

QA International (Packaging) Limited




Effective responses to non-conformities

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Introduction



We have created this guide to aide with effective responses to non-conformities to enhance the value of the certification process for your business. The focus will be on corrective action, root cause analysis and preventive action and how these should be presented on the audit summary sheet; along with submission of appropriate evidence.


As part of this, we will be providing a definition of each along with some examples of common issues. To help with this, we will be using the following (fictional) case study:



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Case Study



The auditor audits the following requirement which states:
Documented cleaning procedures shall be in place and maintained for buildings, equipment and vehicles. Cleaning schedules and procedures shall include the following information:

- responsibility for cleaning
- frequency of cleaning
- cleaning materials to be used
- item/area to be cleaned
- method of cleaning
- cleaning record and responsibility for verification.

The frequency and methods of cleaning shall be based on risk. The procedures shall be implemented to ensure that appropriate standards of cleaning are achieved.


Scenario:
The site presents all the documented procedures for cleaning that show who's responsible for cleaning and verification, area cleaned, how often this should be carried out, method of cleaning, and records to show that the procedures have been implemented. The auditor cannot see documented evidence that the site has used risk assessment to determine frequency and methods of cleaning, so the auditor raised a non-conformance for this.

The auditor records the non-conformance on the audit summary sheet as:
The site has not used risk assessment to determine frequency and methods of cleaning

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Case Study



The auditor audits the following requirement which states:

Protective clothing worn in production areas shall provide adequate coverage. Where there is handling of materials intended for direct contact with food or other hygiene-sensitive products, the clothing shall have no external pockets on the upper body garments or sewn-on buttons. Changes of such clothing shall be available at all times as required.

Scenario:


The site's protective clothing provides adequate coverage and contains no external pockets. However, during the site tour, it was noticed that there were sewn-on buttons on the site-issued fleeces. Changes of clothing were available.

The auditor records the non-conformance on the audit summary sheet as: There were sewn-on buttons on the site-issued fleeces

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Corrective Action/Evidence




What is corrective action?

- Immediate action taken to rectify the detected non-conformity. Corrective action should be completed as soon as possible after detecting the nonconformity (this is particularly important where the non-conformity could affect product safety, integrity or quality).

Types of evidence:


- Photographic – before and after photos
- Documentary – procedures, checklists, HARM plan, invoices, purchase orders, certificates of calibration (list not exhaustive)
- Other – corrective action witnessed at time of audit



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Corrective Action/Evidence



Understanding corrective action & evidence

Understanding the requirement and non-conformance is essential in order to get maximum benefit from correcting a non-conformance. Sometimes the clauses consist of several aspects that are interdependent, therefore it is important they are understood in order to close out the non-conformance appropriately. To gain comprehensive understanding of the non-conformance raised this can be fully discussed with the auditor at the time of audit.

When providing evidence, it is important to ensure sufficient evidence is supplied to supplement the whole of the correction as corrective action can consist of several actions.


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Corrective Action/Evidence

Common Issues – Corrective Action/Evidence

- Supplying evidence only for part of the corrective action taken
- When recording the corrective action, stating it as an intended action rather than a completed action
- For corrective actions taken at the time of the audit, not indicating this on the summary sheet
- Supplying evidence of procedure updates, but not of the procedure being put into practice
- For photographic evidence sent, lack of 'before and after' photos



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Corrective Action/Evidence

Let's look at some examples

Audit Summary Sheet (Packaging Materials)
Company name: _____ Audit Date(s): _____ UK/BRZ/2021

Non-Conformity Summary

No.	Requirement ref.	Detail of Non-Conformity	Critical or Major?	Anticipated Pre-ADR Date		
Major						
No.	Clause	Detail of Non-Conformity	Anticipated Pre-ADR Date			
Minor						
No.	Clause	Detail of non-conformity	Corrective action taken	Proposed preventive action plan	Risk Cause Analysis	Date Reported to Auditor
1	4.8.2	The site has not used risk assessment to determine the frequency and methods of cleaning.				
2	4.8.4	There was poor control of the used floor plates.				

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Corrective Action/Evidence

Common Issues

- Supplying evidence for only part of the corrective action taken

Minor			
No.	Clause	Detail of Non-Conformity	Corrective action taken
1	4.8.2	The site had not used risk assessment to determine the frequency & methods of cleaning	We have conducted a risk assessment and determined the current frequency and methods of cleaning are in line with the assessment result.

The evidence provided here only addresses part of the non-conformance as the risk assessment has not considered the frequency of the cleaning

✓ Evidence provided: Risk assessment containing frequency and methods of cleaning

✗ Evidence provided: Risk assessment containing methods of cleaning

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Corrective Action/Evidence

Common Issues

- When recording the corrective action, stating it as an intended action rather than a completed action

Minor			
No.	Clause	Detail of Non-Conformity	Corrective action taken
✓ 1	4.8.2	The site has not used risk assessment to determine frequency & methods of cleaning	We have conducted a risk assessment and determined that the current frequency and methods of cleaning are in line with the risk assessment results.
✗ 1	4.8.2	The site has not used risk assessment to determine frequency & methods of cleaning	We will carry out a risk assessment and amend frequency and/or methods of cleaning based on result.

The corrective action here is in the future tense, which indicates that this is an intended action. This should be recorded as a completed action

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Corrective Action/Evidence

Common Issues

- For corrective actions taken at the time of the audit, not indicating this on the summary sheet

Minor			
No.	Clause	Detail of Non-Conformity	Corrective action taken
✓ 2	6.5.4	There were sewn-on buttons on site issued fleeces	Fleeces removed from production area and placed in the lockers and witnessed by the auditor.
✗ 2	6.5.4	There were sewn-on buttons on site issued fleeces	Fleeces removed from production area and placed in the lockers.

It has not been stated in the summary sheet that the corrective action was witnessed by the auditor

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Corrective Action/Evidence

Common Issues

- Supplying evidence of procedure updates, but not of the procedure being put into practice

Minor			
No.	Clause	Detail of Non-Conformity	Corrective action taken
2	6.5.4	There were sewn-on buttons on site issued fleeces	Procedure updated to state that sewn-of buttons are not permitted. Buttons removed from all fleeces.
2	6.5.4	There were sewn-on buttons on site issued fleeces	Procedure updated to state that sewn-of buttons are not permitted.

Evidence provided: Updated procedure showing sewn implemented are not allowed & photo of fleeces with buttons removed


Evidence provided: Updated procedure showing sewn-on buttons are not allowed

Evidence provided does not fully close out the non-conformance as it does not show procedure updates having been implemented

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Root Cause Analysis



What is root cause analysis?


- An analysis that identifies the underlying cause of a problem which, if adequately addressed, will prevent a recurrence of that problem



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Root Cause Analysis



Understanding root cause analysis


Root cause analysis is a systematic investigation to identify the fundamental or underlying cause(s) (root causes) of a problem or an incident. The aim of the root cause analysis is to enable the investigators to look beyond the solution to the immediate problem and understand the fundamental or underlying causes of the situation so that preventive action can be taken.

To establish the root cause, it is important to gather and collate evidence. The choice of method for root cause analysis may be a matter of personal choice, company policy or depend on the type of issue/non-conformity being investigated.

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Root Cause Analysis



Common Issues – Root Cause Analysis

- Repeating the non-conformance
- Explaining the circumstances of how the issue occurred, not the cause of the issue
- The root cause identified is outside the control of the company



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Root Cause Analysis

Common Issues

- Repeating the non-conformance

Minor				
No.	Clause	Detail of Non-Conformity	Root Cause Analysis	
✓	1	4.8.2	The site has not used risk assessment to determine the frequency and methods of cleaning	A lack of resources in the HARM team lead to not being able to allocate enough time for a comprehensive review of the Standard when transitioning from issue 5 to issue 6, so the part of the requirement was overlooked.
✗	1	4.8.2	The site has not used risk assessment to determine the frequency and methods of cleaning	We did not use risk assessment to determine the frequency and methods of cleaning.

This does not state the outcome of the root cause analysis; this is simply a repetition of the non-conformance

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Root Cause Analysis

Common Issues

- Explaining the circumstances of how the issue occurred, not the cause of the issue

Minor				
No.	Clause	Detail of Non-Conformity	Root Cause Analysis	
✓	2	6.5.4	There were sewn-on buttons on site issued fleeces	The purchasing department bought the fleeces and there was no procedure in place that stated that the fleeces must be consulted against requirements of the specification.
✗	2	6.5.4	There were sewn-on buttons on site issued fleeces	The purchasing department bought the fleeces with sewn-on buttons

This does not state the outcome of the root cause analysis; this simply describes the circumstances surrounding the non-conformance

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Root Cause Analysis

Common Issues


- The root cause identified is outside the control of the company

Minor				
No.	Clause	Detail of Non-Conformity	Root Cause Analysis	
✓	2	6.5.4	There were sewn-on buttons on site issued fleeces	There was not a technical team approved formal procedure in place for purchasing staff uniforms, as such the exact requirements had not been communicated
✗	2	6.5.4	There were sewn-on buttons on site issued fleeces	The supplier of the fleeces did not offer us the option to buy button-less fleeces

This is not acceptable as the root cause is outside of the company's control


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Preventive Action 


What is preventive action?

- An action to eliminate the fundamental, underlying cause (root cause) of a detected non-conformity and prevent a recurrence



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Preventive Action 


Understanding preventive action

Preventive action is an action plan that addresses the issue(s) established in the root cause analysis and prevents the non-conformity from re-occurring.

It is important to remember that there is a significant difference between corrective action and preventive action. Corrective action is carried out after a non-conformance has occurred, whereas preventive action is planned with a goal of preventing a non-conformity in its entirety and is based on root cause analysis.


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Preventive Action 

Common Issues – Preventive Action

- Repeating the corrective action
- Not addressing the root cause
- Not proposing a planned definitive action



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Preventive Action

Common Issues

- Repeating the corrective action

Minor				
No.	Clause	Detail of Non-Conformity	Corrective action taken	Proposed preventive action plan
✓ 1	4.8.2	The site had not used risk assessment to determine the frequency & methods of cleaning	Risk assessment completed to determine the frequency & methods of cleaning	Risk assessment for frequency and methods of cleaning will be added to the HARA plan, master document list & internal audit schedule
✗ 1	4.8.2	The site had not used risk assessment to determine the frequency & methods of cleaning	Risk assessment completed to determine the frequency & methods of cleaning	We have completed a risk assessment to determine the frequency & methods of cleaning so this will be correct in future

This is a repeat of the corrective action and contains no information on preventing recurrence of the non-conformance

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Preventive Action

Common Issues

- Not addressing the root cause

Minor				
No.	Clause	Detail of Non-Conformity	Proposed preventive action plan	Root Cause Analysis
✓ 1	4.8.2	The site had not used risk assessment to determine the frequency & methods of cleaning	An additional member of staff will be trained & added to the HARM team so that a more comprehensive review can be carried out by the HARM team for any updates to the Standard	A lack of resources in the HARM team lead to not being able to allocate enough time for comprehensive review of the Standard when transitioning from issue 5 to issue 6, so the part of the requirement was overlooked
✗ 1	4.8.2	The site had not used risk assessment to determine the frequency & methods of cleaning	Risk assessment for frequency and methods of cleaning will be added to the HARA plan, master document list & internal audit schedule	A lack of resources in the HARM team lead to not being able to allocate enough time for comprehensive review of the Standard

The preventive action is not based on the established root cause relative to the non-conformance

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Preventive Action

Common Issues


- Not proposing a planned definitive action

Minor				
No.	Clause	Detail of Non-Conformity	Proposed preventive action plan	Root Cause Analysis
✓ 2	6.5.4	There were sewn-on buttons on site issued fleeces	The technical team will implement a procedure that will define the requirements for purchasing staff uniforms and this will be trained to the purchasing team	There was not a technical team approved formal procedure in place for purchasing staff uniforms, as such the exact requirements had not been fully communicated
✗ 2	6.5.4	There were sewn-on buttons on site issued fleeces	We will purchase fleeces without sewn-on buttons in the future	There was not a technical team approved formal procedure in place for purchasing staff uniforms

This does not contain an action plan, only an objective, and therefore does not address the underlying cause

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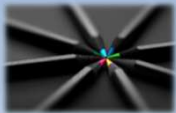
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Summary 

For all non-conformities, satisfactory evidence must be provided, reviewed and accepted by the certification body within the 28 calendar-day period following the recertification audit. For initial audits, this period is extended to 90 calendar days.


We recommend submitting all evidence within no later than 21 calendar-days as this allows time for submission of any further evidence if required.

Submitting evidence as early as possible minimises the risk of the certificate expiring. If satisfactory evidence is not provided within the 28 calendar-day period following the audit, certification may not be granted.




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Summary 


We have looked at the definitions and understanding of corrective action, preventive action, and root cause analysis. We have highlighted the common issues and provided good and bad examples of each.

To finish, we will provide a completed example containing one of the ways to correctly present the audit summary sheet.



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Summary 

Minor						
No.	Clause	Detail of Non-Conformity	Corrective action taken	Proposed preventive action plan	Root Cause Analysis	Date Reviewed by Auditor
1	4.8.2	The site had not used risk assessment to determine the frequency & methods of cleaning	We have conducted a risk assessment and determined that the current frequency & methods of cleaning are in line with the risk assessment result	An additional member of staff will be trained & added to the HARM team so that a more comprehensive review can be carried out by the HARM team for any updates to the Standard.	A lack of resources in the HARM team lead to not being able to allocate enough time for comprehensive review of the Standard when transitioning from issue 5 to issue 6, so the part of the requirement was overlooked	


- Past tense
- Fully addresses non-conformance
- Evidence supplied for all corrective actions taken

- Addresses root cause
- Action plan to prevent recurrence

- Identifies the underlying issue
- Within the control of the company

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Thank you!

If you have any queries, please contact us on:

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