TÜV SÜD America

Choose certainty. Add value.

CAPA Essentials –

Root Cause Analysis Tools and Techniques

Presented by Edna R. Falkenberg

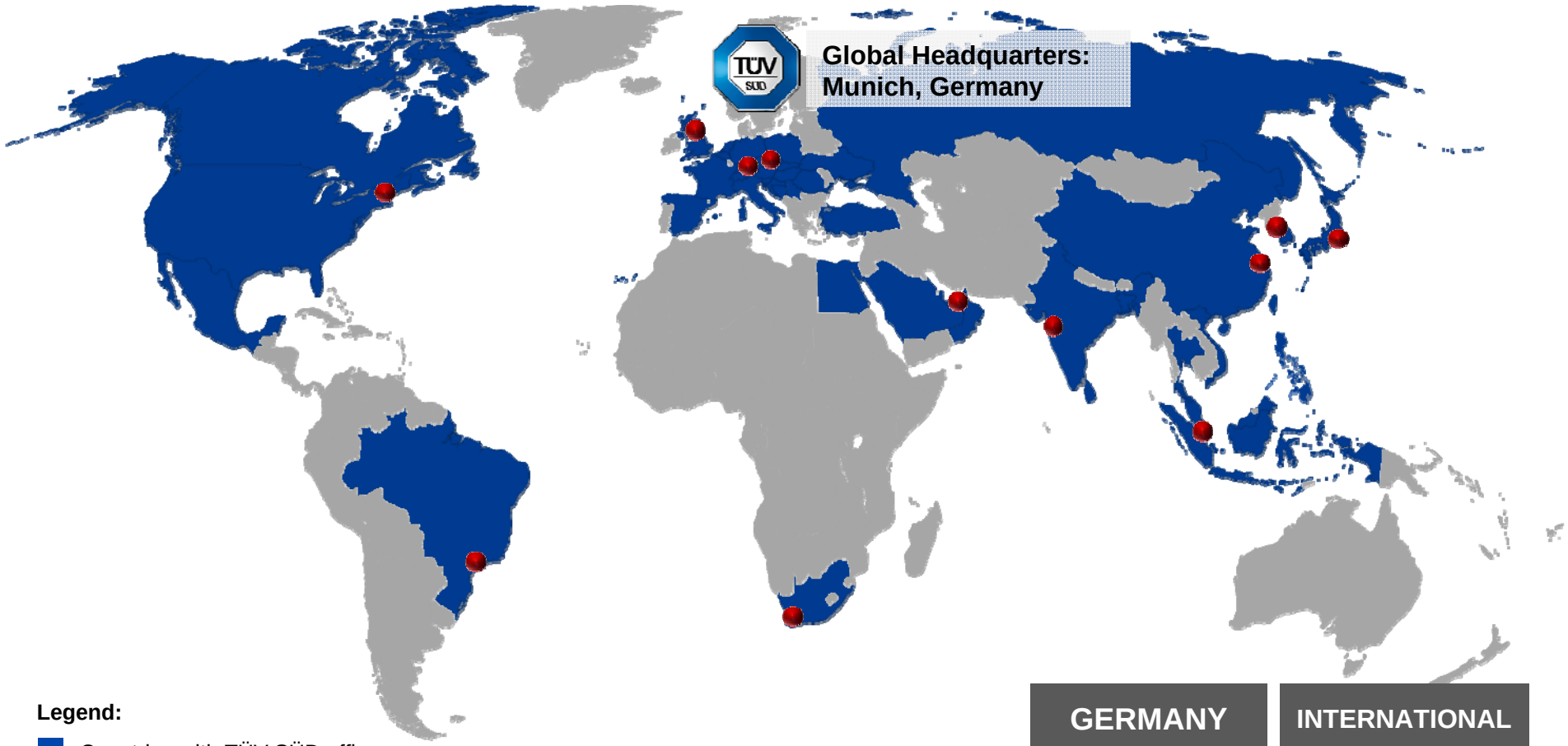
TÜV SÜD in numbers: Growing from strength to strength

America

1	One-stop technical solution provider
150	years of experience
800	locations worldwide
1,900	million Euro in sales revenue 2013
20,200	employees worldwide

Global expertise. Local experience.

America



Legend:

- Countries with TÜV SÜD offices
- Regional headquarters

Note: Figures have been rounded off.

GERMANY	INTERNATIONAL
Euro 1,190 mio 10,400 staff	Euro 750 mio 9,800 staff

TÜV SÜD America Inc.

- TÜV SÜD America Inc., founded in 1987, is the North American subsidiary of TÜV SÜD AG.

- TÜV SÜD America Inc. provides complete services through its divisions:
  - Product Service
  - Management Service
  - Industry Service
  - Chemical, Oil and Gas
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Root Cause Analysis

Defining the root cause is at the heart of problem solving.

- This is often the most difficult and challenging phase.

- If the root cause were apparent then the problem would have been addressed earlier!

Root Cause Analysis

- There are usually three causes to be considered during a problem solving effort: Occurrence, Escape and Systemic.
- The “occurrence” root cause – the specific local cause that resulted in the problem. This is typically the factor that “changed” in the process.
- The “escape” root cause – the cause that resulted in the problem not being “caught” or detected.
- The “systemic” root cause – the broader cause responsible for the local cause to be present in the first place.
- This cause is often procedural in nature. Long term corrective action.

To start:

- Review the problem definition (5W2H) and Is/Is-Not looking for potential occurrence causes.
- Ask “What Changed”?
- Review the process flow for clues to potential root causes.

Tool: Problem Description

Purpose

- Answer the question: “What’s wrong with what?”
- Define a problem statement that includes both an object and a defect.
- Development of a dynamic problem statement that will be the foundation for the investigation.

Tool: Problem Description

Purpose

- “A problem well defined is a problem half solved.”
- A complex problem can not be solved or addressed until it is completely understood and documented.

Goal

- Develop a well-thought out problem description and the resultant problem or deviation statement.
- Describe the problem in terms of its effects on the downstream customer (internal or external).

Tool: Problem Description

The problem description covers a broad range of criteria:

- Who is experiencing the problem?
- What is the problem?
- Where and when did it occur?
- When?
- Why is this a problem? What is the downstream effect?
- How big is the problem? (How much? How many?)

These components are consolidated into the abbreviation: **5W's and 2H's.**

Tool: 5 W's and 2 H's

Who?

- Identify the customers (internal or external) that are experiencing the problem or registering the complaint.
- Which groups are impacted by the effect of the problem?

What?

- Classify the problem in terms of an object and the defect.
- Determine the part or object in question.

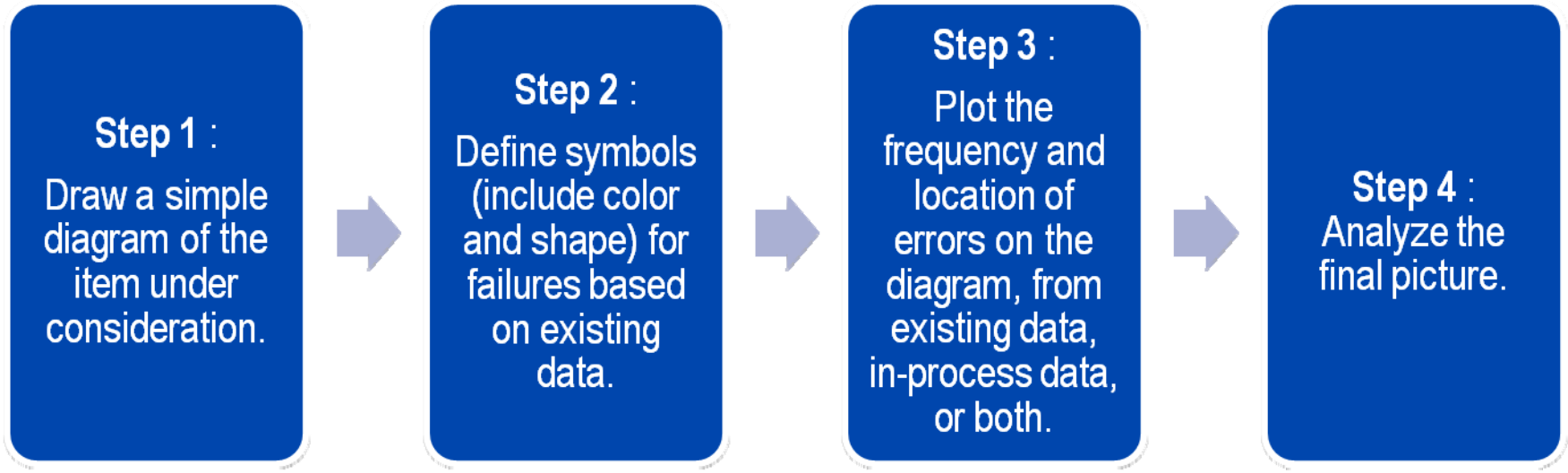
Where?

- Where (geographically) was the defect found? Which plant? Which state/region/country? Which customer location?
- If there is a defective part: Where is the defect located? On the part? In the assembly?
  - Technique: A concentration ("measles") chart may be very helpful.

Technique: “Measles Chart”

Definition: A “measles chart” is a simple map that

- Provides a visual representation of failure data.
- Shows frequency and location of errors.
- Uses a schematic drawing of the product/process.



Technique: “Measles Chart”

- The problems or errors may be of diverse types.
- Unique shapes and color codes can represent different failure modes.
- Different markings also represent degree of severity.
- The chart does not need to be very detailed.
- **Keep it simple** so that there are no problems with visibility.

When?

- Analyze control charts, run charts and/or shipment records to determine exactly when the problem began.
- Ask whether the problem occurs on all shipments or only specific shifts or days of production? Is the issue seasonal? Has this problem previously occurred during the same time of year?
- Or has the problem been present since the start of production?
- An examination of the qualification documentation may reveal some clues.

Tool: 5 W's and 2 H's

Why?

- Identify the effect of the failure. There may be more than one!

- Will help focus containment and identify risk.

How much? How many?

- Determine the magnitude of the problem.
- How much nonconforming material was sent to the customer? How many parts were defective?
- What was the defect count?
- What is the percent defective?
- Compare the magnitude of the problem to prior baseline defect rates.
- Did something change in our process or has the problem been present from the start of production?

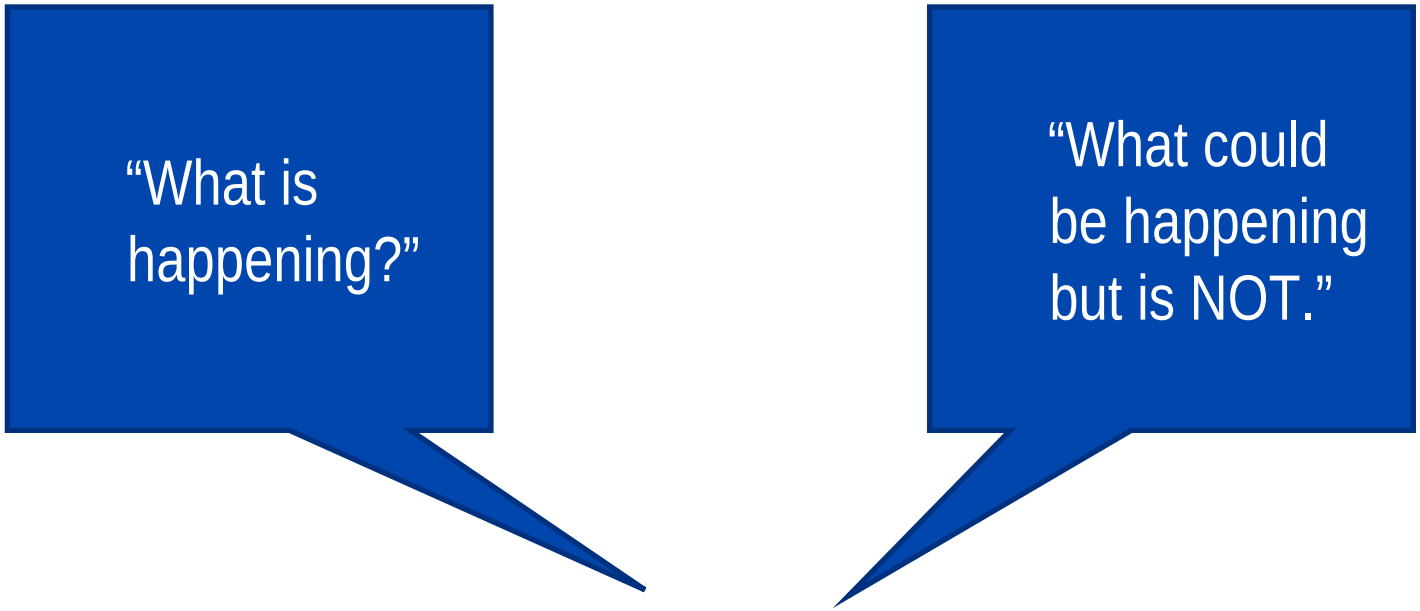
Tool: “Is/Is Not”

A powerful companion tool involves the usage of techniques developed by the consulting firm of Kepner and Tregoe (formerly of the RAND corporation).

- These comparative techniques help “cut the phonebook in half”.
- **For example:** If someone selected a random name in the phone book and asked you to figure out the name through a series of questions -- what question might you ask first? You may want to ask whether the first letter begins with the letters A through K. This cuts the number of potential names roughly in half!

Tool: “Is/Is Not”

- The “Is/Is Not” is the most common tool in comparative analysis.
- “Is/Is Not” is based on examination of the 5W’s and 2H’s and asking paired questions:



Tool: “Is/Is Not”

Example:

- (Q1) “Who is experiencing the problem?”
  - (A1) “The customers in Europe.”

- (Q2) “Who could be experiencing the problem – but is not?”
  - (A2) “The customers in Asia”

- Get Information and clear-up any missing facts.

Tools: 5W2H + Is/Is Not

Problem Statement Worksheet : What is wrong with What?				America
Description of the Problem	**IS**	**IS NOT**	**Get Information On**	**Comments**
Who (What Customer)				
What (Object) - name the object that is having trouble				
(Defect) - name the trouble or problem that the object is having				
Where (Seen on the object) Where on the object is the problem occurring (inside, outside, top, bottom etc)? Where in the process flow did the problem first develop? Describe all other places with regards to where the object and the trouble can be found				
(Seen Geographically) Name the place where the object with the trouble can be found. Name the place where it first showed up. Name all placed where the problem has occurred.				
When (First Seen) - When, with respect to the time, did the trouble/problem first occur? - day, month, year, time of day, etc. Describe any patterns in time. Describe when in the process the trouble first occurred. When in the life cycle did the trouble first occur?				
(When else seen) - Describe other places in process and life cycle when the trouble or problem was observed. Consider all units of time such as hours, days, minutes, shift, quarter, year.				
Why (impact) - Describe the impact of the trouble or problem on the downstream process or customer				
How Much/How Many (How many objects aft the defect) - Describe the size of the problem/effect. Describe the number of objects that have or have had the trouble. How many defects per object? Describe the magnitude of the trouble in terms of percentage, rates, yield, etc. Describe the physical dimensions of the defect or problem. What is the trend or pattern?				

Root Cause Analysis

Continuously ask “What Changed”?

- Unless the problem has existed all along (common cause) – something must have changed.

For example:

For purchased parts, the automotive industry reinforces this hypothesis via the production part approval process (PPAP).

This package demonstrates to the supplier and to the customer that the process can produce an acceptable part.

If a defective product is sent to the customer after the PPAP submittal – the assumption is that something changed!

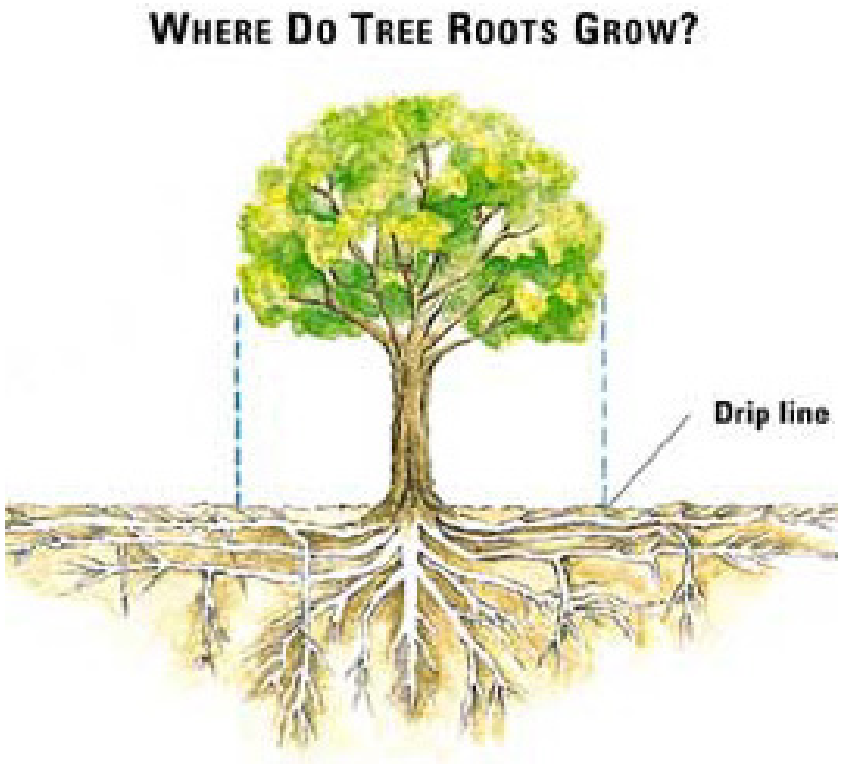
Root Cause Analysis

Continuously ask “What Changed”?

- in the process flow?
- in the equipment?
- in the supply base?
- in the mode of transportation?
- in personnel?
- in calibration?
- in terms of process capability?
- in the weather? Was it unusual?

Focus on the distinctions in the Is/Is-Not analysis!

The 5 Whys Method to Confirm the Path



In order to drive root causes of a failure, whether chronic or sporadic, you can use the WHY TREE

It‘s called a „WHY“ tree because you keep asking „WHY?“ to get to the WHERE DO TREE ROOTS GROW?

The 5 Whys

- Employ the 5 Whys
  - The 5 Whys is a tool that assists in moving from the problem statement and effects of the problem to the true root cause.
  - It can be used on its own or in conjunction with the fishbone diagram analysis in moving from the chosen root cause to the true root cause.
- Simply ask Why 5 times starting with the effect of the problem.
- 5 Whys focuses the investigation toward true root cause and away from mere effects of the problem.

Tool: “5 Whys”

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Example:	Why?	Corrective Action:
A functional tester lost power.	The power cord got pulled out.	Re-insert cord and retrain all operators.

1. **Would this be a robust and permanent corrective action?** No. Simply replacing the cord is attacking a symptom.
2. **Why did the cord come loose?** It was kicked loose.
3. **Why?** The cord is long and runs on the floor
4. **Why?** The nearest available power supply is across the aisle.

Corrective Action: Install a power source under the tester to eliminate contact.

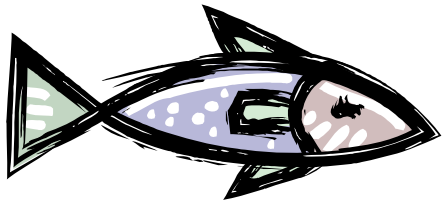
Is this a more robust answer? 5 Whys drives us to a permanent corrective action. At the center is the most robust solution.

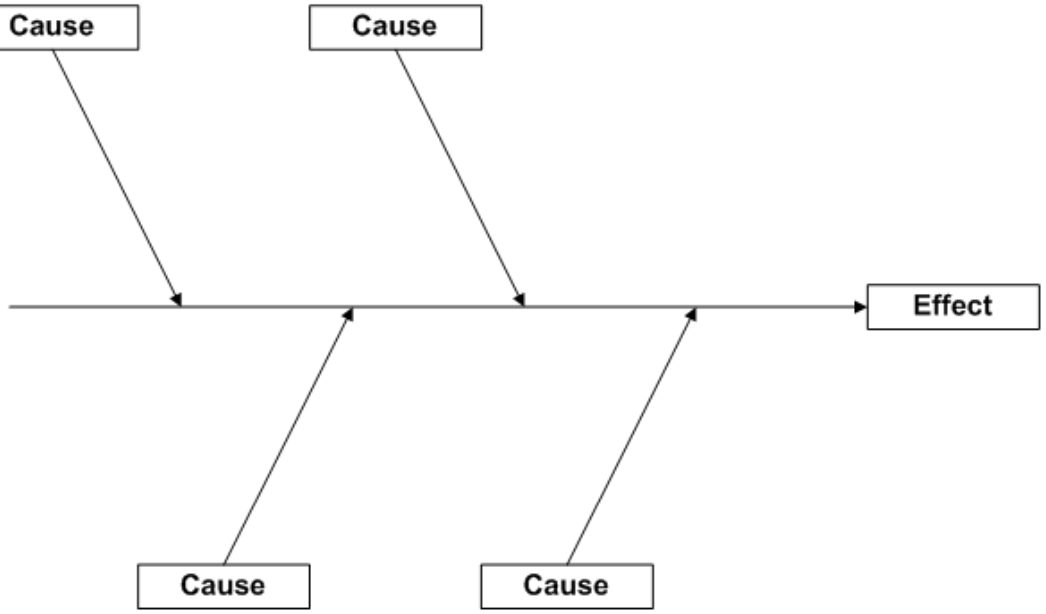
Tool: “5 Whys”

- 5 Why’s is often the only tool you need!
- Simple, anyone can do it!
  - Single failure mode
  - Drives to root cause
  - No special training required
  - Sometimes things get more complicated.
  - Multiple or
  - compounded root causes

Tool: Fishbone / Cause and Effect Diagram

- Develop potential causes using a “fishbone” diagram.
- The head of the fish is labeled with the problem or the effect.
- The major bones of the fish are categories of potential causes.





Tool: Fishbone / Cause and Effect Diagram

There are two primary labeling practices:

1.Mark the major bones with each of the process steps within the process flow.
2.List the potential causes that could occur at each step to produce the effect.
3.Label these on the small bones

- Mark the major bones with broad categories such as the classic 5M's – methods, machines, materials, manpower, and mother-nature.
- Then establish potential causes in each category and mark them on the small bones.

Tool: Fishbone / Cause and Effect Diagram

Example:

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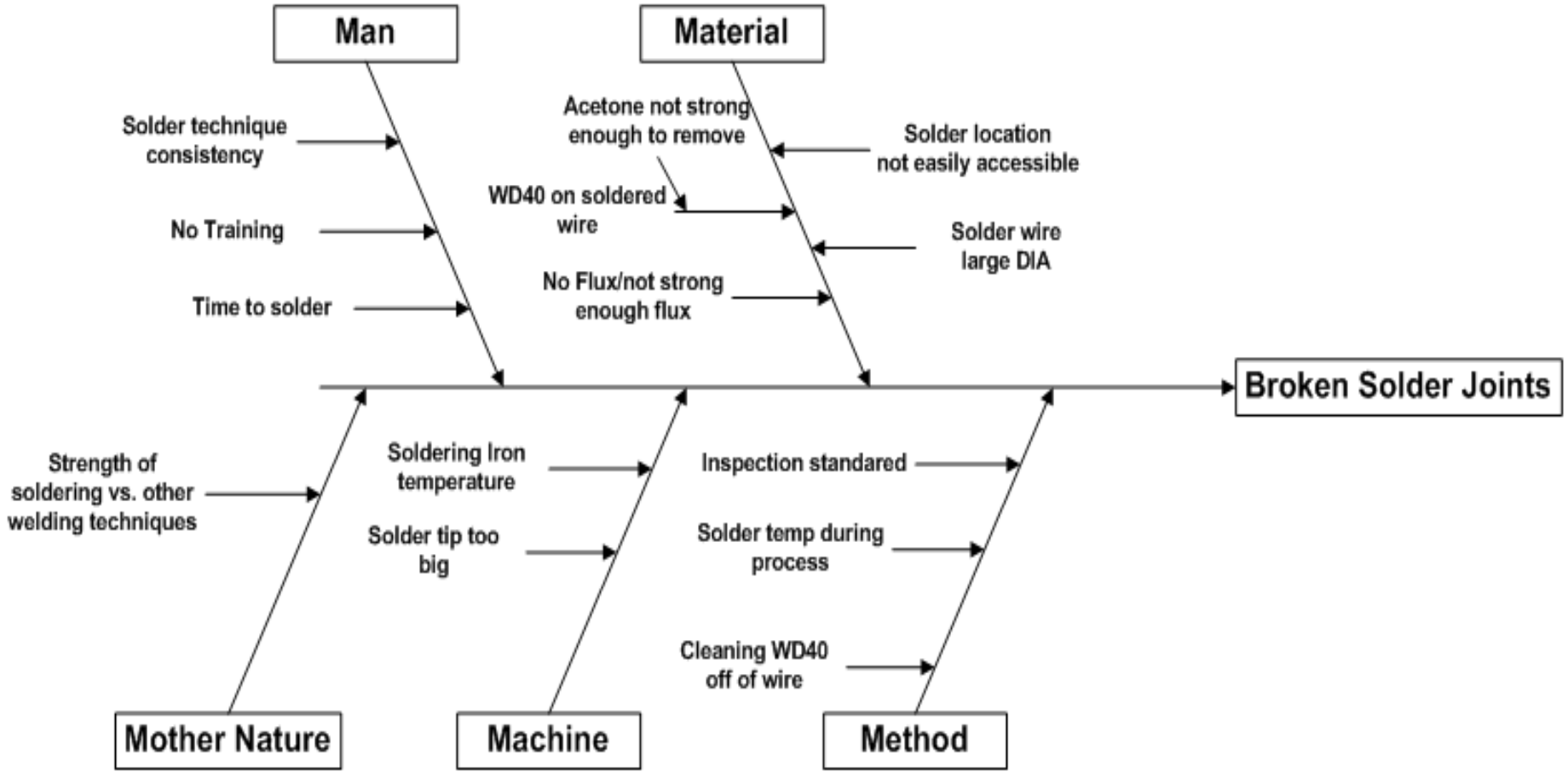

Tool: Fishbone / Cause and Effect Diagram

Where there are multiple potential causes:

- Test the prioritized list of causes. Consider conducting investigations in parallel to reduce time.
- The key part of the investigation is to match-up the true root cause with the problem in a manner that fully explains the 5W2H problem description and the Is/Is Not data.

Root Cause Analysis – Escape Points

Remember to also look for the escape point and determination of what allowed the problem to go undetected.

Escape points are of two types:

1. Controls currently in place in the process flow to detect the problem that failed and allowed the problem to escape

    Examples: Audits, tests, sign-offs, etc.

2. Points in the process flow where the problem could have been detected but no controls were in place.

    These are often referred to as “blind spots.”

Tool: Brainstorming

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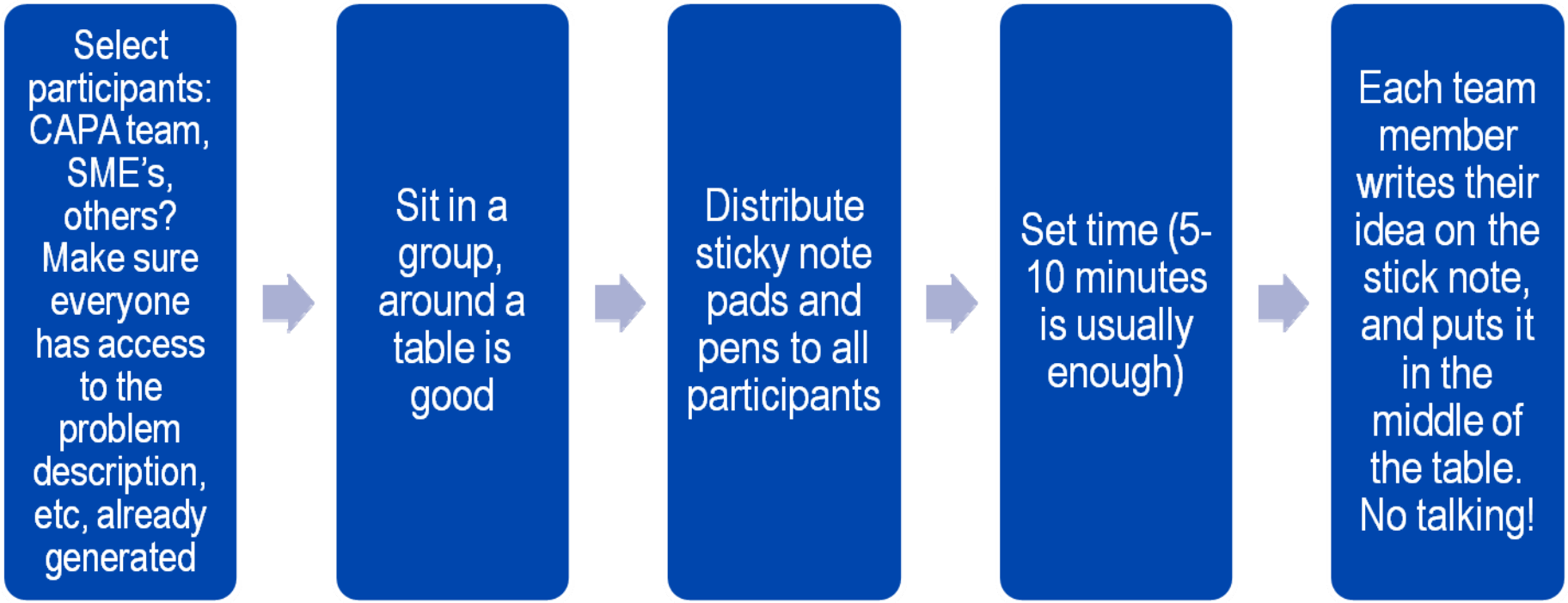
There are four basic rules in brainstorming.

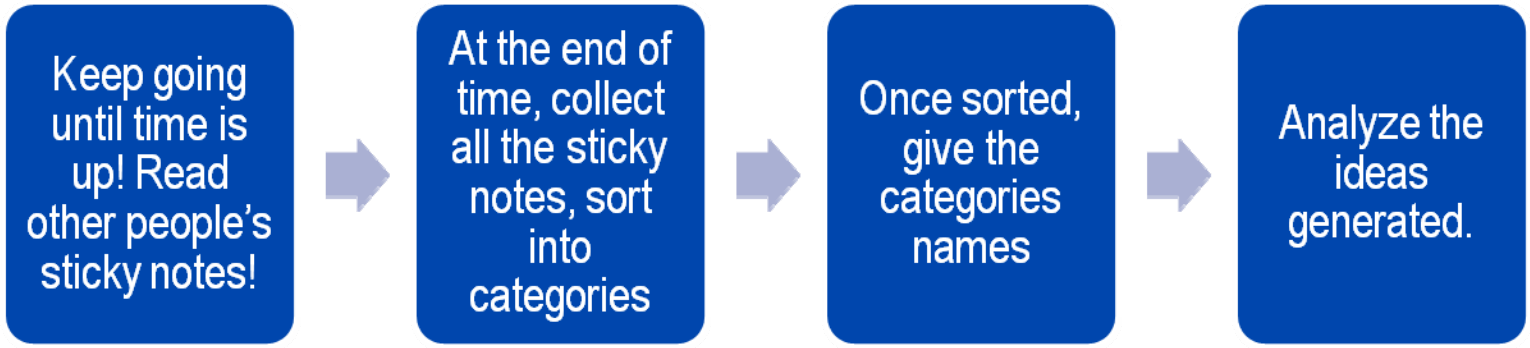
1. **Focus on quantity:** The theory is that the greater the number of ideas generated, the greater the chance of producing a radical and effective solution.
2. **Withhold criticism:** By suspending judgment, participants will feel free to generate unusual ideas.
3. **Welcome unusual ideas:** Unusual ideas can be generated by looking from new perspectives and suspending assumptions. These new ways of thinking may provide better solutions.
4. **Build on what has already been "stormed":** Good ideas may be combined to form a single better good idea. Stimulate the develop ideas by the process of association.

Tool: Brainstorming

Technique



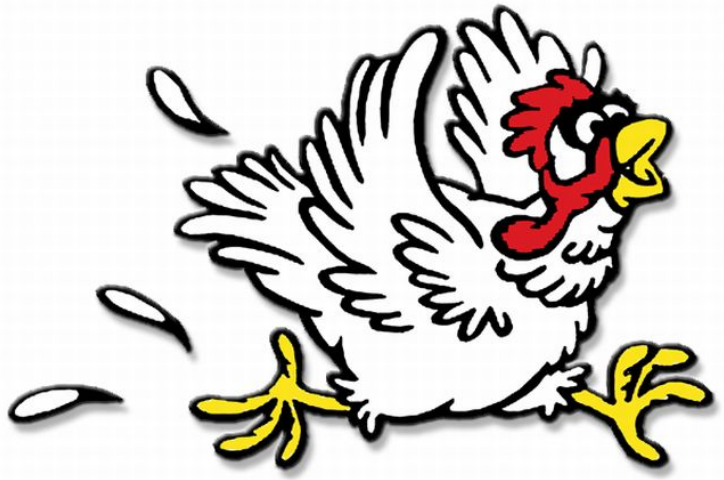
Technique (cont'd)



Tool: Brainstorming

You can easily practice! How many reasons can a team brainstorm for the following question:

Why did the chicken cross the road?



Other Tools for Root Cause Analysis

There are many other tools for root cause identification besides those presented during this short exercise (e.g. Pareto, Fault Tree, Process Analysis.)

Each company has to find the appropriate tool for itself, but to start with the 5 Why Method is the most recommended tool.

Common Pitfalls of Root Cause Analysis

- Not considering all possible (failure) causes
- Not understanding the problem and therefore not defining it correctly
- Not identifying all root causes and therefore just „bandaiding“ the problem
- Not involving the reponsible and involved parties
- Failing to follow through
- Jumping to conclusions
- Building a system apart without a plan

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Thank you for attending!

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