

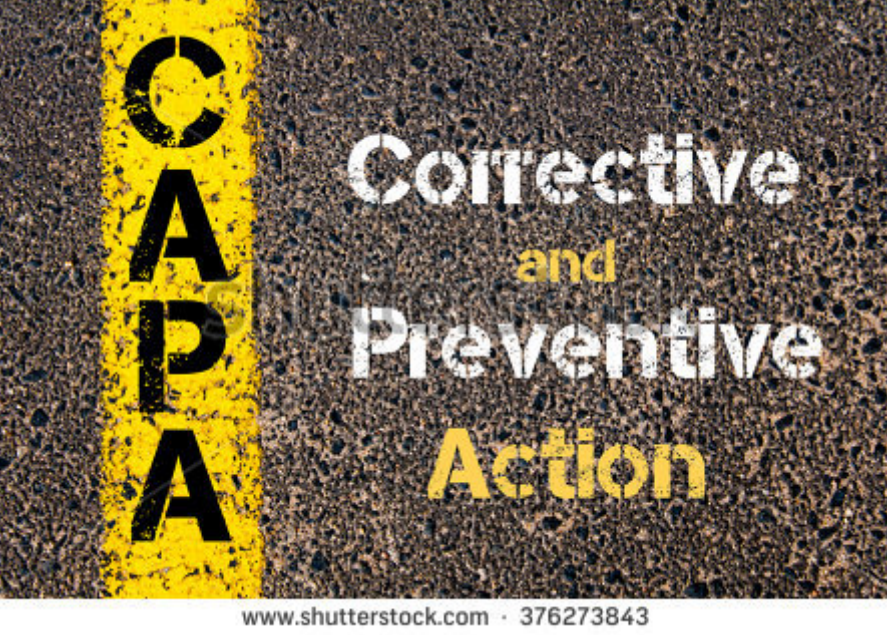


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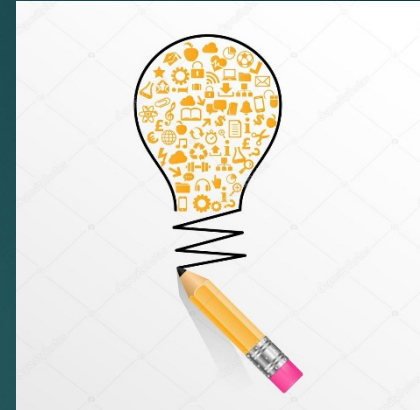


Title	Corrective and Preventive Action Basics
Ref	Tat_RL_2016_501

Learning Objectives

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- ▶ Know the purpose of Corrective and Preventive Action
- ▶ Have the ability to distinguish between each defined term



Purpose of the Corrective and Preventive Action

- ▶ To collect and analyze information to identify actual and potential product and quality problems
- ▶ To investigate product and quality problems and take appropriate and effective corrective or preventive action
- ▶ To verify or validate the effectiveness of corrective and preventive actions
- ▶ To communicate corrective and preventive actions to the appropriate people
- ▶ To provide information for management review
- ▶ To document activities

Correction

- ▶ “Correction” action to eliminate a detected nonconformity
 - ▶ A correction can be made in conjunction with a corrective action.
 - ▶ A correction can be, for example, rework or regrade
- Correction is like first-aid, its the instant action that is taken to correct the nonconformity or to reduce the impact nonconformity that has occurred



Corrective Action

- ▶ “Corrective action” action to eliminate the cause of a detected non-conformity or other undesirable situation
 - ▶ There can be more than one cause for a nonconformity
 - ▶ Corrective action is taken to prevent recurrence
 - ▶ There is a difference between correction and corrective action
- ▶ Corrective action will target the root cause so that the non-conformity or undesirable situation do not re-occur. Corrective Action can be considered as a ‘Problem Solving’.
- ▶ Investigate the cause of nonconformities relating to product, processes, and the system



Preventive Action

- ▶ Preventive action” action to eliminate the cause of a potential non-conformity or other undesirable situation
 - ▶ There can be more than one cause for a potential nonconformity
 - ▶ Preventive action is taken to prevent occurrence
- Preventive action is like Failure Mode Effect Analysis (FMEA) or risk management. Where the non-conformity or undesirable situation have not actually occurred. We need to anticipate the risks or un-desirable situation that may occur and than think of actions that shall eliminate the cause of non-conformity.



Corrective and Preventive Actions Further Actions

- ▶ Verify or validate the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device
- ▶ Implement and record changes in methods and procedures needed to correct and prevent identified quality problems
- ▶ Disseminate information related to quality problems or nonconforming products to those directly responsible for assuring the quality of such product or the prevention of such problems
- ▶ Submit relevant information on identified quality problems, as well as corrective and preventive actions, for management review.
- ▶ Document all activities required under this section, and their results

Questions or Concerns?

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Thank You