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**Periodic Quality Audits and CAPA**

**1. Introduction**

This document outlines the procedures for conducting periodic quality audits and implementing Corrective Actions and Preventive Actions (CAPA) within a food manufacturing facility (NIC Code 10101). Regular audits and effective CAPA are essential for maintaining product quality, ensuring food safety, and achieving regulatory compliance.

**2. Periodic Quality Audits**

Periodic quality audits are systematic and independent examinations of the food safety and quality management system. These audits should be conducted at regular intervals (e.g., monthly, quarterly, annually) based on the risk profile of the facility and the criticality of the processes.

* Audit Scope: The scope of the audit should be defined clearly, outlining the specific areas to be reviewed. This may include raw material inspection, process monitoring, finished product testing, sanitation, and documentation review.
* Audit Checklist: A detailed checklist should be developed to ensure consistency and thoroughness. The checklist should be based on relevant standards, regulations, and internal procedures.
* Audit Team: An audit team should be assembled comprising personnel with appropriate expertise and experience. The team should be independent from the areas being audited.
* Audit Report: A comprehensive audit report should be generated, documenting findings, observations, and recommendations. The report should be reviewed and approved by management.

**3. Corrective Actions and Preventive Actions (CAPA)**

The CAPA process is designed to address identified non-conformities and prevent their recurrence.

* Non-Conformity Reporting: A system should be in place for reporting non-conformities (deviations from established procedures or specifications).
* Root Cause Analysis: A thorough root cause analysis should be conducted to determine the underlying causes of the non-conformity. Tools such as fishbone diagrams or 5 Whys can be used.
* Corrective Action: Effective corrective actions should be implemented to address the immediate problem.
* Preventive Action: Preventive actions should be implemented to prevent the recurrence of the non-conformity. This may include changes to procedures, training, equipment upgrades, or other improvements to the system.
* Verification: The effectiveness of the corrective and preventive actions should be verified.
* Documentation: All aspects of the CAPA process should be meticulously documented.

**4. Compliance Notes**

* FSMA (Food Safety Modernization Act): The CAPA process must comply with the preventive controls for human food rule under the FSMA.
* ISO 22000: A robust CAPA system is a key requirement for ISO 22000 certification.
* GMP (Good Manufacturing Practices): The CAPA process should align with GMP principles.

**5. Practical Guidelines**

* Training: Provide thorough training to personnel on the procedures for conducting audits and implementing CAPA.
* Regular Review: The effectiveness of the CAPA system should be reviewed regularly.
* Management Review: The results of audits and CAPA actions should be reviewed by management.

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