Non-Conformances Efficiency Notes – Quality Series

What They Are

Non-conformances are problems that have been found and need be addressed. They can be found anywhere – in a product, in service delivery, in work execution, in a process or even in the Quality Management System itself.

What You Need

- 1. A Quality Management System (QMS) Business processes to manage quality in the organization and in work product delivery.
- Non-Conformance Report (Form) A way to efficiently and consistently capture identified non-conformances
- 3. Non-Conformance Register A log of identified non-conformances
- 4. Actions / Corrections Document what you are doing to fix it

Why You Need Them

Non-conformances are a core pillar of a Quality Management System (QMS). The QMS will require you to document and maintain a record of non-conformances, actions taken to address the issue and record of close-out of the issue.

5. Correction Verification

Objective evidence of what was done against each documented action to fix the problem

6. Correction Acceptance

Sign-off on verification that NCR is closed

7. Root Cause Analysis (RCA)

Drill in to get to the heart of what went wrong using an RCA method like 5-Why

8. Corrective Actions

Do any significant systemic changes need to be made to the quality management system

Non-Conformance Register - Example

#	Issue	Raised By	Raised	Findings	Actions	Evidence	Status	Closed
001	Defect in steel	J. Smith	1/1/2015	Steel beam structurally damaged	Replace	New beam received (see report)	Closed	1/5/2015

Minor Non-Conformance

- Isolated occurrence
- Minimal customer impact
- Issue can be resolved quickly / efficiently
- Creates little / no waste

Major Non-Conformance

- · Regulatory requirements issue
- · Causes major delay impacting schedule
- Results in rework or cost overrun
- Same minor issue repeated frequently

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Not every QMS categorizes non-conformances as Minor and Major.

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Anatomy of a Non-Conformance Report

. Non-Conforma		Event Data	
NCR #		Event Date	
Status		Verification	
Raised By		Closed By	
Title		Title	
Raised On		Closed On	
. Issue Descripti	on		
. Actions Taken			
Actions Taken			
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1. The general details of the non-conformance. Identify who found the issue and important dates toward close. QMS may require someone to actually accept the NCR.

2. Describe NCR in enough detail that someone not at the point of the event can read and understand exactly what it is and what should be done.

3. Damage control – what are you doing immediately to address the issue.

4. What objective evidence was reviewed to confirm the actions were taken and the issue can be closed out.

5. Sign-off typically required by the people responsible for reviewing the objective evidence of actions taken.

6. The organization may decide to undertake a deeper systemic analysis to prevent future occurrences.

7. The RCA may result in corrective actions – process-level changes to prevent recurrence of non-conformances like this.

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