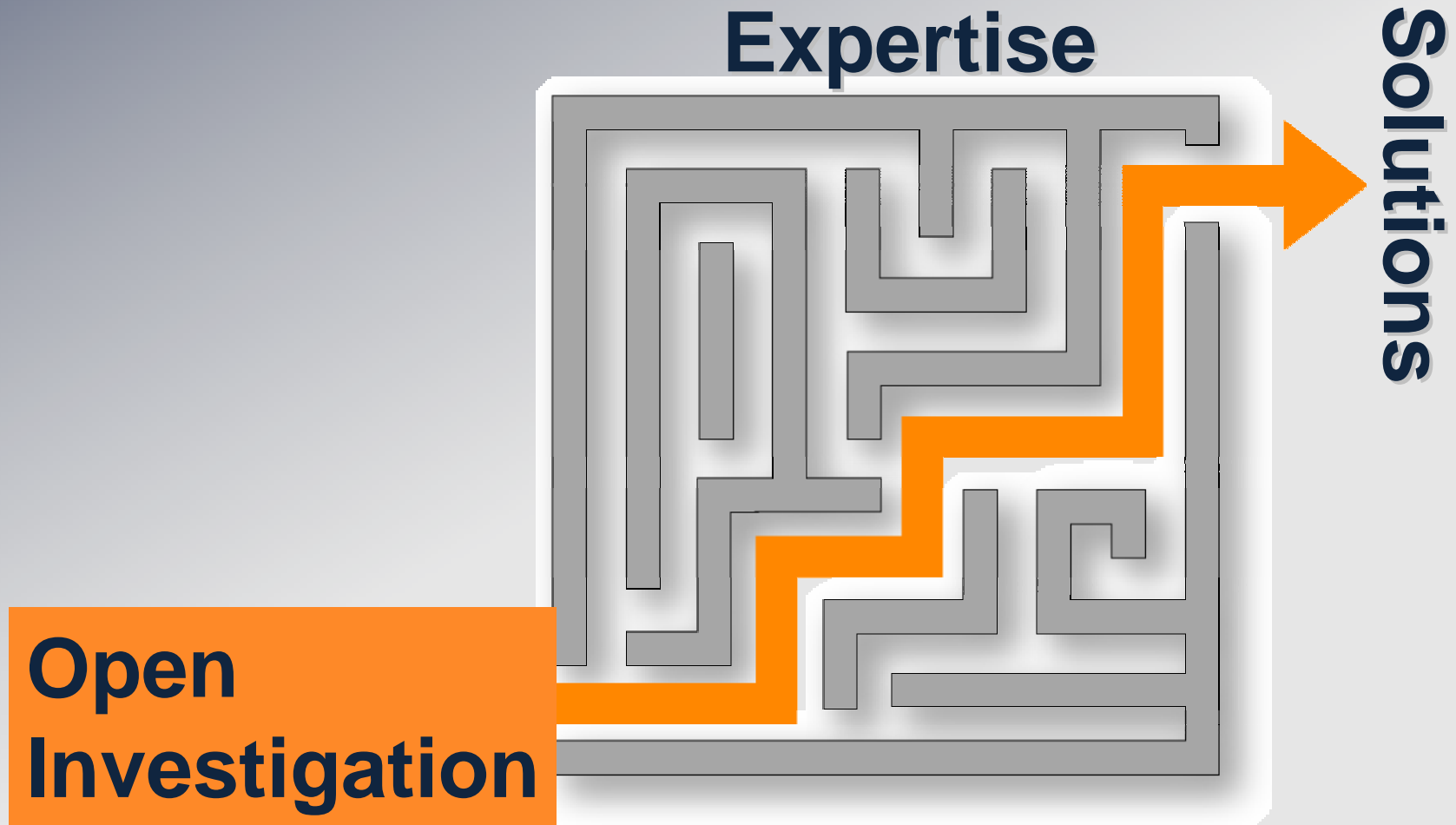




CAPA Investigations

Investigations

Getting to Performance



Expertise...

...having, involving, or displaying special skill or knowledge derived from training, education or experience.

“You must continue to gain expertise, but avoid thinking like an expert”

Denis Waitley

Read the following sentence...

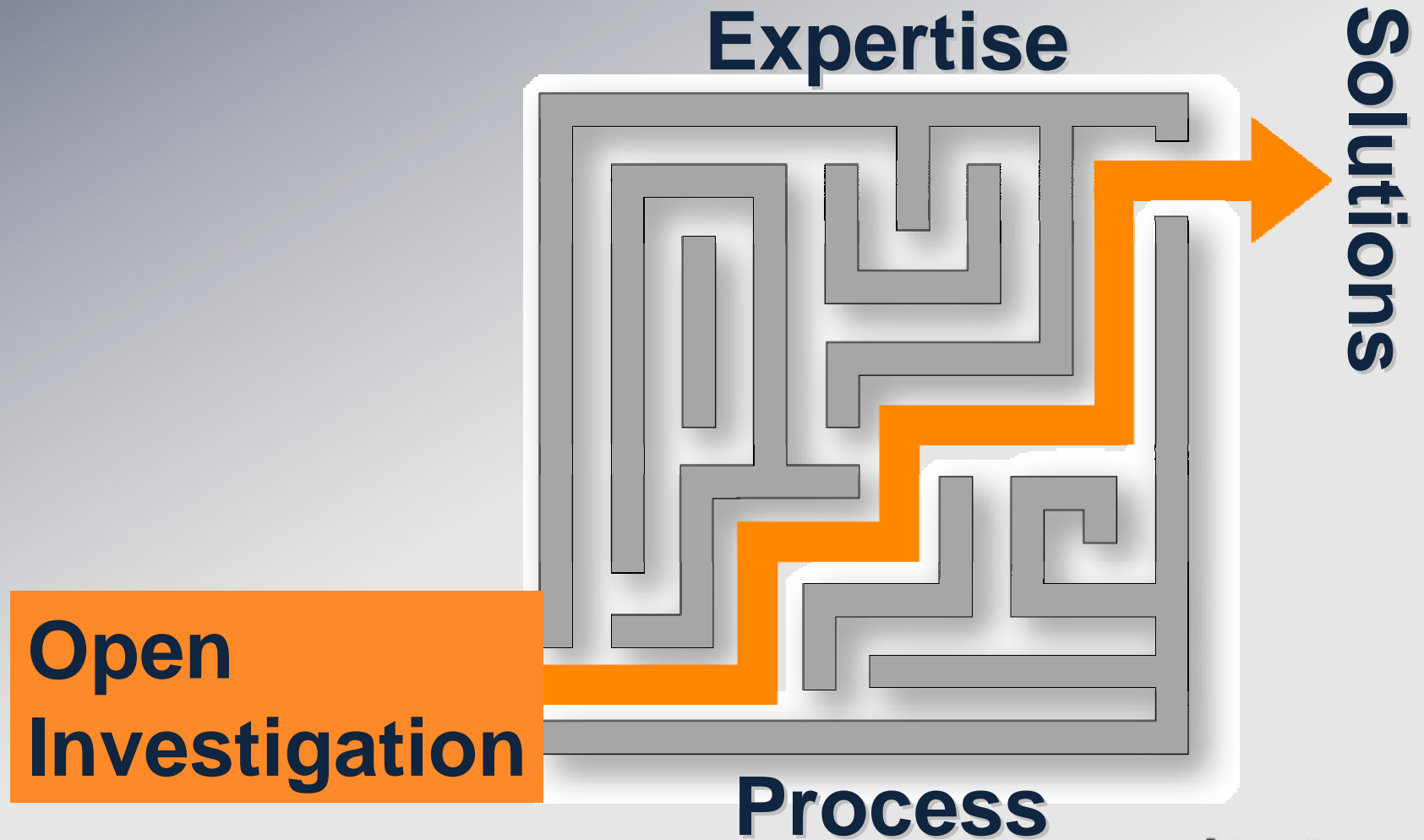
FINISHED FILES ARE THE RESULT
OF YEARS OF SCIENTIFIC
STUDY COMBINED WITH THE
EXPERIENCE OF MANY YEARS.

Finished Files Exercise

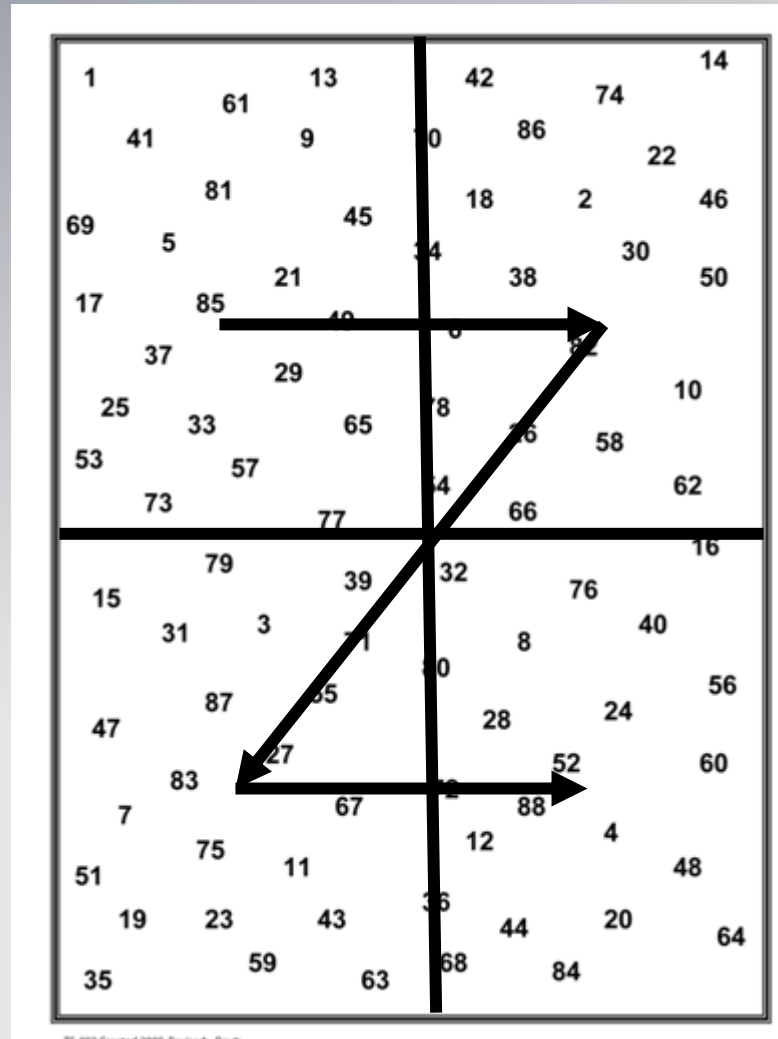
“The Expert Scotoma”

**FINISHED FILES ARE THE
RESULT OF F YEARS OF F
SCIENTIFIC STUDY
COMBINED WITH THE
EXPERIENCE OF F MANY
YEARS.**

Getting to Performance



Power in the Process!



A hand in a dark suit sleeve is pulling a chain from a white incandescent light bulb. The background is a soft, out-of-focus gradient of light colors. The text "Lights Out" is overlaid in the center in a blue, serif font.

“Lights Out”

Comparing Responses

Response	Pros (+)	Cons (-)
Trial & Error	<ul style="list-style-type: none"> ▪ instant gratification ▪ can reduce damages ▪ might find solution on first try 	<ul style="list-style-type: none"> ▪ reactive ▪ may add to variability in problem ▪ risky
Expert / Experiential	<ul style="list-style-type: none"> ▪ expand participation ▪ more proactive ▪ use experience 	<ul style="list-style-type: none"> ▪ educated guesswork vs. facts ▪ risk of “group think,” challenge of consensus ▪ when consultant leaves so does expertise
Comparative	<ul style="list-style-type: none"> ▪ fact-based ▪ objective ▪ very proactive ▪ works with experience/expertise 	<ul style="list-style-type: none"> ▪ requires facts ▪ may take time at first ▪ people may resist

How Does Comparative Analysis Work?



“ELEMENTARY MY DEAR WATSON, IT WAS MERELY DEDUCTIVE REASONING”.

Step 1 – Define the Problem

Why is this important?

- Creates a sense of **ownership**
- **Focuses** the team on an accepted problem
- Describes the symptoms in **measurable** terms.



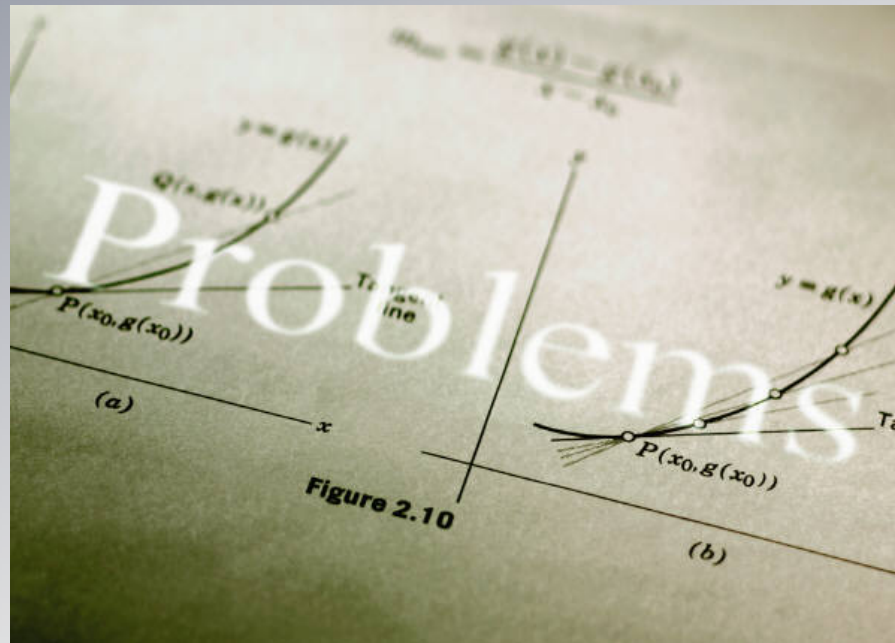
Step 1 – Define the Problem (cont.)

- Key Questions
 - What is wrong with what?
 - What is happening?
 - What are the symptoms?
- Object
- Non-conformance
- Extent

Step 1 – Define the Problem - Pitfalls

- 💣 Trying to address more than one problem
- 💣 Assigning cause
- 💣 Vague statements
- _____
- _____

What's the Problem Here?



A correctly defined problem is
50% solved!

Baby Formula

What's the problem?



Step #2 - Investigate

Why is this important?

- Ensures you gather all the **facts**.
- To understand **exactly** what happened.



Step #2 – Investigate (cont.)

Key Questions – 4 **W**'s:

- **W**hat is wrong
- **W**here is the problem happening?
 - Geographically?
 - On the object?
- **W**hen did it go wrong?
 - In the history, life cycle or process?
 - How does it repeat itself?
- **W**eight – how big is the problem?

Step #2 – Investigate - Pitfalls

- 💣 Accepting opinions or inferences as facts
- 💣 Failure to dig deep
- 💣 Bias / prejudice / tunnel vision
- 💣 Failure to use existing data when applicable
- 💣 _____
- 💣 _____

Facts or Inference

- Facts
 - Problem
 - Investigate
 - Compare
 - Test
- Inference
 - Clues
 - Cause

Framing the Investigation

W

W



W

W

When Do I Use...

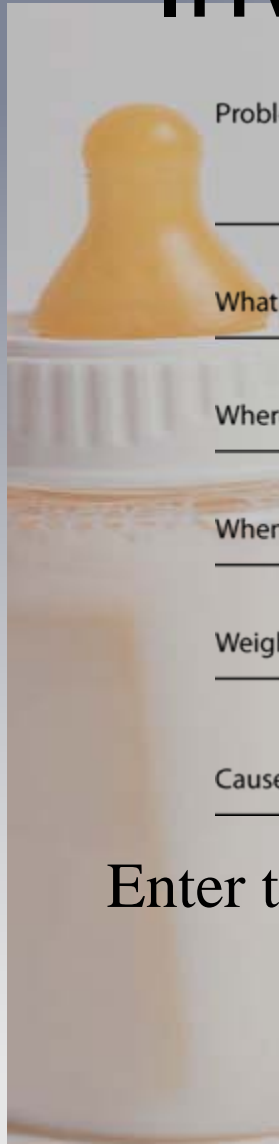
	What	When	Where	Weight	Clues	Cause
Bar Chart	✓			✓		
Brainstorming	✓		✓		✓	✓
Cause & Effect	✓				✓	✓
Check Sheet	✓			✓		
Control Chart		✓		✓		
Flow Chart		✓	✓			
Force Field Analysis					✓	
Histogram	✓			✓		
Input/Output Diagram		✓	✓			
Pareto Diagram	✓			✓		
Pie Chart	✓			✓		
Questionnaire/Interview	✓	✓	✓	✓		
Run Chart	✓	✓				
Scatter Diagram	✓	✓			✓	
Location Diagram	✓		✓			
Timeline		✓				

Investigate - Baby Formula

Problem Statement: Baby formula on line #3 is testing low for vitamin C.

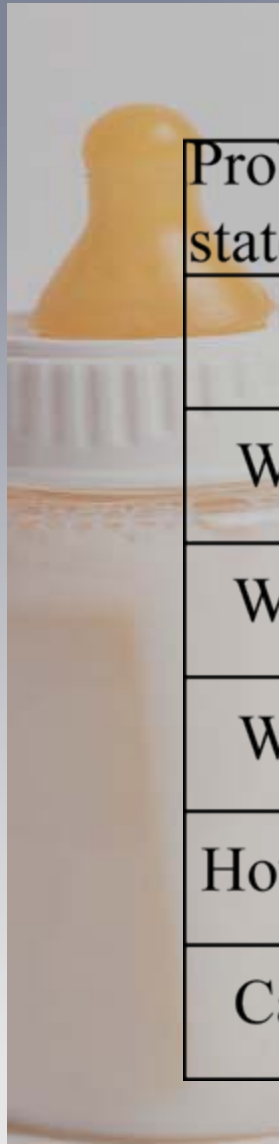
	Is	Is Not	Clue
What			
Where			
When			
Weight			
Cause:			

Enter the investigation facts (IS) in the chart on page 24.



“IS” Data

Problem statement:	Baby formula on line #3 is testing low for vitamin C.		
	IS	IS NOT	CLUE
What	Vitamin c has dropped below minimum specifications		
Where	Only line 3 is affected		
When	Started 2 - 1/2 weeks ago		
How Much	100% of product		
Cause:			



Step #3 - Compare

Why is this important?

- Establishes **boundaries**.
- Keeps you from working in **unproductive** areas.
- Sets up **deductive** thinking.
- Provides critical test data for **evaluating** likely cause.



Step #3 – Compare (cont.)

Key questions:

- What similar items can we compare the problem to?
- What else could be wrong?
- Where else would we expect to see the problem?
- When else could the problem have occurred?
- How else could the problem have repeated?

Step #3 – Compare -Pitfalls

- 💣 Using comparisons that aren't valid.
- 💣 Not finding enough comparisons – no comparisons = no clues
- 💣 Using comparisons that share the problem
- 💣 _____
- 💣 _____

Compare - Baby Formula

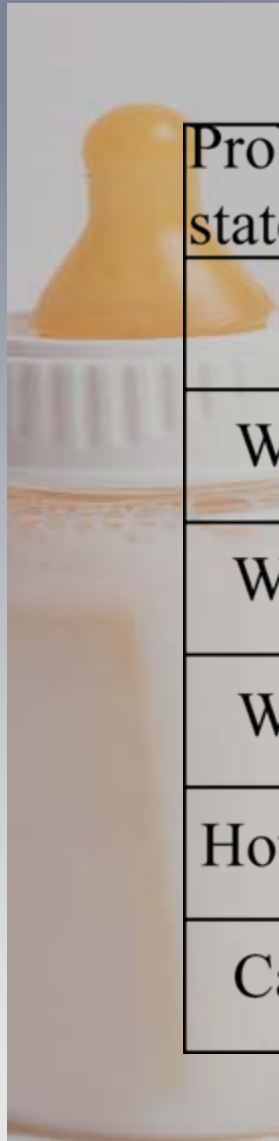


Problem statement:	Baby formula on line #3 is testing low for vitamin C.		
	IS	IS NOT	CLUE
What	Vitamin c has dropped below minimum specifications		
Where	Only line 3 is affected		
When	Started 2 - 1/2 weeks ago		
How Much	100% of product		
Cause:			

Enter the comparison facts (IS NOT) in the chart on page 26.

“IS NOT” Data

Problem statement:		Baby formula on line #3 is testing low for vitamin C.		
		IS	IS NOT	CLUE
What	Vitamin c has dropped below minimum specifications	All other additives (Vit A, Calcium, etc.) test fine		
Where	Only line 3 is affected	Lines #1 and #2 are fine		
When	Started 2 - 1/2 weeks ago	Line 3 was fine 3 weeks ago		
How Much	100% of product	More than 100%		
Cause:				



Step #4 - Clues

Why is this important?

- Filters relevant and irrelevant data.
- Effectively merge the problem solving process with expertise.
- Points us towards likely cause(s).



Step #4 – Clues (cont.)

Key Questions

- What is unique between the observed facts and its comparison?
- What has changed (use 4 M's)?
- What was different in the problem object that may have caused the undesirable results?

Step #4 – Clues - Pitfalls

- 💣 Failure to use expertise in identifying differences.
- 💣 Allowing biases, preconceived Ideas to dictate clues.
- 💣 Focusing on the uniqueness of the “IS NOT” data.





Clues - Baby Formula



Problem statement:		Baby formula on line #3 is testing low for vitamin C.	
	IS	IS NOT	CLUE
What	Vitamin c has dropped below minimum specifications	All other additives (Vit A, Calcium, etc.) test fine	
Where	Only line 3 is affected	Lines #1 and #2 are fine	
When	Started 2 - 1/2 weeks ago	Line 3 was fine 3 weeks ago	
How Much	100% of product	More than 100%	
Cause:			

Enter the clues in the chart on page 32.

Clues - Baby Formula



Problem statement:	Baby formula on line #3 is testing low for vitamin C.		
	IS	IS NOT	CLUE
What	Vitamin c has dropped below minimum specifications	All other additives (Vit A, Calcium, etc.) test fine	Vitamin C is more temperature sensitive than other additives
Where	Only line 3 is affected	Lines #1 and #2 are fine	Line 3 is the only line to use glass containers (others use plastic)
When	Started 2 - 1/2 weeks ago	Line 3 was fine 3 weeks ago	New sterilizers were installed on all lines 2 1/2 weeks ago
How Much	100% of product	More than 100%	N/A
Cause:			

Step #5 - Cause

Combination of clues +
knowledge + experience.



Why is this important?

- Likely causes are an **explanation** of how and why the problem occurred.
- It is the logical **conclusion** from the investigation's clues.





Step #5 – Cause (cont.)

Key Questions:

- What causes are suggested by the clues?
- If this is the likely cause and had not been present – would the problem still have occurred?

Likely Causes Tell the Story...



-  **Of cause & effect**
-  Of how the clues explain the deviation.
-  Of how each clue may have played a part in what caused the problem.
-  Is based on experts' knowledge and experience with similar situations.

Step #5 – Cause - Pitfalls

- 💣 Groupthink
- 💣 Failure to use expertise / knowledge / experience.
- _____
- _____

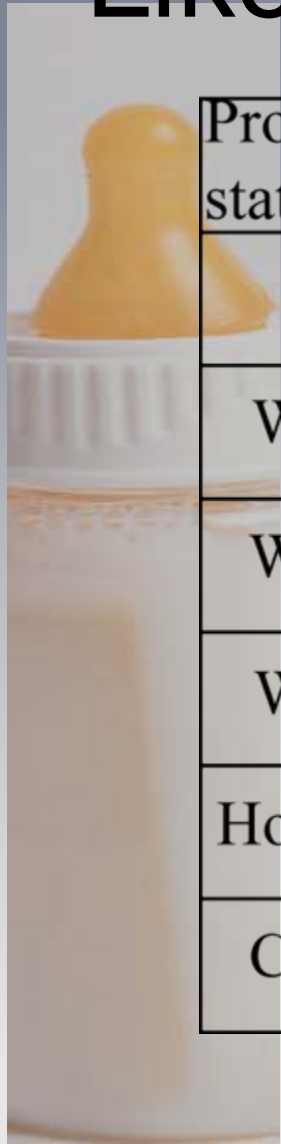
Likely Cause - Baby Formula



Problem statement:		Baby formula on line #3 is testing low for vitamin C.		
	IS	IS NOT	CLUE	
What	Vitamin c has dropped below minimum specifications	All other additives (Vit A, Calcium, etc.) test fine	Vitamin C is more temperature sensitive than other additives	
Where	Only line 3 is affected	Lines #1 and #2 are fine	Line 3 is the only line to use glass containers (others use plastic)	
When	Started 2 - 1/2 weeks ago	Line 3 was fine 3 weeks ago	New sterilizers were installed on all lines 2 1/2 weeks ago	
How Much	100% of product	More than 100%	N/A	
Cause:				

Enter the likely cause in the chart on page 34.

Likely Cause - Baby Formula



Problem statement:	Baby formula on line #3 is testing low for vitamin C.		
	IS	IS NOT	CLUE
What	Vitamin c has dropped below minimum specifications	All other additives (Vit A, Calcium, etc.) test fine	Vitamin C is more temperature sensitive than other additives
Where	Only line 3 is affected	Lines #1 and #2 are fine	Line 3 is the only line to use glass containers (others use plastic)
When	Started 2 - 1/2 weeks ago	Line 3 was fine 3 weeks ago	New sterilizers were installed on all lines 2 1/2 weeks ago
How Much	100% of product	More than 100%	N/A
Cause:	Glass containers allow baby formula to overheat during sterilization, which breaks down vitamin C		

Test Likely Causes

- Test against each set of observed and comparative facts.

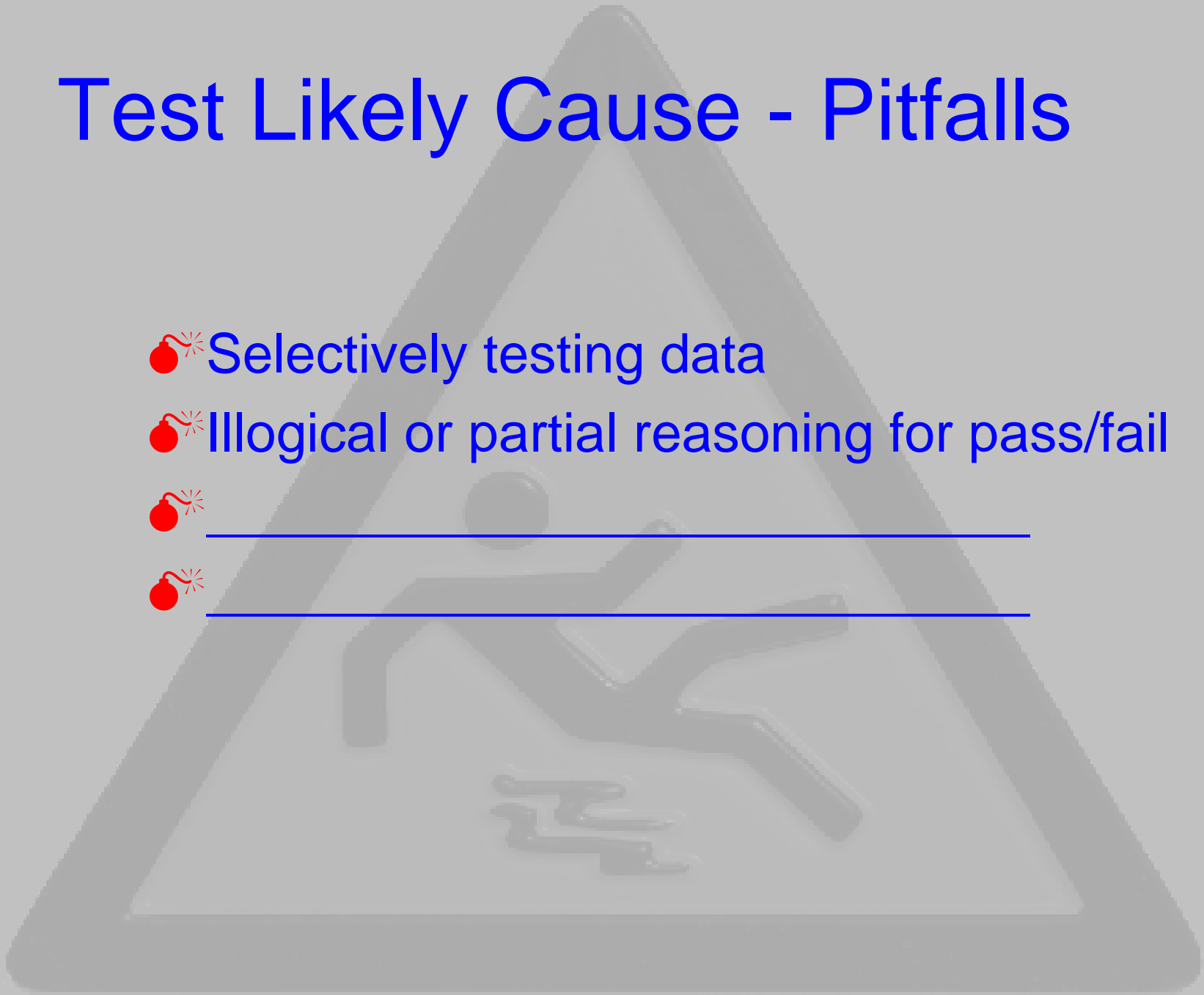


If I'm not wrong, then I must be _____!

- Resist testing selectively against just some of the facts.

Test Likely Cause - Pitfalls

- 💣 Selectively testing data
- 💣 Illogical or partial reasoning for pass/fail
- 💣 _____
- 💣 _____

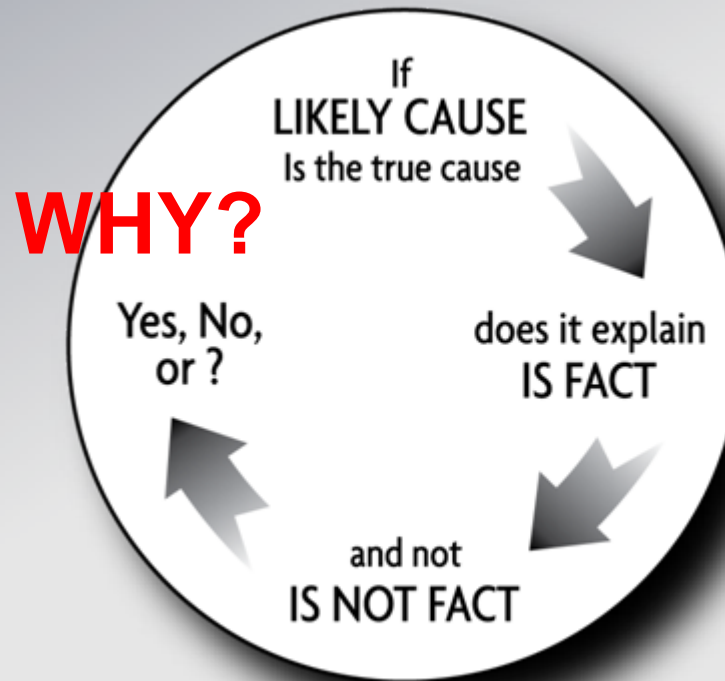


Test Likely Cause

- A true cause will explain both the “Is” (observed) and the “Is Not” (comparative) facts.
- This is checked by asking:

“Does [*Likely Cause*] explain that the problem is [*Observed Fact*] and not [*Comparative Fact*].”

Test Likely Cause



Investigation Report

Baby Formula

Data Outline

Problem:

- Baby formula on line #3 is testing low for vitamin C at final inspection.

Investigate:

- Vitamin C has dropped below minimum specification.
- Only line 3 is affected.
- Started 2 ½ weeks ago.
- 100 % of product is testing low.

Compare:

- All other additives (Vitamin A, Calcium, etc...) test fine.
- Lines #1 and #2 are fine.
- Line #3 was fine 3 weeks ago.

Clue:

- Vitamin C is more temperature sensitive than the other additives.
- Line 3 is the only one to use glass containers (others use plastic).
- New sterilizers were installed on all lines 2 ½ weeks ago.

Most Likely Cause:

- Glass containers allow baby formula to overheat during sterilization, which breaks down the Vitamin C.

CA Investigation Key Points

- Problem
- Investigate (IS)
- Compare (IS NOT)
- Clues
- Likely Cause
- Test