Quality Management System Guidance

Root-cause Analysis & Corrective Action
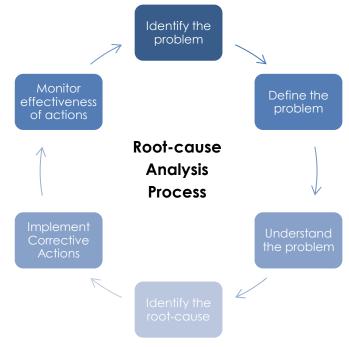
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1 Root-Cause Analysis & Corrective Action

There is a clear link between ISO 9001:2015 Clause 8.7 Non-conforming Outputs and Clause 10.2 Non-conformity and Corrective Action, this guidance document provides a 6-step methodology for meeting the requirements in each of these clauses. These clauses state the requirements for the occurrence of a non-conformity and include actions to prevent a similar non-conformity or problems occurring.

Your organization is required to take whatever action is necessary to control and correct the non-conformity, and to deal with any resulting impact by determining what caused the non-conformity and considering whether the potential for a similar problem remains.

This is done by considering whether any further action is required to prevent a similar non-conformity arising at the same place or occurring somewhere else, at some point in the future and by determining if similar non-conformities have occurred elsewhere; and consequently, whether it needs to take similar corrective action.

Taking appropriate action to address the effects of the problem may require a simple correction by the process owner or operator where it was discovered, or, if a major failure or defect exists, more significant levels of resource would be needed for problem solving and corrective action.

There may be instances where it is impossible to completely eliminate the cause of the non-conformity, so in these instances, the best you can do is to reduce the likelihood or the consequences of a similar problem happening again in order to reduce the risk to an acceptable level.

Any non-conformities and subsequent actions to prevent their reoccurrence and the effectiveness of the corrective action(s), should be duly documented and retained. Therefore, consideration should be given to the development and use of the _Corrective Action Log_ to capture this information.

The following guidelines are for completing root-cause analysis and corrective action responses to audit non-conformity reports (NCRs). However, these guidelines should also be applied to corrective action responses from other sources (customer complaints, internal defects, etc.)

1.1 Identify the Problem

Once a problem has been identified through inspection, customer complaints, or audit results, it should be captured using non-conformity reports (NCRs) or corrective action reports (CARs) in order to identify who is affected by the problem and what the impact is. Considering the following:

1. What are the operations, products, materials, defects, malfunctions that may characterise the problem? What is it about?

2. Who is concerned with the problem? Who is reporting the problem? Who is rectifying the problem? Who is the problem affecting?

3. Where are all the places where the event takes place; shop floor, services, machine, process step?

4. Where is it seen? Where does it originate?

5. When does the event appear (time, date, when does it start, how long does it last, how often)

6. When is the problem reported defective? When is the problem repaired?

7. Has it occurred before? If yes, what is the history?

8. How do we know there's a problem (how is it detected)?

9. How does the event appear, how does it stop?

10. How frequently is the problem experienced?

11. How is the effect of the problem being measured (costs, delays, scrap rate, customer complaints, return rate, concessions, reliability rate, etc)?

12. How is the problem currently addressed? How is it corrected?

This step helps to fully describe a situation, precisely analyse all its elements and gain a common understanding of them, allowing the definition of an action plan. Ensure that all team members agree about the definition of the issue and resulting impact.

1.2 Define the Problem

1.2.1 Generate a Problem Description

The problem description should describe the problems in terms of what, where, when, and how big. On a flip chart, presentation board, or even paper; write out a description of what you know about the problem. Try to document the problem and describe it as completely as possible.

The description should contain facts; such as observations and documentary evidence and not assumptions. All information must be gathered before identifying the root-cause can begin. Make sure both of the above factors are true before you move to the next step. Consider any new information that the team may have gathered since completing the initial problem description.

Describe the problem by identifying what is wrong and detail the problem in quantifiable terms. Define, verify and implement the interim containment action to isolate the effects of the problem from any internal/external customer until Permanent Corrective Actions (PCA) are implemented.

Now that you have narrowed down the possible root-causes, you need to develop theories about how the problem occurred. Theories are statements that describe how a change may have created the problem. To develop root-cause theories, use brainstorming techniques to generate ideas:

1. Ask: 'how could this change have caused the problem?'

2. Continue to ask the question until all possible theories are developed;

3. List at least one theory for each change;

4. List each theory individually on a worksheet;

5. List every possibility, no matter how strange or unlikely;

6. Don't reject or qualify any theory;

7. Start with the simplest single change theory first, then work up to more complex theories.

Note: Be specific; don't use generalities such as 'poor quality' or 'doesn't work'.

1.2.2 Establish a Response Team

Identify representatives from functions that may have an influence on the corrective action process, including the identification of the root causes. Remember to assign responsibilities and objectives to the team members. Remember, those performing the job, such as operators, inspectors, drivers, etc., are the best people to help identify the real causes, don't leave them out of the team!

The size and composition of the team should depend on the complexity and the impact of the problem. The composition of the team is not fixed forever and may evolve depending on the analysis results and the required actions. New team members should join the team if analysis shows they are identified as being in the scope, some others will leave if their area is definitely identified as out of the scope.

However, consideration should be made that expending the size of the core team over 6 to 8 members generally results in less efficiency. When more members or special skills are required, sub teams should be considered. Don't forget, root-cause analysis **must not** be used for assigning blame or transferring responsibility. In summary, you should establish an investigation team with:

1. Process and/or product knowledge;
2. Allocated time and resources;
3. Authority to solve the problem and implement corrective actions;
4. Skill in the required technical disciplines;
5. A designated Team Leader.

Brainstorming sessions should be used to identify potential causes to investigate each potential cause. Coordinate parallel activities with different team members to help expedite the process of verification.

1.2.3 Effective Communication

Continual communication between all team members is mandatory, for instance trough regular reviews until root-cause are clearly identified and agreed by all. Inside the organization where the problem originated, between all actors of the supply chain to ensure effective root-cause analysis and definitive corrective action implementation.

A team leader needs to know that he has been chosen and why he has been assigned this role, along with a description of the team's objectives and constraints, while each team member needs to understand his role and objectives. The line managers of each team member need to know each members' level of involvement, e.g. their time, duration, and role. All stake-holders must be informed of the team's composition and objectives.

Root-causes must be communicated to all stake-holders and agreed, especially by the customer when he is impacted. Communication internally and between various tier levels and between the supplier and customer to immediately stop the problem getting worse, ensure full understanding of the problem and verify that implemented solutions are satisfactory.

1.3 Understand the Problem

1.3.1 Comparative Analysis

Once you have reviewed the problem description, you can undertake a comparative analysis. A comparative analysis will help you identify relevant changes in a change-induced situation. Then you can reduce the number of possibilities that you must consider to determine root-cause. To complete a comparative analysis: