PrimusGFS Guidance for Root Cause Analysis

Root cause analysis is a problem-solving process for investigating the underlying cause(s) of an incident, problem, concern, or non-conformity. Root cause analysis is a separate process from an immediate corrective action of significant non-conformances or other adverse food safety events and looks beyond the immediate solution to the fundamental cause(s) in order to prevent re-occurrence of the same issue.

Definitions
Continuous improvement: ongoing evaluation of actions implemented to increase the ability to fulfill requirements.
Contributing factor: the physical, biological, behavioral or attitudinal factors that directly or indirectly resulted in a non-conformity or other incident.
Correction: immediate action to eliminate a detected non-conformity.
Corrective Action: action to eliminate the cause of a detected non-conformity or other undesirable situation.
Preventive action: action to eliminate the cause of a potential non-conformance or other undesirable potential situation.
Root cause: the underlying core reason(s) that resulted in a problem or non-conformance. If the root cause had not occurred, the event would not have occurred or would have been of significantly lower impact.
Root cause analysis (RCA): methods aimed at identifying the cause(s) of a problem or non-conformance, solving it and preventing it from occurring again.

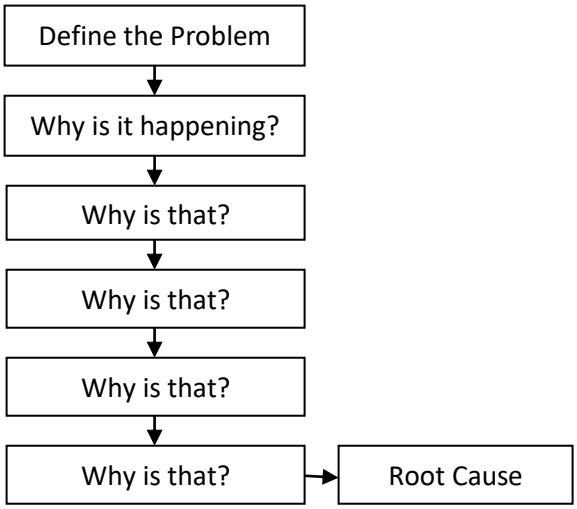
Root cause investigation leads to corrective action which is intended to prevent recurrence of the non-conformance. Preventive action is proactive and intended to prevent occurrence of non-conformance.

There are several general steps to accomplishing a root cause analysis:

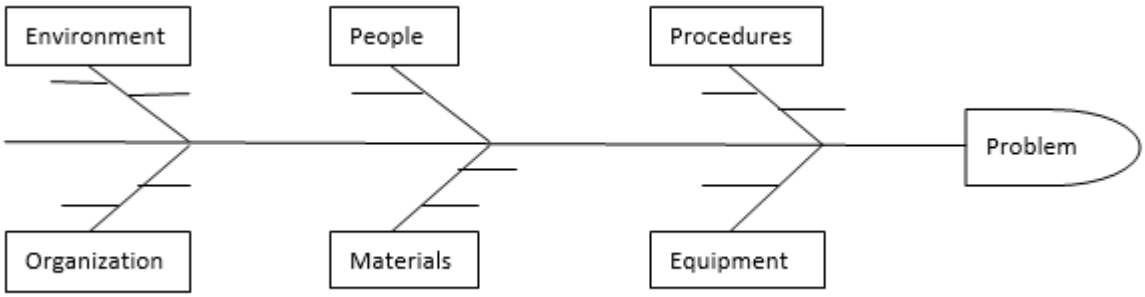
1. Identify a team to conduct the root cause analysis. The team should be made up of people who are closest to the work on a daily basis.
2. Describe the problem, event or non-conformity in detail.
3. Confirm the sequence of events including when it occurred and when it was discovered.
4. Gather data associated with the problem, event or non-conformity including which products/processes are involved, records, test results and details of any immediate corrective action taken.
5. Identify the underlying reason for the problem, event or non-conformity, differentiating contributing factors from root causes. There is no single recommended method of conducting a root cause analysis and choice of methodology may depend on factors such as personal choice, company policy or type of issue being investigated. Popular tools include The Five Whys, Fishbone Diagrams (also called Ishikawa models and Cause & Effect Diagrams), Fault Tree Analysis, etc.

6. Establish a proposed action plan (e.g., updating operating procedures, improving monitoring systems, additional training to gain experience, new technology, etc.) with a clearly defined timeline for the action to be completed in and who is responsible for completion.
7. Implement the action plan.
8. Monitor and verify effectiveness of control strategies in order to ensure any changes, new activity or procedure is effectively managing the root cause and that it does not unintentionally introduce any new or additional problems.
9. If the implemented control strategies are not effective, revisit the root cause to determine why e.g., if incorrect conclusions were drawn, if the control strategy did not address every root cause, if the action plan was not fully implemented. Rarely is the root cause a single issue.
10. Once it is demonstrated that the action is effective, a review can determine whether additional monitoring is still required or can be reduced to a lower frequency.

The Five Whys tool is an example of a root cause analysis technique that is simple and effective. The idea is that by repeatedly asking the question "why?" you will find the root cause of the issue. Don't assume that by asking "why?" five times exactly you will identify the problem; it may take less, or it may take more than five times to get to the root cause. Remember though, that a problem often has more than one cause.



While you can use The Five Whys tool on its own, by first combining it with another tool such as the **Fishbone Diagram** you are able to focus on more than one pathway of analysis.



Steps:

1. Agree on the problem statement (written at the head of the fish).
2. Agree on the major categories of causes of the problem (written as branches from the main spine of the fish).
3. Brainstorm all the possible causes of the problem (written as sub-branches from the appropriate problem).

Root cause analysis is part of a general problem-solving process and an integral part of continuous improvement. The root cause should be something that can be managed, adjusted, or changed rather than conclusions which are generally beyond our control such as “staff shortage”, or “made a mistake”. Ask specific questions such as “why did this happen?” or “why did the process fail?”, “what could be the cause(s)?”, “when could this happen?”.

Be aware that people are generally NOT the ultimate cause of problems; people implement processes. While training may be a contributing factor, it is rarely the root cause of a problem, event or non-conformity. Establish what system, policy or process allowed the human error to occur. Look at redesigning the training approach, rather than simply re-training, and at how to make it hard for people to fail at their job.

ASQ, What is Root Cause Analysis (RCA)? https://asq.org/quality-resources/root-cause-analysis
PEW, A Guide for Conducting a Food Safety Root Cause Analysis
https://www.pewtrusts.org/en/research-and-analysis/reports/2020/03/a-guide-for-conducting-a-food-safety-root-cause-analysis