Agenda

Purpose

Why CAPA

An effective CAPA process

Jabil requirement

Summary

Purpose

To introduce an effective way for problem solving - CAPA

To introduce a typical CAPA approach ï 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

Why CAPA

CAPA: Corrective Action and Preventative Action

Why we need CAPA?

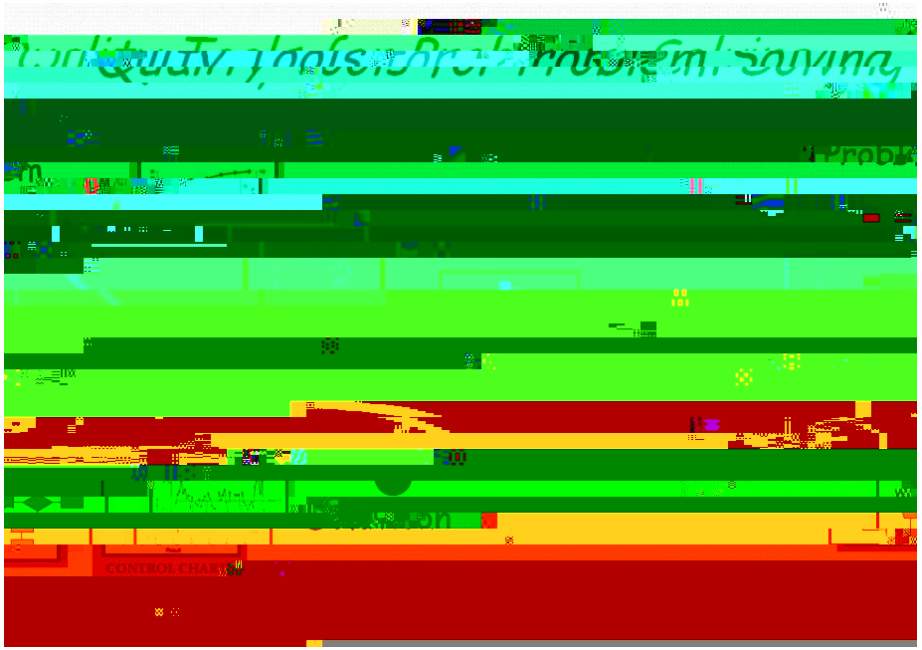
We meet problems and need to solve them almost everyday

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



ISO9001:2008 Requirements

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of

Good CAPA vs

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?

An effective CAPA process　8D

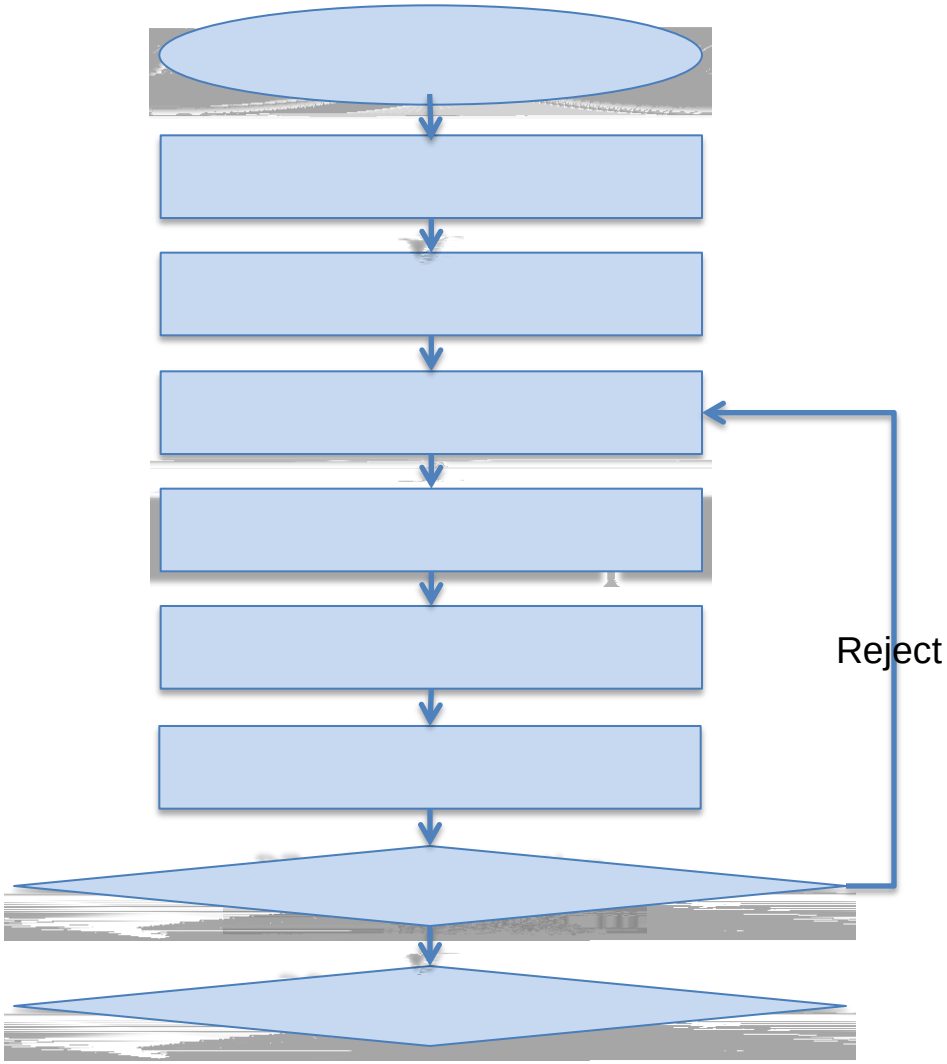
A good CAPA must be effective to solve a problem

Today, we will introduce an effective CAPA process ï 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.

8D process flow



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: justification for the ñwhatò

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

D2 Establish the Team

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

CAPA Team member qualification:

- Å Familiar with process of his/her function
- Å Complete the training of CAPA procedure
- Å 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 machine or modify its settings, to repair a producté etc)

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

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.

Investigation Steps & Tools

Steps:

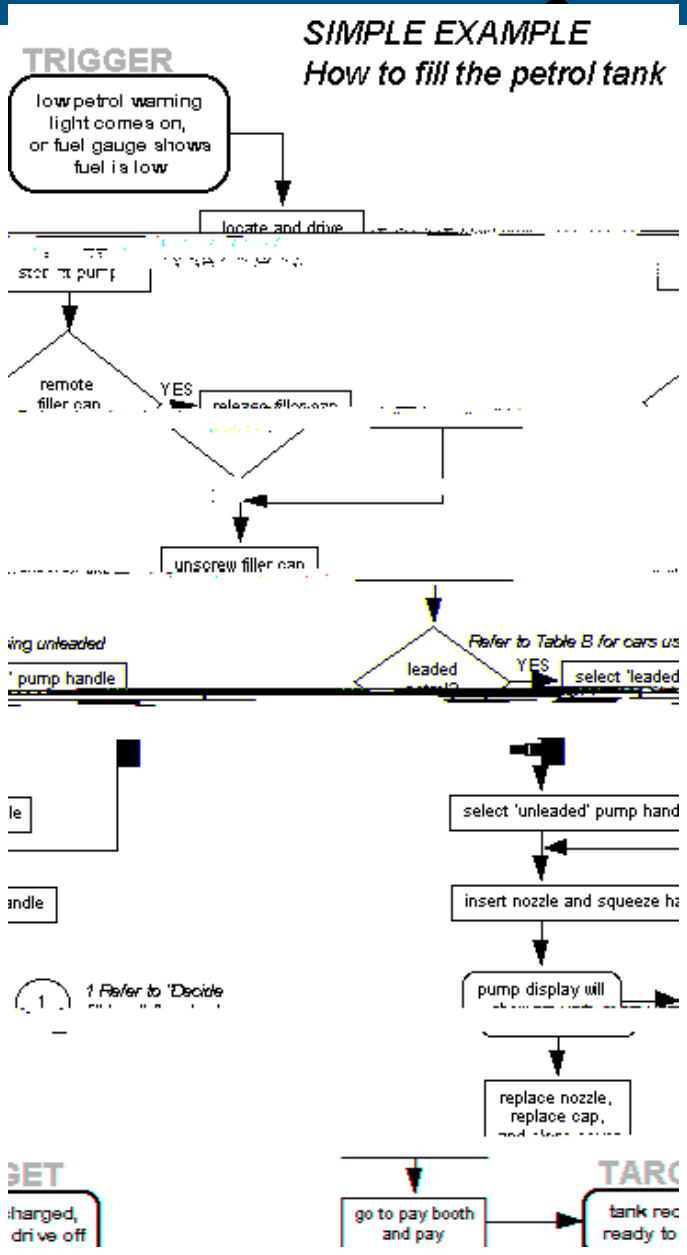
1. List all the potential causes using:
   - ï Fishbone Diagram; Process Maps;
2. Narrow or eliminate potential causes using:
   - Pareto Chart ;Scatter Diagram; Human error checklist
3. Get to root cause using:
   - ï 5 Whys; Pareto Chart; DOE
4. Verify Root cause using(if appropriate):
   - ï Simulation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

Tools:

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

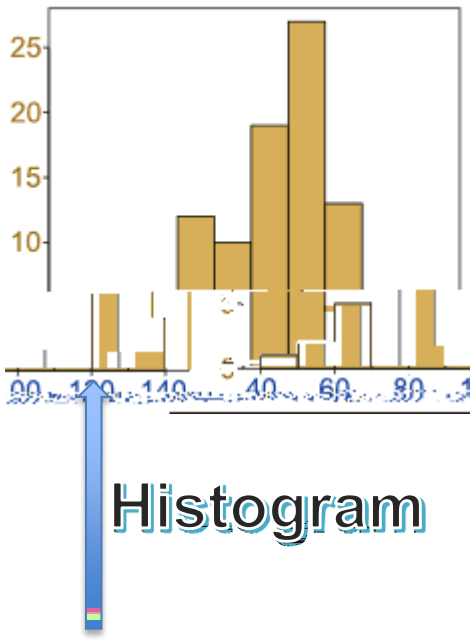
Root Cause Analysis Tools Flowcharts

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



Root Cause Analysis Tools - Pareto Charts & Histograms

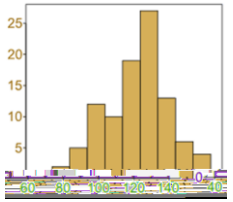
- Histograms - Bar chart, used to graphically represent **groups** of data
- Pareto Charts - A chart for documenting and ranking occurrences by a defined criteria (i.e. Defect Type)
- Pareto ranks data in order (largest to smallest). Histograms ranks data in defined groupings.



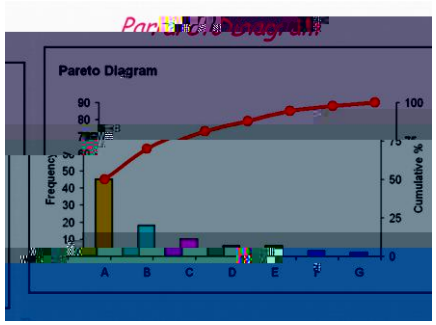
Vs.

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

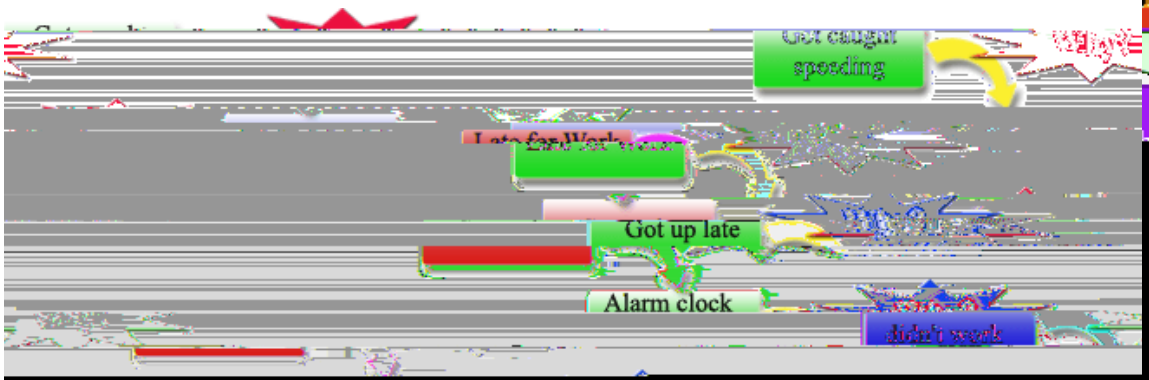


- Discrete Data
  - Data where only one outcome is possible. (i.e. Yes / No, Is / Is Not)
  - Usually defines an attribute (defect type)
    - i.e. Test Fail, Missing Solder, Misassembled, Missing Part, etcé
  - Pareto charts are typically used to identify the biggest problem, defect, etcé Provides a method for prioritizing

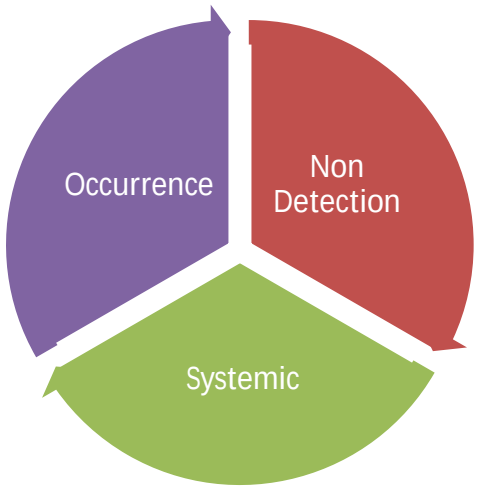


Root Cause Analysis Tools 3 Way / 5 Why Approach

- 5 Why is a method for determining Root Cause through asking the question ñWhyò up to 5 times during problem investigation.
- EXAMPLES:



Root Cause Analysis Tools - 3 Way / 5 Why Approach



- Asking ñWhyò5 Times
- Targeting Three Key Areas
  - Occurrence:
    - Why did the non conformance occur?
  - Non Detection
    - Why didnôt we see (detect) and contain the non conformance?
  - 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)/

Root Cause Analysis Tools - 3 Way / 5 Why Approach

- 3 Way / 5 Why Example:

  Problem Description: Incorrect parts received by Customer

  <u>Occurrence:</u>

  - 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

Root Cause Analysis Tools -

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.

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 pressing ñenterò
  - Why?
    - Training process did not include training to actual procedure
  - Why?
    - Training process did not specifically document this as a requirement
  - Why?
    - Training effectiveness measurement doesnôt include measuring r

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

D5 Corrective Action

Difference between Correction and Corrective Action

Correction: Takes steps to correct a problem it has no bearing on cause.

Corrective Action ï 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.

ÅCorrection - Fix the current issue

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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

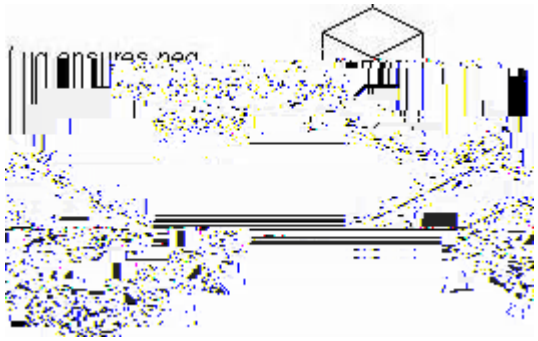
Note: ISO 9001 requires the organization to have a documented procedure for corrective and preventive action.

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 ï Cannot make, cannot pass a defect approach

Example of Mistake proofing:



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

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 owner should revise according to quality managerâs comments, and submit again until it gets approve.

Submit the evidence of sustainability based on the verification plan.

Jabil requirement

Jabil has defined its requirement to supplier on CAPA in **Jabil Supplier Requirement Manual -** 6.9 Product Quality Concern Resolution

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 ï Verification of the effectiveness of the corrective action(s) taken
g. G. Preventive Action(s) ï Actions taken to prevent recurrence

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 ñcertifiedò product as requested

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.

Summary

CAPA is very important way for product quality improvement

From this course, you have learned:

- An effective way to solve a problem ï CAPA
- An effective CAPA process ï 8D
- Jabilês requirement on supplier CAPA

Thank You

Looking forward to a good business cooperation with you