

Procedure 10.2

Nonconformity and Corrective Action

This procedure addresses ISO 9001:2015, clause 10.2.

The purpose of this procedure is to prevent problems from occurring or recurring by correcting their root cause.

Responsibilities

Management is responsible for corrective and preventive action in their functional areas.

Forms

Corrective and Preventive Action Plan

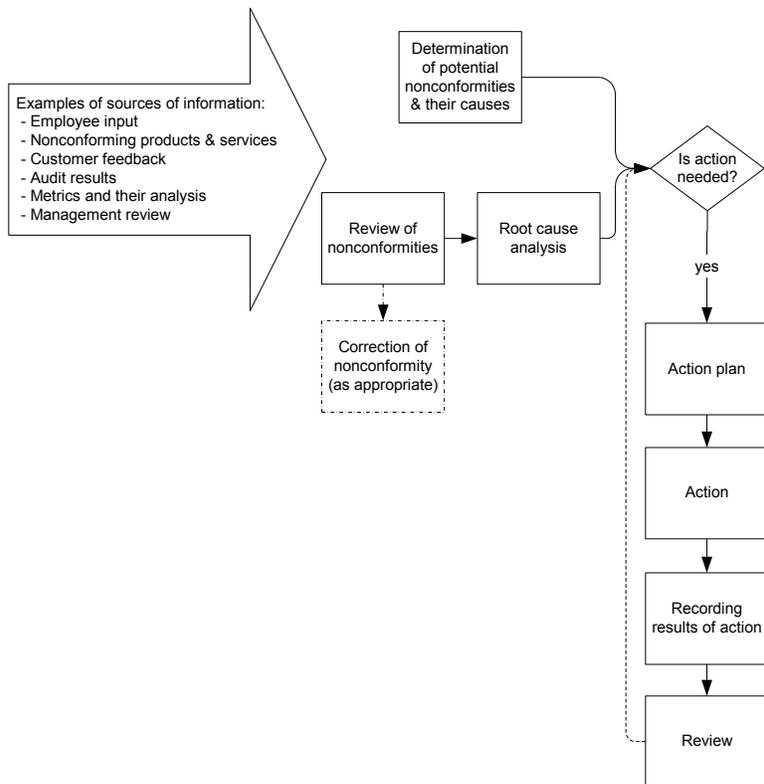
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Overview

Corrective and preventive action is an important tool for the improvement of business processes.

- **Corrective Action**
Corrective action addresses problems that have already occurred by correcting the root cause and, thus, preventing the problem from reoccurring in the future.
- **Preventive Action**
Preventive action addresses potential problems and prevents them from happening.

Corrective and preventive action refers to the improvement of **processes**.



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Management engages in a formal corrective and preventive order to achieve continual improvement.

Step 1: An existing or potential problem is identified

The corrective and preventive action process starts with an existing or potential problem. Existing or potential problems are identified through various sources, including:

- Employee input
- Nonconforming processes, products and services
- Customer feedback
- Audit results
- Metrics and their analysis
- Management review

Existing problem

Existing problems are reviewed and handled appropriately. Appropriate handling may include:

- a) the immediate correction or repair of that particular problem
- b) dealing with any consequences (according to other procedures in the manual).

Note that this is not corrective action, as corrective action is taken to prevent future recurrences.

Potential problem

Potential problems and their causes are determined based on information sources as described above.

Step 2: Root cause analysis

Root cause analysis is the systematic identification of the root cause of a problem. There are many ways to determine the root cause of a problem. The "5 W Approach":

Any root cause analysis starts with the proper identification of the problem. Ask "why?" five times (e.g., "why did the nonconformity xyz." – "why did xyz occur?" - and so on).

Step 3: Do we need to do anything?

Once the root cause is determined, management evaluates the risk of the problem and determines if it is necessary to prevent the problem from occurring or recurring in the future.

Management makes a judgment call under consideration of the risk, customer satisfaction and the absolute importance of safety: does the benefit of the action outweigh the cost of the action?

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