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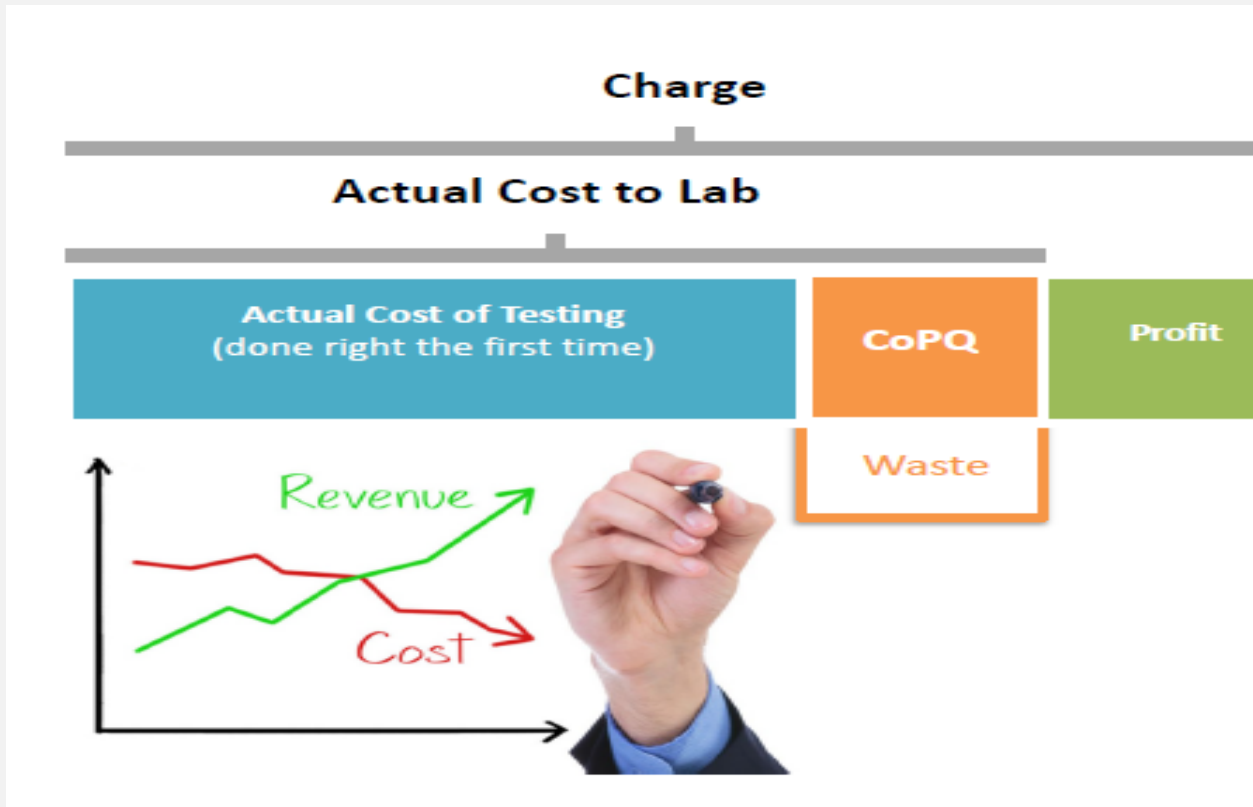
# Reducing the Cost of Poor Quality with an Effective CAPA Program

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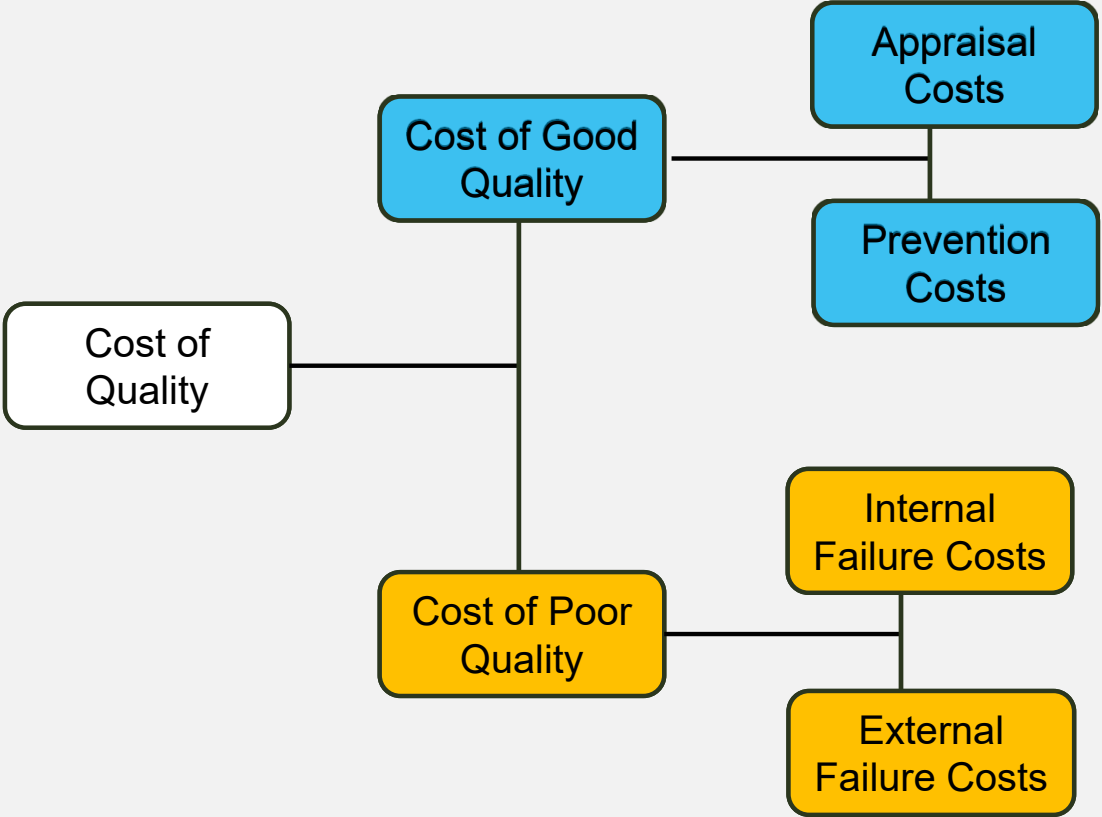
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# Labs are Businesses



Goal is COPQ < 15% of sales

# Cost of Quality



# Cost of Good Quality

## PREVENTION COSTS

- ✓ Quality Planning
- ✓ Training
- ✓ Preventive maintenance
- ✓ Design, Implement and Maintain an effective Quality Management System
- ✓ Trend Analysis
- ✓ Quality Improvement/Risk Reduction activities aka Preventive Action
- ✓ Effective Change Management Process
- ✓ Electronic Records and Control of Documents
- ✓ Supplier Quality Program

## APPRAISAL COSTS

- ✓ Ongoing Analyst DOCs
- ✓ Calibration checks (e.g., CCV)
- ✓ Quality Control (e.g., LCS, Method Blank)
- ✓ Proficiency Testing
- ✓ Internal Audits
- ✓ External Assessments
- ✓ Data Review



# Cost of Poor Quality

- Testing Costs
- Rework
- Waste
- Reinspection Costs

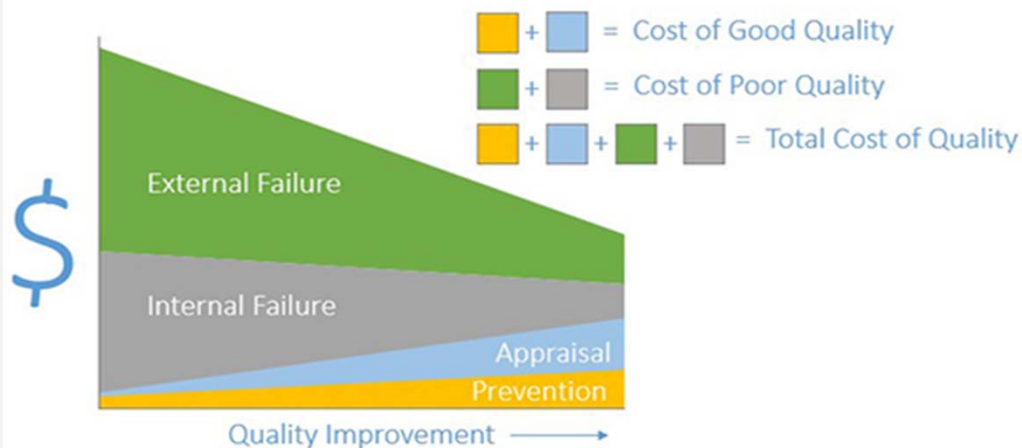
- Failure to meet a customer requirement; customer complaints
- Incorrect decisions made; harm to client's project; harm to public
- Data problems
- Systematic errors
- Loss of accreditation
- Loss of reputation
- Data recalls
- Revised test reports
- Loss of client
- Instrument downtime
- Investigation & Corrective actions
- Management time

# Why Track Cost of Poor Quality?

Do you know how much Cost of Poor Quality is impacting you?

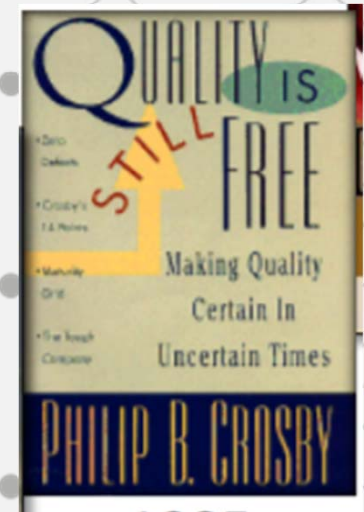
Do you know your biggest problem areas?

Typical Relationship/Progression of Cost of Quality



## Reasons for Not Tracking COPQ\*

- Lack of Knowledge
- Inadequate Tracking Systems
- Lack of Management Support



\* Sower et al. Cost of Quality Usage and its Relationship to Quality System Maturity

# CAPA

- One part of a Quality Management System
- Risk based
- Can be seen as a “check the box” activity
- Utilize for:
  - Data Inquiries / Recheck Requests
  - Quality Incidents (data recalls)
  - Client Complaints
  - Proficiency Testing (PT) Investigations
  - Audit Deficiencies (Internal & External)
  - Deviations from Quality System, SOP, Methods, QAPPs, etc.

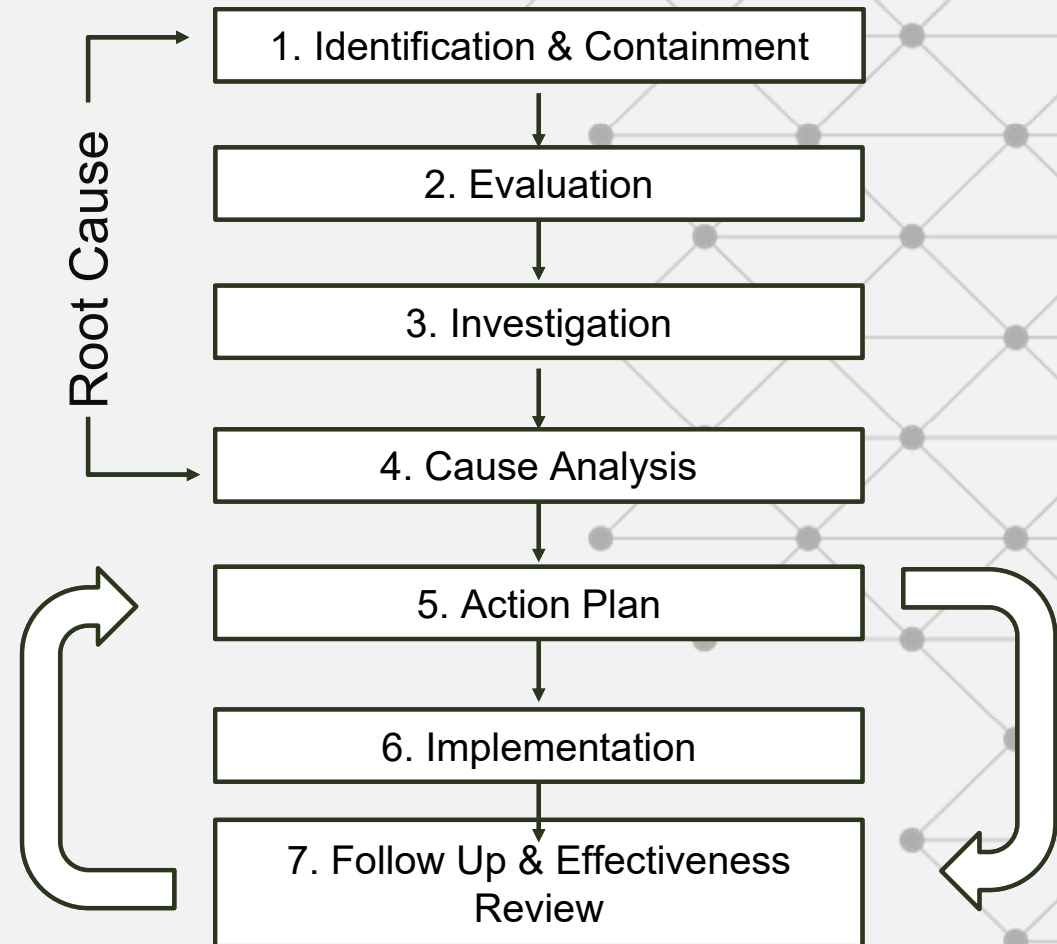




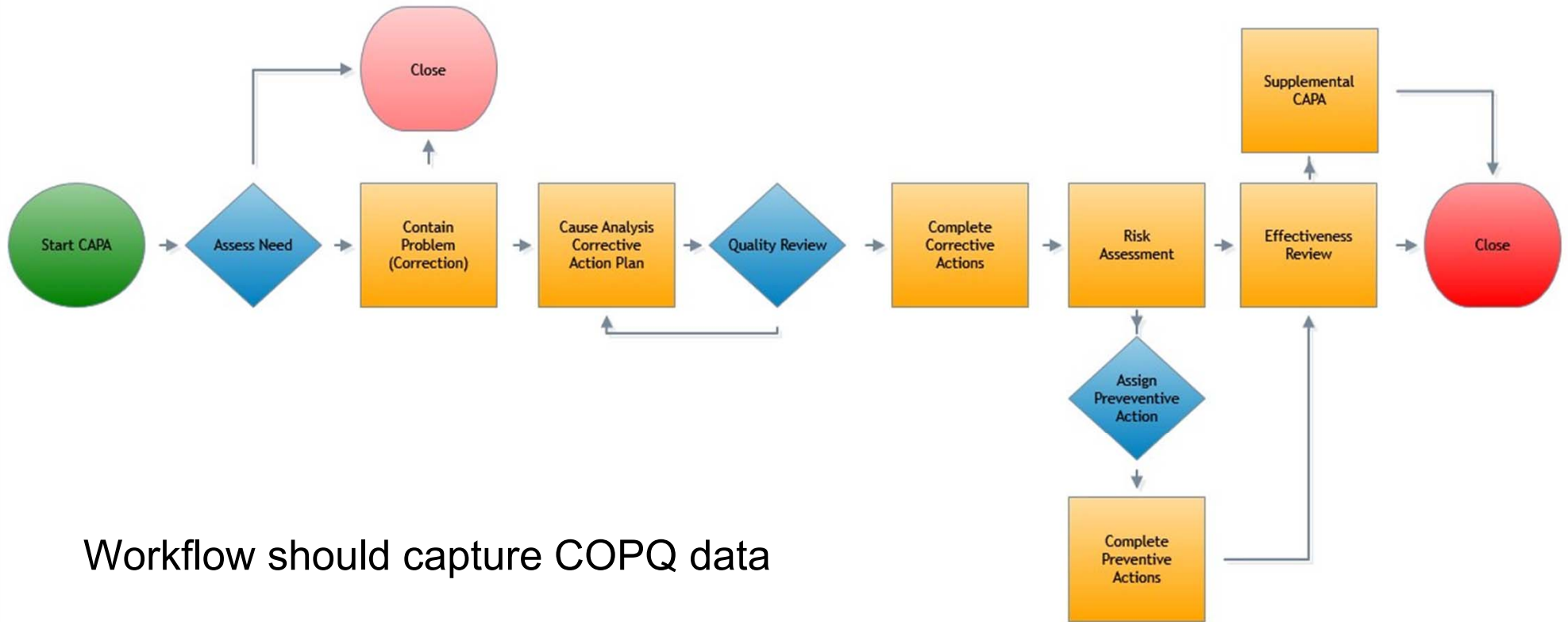
# CAPA Steps

## How to Determine Root Cause

- Assign the task to a person/team knowledgeable of the systems and processes involved
- A facilitator can assist with the process
- Define the problem
- Collect and analyze facts and data
- Utilize Root Cause Analysis tools and methods



# CAPA



Workflow should capture COPQ data



**Who Participates in CAPA?**

**Everyone**

**The responsibility for CAPA does not lie with just the  
Quality Manager or Department Lead/Supervisor**

**CAPA is a participatory process**



## CAPA COPQ Data

- Client information, if applicable
- Work area (metals, wet chem, sample receiving, etc.).
- Test method, as applicable
- Type of error
  - Sample switch
  - Process error
  - Equipment
  - Knowledge gap
  - Etc.
- # Revised reports
- # samples reanalyzed
- Time spent on investigation
  - QA
  - Operations
  - Client Services
- Cost of analysis, as applicable
- Original invoice, as applicable

## Utilize the Data

Client	Is Client's Concern Confirmed?				Total # of Qualtrax Tickets	Total Total Rework Cost (\$)
	No	Yes	# of Qualtrax Tickets	Total Rework Cost (\$)		
Client 1	9	\$5,967.00	3	\$289.50	12	\$6,256.50
Client 2	2	\$112.50	3	\$5,850.00	5	\$5,962.50
Client 3	23	\$1,981.00	21	\$3,269.75	44	\$5,250.75

- Is one client questioning data more than other clients?
- Is there a specific area of concern?
- Even client inquiries where concern is not valid costs time and money.

# Utilize the Data

ENV - Location	(All)
Work Area	# of Qualtrax Tickets
⊕ Row: 1 Wet Chemistry	778
⊕ Row: 1 Metals Analysis	549
⊕ Row: 1 VOA	302
⊕ Row: 1 SVOA	184
⊕ Row: 1 Air - VOA	65
⊕ Row: 1 Project Management	30
⊕ Row: 1 Micro	19
⊕ (blank)	19
⊕ Row: 1 Hg	18
⊕ Row: 1 Organic Prep	18
⊕ Row: 1 Sample Log In	13
⊕ Row: 1 Metals Analysis, Metals Prep	11
⊕ Row: 1 Multiple Work Areas	10
⊕ Row: 1 PFAS	9
⊕ Row: 1 Metals Prep	8
⊕ Row: 1 Metals Analysis Row: 2 Wet Chemistry	7
⊕ Row: 1 Metals Analysis, Wet Chemistry	6
⊕ Row: 1 Sample Receipt	5
⊕ Row: 1 RadChem	5

Row: 1 2540D TSS	16
(blank)	
Process - Analysis, Process - Dilution	4
Process - Analysis	3
Process - Sample Switch	3
Data Entry	2
Data Entry, Dilution	3
Undetermined	1

- Does one area lead in nonconformances?
- Does one method or type of method lead in nonconformances?
- Is a type of error more prevalent?

# Utilize the Data

Equipment Performance	13
Equipment Performance, Failure to Follow SOP/Procedure	1
Failure to Follow Method or Standard	7
Failure to Follow SOP/Procedure	55
Inadequate Method Validation	19
Inadequate Training	32
Inattention to Detail	65
Knowledge Gap	24
Knowledge Loss	1
Miscommunication - Internal	32
Miscommunication - Internal, No SOP / Procedure	1
No / Inadequate Contingency Plan	2
No SOP / Procedure	40
No SOP / Procedure, No Tool / Inadequate Tool	1
No Tool / Inadequate Tool	28
Process Design Flaw	10
SOP / Standard Discrepancy	12
SOP / Test Method Discrepancy	13



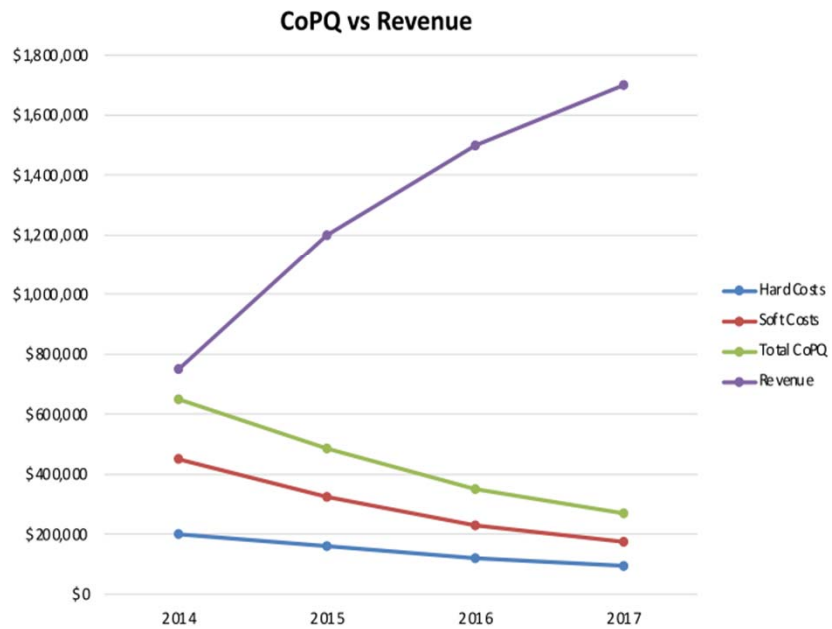
## CAPA Needs for COPQ Evaluation

- Risk based
- Timely investigation
- Appropriate use of cause analysis tools
- Capture the data
- Evaluate the data holistically for trends



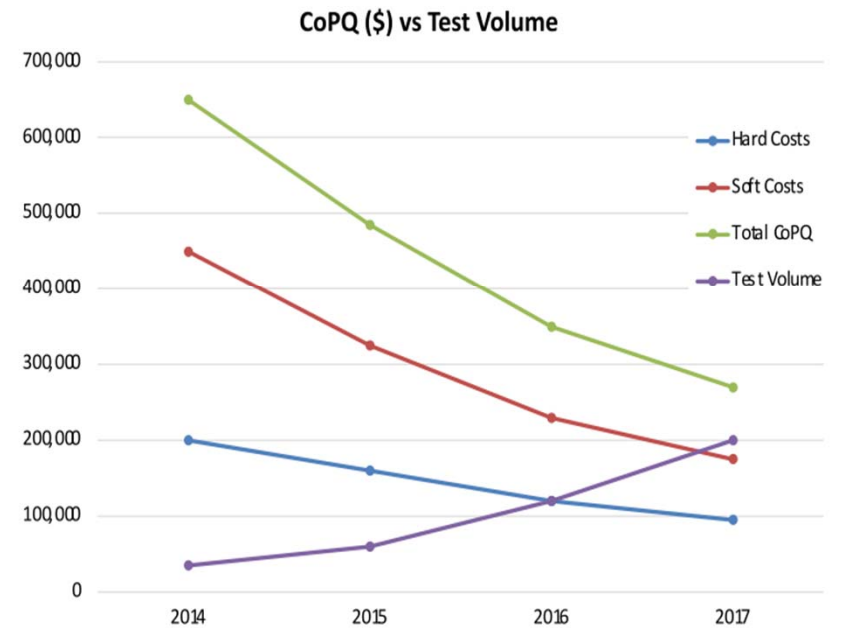
# Present COPQ Data

## Example - Presenting the CoPQ Data



2020 TNI Webinar Training Course - Siders

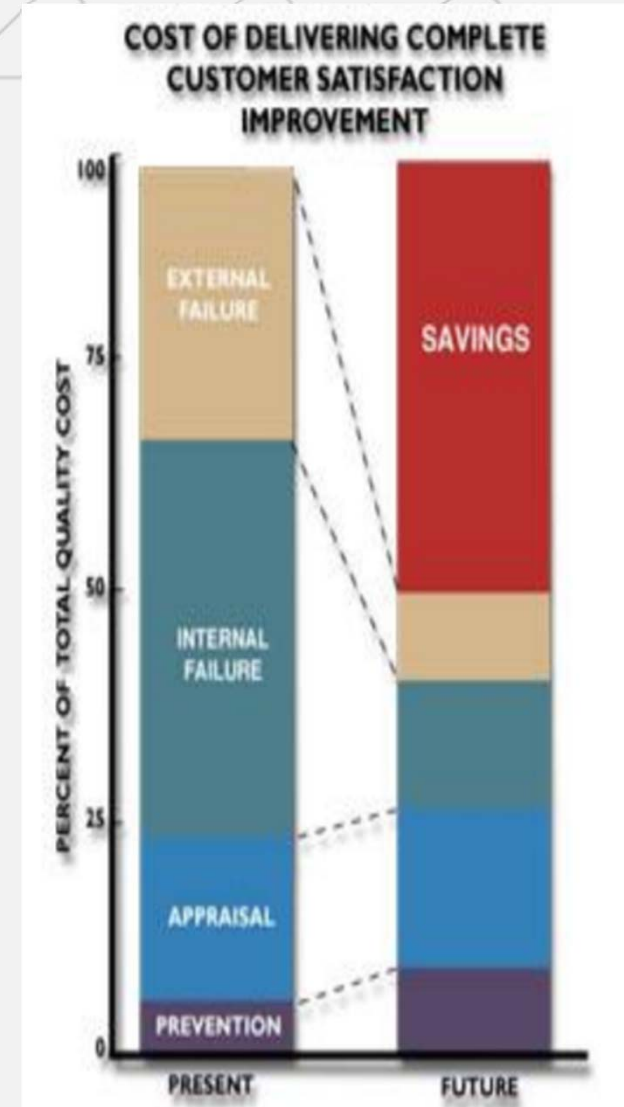
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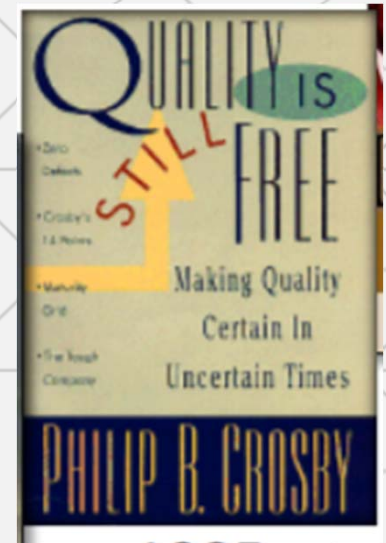
## Summary

- CAPA is a problem solving activity focused on the system.
- CAPA needs to be done effectively and timely.
- Utilize CAPA data in conjunction with other financial information to understand cost of poor quality.
- When CoPQ rises out of control, or is allowed to reach too high a level, failure to address this issue is a sign of ineffective risk management.



## References

- American Society for Quality
- Crosby, Philip. *Quality is Still Free*. McGraw-Hill. 1995
- Sower, Victor et al. *Cost of Quality Usage and its Relationship to Quality System Maturity*. *International Journal of Quality and Reliability Management*. February 2007.





## Acknowledgments

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# THANK YOU – Q&A

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