Quality Procedure

Non-conformity & Corrective Action

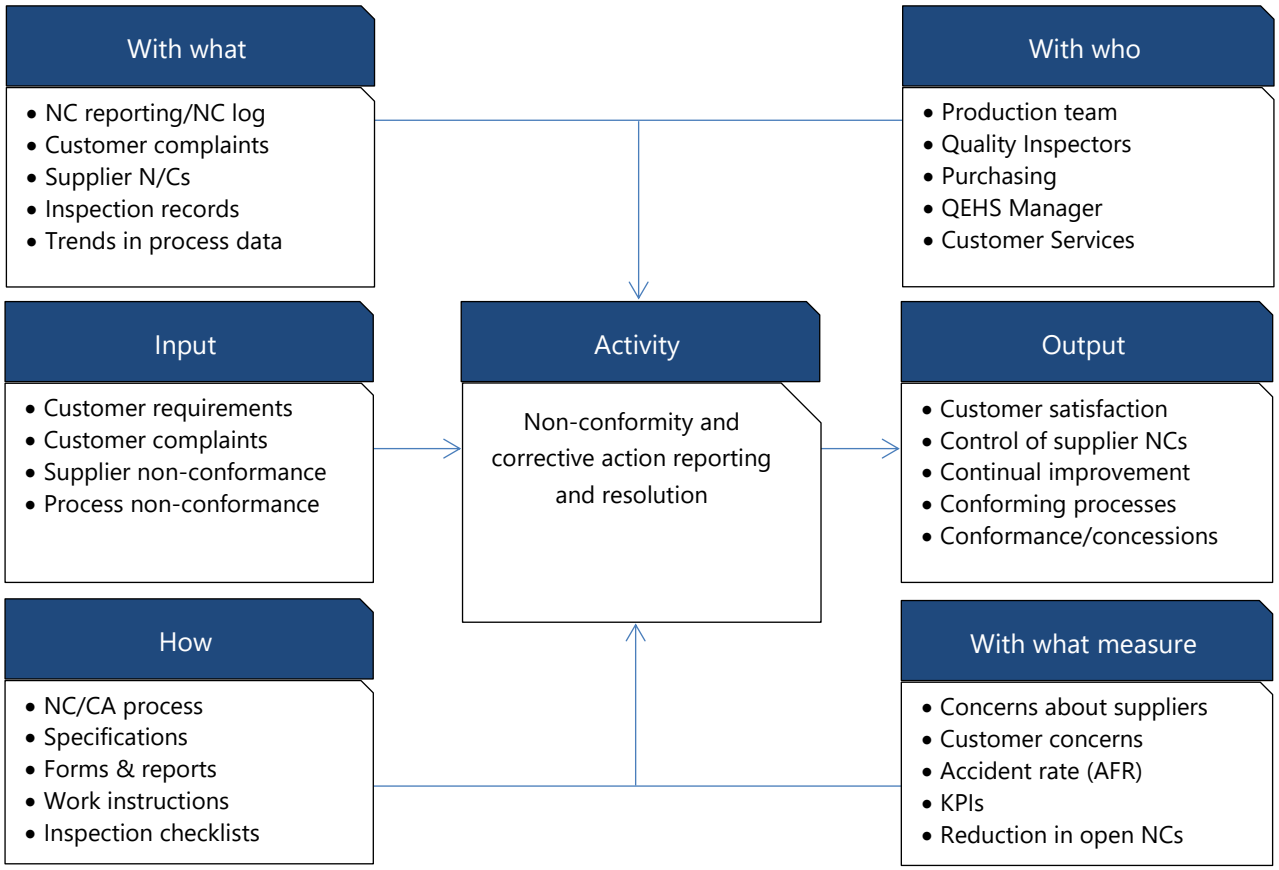
Table of Contents

1 Non-conformity & Corrective Action

1.1 Introduction & Purpose

The purpose of this procedure is to establish the process for identifying, documenting and analyzing non-conformities and implementing appropriate corrective action(s). Your organization's management system is geared toward the proactive elimination of actual and potential failures. Non-conformities arising from complaints, product and service outputs, and management system processes are investigated and action implemented to prevent their occurrence.

1.1.1 Process Turtle Diagram



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 9004:2000	Quality management systems	Guidelines for performance improvements

1.1.3 Terms & Definitions

Term	ISO 9000:2015 Definition
Non-conformity	Non-fulfilment of a requirement (3.6.4)
Defect	Non-conformity (3.6.9) related to an intended or specified use
Corrective action	Action to eliminate the cause of a non-conformity (3.6.9) and to prevent recurrence

1.2 Application & Scope

This procedure is applicable to management system compliance issues, sourced through internal and external audits, customer complaints, or internal reporting. Any corrective action taken to eliminate the cause of non-conformity is appropriate to the magnitude of the problem whilst also being in proportion to the risks presented by the non-conformity. This procedure applies to the following types of non-conformity:

1. Processes producing negative results and defective outputs. Any process which does not produce an acceptable product or services should be reported by any employee through the initiation of the *Corrective Action Request*.
2. Internal issues and quality audits. During the process of conducting internal quality audits, processes may be identified as being non-conforming. These are documented on the *Internal Audit Checklist*, *Internal Audit Reports*, and *Corrective Action Requests*.

The root causes of process non-conformities, including those arising from complaints are investigated and actions implemented to prevent their recurrence.

1.3 Responsibilities

All Employees and Process Owners are required to:

1. Follow this procedure upon detecting non-conformities.
2. Implement necessary actions to achieve resolution;

The Quality Manager is required to:

1. Determine the root causes of non-conformities;
2. Maintain a system for reporting and record keeping;
3. Raise and record concessions;
4. Review the effectiveness of corrective actions taken.

1.4 Non-conformities

1.4.1 Process & QMS Non-conformities

Where problems exist in our process or in our management system, employees are authorized to report the issue to the Quality Manager via the *Corrective Action Report* or the *Internal Audit Report*. The Quality Manager reviews the problem and decides whether to implement any process or system changes necessary using any specialists as required.

The Quality Manager reviews any issue raised by the non-conformity, including those arising from complaints to identify root cause and level of action required. Repeated non-conformities of the same nature or which are significant deviations from procedures or the policies are reported to Top management for action and resolution. Corrective action is taken as a result of:

1. Customer complaints or returns;
2. Non-conforming product received from suppliers;
3. In-process concerns;
4. Internal and external audits;
5. Concerns about management system stability.