

PrimusGFS - Checklist - v3.2

Auditees have the option to present combined HACCP and Preventive Control Systems, but auditors must report/score separately.

This module will always be applicable to all facility operations.

Module 7 - Preventive Controls Program (Sections 7.01 to 7.03)

Preventive Controls Program Requirements

Section	Q #	Question	Total Points	Auditor Comments
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?	10	
Preliminary steps	7.01.02	Is there documented evidence that the preventive control team members have been trained on preventive control program development?	15	
Preliminary steps	7.01.03	Does a product description exist for the products produced?	10	
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?	10	
Preliminary steps	7.01.05	Is there documented evidence that the flow chart(s) has been verified on-site?	10	
Development of the Preventive Controls Program	7.02.01	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?	15	
Development of the Preventive Controls Program	7.02.02	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?	15	
Development of the Preventive Controls Program	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?	10	
Development of the Preventive Controls Program	7.02.04	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)?	15	
Development of the Preventive Controls Program	7.02.05	Have monitoring requirements and frequencies been determined and documented for the preventive controls?	15	

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?	10	
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?	10	
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)?	10	
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?	15	
Development of the Preventive Controls Program	7.02.10	Have recording forms been developed for monitoring the preventive controls?	15	
Development of the Preventive Controls Program	7.02.11	Have verification procedures and schedules been developed for the preventive controls?	15	
Execution of the Preventive Controls Program	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?	15	
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?	15	
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?	10	
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?	15	
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?	15	
Execution of the Preventive Controls Program	7.03.06	Are the records associated with preventive controls reviewed and signed off by a preventive controls qualified individual or trained designate (second signatory)?	10	

Where laws, commodity specific guidelines and/or best practice recommendations exist and are derived from a reputable source, then these practices and parameters should be used. Audit users should allow a degree of risk association if laws, guidelines, best practices, etc., have not been documented.