Nonconformity & Corrective Action

ISO 9001:2015 & ISO 14001:2015

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6. Review the effectiveness of corrective actions taken.

1.3.1.7 Supplier

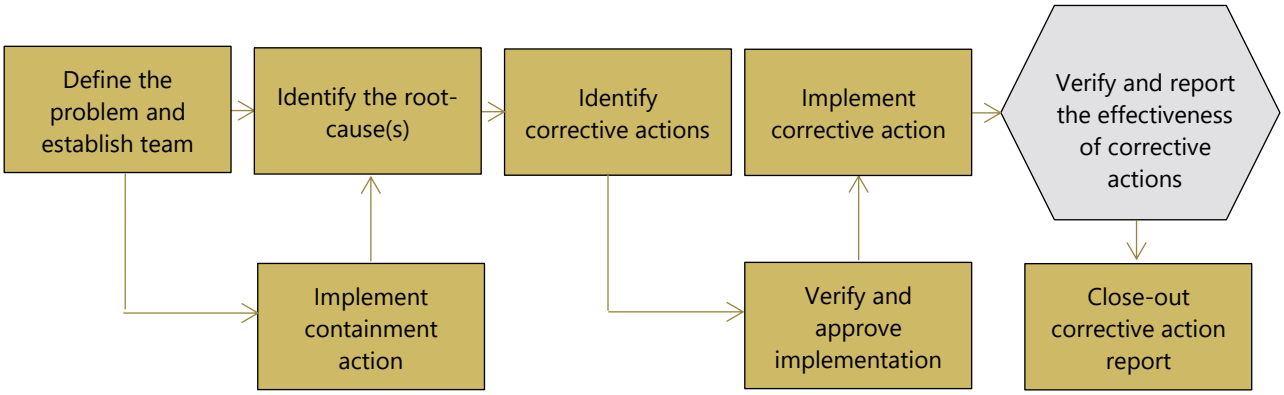
All Suppliers are required to respond to SCAR initiator with timelines indicated on SCAR form as to the feasibility of completion. Follow the description on the form on how to complete SCAR.

1. Utilize quality tools – e.g.: 5Why, Ishikawa - to assist with root-cause Analysis;
2. Follow up and communicate progress on CA(s) and their verification method to SCAR initiator;
3. Implement verified permanent corrective actions;
4. Return completed SCAR (or 8D) form to SCAR Initiator;
5. Handle any charge-back requests as a result of nonconformance in a timely manner.

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 EQMS 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 policies are reported to Top management for action and resolution.

1.4.2 Process Nonconformances

Noncompliances are failures within the management system and usually 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 EQMS Manager via the *Corrective Action Report (CAR)* form or the *Internal Audit Report* form.

The EQMS Manager reviews the problem and decides whether to implement any process or system changes necessary using any specialists as required.

The EQMS Manager reviews any issue raised by the nonconformity, including those arising from complaints, to identify root-cause and the level of action required.

Repeated nonconformities of the same nature or which are significant deviations from procedures or 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.

1.5 Problem Solving

1.5.1 General

Your organization ensures the focus of the corrective action process will stop the recurrence of serious nonconformities, by removing their root-causes. A nonconformance will require formal root-cause analysis and corrective action when:

1. There is an adverse impact on the quality of products:
    a. No easy/specific method of correction/is complex;
    b. Safety impact (product/personal);
    c. Customer complaints;
    d. Product strength, performance, and/or reliability issue;
    e. Critical limits and tolerance exceeded;
    f. High impact on production/maintenance operations:
        i. Stop the line; prevent the next operation from occurring, etc.;
        ii. Regulatory authorities and/or Customer dissatisfaction;
        iii. Costs issue generated to the Customer or organization;
        iv. Disruption of Supplier's process or Customer's operations.
    g. Recurring (based on valid analytical methods);
    h. Severe and continuous;
    i. Repetitive problems to one part or similar operations and processes;
    j. Difficult to detect;
    k. By Customer request;
    l. A design issue;
    m. A manufacturing/processing issue.
2. There is potential for the nonconformance to recur somewhere else in the quality system;
3. There are reports of problems with procedures, processes, forms, work instructions, or guidelines:

Your organization ensures that root-cause analysis is considered when undesirable conditions, defects, and failures are detected and the cause is unknown, not obvious, or inconclusive. The decision to apply or not to apply the process is made by the Operations Manager and the EQMS Manager based on the risk level and whether the associated risk is acceptable.

1.5.2 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 onto the continual improvement programme and reported on at Top management review meetings.

Corrective Action Report (CAR) form is issued for repetitive, ongoing problems during our production processes and issues having a major impact on 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 having major or minor effects:

- **Major**: Where the procedure contradicts working practices and/or working practices do not reflect standard requirements or Customer complaints which require additional corrective action;
- **Minor**: Where the system procedure or process is not being fully adhered to, equipment breakdown or failures which do not affect operational activities. A nonconformance that does not have an immediate impact on the stability of the management system.