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**Address Deviations, Identify Root Causes, and Take Corrective & Preventive Actions (CAPA)**

This document outlines the procedure for addressing deviations from established processes, identifying root causes, and implementing Corrective and Preventive Actions (CAPA) within a food manufacturing facility operating under NIC Code 10101. Compliance with relevant food safety regulations (e.g., FDA, HACCP, local regulations) is paramount throughout this process.

1. Deviation Identification and Reporting

* Step 1: Immediate Action: Upon detection of any deviation from established Standard Operating Procedures (SOPs), Good Manufacturing Practices (GMPs), or regulatory requirements, immediate action must be taken to prevent further issues. This may involve halting the affected process, isolating the affected product, and notifying the appropriate supervisor.
* Step 2: Documentation: A Deviation Report (DR) must be completed promptly and accurately. The DR should include:
* Date and time of deviation.
* Location of deviation (e.g., specific production line, equipment).
* Description of the deviation, including specific details and measurements.
* Personnel involved.
* Immediate actions taken.
* Estimated quantity of affected product (if applicable).
* Photographs or other supporting evidence.
* Step 3: Notification: Depending on the severity of the deviation, notification may be required to higher management, regulatory agencies, or customers. Severity levels should be clearly defined in the company's deviation management system.

2. Root Cause Analysis (RCA)

* Step 1: Investigation Team: Assemble a cross-functional team with expertise relevant to the deviation.
* Step 2: Data Gathering: Gather all available data related to the deviation, including the DR, production records, maintenance logs, employee interviews, and any other relevant information.
* Step 3: RCA Methodology: Use a structured RCA methodology (e.g., 5 Whys, Fishbone diagram, Fault Tree Analysis) to systematically identify the root cause(s) of the deviation. The goal is to identify the underlying problem, not just the symptoms.
* Step 4: Documentation: Thoroughly document the RCA process, including the methodology used, data collected, analysis performed, and conclusions reached. This documentation should be included as part of the CAPA plan.

3. Corrective and Preventive Actions (CAPA)

* Step 1: Corrective Actions: Define specific actions to correct the immediate problem caused by the deviation. This may involve disposing of affected product, cleaning and sanitizing equipment, or retraining personnel.
* Step 2: Preventive Actions: Develop actions to prevent the recurrence of the deviation. This may involve revising SOPs, improving training programs, modifying equipment, or implementing new control measures.
* Step 3: Verification: Verify the effectiveness of the corrective and preventive actions. This may involve monitoring key performance indicators (KPIs), conducting audits, or implementing follow-up investigations.
* Step 4: Documentation: All CAPA actions, verification results, and follow-up activities must be thoroughly documented and maintained.

Compliance Notes:

* All documentation must be retained according to regulatory requirements.
* The CAPA process must be documented and auditable.
* Corrective actions must be implemented promptly.
* Preventive actions must be designed to eliminate the root cause(s) of the deviation.

Practical Guidelines:

* Implement a well-defined deviation reporting system that encourages prompt reporting.
* Provide employees with adequate training on deviation reporting and CAPA procedures.
* Regularly review and update SOPs and GMPs to reflect lessons learned from deviations.
* Use a standardized approach to root cause analysis to ensure consistency and effectiveness.

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