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**Root Cause Analysis and CAPA**

**1. Introduction**

This document outlines procedures for conducting Root Cause Analysis (RCA) and implementing Corrective Actions and Preventive Actions (CAPA) within a food manufacturing facility (NIC Code 10101). Effective RCA and CAPA are crucial for preventing recurrence of non-conformances and improving food safety and quality.

**2. Root Cause Analysis (RCA)**

RCA is a systematic process used to identify the underlying causes of non-conformances or incidents. The goal is to address the root cause, not just the symptoms. Several methods can be used for RCA, including:

* 5 Whys: Repeatedly asking "why" to uncover the root cause.
* Fishbone Diagram (Ishikawa Diagram): A visual tool to identify potential causes categorized by category (e.g., man, machine, material, method, environment, measurement).
* Fault Tree Analysis: A top-down approach to identify the causes of an undesirable event.

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

CAPA involves implementing corrective actions to address immediate problems and preventive actions to prevent recurrence. These actions should be documented, verified, and validated.

**4. Procedures for Implementing RCA and CAPA**

**1. Incident Reporting: Establish a clear system for reporting non-conformances or incidents.**

**2. Investigation: Conduct a thorough investigation to gather information and identify potential causes.**

**3. Root Cause Analysis: Use a suitable RCA method to identify the root cause(s) of the non-conformance or incident.**

**4. Corrective Action: Develop and implement corrective actions to address the immediate problem.**

**5. Preventive Action: Develop and implement preventive actions to prevent recurrence of the problem.**

**6. Verification: Verify that corrective and preventive actions have been effectively implemented.**

**7. Validation: Validate that the implemented actions have achieved their intended purpose.**

**8. Documentation: Maintain complete documentation of the entire process, including the RCA, corrective and preventive actions, verification, and validation.**

**5. Compliance Notes**

Maintaining comprehensive records of RCA and CAPA is crucial for demonstrating compliance with food safety regulations. The effectiveness of the implemented actions should be regularly monitored and reviewed.

**6. Practical Guidelines**

* Use a standardized format for RCA and CAPA reports.
* Assign responsibility for implementing corrective and preventive actions.
* Establish a timeline for completing corrective and preventive actions.
* Regularly review the effectiveness of implemented actions.
* Conduct training for employees on RCA and CAPA procedures.

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