

Corrective Action Guidance

ISO 9001:2015 & ISO 14001:2015

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1 Root-Cause Analysis & Corrective Action

There is a clear link between ISO 9001:2015 Clause 8.7 Nonconforming Outputs and Clause 10.2 Nonconformity and Corrective Action; this guidance document provides a 6-step methodology for meeting the requirements in each of these clauses. These clauses state the requirements for the occurrence of a nonconformity and include actions to prevent a similar nonconformity or problems from occurring.

Your organization is required to take whatever action is necessary to control and correct the nonconformity, and to deal with any resulting impact by determining what caused the nonconformity and considering whether the potential for a similar problem remains.

This is done by considering whether any further action is required to prevent a similar nonconformity from arising at the same place or occurring somewhere else at some point in the future and by determining if similar nonconformities have occurred elsewhere; and consequently, whether it needs to take similar corrective action.

Taking appropriate action to address the effects of the problem may require a simple

correction by the process owner or operator where it was discovered, or if a major failure or defect exists, more significant levels of resources would be needed for problem-solving and corrective action.

There may be instances where it is impossible to eliminate the cause of the nonconformity completely, so in these instances, the best you can do is to reduce the likelihood or the consequences of a similar problem happening again in order to reduce the risk to an acceptable level.

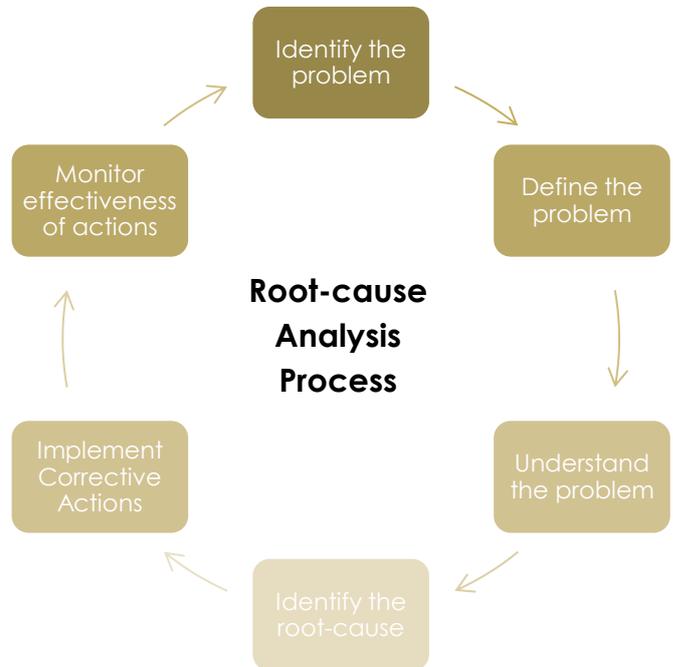
Any nonconformities and subsequent actions to prevent their reoccurrence and the effectiveness of the corrective action(s) should be duly documented and retained. Therefore, consideration should be given to developing and using the Corrective Action Tracker to capture this information.

The following guidelines are for completing root-cause analysis and corrective action responses to audit nonconformity reports (NCRs). However, these guidelines should also be applied to corrective action responses from other sources (customer complaints, internal defects, etc.)

1.1 Identify the Problem

Once a problem has been identified through inspection, customer complaints, or audit results, it should be captured using nonconformity reports (NCRs) or corrective action reports (CARs) in order to identify who is affected by the problem and what the impact is. Considering the following:

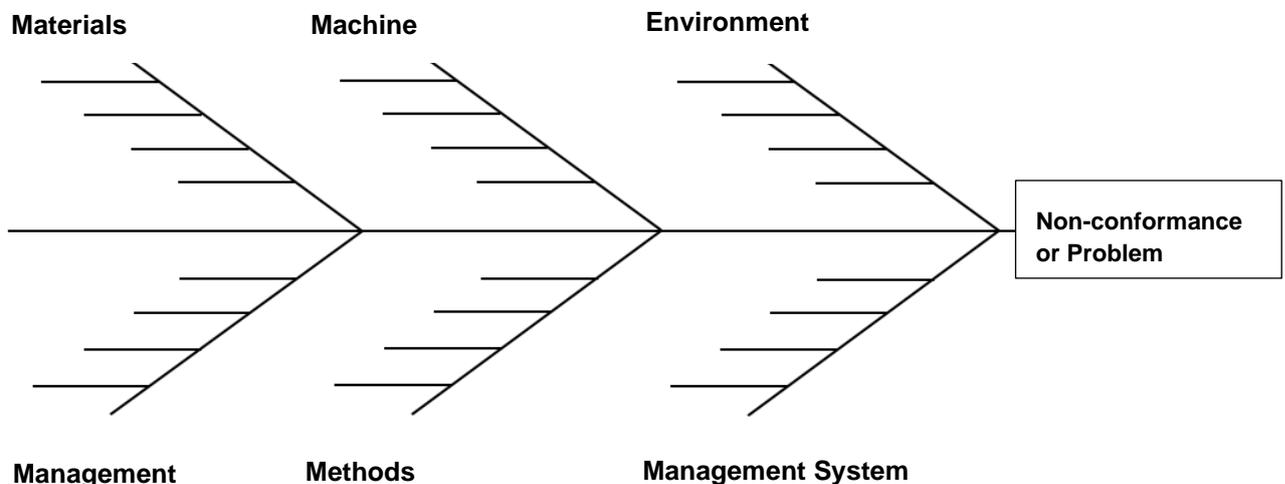
1. What are the operations, products, materials, defects, and malfunctions that may characterize the problem? What is it about?



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- a. Defective raw material, lack of raw material, or wrong type for job (meets specification?);
 - b. Batch-related problems;
 - c. Design problem (wrong material for a product, wrong specifications?);
 - d. Supplier problem (lack of control at a supplier, alternative supplier?).
2. Machine:
- a. Incorrect tool selection, defective equipment or tool;
 - b. Inadequate maintenance or design – calibration?
 - c. Equipment not used as intended by the manufacturer?
 - d. End of life, poor equipment, or tool placement.
3. Environment:
- a. Orderly workplace, job design, or layout of work;
 - b. Surfaces poorly maintained;
 - c. Physical demands of the task;
 - d. Forces of nature.
4. Management:
- a. No or poor management involvement;
 - b. Inattention to task, stress demands;
 - c. Task hazards not guarded properly;
 - d. Other (horseplay, inattention, etc.).
5. Methods:
- a. No or poor procedures;
 - b. Practices are not the same as written procedures;
 - c. Poor communication.
6. Management system:
- a. Training or education lacking;
 - b. Poor employee involvement;
 - c. Poor recognition of hazards;
 - d. Previously identified hazards were not eliminated.



Example 1 - Nonconformance: components are being delivered late to our customers.

1. **Why 1** - Why were we unable to meet the agreed-upon timeline or schedule for delivery? The job took much longer than we thought it would;
2. **Why 2** - Why did it take so much longer? Because we underestimated the complexity of the job;
3. **Why 3** - Why did we underestimate the complexity of the job? Because we made a quick estimate of the time needed to complete it, and did not list the individual stages needed to finish the project;
4. **Why 4** - Why didn't we do this? Because we were running behind on other projects;
5. **Why 5** - Why are we running behind on other projects? Root-cause - We do not allow enough manufacturing/lead time when issuing quotations to our clients.

Example 2 - Nonconformance: the machine keeps failing.

1. **Why 1** - Why did the equipment fail? Because the circuit board burnt out;
2. **Why 2** - Why did the circuit board burn out? Because it overheated;
3. **Why 3** - Why did it overheat? Because it wasn't getting enough air;
4. **Why 4** - Why was it not getting enough air? Because the filter wasn't changed;
5. **Why 5** - Why was the filter not changed? Root-cause - Because there was no preventive maintenance schedule in place informing the operator to do so.

Note that in this example, the fifth-why above suggests a broken process or a behaviour that can be altered and measured for effectiveness.

Nonconformance/Problem:		
Identify and Verify Root-cause(s). Identify all potential causes which could explain why the problem occurred. Isolate and verify the root-cause(s) by testing potential causes against the problem description and test data.		
	Why did the problem occur?	Why was that?
Why 1		
Why 2		
Why 3		
Why 4		
Why 5		
Root-cause (The lowest level of cause that can be counter-measured)		

1.4.4 Verify the Root-Cause(s)

Once you have determined the most likely cause(s), verify that it actually causes the problem. Verification is the proof you need to confirm that you have identified the root-cause. Verification is done passively and actively. Passive verification is done by observation:

1. Look for the presence of the root-cause without changing anything;