

Investigating Root Causes

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Identifying root causes = Understanding sources of waste

What is Waste?

- An act or instance of using or expending something carelessly...
- Output that is not wanted; the unusable remains or byproducts of something.

What is WASTE in Quality and Continuous Improvement (a.k.a. OpEx / LEAN) for R&D and Manufacturing?

- Waste is any activity that the customer would not be happy to pay for. The opposite of waste is value, which is what the customer requests or requires
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- **WASTE = No Value from Customer point of view**

Root cause analysis (RCA) tools

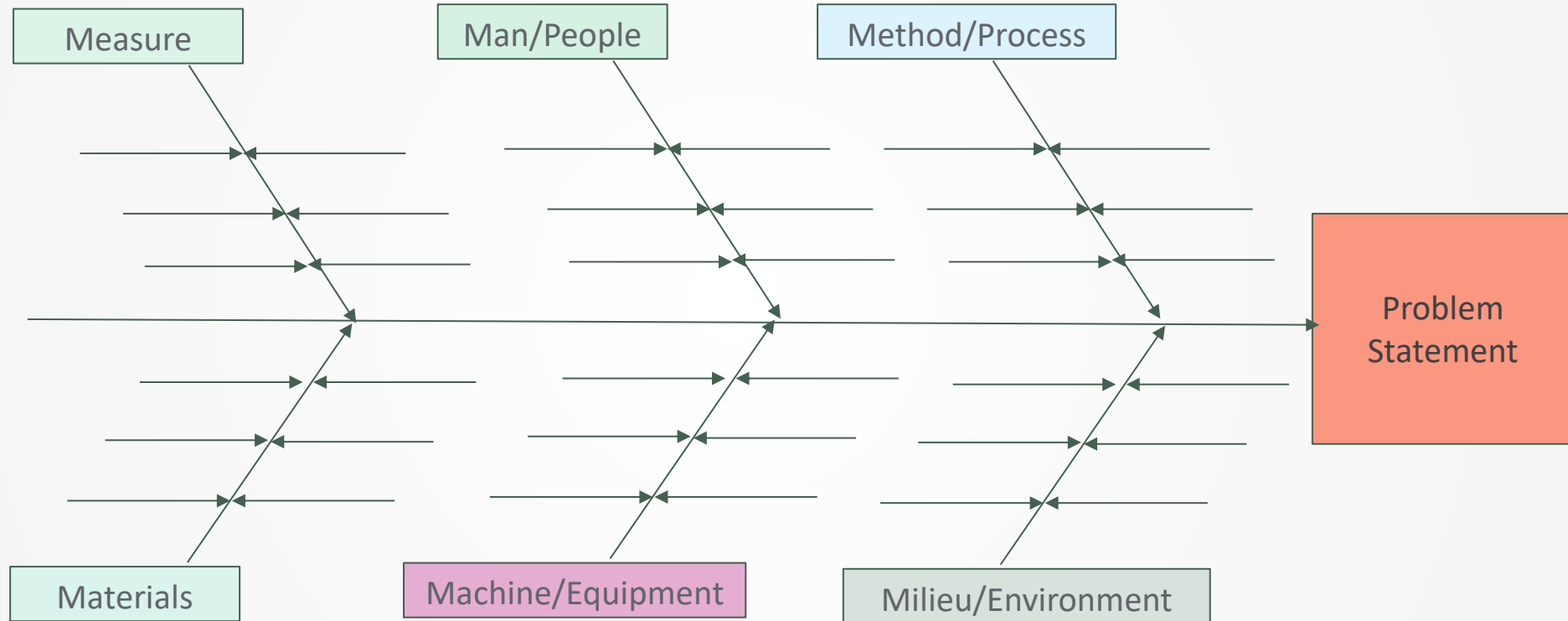
Commonly used for simple or multiple causes

Problem Solving	Quality and/or Process Improvement
<ul style="list-style-type: none">• Fishbone (Ishikawa) Diagram – usually for more complex or/and unclear problems	<ul style="list-style-type: none">• Failure Mode and Effect Analysis (EMEA) – <u>proactive</u> approach of failures and their effects analysis
<ul style="list-style-type: none">• 5 whys – simple analysis	<ul style="list-style-type: none">• Scatter Diagram – relationship between two variables
<ul style="list-style-type: none">• Fault Tree Analysis (FTA) – for more complex systems using top-down deductive approach	
<ul style="list-style-type: none">• Pareto Chart – Identify 20% of causes for 80% results, prioritization, focus effort, etc.	

Comparison of RCA tools

Tool	Pro	Con
1 Fishbone Diagram	Visualizes complex relationships	Static, hard to share
2 5 Whys	Simple, fast analysis	Easy to oversimplify
3 Fault Tree Analysis (FTA)	Maps cascading failures	Hard to update & link actions
4 Pareto Chart	Prioritizes key drivers	Manual setup, no context
5 FMEA	Proactively prevents failure	Time-consuming, error-prone
6 Scatter Diagram	Visualize correlations of variables, Easy to identify outliers	Correlation does not show definitive causation
7 Affinity Diagram	Organizes large data sets	Data gets lost over time

Fishbone Diagram – Technique Example



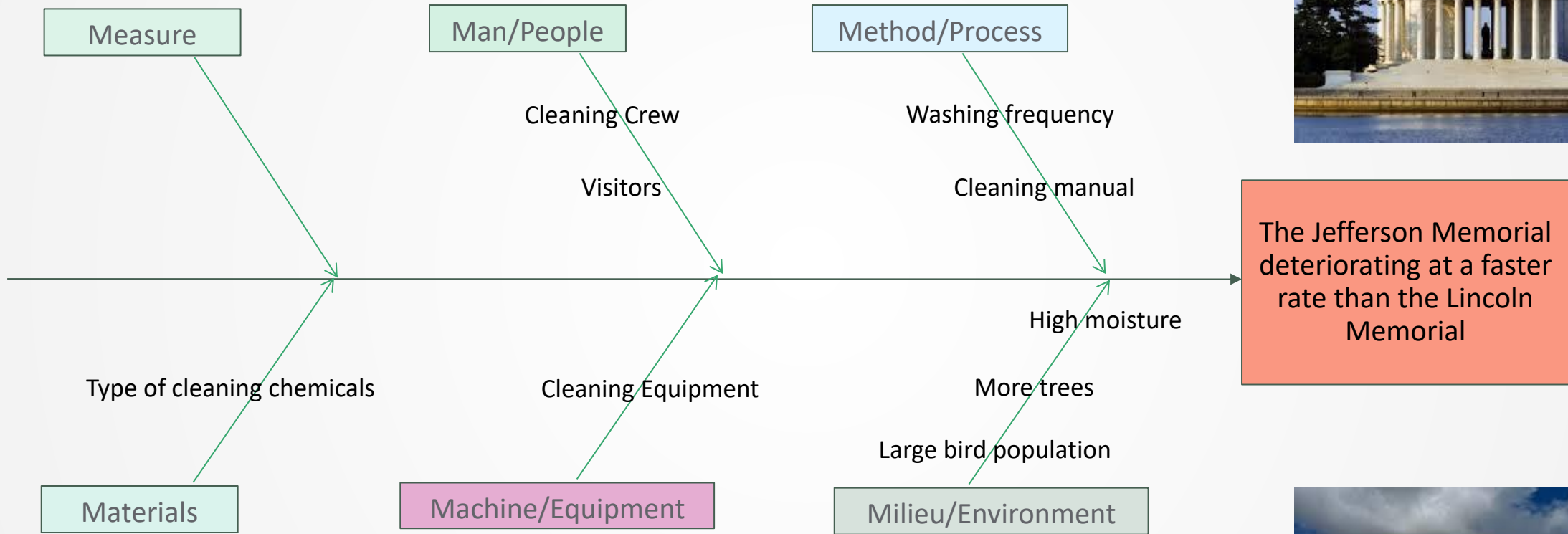
RCA examples

- Jefferson Memorial had deterioration issues

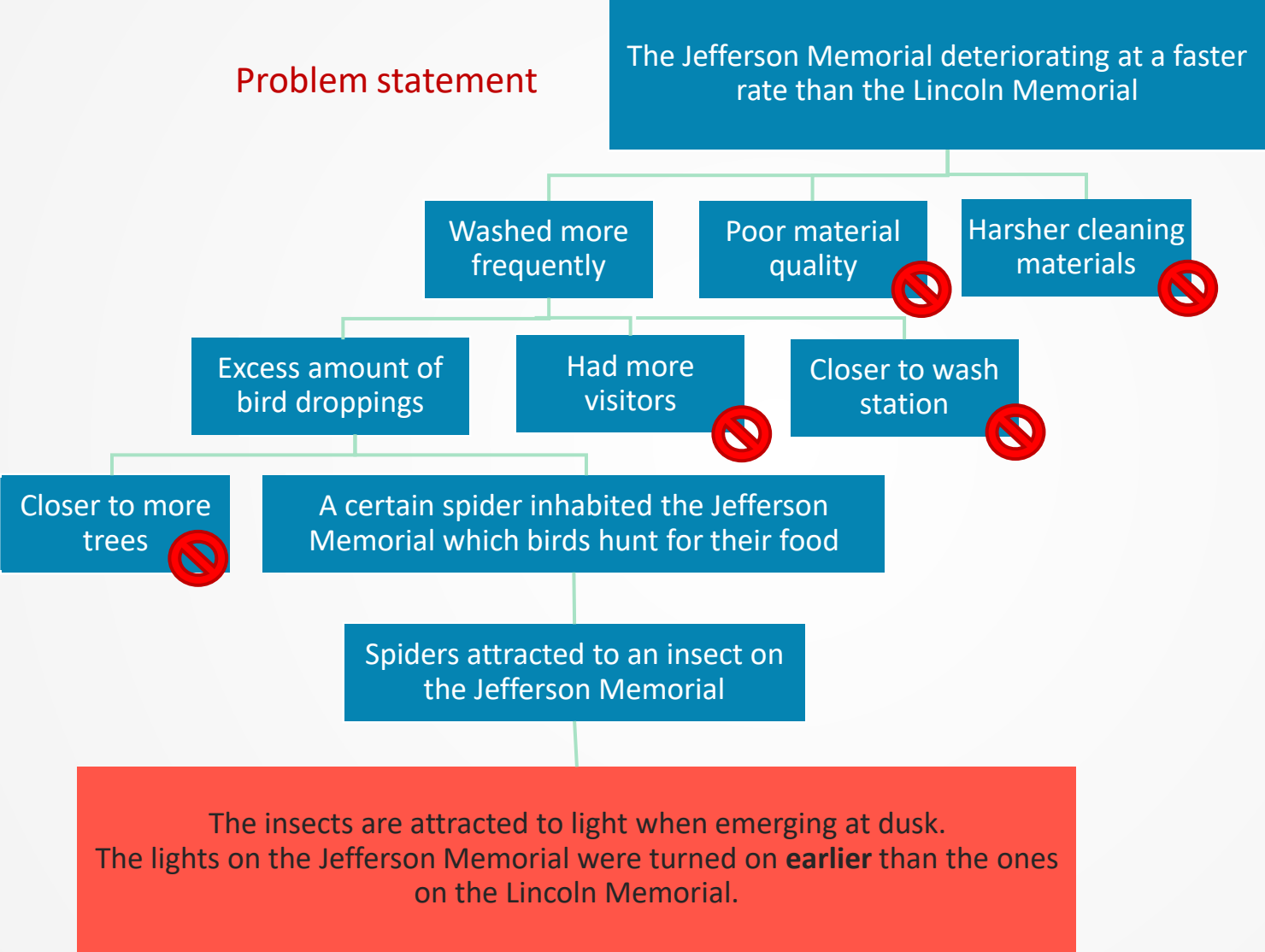
Background:

- In late 1980s, National Park Service noticed significant deterioration and darkening stones at the Jefferson Memorial
- Investigations were conducted in early 1990s

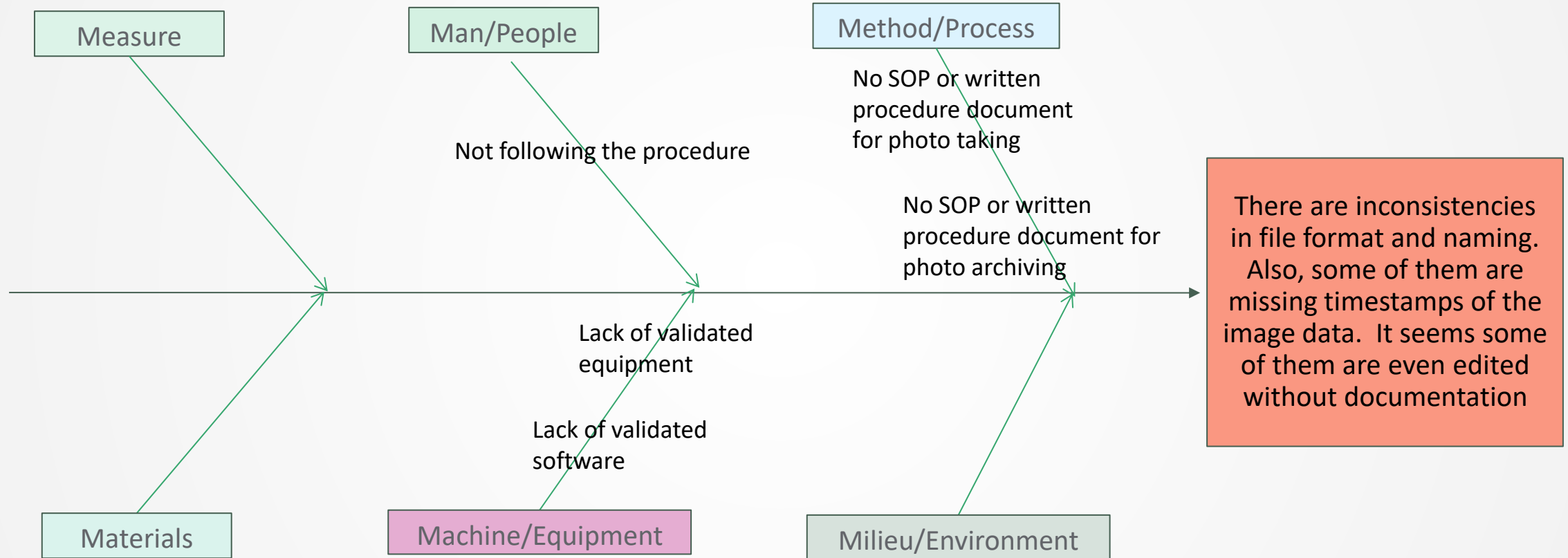
Fishbone Diagram – Technique Example



5 Whys



Fishbone Diagram – Technique Example 2



5 Whys (Example 2)

Problem statement

There are inconsistencies in file format and naming. Also, some of them are missing timestamps of the image data. It seems some of them are even edited without documentation

Technicians used personal smartphones and third-party image apps for their convenience (easier and faster for technicians to store in a cloud-based album)

No specific SOP was existing for the image data capturing and storing

No specific equipment or software available for the image data capturing

The technicians was not aware that image metadata are GLP data

There was a training gap between the technicians and their GLP trainers

Essentials for RCA

General:

- Clearly define the problem
- Include front-line people as the RCA participants
- Conduct Gemba Walk ('Go and See' where actual work happened and the problem occurred)
- Focus on root causes, not symptoms

Keys for Fishbone Diagram:

- Brainstorming exercise – sufficient number of participants (diverse team)
- Participants should be aware that this is not a finger-pointing exercise and should be open-minded in case the potential cause is in their area.

Keys for 5-Why analysis:

- 5-Why analysis is not necessarily ends with 5 steps. Could be 3 – 7 steps (even shorter than 3 steps).
 - “How do I know it is the root cause?” – If the cause is eliminated and solves the issue, that is the root cause. If not, there would be a different cause as the root cause.

It is recommended using Fishbone Diagram & 5-Why Analysis combination

Congratulations!

Root cause was identified!!

However,

The most important part is not done yet.

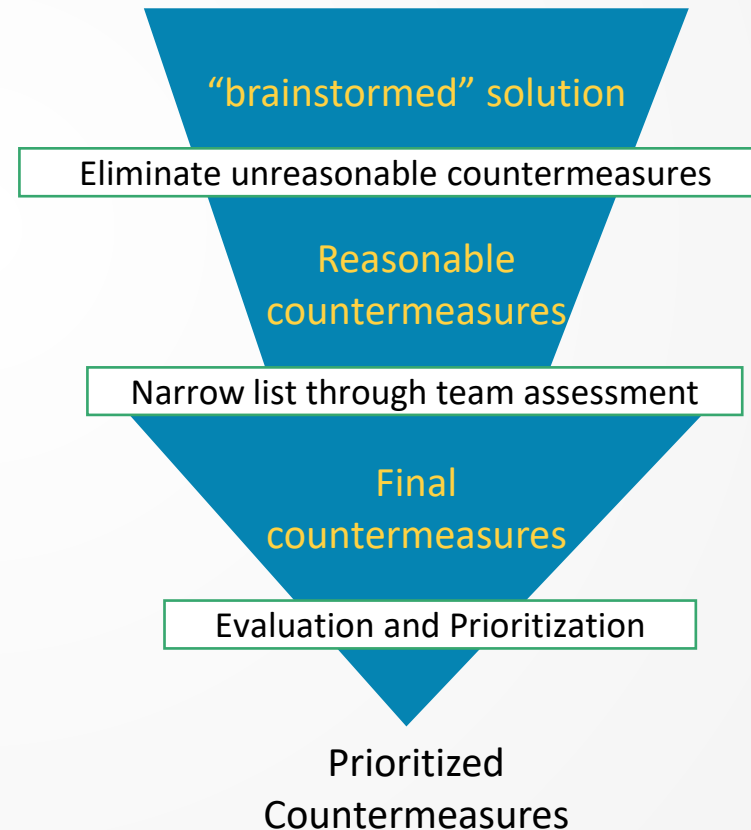
The next step is...

Countermeasure generation

Countermeasure: Potential Solution for a root cause. Note that it is not necessary to have only one countermeasure for one root cause.

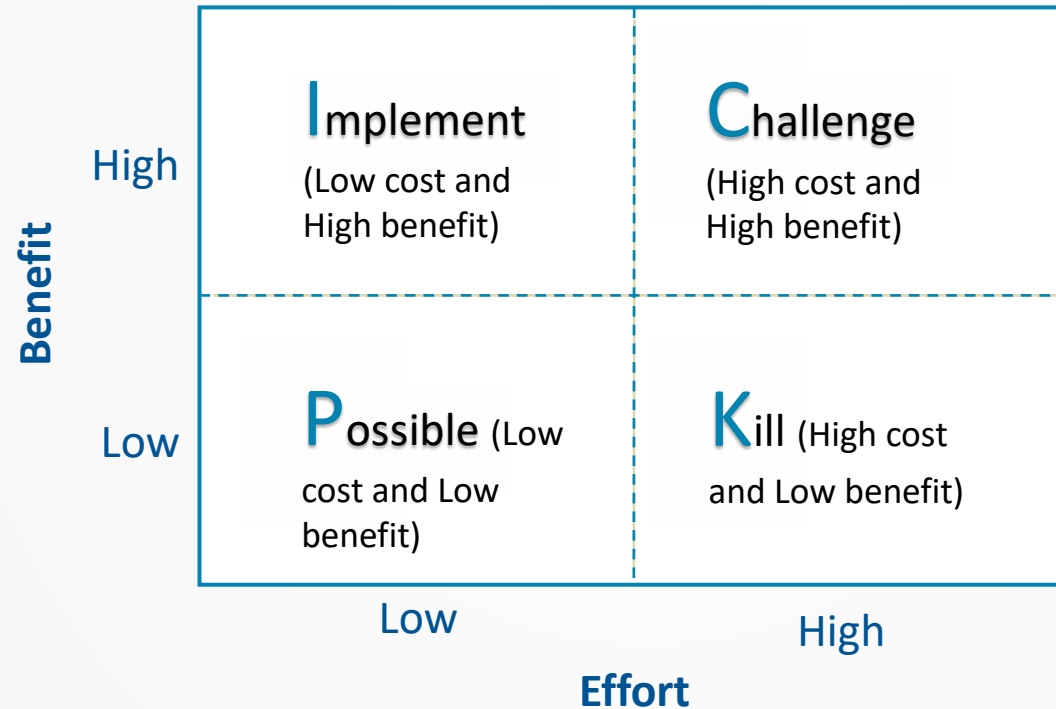
Steps:

1. Generate a number of “brainstormed” countermeasure ideas
2. Narrow down to reasonable countermeasures by combining the best attributes or eliminate unreasonable ones.
3. Evaluate the effort and the benefit for each countermeasures above and prioritize the execution order.



Prioritizing the potential solutions

Evaluate and prioritize all countermeasures (potential solutions) by looking at the relationship of benefit and effort chart (PICK Chart).



Follow up Actions

- Based on the prioritization exercise, develop a RACI* chart to identify the owner of the tasks, and a tracking table or a similar document that contains due timeline.
- The investigation team check the status and report to the stakeholders.

* RACI chart – A chart identifying who is 'Responsible', 'Accountable', 'Consulted', and 'Informed'. Usually, they are also the stakeholders.

Thank you

