Corrective Action

ISO 9001:2015

Contents

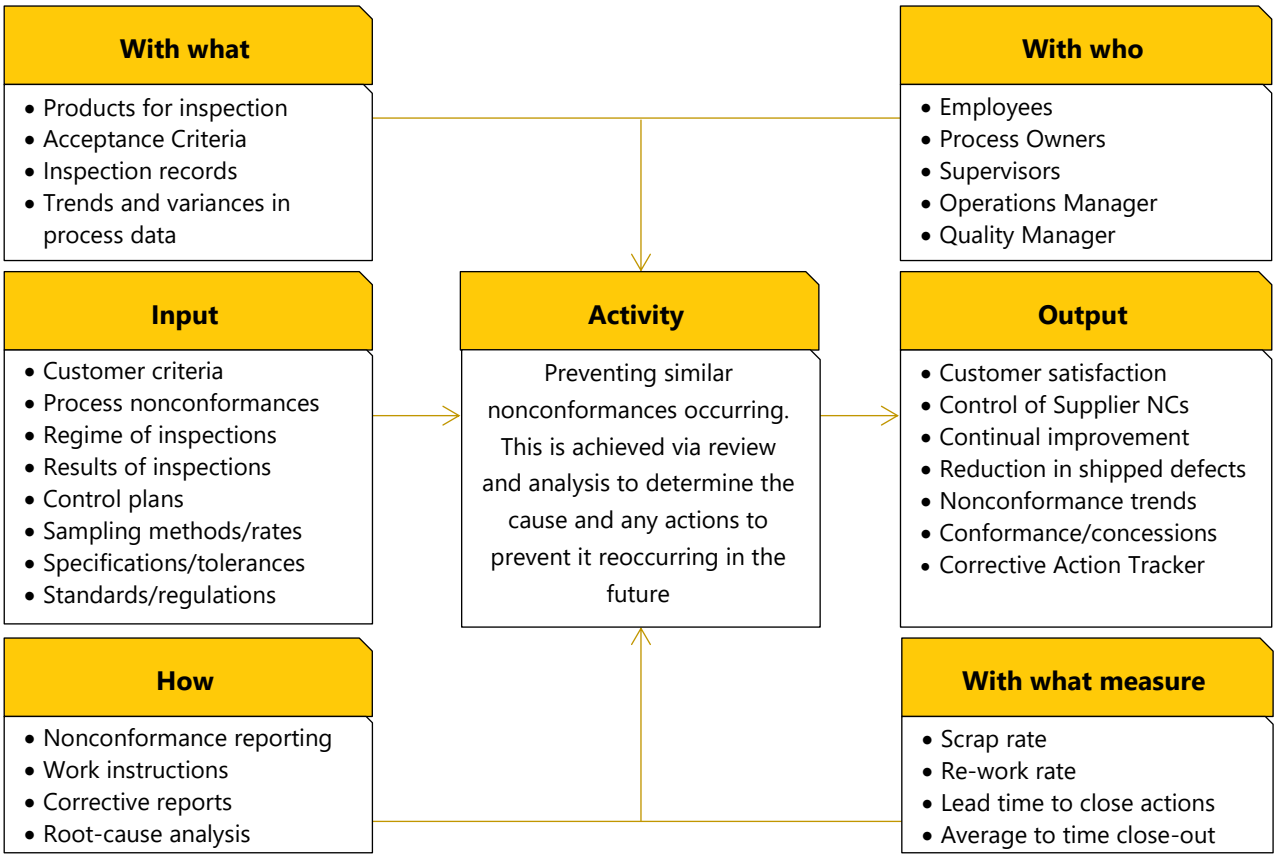
1 Procedure

1.1 Introduction & Purpose

This procedure aims to establish the process for identifying, documenting, and analyzing nonconformities and mitigating their impacts by implementing appropriate corrective actions. Your organization's quality management system is geared toward proactively eliminating actual and potential deficiencies. Repeated nonconformities in processes are investigated, and action is implemented to prevent occurrence.

1.1.1 Process Overview

The process overview (turtle diagram) provides internal and external auditors, process owners, and participants an overview of the elements that are required by the quality management system's nonconformity and corrective action process:



1.1.2 References

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2015	Quality management systems	Requirements
BS EN ISO 9001:2024	Quality management systems	Amendment 1 Climate action changes 2024-02
BS EN ISO 9004:2018	Quality management	Guidance to achieve sustained success
BS EN ISO 19011:2018	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

Term	Definition
Containment action	Action taken to minimize the effect of the nonconformity on the stakeholder
Root-cause analysis	Action to establish how the nonconformity occurred during manufacture/after delivery
Corrective action	Action to eliminate the root cause of a nonconformity and to prevent recurrence

1.2 Application & Scope

Any corrective action taken to eliminate the cause of nonconformity is appropriate to the magnitude of the problem while also being in proportion to the risks presented by the nonconformity. The root causes of process nonconformities, including those arising from complaints, are investigated, and actions are implemented to prevent their recurrence. This procedure applies to:

1. **Processes that produce negative results and repeated defective outputs**. Any process that does not produce an acceptable product or service should be reported by any employee through the initiation of the *Corrective Action Report* form;
2. **Services provided by external sources**. If a service provided from an external source does not comply with the requirements of the purchase order and/or contract, then the *Supplier Corrective Action Request* form is completed and submitted;
3. **Internal issues and internal audits**. During routine internal audits and inspections, processes, procedures, and work instructions may be identified as nonconforming. These are initially documented in the internal audit reports.

This procedure focuses on satisfying ISO 9001 Clause 10.2, which requires our organization to evaluate the need for *corrective action* to prevent the recurrence of a nonconformity.

1.3 Roles, Responsibilities & Authorities

Regardless of the scope, roles and responsibilities are agreed upon by Top management and are incorporated into existing job descriptions, and are included in yearly objectives. All roles and designated person(s), team(s), or group(s) are communicated across your organization to encourage or improve collaboration and cooperation for cross-functional process activities.

1.3.1 Roles & Responsibilities

The roles and responsibilities associated with the nonconformity and corrective action management process are defined in the context of the management function and are not intended to correspond with organizational job titles. A role refers to a set of connected behaviors or actions performed by a person, team, or group in a specific context.

1.3.1.1 Employees

All Employees must report any nonconformance that may have caused customer dissatisfaction, process or service nonconformance, or failure to meet targets.

Specific responsibilities include:

1. Follow this procedure upon detecting nonconformities or when a customer/client has requested a review of a work package or service delivery;
2. Assist in the implementation of corrective action plans when required.

1.3.1.2 Process Owners

A Senior Manager who provides management control and guidance for the process. Accountable for process design, operation, and improvement. Coordinates with supervisors in other departments to ensure common practices are followed where appropriate. Has the responsibility and accountability to ensure the progression of the process.

Specific responsibilities include:

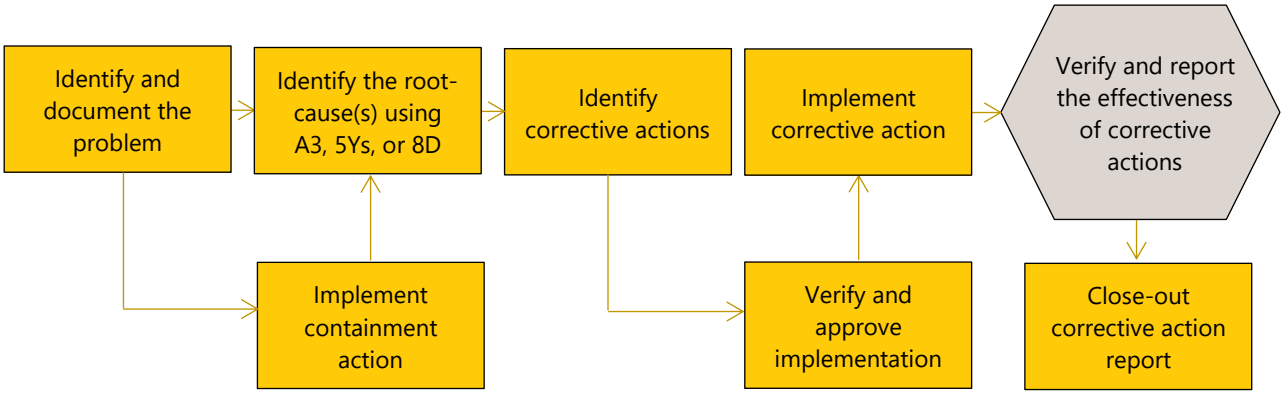
1. Responsible for implementing a specific work process and has the authority and ability to make necessary changes/improvements to the work process identified;
2. Assist in the development and implementation of corrective action plans;

1.4 Document the Corrective Action

1.4.1 General

The Quality Manager reviews any issues raised by each *Corrective Action Report* to identify the level of action required by entering the details into the *Corrective Action Tracker*. Repeated nonconformities of the exact nature or significant deviations from procedures or policies are reported to Top management for action and resolution.

Your organization's nonconformity and corrective action process combines organizational management techniques with individual tools to create a robust closed-loop process to:



Based upon the information captured from the *Corrective Action Report*, the *Corrective Action Tracker* prompts the user to use 1 of 3 increasingly detailed problem-solving methods (e.g., A3, 5-whys, or 8D), depending on the severity or complexity of the nonconformity. This ensures that the appropriate tools and techniques are applied for problem-solving and formulating corrective action.

1.4.2 Define the Problem

Senior Management will be actively involved in any major corrective actions, ensuring that all actions agreed by any multi-functional teams are carried out entirely. Major corrective actions and improvements are placed on the continual improvement programme and reported at Top management review meetings.

A corrective action report form is issued for repetitive, ongoing problems during our production processes and issues that majorly impact customer end product delivery and quality management system noncompliances. Other nonconformities outside these criteria are controlled through the remedial action system. All corrective action reports raised are categorized as follows:

High - A problem that results in major/significant impact or is repetitive. Requires a root-cause analysis, corrective and preventative action(s)
Medium - A problem that results in moderate impact. Requires containment and root-cause analysis, and corrective actions when appropriate
Low - A low-level problem typically closed to 5-whys or 8D, requires cause analysis, containment, and trending
OFI - Improvement opportunity that does not need correction but instead can be enhanced, improved, or made more efficient

The Quality Manager will review any issues raised and update the nonconformity report to identify the cause and the level of action required. Repeated nonconformities of the same nature or significant deviations from procedures or policies are reported to Top management for action and resolution. The Quality Manager is responsible for: