

Nonconforming Product Outputs

ISO 9001:2015 & ISO 14001:2015

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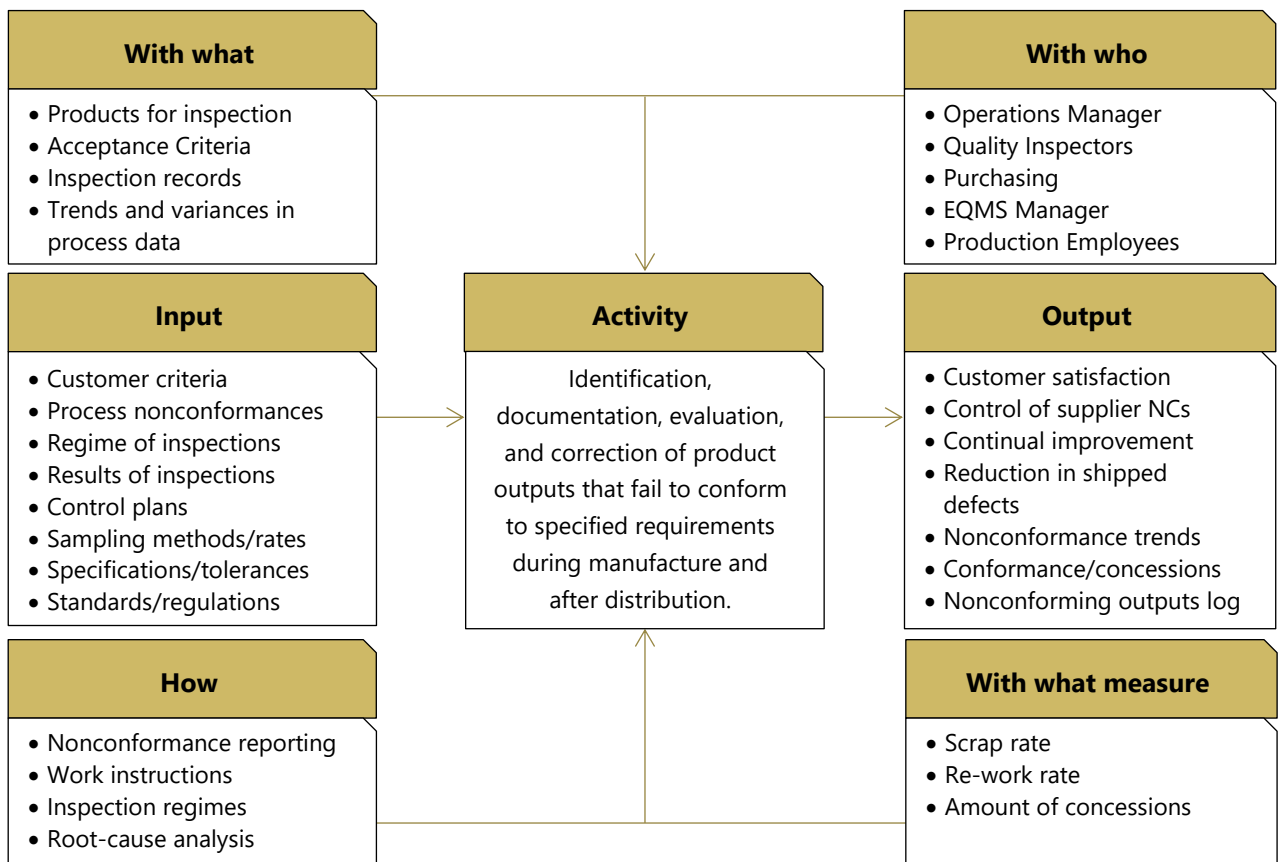
1 Nonconforming Product Outputs Procedure

1.1 Introduction & Purpose

This procedure aims to establish the process for identifying, documenting and correcting product outputs that do not conform to requirements and to prevent reoccurrence where necessary. The document also lists the specific steps required for the definition of product defects, the evaluation of root-causes, and the development of specific corrective action as required.

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 nonconforming products 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 14001:2015	Environmental management systems	Requirements
BS EN ISO 9004:2018	Quality management systems	Guidelines for performance improvements
BS EN ISO 19011:2018	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

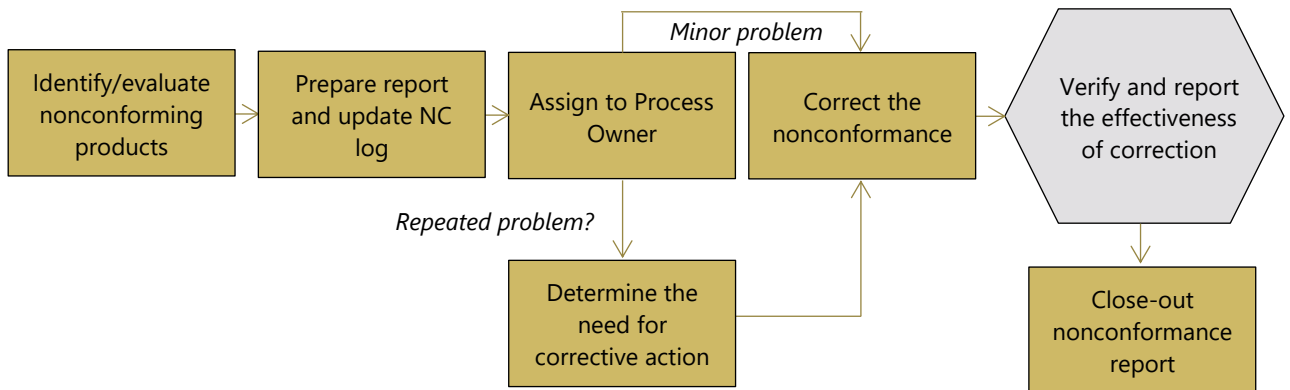
Term	ISO 9000:2015 Definition
Nonconformity	Non-fulfillment of a requirement
Defect	Nonconformity related to an intended or specified use
Correction	Action to eliminate a detected product nonconformity during manufacture/after delivery

Once the roles and responsibilities are assigned, the assignees are empowered to execute the role activities and given the appropriate authority to hold other people accountable. **Your organization** uses an authority matrix as a tool to help understand which parties need to be involved in correction activities.

1.4 Correcting Nonconforming Products

1.4.1 General

Your organization's nonconforming product outputs process combines organizational management techniques with individual tools to create a robust closed-loop process in order to:



Your organization operates two processes for controlling nonconforming products and undertaking corrective action, as each process has separate objectives. The process for nonconforming product reporting helps to correct an instance of service nonconformity, working as part of our customer complaints process when the nonconformance:

1. Is easy to apply specific correction;
2. Is isolated;
3. Is minor;
4. Is not a design issue;
5. Is not a manufacturing issue.

The disposition and correction decisions are made on two different levels depending on the nature of the nonconformity and the decision itself. When it is obvious that the product must be scrapped or resupplied or when it can be easily reworked without degrading its quality, the **Operations Manager** and the **EQMS Manager** are authorized to approve the necessary action.

1.4.2 Identify Nonconforming Products

1.4.2.1 In-process Inspection

Your organization identifies the actions necessary to contain the effect of the nonconformity on other processes or products through data analysis. It includes timely reporting of nonconformities affecting products delivered to the customer and relevant interested parties within (7) business days.

Whenever a nonconformity is identified during production, assembly, handling, storage, first-article inspection, in-process inspection, and final inspection phases, it is dealt with in one or more of the following ways and documented in the Nonconforming Product Report form:

1. Segregation at the workstation until moved to designated locked areas;
2. Segregation in the stock area for engineering analysis;