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Corrective Action

Root Cause Analysis and Corrective Action
Overview Webinar 6: Root Cause Analysis and Corrective Action

• What is Root Cause Analysis (RCA)?
• Why is RCA important?
• When is RCA required?
• Overview of the Corrective Action Process
• Root Cause Analysis Tools:
  ➢ The 5-Whys
  ➢ Ishikawa Cause & Effect (Fishbone) Diagrams
  ➢ Cause Mapping
  ➢ Failure Modes & Effects Analysis
  ➢ Design of Experiments
What is Root Cause Analysis (RCA)?

**Root Cause Analysis (RCA):** The *process* of identifying all the causes (root causes and contributing causes) that have or may have generated an undesirable condition, situation, nonconformity, or failure.

Root Cause Analysis (RCA)

PROBLEM = Weed (obvious)

CAUSE = ROOT (not obvious)
Why Root Cause Analysis (RCA)?

• Helps prevent problems from repeating or occurring.
• Focus on Continuous Improvement throughout the Enterprise.
• Drives Breakthrough Performance.
• Focus on improving processes that actually effect organization performance metrics.
When is RCA required?

- Undesirable condition, defect, or failure is detected
- Safety
- Product strength, performance, reliability
- High impact on Operations
- Repetitive Problems
- Customer Request
- Significant Quality Management System (QMS) issues

» IAQG – Root Cause Analysis and Problem Solving, April 2014
The Corrective Action (CA) Process

- **Objective:** Identify the cause(s) of problems and initiate actions to prevent recurrence.
  - Extent of corrective actions shall be proportional to the effects of the related problems.
  - Corrective action is applicable to the enterprise and not limited to the manufacturing environment.
  - Problems may originate and/or be identified within a product, process, and/or capability in any business area, function, or program.
The Corrective Action Process

- Increased focus on Problem Definition
- Requirement for Evidence-Based Causes
- Requirement to always look for Multiple Causes
- A Corrective Action end state that includes
  - Verified successful mistake proofed solutions
  - Goal of 0% Chance of Recurrence
Overview of the Corrective Action Process

- Step 1: Identify the Problem
- Step 2: Define the Problem
- Step 3: Investigate the Problem (Complete Containment Actions)
- Step 4: Analyze the Problem & Identify Root Cause (s)
- Step 5: Generate, Select and Implement Solutions (CA)
- Step 6: Verify the Results and Document
- Step 7: Monitor and Measure Corrective Actions
Corrective Action Process Flow:

**Inputs:**
- Nonconforming Products or Services
- Noncompliant Processes or Capabilities
- Audit Findings
- Customer Complaints
- Management Directives
- Program Monitoring or Review

**Outputs:**
- Implemented/Verified CA Plan
- Improved Capabilities/Products
- Costs Reduced
- Schedule Improved
- Quality Improved
- Customer Satisfaction
- Record of Corrective Action and Verification
Corrective Action Process

• 7 tools to determine root cause:
  – The 5 Why's
  – Cause & Effect Diagram (Fishbone)
  – Cause Mapping
  – FMEA: Failure Modes & Effects Analysis
  – Fault Tree Analysis
  – DOE: Design Of Experiments
  – Statistical Process Control

• Perform a Cause/Failure Analysis to determine the cause(s) of the problem. The appropriate root cause analysis tool will be used.

• The RCA tools are utilized and retained/attached as objective evidence to support root cause validation.
Severity/Impact Based RCA Approach

Instructions:
1. Use the description of Low, Medium, High to assess issue’s Severity and Likelihood of Recurrence
2. Based on the issue’s Severity and Likelihood of Recurrence, map to the corresponding Level of RCA
3. Using the color of the RCA Level as a guide, assess the requirements for that RCA tool

<table>
<thead>
<tr>
<th>Severity</th>
<th>Occurrence</th>
<th>Level 1 RCA</th>
<th>Level 2 RCA</th>
<th>Level 3 RCA</th>
<th>Level 4 RCA</th>
<th>Highest Risk Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Low</td>
<td>Lowest Risk Items</td>
<td>Level 2 RCA</td>
<td>Level 2 RCA</td>
<td>Level 3 RCA</td>
<td>Level 4 RCA</td>
</tr>
<tr>
<td>Medium</td>
<td>Medium</td>
<td>Level 1 RCA</td>
<td>Level 2 RCA</td>
<td>Level 3 RCA</td>
<td>Level 4 RCA</td>
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<tr>
<td>High</td>
<td>High</td>
<td>Level 1 RCA</td>
<td>Level 2 RCA</td>
<td>Level 3 RCA</td>
<td>Level 4 RCA</td>
<td>Highest Risk Items</td>
</tr>
</tbody>
</table>

Lowest Risk Items:
- May find future isolated failures

Low Risk Items:
- Minor disruption to process
- Output may have to be sorted and a portion reworked
- Fit and finish does not conform
- Noticeable to some customers

Medium Risk Items:
- Minor disruption to process
- Portion may have to be scrapped
- Operable but without all conveniences
- Fit and finish does not conform
- Concerned customer
- DCMA Level II CAR

High Risk Items:
- Major disruption to process
- 100% may have to be scrapped
- Inoperable, loss of primary function
- Dissatisfied customer
- DCMA Level III CAR

Severity:
- Significance of Impact

Likelihood of the Event Recurring:
- Occurrence of the Event
# What RCA Tool Should I Use?

<table>
<thead>
<tr>
<th>RCA Level</th>
<th>Impact</th>
<th>RCA Requirements</th>
<th>Recommended RCA Lead</th>
<th>Typical Analysis Span*</th>
<th>Output Templates</th>
</tr>
</thead>
</table>
| 5         | High-High       | Apollo RCA using RealityCharting Tool                     | Experienced and Certified Apollo RCA Facilitator               | 2 – 6 Weeks            | 1. Summary including Problem Statement  
2. RCA Findings and Conclusions  
3. RCA Corrective Action Solutions and Measurement Strategy  
4. Illustration of Apollo RCA Template  
OR…  
1. Illustration of Apollo RCA Template |
| 4         | High-Medium     | RCA using Think Reliability Tool, Apollo RCA using RealityCharting Tool | Experienced and Certified Apollo or Think Reliability RCA Facilitator | 1– 4 Weeks            | 1. Summary including Problem Statement  
2. RCA Findings and Conclusions  
3. RCA Corrective Action Solutions and Measurement Strategy  
4. Applicable Illustration of RCA Template  
OR…  
1. Applicable Illustration of RCA Template |
| 3         | High-Low        | FMEA - Failure Modes Effects Analysis, Apollo Methodology, Apollo RealityCharting, Think Reliability | FMEA Trained Employee, Apollo or Think Reliability RCA Trained Facilitator or | 1 day – 3 weeks       | 1. Summary including Problem Statement  
2. RCA Findings and Conclusions  
3. RCA Corrective Action Solutions and Measurement Strategy  
4. Applicable Illustration of RCA Template  
OR…  
1. Applicable Illustration of RCA Template |
| 2         | Low-Medium      | 5 Whys, Fishbone Diagram, FMEA - Failure Modes Effects Analysis | Trained Employee, Green Belt / Black Belt | 1 day – 2 weeks       | 1. Summary including Problem Statement  
2. Applicable Illustration of RCA Template |
| 1         | Low-Low         | 5 Whys, Fishbone Diagram | All Trained Employees | 1 – 8 hours | 1. Summary including Problem Statement  
2. Applicable Illustration of RCA Template |

* Analysis Span Time for completion of an effective RCA is dependent upon:  
1) Scope of problem; 2) Quality of preparation; and 3) Resources allocated to RCA and problem resolution
Selecting a RCA Leader

- Problem Complexity
- Data type and availability
- Type analyses required
- Individual or team based approach RCA
- Severity of issue/impact to business
- Internal/external engagement
Root Cause Analysis Tools

- The 5-Whys
- Cause & Effect (Fishbone/Ishikawa Diagrams)
- Cause Mapping
- Failure Modes & Effects Analysis
- Design of Experiments
The 5 Why’s

• What is a 5 Why?
  – A question based technique used to explore cause-and-effect relationships
  – Determine root cause of a problem
  – Ask Why? As *many times as needed*!

• Advantages
  – Easy to use and teach
  – Identifies more than one cause
  – Useful for minor problems
  – Used to generate causes for use in other RCA methods

• Limitations
  – Linear thinking ignores additional causes
  – Not appropriate for formal investigations
  – Perpetuates the myth of single root cause
  – Does not provide guidance for solutions

• Supporting Tools
  – 5 Why Template - this is a text only approach
5 Whys Template

Instructions: Start with your focused problem and then ask WHY five times.

Focused Problem Statement:
Problem: High reject rate of parts used by downstream aircraft assembly process

Why
There is bare material exposed

Why
The primer paint coating does not cover the whole part

Why
The priming process does not ensure full coverage

Why
The priming process is never done the same way twice

Solution: Create a standard work method that defines the exact sequence and tools for priming the parts. This will significantly improve the process yield.

Why
The priming process has always relied on word-of-mouth training and has no standard process defined
A New Look at 5 Why Templates

THE SINGLE CAUSE TEMPLATE

PROBLEM STATEMENT: ___________________________________________________

WHY? ________________________________________________________________
WHY? ________________________________________________________________
WHY? ________________________________________________________________
WHY? ________________________________________________________________

This example is a typical format for narrow problem statements where one cause-path exists. For problem statements with multiple causes, use the template below.

MULTIPLE CAUSES TEMPLATE

PROBLEM STATEMENT: ___________________________________________________

WHY? 1 << % of Pareto ______________________________________________________
WHY? 2 << % of Pareto ______________________________________________________

Proposed Operating Instruction for alternate 5
Why Template

5 Why Operating Instruction
Ishikawa Cause & Effect Diagram (Fishbone)

What is A Cause and Effect Diagram?
• A tool used to illustrate the relationship between an effect and the causes that influence the effect

When to Use It?
• Identify causes of a problem (Effect)
• Can be used to prevent future problems
Advantages
- Encourages brainstorming
- Can be used when time is very limited
- Helps organize many potential causes

Limitations
- Categories may cause investigations to stop at "categorical causes"
- Creates the illusion of equal weight among causes
- No guidance for prioritizing causes or developing solutions
- Usually stops at 1 or 2 levels of causes (stops too soon)
Ishikawa Cause & Effect Diagram (Fishbone)

• For every Effect there are likely to be several Major Causes

• Major Causes include: People, Measurements, Machines, Methods, Materials, Environment

• Any major category that helps people think creatively can be used
Ishikawa Cause & Effect Diagram (Fishbone)

- Methods = work instructions, procedures, test methods
- Material = components and raw materials
- Measurements = standards, calibration, gages, data collection
- People = training and staffing
- Machines = tools, equipment, fixtures
- Environment = temperature, humidity, lighting, noise

Goal is to discover all possible Causes related to the Effect!

Diagram:
- **CAUSES**
  - METHODS
  - PEOPLE
  - ENVIRONMENT
- **EFFECT**
  - P. C. Board Yield Too Low

- HAND WAVE
- SOLDER
- INSERTION
- INCORRECT
- GAGE
- AUTO TEST
- TRAINING
- ABSENTEEISM
- DEBRIS
- ESD
- INCORRECT
- GAGE
- AUTO TEST
- SHORTAGE
- WRONG PARTS
- VENDOR
- PURCHASING
How to Construct a Cause & Effect Diagram:

- Brainstorm – include Subject Matter Experts (SME)
- Add the problem to the EFFECT box.
- Add the Major Cause categories
- Place the potential causes in the Major Cause category.
- For each Cause ask, “Why does it happen?”
- List the responses as branches off the Major cause.

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**CAUSES**

- **METHODS**
  - HAND
  - WAVE
  - SOLDER
  - INSERTION

- **PEOPLE**
  - TRAINING
  - ABSENTEEISM

- **ENVIRONMENT**
  - DEBRIS
  - ESD

- **MACHINES**
  - AUTO TEST

- **MATERIALS**
  - SHORTAGE
  - INCORRECT GAGE
  - MEASUREMENTS
  - VENDOR
  - PURCHASING
  - WRONG PARTS

---

**EFFECT**

P. C. Board Yield Too Low
Ishikawa Cause & Effect Diagram (Fishbone)

How to Interpret?

– Look for causes that appear frequently.
– Reach a team consensus.
– Determine the relative frequencies of the different causes.

P. C. Board Yield Too Low

METHODS

PEOPLE

ENVIRONMENT

CAUSES

MEASUREMENTS

MACHINES

MATERIALS

EFFECT

HAND wave

SOLDER INSERTION

INCORRECT GAGE

AUTO TEST

TRAINING

ABSENTEEISM

DEBRIS

ESD

WRONG PARTS

VENDOR PURCHASING
Example of Cause & Effect Diagram

Car Will Not Start

Materials

- Lost the Keys
- Out of Gas

Machines

- Starter Broken
- Battery Dead
- Engine Overheated
- Battery Cables Corroded

Measurement

- Gas Gauge Broken

Methods

- Not Pressing Accelerator
- Locked Out of Car

People

- Lack of Training
- Using Wrong Key
- Forgot Code to Start Car

Environment

- Too Cold
- No Preventive Maintenance
Example C&E Diagram - Canopy Leakage

- **Design**
  - Cause: Design allows leakage?
  - Cause: Variation in poppet seat design allowing for different decay rates?
  - Cause: Tolerance build up
  - Cause: Check valve design allows FOD to settle at check valve
  - Cause: Relief valve seat leakage
  - Cause: Valve body leakage. Test confirmed no body leakage
  - Cause: Solenoid not fully closing
  - Cause: Solenoid voltage residual drop out
  - Cause: Solenoid failure
  - Cause: Supplier regulator malfunction. Regulator not in action during leakage test

- **Assembly**
  - Cause: FOD induced during assembly
  - Cause: Improper assembly of poppets
  - Cause: Anodize or paint on seat surface

- **Test**
  - Cause: Test bench set up/ ATP. Check for leakage of system at bench
  - Cause: Poppet alignment at assembly level
  - Cause: Seat oversize. Poppet is cone shape. Contained
  - Cause: Check valve seat out of round and surface finish
  - Cause: Poppets out of round & surface finish

- **Rework**
  - Cause: Non standard reseating practices. Removed seating tools to prevent practice. Contained
  - Cause: System leakage. Would pass ATP upon return

- **Material**
  - Cause: Material analysis of poppet and seat assembly
  - Cause: Spring force/ rates. Not in action for reverse flow check
  - Cause: Spring rate variation Not in action for reverse flow
  - Cause: From shipping and handling. Unit is capped at Final out

**Legend**
- No Contribution
- Still Investigating
- Major Contributor

Functional failure of valve (leakage decay) 20 psi to 15 in 20 seconds minimum
What is a Cause Map?

- A visual explanation of why an incident occurred
- Connects single cause-and-effect relationships to a system of causes
- A Cause Map can be basic or very detailed
Cause Mapping for Root Cause

Step 1: Problem Statement
• Identify/Outline the Problem (What, When, Where, Goal)
• The Outline explains why time is spent on an issue

Step 2: Analysis
• Identify/Breakdown the Causes
• This step is where the Cause Map is built

Step 3: Solutions
• Identify Possibilities
• Select the most appropriate Solution
• Implement specific Corrective Action
• Verify/Validate Effectiveness
• Document with Objective Evidence
Cause Mapping - How to read a Cause Map

State the Problem

Ask Why Questions - "Why did this effect happen?"

Record Response = Cause (or causes)
Cause Map Example

Safety Goals Impacted

Melissa Injured Right shoulder

Pushing cart

Standard procedure for picking up/delivering items to work area

Evidence:

Possible Solutions:

Heavy load on cart

There is not current load limit

Possible Solutions:

Cart was not rolling right

Possible Solutions:

Wheel was jammed

Possible Solutions:

Twig/stick stuck in wheel

Evidence:

Standard load limit can not be defined

Evidence:

Possible Solutions:

Carts are also used outside

Evidence:
Cause Mapping

• When to Use It:
  – Use to develop an effective solutions to prevent recurrence of undesired effects
  – Use when you want to fully understand causes of success
  – Use to reveal the entire system of causes
  – Use it when you need to dive deeper into a problem

• Advantages:
  – Reveals the entire system of causes and effects
  – Focuses on cause-effect relationships
  – Emphasizes effective solutions to prevent recurrence
  – Mitigates the hazards of using categories or checklists alone to drive analysis
  – Focuses attention on events and conditions rather than people

• Limitations:
  – Does not prioritize causes or solutions
  – Has a learning curve for facilitators and team members
  – Lengthier process than other tools
  – Does not lend itself to proactive problem solving
Failure Mode & Effects Analysis (FMEA)

What is FMEA?
A systematic method for identifying, analyzing, prioritizing, and documenting potential failure modes and their effects on a system, product, or process and the possible causes of failure.

Where Is FMEA Used?
Used extensively in safety oriented and aerospace businesses.

Why FMEA?
- Reduce development cost by early risk identification
- Documented evaluation of risk
- Minimize product failures
- Track process improvements
- Develop efficient test plans
Failure Modes and Effects Analysis (FMEA)

• When to Use FMEA:
  – Identify and eliminate known or potential failures or errors from a product or a process
    • Engineering – mitigate risk in product design
    • Manufacturing – reduce and eliminate product defects
    • Transactional – reduce and eliminate process errors
  – Use when identification of the root cause may be complex

• Advantages
  – Provides quantitative rankings with defined scale for prioritizing based on severity, occurrence, and detection of current controls
  – Analyzes potential causes
  – Can be used proactively (risk management)
  – Can be used to assess current mitigation plans
  – Provides a structure for developing and prioritizing solutions

• Limitations
  – Does not delineate causal relationships
  – Does not require supporting causes with evidence
  – Addresses specific failure modes individually without taking a systems view
Failure Mode & Effects Analysis (FMEA)

Types of FMEAs

- **Process:** Used to analyze processes and identify potential failure modes

- **Design/Product:** Used to analyze products and identify potential failure modes early in the development cycle

- **Defect:** Used to analyze and prioritize defects to prevent recurrences in products and processes
Failure Mode & Effects Analysis (FMEA) Tool

1. Form Team

3. Brainstorm potential failures that may cause the product or process to fail to meet its intent

4. List product or process

5. Assign a severity score to each failure mode based on severity of impact

6. List the consequences of each failure mode

7. Assign an occurrence score to each failure mode based on frequency of occurrence

8. Identify causes of failure mode

9. Assign a detection score to each failure mode based on ability to detect failure mode

8. Identify controls that detect failure mode

10. RPN (Risk Priority Number) = SEV * OCC * DET
    This serves as the level of priority that should be assigned to each failure mode

<table>
<thead>
<tr>
<th>Process</th>
<th>Failure Mode</th>
<th>Failure Effect</th>
<th>Sev</th>
<th>Cause</th>
<th>Occ</th>
<th>Controls</th>
<th>Det</th>
<th>RPN</th>
</tr>
</thead>
</table>

Form Team
Design of Experiments (DOE)

Why Use DOE?

- Can be used to help improve the capability of a process by identifying the process and product variables that effect the mean and the variance of the quality characteristics of a product.

- Can be used as a powerful tool to achieve manufacturing cost savings by minimizing process variation, reducing rework and reducing scrap

- Use DOE when more than one input factor is suspected of influencing an output.
Design of Experiments (DOE)

When Can I Use DOE?

- When you want to find the input settings that optimize the output of a process
- When you want a mathematical model relating the outputs and/or variance of a process to the inputs
- When you want to identify the most important input factors that influence the mean output or the variance of the output
- When you want to determine the cause of a product failure
Design of Experiments (DOE)

Where Can I Use DOE?

- Any process with measurable quantitative or qualitative inputs and quantitative outputs is a potential application for DOE
- In engineering design, to find component values and tolerances that optimize the response
- In production, to optimize the yield of a machine or assembly process
- In testing, to ensure the fullest coverage of possible inputs with a minimum number of tests

**DOE Applications Are Limited Only By The Imagination**
Summary

• Root Cause Analysis is not easy!
• Be diligent in the pursuit of Root Cause
• Address the Cause not the Symptom
• The RCA Tools presented today will help ensure:
  ➢ Thorough Investigations
  ➢ Identification of Root Cause
  ➢ Effective Corrective Actions

*Root Cause + Effective Corrective Action = Problem Elimination!*
Summary

- **Root Cause Analysis** is the process of applying the cause and effect principle to solve problems. A root cause analysis program should be a systems approach to finding effective solutions to prevent problems from occurring or recurring.

- **RCA Tools** provide a means to conduct systematic analysis of a problem to identify cause and effect relationships and identify appropriate solutions to eliminate nonconformances.

- **Corrective Action**: Action(s) taken to eliminate the cause of nonconformances in order to prevent recurrence.

- **Root Cause Analysis** helps ensure:
  - Continuous improvement
  - Efficient use of resources
  - Focus on actions that are most impactful

*Root Cause + Effective Corrective Action = Problem Elimination!*
Root Cause Analysis References

• IAQG – Root Cause Analysis and Problem Solving (aligned with IAQG 9136 draft) www.iaqg.org/scmh

• The Memory Jogger 2 – Tools for Continuous Improvement and Effective Planning

• The Lean Six Sigma Pocket Tool Book

• Think Reliability www.thinkreliability.com