Nonconformity & Corrective Action

ISO 14001:2015

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1.3.1 Roles & Responsibilities 4

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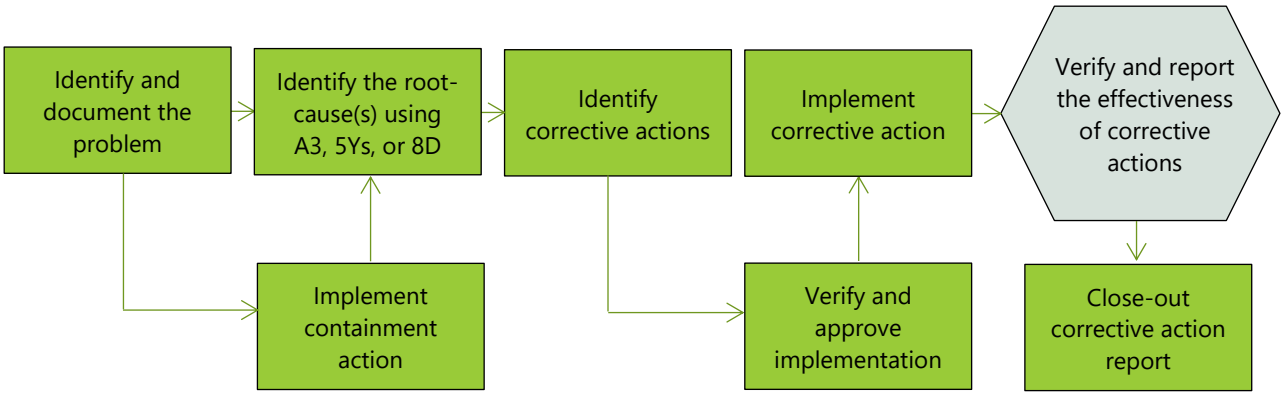
nature or which are significant deviations from procedures or policies are reported to Top management for action and resolution.

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:



Based upon the information captured from the *Corrective Action Report*, the *Corrective Action Tracker* prompts the user to use 1 of 3 increasingly detailed problem-solving methods (e.g. A3, 5-whys, or 8D), depending on severity or complexity of the nonconformity. This ensures the appropriate tools and techniques are applied for problem-solving and the formulation of corrective action.

1.4.2 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 form is issued for repetitive, ongoing problems during our production processes and issues having a major impact on stakeholders, and environmental management system noncompliances. Other nonconformities outside these criteria are controlled through the remedial action system. All corrective action reports raised are categorized:

High - A problem that results in major/significant impact or is a repetitive problem. Requires a root-cause analysis, corrective and preventative action(s)
Medium - A problem that results in moderate impact. Requires containment and root-cause analysis, and corrective actions when appropriate
Low - A low-level problem typically closed to 5-whys or 8D, requires cause analysis, containment and trending
OFI - Improvement opportunity that does not need correction but rather, can be enhanced, improved, or made more efficient

The EMS Manager will review any issues raised and update the nonconformity report to identify root-cause and the level of action required. Repeated nonconformities of the same nature or significant deviations from procedures or policies are reported to Top management for action and resolution. The EMS Manager is responsible for:

a) Identifying the root-cause(s) of the nonconformity;
b) Identifying appropriate corrective actions (including modifying or creating new work practices);

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c) Planning and implementing corrective actions;
d) Verifying the closeout and effectiveness of corrective actions;
e) The EMS Manager verifies the implementation of corrective actions;
f) Where noncompliances are identified outside the audit process, the EMS Manager or designee documents this using the *Corrective Action Report* form as appropriate.

Where applicable, any corrective action taken and controls implemented to eliminate the cause of nonconformity is applied to other similar processes and is controlled by the EMS Manager in liaison with affected process owners. Significant actions are entered into the *Corrective Action Tracker*.

For the analysis of nonconformity, appropriate statistical and non-statistical techniques can be applied. The organization will select the appropriate methodology based on the problem's complexity. Examples of statistical techniques are:

1. Statistical Process Control (SPC) charts;
2. Pareto analysis, and data trending;
3. Linear and non-linear regression analysis;
4. Experimental design (DOE – Design of Experiments) and analysis of variance;
5. Graphical methods (histograms, scatter plots, etc.).

Non-statistical techniques include:

1. Management reviews and the results from meetings;
2. 5W2H: Who, what, where, when, why, how, and how many for both occurrence and non-detection;
3. Product review committees (internal/external);
4. Failure Mode and Effect Analysis (FMEA);
5. Fault Tree Analysis (FTA).

The EMS Manager will detect and determine the extent of the problem (place, time, quantity, number of affected components, versions, projects, vehicles, Customer sites, etc.) in order to check whether the problem is relevant to safety and if relevant stakeholders need to be informed.

1.4.3 Contain the Problem

The intent of this important step is to protect the involved stakeholder. Your organization will trigger immediate containment actions to safeguard the stakeholder and prevent the problem from affecting other stakeholders in order to limit potential liability.

A containment action may include stopping production of a known source of a problem and not shipping any parts or assemblies until the root-cause is identified.

The EMS Manager will notify personnel in the area from which the nonconformance originated that the nonconformance has occurred, including written instructions and visual aids as appropriate. Risk analysis may be used to help to determine the appropriate actions that need to be taken.

1.4.4 Determine Problem-solving Method

Upon the receipt of a *Corrective Action Report* and in order to classify its priority, your organization uses the following matrix to evaluate and select the appropriate response to the risk presented by the problem.

Depending on the level of risk, the suggested response to the nonconformance will include one of the following options: e.g., improvement activity, A3 action plan, 5-Whys Analysis, or 8D Analysis (FMEA and/or Fish-bone analysis), which may be used in combination with other preferred root-cause analysis tools.

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Priority Classification					
Legal or compliance issues?	☐ Concerns must be forwarded to Top management for review				
Safety concerns?	☐ Concerns must be forwarded to the H&S Department for review				
Repeated nonconformities in:	☐ Repeated issues must be forwarded to the EMS Manager for review				
Select	Products/services?	☐ High	☐ Medium	☐ Low	☐ OFI
	Processes?	☐ High	☐ Medium	☐ Low	☐ OFI
	EMS Management system?	☐ High	☐ Medium	☐ Low	☐ OFI

Definition	Response
High - A problem that results in major/significant impact or is a repetitive problem. Requires a root-cause analysis, corrective and preventative action(s)	Use the *F1020-04 8D Worksheet*
Medium - A problem that results in moderate impact. Requires containment and root-cause analysis, and corrective actions when appropriate	Use the *F1020-03 5-Whys Worksheet*
Low - A low-level problem typically closed to 5-whys or 8D, requires cause analysis, containment and trending	Use the *F1020-02 A3 Action Plan*
OFI - Improvement opportunity that does not need correction but rather, can be enhanced, improved, or made more efficient	Use the *F1030-01 Improvement Form*

Capture the data from the corrective action report in Part A of the *Corrective Action Tracker* to determine the most suitable problem-solving method to address the causes of the nonconformance.

1. From the corrective action report, enter the details from Section 1 into the related fields in the tracker;
2. Based upon judgement and experience, categorize the perceived risk level of the problem using the drop-down menu in Column H;
3. Classify the problem by choosing ONE option from either Column I, Column J or Column K;
4. Entering in Ys or Ns results in a risk score which ranges from 1 to 4;
5. Column M will calculate an overall risk score based upon the data previously entered.

The suggested problem-solving method shown Column N is based on the following trigger scores 1 = OFI, 2 = A3 (Who, What, When action plan), 3 = 5Y (5-Whys cause analysis) and 4 = 8-Disciplines (In-depth analysis)

1. From the corrective action report, enter the details from Section 1 into the related fields in the tracker.
2. Undertake root-cause analysis;
3. Issue the chosen root-cause analysis method to the process owner/response team for completion;
4. Once completed, update the root-cause in Part A;
5. Update the 'Corrective Action Plan' in Part B;
6. Monitor the implementation of corrective actions and verify close-out.

1.5 Undertake Problem-solving

1.5.1 General

When problem-solving activities are deemed appropriate by Top management, 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:
    a. No easy/specific method of correction/is complex;
    b. Breach of legal or compliance obligations;
    c. Safety impact (product/personal);
    d. Complaints;
    e. Product strength, performance, and/or reliability issue;

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