

# Do it Right the First Time

How to write corrective actions in response to 3<sup>rd</sup> party audits.

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## The Story of My Experience



## False Sense of Achievement

- Auditors don't always kick back reviews when they should
  - Over worked
  - Frustrated
  - Just get it off my plate
  - Lazy
  - Don't want the hassle
  - Contractors and they don't get paid for the additional time

## Who is Responsible?

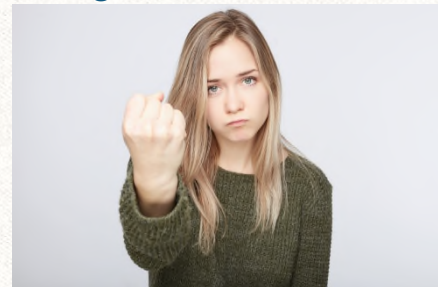
The organization “you” are ultimately responsible for the implementation and effectiveness of the actions you take.

## Why Are Corrective Actions Important

- Wasted Resources
- Negative Impact to the Customer
- Negative Impact to the Organization
- Eliminate Repeats
- Ensures integrity of the Business Management System
- Avoid Major Non-Conformities from 3<sup>rd</sup> Party and Certificate Suspension.

## False Sense of Unimportance by Process Owners

- Typically Focus IS On Customer Complaints
- Get It Off My Plate mentality
- Quality Responding For The Entire Organization
- Not Supported By Management



## Corrective Actions Should be Returned When:

- No containment
- Bad Root Cause
- Bad Corrective Action
- In adequate effectiveness statement
- In adequate effectiveness review
- No evaluation of impact



## Containment

### IS

- Fixing the evidence presented
- Review of the risk
- Review of the impact (how big)
- Training
- Fixing a procedure
- Writing a procedure

### IS NOT

- Left Blank

## Examples: Not Acceptable Root Cause

- Lack of knowledge of the ISO 9001:2008 Standard.
- The minutes for managements review were not adequate
- That person isn't here anymore
- No documented procedure / work instruction
- Procedure not updated
- Training not adequate
- NCR management software does not allow tracking of this verification of effectiveness

## ROOT CAUSE



## Root Cause

### IS

- Systemic
- Management
- Methods
- Lack of Error Proofing

### IS NOT

- Training
- Employee Error
- Restatement of the problem
- Lack of documentation
- Failure to change a procedure
- No procedure in place

## Corrective Action

### IS

- Systemic
- Management
- Methods
- Error Proofing
- Reviewing the entire system

### IS NOT

- Writing a procedure
- Correcting a procedure
- Training
- Correcting the failure found

## Impact

### IS

- Similar Products
- Related Systems
- Similar Processes
- Where else could this occur

### IS NOT

- Left Blank
- Only the area identified
- Only the product identified
- Only the person identified
- Reviewing with blinders on

## Method to Verify Effectiveness

### IS

- Internal Audit
- Management Review
- Layered Process Audits
- Review over time
- Review over quantity

### IS NOT

- Writing a procedure
- Restating the action
- Instruction
- Training

## Verification of Effectiveness

### IS

- Internal Audit
- Management Review
- Layered Process Audits
- Review over time
- Review over quantity

### IS NOT

- Writing a procedure
- Not a statement of “effective”
- Training
- Checking yes

## Submitting Evidence

### IS

- Procedures
- Plans and status
- Management Reviews
- Internal Audit
- Layered Process Audits
- 5S Audits
- Photos ... etc.

### IS NOT

- Submitting training records (alone)
- Documented Procedures (alone)



## Examples of Rejected Responses

- methods to verify the effectiveness are actions not methods to verify effectiveness. Actions should be implemented with evidence sent and verification of effectiveness performed prior to sending in actions for review to the auditor. Where is the evidence of #2, reviewing all job descriptions. What was the outcome and actions needed?

## Examples of Rejected Responses

- where is the evidence of the results of the meetings and what is the status of the tracking the defective material. What is the plan. I don't want just meetings. What is the plan by the team for resolving the pile up of material in the warehouse. No evidence presented other than a meeting notice and corrective action.

## Questions?



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