ETI GROUP

Six Sigma / Lean Six Sigma
Lean Enterprise
Business Management Systems
Strategic Planning
Integrated Performance Measurement

Root Cause Analysis and Corrective Action

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Root Cause Analysis

and

Corrective Action

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Learning Objectives

Upon successful completion of this training course, you will be able to:

- ☑ Describe the components of good corrective and preventive action.
- ☑ Differentiate between containment actions and root cause analysis.
- ☑ Create meaningful problem statements.
- ☑ Select and use tools to investigate true root causes of problems, including Technical, Escape, and System levels as well as Human Factor errors.
- ☑ Evaluate and prioritize solutions.
- ☑ Evaluate effectiveness, suitability and adaptability of implemented solutions for corrective and preventive actions.

Introductions

- Please introduce yourself
- What do you do in your organization?
- How long have you worked there?
- What are your expectations for today?

The Improvement System

- Corrective Action (CA) and Preventive Action (PA) are key components of maintaining and improving performance effectiveness.
- This element of your Quality Management System, if executed consistently and well, provides the greatest return on your investment.
- Effective Improvement means finding the root causes of actual and potential problems and developing permanent solutions.

Why are CA & PA important?

The Rule of 10's

Where Defects Found:	Own Process	Next Process	End of Line	Final Check	End User
Relative Cost to the Company					
Impact to the Company	• Very minor	• Minor delay	• Rework • Reschedule work	• Significant rework/re-do • Delay in delivery • Additional checking	• Warranty cost • Admin. cost • Loss of reputation • Loss of market

Typical Improvement System Problems

- Misunderstand difference between CA and PA
- Procedures do not adequately define the process
- Lack of an integrated approach
  - ☑ One person “fixes” each problem
  - ☑ No or little consideration of involving others or affect on others
- No verification of effectiveness of solutions, especially long-term
- No follow-up method to ensure closure or follow-up is ineffective
- No escalation policy or process (for lack of response, disputes, etc.)
- No analysis of trends or use of available data
- Do not use good root cause analysis
- Limited to ‘product’ problems &/or audit findings

Timeline of Corrective & Preventive Action

CA:	Cause Occurs	Problem Discovered	Effects Contained	Problem Prevented from Recurring
PA:	Risk Assessment, Monitoring & Measurement, Data Analysis…	Potential Problem Identified	Contingency Actions Taken	Problem Prevented from Occurring

Root Cause Analysis

When a potential cause cannot be prevented from occurring, a typical approach is to try to reduce the severity of the effects…this is where contingency actions are appropriate.

ISO 9000:2015 Definitions

- Correction

  action to eliminate a detected nonconformity

- Corrective Action

  action to eliminate the cause of a nonconformity and to prevent recurrence

- Preventive Action

  action to eliminate the cause of a potential nonconformity or other potential undesirable situation

Source: *ISO 9000:2015 Quality management systems — Fundamentals and vocabulary*

Notes to these definitions include the explanation that there can be more than one cause, and the contrast of prevention of recurrence for CA with that of occurrence for PA.

Characteristics of Effective Improvement Systems

- Strong management support & demonstrated use of the Improvement system
- CA and PA performance regularly reported & is very visible (both successes and failures)
- Excellent tracking system — diligently used!
- Widespread knowledge & use of problem-solving skills
- **Not** just a "quality" responsibility — all staff uses it
- Screening process that uses limited resources wisely
- Improvement results link to organizational goals
- Solutions are permanent, accepted, effective and efficient

Risk Management is a requirement for any ISO 9001-based Quality Management System; top management is given the initial responsibility for establishing risk-based thinking and practices.

The problem solving methods we'll discuss in this course can be applied to day-to-day issues (like dealing with nonconforming products or processes), as well as to broader systemic issues and initiatives that require deeper investigation into organization structures and policies and may involve multiple areas of an organization. These larger issues are typically addressed through a formal Corrective/Preventive Action system (aka CAPA).

An effective screening process will combine data analysis with risk assessment to prioritize where and when to initiate a formal CAPA request.

What Initiates a Corrective Action?

- A single major failure incident occurs for a product, service &/or process
- Aggregated discrepancy data indicates a major problem category
  - incoming product inspection/ test failures
  - internal product inspection/ test failures
  - warranty returns
  - process/machine failures
  - installation/service issues
  - customer complaints, poor customer scorecard results, etc.
- A customer request for Corrective Action is received
- External/internal audit results in a Finding of Nonconformance &/or Noncompliance

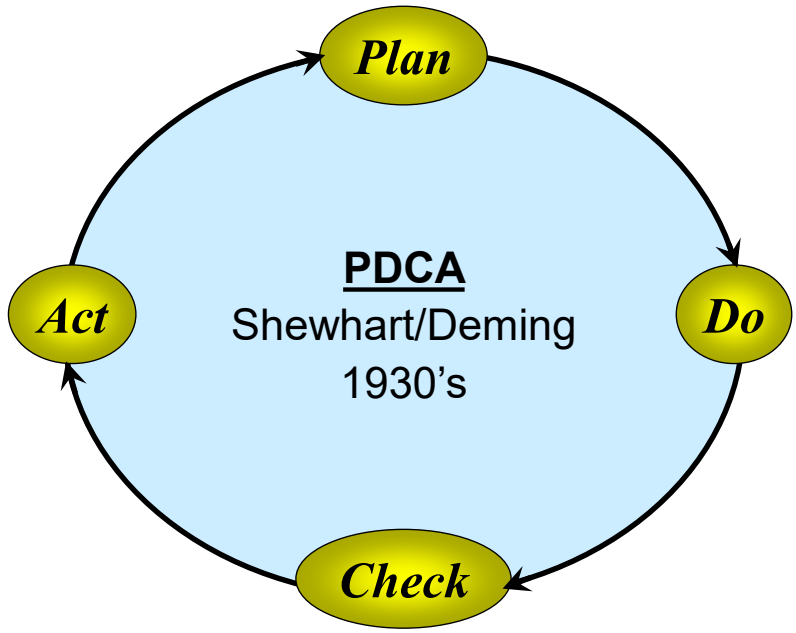
Initiation of a Preventive Action Project is similar, with the difference that the issue is a potential problem, i.e., it has not yet occurred. Data analysis may indicate an undesirable trend, risk assessment may result in the identification of potential issues, an auditor may give Observations, etc.

An organization's system for Improvement could also encompass Lean Six Sigma projects.

Structured Problem Solving

- Effective root cause problem-solving requires a disciplined, understandable methodology
- Flexibility is also important, since problems are not all created equal — they vary in degree of complexity, urgency, scope and impact
- A problem-solving structure than can be used for both minor day-to-day nonconformances as well as major customer or internal product & process issues is desirable

Plan-Do-Check-Act Cycle



Root Cause Analysis

PDCA is the oldest improvement cycle aimed at manufacturing, business and service processes. It was developed in the 1930's by Walter Shewhart and popularized by W. Edwards Deming. Deming later added "Study" as an alternative to the "Check" phase.

Plan
Define the problem to be solved, collect and analyze data on the current process, brainstorm possible causes of the problem.

Do
Brainstorm possible solutions, select the most likely solution, pilot the solution.

Check
Analyze the results to see if the problem is solved.

Act
Depending on the result of the Check step, either implement the successfully piloted solution, or abandon the unsuccessfully piloted solution and start the cycle over again. Also, look for other applications for the solution.

The 8 Disciplines (8-D) Method

The Ford Motor Company developed The Eight Disciplines as a problem solving process, a standard, and a reporting format for corrective action. It spread throughout the automotive supply chain and beyond. It expands on the P-D-C-A cycle and is used when the cause of a problem is unknown. The Eight Disciplines are followed in order and consist of:

D 1: Establish the Team

A team is formed containing 4 to 10 people with the process/product knowledge, allocated time, authority, and skill in the required technical disciplines. The team must also have a designated champion.

D 2: Describe the Problem

The internal/external customer problem is specified by describing in quantifiable terms who, what, when, where, why, how and how many.

D 3: Develop Containment Action

Containment actions are developed and implemented to isolate any internal/external customers from the effects of the problem until corrective action is implemented. Containment should consider needs for immediate, remedial and interim action. Effectiveness of the containment action is verified.

D 4: Determine and Verify Root Cause and Escape Point

All potential causes that could explain why the problem occurred are identified. The team also determines how and at what point in the system the problem "escaped" to the customer. The root cause is isolated and verified by testing each potential cause against the problem description and test data. Alternative corrective actions are identified for eliminating the root cause.

D 5: Choose and Verify Permanent Corrective Actions for Root Cause and Escape Point

Preproduction test programs are used to quantitatively confirm that the selected corrective actions will resolve the problem for the customer, and will not cause undesirable side effects. Contingency actions, if necessary, are defined based on risk assessment.

D 6: Implement and Validate Permanent Corrective Actions

Action plans are used for successful implementation of corrective actions. Ongoing controls are established to validate the effectiveness of the corrective action for the customer.

D 7: Prevent Recurrence at the Systems Level

Management and operating systems, practices, and procedures are modified to prevent recurrence of the problem and similar problems.

D 8: Recognize Team and Individual Contributions

The collective efforts of the team are recognized and the significance and value of the solution is acknowledged. Knowledge gained during the process is documented and shared.

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D1: Establish the Team

A team is formed containing 4 to 10 people with the process/product knowledge, allocated time, authority, and skill in the required technical disciplines. The team must also have a designated champion.

Assignment of Responsibility

- Decide three issues
  - ☑ How many people should be involved?
    - ✓ Information
    - ✓ Expertise
    - ✓ Resources
  - ☑ How many other departments & which ones?
    - ✓ Might also be other organizations (suppliers, customers)
  - ☑ How complex or simple is this problem?
- Always assign to the lowest level possible that is capable of solving the problem

Assignment Decision

Best Use of People		
Single Person	Intra-group Team	Inter-group Team
• Clear solution • Person has expertise • Relatively routine issue • Need fast action • Very little / no impact on others • No interdependency with other problems	• Problem causes likely exist within Group's area of control • Group possesses expertise & information • Resources needed are minimal & available • Low impact on others • Low interdependency with other problems • Political consequences minimal	• Problem causes likely are difficult to find & might be anywhere in process • Need expertise & information beyond control of one group • Resources needed are larger & controlled by different managers • Impact on others is larger • High interdependency with other problems • Political consequences need to be considered

- Communicate expectations clearly
- Act quickly on recommendations
- Review progress regularly
- Keep others informed

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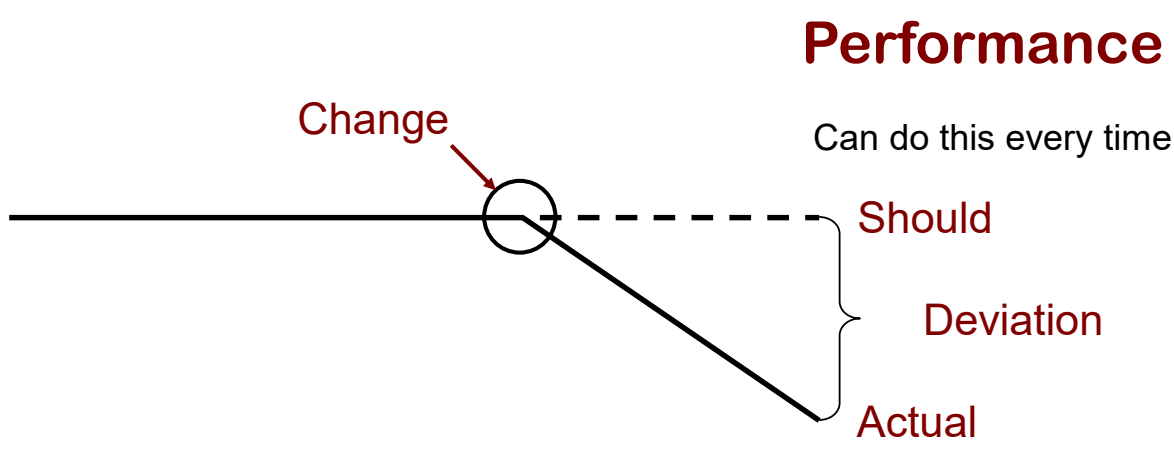
D2: Describe the Problem

The internal/external customer problem is specified by describing in quantifiable terms who, what, when, where, why, how and how many.

Structure of a Problem



Search for a cause entails a search for a specific change

Root Cause Analysis

Sketch a similar model for the structure of an Opportunity:

Problem Statements

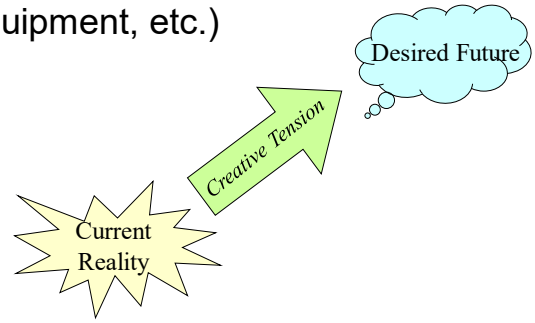
WHAT: Is happening?
Should be happening?
Is Involved? (Processes, Equipment, etc.)

WHO: Is Generating the Problem?
Is Affected by the Problem?

WHERE: Is it Happening?

WHEN: Is it Happening?
(Time of Day, Part of Process, How Often)

HOW: Serious is it? (Widespread, Costly, Painful)



Root Cause Analysis

A good problem statement will answer the questions above in quantifiable detail and will *not* include a "Why."

"Who" is not meant to be a person's name, but rather a work area, customer segment, etc.

Robert Fritz, M. D. originated the model of Current Reality, Creative Tension and Desired Future.

Problem Statement Criteria	Some things to remember when writing problem statements:
A. State the Effect	State *what* is wrong, not *why* it is wrong. Avoid "due to" or "because of" statements because they imply a solution.
B. Be Specific	General categories like "morale," "productivity," "communication" and "training" tend to have a different meaning in each person's mind. Clarification is necessary to help everyone narrow the category to a specific aspect of the problem.
C. Make It Measurable	Say how often, how much, when. (Giving measurement method and units of measure may also be helpful.)
D. Use Positive Statements	Avoid "lack of" statements (e.g. not enough, we need, we should). These negative terms usually imply solutions. Also, do not state problems as questions, as you will imply that the answer to the question is the solution.
E. Focus on the Gap	The gap is the change or deviation from the norm, standard or the reasonable expectation.
F. Focus on the Pain	Highlight how people are affected; describe the consequences and the areas of discomfort, hurt or annoyance.

Evaluate the following sample problem statements:

Problem Statement Evaluation Aid						
Problem Statement (Who, what, when, where, but not why)	(A) States effect, not cause	(B) Specific: who, what, when, where, not why	(C) Measure-able	(D) Stated in a positive manner	(E) Focuses on gap: is vs should be	(F) Describes the pain
1. Hand cuts to hourly workers during hand deburr operations on fuel tanks in process assembly increased from 26 to 172 in August, 20XX. The goal is no more than 10 per month.						
2. There was an overrun in the Development & Maintenance budget.						
3. Twenty percent of initial resumes sent to clients were rejected in the first quarter of 20XX.						
4. Fifteen percent of the Manufacturing clients were required to wait more than 3 days for a proposal response in the first quarter of 20XX. Sales reps need to complete their order entry faster.						
5. Manufacturing rejected 75% of subassembly kits back to Material Control during the first 6 months of this year (for no legitimate reason either).						
6. Time to market for the initial release of the Bantha product line was 3 months longer than projected which resulted in a loss of $3 MM in revenue.						

Problem statement checklist

- ❑ What is happening?
- ❑ Who is affected by the problem?
- ❑ What are the "gaps"?
- ❑ What are the consequences of not solving the problem?
- ❑ Where does the problem occur?
- ❑ When does the problem occur?
- ❑ When did the problem start?

Problem Statement Guidelines

- State the effect
- Be specific
- Use positive statements
- Quantify the problem
- Focus on the "gaps"

Root Cause Analysis

This checklist is helpful for drafting a problem statement in outline form first, in addition to being a critique aid afterward. Once the content elements are complete, you can then put the statement in sentence form, such as:

_____ **occurred** _____ **affecting**

(what?) **(who, where?)**

_____ **during** _____.

(how much?) **(when?)**

It should be _____. **The consequence is** _____.

(target, goal?) **(pain, how things are affected)**

D3: Develop Containment Action

Containment actions are developed and implemented to isolate any internal/external customers from the effects of the problem until corrective action is implemented. Containment should consider needs for immediate, remedial and interim action. Effectiveness of the containment action is verified.

D3: Develop Containment Action

Take Immediate Action

- ☑ Take responsibility
- ☑ Take action to stop any further problems
- ☑ Fix the symptom

Put out the fire

Root Cause Analysis

Some Guidelines for Immediate Action:

- **First** person to discover problem "owns" the problem.
- This "owner" is responsible for performing Step 2 or escalating the problem to the appropriate person.
- This first person owns the problem until the appropriate person "accepts" the problem.

Management support of this culture is essential.

D3: Develop Containment Action

Take Remedial Action

- ☑ Look back to assess damage done, find other affected items
- ☑ Determine whether rework or recall is needed

Put out any other blazes caused by 1st fire

Root Cause Analysis

Containment Considerations:

Internally, evaluate impact on upstream and downstream work areas, test and inspection areas, packaging, outsourced processes, hub sites, finished goods inventory, etc.

Externally, evaluate whether product has shipped, whether it is in transport, in the customer's facility, at a distributor, in the End User's hands, etc.

D3: Develop Containment Action

Take Interim Action

- ☑ Put temporary controls in place
- ☑ Don't let problem get worse or expand.
- ☑ Determine short-term, temporary fixes needed until permanent solution implemented
- ☑ Revisit containment needs once root cause is identified

Make sure the fire doesn't reignite

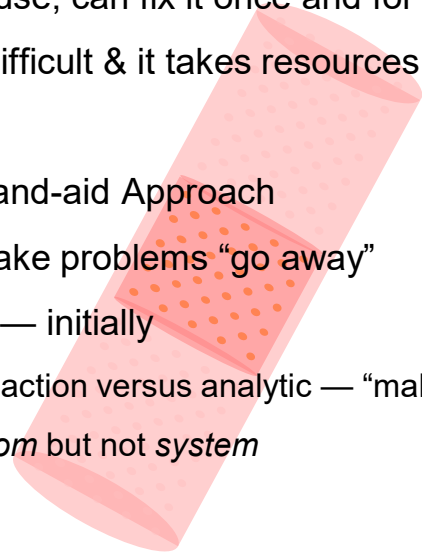
Root Cause Analysis

If containment requires interim actions, consider as before, internal and external suppliers, customers and partners, and the effects and consequences of the failure on their processes and products.

Short-Term Fixes

- Easier to find symptoms than root cause(s)
- Must be painfully honest; otherwise just applying a band-aid
- If get at root cause, can fix it once and for all

  BUT, it's difficult & it takes resources!



Attraction of the Band-aid Approach

- Tendency to make problems "go away"
- Easier to solve — initially
  - ☑ Emotional reaction versus analytic — "make this go away right now!"
  - ☑ Fixes *symptom* but not *system*

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D4: Determine the Root Cause & Escape Point

All potential causes that could explain why the problem occurred are identified. The team also determines how and at what point in the system the problem "escaped" to the customer. The root cause is isolated and verified by testing each potential cause against the problem description and test data. Alternative corrective actions are identified for eliminating the root cause.

Find out why the fire started in the first place

D4: Determine the RootCause & Escape Point

- Structured problem solving, “formal” corrective action system
- Goal: find & eliminate the root cause of the problem in the process/system
- Identify the escape point, i.e., where the problem first should/could have been detected and how it eluded discovery

Roadblocks to Root Cause Analysis

- Lack of time &/or resources
- Lack of problem ownership
- Beginning with a solution already in mind
- Errors/Rework as a way of life
- Ignorance of the importance of problems
- Protection of status quo
- Poor balance between schedule, cost, and quality
- Holding positions instead of exploring issues
- Fear of making a mistake

Common attitudes toward problems:

- A problem is a burden.
- Ignore it & hope the problem goes away.
- A problem is an opportunity.

Investigating Root Causes

- Teams often run the risk of jumping straight from problem definition to solution. Unfortunately, what gets treated is usually the symptom and not the root cause of the problem.
  - ☑ The symptom is the outward indication of a problem and is usually easier to spot.
  - ☑ The root cause is the underlying system breakdown or inadequacy that allowed the problem to happen.

Investigating Root Causes

- If the symptom only is treated (a “band aid” fix), the problem will reoccur.
- To complicate the issue, there could be multiple root causes; some may be temporary while others are permanent.
- Usually, systemic problems have a primary (most deeply rooted) cause.
- The challenge during the RCA investigation phase is to take the time to look deeper than the obvious.

Simple Tools

- Problem Statement
- Brainstorming
- SIPOC
- Process Mapping, Analysis
- Check Sheets
- 5 Why's
- Cause & Effect Diagram
- Pareto Analysis
- FMEA/Fault Tree Analysis
- Affinity Analysis

These tools can be used informally for day-to-day issues as well as for formal Corrective/Preventive Actions.

Root Cause Analysis

The tools above can also be applied to potential problems (preventive actions).

Brainstorming and the related tool of Affinity Analysis are helpful at any point where ideas are needed— whether in identifying problems, generating possible root causes, coming up with possible solutions, imagining potential risks or obstacles to a solution, etc.

Brainstorming

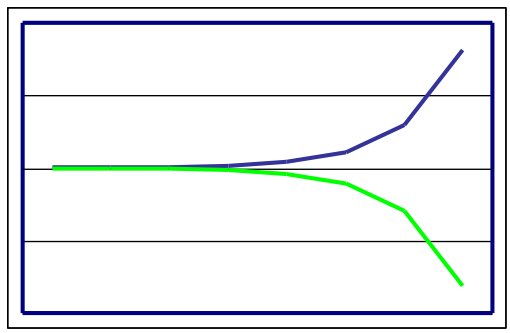
- Brainstorming is helpful throughout the problem-solving process, to identify problems, root causes and solutions.
- It is an unrestrained process for offering ideas or suggestions by all members of a group.
- Brainstorming is “synergistic” — it produces a greater total effect than that which can be produced by individual effort.
- Brainstorming uses two types of thought processes:
  - ☑ Divergence
  - ☑ Convergence

Brainstorming

With Brainstorming, our goal is to use divergence to:

- ☑ Generate an extensive number of ideas
- ☑ Create an atmosphere of openness and creativity
- ☑ Ensure all team members contribute
- ☑ Ensure nothing is overlooked

Divergence



Brainstorming Ground Rules

Because divergence can be difficult, we need to follow some ground rules. They are:

- ☑ Do not evaluate or criticize
- ☑ List all ideas
- ☑ Do not discuss
- ☑ Repetitions are okay
- ☑ Questions for clarification are okay

Brainstorming Guidelines

Even if all participants have brainstormed before, it's a good idea to go over the process:

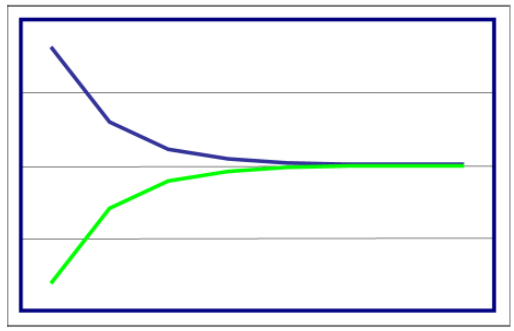
1. Frame an open-ended question about the topic
2. Make sure all members understand the question
3. Review and post the ground rules
4. Before starting, give two to three minutes to jot down ideas
5. Have a person recording ideas; keep them visible
6. Take turns; say "pass" or use the "popcorn" method

Brainstorming — Convergence

Convergence occurs after brainstorming is completed:

- ☑ Inputs may be grouped by categories
- ☑ Duplicated/similar inputs may be consolidated
- ☑ Inputs may be prioritized; multi-voting is a helpful tool
- ☑ Unrelated inputs can be saved in a “parking lot”

Convergence



Multivoting

- When you have a long list, a good first step is to narrow it by having members vote on the items.
- Give each member of the team a certain number of votes (5–10 depending on list length).
  - ☑ Members use their votes for those items they feel would bring the most benefit to the organization.
  - ☑ Members vote individually, then tally the results as a team.
  - ☑ The ten (or so) items with the most votes are selected for prioritization.

BRAINSTORMING

Worksheet

Instructions: Record ideas on this sheet as they pop into your mind.

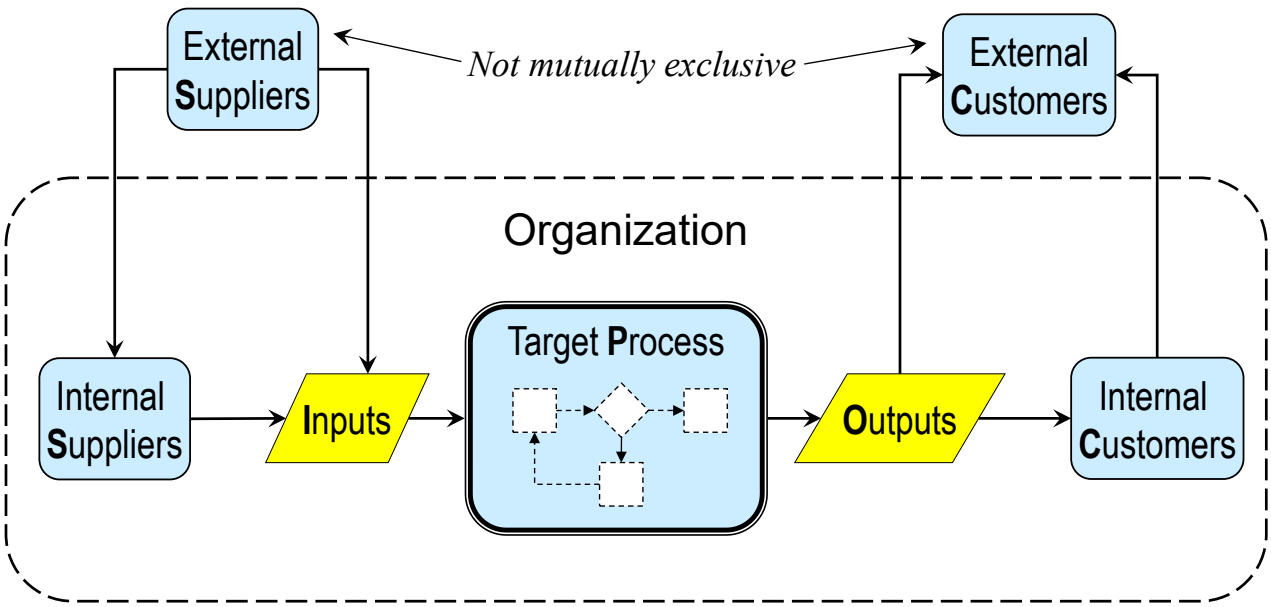
Guidelines

- Do not evaluate or criticize
- List all ideas
- Do not discuss
- Repetitions are okay
- Clarification questions are okay

Hints

- Use opposites
- Use radical ideas
- Visualize the process
- Think of five senses
- Piggy-back on other ideas

Process Definition (SIPOC)



Root Cause Analysis

SIPOC is a tool used in both Lean and Six Sigma to define a process prior to detailed mapping.

Being clear on Suppliers and Customers, and the boundaries of the process is essential before beginning a detailed process map.

If the terms “internal suppliers and customers” are confusing, these roles could be described as “internal providers and receivers.”

Process Mapping and Analysis

- Detailed process maps using a variety of formats can highlight problem areas:
  - ☑ Functional
  - ☑ Geographic
  - ☑ Information Flow
- Various techniques for process analysis may also be helpful in determining solutions:
  - ☑ Value Assessment
  - ☑ Standardizing
  - ☑ Early Control (moving inspection points forward)
  - ☑ Mistake-Proofing
  - ☑ Analyzing Inputs

Root Cause Analysis

Having a detailed map of the process that led up to a particular process/product problem is an important part of root cause analysis.

Often, the types of flow charts/maps created for quality system documentation purposes will not have enough detail (for good reason!) to aid in deep root cause analysis.

Check Sheets

- Check Sheets are used to gather data on how often and when certain things happen.
- They are useful in problem solving because they can detect patterns and validate (or not) peoples' "gut feelings" for when and why things happen.

Root Cause Analysis

Consider whether data can be gathered from "mining" existing records.

Problems with Meetings

	Mon.	Tues.	Wed.	Thurs.	Fri.	Total
People Late	III	II	I	II	I	9
People absent	IIII	I			II	7
Wrong attendees	I		II		I	4
No agenda	III	IIII	III	IIII	II	16
No refreshments	II	I				3
No decision made	I		I	II		4
Got off track	II	III	II	I	II	10
Total	16	11	9	9	8	53

Root Cause Analysis

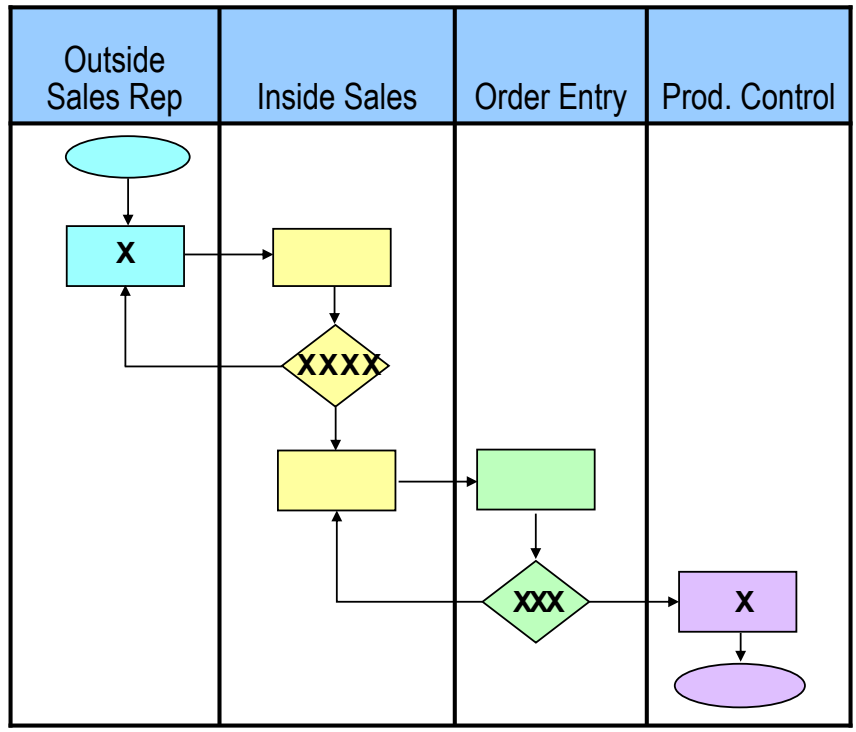
A check sheet can be a simple paper and pencil tool, a standard form or computer spread sheet. Steps in creating the check sheet are:

- Make a list of events that you want to study; write these in the horizontal rows.
- Set up the vertical columns as appropriate for occurrences. They may be times (dates, days of the week, hours, months), or some other category like supplier name, material type, machine number, etc.
- Collect data on the form by entering a tally or check mark whenever that type of event occurs.
- Make decisions based on the data. Look for trends and patterns.

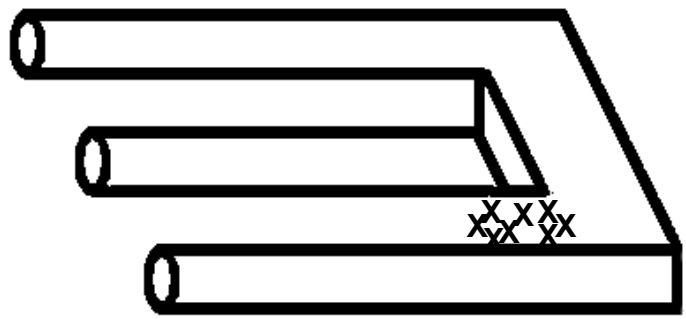
Location Check Sheets

- Sometimes we need to know *where* a problem is happening, rather than the *what* and *when* tracked on a row and column format.
  - ☑ In these cases, we use a picture or map of the product or area of interest.
  - ☑ Defects/occurrences are marked on the picture corresponding to the location where they were observed.
  - ☑ Over time, the location of problems may show a pattern that sheds some light on the cause or helps identify possible preventive actions.

Location Check Sheet for Order Entry Errors



Location Check Sheet for Product Defects

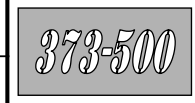


The 5 Why's

- The "5 Why's" is an easy-to-use verbal technique that can be effective for getting at hidden causes of problems.
- By asking "Why?" five times (more or less), you will often get through to the root cause of the problem.

The 5 Why's — Example 1

	Scenario: Parts are failing at Final Inspection.
1.	**WHY** are parts failing? Part marking does not match print: customer part ID is missing.
2.	**WHY** is the customer part ID missing? The old stencil with just the internal part ID was used.
3.	**WHY** was the old stencil used? It was what has always been used and was in the marking bin location for that job.
4.	**WHY** was the old stencil there and not the new one? The new print was uploaded properly when the order was taken, but no one remembered to tell Production to make a new stencil.
5.	**WHY** did no one remember? The order review checklist does not include evaluation of needed production changes like new stencils, tools, etc. **Solution:** Have a cross-functional group evaluate and revise the order review checklist to prevent future errors.



Root Cause Analysis

Branching out with 3 x 5 Why's

The 5 Why's interviewing technique is designed to naturally lead to the systemic reason for a problem but being prepared with these three "Why" categories will assure effectiveness:

- Technical
- Escape
- System

3 x 5 Why's

Technical

- Reason the problem (failure mode) occurred
- Describe the chain of physical events that caused a process step to malfunction, resulting in the observed nonconformity

Escape

- Reason the problem was not caught at the immediate process or work area
  - ☑ If the failure "escaped" past the planned, implemented prevention or detection control method, reason the control method failed
  - ☑ If the problem was caught by the designated control method prior to customer delivery, there is no "escape"
  - ☑ If "No control method" is the cause, reasons for this omission should be identified (e.g., failure mode was considered low risk, it had never been seen, it was previously undetectable, etc.)

3 x 5 Why's

System

- Underlying systemic reason(s) the problem occurred or was not caught
- Think in terms of organization-level structures and methodologies:
  - ☑ Policies and Procedures governing the process where the failure mode occurred
  - ☑ Training program structure, software platforms in use
  - ☑ Communication and Reporting systems
  - ☑ Networks, Enterprise Management Systems (engineering change control, inventory management, document/records control, process control, etc.)
  - ☑ Facility layout
  - ☑ 5S and Preventive Maintenance Program
  - ☑ Corporate-culture norms

The 5 Why's Technique

- It may be necessary to speak to people in more than one functional area in order to answer the 5 Why's; the questions may lead outside the organization to suppliers and/or customers.
- Often, multiple path options will appear. Follow one at a time.
- While face-to-face communication is usually best, when working across shifts and time zones, email can be an effective way to ask the 5 Why's.

The 5 Why's Technique

- Be considerate when using this technique.
  - People may get impatient if the "Why's?" sound like the questioning of a three-year-old child.
  - Or worse, get defensive if the questions feel like lecturing or shaming.
- Ask why, but make it part of a complete, open-ended sentence that leads people into further discussion on the subject, rather than putting them on the defensive.
- For example, "I heard you say these new tools keep breaking. Why do you think that is happening?"

Checking the 5 Why's

- Whether using a simple 5 Why's or a 3 x 5 Why's, it's a good idea to double-check the logical flow of the Why's:

Problem Statement:					
Why did the problem occur?	1. Why?	2. Why?	3. Why?	4. Why?	5. Why?
Technical root cause					
Why did the problem Escape?	1. Why?	2. Why?	3. Why?	4. Why?	5. Why?
Escape root cause					
What system failed?	1. Why?	2. Why?	3. Why?	4. Why?	5. Why?
System root cause					

Ask "Why" in this direction

Test accuracy in this direction for each Why, using "therefore"

Root Cause Analysis

To check the accuracy of the Why statements and that they're in the correct order, we read right to left. Using Example 1, where an incorrect part marking stencil was used, it would look like this:

Answer to Why #5: "The order review checklist does not include evaluation of needed production changes like new stencils, tools, etc.,"
therefore

Answer to Why #4: "….no one remembered to tell Production to make a new stencil."
therefore

Answer to Why #3: "….[the old stencil] was in the marking bin location for that job."
therefore

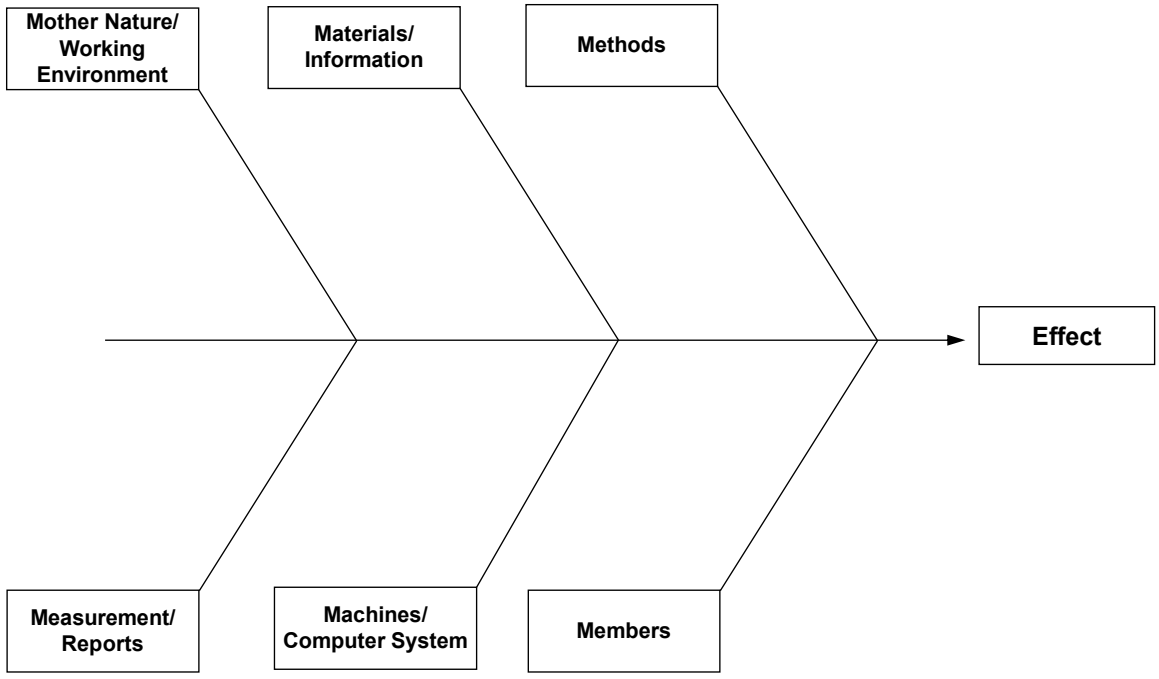
and so on back to Why #1.

Cause & Effect Diagram

- The Cause and Effect diagram was developed in 1943 by Kaoru Ishikawa. It is also referred to as a “fish bone” diagram.
- This tool uses structured brainstorming to focus a team on root causes of problems, not symptoms.
- It uses a visual technique to create a process view of the situation that considers all possible categories of variation.

Even if all participants have brainstormed before, it’s a good idea to go over the process and ground rules before beginning.

Cause & Effect Diagram



Root Cause Analysis

Method

1. Use systemic problem symptom as “effect”
2. Define major cause categories; options are shown for both “Manufacturing” and “Business” processes.
3. Brainstorm all possible causes under major categories
4. Prioritize importance of each cause for further investigation.

Cause & Effect Diagram

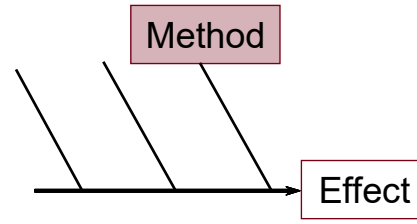
- It is important to note that Cause and Effect diagramming is a team process. Getting ideas from a variety of people involved in the process will be more effective than if one person tried to think of all the possibilities.
  - ☑ This tool uses brainstorming, so remember to use the ground rules discussed previously.
  - ☑ A good technique is to draw the “fish bones” with headings on a piece of chart paper, have people write ideas on sticky notes (one idea per note), and place the notes under the appropriate heading.

Cause & Effect Diagram — Questions

The **Method** category groups root causes related to how the work is done, the way the process is actually conducted:

Examples of questions to ask:

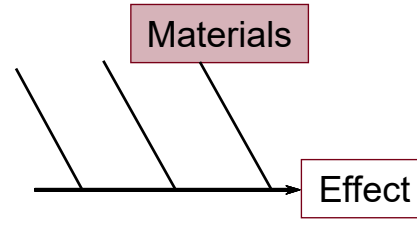
- Is the process adequately planned/designed?
- Are procedures correct, adequate, followed?
- Are checks in place?
- What might be an unusual situation?



The **Materials** category groups root causes related to parts, supplies, forms or information needed to execute a process:

Examples of questions to ask:

- Are bills of material current?
- Are parts or supplies obsolete?
- Are there defects in the materials?



Root Cause Analysis

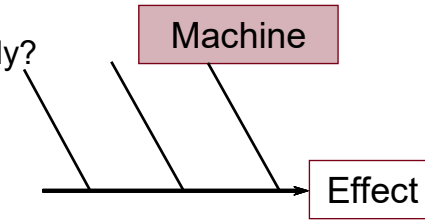
The example questions are not meant to be an exhaustive list. Much will depend on the problem context.

Cause & Effect Diagram — Questions

The **Machine** category groups root causes related to tools used in the process:

Examples of questions to ask:

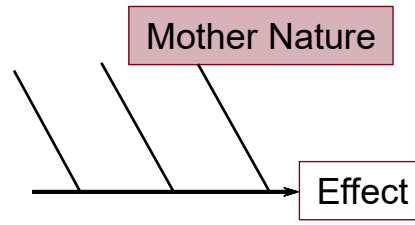
- Have machines been serviced/changed recently?
- Have equipment/tools been properly maintained?
- Are proper equipment/tools available?
- Is there machine to machine variation?



The **Environment** (a.k.a. Mother Nature) category groups root causes related to our work environment, market conditions, and regulatory issues.

Examples of questions to ask:

- Are there impacts from physical factors (temperature, humidity, lighting, particles, etc.)?
- Is the workplace safe and comfortable?
- Are outside regulations a factor?
- Does the company culture aid the process?

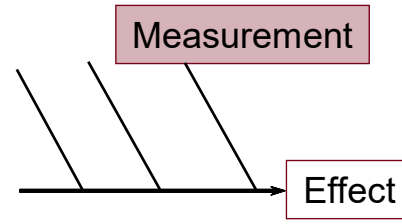


Cause & Effect Diagram — Questions

The **Measurement** category groups causes related to the measurement and measuring of a process activity or output:

Examples of questions to ask:

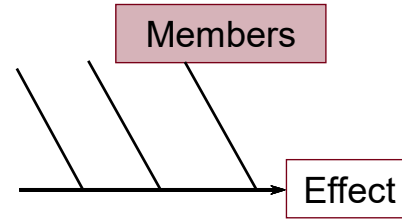
- Is there an appropriate measurement?
- Is there a valid measurement system?
- Is the data accurate &/or precise enough?
- Is data readily available?



The **Members** category groups root causes related to people, staffing, and organizations:

Examples of questions to ask:

- Are people trained properly, do they have the right skills and mental/physical capabilities?
- Is there person to person variation?
- Are people over–worked, stressed, etc.?
- Are short-cuts/noncompliance tolerated by management?



What if People are the Cause?

- When considering variation from “Members,” we have to dig deeper than a simple root cause of “operator error.”
  - A symptomatic “fix” of retraining a single operator won’t necessarily prevent another person from making the same error.
  - Training may not be an effective solution if the process itself is poorly designed, not documented, ineffective, etc.

Considering Human Factors

- Studying human factors will be helpful in situations where the initial cause appears to be a person's behavior.
- A simple method used by the FAA is to categorize human factor errors into two types:
  - A **Mistake** happens when a person takes an action on purpose that is misguided or wrong, possibly due to an incorrect assumption, lack of understanding, misinterpretation, etc.
  - A **Slip** is when a person plans to do one thing, but inadvertently does something else due to forgetfulness, confusion, time pressure, fatigue, etc.

Root Cause Analysis

FAA = Federal Aviation Administration

Source: Federal Aviation Administration's "Dirty Dozen"
https://www.faasafety.gov/files/gslac/library/documents/2012/Nov/71574/DirtyDozenWeb3.pdf

The FAA's "Dirty Dozen" list has been re-ordered on the following pages in order to categorize the factors according to Mistakes and Slips.

12 Common Causes of Human Factors Errors

Mistakes are often due to a *lack* of something:

1. Lack of Communication	Failure to transmit, receive, or provide sufficient feedback in order to complete a task.
2. Lack of Knowledge	Failure to have training, information, &/or ability to conduct a task.
3. Lack of Teamwork	Failure to work together to complete a shared goal.
4. Lack of Resources	Not having enough people, equipment, information, documentation, time, parts, materials, supplies, etc., to complete a task.
5. Lack of Assertiveness	Failure to speak up or otherwise document concerns about instructions/orders or actions of others.
6. Lack of Awareness	Failure to recognize a situation, understand what it is, and predict the possible results.

12 Common Causes of Human Factors Errors

Slips are often due to the *presence* of something; often too much of it:

7. Complacency	Overconfidence from repeated experience on a specific activity.
8. Distractions	Anything that draws attention away from the task at hand; can be events or surrounding conditions.
9. Fatigue	Physical or mental exhaustion that threatens work performance.
10. Pressure	External or internal forces demanding high-level job performance; can be real or perceived.
11. Stress	Physical, emotional or chemical factor that causes physical or mental tension.
12. Norms	Expected, yet unwritten, rules of behavior.

Cause & Effect Diagram

- Only after brainstorming is completed, are the ideas evaluated.
- The goal is to identify a few top causes for further investigation.
- The 5 Why's tool is a great way to drill deeper into root causes and expand the C & E diagram.
- Additional data collection (Check Sheets, Pareto charts, Run charts, DOE, etc.) may be needed to validate root causes.

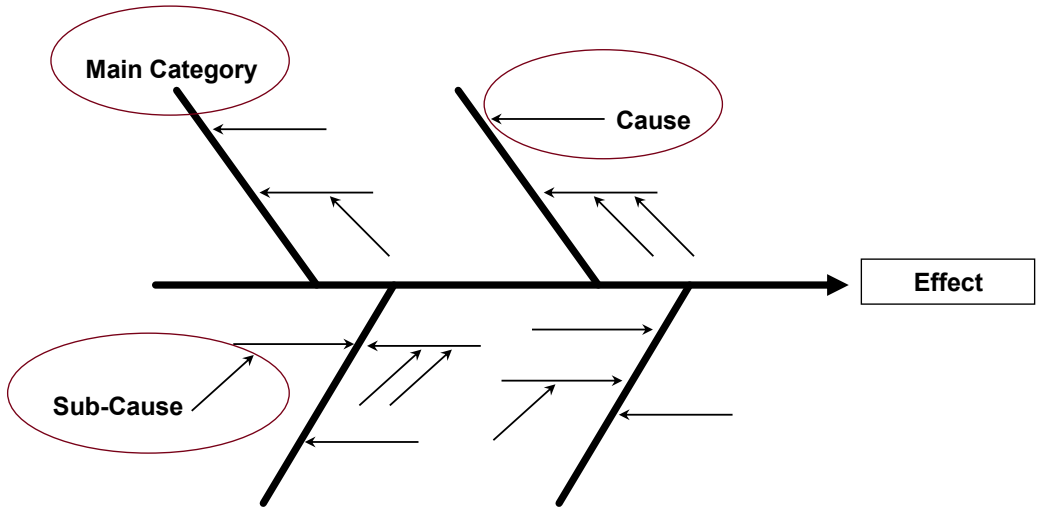
DOE = Design of Experiments

Look for categories that do not have many ideas, a second round of brainstorming may be needed to be sure all possibilities are covered.

Eliminate causes that do not apply (consider using a "Parking Lot" for good ideas that may relate to another problem or project).

A team may go through several rounds of brainstorming and evaluation before they feel the C & E diagram is complete.

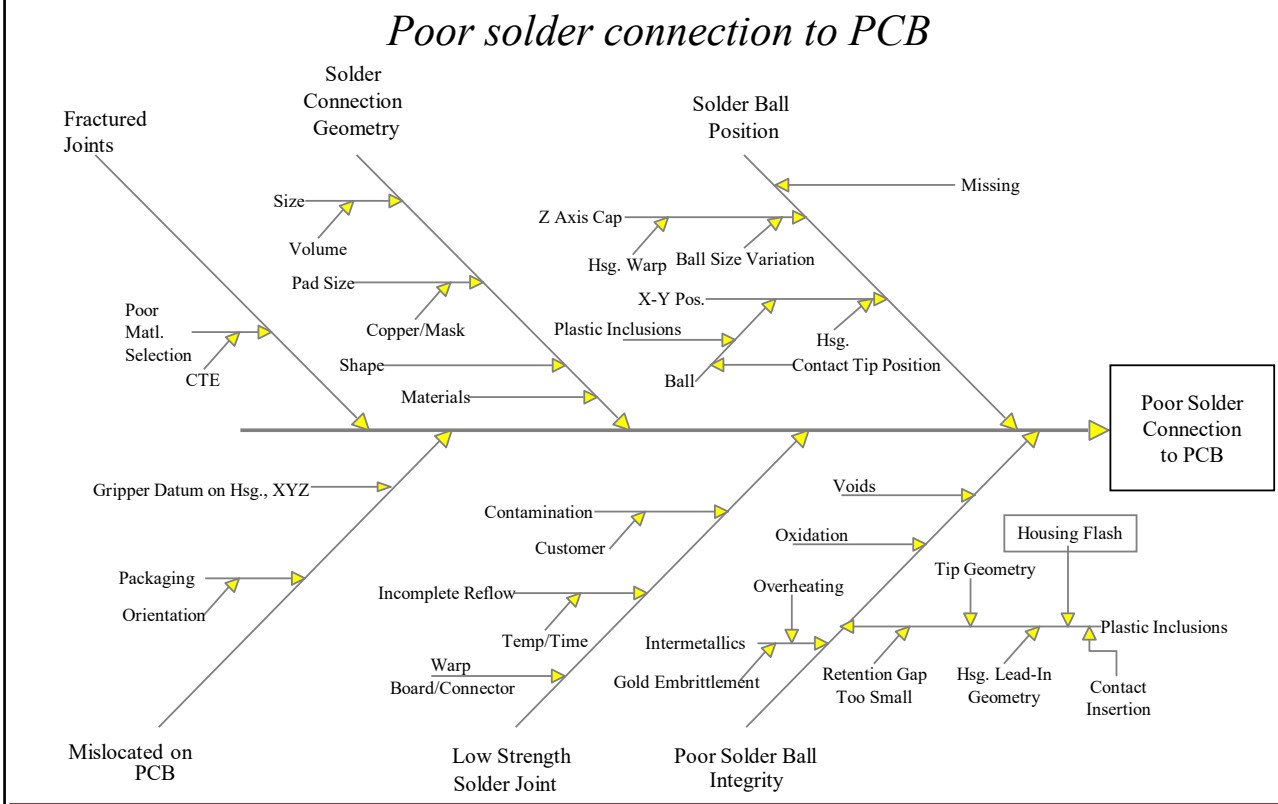
Cause & Effect Diagram with Sub-Causes



Root Cause Analysis

It may be helpful to show sub-causes for an identified cause.

Cause & Effect Diagram — Example



The major cause categories can be customized to a particular application, as shown above.

Some organizations publish Cause and Effect diagrams for use in troubleshooting product and/or processes issues. The example shown above could serve this purpose.

Pareto Charts

- The Pareto principle is named after an Italian polymath of the late 19th century, named Vilfredo Pareto (1848–1923), who developed a theory of unequal wealth distribution and proposed the “80/20 Rule,” i.e., 80% of the wealth is held by 20% of the people.
- Joseph Juran applied the Pareto principle in the late 1940s to quality problems. He had noticed that the majority (80%) of problems (defects, errors, complaints, etc.) were the direct result of only a few (20%) of the causes.
  - ☑ Juran developed a charting technique for separating these “vital few from the other many” causes and called it Pareto analysis.

Vilfredo Pareto fits the definition of a polymath perfectly: a person of wide-ranging knowledge or learning. He was trained in physics and mathematics. He began work as a civil engineer and earned a doctorate in engineering. His interests and influence expanded into the fields of economics, political science and sociology, where he applied mathematical and statistical models in these areas. He was described as “one of the last Renaissance scholars.”

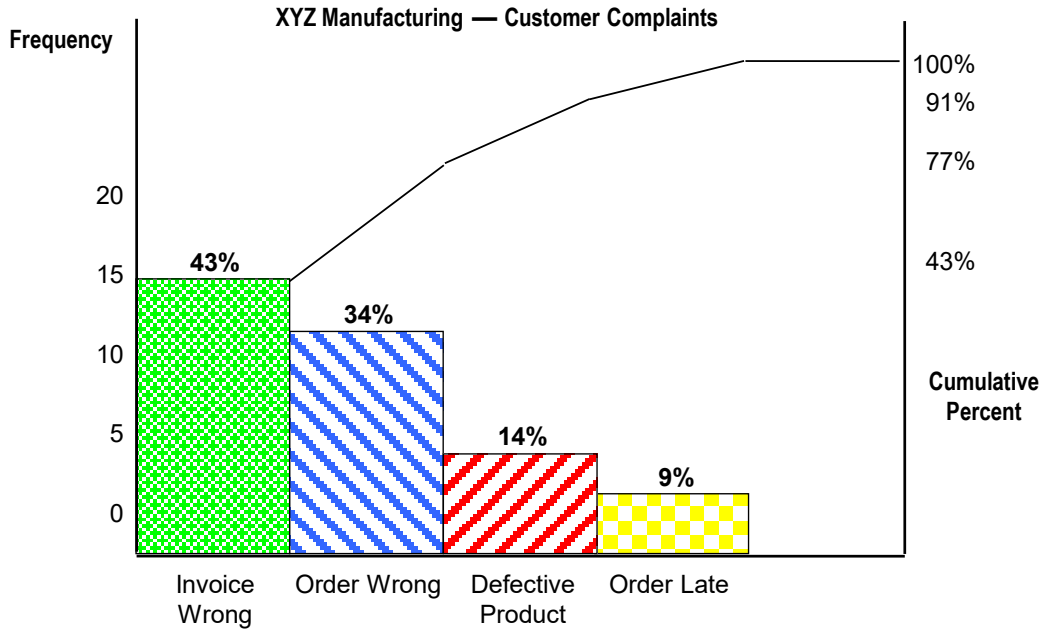
Source: Wikipedia; Juran’s Quality Control Handbook

Pareto Charts

- We use Pareto analysis when we need to identify or collect data on defect sources and decide which problems to tackle first.
  - ☑ If we're trying to improve a process, we want to concentrate on the areas where we can have the most impact.
  - ☑ Our efforts will be most effective if we can eliminate 80% of the problems by removing just one or two causes.
  - ☑ Pareto charts are an effective way to collect data on "hypotheses" for possible causes identified during brainstorming activities.

Pareto analysis can be applied at different levels of diagnosis, such as finding the vital few defects, or the vital few symptoms, or the vital few causes for one symptom.

Reasons for Customer Complaints



Root Cause Analysis

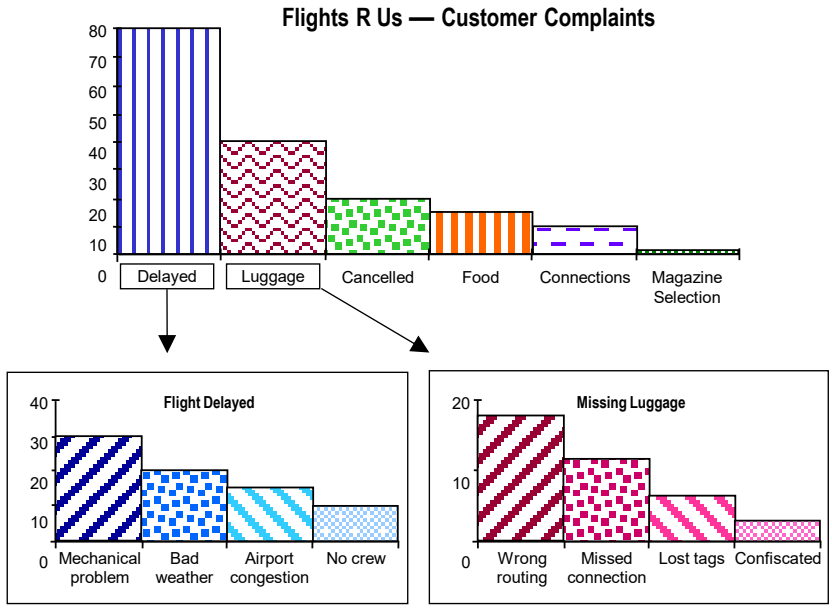
Method:

1. Collect data by category over a specified time period.
2. Rank by category, highest to lowest.
3. Fill in chart title, frequency/cost scale, and category titles.
4. Draw bars in ranked order.
5. Determine cumulative percentages.
6. Add percentages to chart (this cumulative % line is often left off).

Interpreting Pareto Charts

- Once the Pareto chart is plotted, we can see the biggest problems, most frequent defects, etc.
  - ☑ We may want to look at how often a defect or problem occurs and at how much the defects cost.
  - ☑ A small number of very expensive defects may have a higher priority than a larger number of inexpensive defects.
  - ☑ In addition to frequency and cost, defects/problems could be tracked in terms of how much downtime they caused, or what their yield loss percentage was.

Pareto Chart



Root Cause Analysis

Pareto charts can be used to summarize data collected on a check sheet.

It can also be helpful to take the highest categories in a Pareto chart and break them down into further categories to gain more information on a problem.

Failure Modes and Effects Analysis

- Meant as a prevention tool, to be performed during product/process design planning and review.
- Goal is to eliminate or reduce the risk of potential product and/or process failures.
- It can also be used post-mortem on actual failures for root cause analysis.

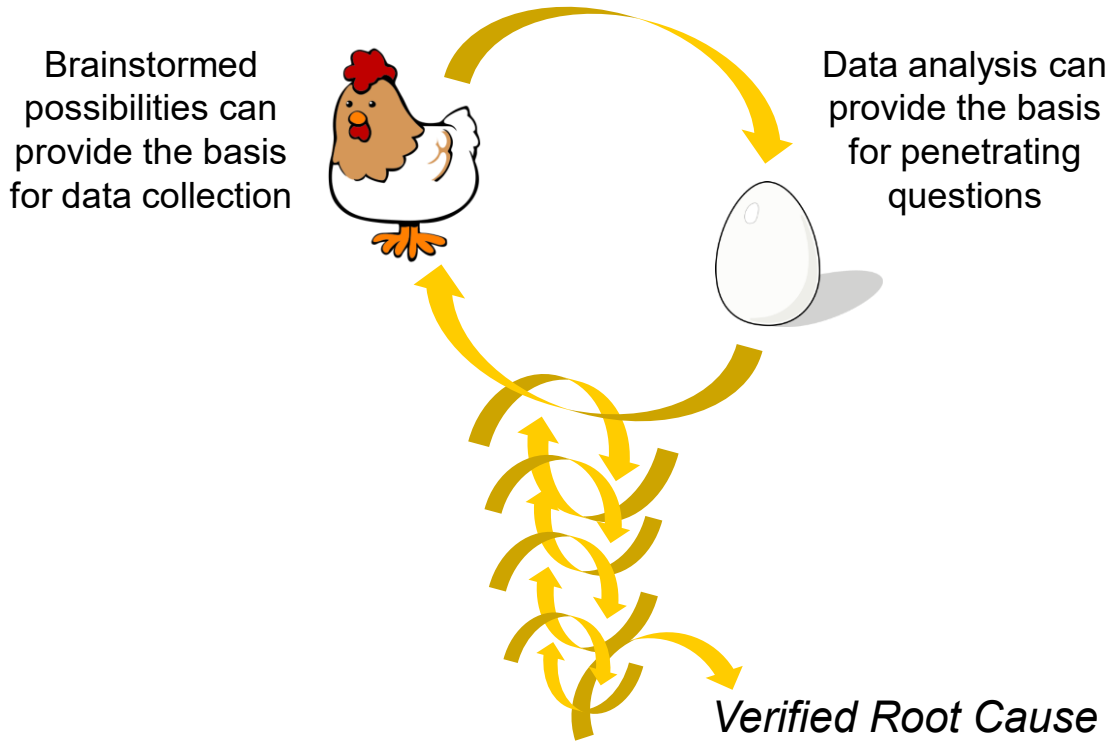
Root Cause Analysis

FMEA method when used proactively (i.e., for preventive action):

- Identify potential failure modes of the proposed future state process
- Identify the ultimate effects of each failure mode
- Assign severity ratings to failure modes based on severities of effects
- Identify root causes of each failure mode
- Assign occurrence and detection ratings to root causes
- Prioritize failure modes for corrective action by "risk priority number" (aka RPN, uses a combined evaluation of severity of effects, likelihood of occurrence and ability to detect a failure mode)

Fault Tree Analysis (FTA) is another tool that may get used in conjunction with FMEA or on its own.

Iterating to a Root Cause



Root Cause Analysis

Several cycles of structured brainstorming, interviewing, and/or mapping followed by focused data collection and analysis may need to occur before a root cause can be determined and verified.

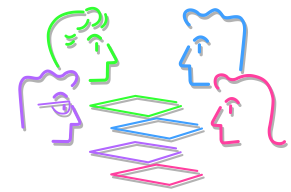
Analyzing Root Observations

- May have many observations from multiple sources
- Identify redundant or closely related observations, verify with interviewees, combine if appropriate
- Identify cause-effect relations among the observations, verify with interviewees, connect if appropriate
- Group together causes that seem to have common solutions
- Useful tool: *affinity analysis*

Affinity Analysis

Affinity Analysis is helpful whenever:

- ☑ the current situation appears chaotic
- ☑ an overabundance of information or ideas is available
- ☑ there is a need to focus on key items



Affinity Analysis

Affinity Analysis steps are to:

1. Assemble a team.
   A group of about five works best, but it's also doable with large groups.
2. Frame the question and make sure everyone understands it.
3. In silence, brainstorm ideas by having each person write on sticky notes (one idea per note).
4. Randomly lay out all the ideas in one location (on a table or wall).
5. Team members arrange the cards in relational groups (still in silence).
6. Using discussion, generate headings for the idea groups. Write them above the groups and draw a border around them for easy identification.
7. Discuss the results.

Affinity Analysis

Again, it is helpful to review the process and ground rules before beginning:

- ☑ Write largely and neatly.
- ☑ Include noun/adjective or noun/verb combinations on the cards.
- ☑ Operate in silence when brainstorming and arranging the ideas.
- ☑ Any person can move another's ideas.
- ☑ No criticism allowed.

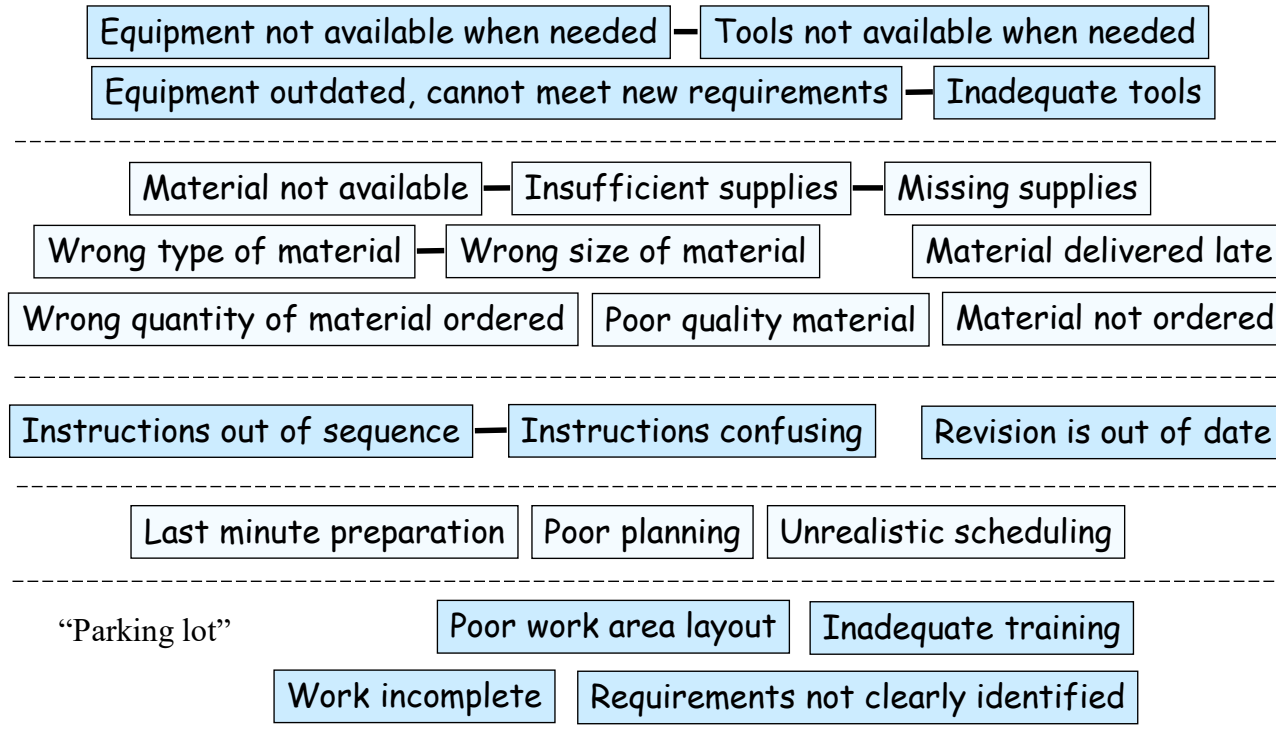
Affinity Analysis Example

Root cause observations for "mistakes and delays"

- Requirements not clearly identified
- Inadequate tools
- Poor planning
- Inadequate training
- Equipment not available when needed
- Material not ordered
- Poor work area layout
- Last minute preparation
- Material not available
- Instructions confusing
- Insufficient supplies
- Wrong type of material
- Material delivered late
- Missing supplies
- Instructions out of sequence
- Poor quality material
- Revision is out of date
- Wrong quantity of material
- Work incomplete
- Unrealistic scheduling
- Equipment outdated, cannot meet new requirements
- Wrong size of material
- Tools not available when needed

Affinity Analysis Example

Redundant or closely related, initial affinity groupings

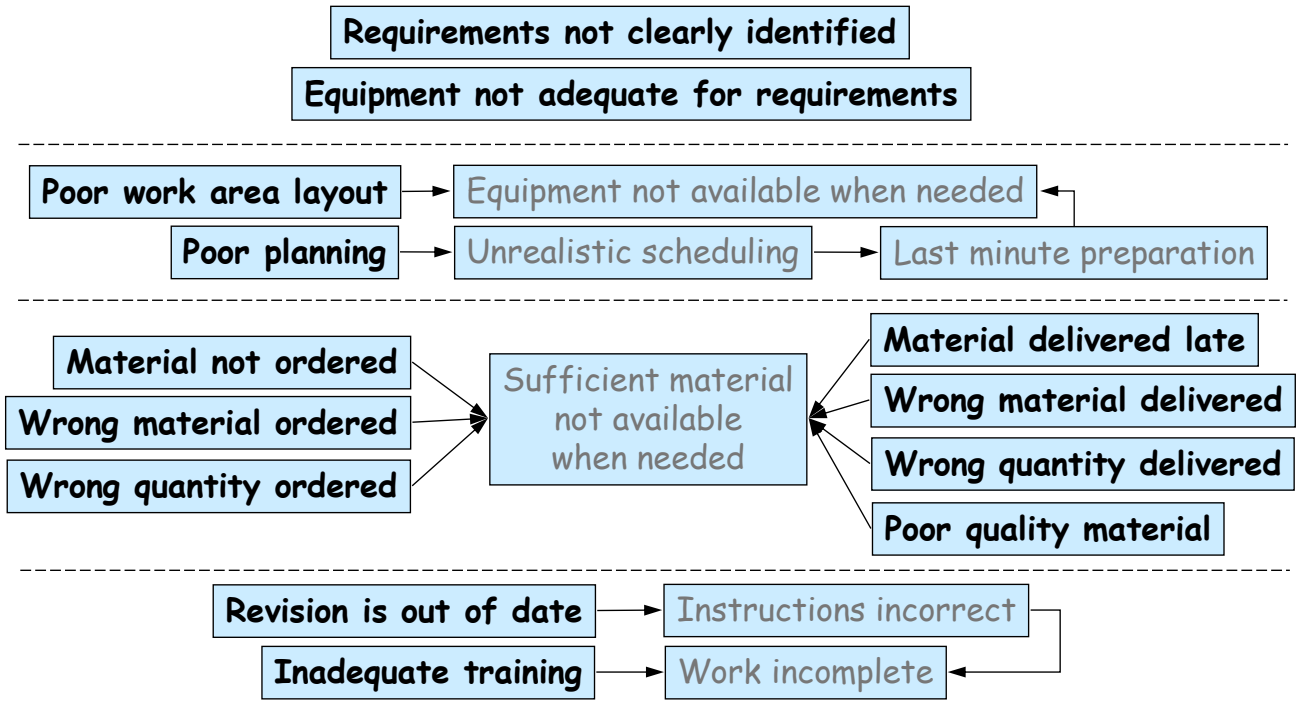


Root Cause Analysis

In the slide above we did some grouping by common themes. Often items sharing common themes will share common solutions. We also connected what seemed to be redundant items — same thing expressed in different words. The verified redundancies are connected by thick lines.

Affinity Analysis Example

Cause-effect relations, final root causes in bold

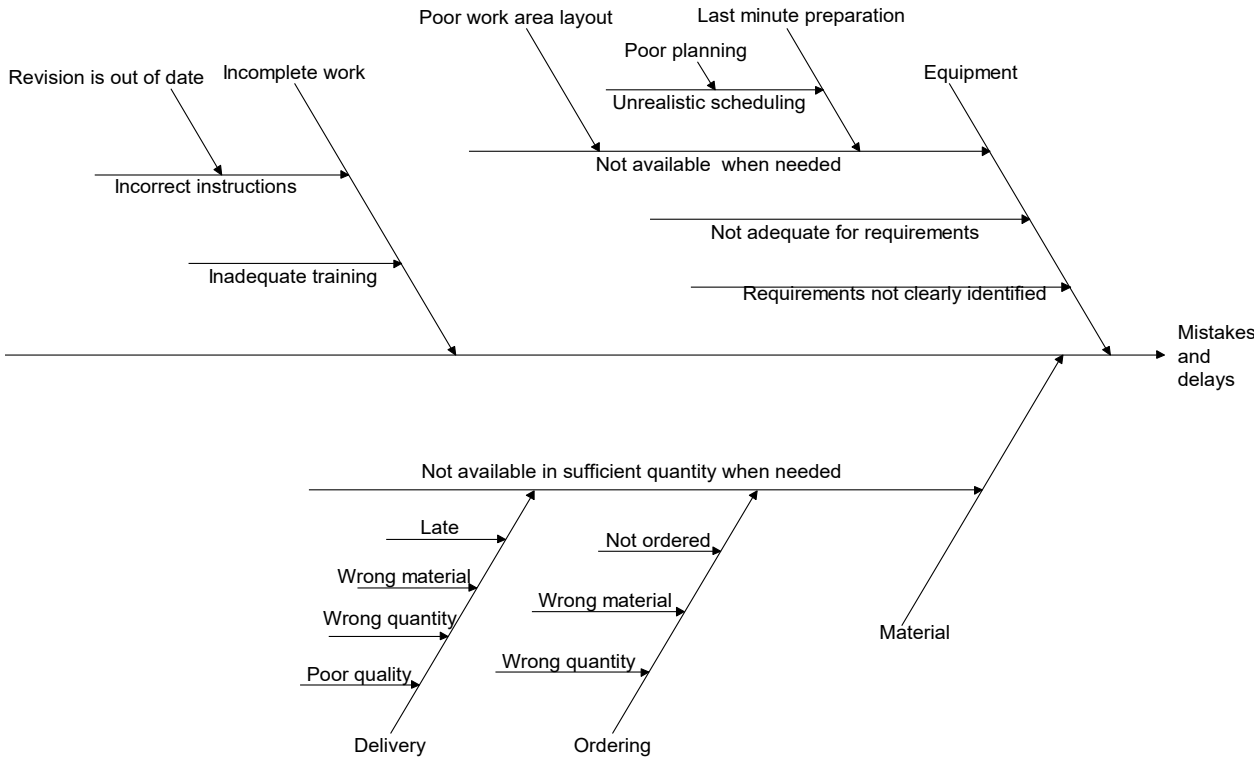


Root Cause Analysis

Although we start with what is presented as a collection of root causes, there may well be cause-effect relations with the "root causes." Identifying these will reduce the number of items to consider. And, seemingly unrelated "parking lot" items may become connected.

The same information may be presented as a traditional fishbone diagram (next slide).

Cause & Effect Diagram of Same Info



Root Cause Analysis

Some people may prefer to go straight to a Cause and Effect Diagram, while others may find it easier to brainstorm first, using Affinity Analysis, and organize the groups into the C & E format later.

How Do You Know When to Stop RCA?

- You have the root cause when….
  - ☑ the problem can be replicated at will.
  - ☑ the system &/or process reason(s) for the problem have been identified (both internal and external to the organization).
  - ☑ A clear root cause statement can be written and agreed upon.
- But don't stop there!
  - ☑ Once the root cause is known, additional risk assessment should be performed:
    - ✓ Revisit containment needs (D3)
    - ✓ Consider whether other processes, products, services etc. could be affected by the cause.
    - ✓ Update risk management plans as necessary.
  - ☑ If multiple root causes are identified, prioritize actions according to risk: take action to eliminate causes with a higher risk of occurrence.

Root Cause Analysis

The rationale for prioritizing risk based on likelihood of occurrence here, is that the severity of the effects of the problem are what initiated the root cause analysis in the first place. That said, severity should be part of the conversation when considering additional containment needs.

D5: Choose & Verify Corrective Actions

Preproduction test programs are used to quantitatively confirm that the selected corrective actions will resolve the problem for the customer, and will not cause undesirable side effects. Contingency actions, if necessary, are defined based on risk assessment.

Ensure the fire never occurs again

Root Cause Analysis

Other questions for implementation evaluation:

Has the solution been implemented and maintained as intended (are control plans, response plans, etc. being followed) ?

Are there measurements for evaluation (run charts, control charts, checklists, Pareto charts, surveys, etc.)?

Does the solution remain effective (what do measurement results show)?

Is the solution suitable, e.g., is the process more efficient, does the solution fit the organizational culture?

Is the solution adaptable — can it be applied to other locations, work areas, products, processes, etc.?

D5: Choose & Verify Corrective Actions

- Implement controls to prevent problem recurrence or occurrence
- Verify effectiveness of the solution *before* making permanent changes
- Develop an Action Plan for implementing the solution
- Make changes to the system (e.g., change documents)
- Train employees in new methods
- Audit for assurance

Root Cause Analysis

Other questions for implementation evaluation:

Has the solution been implemented and maintained as intended (are control plans, response plans, etc. being followed) ?

Are there measurements for evaluation (run charts, control charts, checklists, Pareto charts, surveys, etc.)?

Does the solution remain effective (what do measurement results show)?

Is the solution suitable, e.g., is the process more efficient, does the solution fit the organizational culture?

Is the solution adaptable — can it be applied to other locations, work areas, products, processes, etc.?

Iterating to a Solution

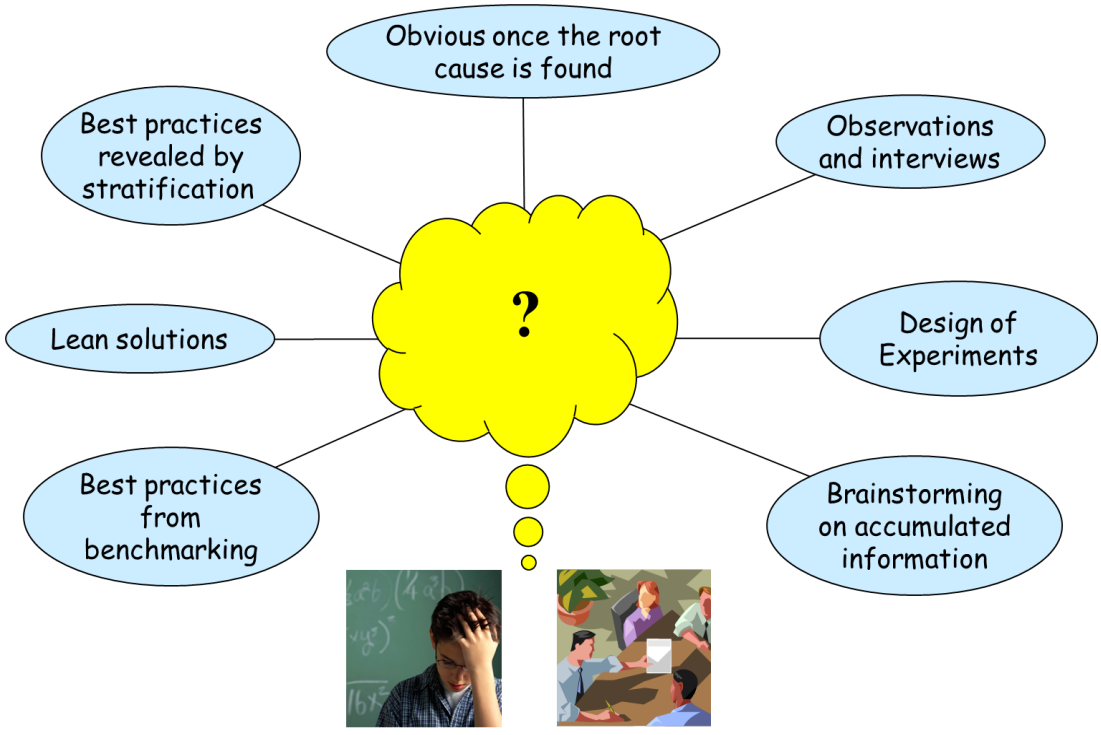
Verified root cause

Generate possible solutions

Test solutions

Verified Solution

Some Solution Sources



Solution Notes

Mitigation for Human Factors Errors — Mistakes

1. Lack of Communication	• Never assume anything. • Improve communication: only 30% of verbal communication is remembered — usually the first and last part. Say the most important things at the beginning and repeat at the end. • Document instructions.
2. Lack of Knowledge	• Don't guess or assume, ask when you don't know. • Use current documentation. • Access training/sources for knowledge.
3. Lack of Teamwork	• Build a solid team; develop trust in the team. • Discuss how a task should be done. • Make sure everyone understands and agrees on tasks/commitments.
4. Lack of Resources	• Plan for resource needs, including sharing or pooling resources. • Identify and mitigate resource constraints.
5. Lack of Assertiveness	• Put safety first. • Express feelings, opinions, beliefs and needs in a positive, productive manner (offer positive solutions, resolve one issue at a time).
6. Lack of Awareness	• See the whole picture: see dependencies and relationships between processes and systems. • Fully understand the procedure(s) to be used.

Mitigation for Human Factors Errors — Slips

7. Complacency	• Expect to make/find errors. • Learn from the mistakes of others. • Use checklists/documentation. • Don't sign/check-off if you didn't/haven't yet done it.
8. Distractions	• Get back in the groove after a distraction/interruption. • Use checklists/documentation. • Go back 3 steps when restarting a task.
9. Fatigue	• Watch for symptoms of fatigue in yourself and others. • Use buddy checks.
10. Pressure	• Put safety first. • Communicate concerns. • Ask for extra help.
11. Stress	• Use rational problem-solving approaches. • Take a short break when needed. • Discuss the problem with someone who can help.
12. Norms	• Put safety first. • "We've always done it that way" doesn't make it right. • Identify and eliminate negative norms.

General Solution Categories

- "Just do it" solutions that haven't yet been implemented
- Modification and/or standardization of procedures
- Moving control points upstream (decisions on process map)
- Mistake proofing
- Lean solutions
- Technology upgrades (measurement systems, for example)
- Optimization of processes or products (DOE)

Root Cause Analysis

There are many techniques for arriving at a solution. The particular technique will depend on the type of problem and is only limited by the team's imagination. Lean solutions can include process and/or value-stream mapping which could result in "Standard Work" flows, streamlined processes, work balancing, etc. Lean solutions could also include looking at a process or system through a "Voice of the Customer" approach, thinking horizontally in terms of the value stream of the customer rather than a vertical "departmental" focus within an organization. Lean also encompasses solutions like pull systems, kan bans for inventory, etc.

Design of Experiments (DOE) can be a stand-alone tool and is often used as part of Six Sigma projects.

Brainstorming can include "classic" brainstorming or Affinity Analysis or other creative methods.

Think back to some solutions you've seen &/or implemented…what techniques were used?

6 Levels of Solutions

0. **Containment** only, no deeper corrective action
1. **Training** only, retrain to existing process
2. **Visual guides** only, e.g., signage with cautions, reminders, visual standards/aids, etc.
3. **Detection** improvement only, no Poka-Yoke, e.g., add inspection/test
4. **Poka-Yoke** for immediate problem situation, such as simple error-proofing through fixturing, limiting access to process/equipment adjustments, fail-safe mechanisms, change to work area/environment, etc.
5. **Human Factor Error Elimination**: broader, systemic error-proofing for the work area(s) associated with the immediate problem to remove human factors causes, e.g., automation, paperless processes, AI, etc.
6. **Failure Mode Elimination**: fundamental design change to the product &/or process to render the failure mode impossible. Examples: alter product geometry, replace materials/components, remove/alter operation step where failure occurs, modify/replace equipment, etc.

Root Cause Analysis

The solution levels above are listed by increasing level of complexity, which typically correlates to the amount of resources (time, money, people), necessary to implement the solutions.

When solutions are proposed, it can be helpful to identify them by their level and challenge the team to think about possible solutions at all levels.

A zero rank is given to “containment only” because while it’s critical in avoiding escapes of nonconformities to customers, used alone, containment does nothing to address root cause.

Simpler solutions, as in levels 2 through 4, may be easier and less expensive to implement but may not address deeper systemic root causes. Solutions at these levels have a higher risk of problem recurrence and should be monitored accordingly.

Maintaining a record of *all* solutions considered technically viable, not just those implemented, may be useful in case of future problem recurrence.

It should be noted that level 6 solutions are rare because in addition to technical difficulty and resource challenges, there may be customer and/or regulatory obstacles to face.

Return on Investment

- Most of the tools used to identify both opportunities and root causes have a common theme: to get the greatest return (biggest problems, highest impact, root cause, etc.) for our investment (energy, time, dollars, etc.).
- Consideration of ROI is also important when developing solutions. Before investing resources, Management will likely want to know the ratio of potential benefits to the costs required. You can generate this data by:
  - ☑ summarizing "current reality" measures in terms of quality, time, cost, satisfaction, etc.
  - ☑ projecting savings in the above dimensions
  - ☑ comparing "current reality" to results seen from testing the solution

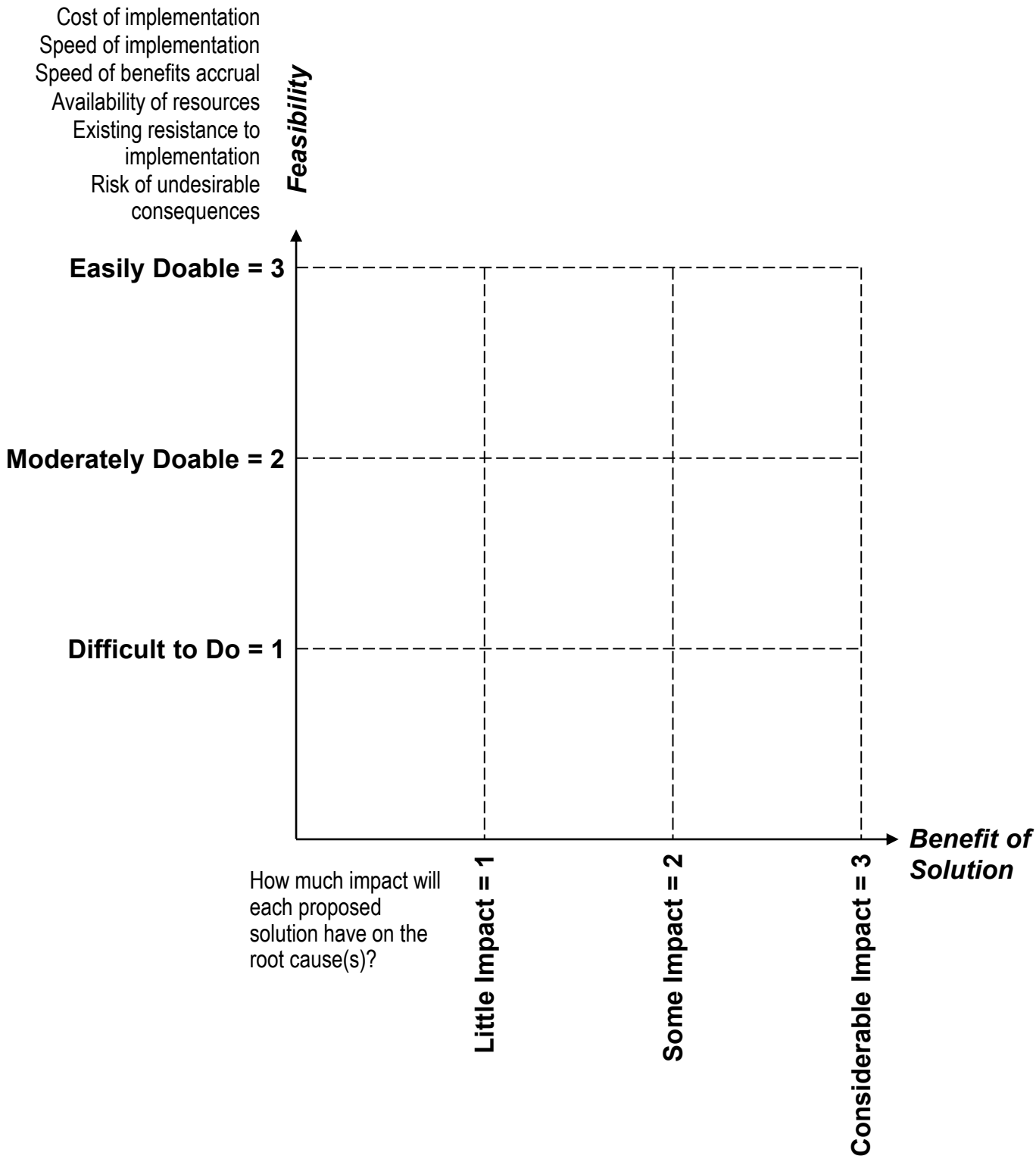
Root Cause Analysis

ROI = Return on Investment

Prioritizing Solutions

- It is also important to consider the feasibility of solutions when prioritizing.
- A good solution may fail during implementation because important change factors were not considered.
- Taking a two-dimensional approach to prioritizing gives the organization a basis for making sound decisions:
  - ☑ solutions with high impact &/or high feasibility can be expedited
  - ☑ solutions with low impact &/or low feasibility can be postponed or discarded

Benefit Feasibility Analysis Worksheet



Benefit Feasibility Analysis Method

A small group (5–8 people) works best with Benefit Feasibility Analysis. Participants should be familiar with the identified solutions and have the knowledge and authority to set priorities. Steps are to:

1. Review/modify the benefit and feasibility dimensions.
2. Rank each idea by consensus on benefit and feasibility using the following scales:
3. How much impact would this solution have on addressing the identified root causes of the problem?
   (1=little impact, 2=some impact, 3=considerable impact)
4. How feasible (doable) will it be to implement this solution?
   (1=difficult, 2=moderate effort, 3=little or no effort)
5. Use the Priority chart to label the relative priority of each item.
6. Consider the rankings and make final selections.

Root Cause Analysis

Consensus is preferred because voting can overlook a potentially valuable minority opinion and/or create opposition.

In the case of true consensus, all participants are contributing to the final priority numbers through a thorough consideration of key factors rather than personal preferences or opinions.

Ground Rules for Consensus

- As with any group process, reviewing ground rules before beginning will improve the results.
  Consensus ground rules are to:
  - ☑ Listen. Pay attention to others.
  - ☑ Encourage participation of all members.
  - ☑ Share information.
  - ☑ Avoid changing your position only to reach agreement.
  - ☑ Don’t bargain or trade support.
  - ☑ Avoid arguing blindly for your own views.
  - ☑ Avoid conflict-reducing methods such as voting or coin tossing.
  - ☑ Seek out differences of opinion.
  - ☑ Discuss underlying assumptions.
  - ☑ Create a solution that can be supported.
  - ☑ Seek a win-win solution.

Proposed Solutions – Exercise

Revise documentation to clearly identify requirements

Incorporated into solution below

Replace equipment that doesn't meet requirements

Redesign work area layout in a Lean Kaizen event

Six Sigma or Lean project to improve planning process

Six Sigma or Lean project to improve material ordering process

Joint Six Sigma or Lean project to improve supplier's order fulfillment process

Joint Six Sigma project to improve supplier quality

Update all current documents

Implement a document control system

Implement training in the document control system

Previous Root cause observations for "mistakes and delays"

Requirements not clearly identified

Equipment not adequate for requirements

Poor work area layout → Equipment not available when needed

Poor planning → Unrealistic scheduling → Last minute preparation

Material not ordered

Wrong material ordered

Wrong quantity ordered

→ Sufficient material not available when needed →

Material delivered late

Wrong material delivered

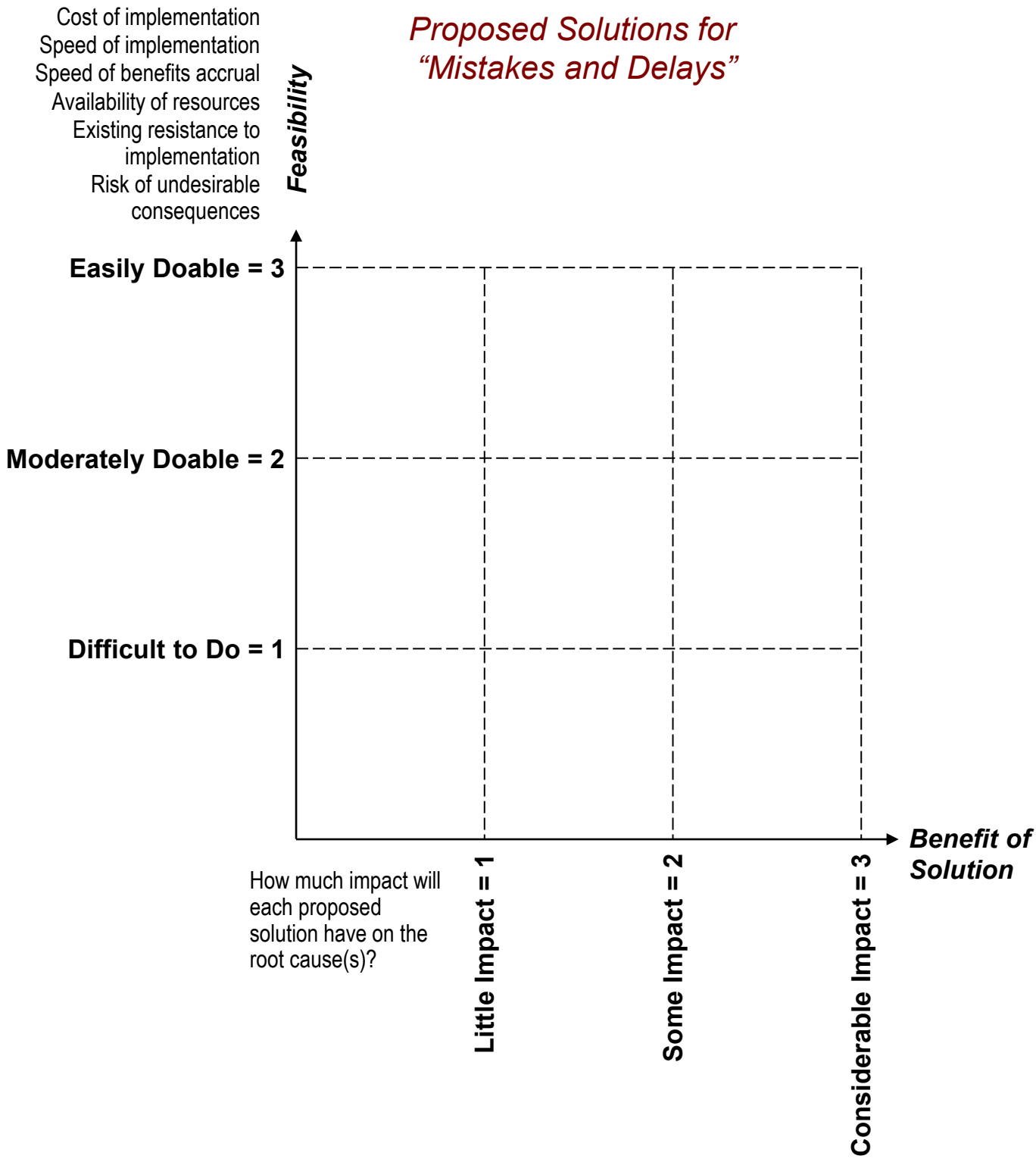
Wrong quantity delivered

Poor quality material

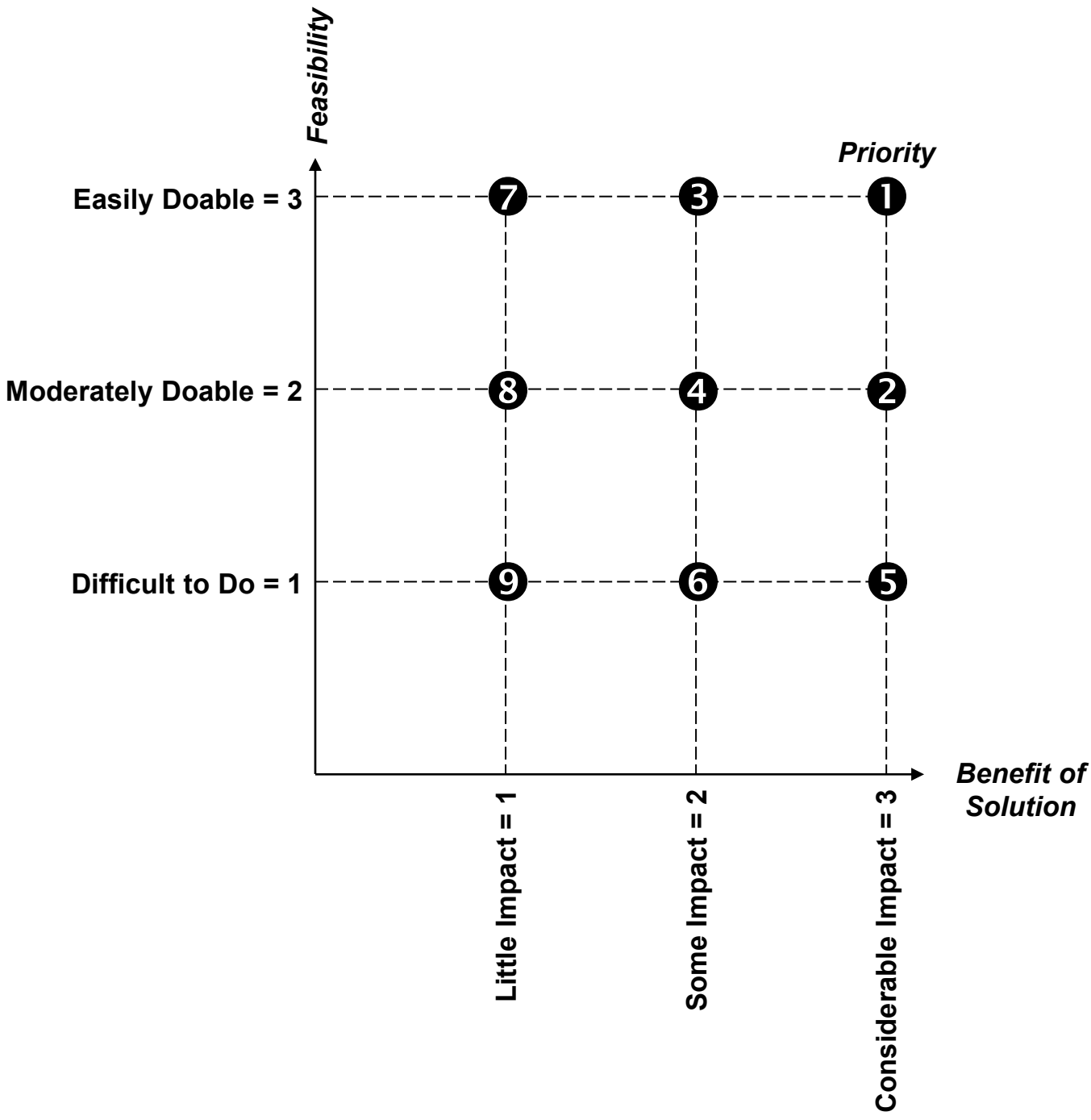
Revision is out of date → Instructions incorrect

Inadequate training → Work incomplete

Exercise: Benefit Feasibility Analysis



Benefit Feasibility Priorities

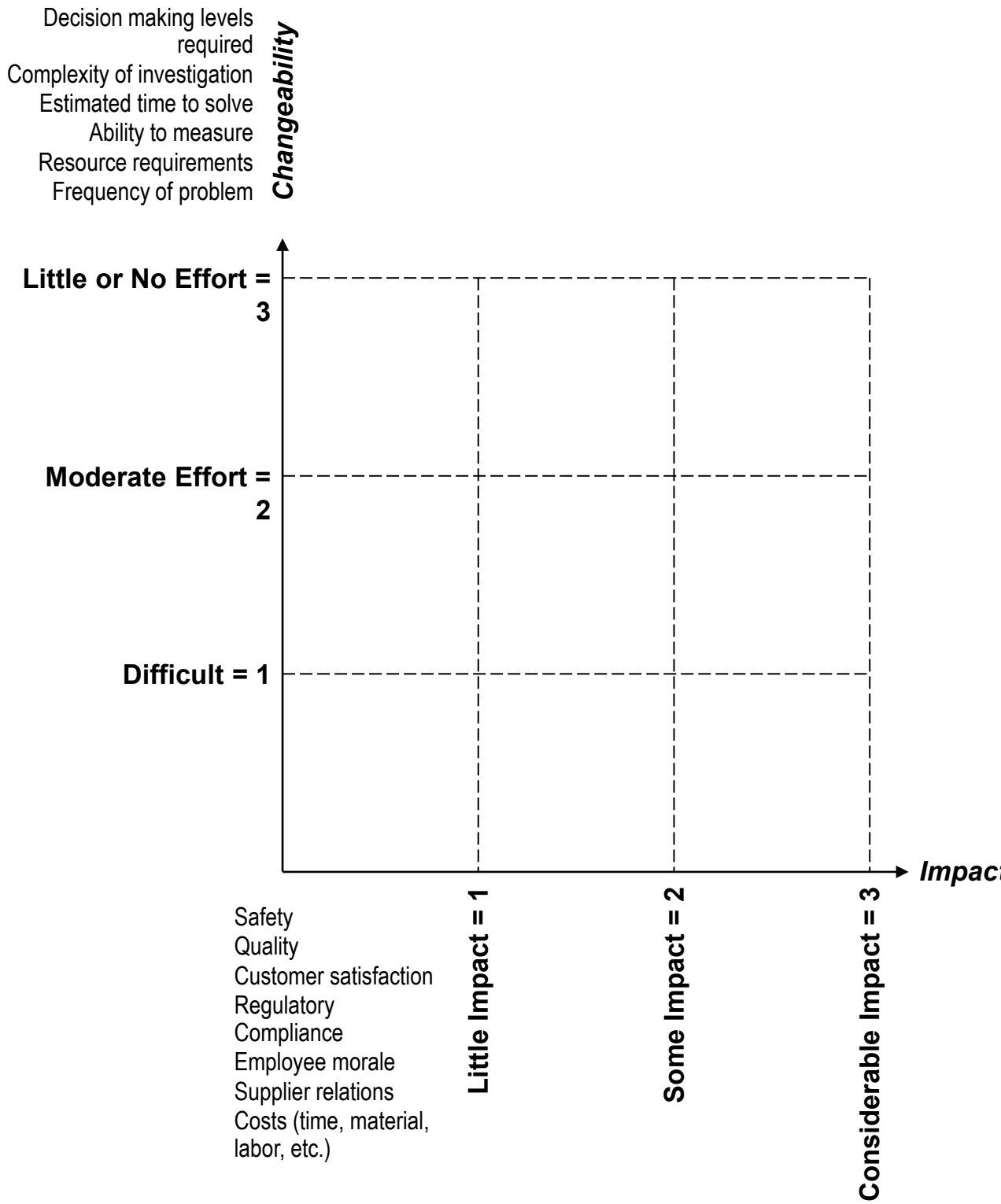


The Benefit by Feasibility plot helps to visualize priorities for solution implementation, especially when resources are scarce.

Redux: Prioritizing Issues — Impact Changeability

- A similar two-dimensional approach can also serve as a screening method for prioritizing formal Corrective Action requests.
- In prioritizing issues to solve, the goals are to:
  - ☑ Consider problems/opportunities by degree of impact on internal and external factors and ease of changeability of the underlying process/system.
  - ☑ Prioritize and select problems/opportunities for further analysis.
- "Changeability" replaces Feasibility
- The dimensions to consider for Impact and Changeability are different but the methodology is the same

Impact Changeability Analysis Worksheet



D6: Implement & Validate Corrective Actions

Action plans are used for successful implementation of corrective actions. Ongoing controls are established to validate the effectiveness of the corrective action for the customer.

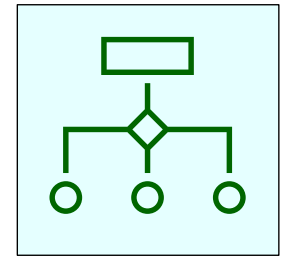
Root Cause Analysis

D6: Implement & Validate Corrective Actions

- Effectiveness of corrective must be reviewed and records kept.
- Methods of Corrective Verification:
  - ☑ Lots inspected without defects
  - ☑ Supplier Development data
  - ☑ Defect level reduction information
  - ☑ On-line audit data
  - ☑ Out-of-box audit data
  - ☑ Quantity of units produced without defect
  - ☑ Burn-in data
  - ☑ Internal audits
  - ☑ Early quality indicator reports
  - ☑ Testing data
  - ☑ Length of time without defect

D7: System-level Recurrence Prevention

Management and operating systems, practices, and procedures are modified to prevent recurrence of the problem and similar problems.



D7: System-level Recurrence Prevention

- Ensure that corrective actions address the systems that allowed the problem to occur and to escape informal or formal control methods
- Think broadly regarding systems: business, finance, quality, environmental, leadership, training, etc.
  - ☑ Consider whether the solution(s) implemented are suitable for the operational environment and if they can be adapted to improve other products, services or processes
  - ☑ Update documentation as needed
- Develop and execute action plans
  - ☑ Validate actions taken
  - ☑ Validation may require running the improvement process for a period of time to check longer term stability
- Fan out solutions the rest of the organization and partners, affiliates as appropriate

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CA Evaluation Checklist

A tool to check whether a CA is complete and effective.

CA Response Checklist						
CA #	D3: Immediate?	D3: Remedial?	D3: Interim?	D4: Root Cause?	D5 & D6: CA Implemented & Validated?	D7: Recurrence Prevention?

CA Evaluation Questions

Note: "problem" = nonconformance, discrepancy, deficiency, etc.

D3–Immediate: Was the specific discrepancy/deficiency observed corrected?

- Does the response state what correction was/will be made and when?
- If not, does the response explain how the observed problem can be accepted without adverse effect on quality?

D3–Remedial: Was the immediate problem contained? Was the existing "population" from which the problem evidence was drawn searched for other instances of the same or similar discrepancies/deficiencies?

- If not, does the response explain how the decision not to locate and correct all existing problems of the observed type is justified in terms of lack of effect on quality?
- If the "population" will be purged, does the response explain how and when?
- Does the response include consideration of containment needs for similar products/processes?
- Were containment needs for revisited once the root cause was found?

D3–Interim: Does the response describe any interim measures taken while root cause was determined? (Or is justification given if interim action was deemed unnecessary?)

- There should be interim measures put in place if the corrective action requires some time before it can be fully implemented.
- Were interim measures removed as appropriate once the permanent solution was implemented?

D4–Root Cause: Does the response describe the conditions, circumstances, or situation(s) that caused the problem (i.e. root cause found)?

- If the response suggests that the observed problem was an isolated instance, was an extensive survey of the "population" performed which provides firm evidence that this is the case?
- If the response suggests that the problem resulted from one individual's failure to understand or comply with a requirement, was an investigation performed to establish such a fact beyond dispute (i.e., product and process instructions/requirements and training validated as correct)?

D5, D6, D7–Permanent CA: Does the response describe the action that will be taken to correct and prevent recurrence of problems like the one(s) observed from recurring?

- Will the described action remove the cause(s) identified in D4?
- Does the action include making changes to appropriate documents?
  - ✓ It is acceptable to revise existing procedures to better match the controls actually being used, provided such controls have been determined to be adequate.
  - ✓ It is not acceptable to change procedures merely to relax requirements, unless these procedures can be clearly shown to exceed requirements.
- The response should not propose to caution individuals to be "more careful" or to "comply with requirements." However, formal training sessions would be acceptable where such a course of action suited the problem.
- Was "out of the box" thinking used? For example, was there consideration of whether the solution could be applied in other areas (processes, products, services, internal/external, etc.)?

CA Evaluation Exercise

Problem Statement and CA Response	Q 1: Immediate?	Q 2: Remedial?	Q 3: Interim?	Q 4: Root Cause?	Q 5: Permanent?
Hand cuts to hourly workers during hand deburr operations on fuel tanks in process assembly increased from 26 to 172 in August, 20XX. The goal is no more than 10 per month. Response: Workers were not being careful enough. They were instructed in the staff meeting on Sept. 20th to be more aware of safety during this process.					
Fifteen percent of the Manufacturing clients were required to wait more than 3 days for a proposal response in the first quarter of 20XX. Sales reps need to complete their order entry faster. Response: The order entry process was studied. It was determined that order entry was taking place as fast as the current system allowed. A process team was created to optimize the entry process. They revised the data entry process to streamline and reduce redundant steps. The wait time is now less than 1 day for all Manufacturing clients.					
Manufacturing rejected 75% of subassembly kits back to Material Control during the first 6 months of this year (for no legitimate reason either). Response: Immediate actions take place at the time of rejection, with kits being corrected as needed. An analysis of reject reasons was conducted. A cross-functional process map of the kitting process was created to mistake-proof the process and clarify responsibilities for accuracy checks. The new process was piloted on 6 kits with no defects found by Manufacturing.					

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D8: Recognize the Team

The collective efforts of the team are recognized and the significance and value of the solution is acknowledged. Knowledge gained during the process is documented and shared.

D8: Recognize the Team

- Acknowledging and recognizing efforts of individuals and the team collectively is important reinforcement for creating a culture of continuous improvement
- Evaluate what worked well during the 8D process & what could be done better next time
- Share successful solutions in organization-wide communications to strengthen the connection between effective corrective action and improved quality, delivery, cost, and satisfaction (internally & externally)
- Consider each 8D investigation to be a valuable contribution to organizational knowledge

Summary

Root Cause Analysis for Corrective Action is one of the hardest things to do well, but it also brings the greatest returns.

- Problem statements need to effectively describe the problem without jumping to the root cause &/or a solution.
- Effective Root Cause Analysis means investigating the issue at technical, escape and systems levels.
- Human Factors errors need to be recognized and addressed at a system level, not just with the individual “operator.”
- Corrective Actions need thorough review and validation to ensure solutions are effective.

What were some significant learnings for you? Which techniques and tools do you think will be most helpful in your organization and to you individually?

Appendix

- CAPA Response Checklist Tool (blank form)
- CAPA Form Samples

CA Response Checklist Tool

CA/PA Number Being Evaluated	Q 1: Immediate?	Q 2: Remedial?	Q 3: Interim?	Q 4: Root Cause?	Q 5: Permanent?

XYZ Company	
Corrective, Preventive and Improvement Action Form	
Corrective Action: ☐ Preventive Action: ☐ Improvement Opportunity: ☐	
Requested by:	Date:
Type of Issue: Customer: ☐ Internal: ☐ Supplier: ☐	
Problem Description (Problem Statement: What? Who? Where? How Much? When? Goal or Pain? Include any immediate/remedial action taken.	
Steps # 1 – 5 below are to be completed by the person assigned as the Owner of the Action Form	
Steps # 1 – 5 require a response within 10 work days	Response Due:
CA Assigned to:	CA #:
1. Acceptance or Rejection of Responsibility for taking Action	
Accept: ☐ Reject: ☐	
If rejected, explain reason for rejection (final decision is up to CA Coordinator)	
2. Perform Analysis & Identify Root Cause	
3. Action Solution (attach Action Plan as needed)	See attachment: ☐
4. Action Taken to Prevent Recurrence or Occurrence (as appropriate)	See attachment: ☐
5. Action Owner Signature:	Date:
6. Verify Effectiveness of Action Taken	
Acceptable and Verified: ☐ Not Acceptable: ☐	
Describe How Effectiveness was Determined	
Verified by:	Date:
Action Closed by:	Date:
Please read other side – important guidelines for Action are provided	

Corrective Action Guidelines

Congratulations! You have been selected as our next corrective action owner. The following suggestions can help you generate the most successful solutions possible.

1. Stay Calm!
As the owner, you are not expected to be a lone ranger, doing all of the investigation and solving all of the problems unaided. Instead, your objective is to gather together those who are most likely to offer the best contributions toward:

- Fixing what is defective
- Discovering what has gone wrong
- Developing procedures to prevent it from happening again

Important: Guard against the first reaction to a corrective action request, which is to fire the operator. The operator might very well be the individual who can contribute the most to solving the real problem. Throwing blame around is a good way to get people to hate you, not help you.

Important: Operators do make mistakes, just like the rest of us. The point is to discover what can be done to eliminate the causes of those mistakes (other than random human error).

2. Ask “Why?” when a cause is discovered.
Often something went wrong, which caused something else to go wrong, which finally messed up some parts. You want to discover all of the bad parts or processes; be aware that some might try to hide out.

Example: Cause = worn vise jaws

This failure is going to be fixed by repairing the vise jaws, but if you don't ask "Why?" the failure can and will happen again. You should ask such questions as: Why didn't we find out about the worn vise jaws before defective parts were made? Did the jaws wear out due to natural causes, or were they used improperly?

Important: Corrective action is intended to produce permanent solutions.

3. Be specific.
Avoid listing an ambiguous cause, such as "bad tool," because it could refer to a variety of actual causes. To be specific, you might ask:

- Was the tool calibrated? If not, why? (Maybe calibration doesn't exist for the tool.)
- Did the operators use the tool they were given? If not, why? (Maybe they knew better, but fear kept them from speaking out.)
- Was the tool used properly? If not, why? (Maybe the leader was too busy to train the operators.)
- Was the tool maintained? If not, why? (Maybe it was considered too expensive to have it serviced.)

(Note: All of these responses imply the need for management change. This is very common.)

4. What's the point?
- We want to solve all of the causes so the problems cannot happen again.
- Once a cause is discovered, we can ask: Does this cause affect anything else we do? When the answer is yes, we might be able to fix a problem before bad parts are made.

If you have any questions about this CAR or these guidelines please call _____ right away.

Improvement Action / Document Change Request

IAR#:_____

Section 1 – Initiate Request (completed by Submitter)		
☐ Actual Problem	☐ Potential Problem	☐ Improvement Suggestion
☐ Audit Finding	☐ Document Change Request	
Describe Action Requested:		Date:
Action Taken on Initial Problem (must be completed for Actual Problems):		
Submitted by:	Work Group:	Phone/Email:
Submit to Improvement Action Review Board (IARB)		

Completed by IARB	
IAR Number Assigned:	Group(s) Involved:
Date Assigned:	Follow-up with Submitter:
Assigned to:	Action Plan Due Date:

Section 2 – Determine Action to Take (completed by Assigned Action party)	
Root Cause:	
Permanent Correction or Solution:	
For Document Changes – refer to reverse side	
Date sent to next of level of Management (optional):	
Action Person for Implementation:	Effective Date:
Completed Form or Action Plan must be returned to IARB by Action Plan Due Date (shown above)	
IARB Approval:	Date:
Date Returned (optional):	Reason for return:
Follow-up Date:	

Section 3 – Follow-up		
☐ IAR closed and filed:	☐ IAR reopened:	
	New IAR #:	Date:
IARB Leader Signature:		

Improvement Action / Document Change Request

Document Change Request
Completed by Document Control
Action Decision: ☐ Implement change/revision ☐ New document ☐ Wait for next revision ☐ No Action Document #: _____ Revision from: _____ to: _____ Incorporation date: _____ Document Owner: _____ Document Title: _____ Short description of changes: