June Quality Improvement Forum

Root Cause Analysis (RCA) Case Studies

Disclaimer

- I am speaking as an independent subject matter expert and not as a representative of my place of employment.
- The information in this presentation is a summary of my own opinions and should not be interpreted as the opinion of my employer.

NCE documentation - Poll

- How do you currently document non-conforming events?
  - A. Electronically with a software system
  - B. Paper form
  - C. Mix of electronic and paper
  - D. Email or conversation with supervisor/peers
  - D. Other
  - E. Not sure / We don’t have a standardized method

RCA Tools Recap from April

- RCA tools can be used individually or in a complementary fashion
- Identifying contributing factors
  - Is/Is Not
  - Fishbone diagram
  - Pareto analysis
- Driving root cause
  - 5 Whys

Is/Is Not Overview

- Helps clarify contributing or causative factors
- Creates clear boundaries (scope)

Is Contributing/Causative	Is Not Contributing/Causative
What is the problem?	What is not the problem?
Where is it occurring?	Where isn't it occurring?
When does it happen?	When isn't it happening?
How big is the problem? (time to resolution)	How small is the problem? (time to resolution)

- In scope
- Out of scope

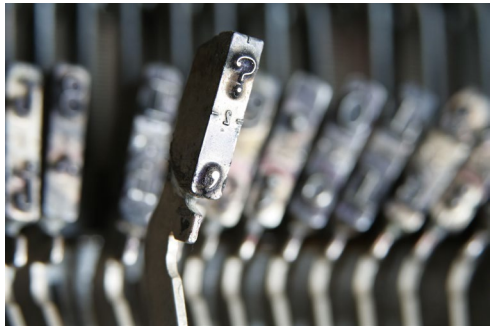
Is/Is Not Example

Is Contributing/Causative	Is Not Contributing/Causative
What is the problem? Continuous monitoring system(CMS) hardware failures not addressed within 24 hours	What is not the problem? CMS hardware failures are addressed within 24 hours
Where is it occurring? In Chemistry	Where isn't it occurring? Areas other than Chemistry
When does it happen? On weekends/holidays	When isn't it happening? During normal work hours

- In Scope
  - CMS hardware failures occurring outside of work hours in the Chemistry area that are not addressed within 24 hours
- Out of Scope
  - CMS hardware failures that are addressed

5 Whys Overview

- Helps determine the true root cause
- Training/long explanations not needed
- Continually ask why until you get to the true root cause
- 5 is not a magic number, each instance is different
- Only works if you go deep enough
  - Is this a root cause or a symptom?



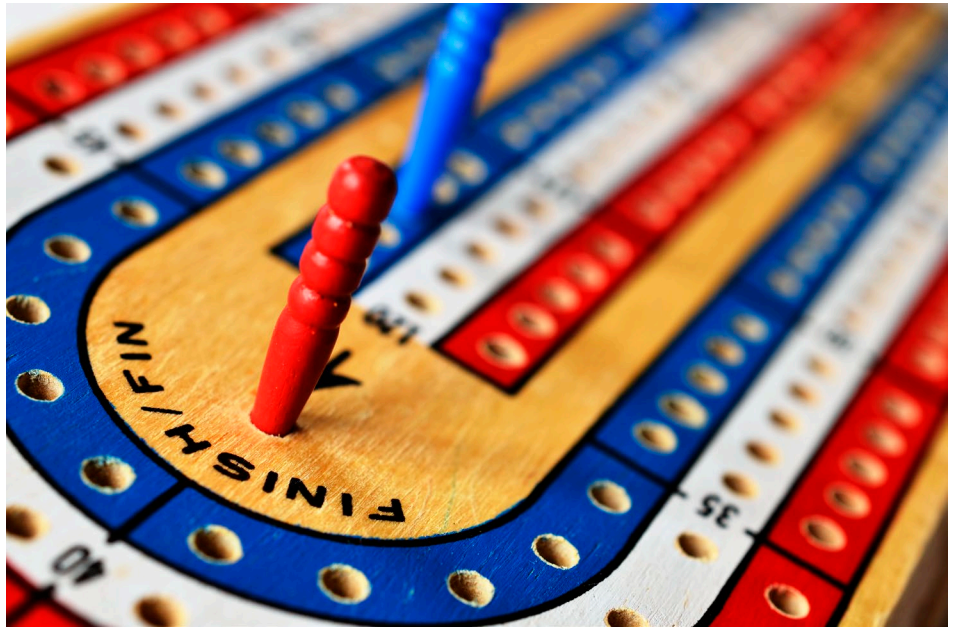
5 Whys Example

Why are CMS hardware failures occurring outside of work hours in the Chemistry area not addressed within 24 hours?
Responders only address issues that can be resolved remotely*
Why?
Because when they drive in, hardware issues can't be resolved on-site
Why?
Because the CMS hardware in Chemistry can't be replaced by responders when Chemistry staff aren't also here**
Why?
Because probes have to be replaced when hardware changes are made, *and responders can't get to the probes****
Why?
Because the fridges and freezers are locked, and responders don't have the key box code

*Contributing or causative factors can also be identified using the 5 Whys
** Recognize symptoms
*** Avoid possible sidetracks away from the scope

Deliverable

- Staff that respond to CMS hardware issues have access to key boxes in laboratory areas* that lock fridges/freezers.



*Keep within the scope during the process. Broadening the scope of the solution can be beneficial as a preventive action.

Questions

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Turning Over a New Leaf

Root Cause Analysis from a Reported False Positive Result

New Hampshire Public Health Laboratories

June 4, 2025

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Supervisor Food Safety Microbiology Unit

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Deputy Lab Director

Objectives

- NH PHL quality role in root cause analysis (RCA)
- Fishbone Diagram
- Timeline of false positive event
- RCA of event
- Corrective action plan
- Conclusions

Poll

How many RCA events occur annually at your agency?

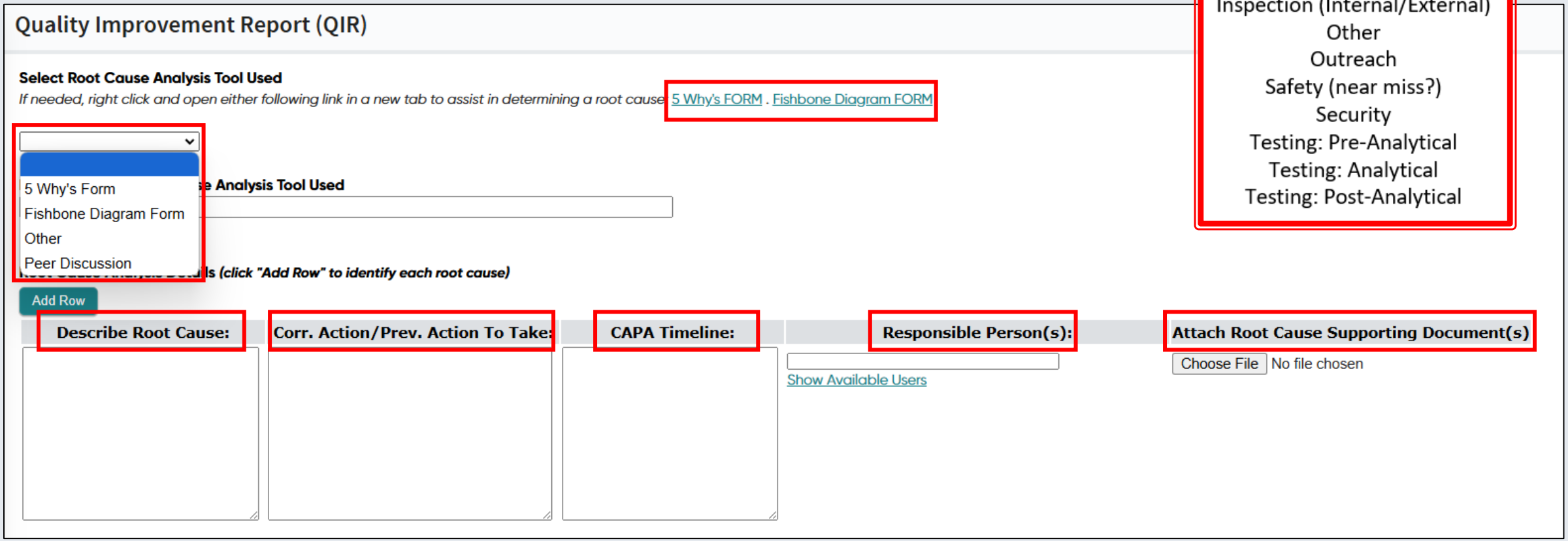
A. Less than 10
B. 11-50
C. 51-100
D. More than 100

NH PHL Role in Quality Events

- Notify Quality Team (includes Quality Manager, Deputy Lab Director)
- Document with a Quality Improvement Report (QIR) workflow instance in QM Essentials (Ideagen, Inc., aka “Qualtrax”)
- Based on QIR category and determined Impact, RCA is performed

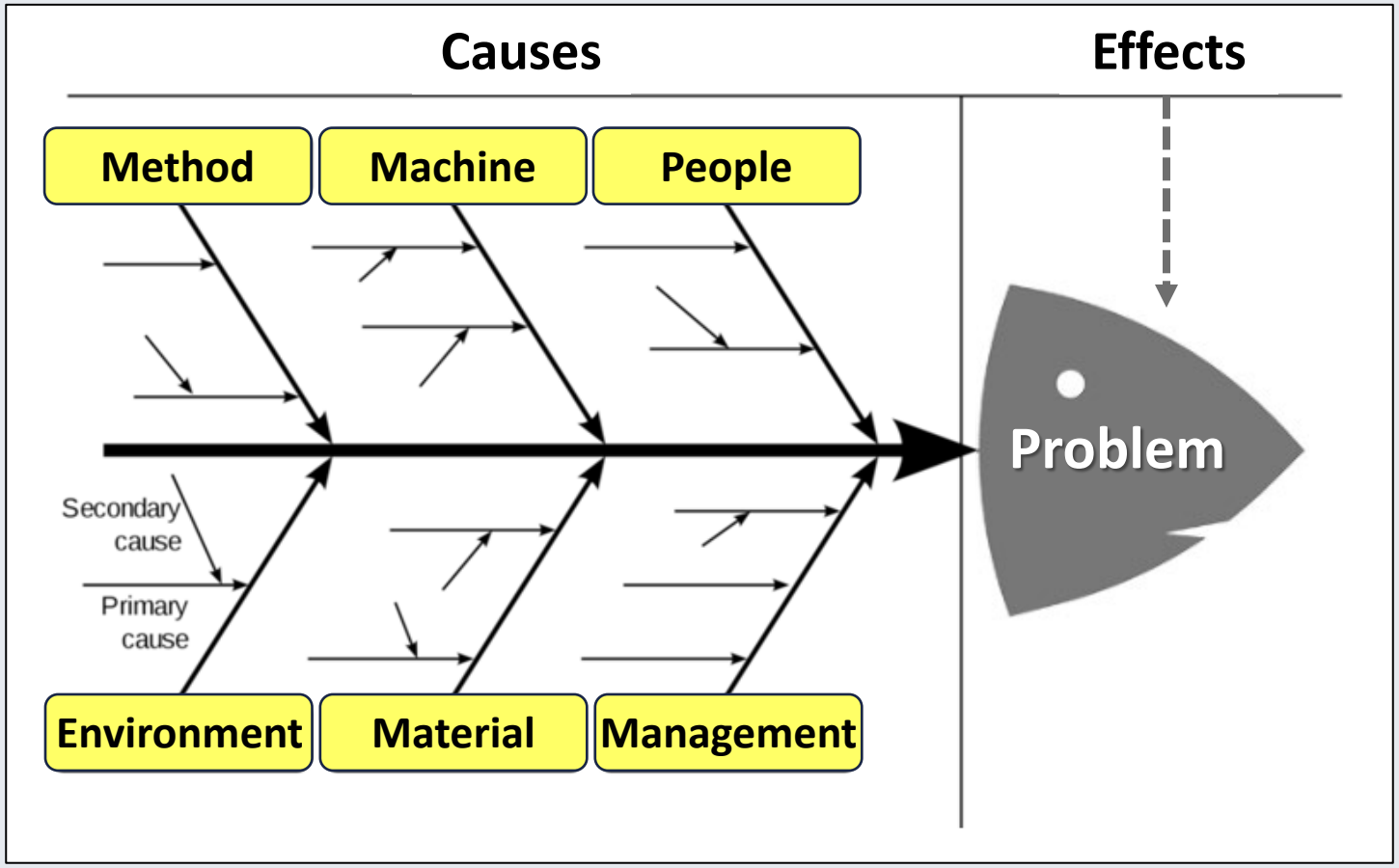
QIR Category

Building/Environment/HVAC
Conference/Meeting
Customer Service
Drill/Exercise
Education/Training
Equipment
Inspection (Internal/External)
Other
Outreach
Safety (near miss?)
Security
Testing: Pre-Analytical
Testing: Analytical
Testing: Post-Analytical



RCA Using the Fishbone Diagram

- Also known as the cause-and-effect diagram or Ishikawa diagram
- The diagram can help visually organize potential causes and effects that contribute to a problem.



Timeline of False Positive Event at NH PHL

4/27/23: Leafy green sample from a commercial farm screened positive for EHEC using real-time PCR.

4/28/23: FDA and State Regulatory Partner (SRP) were notified.

5/2/23: Organism was cultured and isolated, confirmed to be *E. coli* O157:H7 using VITEK 2 Compact. WGS process started 5/3/23.

5/5/23: After SRP notified Farm and conducted inspection, Farm initiated voluntary recall of product.

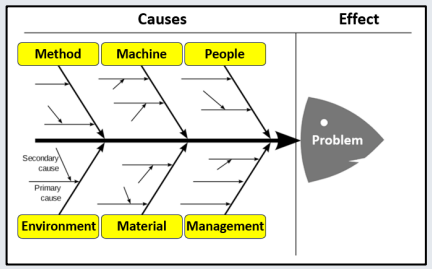
5/9/23: Sequence analysis concluded the sample isolate was genetically inseparable from lab's positive control organism. Root cause analysis was begun.

5/10/23: Farm was notified of false positive result. NH DHHS published correction notice regarding recall on 5/12/23.

RCA (Peer Discussion) – Main Findings

- A new ATCC non-fluorescent control organism was verified during the sample run:
  - Control organism shipped in lyophilized vial
  - Analyst A prepped control in biosafety cabinet
- Leafy green samples weighed out on the bench near the biosafety cabinet:
  - Analyst B struggled to aseptically add product to stomacher bag.
  - Analyst A assisted holding the bag open without changing gloves from handling control.

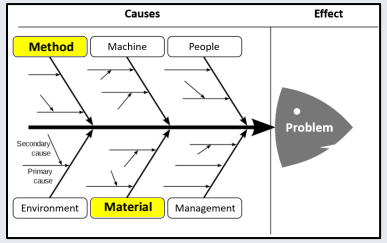
Further RCA Using Fishbone Diagram

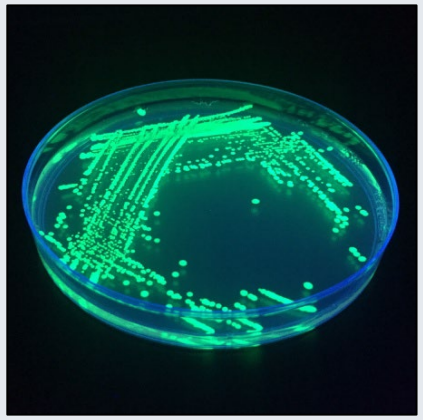


Category	Cause	Effect
Method	Verification of control organism not conducted properly	Non-fluorescent organism in live culture (could not visualize) rather than extracted separately for PCR use
Machine	BSC good practice not followed	Control organism transferred out of BSC
People	Lab hygiene protocols not followed	Unchanged glove introduced control organism to sample
Environment	Layout of the laboratory sub-optimal	Samples weighed out too close to BSC where cultures are manipulated
Material	Control organism being verified not fluorescently tagged	Contamination could not be ruled out without WGS
Management	Preliminary status of results not communicated well enough	Preliminary results acted upon as though final results

Corrective Action Plan – Method/Material

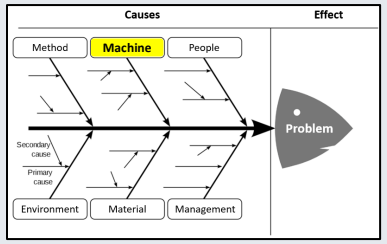
Cause	Effect	Corrective Action(s)
Verification of control organism not conducted properly	Non-fluorescent organism cultured rather than extracted separately for PCR use	Resume exclusive use of fluorescently tagged organisms for culture controls; extract PCR control separately for molecular use
Control organism being verified not fluorescently tagged	Contamination could not be ruled out without WGS	Ensure all analysts review the “Cultural Controls used in Food Methods” SOP to review proper use of positive control organisms

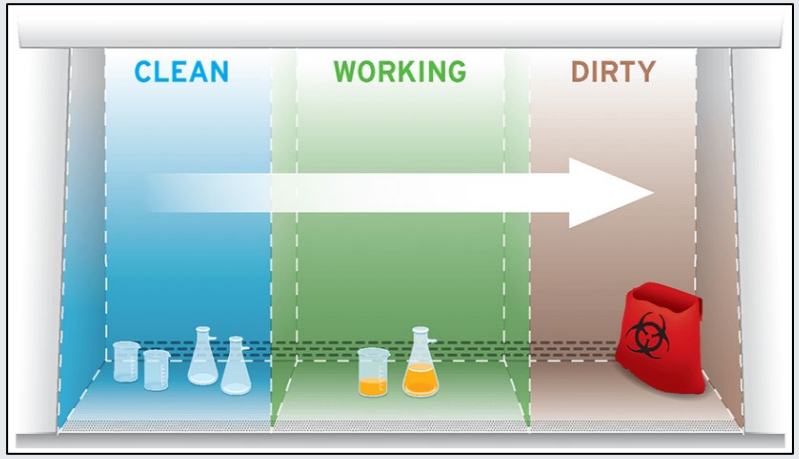




Corrective Action Plan – Machine

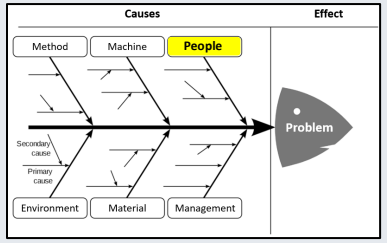
Cause	Effect	Corrective Action
BSC good practice not followed	Organism transferred out of BSC	Decontaminate BSC and perform swab testing to confirm success
		All analysts took biosafety cabinet refresher training in CDC TRAIN





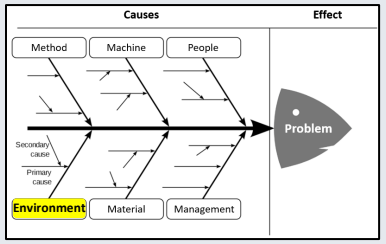
Corrective Action Plan – People

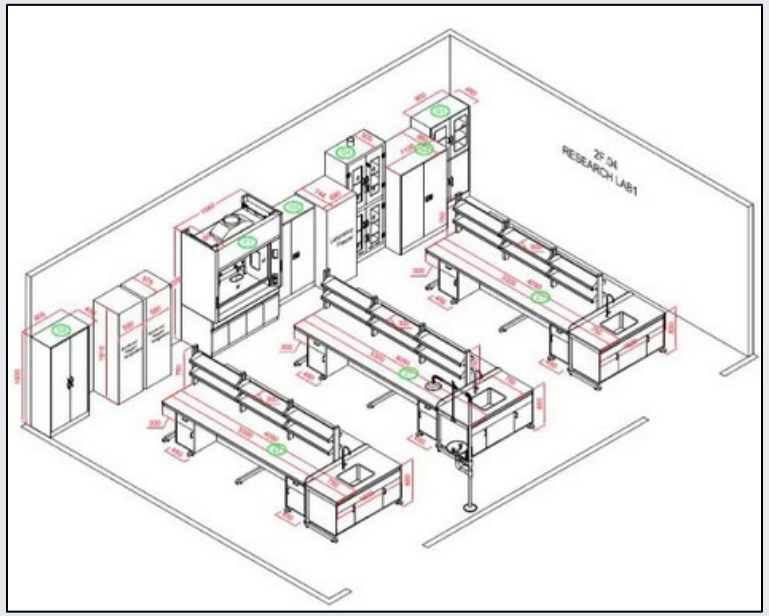
Cause	Effect	Corrective Action
Lab hygiene protocols not followed	Unchanged glove introduced control organism to sample	Management review of “Environmental Monitoring in the Food Lab” SOP and subsequent re-training of personnel
		Analyst A and Analyst B testing competency re-assessed for this method using PT



Corrective Action Plan – Environment

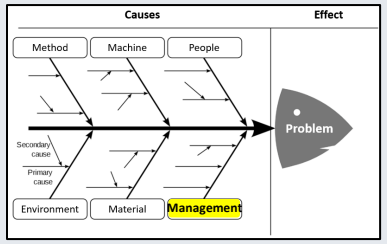
Cause	Effect	Corrective Action
Layout of the laboratory sub-optimal	Samples weighed out too close to BSC where cultures are manipulated	Layout evaluated by management/laboratory staff and changed accordingly





Corrective Action Plan – Management

Cause	Effect	Corrective Action
Preliminary status of results not communicated well enough	Results acted upon as though final by Farm and by NH Ag	Drafted and finalized a Communications Plan in conjunction with our partners and SRPs



Conclusions

- We followed FDA protocols for reporting violative results.
- Honest and cooperative participation from all involved
- Support from laboratory management
- Good communication between state and federal agencies
- Good learning opportunity
- Successful After-Action Report (AAR) to summarize findings

Thank you!
Questions/Discussion

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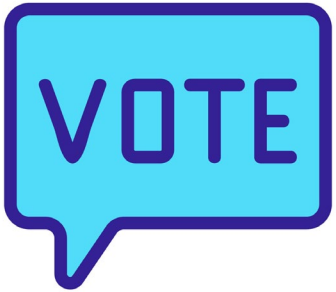
June Quality Improvement Forum

Root Cause Analysis

ARIZONA
DEPARTMENT OF
HEALTH SERVICES



What RCA tools have you used?

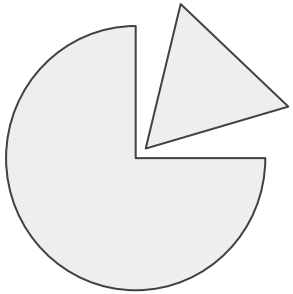
A. Is/Is not
B. 5 Whys
C. Fishbone Diagram
D. Pareto Chart
E. Peer discussion
F. Other

RCA Tools from April QIF

- RCA tools can be used individually or in a complimentary fashion
  - Is/Is Not
  - Fishbone diagram
  - Pareto analysis

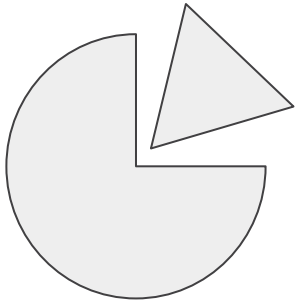
- Driving root cause
  - 5 Whys

Pareto



- Named after the sociologist and economist Vilfredo Pareto
  - First to discuss in 1906 how 80% of Italy was owned by 20% of population
- In 1941 management consultant Joseph M Juran developed into the quality control and improvement concept we know today
  - 80/20 is shorthand for the general principles
    - Based on mathematical Power Law relationship
    - Not always 80/20 - can be 90/10 or 70/30 or 60/40

Pareto Overview



Pareto or the 80/20 Rule

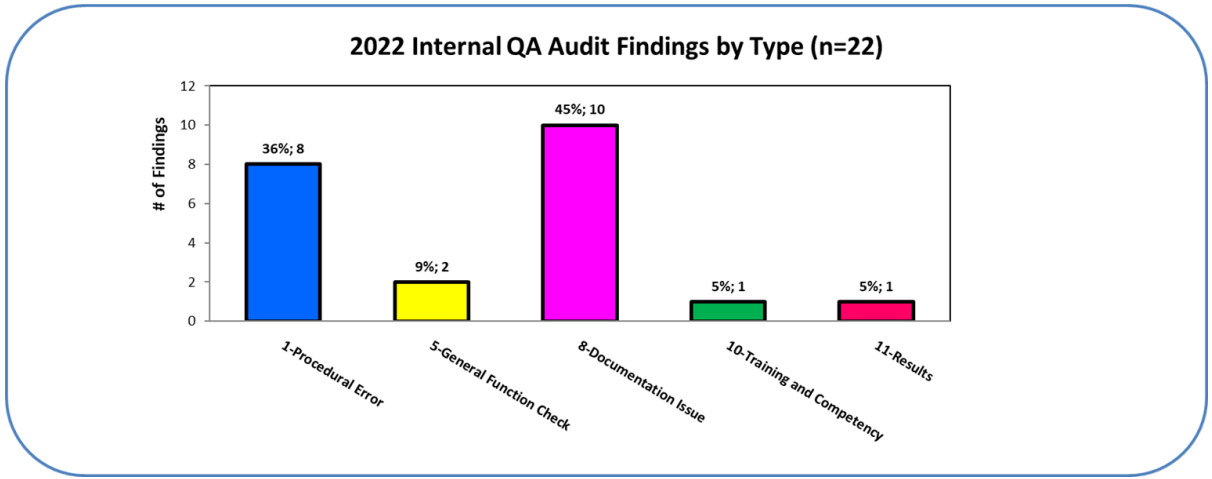
- Tool used to assist with focusing root cause analysis
- Use when
  - Analyzing data regarding frequency of issues
  - When there are a large number of issues
  - Communicating about the data

Can be a good tool when reviewing corrective action trends within your organization or reviewing complaints over times

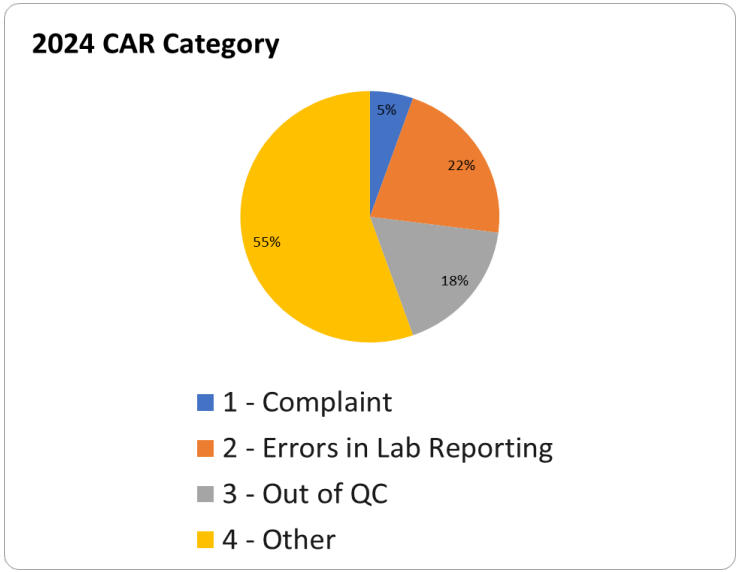
Typically represented by bar graphs but can be seen in pie charts also

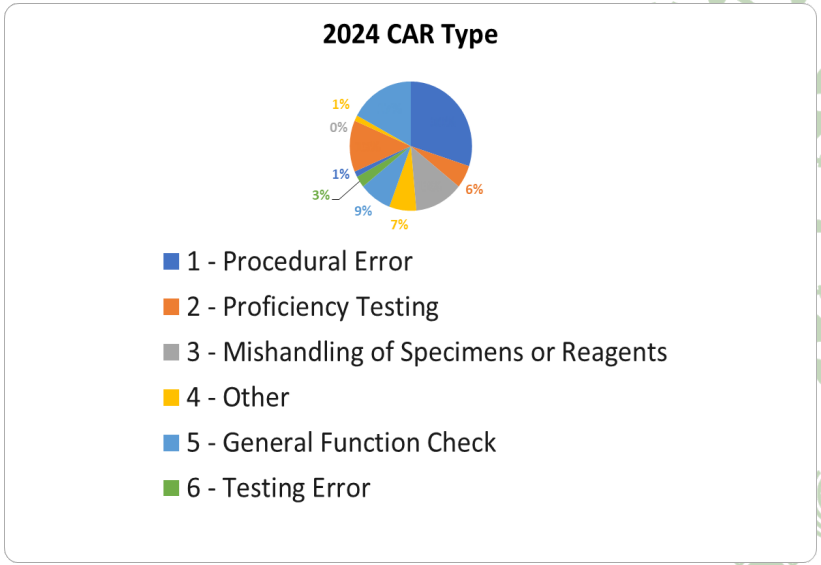
Example - Internal Audit Trends

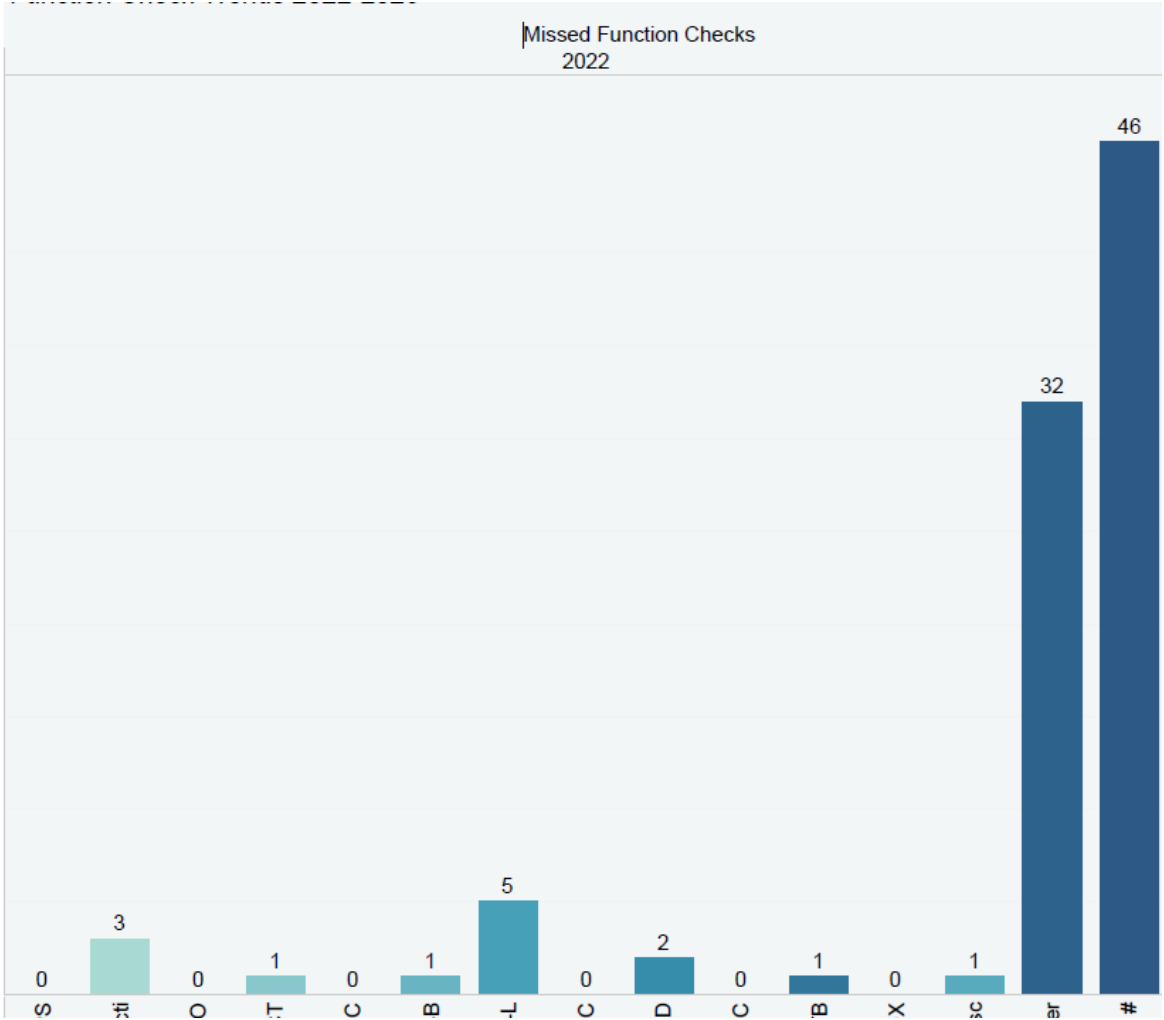
- Review of annual internal audits
  - Areas of focus highlighted



Example CAR/CAPA Category and Type






Missed Function Checks
2022
0
3
0
1
0
1
5
0
2
0
1
0
1
32
46

Resources

- American Society for Quality (ASQ)
  - https://asq.org/
  - Pareto Chart - https://asq.org/quality-resources/pareto

Thank you

Shout Out to the Arizona Quality Assurance Unit:

Melissa Spencer, Miranda Schaab, Rachael Yeskey and Caitlyn Libby

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