

Corrective Action Guidance

ISO 9001:2015

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1 Corrective Action & Problem-solving

Clause 10.2 Nonconformity and Corrective Action requires businesses to react to nonconformities by controlling and correcting the problem. This guidance document provides a 6-step methodology for meeting each clause's requirements. The clause states the requirements for when a nonconformity occurs and includes requirements for actions to prevent similar problems from occurring.

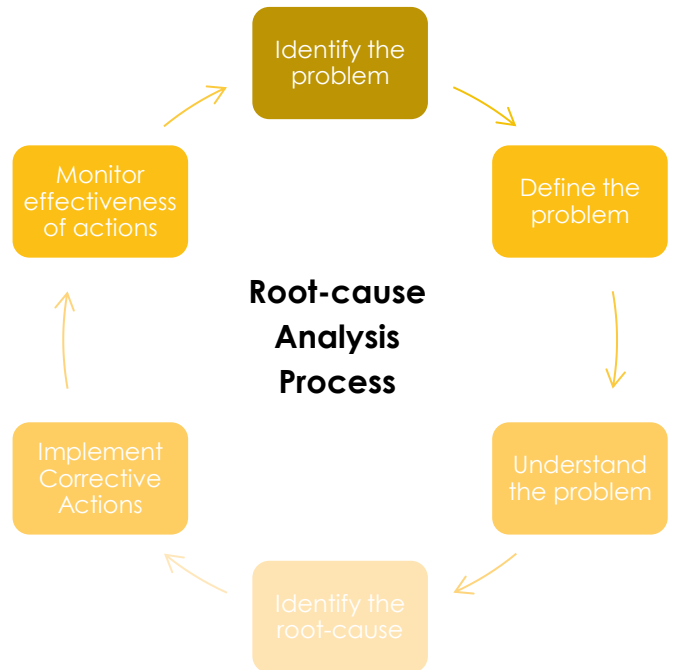
Your organization must take whatever action is necessary to control and correct the nonconformity and to deal with any resulting impact by determining what caused the nonconformity and considering whether the potential for a similar problem remains.

This is done by considering whether any further action is required to prevent a similar nonconformity from arising at the same place or somewhere else in the future and determining if similar nonconformities have occurred elsewhere and 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 completely eliminate the cause of the nonconformity; in these instances, the best thing to do is to reduce the likelihood or the consequences of a similar problem happening again to minimize the risk to an acceptable level.

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



1.1 Using the Corrective Action Tracker

1.1.1 Part A – Problem Definition

- Enter the Data from the Corrective Action Report;
- Capture the data from the corrective action report in Part A to determine the most suitable problem-solving method to address the causes of the nonconformance;
- From the corrective action report, enter the details from Section 1 into the related fields in the tracker;
- Based upon judgment and experience, categorize the perceived risk level of the problem using the drop-down menu in Column H;
- Classify the problem by choosing ONE option from either Column I, Column J, or Column K;

- Entering in Y's or N's results in a risk score that ranges from 1 to 4;
- Column M will calculate an overall risk score based on the data previously entered;
- The suggested problem-solving method shown in 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).

CAR ID.	Process Name	Reported By	Date Found	How was the NC detected?	Description of the Issue	Perceived Root-cause	Perceived Risk Level	Compliance issue?	Safety Concern?	Repeated NC?	Actual Risk	Suggest Method
1	Facilities & Maintenance	Auditor	25-Feb-23	Audit - Internal	Design review minutes not authorized prior to release to client	Human - Supervisor did not find the error	2	N	N	Y	3	5Y
2	Storage, Packing & Shipping	Customer	20-Mar-23	Feedback - Customer	Incorrectly shipped item	Human - Inadequate training	1	N	Y	N	4	8D
3	Production/Manufacturing	QC Inspector	12-Apr-23	First article inspection	Item incorrectly manufactured, out tolerance with specification	Environment - Job design/layout of work	2	Y	N	N	3	5Y
4	Procurement & Supply	Supplier	09-May-23	Audit - Internal	Product codes on purchase order are incorrect	Human - Inadequate training	1	N	N	Y	4	8D
5	Business Planning	Man/Manager	12-May-23	Feedback - Stakeholder	Product codes on purchase order are incorrect	Human - Supervisor did not find the error	1	N	Y	N	2	A3
6	Sales & Marketing	Customer	28-May-23	Feedback - Customer	Product codes on purchase order are incorrect	Human - Inadequate training	2	Y	N	N	3	5Y
7	Production/Manufacturing	ProManager	02-Jun-23	In-process inspection	Product codes on purchase order are incorrect	Machinery - Defective equipment or tool	1	N	N	Y	2	A3
8	Operational Planning	QuaManager	19-Jun-23	First article inspection	Product codes on purchase order are incorrect	Human - Poor recognition of hazard	1	N	N	N	1	OFI
9	EOMS & Processes	Auditor	30-Jun-23	Audit - Internal	Product codes on purchase order are incorrect	Human - Inadequate training	1	Y	N	N	2	A3
10	Order/Quote Fulfillment	Supplier	02-Jul-23	Audit - Internal	Product codes on purchase order are incorrect	Process - Product failure risk or liability risk	1	N	N	N	1	OFI
11	Order/Quote Fulfillment	ProManager	14-Jul-23	Feedback - Employee	Product codes on purchase order are incorrect	Process - Product failure risk or liability risk	1	N	Y	N	4	8D
12	Order/Quote Fulfillment	PurManager	01-Aug-23	Feedback - Stakeholder	Product codes on purchase order are incorrect	Process - Product failure risk or liability risk	2	N	N	Y	3	5Y

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1.1.2 Part B – Corrective Action Plan

- Undertake root cause analysis;
- Issue the chosen root cause analysis method to the process owner/response team for completion;
- Once completed, update the root cause in Part A;
- Update the 'Corrective Action Plan' in Part B;
- Monitor the implementation of corrective actions and verify close-out;
- The status of the corrective action will remain 'Open' until 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.'

Process Owner	Description of Corrective Action	Response Time (Days)	Date Assigned	Days to Complete	Target Completion	Status	Due (Days)	Deadline	How was Close-out Verified?	Date Close-out Verified
Jane Doe	Department to ensure templates are updated	4	01-Mar-23	30	31-Mar-23	Closed	125	Overdue	Visually confirmed that the correct template is available and is being used	11-Apr-23
John Doe	Warehousing to investigate and correct labelling errors	3	23-Mar-23	60	22-May-23	Closed	73	Overdue		
Jan Doe		8	20-Apr-23	30	20-May-23	Closed	75	Overdue		
Jon Doe	Add to opportunity register, discuss at next review	3	12-May-23	60	11-Jul-23	Closed	23	Overdue		
		1	13-May-23	15	28-May-23	Closed	67	Overdue		
		4	01-Jun-23	30	01-Jul-23	Closed	33	Overdue		
		7	09-Jun-23	15	24-Jun-23	Closed	40	Overdue		
		12	01-Jul-23	10	11-Jul-23	In-progress	23	Overdue		
		1	01-Jul-23	15	16-Jul-23	In-progress	18	Overdue		
		2	04-Jul-23	10	14-Jul-23	In-progress	20	Overdue		
		1	15-Jul-23	60	13-Sep-23	In-progress	-41	Due		
		1	02-Aug-23	30	01-Sep-23	Open	-29	Due		
		0		FALSE	00-Jan-00		0			
		0		FALSE	00-Jan-00		0			
		0		FALSE	00-Jan-00		0			
		0		FALSE	00-Jan-00		0			
		0		FALSE	00-Jan-00		0			
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		0		FALSE	00-Jan-00		0			

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