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**Periodic Audits and CAPA**

**1. Introduction**

This document outlines the procedures for conducting periodic audits and implementing Corrective and Preventive Actions (CAPA) within a food manufacturing facility operating under NIC Code 10101 – Manufacture of Food Products. Regular audits ensure compliance with relevant food safety regulations (e.g., HACCP, GMP, FSMA), internal quality standards, and legal requirements. The CAPA system ensures timely identification, investigation, and resolution of non-conformances and potential risks.

**2. Audit Schedule and Scope**

* Frequency: Audits will be conducted at least annually, with more frequent audits (e.g., quarterly) for high-risk areas or processes identified through risk assessment. A detailed audit schedule will be maintained and reviewed annually.
* Scope: Audits will cover all aspects of the manufacturing process, including:
* Raw material handling and storage.
* Production processes (mixing, processing, packaging).
* Sanitation and hygiene practices.
* Equipment maintenance and calibration.
* Personnel training and competency.
* Traceability and record-keeping systems.
* Product quality and safety.
* Compliance with relevant legal and regulatory requirements.
* Audit Team: Audit teams will comprise personnel with relevant expertise and experience, including at least one individual independent of the area being audited.

**3. Audit Procedures**

* Pre-audit Activities: The audit team will review relevant documentation (e.g., SOPs, specifications, training records) and plan the audit scope. A pre-audit meeting with the audited area's management may be conducted.
* Audit Execution: The audit team will conduct a thorough inspection of facilities, equipment, and processes. Observations will be documented using a standardized checklist and audit report template. Any non-conformances or potential risks will be clearly identified and documented with supporting evidence (e.g., photographs).
* Post-audit Activities: The audit team will present the audit findings to the management of the audited area. The findings will be documented in a formal audit report.

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

* Non-conformance Reporting: Any non-conformances identified during audits will be documented in a formal non-conformance report, including a detailed description, root cause analysis, and proposed corrective actions.
* CAPA Implementation: The appropriate personnel will be assigned responsibility for implementing corrective actions to address the identified non-conformances. The effectiveness of corrective actions will be verified.
* Preventive Actions: Preventive actions will be implemented to prevent similar non-conformances from recurring. These actions might involve process improvements, revised SOPs, or enhanced training programs.
* CAPA Closure: Once corrective and preventive actions are fully implemented and verified as effective, the CAPA will be formally closed. The closure will be documented and the relevant records maintained.

**5. Compliance Notes**

* Compliance with all applicable food safety regulations (e.g., HACCP, GMP, FSMA) is mandatory.
* All audit records and CAPA documentation must be maintained in accordance with regulatory requirements.
* Audits must be conducted by qualified personnel.
* Effective CAPA implementation is crucial to prevent food safety hazards and ensure product quality.

**6. Practical Guidelines**

* Use standardized checklists and report templates to ensure consistency and thoroughness.
* Implement a robust document control system to manage audit records and CAPA documentation.
* Conduct regular training for audit team members and personnel involved in CAPA implementation.
* Regularly review and update the audit schedule and scope to reflect changes in the manufacturing process or regulatory requirements.

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