JABIL

Supplier University

- CAPA

Jun 2015

Agenda

- Purpose
- Why CAPA
- An effective CAPA process
- Jabil requirement
- Summary

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Purpose

- To introduce an effective way for problem solving - CAPA
- To introduce a typical CAPA approach 8 Discipline Problem Solving Approach
- To introduce the typical tools used during CAPA process
- To introduce Jabil requirements on CAPA
- To set up better communication between Jabil and supplier

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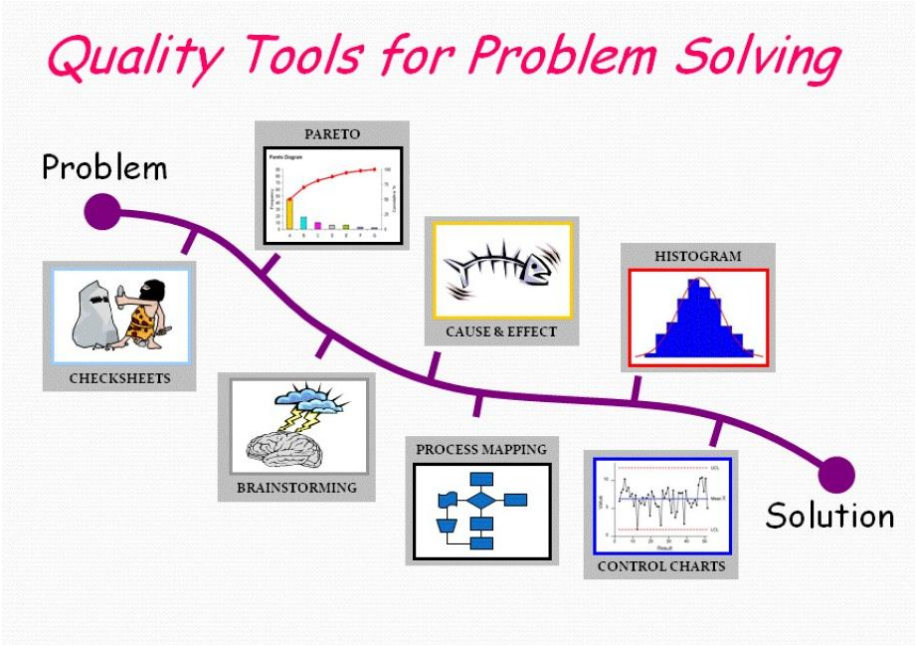
Why CAPA

- CAPA: Corrective Action and Preventative Action
- Why we need CAPA?
  - ❖ We meet problems and need to solve them almost everyday
  - ❖ CAPA is an effective way to identify the root cause of problem, solve it and minimize the impact of it
  - ❖ CAPA is an effective way to identify the potential problem, avoid future issue and reduce loss
  - ❖ CAPA can help us to meet customer satisfaction
  - ❖ ISO requirement



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ISO9001:2008 Requirements

An ISO requirement

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints)

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that non-conformities do not recur,

d) determining and implementing action needed

e) records of the results of action taken and

f) reviewing the effectiveness of corrective action taken.

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ISO9001:2008 Requirements

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive action shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,

b) evaluating the need for action to prevent occurrence of nonconformities.

c) determining and implementing action needed,

d) records of results of action taken, and

e) reviewing the effectiveness of the preventive action taken.

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Good CAPA vs Bad CAPA

- We see CAPA report almost everyday, can you tell a good CAPA versus a bad CAPA?

  - ✓ A good CAPA can find the root cause of a problem, while a bad CAPA only identify the direct cause, will never get to the root cause

    Example:

    Bad CAPA - Root cause: Operator mistake / Human error

    Good CAPA will think about why the operator made the mistake? Why the training not work? Is there any system problem?

  - ✓ A good CAPA will solve the problem at a system level, while a bad CAPA only address the direct cause, but not eliminate the root cause

    Example:

    Bad CAPA - Corrective action: Retraining the operator

    Good CAPA will think about what if retraining still not work? What is an effective action to solve the problem from system level?

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Good CAPA vs Bad CAPA

- ✓ A good CAPA can prevent the problem repeating in a same and similar situation, while a bad CAPA only solve the problem for a moment and the problem will come back.

  Example:

  Bad CAPA - Preventative action: More frequent inspection

  Good CAPA will think that inspection only can find the fail, but how to stop the fail and reduce loss? Will this problem happen in other place?

- ➢ A good CAPA just like a good doctor. If you have a headache, a good doctor will try to find the root cause of your headache and eliminate it, not only give you some pills to relieve your headache.

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An effective CAPA process – 8D

- A good CAPA must be effective to solve a problem
- Today, we will introduce an effective CAPA process 8D (8 Disciplines) problem solving
- 8 Disciplines Problem Solving is a method developed at Ford Motor Company used to approach and to resolve problems
- 8D is a typical method implemented by most international companies, including Jabil, for their CAPA process.

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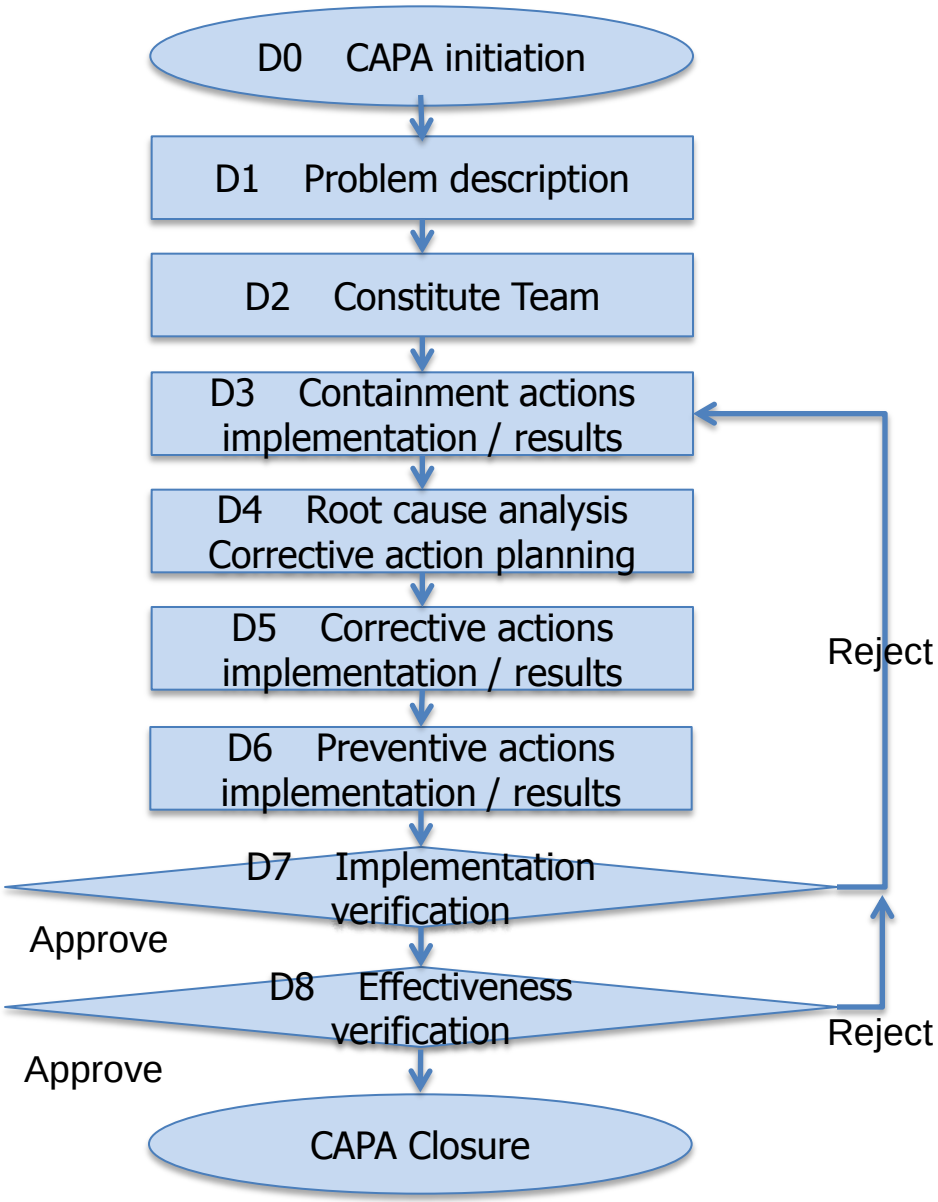
8D process flow



Ownership

CAPA Initiator

CAPA Owner

CAPA Owner

D3 Owner

D4 Owner

Task owners (as defined in D4) or D4 owner

D6 Owner

D7 Owner (QM or designee / Auditor)

D8 Owner (QM or designee)

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D1 Problem Description

CAPA initiator describes the problem using **5 W** and **2 H**. This could help the team to understand the problem better.

What: Describe the problem

For product related issues, product information includes part number/assembly number, serials number, failure symptom (defect image for cosmetic issue), and quantity of defect should be defined here.

Why:

Who: who is associated with the problems

When: when the problem occurred and or detected

Where: where the problem occurred and or detected

How much: To describe the scope impacted

e.g. Number of batch quantity affected.

How frequently: how frequently the issue occurred

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D2 Establish the Team

Involved all related function to the CAPA team based on the nature of problem.

CAPA Team member qualification:

- Familiar with process of his/her function
- Complete the training of CAPA procedure
- Complete the training of root cause analysis tools

Assign the action owner for below steps according to discussion result.

D3 Containment Actions

Short term action

- Identify all potentially impacted processes, products, or components and take immediate action to prevent their use or distribution.
- Eliminate the non-conformity detected through immediate corrections (e.g.: To correct an instruction, a procedure, to repair a
- Containment should address product located in:
  - ✓ internal locations include production line and storeroom,
  - ✓ supplier inventory,
  - ✓ customer site,
  - ✓ In-transit.
- Provide the objective evidence into D3 Containment action

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D4 Root Cause Analysis

Investigation requirements

The purpose of investigation is identifying potential cause through gather, review and evaluates related information.

The investigation scope:

Should cover man, machine, material, method, and environment and so on.
Consider the cause of the occurrence as well as the non-detection of the issue

Investigation tools include:

Flow chart, fish bone, Control Chart, Pareto charts, five whys, Human error checklist.
Note: at least one tool should be used.

Root Cause Identification

Root Cause

The identifiable factor(s), based on objective evidence, which has (have) been verified to be responsible for the nonconformity, trend, or aberrant or unexpected result.

Probable Cause

The identifiable factor(s), which is(are) most likely to be responsible for the event, trend, or result.

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Investigation Steps & Tools

Steps:

1. List all the potential causes using:
   Fishbone Diagram; Process Maps;
2. Narrow or eliminate potential causes using:
   Pareto Chart ;Scatter Diagram; Human error checklist
3. Get to root cause using:
   5 Whys; Pareto Chart; DOE
4. Verify Root cause using(if appropriate):
   Simulation testing ; Control Chart

Tools:

Fishbone
Process flow chart
Pareto chart
5 Whys
Human error checklist
Notice: they can be used mixture**.**

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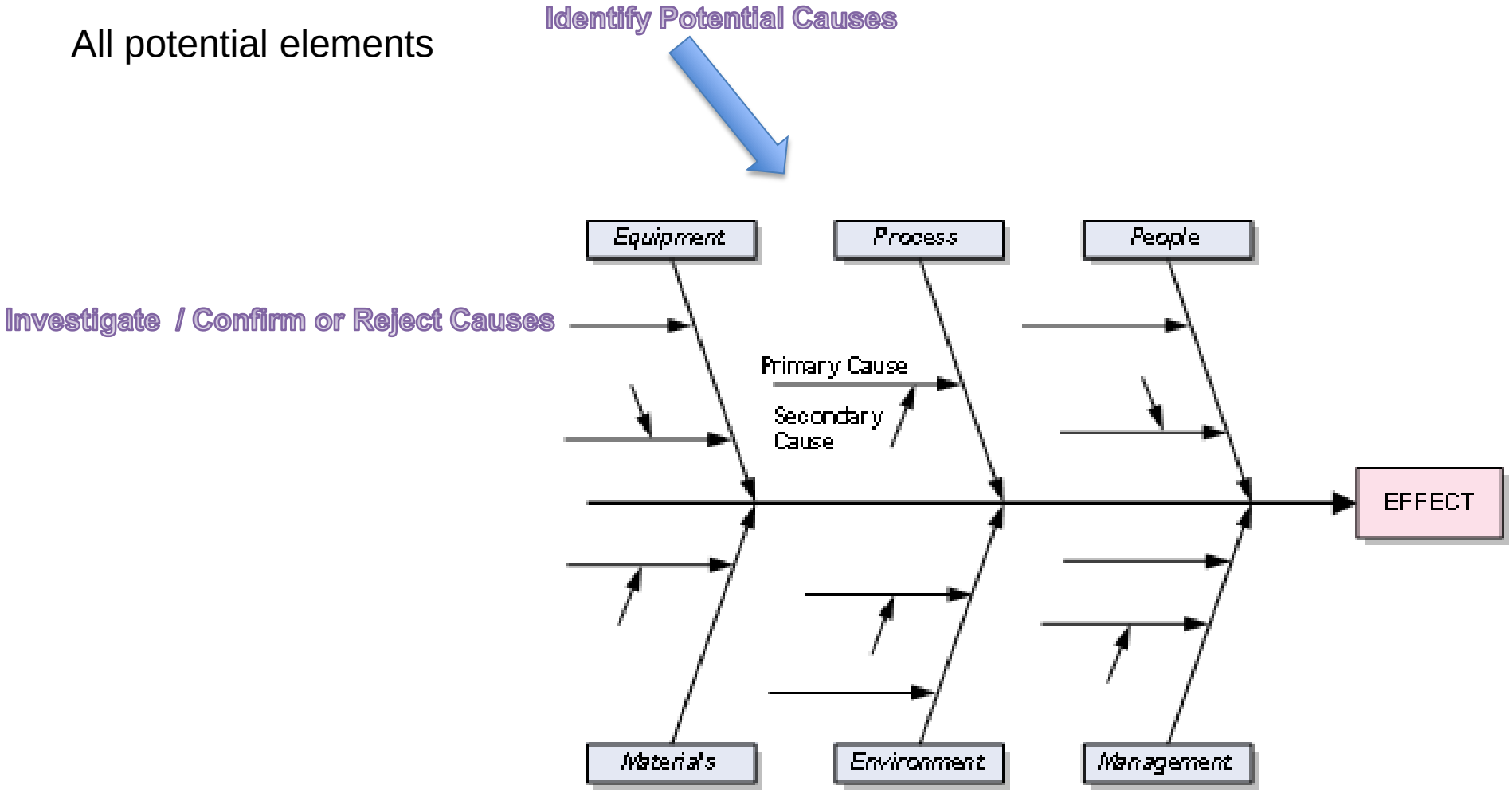
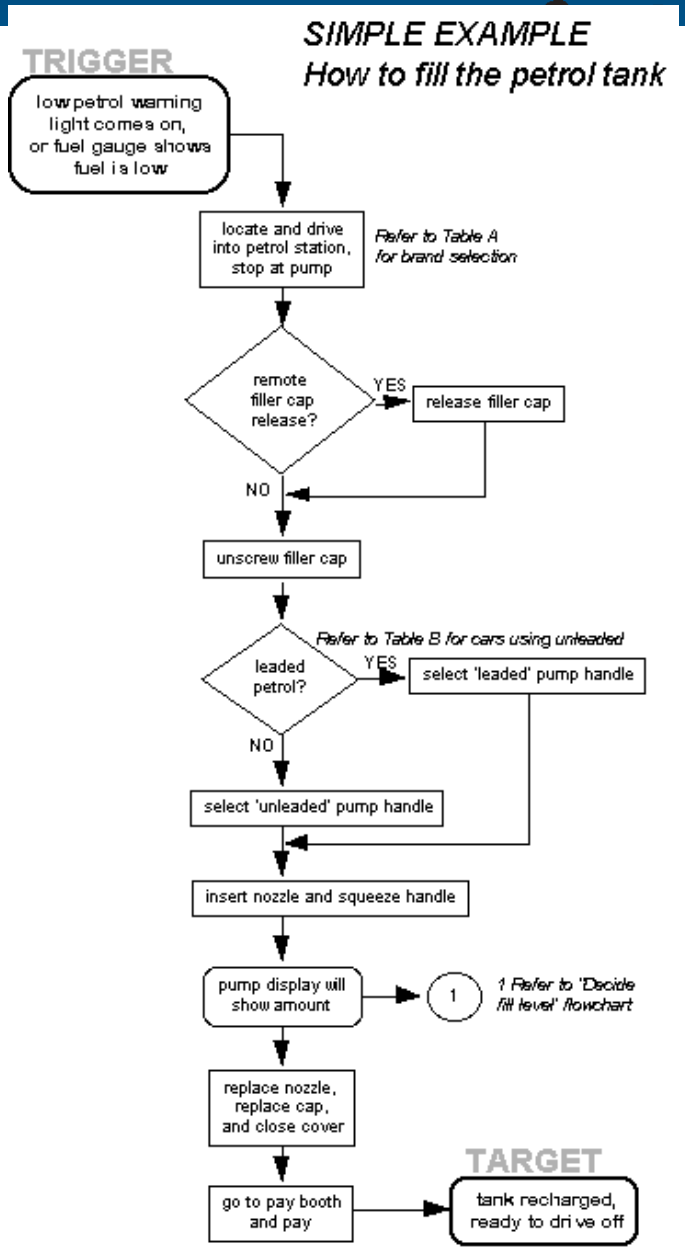
Root Cause Analysis Tools - Fishbone Diagrams

All potential elements



Root Cause Analysis Tools – Flowcharts

Flow Charts Provides a visual description of a process(es) and interrelationships

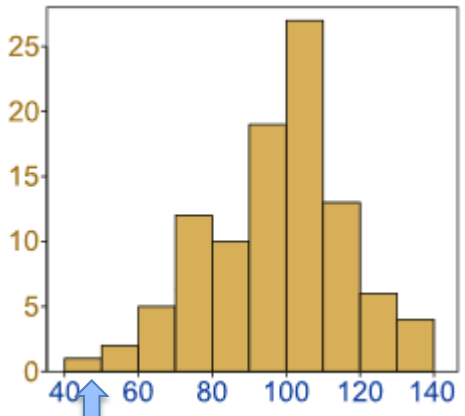


Root Cause Analysis Tools - Pareto Charts & Histograms

Histograms - Bar chart, used to graphically represent **groups** of data

Pareto Charts - A chart for documenting and ranking occurrences by a defined criteria (i.e. Defect Type)

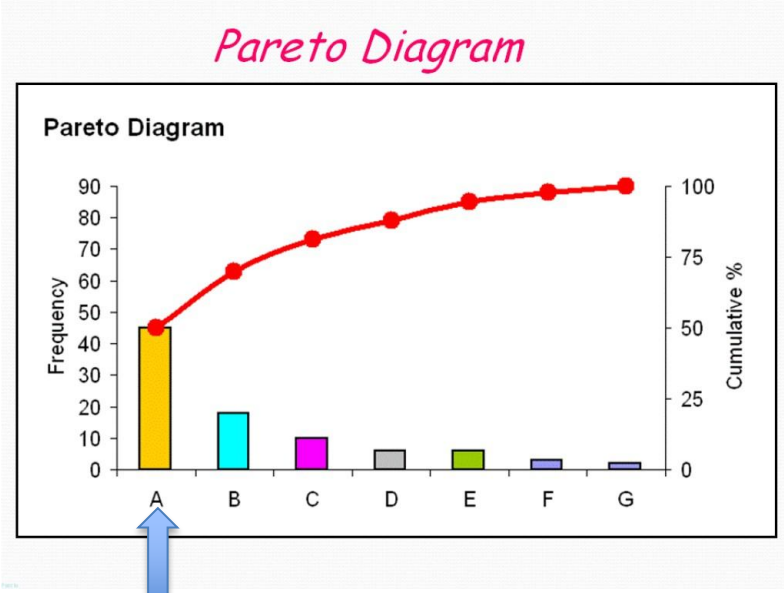
Pareto ranks data in order (largest to smallest). Histograms ranks data in defined groupings.



Histogram

Number of events
in a range (i.e. 40-50)

Vs.



Number of events
with an exact value (i.e. defect A)

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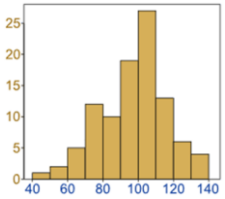
Root Cause Analysis Tools - Pareto Charts & Histograms



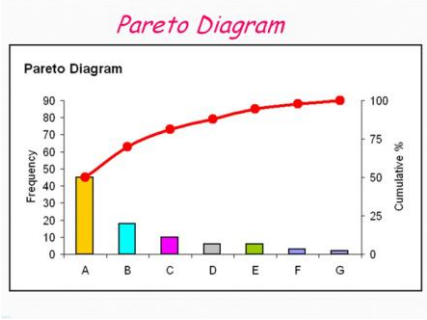
Variable Data

- Data where there can be more than one possible outcome
  - Examples: Temperature, Voltage, Pressure, Length, Width
- For Analysis or Control Purposes data is categorized into ranges (i.e. 0-10 volts)
- Histograms are typically used to show the distribution of the values by number of occurrences. Ranking by range order not occurrence order

Discrete Data

- Data where only one outcome is possible. (i.e. Yes / No, Is / Is Not)
- Usually defines an attribute (defect type)

- Pareto charts are typically used to identify the biggest problem, defect,



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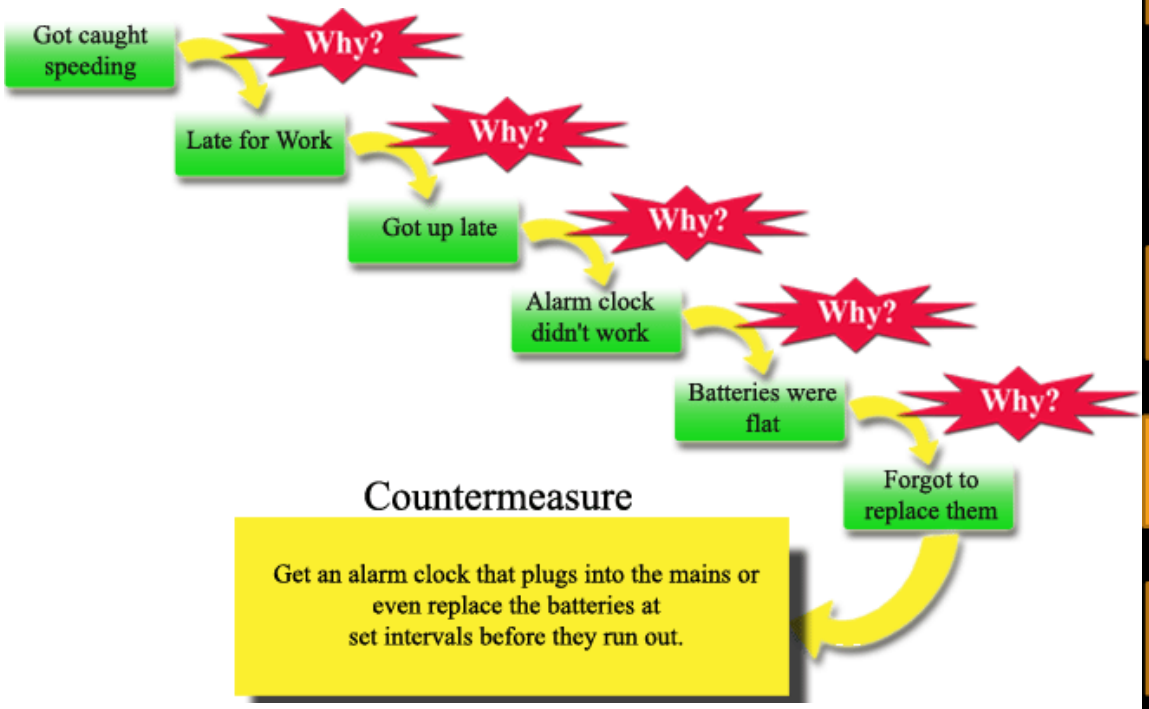
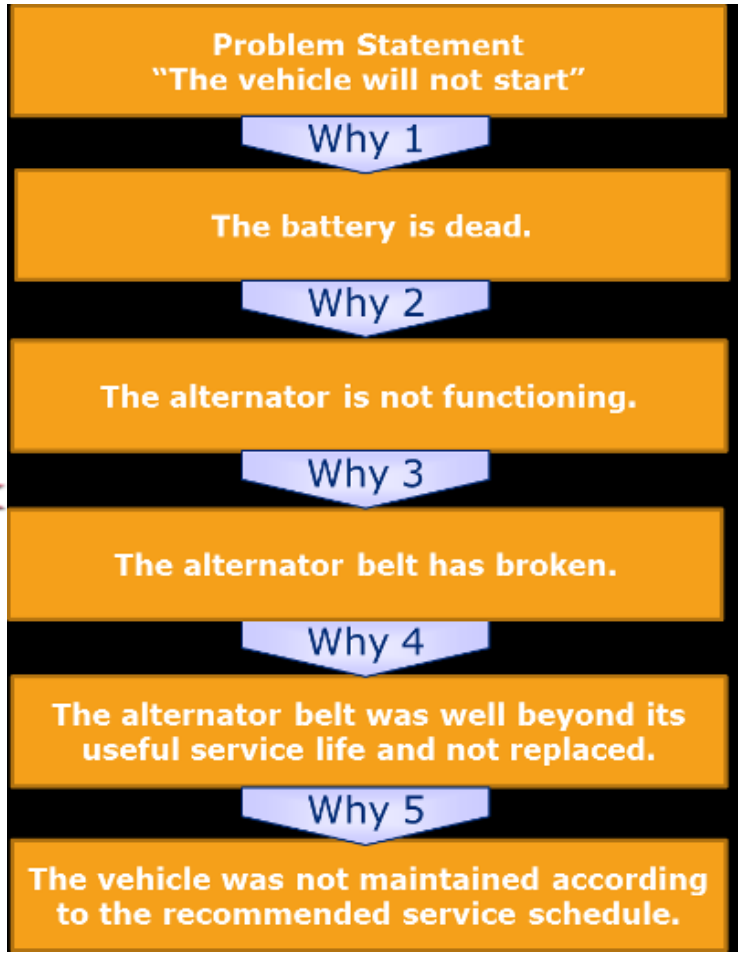
Root Cause Analysis Tools – 3 Way / 5 Why Approach

to 5 times during problem investigation.

EXAMPLES:





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Root Cause Analysis Tools - 3 Way / 5 Why Approach

Targeting Three Key Areas

Occurrence:

Why did the non conformance occur?

Non Detection

Systemic

Why did our system(s) allowed this to happen and/or did not prevent it?

Systemic Root Cause is the most missed cause. Opportunities for system improvement are commonly missed (i.e. mistake proofing)/

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Root Cause Analysis Tools - 3 Way / 5 Why Approach

3 Way / 5 Why Example:

Problem Description: Incorrect parts received by Customer

- Occurrence:

  Why?

  Part Number from customer order incorrectly entered

  Why?

  Entry clerk did not verify correct entry before pressing enter

  Why?

  Entry clerk was not aware this was required

  Why?

  Training material did not contain instruction on how and when to verify

  Why?

  Training material did not fully match procedure and procedure not included in the training

From this analysis we should also be led to look at the training procedures and systems

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Root Cause Analysis Tools - 3 Way / 5 Why Approach

- Non -Detection:

  Why?

  Part number received matched internal part number.

  Why?

  Order was processed using only internal part number.

  Why?

  No process steps, after order entry, verify order to customer provided part number

  Why?

  The inspection processes in place do not include verification to customer provided part number, only internal part number

  Why?

  When designing the inspection process, the potential for order entry error was not considered.

From this analysis, the inspection process should be considered for improvement to include verification of orders against the customer provide part number. An opportunity to improve the effectiveness of advanced quality tools such as Process FMEA is also present.

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Root Cause Analysis Tools - 3 Way / 5 Why Approach

- Systemic:

  At least three elements could be explored here:

  1. Training process and gaps
  2. Manual data entry process and opportunity for entry error
  3. Subsequent processes for their ability to detect wrong parts

  Looking at element 1:

  Why?

  Entry Clerk not aware of procedure requirement to verify correct entry prior to

  Why?

  Training process did not include training to actual procedure

  Why?

  Training process did not specifically document this as a requirement

  Why?

  actual procedures and specified requirements

  Why?

  Effectiveness measurements and results did not indicate any concerns.

From this analysis, the inspection process should be considered for improvement to include verification of orders against the customer provide part number. An opportunity to improve the effectiveness of advanced quality tools such as Process FMEA is also present.

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D5 Corrective Action

Remember: Effective Root Cause Analysis before Corrective Action

- Identify Action plan
  - ✓ CAPA team should identify actions according to root course identified.
  - ✓ Each action should be described clearly to ensure that action owner understand how to do and what output is the completion point.
  - ✓ If actions include quality procedure revision, procedure number, description and version should be defined.
- Action plan review and approval
- Implementation

Definition:

- Correction: Action to eliminate a detected nonconformity.
- Corrective Action: action taken to eliminate the causes of an identified nonconformity, defect or other undesirable situation in order to prevent recurrence.

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D5 Corrective Action

Difference between Correction and Corrective Action

- Correction: Takes steps to correct a problem it has no bearing on cause.
- Corrective Action Takes actions to address the cause(s) of a problem

- Correction fixes the CURRENT set of issues
- Corrective action prevents it from happening again by considering and addressing the causes

Example: A customer orders 500 parts, but only 450 are delivered.

Correction - Fix the current issue

get the customer 50 more parts

Corrective Action - Why were we short?

Operator miscounted 9 boxes of 50 as 10 boxes of 50

Preventive Action - make sure it doesn't happen again (anywhere / anyplace)

Weigh products on scale so you know if quantity is met

Note: ISO 9001 requires the organization to have a documented procedure for corrective an preventive action.

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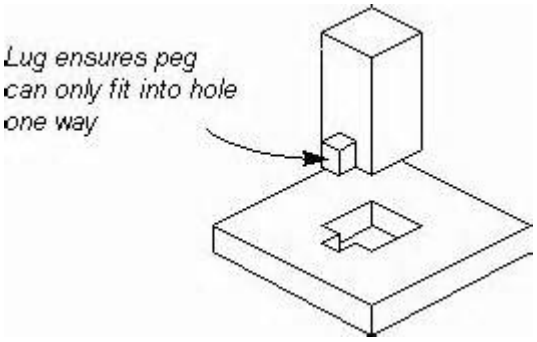
D6 Preventive Action

- Action taken to eliminated the causes of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence in the same or similar product or situation.
- Actions that are taken make sure it doesn't happen again (anywhere / anyplace)
  - ✓ e.g. Weigh products on scale so you know if quantity is met
  - ✓ Note: ISO 9001 requires the organization to have a documented procedure for corrective and preventive action.
- Looks for all areas where the corrective actions can be applied and applies them.
- Applies corrective actions to new products as applicable
- Looks at opportunities for mistake proofing Cannot make, cannot pass a defect approach

Example of Mistake proofing:



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D6 Preventive Action

Difference between Corrective Action and Preventive Action

- Corrective action addressed a problem, concern or issue that already has occurred.

- Preventive action seeks to prevent a problem, concern or issue from happening.
  - ✓ Take **proactive** steps to ensure a potential nonconformity does not occur.
  - ✓ Employ process and system analysis to determine how to build in safeguards and process changes to prevent nonconformance. For example, use a failure mode and effects analysis to identify risks and

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D7-D8 Implementation & Effectiveness Verification

- Each action owner shall implement actions according to plan and keep the records or other supporting documentations.
- CAPA owner is responsible for monitor the progress and follow all the action owner to ensure all the actions completed timely.
- Quality manager shall verify corrective and preventive actions have been implemented and are effective based on the effectiveness verification plan
- If any deficiencies identified during verification , it may need conduct root cause again or improve corrective/preventive action. Action

  submit again until it gets approve.
- Submit the evidence of sustainability based on the verification plan.

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Jabil requirement

- Jabil has defined its requirement to supplier on CAPA in **Jabil Supplier Requirement Manual** - 6.9 Product Quality Concern Resolution
  http://media.jabil.com/documents/JABIL-Supplier-Requirements-Manual.pdf

- manufacturing operations, additional costs being incurred and potentially impact our customer.

- You can find the guidelines for the supplier CAPA submission process in **Jabil Supplier Requirement Manual**

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Jabil requirement

- As Jabil supplier, you may be sent a particular template to be used for the completion of a requested corrective action. If no template is provided, your own format can be used provided that it contains **the minimum elements** listed below.

  a. Identification of the Corrective Action Team
  b. Problem Description (5W, 2H)
  c. Interim Containment Actions
     i. Actions Taken
     ii. Data showing effectiveness
  d. D. Root Cause (s)
     i. Root Cause for Occurrence
     ii. Root Cause for Not Detection
  e. E. Corrective Action(s)
  f. F. Verification Verification of the effectiveness of the corrective action(s) taken
  g. G. Preventive Action(s) Actions taken to prevent recurrence

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Jabil requirement

- Upon notification of a quality concern / request for corrective action, suppliers are expected to:

Immediate - Institute containment action(s) for product within your facility(ies), in transit and at Jabil facilities.

24 hours - Submit an initial containment plan to the Jabil requestor. Provide

5 days - Submit an initial failure analysis and corrective action report

10 days - Provide verification and recurrence prevention actions / evidence

30 days - Provide a final corrective action report with supporting data. Continue containment activities until corrective action closure confirmation has been received from Jabil.

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Summary

CAPA is very important way for product quality improvement

From this course, you have learned:

- An effective way to solve a problem CAPA
- An effective CAPA process 8D
-

Thank You

Looking forward to a good business cooperation with you

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