Quality Procedure

10.2 Nonconformity & Corrective Action

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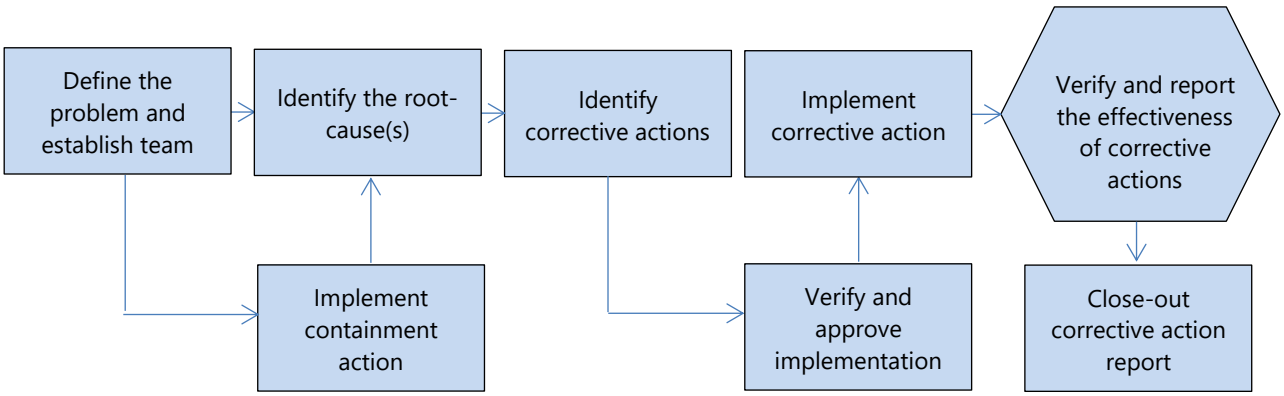
1.4 Document the Corrective Action

1.4.1 General

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



The Quality Manager reviews any issues raised by each nonconformity to identify root-cause and level of action required. Repeated nonconformities of the same nature or which are significant deviations from procedures or the policies are reported to Top management for action and resolution.

1.4.2 Process Nonconformances

Noncompliances are failures within the management system and usually these relate to differences between how duties are being carried out and those set out in procedures.

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 (CAR)* form or the *Internal Audit Report* form. 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 nonconformity, including those arising from complaints to identify root cause and level of action required. Repeated nonconformities 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. In-process concerns;
2. Internal and external audits;
3. Concerns about management system stability.

1.4.3 Customer Returns

Upon receipt of notification of a product rejection by the Customer, the Goods Inwards Department passes the product and the paperwork onto the Quality Manager for review and disposition.

The rejected parts will be placed in the returns bay and the Operations Manager or Quality Manager will identify the parts with a **Reject Tag** and placed in the quarantine area prior to its disposition and the details are entered onto nonconformity report.

Your organization ensures that staff of all professional levels are trained, empowered, and competent to properly apply basic problem-solving tools and root-cause analysis techniques. The process is monitored by Quality Manager for effectiveness in addressing the cause of the original nonconformance

The Quality Manager reviews any issues raised and completes a nonconformance report to identify root cause and evaluate the level of action required. Repeated nonconformances of the same nature or significant deviations from procedures or the policies are reported to Top management for resolution.

The corrective action will explore the root-cause of the nonconformance and provide a plan to eliminate the root-cause. Investigate reasons for the nonconformance, using e.g., 3W, 5-whys, 8D, FMEA, Fish-bone analysis, in combination with other preferred root-cause analysis tools.

1. Interview personnel concerned;
2. Review records;
3. Verify with Customers/clients.

Look closely at what 'checks' you are doing to detect any nonconformances before and after delivery to the Customer/client. Focus very closely on your existing manufacturing process and accompanying procedures.

1. Does it clearly cover all the quality checks that must be done?
2. Does it cover what someone must do if a quality check isn't passed? (e.g., clarify with client, get new parts, verify, retest, etc?)

In any event the following steps are taken to complete the root-cause analysis:

1. Determine the problem;
2. Review data about the problem including control charts and a review of the outcomes;
3. Determine the source of the problem;
4. Determine the best procedures to eliminate the problem;
5. Implement procedural changes;
6. Monitor the outcome of the solution and make changes if necessary;
7. Document the entire process;
8. Send documentation to all involved parties and the Management Review committee.

Determine the root-cause of nonconforming products, record in the *NC & Corrective Action Log*. Prepare a summary of the nonconforming products at the end of the month for reference purposes. If deemed applicable, the root-cause will be discussed at the next Management Review meeting, and necessary actions (if applicable) are communicated to staff members concerned.

Search for all possible causes that could explain the occurrence of the problem (and why it has not been detected by the defined quality assurance measures). Determine the probable cause(s) and evaluate, through comparisons with the problem description and the available data, whether the most probable cause is the root-cause.

Potential root-causes that are under our control are validated. Your organization applies the following validations to our answers for root-causes by asking the following questions for every possible root-cause identified at all levels of the 5-Whys:

1. It there any proof, something you can measure or observe, to support the root-cause determination?

Key Performance Indicator	Definition
Total number of corrective actions	Number of open/closed/overdue corrective actions/total number for a given period/process/lot/batch
External providers' nonconformities	Ratio between the number of supplier nonconformity reports issued to suppliers by the entity during a period in relation to number of production hours over the same period x multiplied by 1000.

The following table provides examples of metrics related to nonconformances. There is no obligation to apply all examples, each organization is free to define their own KPIs and metrics.

Metrics	Definition
Nonconformity processing time	Average time to close all related actions after the opening date (measured over x rolling months)
Complaint processing time	Average time to close all related actions after the opening date (measured over x rolling months)
Rate of total cost of non-quality	Sum of all costs related to scrap, rework and repair, modifications, penalties, extra warranty costs in relation to sales revenue
Claim and warranty costs	Total costs of claim and warranty in relation to sales revenue
Nonconformance-costs before delivery	Nonconformance-costs (e.g., all kind of unplanned costs) before delivery in relation to the revenue of the product

1.6.2 Status of Corrective Actions

Corrective actions and their status are tracked in the *CAR & SCAR Log* and supported by a unique identification code. The following status codes are used to reflect the status of the corrective action request:

- **Open** – The actions to correct the nonconformance have been acknowledged;
- **In-Progress** – Work is in progress to fulfil the correction request;
- **Closed** – The nonconformance and/or correction has been completed and verified;
- **Cancelled** – The nonconformance and/or corrective action has been cancelled.

The status of the corrective action will 'Open' until such time as work to correct the nonconformance begins, then the status becomes 'In-Progress'. This means the status stays 'In-Progress' until the associated corrective action is verified. The status of the nonconformance would then change to 'Closed'. Should the corrective action request be withdrawn, the status is set to 'Cancelled'.

1.7 Documentation

Documentation concerning the nature of the corrective actions taken, including Customer/client approvals or concessions obtained, are maintained and uploaded into the appropriate databases. This will ensure accuracy, communication, consistency, and agreement upon the understanding the root-causes, and to support organizational knowledge.

All documentation and records generated by the nonconformity and corrective action process is retained and managed in accordance with the *Documented Information Procedure*, by the Document Controller on the local area network.