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Root Cause Analysis as a Component of the Deviation Investigation

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Introductions and Overview

- Course Objectives
- What is Root Cause?
- Benefits
- Problem Solving Process
- Examples
- Root Cause “Hints
- Additional Resources

Upon Completion of this Course

- Participants should be able to:
 - Understand the importance of performing root cause analysis
 - Identify the root cause of a problem using the problem solving process
 - Understand the application of basic quality tools in the problem solving process

Definition

- Root Cause is...
 - The causal or contributing factors that, if corrected, would prevent recurrence of the identified problem
 - The “factor” that caused a problem or defect and should be permanently eliminated through process improvement
 - That factor that sets in motion the cause and effect chain that creates a problem
 - Multidisciplinary
 - Focuses on systems, not people
 - The “true” reason that contributed to the creation of a problem, defect or nonconformance

Definition, cont'd

- A standard process of:
 - Identifying a problem
 - Containing and analyzing the problem
 - Defining the root cause
 - Defining and implementing the actions required to eliminate the root cause
 - Validating that the corrective action prevented recurrence of problem

Benefits to Analyzing Down to the Root Cause

- By eliminating the root cause...

— You save time and money!!

- Problems are not repeated
 - Reduce rework, retest, re-inspect, poor quality costs, etc.
- Problems are prevented in other areas
- Communication improves between groups
- Process cycle times improve (no rework loops)
- Secure long term company performance and profits

\$\$ Less rework = Increased profits! \$\$

When to Perform Root Cause Analysis

- When PROBLEMS occur!!

Supplier Defects

Excess Inventory

Out of Control Process

Computer issues

Scrap Problems

Human Error

Audit Finding

Missed Deliveries

Machine Defects

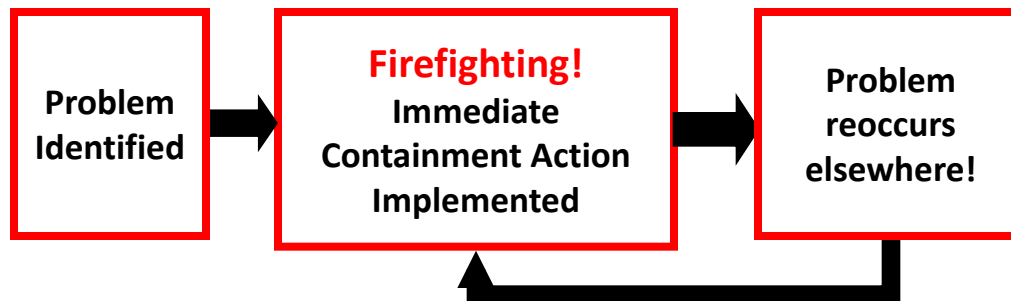
Workmanship Defects

Overspending Budget

Safety Issues

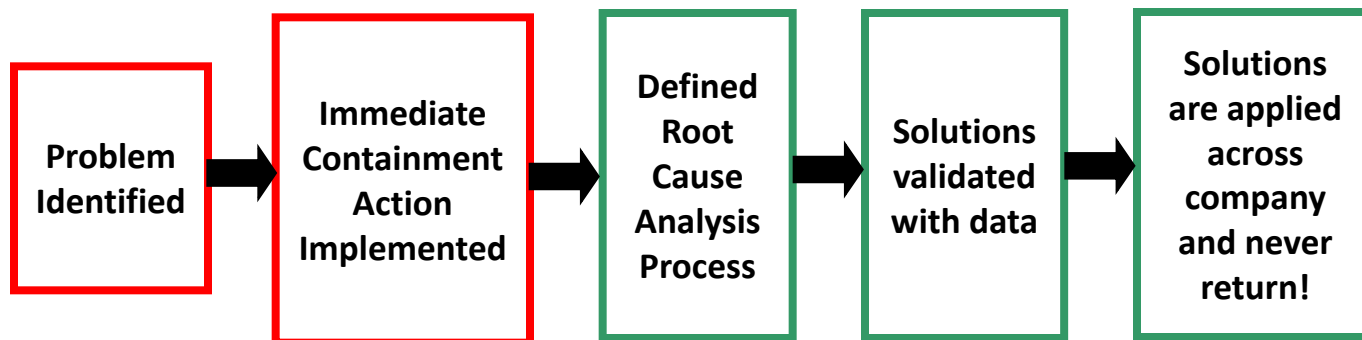
Usual Approach to Problem Solving

- In most companies, when a problem surfaces, we firefight and try to put out the “fire” immediately. This involves some kind of quick fix or work around to keep the process moving. Just as we find an acceptable “band aid” fix that works, another “fire” starts somewhere else and we rush to fix it
- We never take the time to revisit these “fires” to figure out why they happened in the first place. We keep dealing with the same problems over and over again



Preferred Approach to Problem Solving

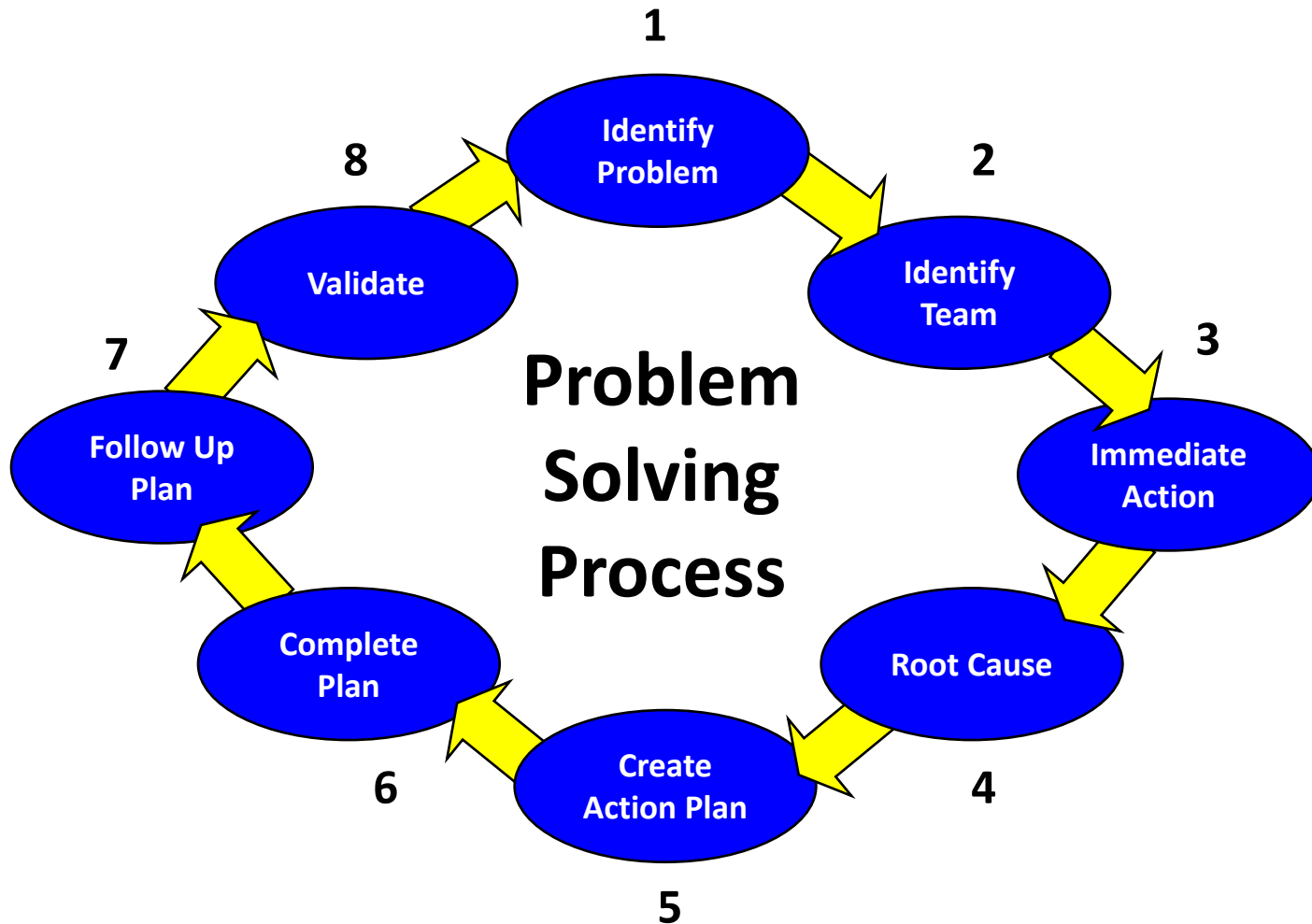
- First, identify as much of the salient information about the problem as possible and this should be done as soon as the problem is identified
 - Example – when did it occur, what lot was impacted, what shift did the problem occur on, what equipment/personnel was involved, what building did the issue occur in, etc.
- Launch a mechanistic investigation into what possible failure modes would have caused the problem statement based on the preliminary information gathered on the problem
- We then implement the process change and check to see that it does not return
- Obviously this approach will take much longer, so why should we take the time?

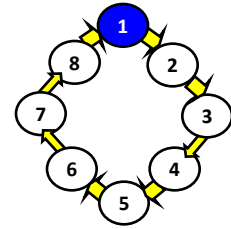


Why Perform a Thorough Root Cause Investigation?

- We must think in the long term – do we want to be dealing with the same number of problems as we are today, or do we want to have more time available to work on improving the process and other value added activities?
- The root cause investigation is the documentation behind the facts of the problem statement and provides support and justification to the underlying failure mode(s) which occurred within the process and become the focus for corrective action
- This is a component of the problem solving process

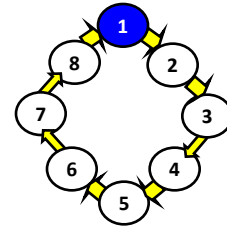
Problem Solving Process





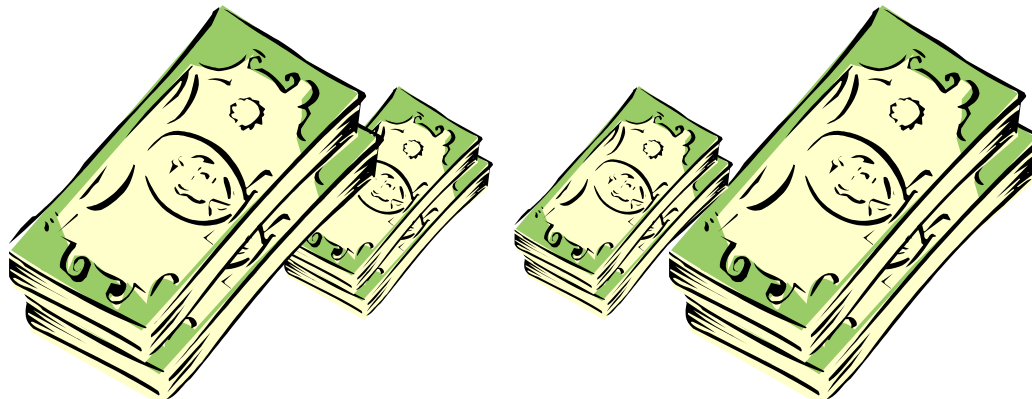
Step #1 – Identify the Problem

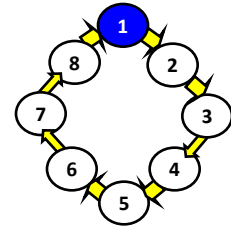
- **Very important!!**
- Clearly state the problem the team is to resolve
 - Teams should refer back to problem statement to avoid getting off track
- The problem statement should speak to the part of the process which did not perform as expected
- Use 5W2H approach
 - Who? What? Why? When? Where?
 - How? How many?



Step #1 – Problem Statement

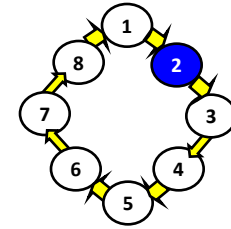
- State the problem in terms of dollars
 - This is the language of management
 - Determine how much each occurrence of the problem costs the company
 - Justifies any spending on root cause analysis and corrective actions
 - Prioritizes financial impact of problems
- Use Goal Question Metric (GQM) as a model for clarifying statements
 - Clearly define: Object, Purpose, Focus, Environment, and Viewpoint





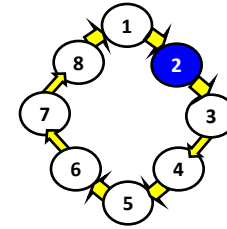
Step #1 – 5W2H

- **Who?** Individuals/customers associated with problem
- **What?** The problem statement or definition
- **When?** Date and time problem was identified
- **Where?** Location of complaints (area, facilities, customers)
- **Why?** Any previously known explanations
- **How?** How did the problem happen (root cause) and how will the problem be corrected (corrective action)?
- **How Many?** Size and frequency of problem



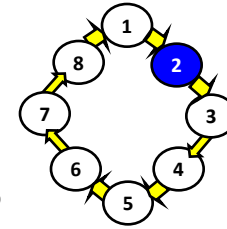
Step #2 – Identify Team

- When a problem cannot be solved quickly by an individual, use a team!
- Should consist of domain knowledge experts
- Small group of people (4-10) with process and product knowledge, available time and authority to correct the problem
- Must be empowered to “change the rules”
- Should have a designated Champion
- Membership in team is always changing!



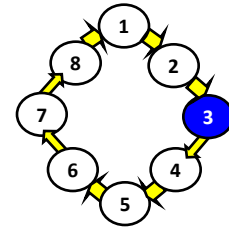
Step #2 – Tips for Team Success

- Define roles and responsibilities
- Identify external customer needs
- Identify internal customer needs
- Appropriate levels of organization present
- Clearly defined objectives and outputs
- Solicit input from everyone!
- Good meeting location
 - near work area for easy access to info
 - quiet for concentration and avoiding distractions



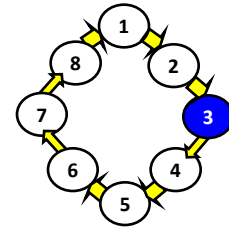
Step #2 – Roles and Responsibilities

- **Champion:** Mentor, guide and direct teams, advocate to upper management
- **Leader:** day-to-day authority, calls meetings, facilitation of team, reports to Champion
- **Record Keeper:** Writes and publishes minutes
- **Participants:** Respect all ideas, keep an open mind, know their role within team



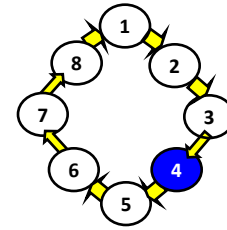
Step #3 – Immediate Action

- Must isolate effects of problem from customer
- Usually “Band-aid” fixes
 - 100% sorting of parts
 - Re-inspection before shipping
 - Rework
 - Recall parts/documents from customer or from storage
- Only temporary until corrective action is implemented (very costly, but necessary)
- Must also verify that immediate action is effective



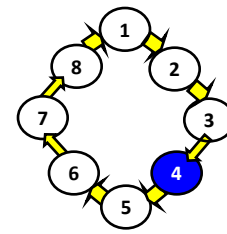
Step #3 – Verify Immediate Action

- **Immediate action** = activity implemented to screen, detect and/or contain the problem
- Must verify that immediate action was effective
 - Run Pilot Tests
 - Make sure another problem does not arise from the temporary solutions
- Ensure effective screens and detections are in place to prevent further impact to customer until permanent solution is implemented

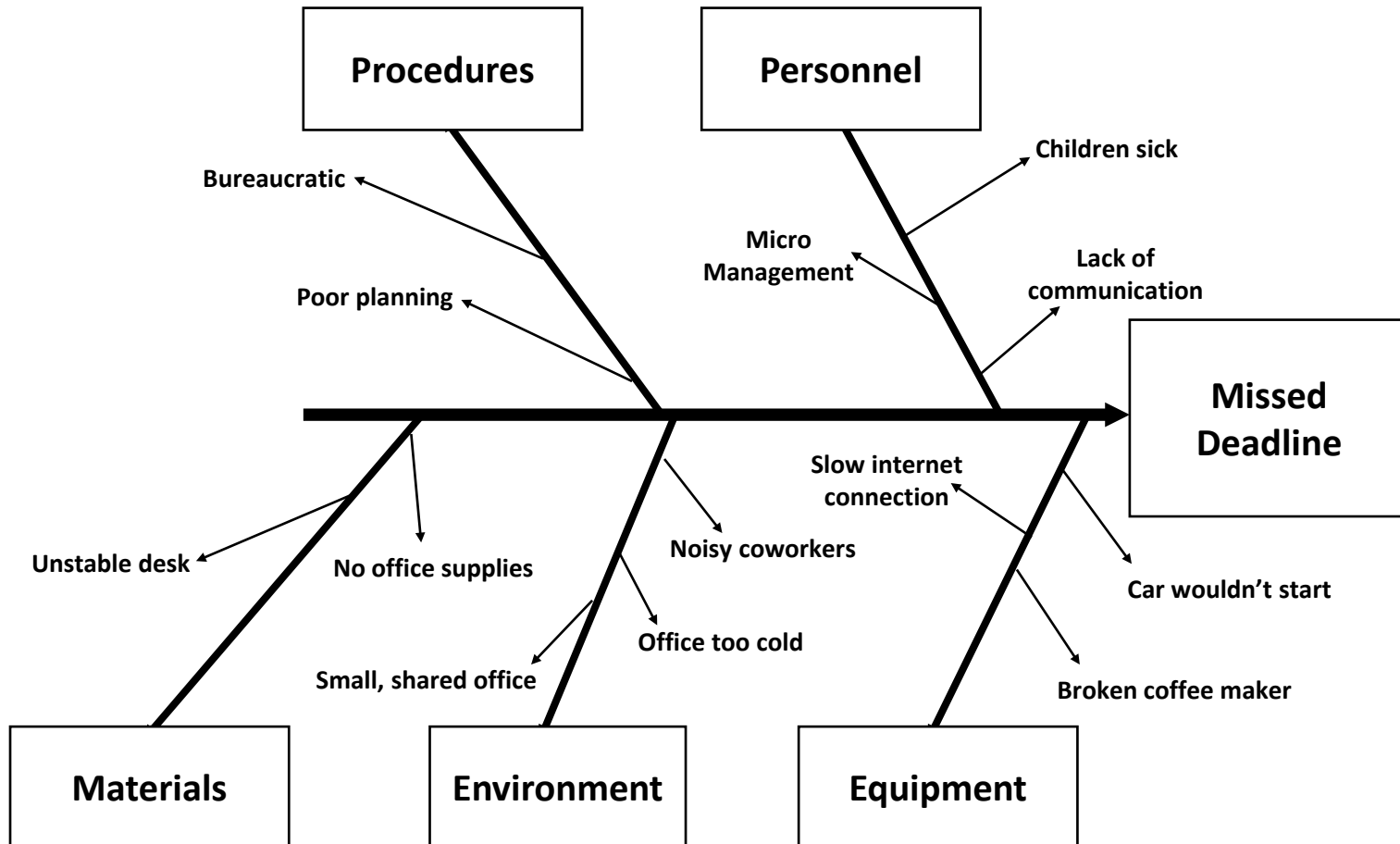


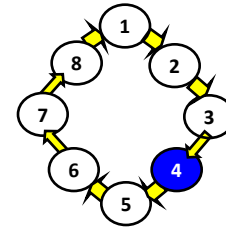
Step #4 – Root Cause

- Must identify the process that caused the problem
 - What happened?
 - Why did it happen?
 - What were the most proximate causes?
 - If issue is company-wide, escalate the issues to upper management
- Events and Causal Factors
 - Brainstorm and organize possible causes of problem with team
- Change Analysis to interpret shifts/negative trends
- Barrier Analysis to examine what detection/prevention method of the process failed
- Use 5 Why method to further define the root cause of symptoms
 - May involve additional research/analysis/investigation to get to each “Why?”

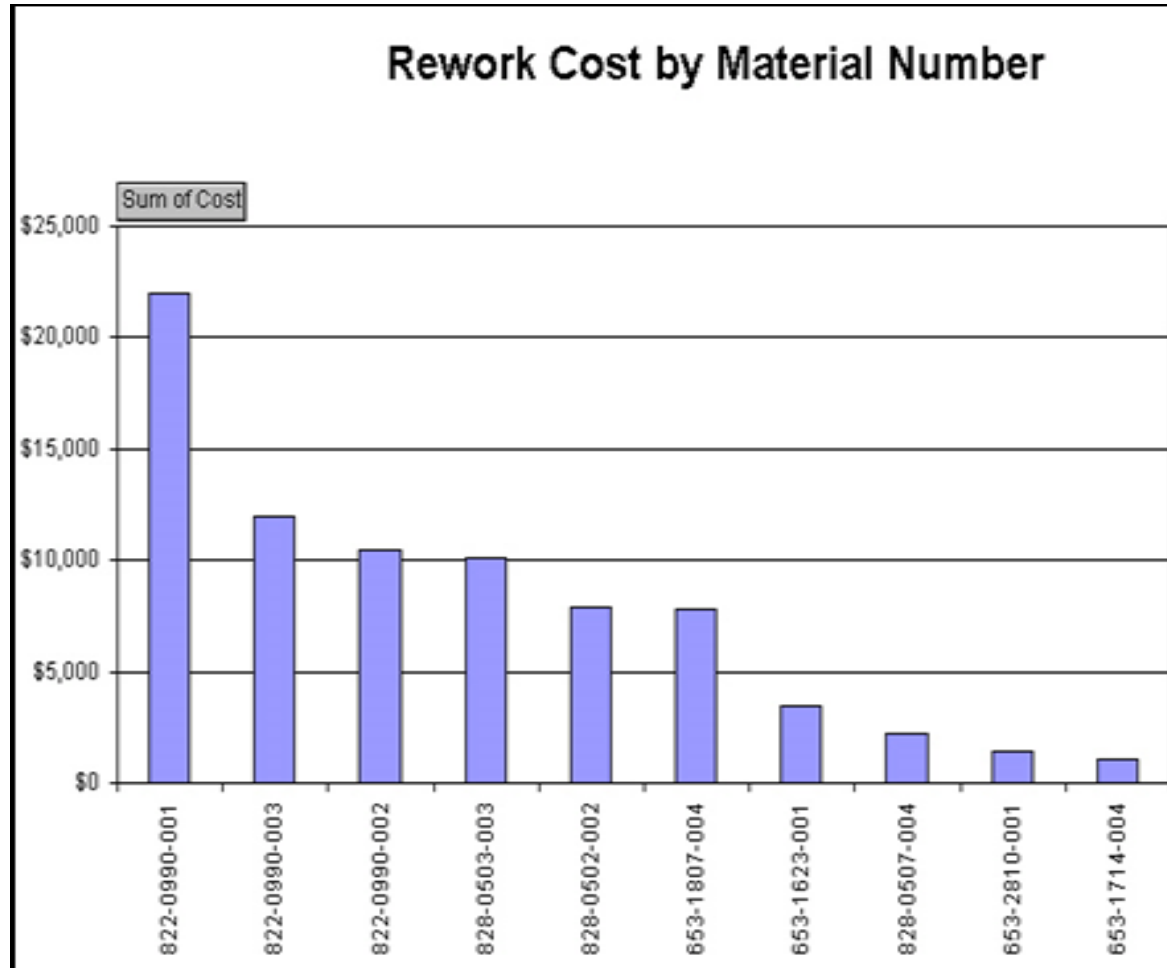


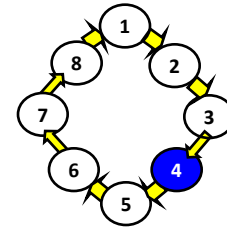
Step #4 – Ishikawa Diagram / Cause & Effect



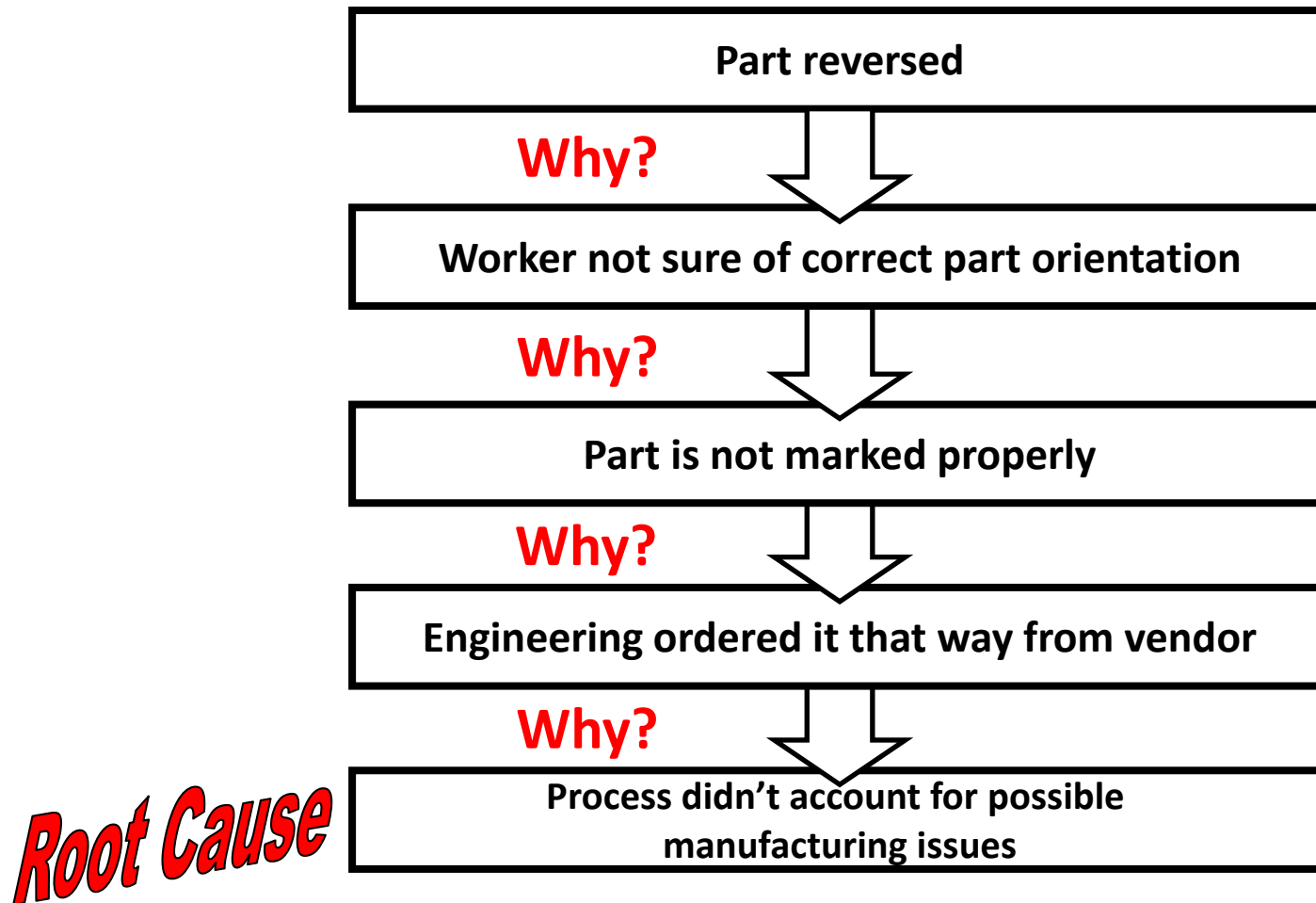


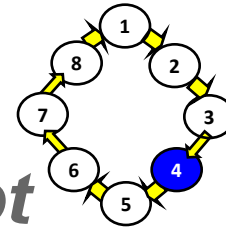
Step #4 – Pareto Chart





Step #4 – 5 Why's

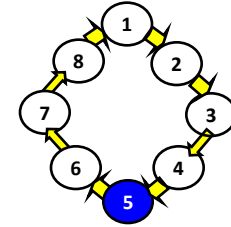




Step #4 – *Is and Could Be But Is Not*

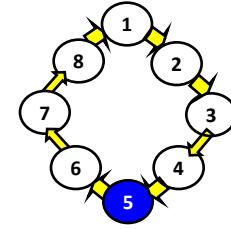
Problem: Michele's Chocolate Cake, Batch 12345, Baked on 16Mar2015 At 02:53AM Did Not Meet the Moisture Requirement

Aspect	IS	COULD BE But IS NOT	Differences	Changes
What	Michele's chocolate cake, lot 12345, too dry	Other chocolate cakes that Michele bakes	Different bakers made lot 12345	Only one egg instead of two eggs was added
Where	Cake Bakery	Anywhere else this cake recipe is baked	Normally baked by Michele	First time these bakers followed this recipe
When	16Mar2015 at 03:21	Any other time or location	Michele normally bakes between 09:00-14:00	First time these bakers followed this recipe
Extent	Michele's chocolate cakes	Other cakes	None noted	None noted



Step #5 – Corrective Action Plan

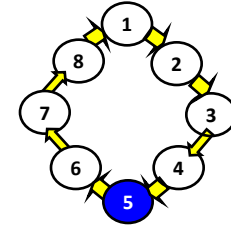
- Must verify solution will eliminate cause of the problem
 - Verification before implementation whenever possible
- Define exactly...
 - What actions will be taken to eliminate the problem?
 - Who is responsible?
 - When will it be completed?
- Make certain customer is happy with actions
- Define how the effectiveness of the corrective action will be measured.
 - Pareto charts, Paynter charts, check sheets, etc...



Step #5 – Verification of Solution

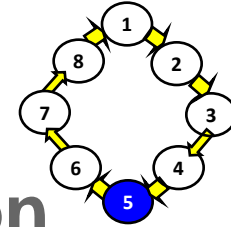
Potential Root Cause:	True If:	Probable Root Cause
Recipe steps incorrect	Other cakes were also too dry	Probably not
The egg added has something wrong with it	Only cake 12345 has this problem	Maybe
Baker made an error	Problem did not always reoccur	Probably

Answer the Question: If _____ is the root cause of this problem, does it explain the problem IS and what the problem COULD BE but IS NOT”



Step #5 – Corrective Action Plan

- Action Plan identifies the strategies that the organization intends to implement to reduce the risk of similar events occurring in the future
 - Addresses implementation (who & when)
 - Measures ongoing effectiveness



Step #5 – 3 Types of Corrective Action

- **Immediate action**

- The action taken to quickly fix the impact of the problem so there is no further impact

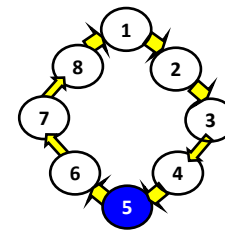
- **Permanent root cause corrective action**

- The action taken to eliminate the error on the affected process or product

- **Preventive (Systemic) root cause corrective action**

- The action taken to Prevent the error from recurring on any process or product

If preventive not addressed, problem will return!!



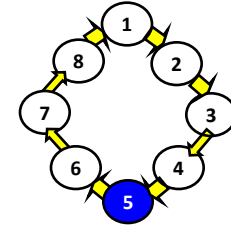
Step #5 – Permanent versus Preventative

Permanent

- Trained employee on proper machine use
- Changed product design to make parts easier to assemble manually
- Specific customer document critical to project is identified with red folder
- Update all customers with latest software revision to fix problem
- Fallen patient given full-time assistant to provide help moving around hospital
- Employee fired for ethical violation

Preventive

- Made training a requirement to new employees working in that area
- Changed design guidelines to not allow for use of part in full scale production
- All documents that are critical to project are identified with red folders
- Check for those software bugs added to checklist and performed prior to release of software
- Process developed to identify “at risk” patients for falls who require assistant
- Ethics training developed and provided to all employees



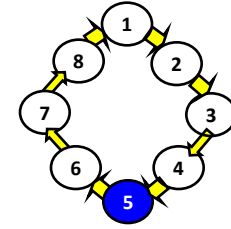
Step #5 – Verification vs. Validation

- **Verification (Before)**

- Assures that at a point in time, the action taken will actually do what is intended without causing another problem

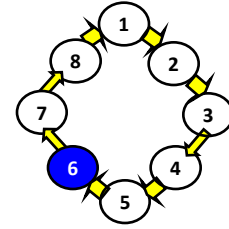
- **Validation (After)**

- Provides measurable evidence over the long term that the action taken worked properly, and the problem has not recurred



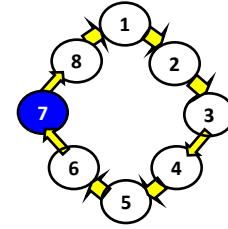
Step #5 – RCA Metrics for Success

- Consider more than just eliminating the problem for good...
 - What are the costs associated with the Corrective Action(s)?
 - How big are the problems we are correcting?
 - Is once in every 100 lots acceptable? Once in every 1000 lots?
 - Timelines for completion of Corrective Action(s)
 - What is the net return?



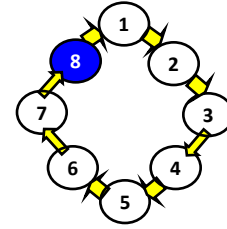
Step #6 – Complete Action Plan

- Make certain all actions that are defined in Step #5 are completed as planned
- If one task is still open, verification and validation cannot be completed
- If the action plan is not fully and only partially completed, most likely the solution will not be as effective



Step #7 – Follow Up Plan

- What actions will be completed in the future to ensure that the root cause has been eliminated by this corrective action?
- **Who** will look at what data?
- **How long** after the action plan will this be done?
- **What criteria** in the data results will determine that the problem has not recurred?



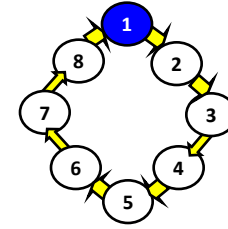
Step #8 – Validate and Celebrate

- Finally, the team should review the data results to conclude whether the root cause was adequately defined, or that the corrective action put in place was effective
- If the problem still exists, go back to either Step #4 and redefine the root cause, or Step #5 to readdress the corrective actions put in place
- If the problem did not reoccur, formally close the problem and celebrate success!
- It is extremely beneficial to calculate any financial savings impact of resolving the problem
 - Many companies will redistribute a percentage of the cost savings back to the team members to further support the importance of solving problems



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Root Cause Analysis Example

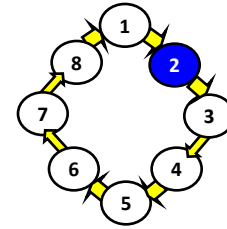


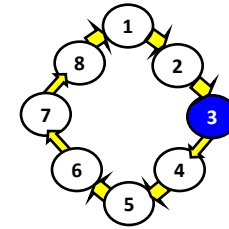
Identify Problem

- Department didn't complete their project on time

Determine Team

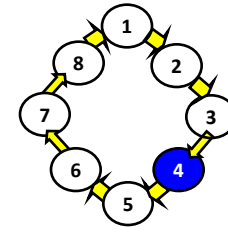
- Team members:
 - Boss – Jim
 - Worker – Tom
 - Worker – Karen
 - Project Manager – Bob
 - Administrator – Sally





Immediate Action

- Additional resources applied to help get the project team back on schedule
- No new projects started until Root Cause Analysis completed

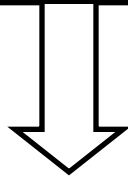


Root Cause

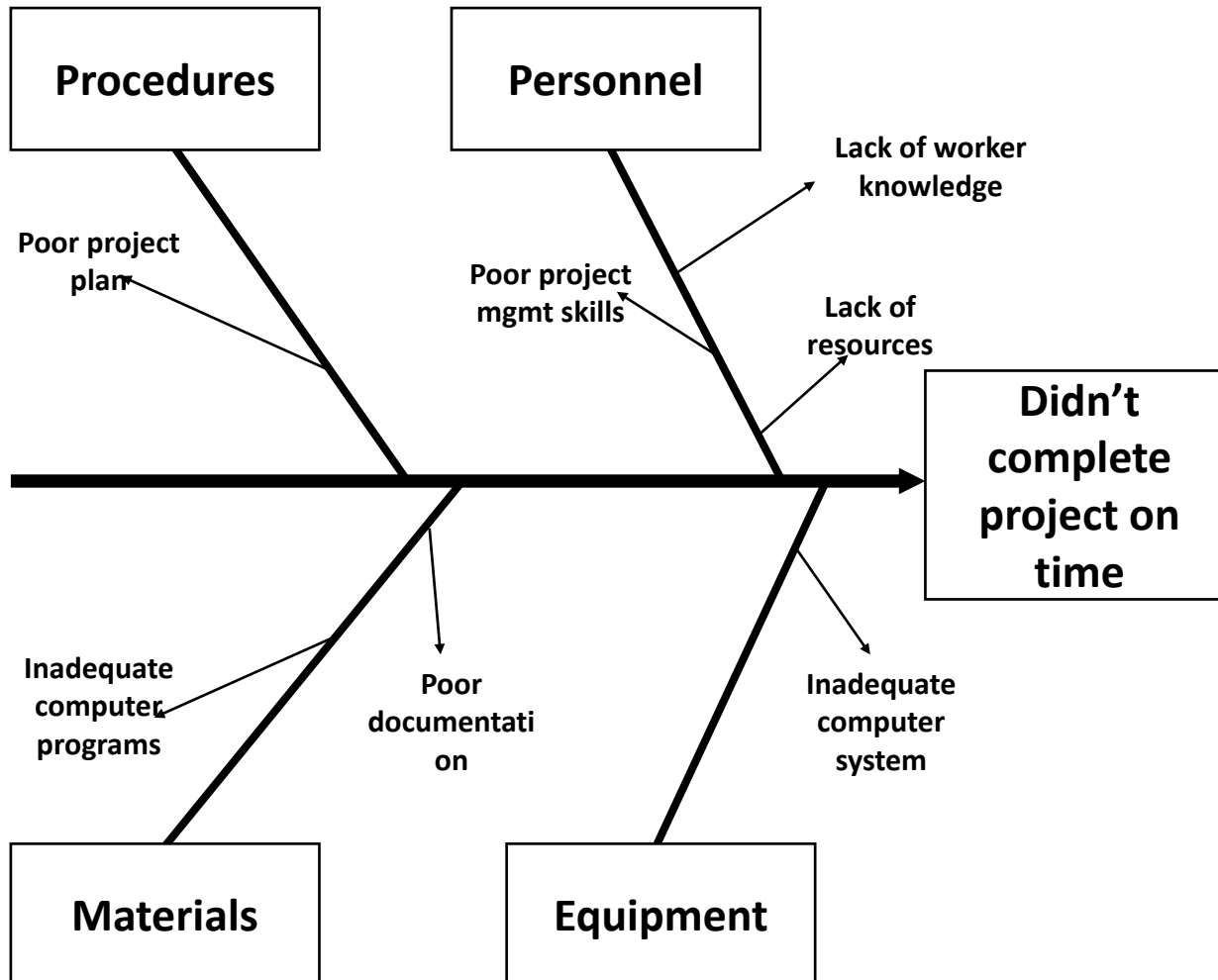
5 Why's

Didn't complete project on time

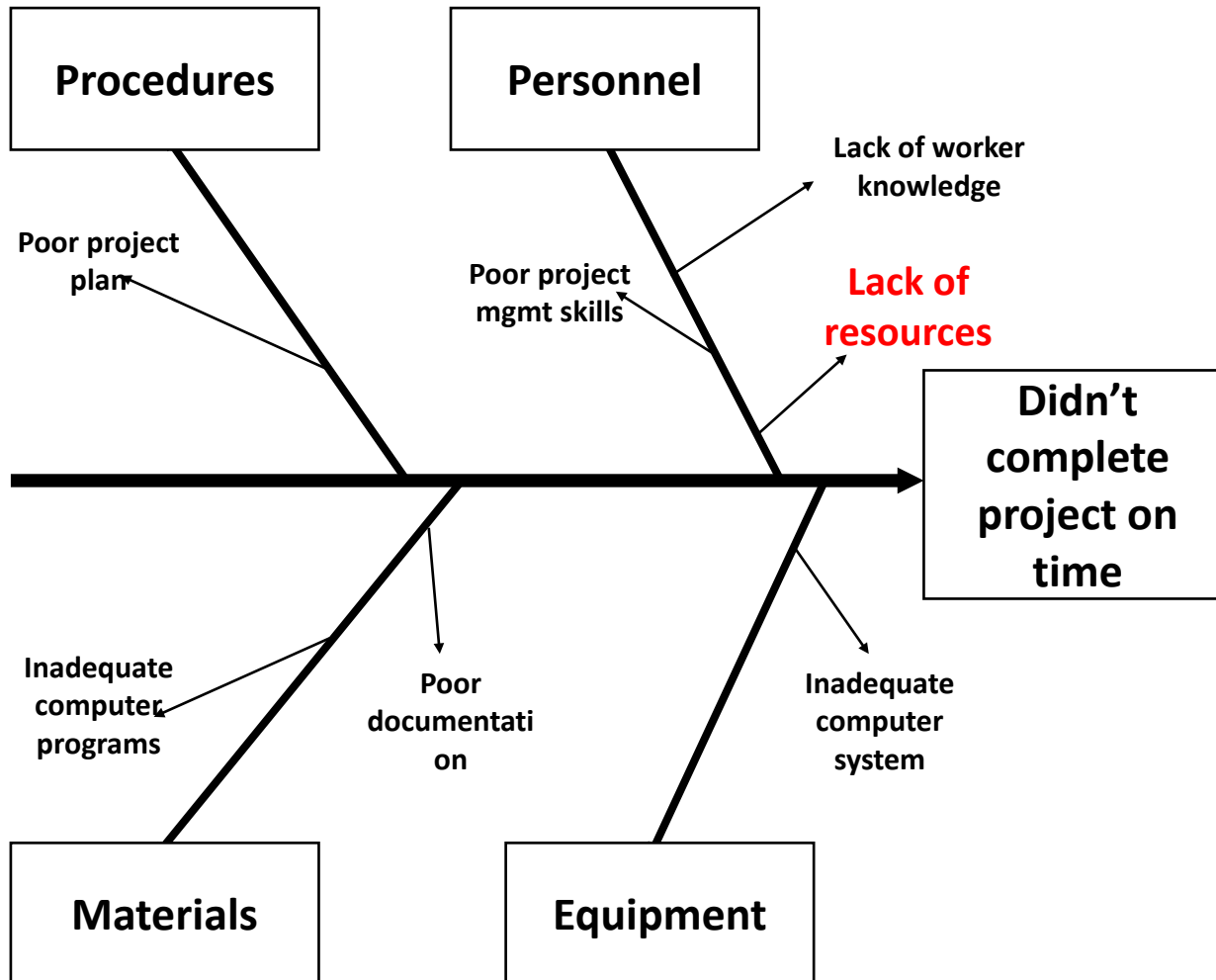
Why?



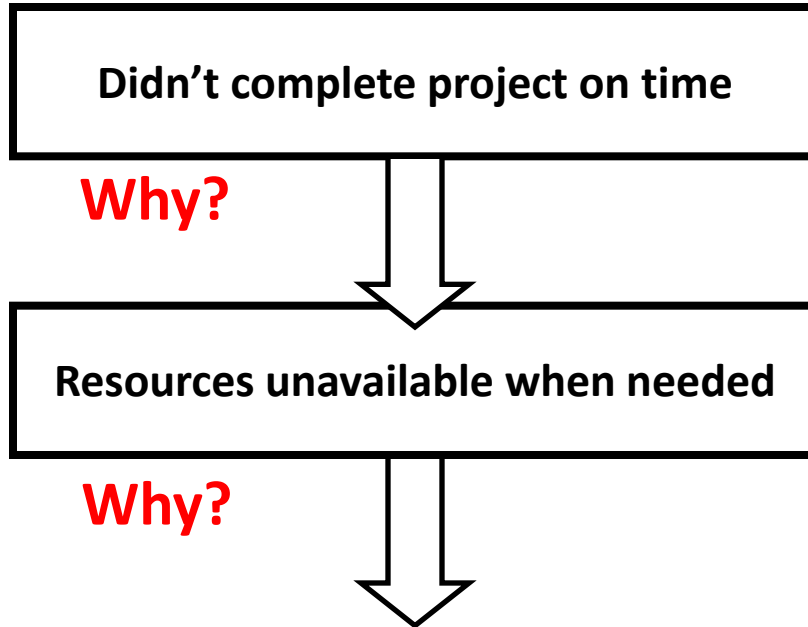
Cause and Effect



Cause and Effect, cont'd

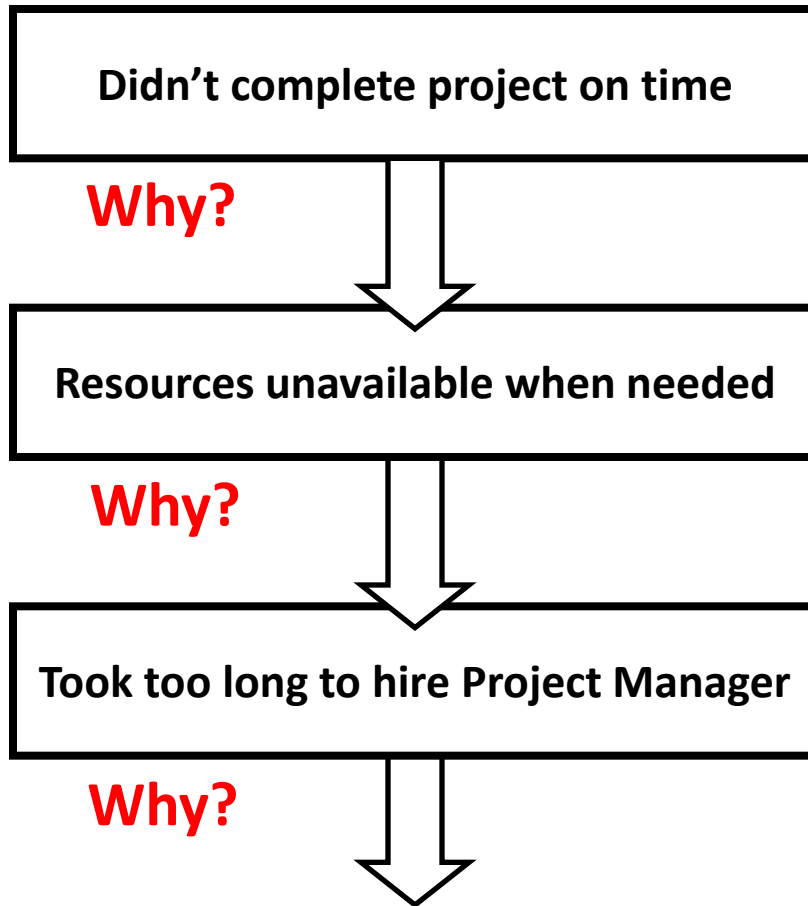


Root Cause

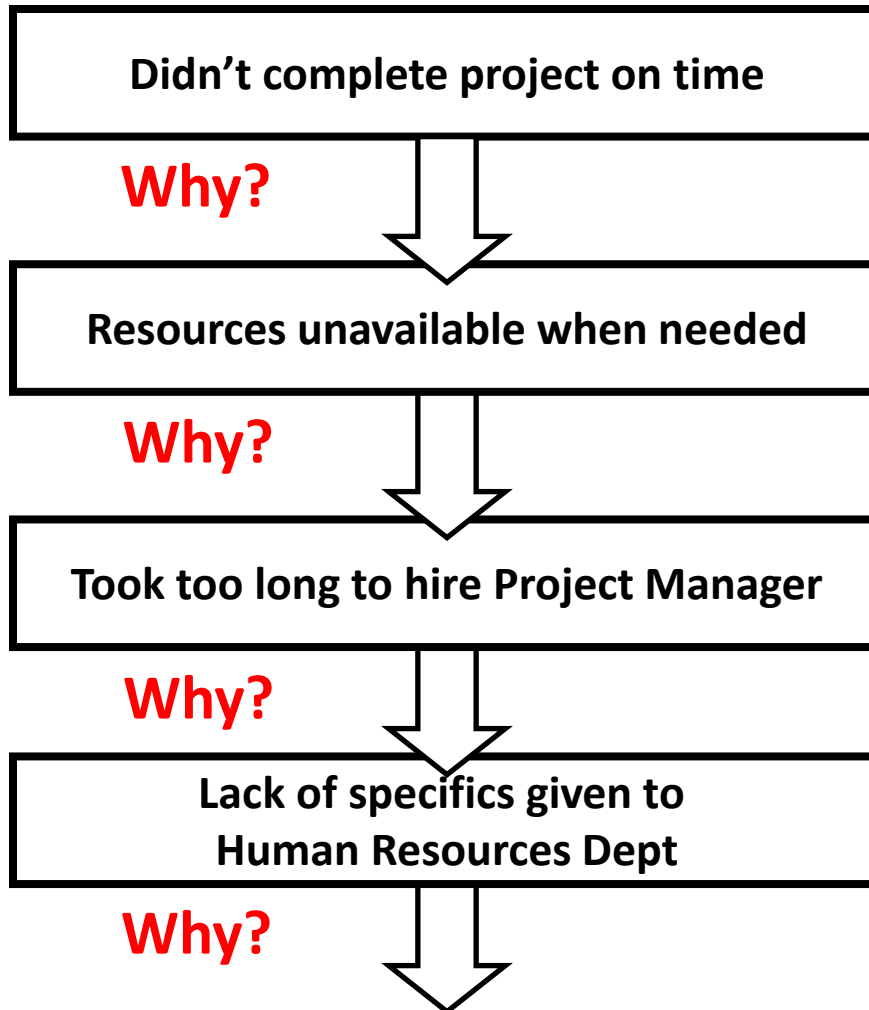




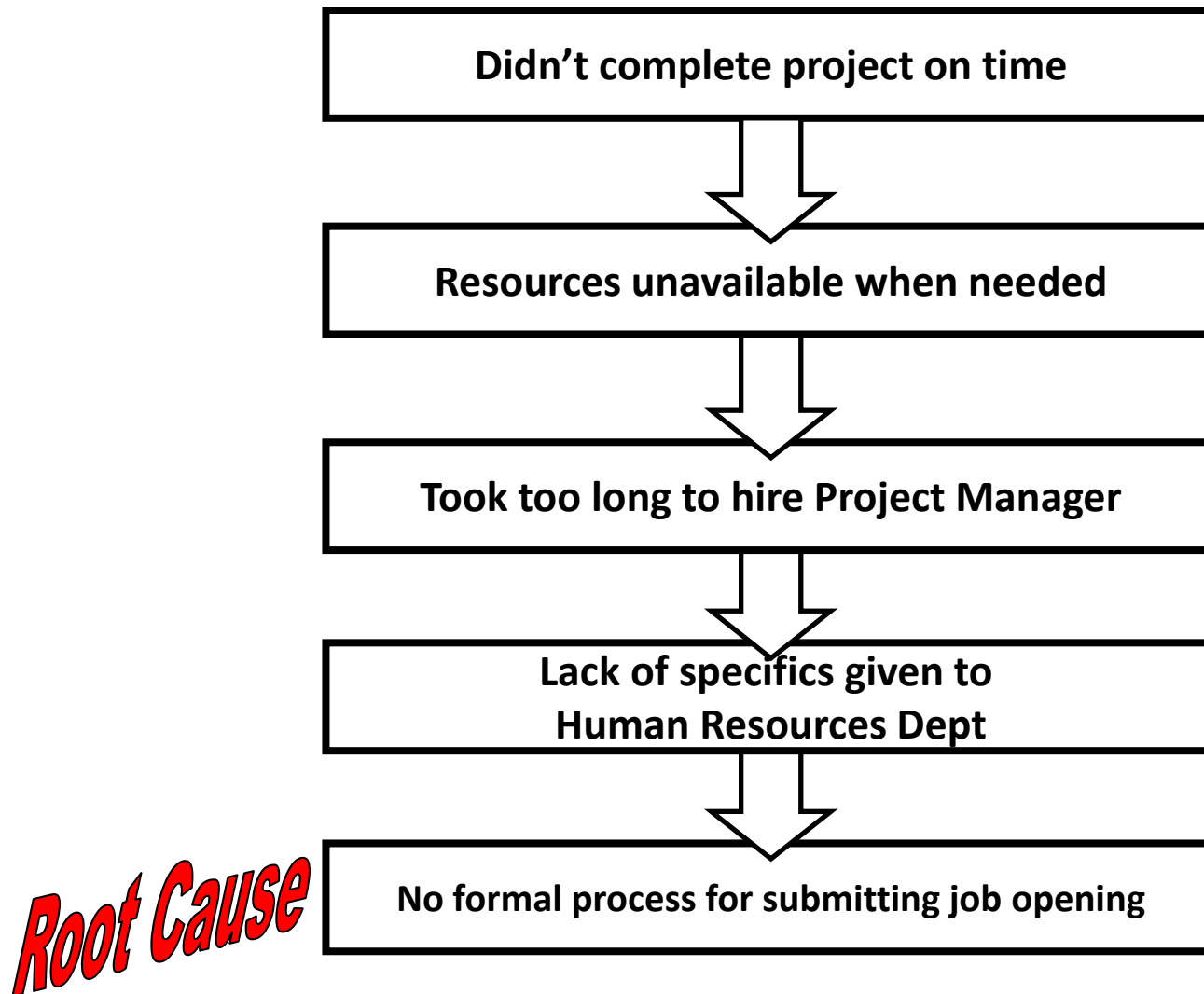
Root Cause, cont'd

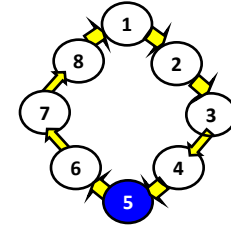


Root Cause, cont'd



Root Cause, cont'd





Corrective Action

- Permanent:
 - Hired another worker to meet needs of next project
- Preventive:
 - Developed checklist form with HR for submitting job openings in the future

Hints About Root Causes

- Just as one problem may have multiple root cause possibilities, one root cause may be causing multiple problems
- Look at all the “possible” ways in which it could go wrong, you will find multiple things that need to be improved
- When the root cause is not addressed, the process that creates it continues to send more problems and the problem will eventually return
 - Many times a short period of time without reoccurrence does not mean the root cause has gone away
- Prevention is the key!

Conclusion

- You learned:
 - How to identify the root cause
 - Why it is important
 - The process for proper root cause analysis
 - How basic quality tools can be applied to examples



Contact Information

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