



**INTERNATIONAL  
ACCREDITATION SERVICE**

Leading Accreditors Since 1975

# ROOT CAUSE ANALYSIS

BY Mohan Sabaratnam  
Director, Quality and Accreditation



- Root Cause can be described as that cause, which if it were controlled or eliminated would make the problem go away.

# What is Root Cause Analysis?

- A system of problem solving which aims to identify the root causes of problems or incidents.
- When a problem is identified, the tendency is to simply “fix the problem.” This is necessary, but not sufficient under ISO/IEC 17025.
- With “root cause analysis,” the reason(s) the problem occurred in the first place are identified, so that these may also be addressed.
- Goal of “root cause analysis” is to reduce the likelihood of recurrence of the problem.

*Reactive*



*Proactive Approach to Quality*

- **Consider Costs/Benefits vs. Risks:**

Level of effort expended on root-cause analysis should align with the significance or severity of the incident.

- Most incidents require only a scaled-down effort, while significant incidents should be investigated using one or more of the formal analytical models.
  - Usually not cost-effective to eliminate all risk. Focus on the one action that is most likely to correct the problem.
- **Root Cause Analysis identifies** the “**what,**” the “**how,**” and the “**why**” associated with incidents that are investigated.
  - **A successful Root Cause Analysis** will identify the controllable, causal factors that can be corrected to reduce the chance of recurrence of similar incidents in the future.

**Phase 1** - Collecting of relevant data and information about an incident (failure event)

**Phase 2** – Root-Cause Analysis

- What are the causes (conditions or actions) immediately preceding and surrounding the problem?
- Identify the reasons why the causes existed, working back to the root causes (the fundamental reason which, if corrected, will reduce the odds of recurrence).

**Phase 3** - Correcting: Implementing effective corrective actions for each root cause.

**Phase 4** – Informing: Management and personnel involved with the incident should be informed of the results of any investigation.

**Phase 5** – Verifying: Verifying if corrective action has been effective in resolving the problem.

*The laboratory shall establish a policy and procedure for implementing corrective action.*

*The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.*

APLAC TC 002 (9/10) – Internal Audits for Laboratories and Inspection Bodies:  
(Sec. 7.3): *The formal corrective action procedure may need to be followed to reveal the root causes of some problems and to implement effective corrective and preventive actions.*

- **ISO/IEC 17025 (Testing and Calibration Laboratories)**
  - ✓ Complaints and Appeals (Sec. 4.8)
  - ✓ Nonconforming Tests (Sec. 4.9)
  - ✓ Corrective Actions (Sec. 4.11 – *Mandatory Root Cause Analysis*)
  - ✓ Internal Audit Findings (Sec.4.14)
  - ✓ PT/ILC Outliers (Sec. 5.9)
  
- **ISO/IEC 17020 (Inspection Bodies)**
  - ✓ Complaints and Appeals (Sec. 7.5)
  - ✓ Internal Audit Findings (Sec. 8.6)
  - ✓ Corrective Actions (Sec. 8.7)
  - ✓ impartiality and operational integrity in work?

- **Must be performed systematically as an investigation**
  - ✓ Objective assessment – not assigning blame
  - ✓ Broader input is best (not just one person)
  - ✓ Not limited to fixing the identified problem
  - ✓ “Dig deeper” – What are the reasons that this problem occurred?
- **Look closely at:**
  - ✓ Standards and procedures - personnel and equipment
    - ✓ Are these incomplete or ambiguous?
    - ✓ Can a written checklist be helpful?
    - ✓ Is there a machine/automated solution for checking this?
  - ✓ Training and qualifications of personnel
- **Document the process and findings!**



## **Invite anyone affected by the issue**

- Identify the problem or situation I
- Invite anyone affected or noticed the issue to a 5 whys meeting

## **Select a 5 Whys master for the meeting**

- 5 Whys master will lead the discussion
- assign responsibility for the solutions
- Record the notes of the meeting

Note: No special qualifications to be a 5 Whys master

## **Ask “why” 5 times**

- Dig at least 5 levels deep into the issue with 5 levels of “whys.”
- Discuss all potential paths
- Picking one path to perform just the amount of corrective actions needed to solve a problem.
- If the same problem seems to occur again, then choose another route.
- Identify actionable steps that have been or will be taken.

## **Assign responsibility for solutions**

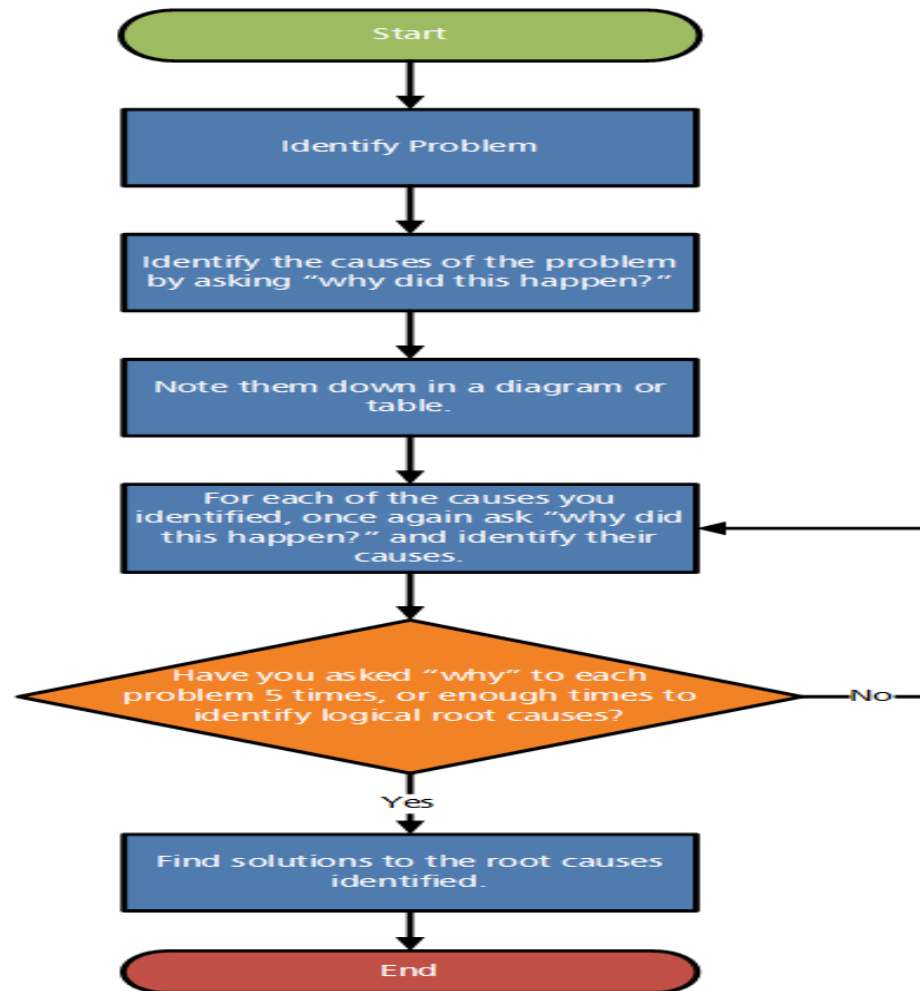
- At the end of the exercise come up with 5 related “corrective actions” that all agree on.
- Master assigns responsibility for the solutions to various participants in the discussion.

## **Email the whole team the results**

- Notes are emailed to the whole team with the results.
- This makes the team stay in the loop and understand any steps taken as a result of 5 Whys.
- Sharing this information widely gives everyone insight into the kinds of problems and solutions the team is facing

# 5 Whys Process Flowchart

## 5-why Process Flowchart

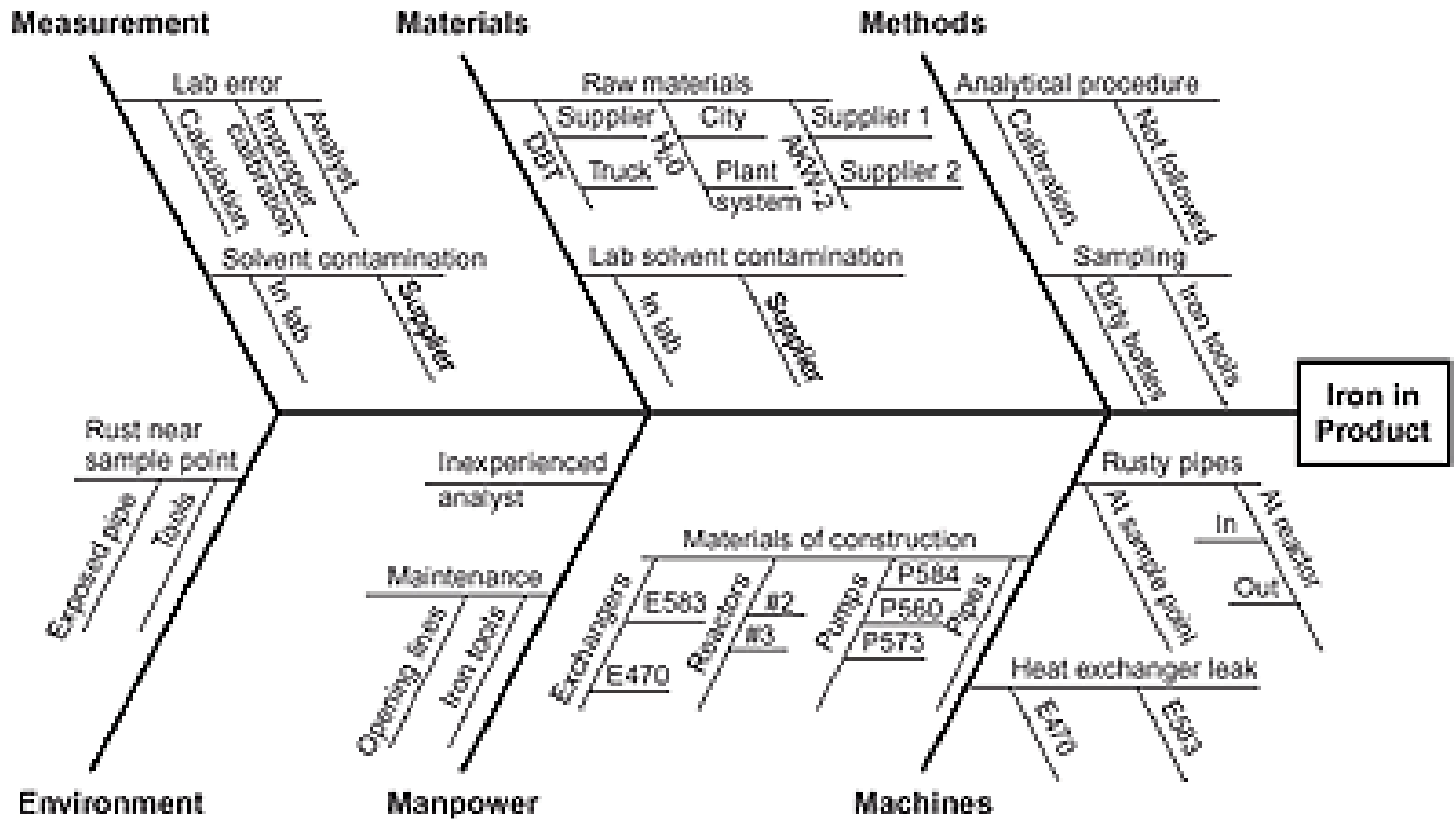


- Class Exercise

- **Fishbone (Ishikawa) diagram:** identifies many possible causes for an effect or problem and sorts ideas into useful categories. (Brainstorm)
- **Pareto chart:** shows on a bar graph which factors are more significant. (Cause and Effect)
- **Scatter diagram:** graphs pairs of numerical data, with one variable on each axis, to help you look for a relationship. (Trend Analysis)

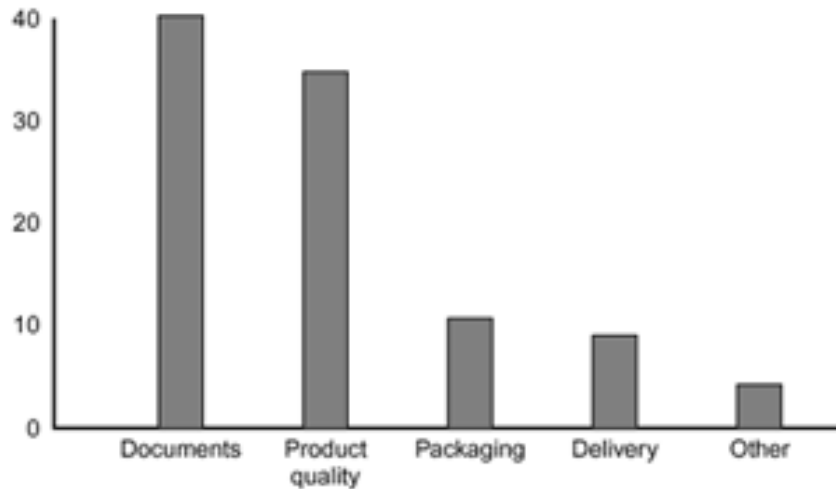
Source: <http://asq.org/learn-about-quality/cause-analysis-tools/overview/overview.html>

# Fishbone Diagram Example

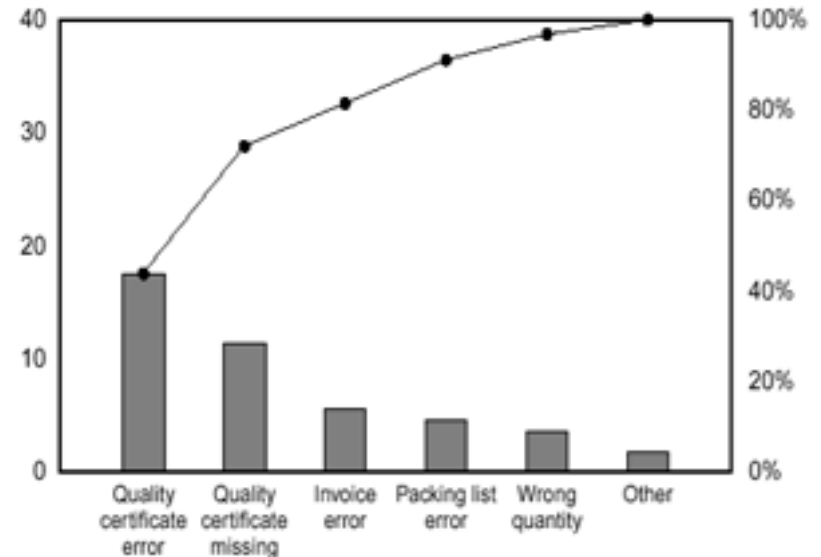


# Pareto Chart Examples (Cause and Effect)

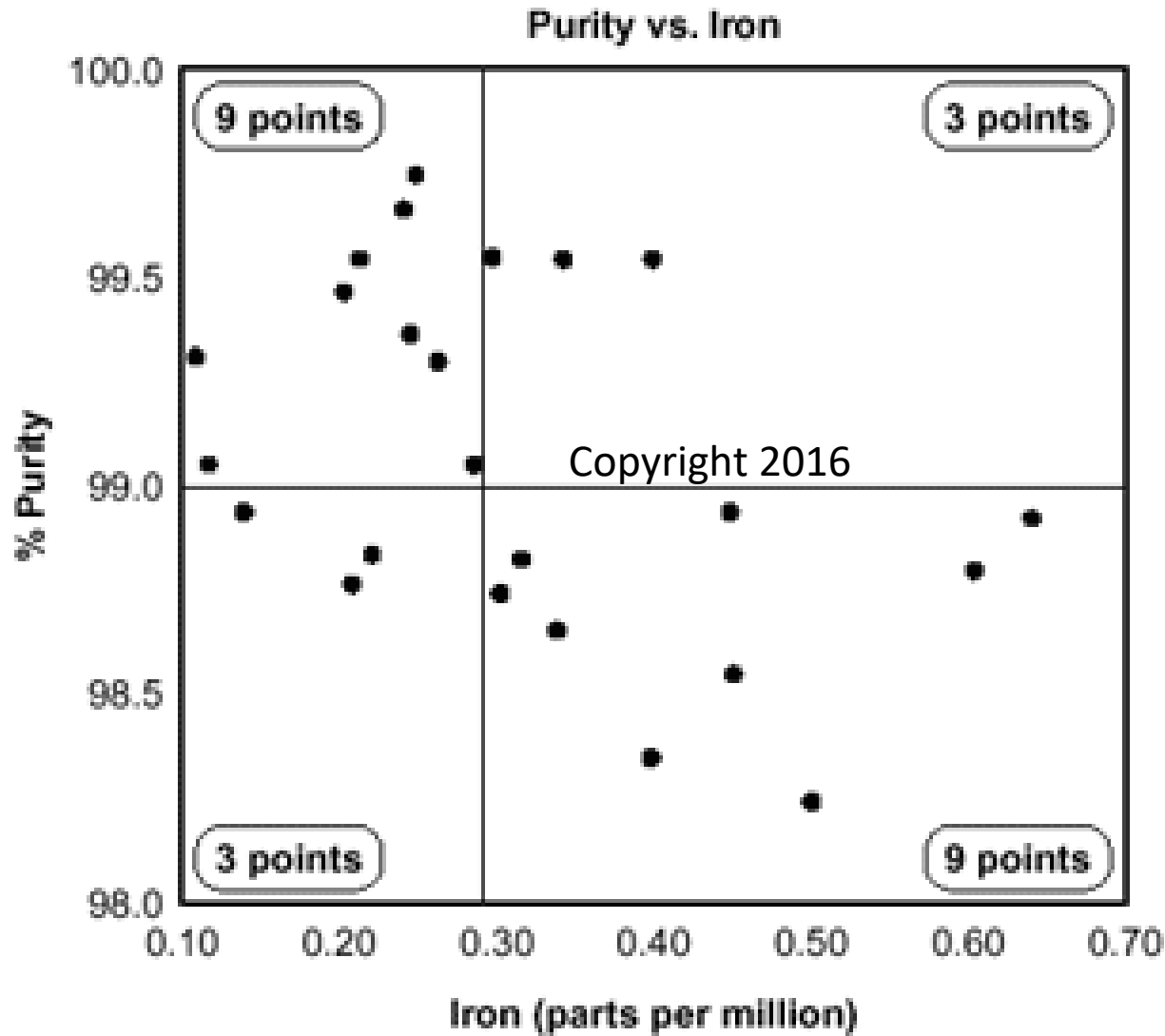
**Types of Customer Complaints**  
Second Quarter 2005



**Types of Document Complaints**  
Second Quarter 2005



# Scatter Chart Example (Trends)



## **Root Cause Analysis helps to solve difficult problems in our environment:**

- ... investigate an accident or safety incident;
  - ... eliminate waste and maximizes value;
  - ... figure out why equipment keeps failing;
  - ... prevent simple mistakes from becoming huge problems;
  - ... increase the reliability and availability of your systems;
  - ... understand how a problem occurred so you can make sure it never happens again;
  - ... etc.
- 
- **Root cause analysis is the answer for long term solutions.**
  - **Treats underlying factors that creates the problem in the first place.**



- Class Exercise