Corrective and Preventive Action

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September 10, 2013

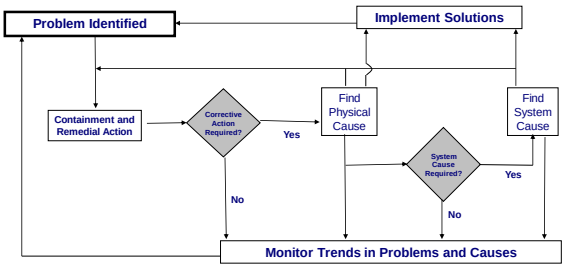
Correct Terminology

- Correction gets rid of the original problem
- Corrective action addresses the causes to prevent recurrence
- Preventive action is taken prior to a problem to reduce the likelihood of occurrence
  - Process planning
  - Spreading successful corrective actions

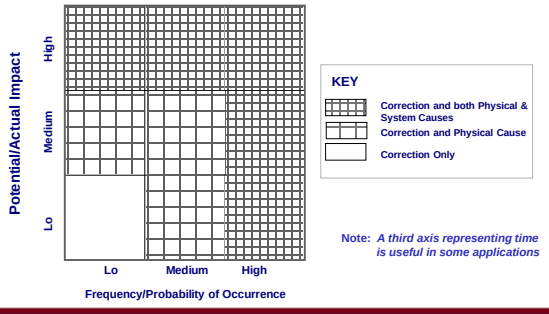
Typical Corrective Action Process

1. Problem is identified and documented
2. Corrective action request is assigned
3. Root cause is determined
4. Action is taken to eliminate root cause
5. Effect of actions taken is evaluated

The CA Process



Nonconformity Risk Matrix



What Is Root Cause Analysis (RCA)?

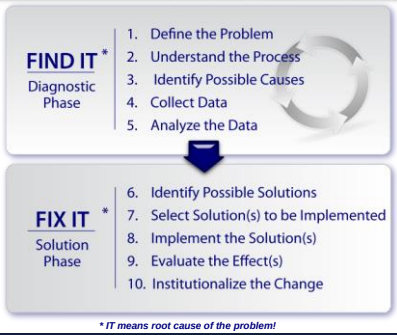
Corrective Action
- Identify need
- Document and assign
- Contain and remediate
- Track

Root Cause Analysis
- Identify possible causes
- Collect and analyze data
- Determine actual cause(s)

Problem Solving
- Identify solutions
- Implement solutions
- Evaluate results

RCA drills down into a system/process to help identify the cause of failure

The DO IT^2 Problem Solving Model



** IT means root cause of the problem!*

Typical Issues

- Don't know what a root cause is
- Don't know how to find it (opinions vs. facts)
- Don't look for other instances of same causes
- Stop too soon (especially for human error)
- Solutions don't logically align to causes
- Don't follow up to evaluate effectiveness
- Don't leverage success

Dealing with the Laggards

- Sit down with the problem person and ask what the issues are and whether there is anything you can do to help.
- Issue a regular report (e.g., monthly) using color coded status indicating where each department is relative to CAR responses.
- Escalate the CAR by sending it to the next higher level of management for the process.
- Issue another CAR for (a nonconformity against the corrective action process) based on lack of response to the initial problem.
- Conduct another audit in the area to see if things have deteriorated, stayed the same, or gotten better.
- Make sure the lack of response is reported and documented at the next management review, along with actions to be taken (or not, if that is the decision)
- Sit down with senior management and present the issue (without names), including what you done and the results. Both offer and elicit suggestions, and follow through until issue is resolved or you are asked to stop.
- Point out the problem to the registration auditor during the next audit.

Problems with Preventive Action

- Don't do it
- Humans not good at evaluating probabilities
- Bias estimates towards less work
- Don't follow up

Surprise!

- "Preventive action" is likely to go away (not included in CD version of ISO 9001:2015)
- Nearly all portions of a QMS are for the purpose of preventive action (e.g., defining & documenting processes, training, contract review, supplier evaluation, calibration, material identification …)
- Risk management will be the new terminology

The Risk Management Process

- Risk Identification – What risks exist?
- Risk Ranking – How significant are they?
- Risk Mitigation – What should be done?
  - Avoid
  - Reduce
  - Transfer
  - Accept
- Risk Monitoring – How well is the plan working?

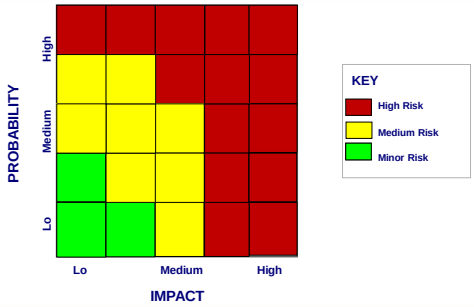
For Which QMS Elements?

- Product design
- Supplier management
- Process control
- Calibration
- Training
- Infrastructure

For What Types of Risks?

- Product risks
- Process risks
- Supply chain risks
- Reputational risks
- Financial risks
- Regulatory risks

Risk Matrix



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