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REVIEW ARTICLE: ROOT CAUSE ANALYSIS (RCA)

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ABSTRACT

Root Cause Analysis is used as a guidance for the investigation. Root cause analysis (RCA) describes a wide range of approaches, tools, and techniques used to uncover causes of problems. Root Cause Analysis is a systematic approach through the use of set tools and investigative techniques to get to the true root cause of the Quality system issue. Different tools can be used for the Root Cause Analysis to carry out the investigation of any quality system related issues. The general steps of Root cause analysis are to Define the problem, Analyze what is seen and identify the precise symptoms so that one can form a problem statement, Collection of data, Identifying causal factors, Determine the root cause(s), Recommending and implementation of solutions. The main benefit of RCA is that it finds the fundamental errors in the development process, enables teams to enact right measures to fix the problems and stop them from recurring ahead. This article gives a guidance how RCA is performed stepwise to address a problem statement, reach to appropriate solution and implement necessary corrective and preventive actions.

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INTRODUCTION

In Science and Engineering, root cause analysis (RCA) is a method of problem solving used for identifying the root causes of faults or problems. It is widely used in field of telecommunication, IT, accidental issues, industrial process issues and medicinal & healthcare industry.¹

Root cause analysis is part of a more general problem-solving process and an integral part of continuous improvement. Because of this, root cause analysis is one of the core building blocks in an organization's continuous improvement efforts. It's important to note that root cause analysis in itself will not produce any results; it must be made part of a larger problem-solving effort for quality improvement.²

The purpose of the review article is to give a guidance how RCA is performed stepwise to address a problem statement, reach to appropriate solution and implement necessary corrective and preventive actions.

Definition

A root cause is defined as a factor that caused a nonconformance and should be permanently eliminated through process improvement. The root cause is the core issue the highest-level cause that sets in motion the entire cause-and-effect reaction that ultimately leads to the problem(s).

Root cause analysis (RCA) is defined as a collective term that describes a wide range of approaches, tools, and techniques used to uncover causes of problems. Some RCA approaches are geared more toward identifying true root causes than others, some are more general problem-solving techniques, and others simply offer support for the core activity of root cause analysis.²

Benefits of RCA³

- It helps to identify and causes of the problem so that a permanent solution can be found and implemented.
- It helps in developing the logical solution by utilizing the data that already exists
- Helps to find the current and future needs of a firm
- Establish repeatable, step-by-step processes, in which one process can confirm the results of another.

Basic method to use³

- Define the problem.
- Gather information, data and evidence.
- Identify all issues and events that contributed to the problem.
- Determine root causes.
- Identify recommendations for eliminating or mitigating the reoccurrence of problems or events.
- Implement the identified solutions.

Steps involved in the Root Cause Analysis

The Root cause analysis seeks to identify the origin of the problem and involves specific steps with associated tools to identify the primary cause of the problem.

The Root cause analysis should be completed with following steps:

Step One: Define the problem

Define the problem or describe the event factually and give effective problem statement. Provide as many details, as available, to describe the event or failure. Simultaneously identify the person who shall perform the investigation.

Step Two: Collection of Data

For collection of data refer relevant documents.

Step Three: Review / evaluation of data and Identification of Possible Root Causes

For identifying the causal factors for the error conditions, list down as much factors as possible. Gather data and evidence through interaction and Brainstorming with the people involved and by review of the required documents. Build different hypothesis based on following factors, but not limited to. Review / Evaluation of Data: Details shall include followings (but, not limited to)

- What sequence of events led to the problem?
- What conditions allowed the problem to occur?
- What other problems surround the occurrence of the central problem (e.g., the moisture problem in product may be due to frequent obstructions in utility supplies to the drying equipment).
- Break down the problem into small, detailed parts to better understand the process.
- Use facts and ask, "So what?" to determine all the possible consequences of a fact.

Step Four: Impact Assessment

Based on nature of problem, root cause identified and risk involved; impact assessment shall be performed.

Step Five: Root Cause Analysis Summary

- Write the summary of all reviewed documents
- Outcome of the interaction with people involved
- Review and observations of Material
- Review and observations of all Equipment, machineries and instruments
- Review of observations of Methods, Process involved
- Review of Environments and other related activities
- Review and Record observations of Hypothesis / Experimental results, Risk Analysis and Risk rating

Step Six: Recommendation of CAPA

- For a quality issue, there can be multiple causes and hence there may be multiple corrective and preventive actions required
- Corrective action shall be taken to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.
- The preventive actions shall be identified by the investigation team for fixing the contributing causes and the root cause. A contributing cause, if not addressed, could be a future root cause.

Step Seven: Conclusion

- Contains all associated documentation.
- Comprehensive and justified root cause analysis was performed.
- Appropriate CAPA assignment and adequate effectiveness checks are in place.
- Investigation completeness and RCA report and reference within the appropriate Quality system record in TrackWise.
- Issue resolution and/or potential identification of mitigation plans.

CONCLUSION

The main benefit of RCA is that it finds the fundamental errors in the development process, enables teams to enact right measures to fix the problems and stop them from recurring ahead. Hence, there is lesser rework and fewer defects in the final product. Root cause analysis is a useful process which will be beneficial in future researches in order to solve a problem by knowing the root cause and implementing corrective and preventive action to prevent recurrence of the same problem again.

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