Root Cause Analysis

Definition

Root Cause Analysis (or RCA) is a method of problem solving to identify and resolved the core issue (s) that cause a non-conformity, deviation, or other adverse food safety or quality event.

Review Glossary Terms

1. Root Cause Analysis
2. Correction
3. Corrective Action
4. Deviation
5. Non-conformance

Implementation & Audit Guidance

What does it mean?

Part A of the Code requires a documented root cause analysis as part of the corrective action evidence for every major non-conformance.

The Code requires the identification of root cause of non-compliance of critical food safety limits and deviations from food safety requirements as part of the site's corrective and preventative action program.

The site is required to retain records of root cause analysis when conducted.

Why is it in the Code & why is it important?

This is a mandatory clause.

When non-compliance with critical food safety limits or a deviation from food safety requirements happen, there may be a tendency to assume the cause. Root cause analysis seeks to move past assumptions to uncover the true cause. This is often accomplished using an investigative tool. Uncovering the root cause allows the site to identify where the process failed so that a corrective action and potentially a preventative action to be implemented. This ultimately improves the sites' management of food safety and quality.

The process of conducting a root cause analysis typically involves six steps, a pre step and post process follow up. The steps are:

Pre-step – identify the investigation team.

1. Describe the problem, non-conformance, or deviation event in detail.
2. Gather data associated with the problem, non-conformance, or deviation event.
3. Determine the causes and identify the root cause. In this step an analysis tool such as a fishbone diagram, flowchart, 5 Whys, TRIZ, Is/Is Not can be used.
4. Identify corrections, corrective actions and explore preventative actions.
5. Define and implement the identified solution.
6. Verify the effectiveness of the solution.

Post process – Collect and maintain records associated with the development and use of the process, including reasons for the investigative tool used, any corrections made, corrective actions implemented, and the verification records.

Root Cause Analysis
Guidance Document

RIO Road to Audits (Records, Interviews, and Observations)

Records	Interviews	Observations
The following are examples of records and/or documents to assist in the implementation and review of this topic: ▪ Corrective and Preventative Action Program or Policy ▪ Root cause analysis process ▪ Deviation records (such as audit reports, monitoring records, customer complaints, product withdrawals and recalls, non-conforming product and equipment) ▪ Investigations of deviations and non-conformances using root cause analysis ▪ Evidence of verification of corrective action ▪ Training records, if applicable ▪ Annual review and verification of the program	The following are examples of people to interview to assist in the implementation and review of this topic: ▪ SQF Practitioner ▪ Internal Audit Team The following are examples of questions to ask to assist in the implementation and review of this topic: ▪ Briefly describe the process for conducting root cause analysis. ▪ What documents and records did the team retain after a root cause analysis of a deviation or non-conformance? ▪ Provide some examples of situations when a root cause analysis was conducted on something besides an audit non-conformance. ▪ How did the team know when they had identified the root cause? ▪ What root cause analysis investigation tool (s) is/are used and why was/were it/they chosen?	The following are examples of observations to assist in the implementation and review of this topic: ▪ Describe the process for investigating deviations and non-conformances? ▪ Evidence of a successfully utilized root cause analysis to identify and rectify deviations and non-conformances? ▪ An understanding of when to use a root cause analysis? ▪ Who is on the root cause analysis team? Does the site bring in other personnel as necessary to investigate deviations and non-conformances? ▪ Is there more than one root cause analysis tool used, as appropriate? ▪ Does the team understand which root cause analysis tool to use depending upon the deviation or non-conformance? ▪ Is root cause analysis used to improve the food safety and/or quality systems? ▪ Are the root cause analyses submitted in response to a non-conformance identified during a certification audit appropriate? IS documentation submitted unprompted?

Additional References

- March 2015 SQFI Learning Lunch: A Practical Approach to Root Cause Analysis https://youtu.be/Nk1rrId1X2w?list=PLOuh0zb5v1tT445EnBiEKKzlqKg37rAA7
- Root Cause Analysis: Steps, Tools, and Best Practices https://thebusinessanalystjobdescription.com/root-cause-analysis-steps-techniques-and-best-practices/
- The Business Analyst, Root Cause Analysis: Steps, Tools, and Best Practices https://thebusinessanalystjobdescription.com/root-cause-analysis-steps-techniques-and-best-practices/
- ASQ, What is Root Cause Analysis (RCA)? https://asq.org/quality-resources/root-cause-analysis
- Quality One, Root Cause Analysis (RCA) https://quality-one.com/rca/