminary steps | 7.01.03 | Does a product description exist for the products produced? | The description should detail the products' composition (ingredients), packaging used, storage conditions, distribution requirements, important food safety characteristics (if any) (e.g., pH, water activity), label instructions, the intended use, statement on whether the product is RTE and who the intended consumer is. | Total compliance (10 points): Product description(s) should clearly indicate the item(s) intended use i.e. does it need washing, peeling, cooking prior to consumption, 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. | | No change in v3.2 | 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 detail the products' name and composition (ingredients), packaging used, storage conditions, shelf life, distribution requirements, important food safety characteristics (if any) (e.g., pH, water activity), label instructions, the intended use, statement on whether the product is RTE and who the intended consumer is. | 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 customers are (general public, restricted to certain sectors, e.g. people not suffering from a certain allergy, diabetic issues, other at-risk groups, etc.). The product description can be generic if the products and processes are similar. Where the products and/or processes are not similar to each other, specific product descriptions are required. |
| Preliminary steps | 7.01.04 | Has the process(es) been flow charted in sufficient detail to completely describe the process or product handling/processing steps? | The information (from receiving through to shipping) on the flow diagram is used to evaluate whether or not hazards exist associated with each step of the process. Groups of similar products going through the same process can be grouped in the same flow chart. Diagram should show rework processes and when product is diverted to be used for other purposes. Process flows can be augmented by written process descriptions (where helpful). | 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). | | No change in v3.2 | The information (from receiving through to shipping) on the flow diagram is used to evaluate whether or not hazards exist associated with each step of the process. Groups of similar products (including ingredients) going through the same process can be grouped in the same flow chart. 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. Diagram should show rework processes and when product is diverted to be used for other purposes. Process flows can be augmented by written process descriptions (where helpful). | 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). |
| Preliminary steps | 7.01.05 | Is there documented evidence that the flow chart(s) been verified on-site? | The diagram(s) should be verified on-site and signed and dated by the preventive control team coordinator to confirm it reflects the conditions of the process at different moments and there are no missing steps. | 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. | | Is there documented evidence that the flow chart(s) has been verified on-site? | The diagram(s) should be verified on-site and signed and dated by the preventive control team coordinator to confirm it reflects the conditions of the process at different moments in time (auditor should confirm how and when flow chart(s) were verified) and there are no missing steps. | Total compliance (10 points): The steps in the flow chart are used to organize the hazard analysis. Flow diagrams should be verified on-site by the food safety team and the team should make any changes required to the flow diagram. Any significant changes to the process must be accurately reflected in the flow diagram and evaluated to determine if the changes have an impact on the hazard analysis and 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 (7.02.01). Any inaccuracies in the flow diagram should be scored in 7.01.04. |

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| 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? | The hazard analysis is required to identify biological, chemical (including radiological), physical, and economically motivated hazards for food safety at each stage of the production process. The analyses must evaluate if the risk requires a preventive control and evaluate the severity and likelihood of occurrence in the absence of control. All decisions must be justified in a documented manner. Preventive controls, such as process, allergens, sanitization, and supply chain should be identified for the identified hazards. The hazard analysis document(s) should show the control measures. Each step identified in the process flow diagram should be assessed in the hazard analysis. The hazard analysis should be reviewed when changes occur affecting the product description and/or the process flow. | 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.<br><br>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. | | 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? | 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. Similar products (e.g. similar in formulation, have similar processing steps and are prepared and packaged in a similar manner) may be grouped. 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. Preventive controls, such as process, allergens, sanitization, and supply chain should be identified for the identified hazards. | 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.<br>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. |
| Development of the Preventive Controls Program | 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)? | The preventive control decisions should be created from the documented hazard analyses, i.e. there should be a logical documented approach showing why the process was deemed a preventive control or not. 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 plans/charts and procedures involved, including monitoring requirements, thresholds, corrective actions and verification parameters in order to control the hazard. | 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.<br>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. | | 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? | Preventive control decisions should be properly justified with supporting documents and evidence. Preventive controls may include process preventive controls, food allergen preventive controls, sanitation preventive controls, and supply chain program as well as other preventive controls. Preventive control decisions should be created from the documented hazard analyses, i.e. there should be a logical documented approach showing why the process was deemed a preventive control or not. The preventive controls defined in the hazard analysis should be developed to define in detail the parameters involved and monitoring requirements, thresholds, corrective actions and verification requirements in order to control the hazard(s). | 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. |
| Development of the Preventive Controls Program | 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 the answer is YES, continue with the next question. If the answer is NO, the rest of "Module 7 Preventive Controls" is not applicable. | | | | Question removed | | |
| Development of the Preventive Controls Program | 7.02.04 | 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? | 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. 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. Ideally, other preventive control types (e.g., sanitation controls) should have validation documentation (where useful). | 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.<br><br>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.<br><br>Minor deficiency (10 points) if:<br>• Single/isolated instance(s) of omissions or incorrect CL validation details.<br>Major deficiency (5 points) if:<br>• Numerous instances of omissions or incorrect CL validation details.<br>Non-compliance (0 points) if:<br>• There is no documentation to support preventive control critical limits.<br>• Systematic omissions or incorrect CL validation details. | | 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)? | 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. 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. 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. 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. | 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.<br>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.<br>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.<br><br>Minor deficiency (10 points) if:<br>• Single/isolated instance(s) of omissions or incorrect CL validation details for process preventive controls.<br>• Single/isolated instance(s) of errors or omissions in non-process preventive control details.<br>Major deficiency (5 points) if:<br>• Numerous instances of omissions or incorrect CL validation details for process preventive controls.<br>• Numerous instances of errors or omissions in non-process preventive control details.<br>Non-compliance (0 points) if:<br>• There is no documentation to support preventive control critical limits for process preventive controls.<br>• Systematic omissions or incorrect CL validation details for process preventive controls.<br>• There is no documentation to support non-process preventive controls decisions. |
| Development of the Preventive Controls Program | 7.02.05 | Have monitoring requirements and frequencies been determined and documented 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. The plans and/or procedures should note the frequencies of monitoring for each preventive control. Monitoring activities will vary between preventive control types. | 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. | | No change in v3.2 | 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 and/or procedures should note the frequencies of monitoring for each preventive control. Monitoring activities will vary between preventive control types. | 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. |

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| Development of the Preventive Controls Program | 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? | Process preventive controls should document~~ed~~ 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 support by validation work dated within 90 days of starting production. | 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.<br><br>Minor deficiency (7 points) if:<br>• Single/isolated instance(s) of an omission in the validation work.<br>Major deficiency (3 points) if:<br>• Numerous instances of an omission in the validation work.<br>• Validation work was not overseen by a Preventive Control Qualified Individual.<br>Non-compliance (0 points) if:<br>• No validation work has been performed. | | No change in v3.2 | Validation is applying scientific concepts and demonstrating that following the plan will control the identified hazards. Process preventive controls should document validation work performed or overseen by a qualified individual. 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. | 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.<br><br>Minor deficiency (7 points) if:<br>• Single/isolated instance(s) of an omission in the validation work.<br>Major deficiency (3 points) if:<br>• Numerous instances of an omission in the validation work.<br>• Validation work was not overseen by a Preventive Control Qualified Individual.<br>• Validation was not done within the first 90 calendar days of production, there is appropriate justification from PCQI for a longer timeframe<br>Non-compliance (0 points) if:<br>• Validation was not done within the first 90 calendar days of production, there is no appropriate justification.<br>• No validation work has been performed.<br>• Changes in the process or product that may impact the effectiveness of the product has not resulted in a revalidation. |
| Development of the Preventive Controls Program | 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? | Specific responsibilities should be assigned for the monitoring, recording and corrective action implementation of each preventive control to ensure compliance. | Total compliance (10 points). Specific responsibilities should be assigned for the monitoring, recording and corrective action implementation of each preventive control to ensure compliance.<br><br>Minor deficiency (7 points) if:<br>• Single/isolated instance of a responsibility not being assigned.<br>Major deficiency (3 points) if:<br>• Numerous instances of a responsibility not being assigned.<br>Non-compliance (0 points) if:<br>• No responsibilities have been assigned.<br>• Systematic failure to assign responsibilities. | | No change in v3.2 | No change in v3.2 | 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. |
| Development of the Preventive Controls Program | 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)? | | | | No change in v3.2<br>**Point change from 5 to 10** | No change in v3.2 | No change in v3.2 |
| Development of the Preventive Controls Program | 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 process back into control? | There should be a documented, detailed plan with procedures to follow when there is a loss of control (deviation) of a preventive control so that adjustments can be made in a timely manner and to assure that the process is back under control. The procedures include details regarding how to handle affected products (if necessary). Corrective action procedures should also include requirements to review preventive controls to try and avoid a repeat of the loss of 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.<br><br>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. | | No change in v3.2 | 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. Requirements vary for process, food allergen, sanitation and supply chain program preventive controls. 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. Preventive measures and root cause analysis may be appropriate. | 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.<br>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 food safety plan (7.02.03) to determine whether modifications are required. |
| Development of the Preventive Controls Program | 7.02.10 | Have recording templates (recording forms) been developed for monitoring the preventive controls? | Defined record templates are required for recording preventive control monitoring. The parameters on the records should reflect those in the preventive control program. These templates should be managed under the document control program. Monitoring recording requirements vary depending on preventive control type. | 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).<br><br>Minor deficiency (10 points) if:<br>• 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.<br>Major deficiency (5 points) if:<br>• 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.<br>Non-compliance (0 points) if:<br>• 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.<br>• Single instance where a preventive control has been created but a record for the monitoring data has not been developed. | | Have recording forms been developed for monitoring the preventive controls? | No change in v3.2 | 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 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 (1.02.01).<br><br>Minor deficiency (10 points) if:<br>• 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.<br>• Single instance of recording forms lacking required details.<br>Major deficiency (5 points) if:<br>• 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.<br>• More than one instance of recording forms lacking required details.<br>Non-compliance (0 points) if:<br>• 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.<br>• Single instance where a preventive control has been created but a record for the monitoring data has not been developed. |
| Development of the Preventive Controls Program | 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. | | No change in v3.2<br>**Point change from 10 to 15** | No change in v3.2 | 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. |

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| Development of the Preventive Controls Program | 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? | 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. | 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.<br><br>Minor deficiency (7 points) if:<br>• Single/isolated instance(s) of an omission in the review.<br>Major deficiency (3 points) if:<br>• Numerous instances of omissions in the review.<br>• A review was performed within more than three but less than four years.<br>• A review did not take place after an emerging issue took place with a similar crop in the industry.<br>Non-compliance (0 points) if:<br>• No review has occurred. | 7.02.03 | 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? | The preventive controls should be reviewed by the preventive controls team when significant changes are made and at least every 3 years 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. 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. | 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 food safety 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.<br><br>Minor deficiency (7 points) if:<br>• Single/isolated instance(s) of an omission in the review.<br>Major deficiency (3 points) if:<br>• Numerous instances of omissions in the review.<br>• A review was performed within more than three but less than four years.<br>• A review did not take place after a significant change.<br>• A review did not take place after an emerging issue took place with a similar product in the industry.<br>• No record of workers involved being informed of review outcomes.<br>Non-compliance (0 points) if:<br>• No review has occurred. |
| Development of the Preventive Controls Program | 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? | | | 7.03.01 | Is there documented evidence that all plant workers have attended a preventive control training, including specific training for workers directly involved with preventive controls? | No change in v3.2 | Total compliance (10 points): All site workers (excludes office personnel) 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. 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.<br><br>Minor deficiency (7 points) if:<br>• Not all plant workers are trained in preventive controls (but all key operators and majority of workers have been trained).<br>• Single/isolated instance(s) of omissions or incorrect data in the records.<br>Major deficiency (3 points) if:<br>• One or more key operators have not been trained in their specific functions.<br>• Numerous instances of omissions or incorrect data in the records.<br>Non-compliance (0 points) if:<br>• No formal training session developed for workers.<br>• 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? | | | | Question removed | | |
| Execution of the Preventive Controls Program | 7.03.02 | Are the preventive control monitoring activities and frequencies in compliance with the preventive control plans, charts, and procedures? | The monitoring records should show that testing frequency, parameters and any other details match what is written in 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.<br><br>Minor deficiency (10 points) if:<br>• Single/isolated instance(s) where information or requirements on the records does not match what is noted in the preventive control program.<br>Major deficiency (5 points) if:<br>• Numerous instances where information or requirements on the records does not match what is noted in the preventive control program.<br>Non-compliance (0 points) if:<br>• Systematic failure to have information or requirements on the records matching what is noted in the preventive control program.<br>• Single instance where a preventive control has been created but monitoring data has not been recorded. | | No change in v3.2 | The monitoring records should show that testing frequency, parameters and any other details match what is written in the preventive control plans, charts, and procedures. The records should show actual values or observations, be accurate and legible, be real-time recording and have adequate detail. | 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.<br><br>Minor deficiency (10 points) if:<br>• Single/isolated instance(s) where information or requirements on the records does not match what is noted in the preventive control program.<br>• Single/isolated instance(s) of issues with how records are being filled out.<br>Major deficiency (5 points) if:<br>• Numerous instances where information or requirements on the records does not match what is noted in the preventive control program.<br>• Numerous instances of issues with how records are being filled out.<br>Non-compliance (0 points) if:<br>• Widespread failure to have information or requirements on the records matching what is noted in the preventive control program.<br>• Records are consistently being filled out incorrectly.<br>• Single instance where a preventive control |
| Execution of the Preventive Controls Program | 7.03.03 | Do workers directly involved with preventive control operations understand basic preventive control principles and their role in monitoring preventive controls? | 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. Auditor should interview operators to verify. | 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.<br><br>Minor deficiency (7 points) if:<br>• Single/isolated instance(s) where the workers are lacking in basic knowledge about preventive controls.<br>• 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.<br>Major deficiency (3 points) if:<br>• Numerous instances where the workers are lacking in basic knowledge about preventive controls.<br>• 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.<br>Non-compliance (0 points) if:<br>• Systematic failure of the interviewed worker to show basic knowledge about preventive controls.<br>• 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. | | No change in v3.2 | 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. Auditor should interview operators to verify. | 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.<br><br>Minor deficiency (7 points) if:<br>• One instance where the workers are lacking in basic knowledge about preventive controls.<br>• 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.<br>Major deficiency (3 points) if:<br>• More than one instance where the workers are lacking in basic knowledge about preventive controls.<br>• 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.<br>Non-compliance (0 points) if:<br>• Systematic failure of the interviewed worker to show basic knowledge about preventive controls.<br>• 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. |
| Execution of the Preventive Controls Program | 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? | Legibly signed off records should be recorded in order to show who actually performed the preventive control monitoring activities. If initials are used, there should be a way to easily determine who the initials refer to. | | | No change in v3.2 | Records should be legibly signed off in order to show who actually performed the preventive control monitoring activities. If initials are used, there should be a way to easily determine who the initials refer to. | No change in v3.2 |

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| Execution of the Preventive Controls Program | 7.03.05 | Is there a deviation record detailing documented corrective actions when a deviation or deficiency of a preventive control occurs? | When a monitoring or verification step shows a deviation or deficiency against a preventive control (including when a critical limit is exceeded), the incident should be recorded on a deviation record (or similar form), along with actions taken. This includes recording what happened to the affected product, how the situation was rectified and any preventative actions taken to avoid future similar issues in the future. | 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.<br><br>Minor deficiency (10 points) if:<br>• Single/isolated instance(s) of corrective action(s) being recorded, but lacking some details.<br>• Single/isolated instance(s) of corrective action(s) being recorded, but not meeting the requirements as noted in the preventive control program.<br>Major deficiency (5 points) if:<br>• Single instance of preventive control critical limit breach not being recorded and/or corrective actions not being recorded.<br>• Numerous instances of corrective action(s) being recorded, but lacking some details.<br>• Numerous instances of corrective action(s) being recorded, but not meeting the requirements as noted in the preventive control program.<br>Non-compliance (0 points) if:<br>• More than one instance of preventive control critical limit breach not being recorded and/or corrective actions not being recorded.<br>• Systematic failure to properly record corrective action details or the details recorded in no way meet what is required by the preventive control program. | | No change in v3.2 | When a monitoring or verification step shows a deviation or deficiency against a preventive control (including when a critical limit is exceeded), the incident should be recorded on a deviation record (or similar form), along with actions taken. This includes recording what happened to the affected product, how the situation was rectified and any preventative actions taken to avoid future similar issues in the future. This may include root cause analysis. | 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.<br>The corrective action details should match what is described in the written procedure (7.02.09).<br><br>Minor deficiency (10 points) if:<br>• Single/isolated instance(s) of corrective action(s) being recorded but lacking some details.<br>• Single/isolated instance(s) of corrective action(s) being recorded, but not meeting the requirements as noted in the written procedure.<br>Major deficiency (5 points) if:<br>• Single instance of preventive control critical limit breach not being recorded and/or corrective actions not being recorded.<br>• Numerous instances of corrective action(s) being recorded but lacking some details.<br>• Numerous instances of corrective action(s) being recorded, but not meeting the requirements as noted in the written procedure.<br>Non-compliance (0 points) if:<br>• More than one instance of preventive control critical limit breach not being recorded and/or corrective actions not being recorded.<br>• Systematic failure to properly record corrective action details or the details recorded in no way meet what is required by the written procedure. |
| Execution of the Preventive Controls 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)? | Records should be signed off by the designated person(s) responsible (i.e. qualified individual for preventive controls) for internal verification of the company's preventive control program. The sign off should not be done by the same person who carried out the preventive control monitoring activities. If any issues are detected, corrective actions should be recorded. | Total compliance (10 points): Preventive control records should be reviewed and signed off 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.<br><br>Minor deficiency (7 points) if:<br>• 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).<br>• Single/isolated instance(s) of the preventive control records being signed off by the second signatory<br>Major deficiency (3 points) if:<br>• Numerous instances of preventive control records not reviewed and signed off within 7 days by the quality control supervisor or manager (second signatory).<br>• 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.<br>Non-compliance (0 points) if:<br>• Systematic failure for preventive control records to be reviewed and signed off.<br>• Systematic errors on the preventive control records that are being signed off by the second signatory. | | Are the records associated with preventive controls reviewed and signed off by a preventive controls qualified individual or trained designate (second signatory)? | 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 off should not be done by the same person who carried out the preventive control monitoring activities. If any issues are detected, corrective actions should be recorded. | 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 (e.g. quality control supervisor and/or management 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 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 (7.03.05).<br><br>Minor deficiency (7 points) if:<br>• Single/isolated instance(s) of preventive control records not reviewed, dated and signed off within 7 working days by a PCQI e.g. quality control supervisor or manager (second signatory).<br>• Single/isolated instance(s) of the preventive control records being signed off by the second signatory<br>Major deficiency (3 points) if:<br>• Numerous instances of preventive control records not reviewed, dated and signed off within 7 working days by a PCQI e.g. quality control supervisor or manager (second signatory).<br>• 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.<br>Non-compliance (0 points) if:<br>• Fundamental failure for preventive control records to be reviewed, dated and signed off as required. |