Do it Right the First Time

How to write corrective actions in response to 3\textsuperscript{rd} party audits.

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CEO Cogent GPS, Director Automotive SBU-DQS

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 3rd 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
- Inadequate effectiveness statement
- Inadequate 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

- 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

<table>
<thead>
<tr>
<th>IS</th>
<th>IS NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic</td>
<td>Training</td>
</tr>
<tr>
<td>Management</td>
<td>Employee Error</td>
</tr>
<tr>
<td>Methods</td>
<td>Restatement of the problem</td>
</tr>
<tr>
<td>Lack of Error Proofing</td>
<td>Lack of documentation</td>
</tr>
<tr>
<td></td>
<td>Failure to change a procedure</td>
</tr>
<tr>
<td></td>
<td>No procedure in place</td>
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</tbody>
</table>

### Corrective Action

<table>
<thead>
<tr>
<th>IS</th>
<th>IS NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systemic</td>
<td>Writing a procedure</td>
</tr>
<tr>
<td>Management</td>
<td>Correcting a procedure</td>
</tr>
<tr>
<td>Methods</td>
<td>Training</td>
</tr>
<tr>
<td>Error Proofing</td>
<td>Correcting the failure found</td>
</tr>
<tr>
<td>Reviewing the entire system</td>
<td></td>
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</tbody>
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5/24/2018
## Impact

<table>
<thead>
<tr>
<th>IS</th>
<th>IS NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similar Products</td>
<td>Left Blank</td>
</tr>
<tr>
<td>Related Systems</td>
<td>Only the area identified</td>
</tr>
<tr>
<td>Similar Processes</td>
<td>Only the product identified</td>
</tr>
<tr>
<td>Where else could this occur</td>
<td>Only the person identified</td>
</tr>
<tr>
<td></td>
<td>Reviewing with blinders on</td>
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</tbody>
</table>

## Method to Verify Effectiveness

<table>
<thead>
<tr>
<th>IS</th>
<th>IS NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal Audit</td>
<td>Writing a procedure</td>
</tr>
<tr>
<td>Management Review</td>
<td>Restating the action</td>
</tr>
<tr>
<td>Layered Process Audits</td>
<td>Instruction</td>
</tr>
<tr>
<td>Review over time</td>
<td>Training</td>
</tr>
<tr>
<td>Review over quantity</td>
<td></td>
</tr>
</tbody>
</table>
## Verification of Effectiveness

<table>
<thead>
<tr>
<th>IS</th>
<th>IS NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Internal Audit</td>
<td>• Writing a procedure</td>
</tr>
<tr>
<td>• Management Review</td>
<td>• Not a statement of “effective”</td>
</tr>
<tr>
<td>• Layered Process Audits</td>
<td>• Training</td>
</tr>
<tr>
<td>• Review over time</td>
<td>• Checking yes</td>
</tr>
<tr>
<td>• Review over quantity</td>
<td></td>
</tr>
</tbody>
</table>

## Submitting Evidence

<table>
<thead>
<tr>
<th>IS</th>
<th>IS NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Procedures</td>
<td>• Submitting training records (alone)</td>
</tr>
<tr>
<td>• Plans and status</td>
<td>• Documented Procedures (alone)</td>
</tr>
<tr>
<td>• Management Reviews</td>
<td></td>
</tr>
<tr>
<td>• Internal Audit</td>
<td></td>
</tr>
<tr>
<td>• Layered Process Audits</td>
<td></td>
</tr>
<tr>
<td>• 5S Audits</td>
<td></td>
</tr>
<tr>
<td>• Photos … etc.</td>
<td></td>
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</tbody>
</table>
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.