Nonconformance Writing and Corrective Action
ARP9136

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• Organizations, as part of continual improvement, desire to reduce the number of issues and to minimize their impact on quality, delivery, and cost.

**ARP9136**

• Methodology to improve the way escapes and issues are managed, including communication between all parties, to reduce their impact, contain them as far upstream as possible, and prevent reoccurrence.
Robust root cause analysis and problem solving process

- Should provide for:
  - How the issue is managed and communicated between all stakeholders
  - How containment actions taken to protect the customer and production efforts are identified and managed
  - How it is ensured that the actual root cause has been identified
  - How it is ensured that the right measures are taken at the right location, at the right time, and by the right individuals
Robust root cause analysis and problem solving process

• Expected behavior:
  – Seek total understanding of the process – “How did that happen?” WHY????
  – Focus on improving processes; actually effecting process performance
Identifying the issue

• Often the first time a problem is put into words it is vague, subjective, or even abstract. Without a proper problem statement (definition), it is unlikely that the root cause will be identified and incorrect or insufficient corrective actions will be put in place.

• The accuracy and completeness of the problem description are decisive factors for the quality of the root cause analysis and associated problem solving efforts. The team will benefit from investing adequate time upfront defining the problem to ensure subsequent process steps proceed accurately and efficiently.
3 part Nonconformance

• **Statement of Nonconformity**: This is the action/process that was observed to not be in compliance. The nonconformance should be written to identify the process that is not adequate.

• **The Requirement**: This is the action that is required that was observed not in compliance. Typically the Standard, Procedure, Work Instruction, etc. is quoted.

• **Objective Evidence Observed that Supports the Statement of Nonconformity**: This is what was observed during the audit that caused the Nonconformance to be written. Typical examples are records, procedures, work instructions, information from interviews, etc.
For Example

• If during the audit you found that procedure 7.2 required that all auditors must have formal training on corrective action every year. You looked at records for EMP1, EMP2, and EMP3 who are auditors and there are no records of them being trained in 2018. The Nonconformance would be:

• Nonconformance: The process for ensuring that required training is given is not always effective as the organization was unable to provided evidence that the annual required auditor training was completed for all auditors.

• Requirement: Procedure 7.2 – All auditors must have formal training on corrective action every year.

• Evidence: Training records for employee EMP1, EMP2, and EMP3 who are internal auditors showed that they had not been given formal training in 2018 on corrective action.
Another Example

• During an audit, it was found that not all suppliers currently being used to procure product/services from are included on the approved supplier list. Supplier ABC and Supplier XYZ shipped product in and was observed in the receiving inspection department being inspected and accepted yet the suppliers are not on the ASL.

• Nonconformance: The process for ensuring that all active suppliers are on the ASL is not always effective.

• Requirement: AS9100 Paragraph 8.4.1.1 b) The organization shall: maintain a register of its external providers that includes approval status and the scope of the approval

• Evidence: Suppliers ABC & XYZ were not found on the current ASL yet parts were received, inspected and accepted.
Elements of Corrective Action

- Containment
  - Correction
  - immediate corrective action
  - immediate communication
  - verification that problem does not further degrade

- Root Cause Analysis
- Corrective Action
- Evidence of Correction
- Evidence of Implementation
- Evidence of Effectiveness
Containment
Definition of Containment

- **Containment** - Action to control and mitigate the impact of a problem and protect the organization and/or customer (i.e., stop the problem from getting worse), includes correction, immediate corrective action, immediate communication, and verification that problem does not further degrade.

Immediate containment = temporary update and/or reinforcement of processes, activities, and documents; particularly in the case of QMS deficiencies.
Definition of Correction

- **Correction** - (also referred to as Immediate Correction) Action taken to eliminate a detected nonconformity (adapted from ISO 9000:2005).
  - NOTE 1: A correction can be made in conjunction with a corrective action.
  - NOTE 2: For product nonconformity, correction might be understood as reworking the part, accepting the nonconformance through concession process, or scrapping the product.
  - NOTE 3: For a system issue, it may include correcting the paper work or issuing a new purchase order.
  - NOTE 4: For a delivery issue, it may include revising to air transportation instead of delivering product by truck or ship, increasing production rate, etc.
Definition of Immediate Corrective Action

- **Immediate Corrective Action** - Action taken to eliminate, prevent, or reduce the probability of any additional nonconformances related to the apparent cause from happening again in the short term.
  - NOTE: These actions may be temporary and should remain in place until the root cause(s) is identified and permanent RCCA is implemented and verified to be effective.
Communication

• The conditions where the customer must be notified should be established and documented. If the conditions cannot be specified with tangible trigger points, then direction should be given for how to evaluate each situation to ensure the customer is kept informed, as appropriate.
Containment/Correction

- This should include information about what was done in regards to the evidence recorded in the Nonconformance, the extent of the nonconformity, and what was done to ensuring no more nonconformities are created.

- It should include how to prevent the same issue from happening at other sites, products, or production lines.

- Containment/Correction does not only apply to product related nonconformities. It is applicable for all Nonconformance’s.
Containment/Correction

Going back to the Nonconformance for suppliers not on the approved list

- Containment activities would include what they did about the suppliers identified during the audit (reviewed them and recorded the results) and what they are going to do immediately so that this stops happening (send an e-mail to all employees purchasing applicable items and explain what must be done or hold a training session with these employees). Also, to what depth is this nonconformance (how many other suppliers are not on the list)?
Root Cause Analysis – Methods

![Fishbone Diagram]

- **People**
  - Children
  - Demotivated
  - Tired
  - Lazy
- **Method**
  - Alarm Clock
  - Waking Time
  - Route to Work
  - Distance to Work
- **Measurement**
  - Bonus
  - Clocking In
  - Incentive
  - Late for School

- **Machine**
  - Coffee Machine
  - Car
  - Train
  - Alarm Clock
- **Environment**
  - Traffic Jam
  - Fog
  - Rain
  - Holiday
- **Materials**
  - Food
  - Clothes
  - Petrol
  - Electricity
Definition of Root Cause

- The process of identifying all the causes (root cause and contributing causes) that have or may have generated an undesirable condition, situation, nonconformity, or failure.

5 Why Analysis

Problem Statement

Why?

Why?

Why?

Why?

Why?

Countermeasures

Why didn’t the countermeasures work?

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When to apply a structured root cause

• The process should be applied if:
  - Safety impact (product/personal).
  - Product strength, performance, and/or reliability issue.
  - High impact on production/maintenance operations.
    » Stop the line; prevent next operation to occur, etc.
    » Regulatory authorities and/or customer dissatisfaction.
    » Costs issue (generated to the customer or the organization).
    » Disruption of supplier’s process or customer’s operations.
  - Repetitive problems to one part or similar activities/processes.
  - Difficulty to detect.
  - Customer request.
  - Significant quality or QMS issue.
  - Complex problem that cannot be solved without assistance of other people than those located where the problem occurred.
When to apply a structured root cause

- Should always be considered, when an issue (undesirable conditions, defects, and failures) is detected and the cause is unknown or inconclusive (not obvious). The decision to apply or not apply the process should be made at the appropriate level of management within the company based on the level of risk and whether the risk associated is acceptable or not.

\[
\text{RISK} = \text{severity of issue} + \text{detectability} + \text{probability of occurrence}
\]
Root Cause

• There can be more than one cause for a nonconformity.

• During the analysis, different levels of causes are found (i.e., direct, intermediate, and root causes). It is useful to distinguish the cause for the creation of the problem and the cause for the non-detection of the problem.

• Identify what failed in the QMS to allow the undesirable condition, situation, nonconformity, or failure not to be detected.
Root Cause

You guessed it, back to the Nonconformance on the approved supplier list...

• Why were purchase orders issued for suppliers not on the list?
• The purchasing employee has purchased from them before and remembered them being on the list and no one has revised the list since the last purchase.
• Why were they not on the list now?
• The programming of the system that generated the list was set up such that if a supplier was not used in more than 1 month, the supplier was removed.
Corrective Action
Definition of Corrective Action

- Action implemented to address the root cause(s) and contributing cause(s) of the undesirable condition, situation, nonconformity, or failure; action taken to prevent recurrence.
Corrective Action

In regards to the Nonconformance on approved suppliers

- Corrective action taken was to change the programming of the system to not remove the suppliers after inactivity but to put a note in a newly created field on the report.
Evidence of Correction/Containment
Evidence of Correction/Containment

• This would include the items that were reviewed to show that the actions identified for correction/containment were done.
• Auditor is to document what they reviewed not a generic statement.
Back to the Nonconformance for approved supplier list

- Evidence of Correction/Containment includes:
  - Records of the approval/re-eval of the suppliers not seen during the audit and updated ASL;
  - copy of the e-mail to all employees that purchase applicable items explaining what needs to be done.
  - The review for the last 3 months to see who all was missing from the list and evidence that they are now on the list.
Evidence of Implementation of Corrective Action
Definition of Corrective Action Implementation Verification

- Action taken to verify that the planned actions were taken as scheduled.
  - NOTE: This includes specific actions, milestones, completion dates, and responsibilities.
Evidence of Implementation of Corrective Action

- This would include the items that were implemented to ensure that the root cause does not recur.
- Auditor must record what they reviewed.
Evidence of Implementation of Corrective Action

Back to the Nonconformance for approved supplier list

• Evidence of Implementation of Corrective Action includes: The revised approved supplier list with the new field identifying those suppliers that have been inactive.
Evidence of Effectiveness
Definition of Corrective Action Effectiveness Verification

- Action taken to verify that the planned corrective action(s) have prevented recurrence of the identified root cause or contributing causes, and have consequently eradicated the problem.
  - NOTE: This may include auditing, monitoring of specific metrics, or any other reporting methodologies.
Evidence of Effectiveness

• This would include items that show that the actions taken have prevented the cause from reoccuring.
Evidence of Effectiveness

In regards to the Nonconformance for the approved supplier list

• It could be a list of all the purchase orders issued for the previous 3 months and a copy of the ASL list in which you can verify that all of the suppliers that were purchased from were on the list.
IN SUMMARY

• Make sure the NCRs we issue are well written – clear and concise.

• Root cause must address the nonconformance.

• Corrective action must address the root cause.

• Make sure evidence is included for correction, containment, and corrective action implementation and corrective action effectiveness (as applicable).

• If there is a plan, make sure there are clear actions and responsibilities and dates.
Questions?