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**Periodic Audits and CAPA**

**1. Introduction**

This document outlines the procedures for conducting periodic audits and implementing Corrective Actions and Preventative Actions (CAPA) within a food manufacturing facility (NIC Code 10101). Regular audits are crucial for maintaining compliance with food safety regulations, ensuring product quality, and identifying areas for improvement within the production process. This process is designed to proactively identify and address potential hazards and deviations before they impact product safety or quality.

**2. Audit Schedule and Scope**

* Frequency: Audits should be conducted at least annually, with more frequent audits (e.g., quarterly or monthly) for critical areas identified through risk assessment. The frequency should be documented and justified based on the inherent risks associated with specific processes and the historical performance of the facility.
* Scope: Audits should encompass all aspects of the food manufacturing process, including:
* Raw Material Handling and Storage: Inspection of storage conditions, temperature control, FIFO (First-In, First-Out) adherence, and proper labeling.
* Production Process: Review of Good Manufacturing Practices (GMPs), Sanitation Standard Operating Procedures (SSOPs), equipment calibration and maintenance, and process controls.
* Packaging and Labeling: Verification of accurate labeling, seal integrity, and adherence to regulatory requirements.
* Finished Product Storage and Distribution: Assessment of storage conditions, temperature control, and handling procedures during transportation.
* Waste Management: Inspection of waste disposal procedures to ensure compliance with environmental regulations.
* Personnel Hygiene and Training: Evaluation of employee training records, hygiene practices, and adherence to company policies.
* HACCP (Hazard Analysis and Critical Control Points) System: Thorough review of the HACCP plan's effectiveness, verification of critical limits, and documentation of monitoring activities.
* Audit Team: The audit team should consist of individuals with relevant expertise and experience in food safety and quality management. This may include internal personnel, external consultants, or a combination thereof. Team members should receive appropriate training on auditing techniques and regulatory requirements.

**3. Audit Methodology**

Audits should follow a structured approach, incorporating the following elements:

* Planning: Defining the audit scope, objectives, and schedule.
* Data Collection: Gathering evidence through observation, interviews, document review, and sampling.
* Analysis: Evaluating the collected data against established standards and regulatory requirements.
* Reporting: Documenting audit findings, including observations, non-conformances, and recommendations.

**4. Corrective and Preventative Actions (CAPA)**

* Identification of Non-Conformances: Any deviations from established procedures, standards, or regulatory requirements should be documented as non-conformances.
* Root Cause Analysis: A thorough investigation should be conducted to determine the root cause of each non-conformance.
* Corrective Action: Immediate actions should be taken to correct the non-conformance and prevent its recurrence.
* Preventative Action: Actions should be implemented to prevent similar non-conformances from occurring in the future.
* Verification: The effectiveness of corrective and preventative actions should be verified through follow-up audits and monitoring.
* Documentation: All CAPA activities should be meticulously documented, including the nature of the non-conformances, root cause analysis, corrective actions taken, preventative actions implemented, verification activities, and responsible parties.

**5. Compliance Notes:**

* Adherence to relevant food safety regulations (e.g., FSSAI in India, FDA in the USA, etc.) is mandatory.
* All documentation must be retained according to regulatory requirements.
* Audits should be conducted by qualified personnel.
* CAPA processes should be documented and regularly reviewed.

**6. Practical Guidelines:**

* Utilize checklists and standardized audit forms to ensure consistency and thoroughness.
* Employ a documented risk-based approach to prioritize audit areas.
* Conduct regular training for personnel involved in audits and CAPA implementation.
* Maintain a system for tracking and managing CAPA actions.
* Regularly review and update the audit program to reflect changes in regulations, technology, and best practices.

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