Quality Procedure

Non-conformity & Corrective Action

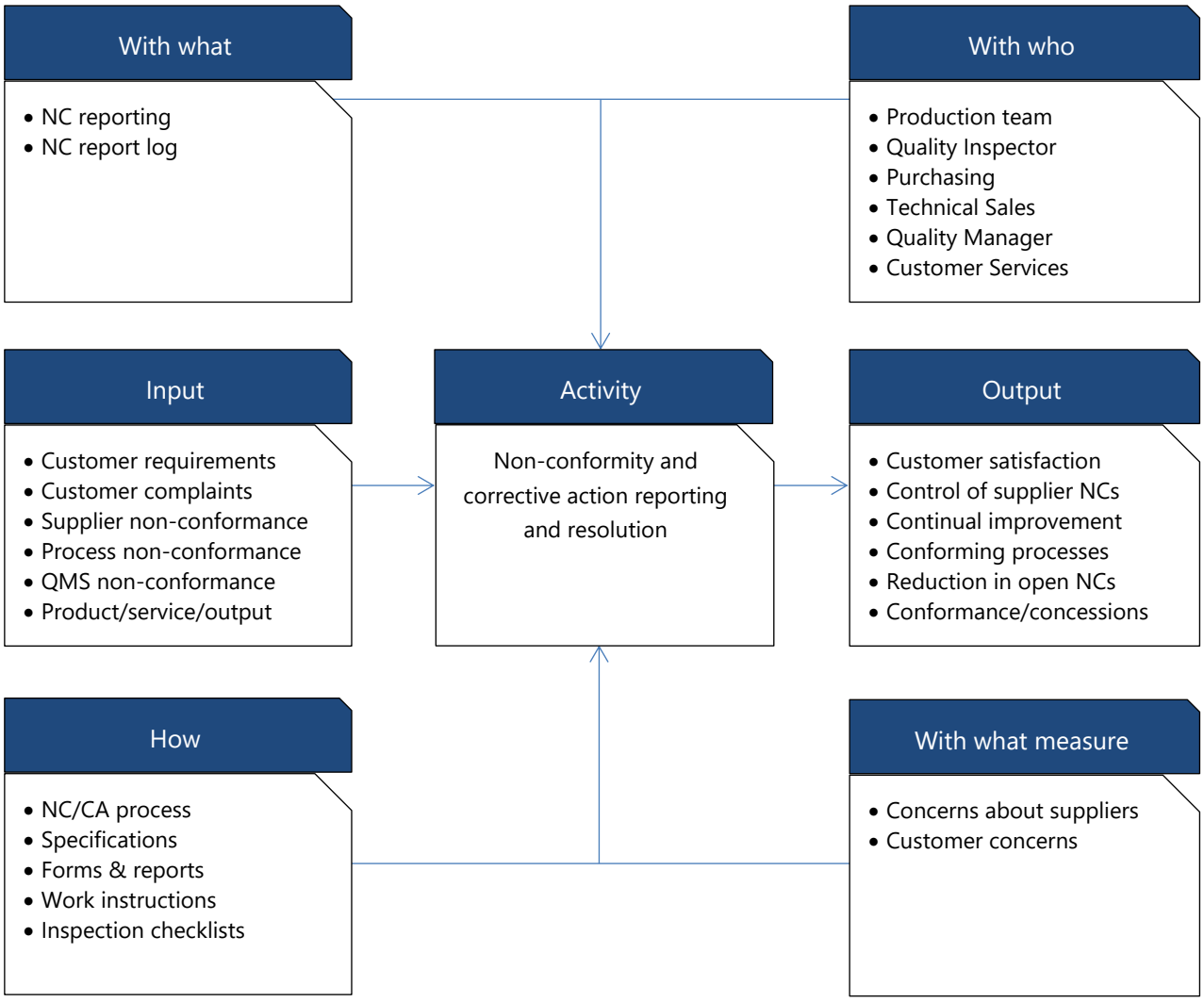
Table of Contents

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 mitigating their impacts by implementing appropriate corrective actions. Your organization's quality management system is geared toward the proactive elimination of actual and potential deficiencies. Non-conformities in products, services, processes and our management system are investigated and action implemented to prevent their occurrence.

1.1.1 Process Activity Map



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
BS EN ISO 19011:2011	Auditing management systems	Guidelines for auditing

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
Conformity	Fulfilment of a requirement (3.6.4)
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 all non-conforming products, services, processes and any aspect of our quality management system. 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. Root causes of process non-conformities, including those arising from complaints are investigated and actions implemented to prevent their recurrence. This procedure applies to:

1. **Processes producing negative results and defect 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 Form.
2. **Incoming products from suppliers or customers**. Product received from suppliers which is found to be non-conforming are identified, reported and returned to the supplier. Recurring problems with discrepant materials from a vendor are reported to the Purchasing Department.
3. **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 Corrective Action Request Form is completed and submitted.
4. **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 Report Form, and the Corrective Action Request Form

1.3 Responsibilities

All employees & Process Owners are required to:

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

The Quality Manager <amend as appropriate> is required to:

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

1.4 Non-conformity Process

1.4.1 Discovering a Non-conformity

Any product, material or service that is found to be suspect or non-conforming at any point during the manufacturing or development process is removed from work in progress, and is clearly identified with a **REJECT** label. The product or material will either be held in the Quarantine Area to await disposition. Disposition of a non-conforming product, service or output will either be:

1.7 Non-conformity & Corrective Action Process Map