|  |  |  |
| --- | --- | --- |
|  | **TCS** Vijay | **DOC.NO: M.122.NC** |
| **EFFECTIVE DATE: 04/05/2009** |

**Periodic Quality Audits and CAPA**

**1. Introduction**

This document outlines 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 complying with regulations.

**2. Types of Audits**

**Several types of audits may be performed:**

* Internal Audits: Conducted by internal personnel to assess compliance with established procedures and standards.
* External Audits: Conducted by third-party organizations to verify compliance with industry standards and regulations.
* Supplier Audits: Audits of suppliers to verify the quality and safety of their products and processes.

**3. Audit Scope and Frequency**

The scope and frequency of audits should be determined based on risk assessment and regulatory requirements. High-risk areas should be audited more frequently.

**4. Audit Process**

**The audit process typically includes the following steps:**

* Planning: Define the scope, objectives, and methodology of the audit.
* Execution: Conduct the audit according to the planned methodology, collecting evidence and documenting findings.
* Reporting: Prepare a comprehensive audit report summarizing the findings, including any non-conformances.
* Follow-up: Implement corrective and preventive actions to address non-conformances.

**5. Corrective Actions (CA) and Preventive Actions (PA)**

* Corrective Action (CA): Addresses existing non-conformances or deviations from standards.
* Preventive Action (PA): Aims to prevent potential non-conformances or deviations from occurring in the future.

**6. CAPA System**

**An effective CAPA system should include:**

* Root Cause Analysis: A thorough investigation to identify the root cause of the non-conformances.
* Corrective Action Plan: A detailed plan to address the non-conformances and prevent recurrence.
* Verification: Verification of the effectiveness of the corrective action.
* Documentation: Maintain complete documentation of all CAPA activities.

**7. Compliance Notes**

* Audits should be conducted according to established procedures and documented thoroughly.
* All non-conformances should be investigated, and appropriate corrective and preventive actions implemented.
* Records of all audit activities, including non-conformances and CAPA, should be maintained.

**8. Practical Guidelines**

* Use checklists and standardized audit forms to ensure consistency.
* Train auditors on proper audit techniques and documentation procedures.
* Implement a system for tracking and managing CAPA.
* Regularly review the effectiveness of the CAPA system.