2018 NEMC
Data Quality, Management & Review Session

Integrating Data Review with Quality System Elements to Lower the Cost of Poor Quality (CoPQ)

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Presentation Objectives

- Data Review and other Quality System Elements represent the Cost of Good Quality. When effective and fully integrated into laboratory.
- How Cost of Poor Quality impacts on your laboratory and hurts the bottom-line.
- The value of quality programs & initiatives through CoPQ.

Non-conformance or "O' Crap Moment"

Dorothy Love – TNI Mentor Session

- Failure to meet a customer requirement
- Data Problem
- Systematic Error
- Investigations
- Loss of Accreditation
- Data Recalls
- Revised Test Reports
- Loss of Client

"If we learn from our mistakes, shouldn't I try to make as many mistakes as possible?"

Non-Conforming Event Management

- ***Purpose:*** Identify and characterize problems so investigations can be carried out, root causes identified, and improvement projects initiated, thus eliminating reoccurrence.
  - ✓While considering the degree of risk

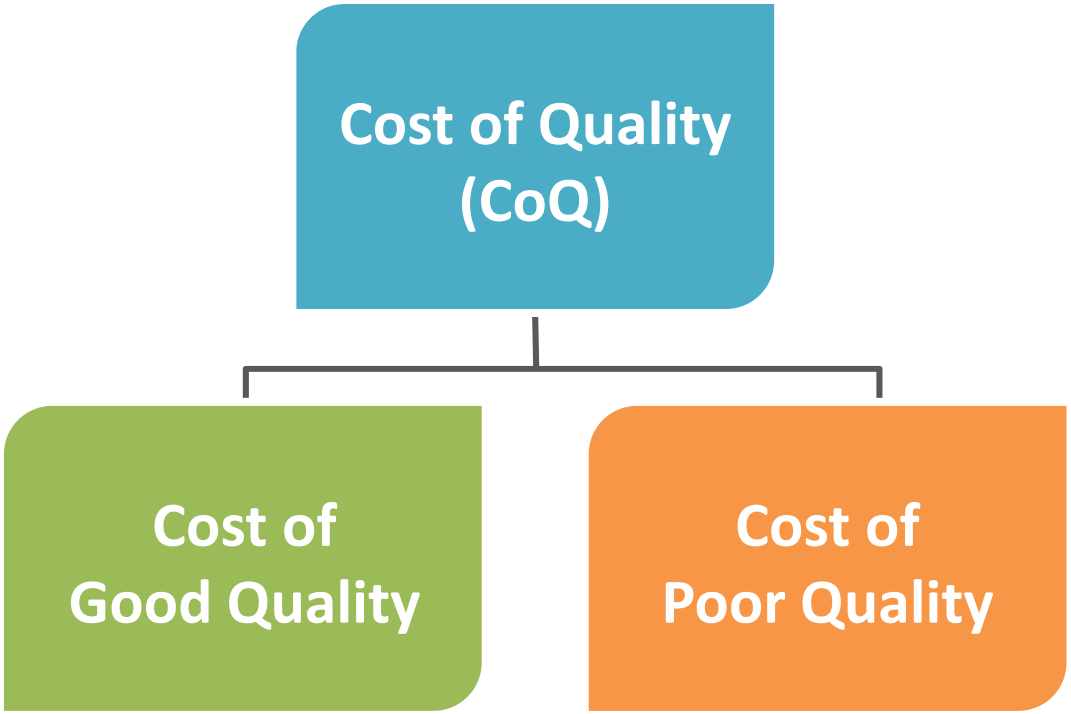
The Struggle is Real

- ***Many labs struggle with:***
- Maintaining compliance
- Enough resources
- Production pressures
- Addressing problems adequately
- Justifying expending additional resources for FTEs and software for Quality
- Effective CAPA
- Adequate Data Review
- Root Cause Analysis
- Understanding need to invest in Quality
- Perceived QA overkill

Cost of Quality

Cost of Quality

Cost of Quality = Cost of Good Quality + Cost of Poor Quality



Cost of Good Quality

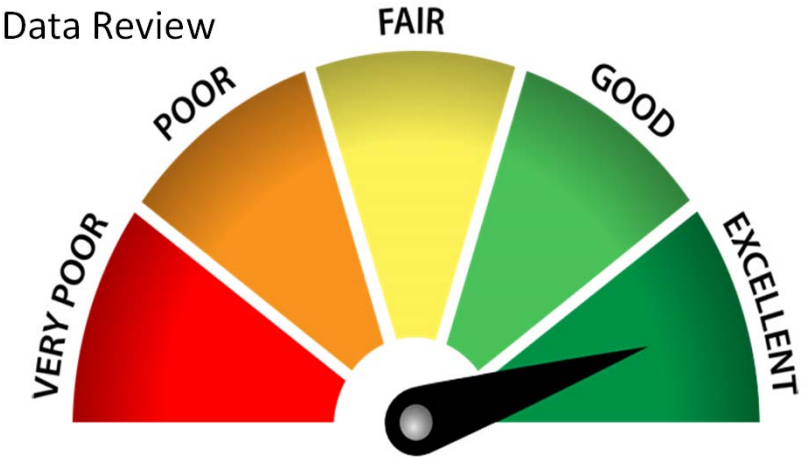
Cost of Good Quality

PREVENTION COSTS

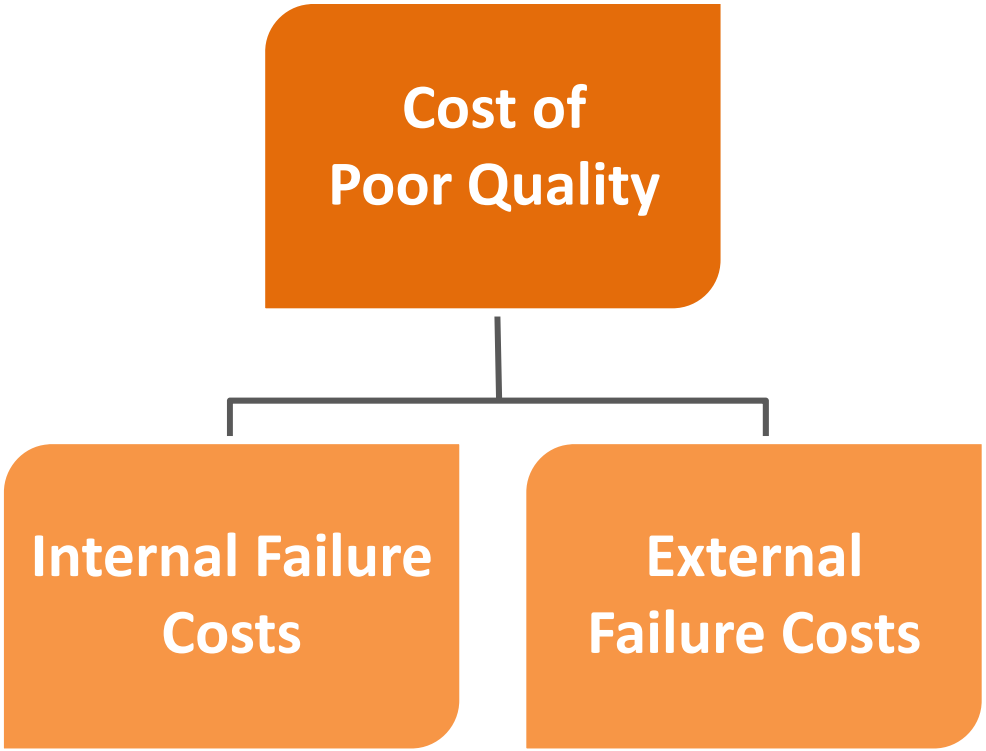
- ✓ Quality Planning
- ✓ Training
- ✓ Preventive maintenance
- ✓ Design, Implement and Maintain an effective Quality Management System
- ✓ Trend Analysis
- ✓ Quality Improvement/Risk Reduction activities aka Preventive Action
- ✓ Effective Change Management Process
- ✓ Electronic Records and Control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



Cost of Poor Quality

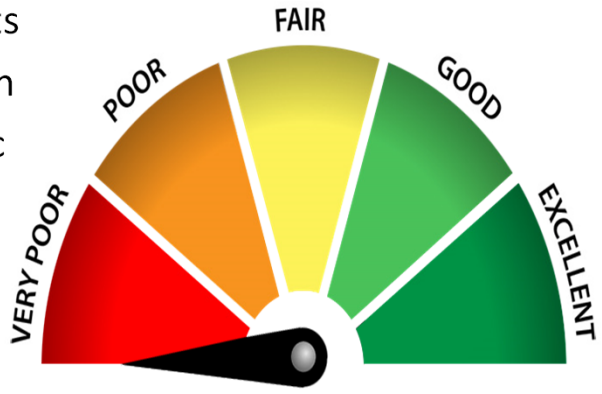
the “O’ Crap Moments” from TNI Mentor Session

INTERNAL FAILURE COSTS

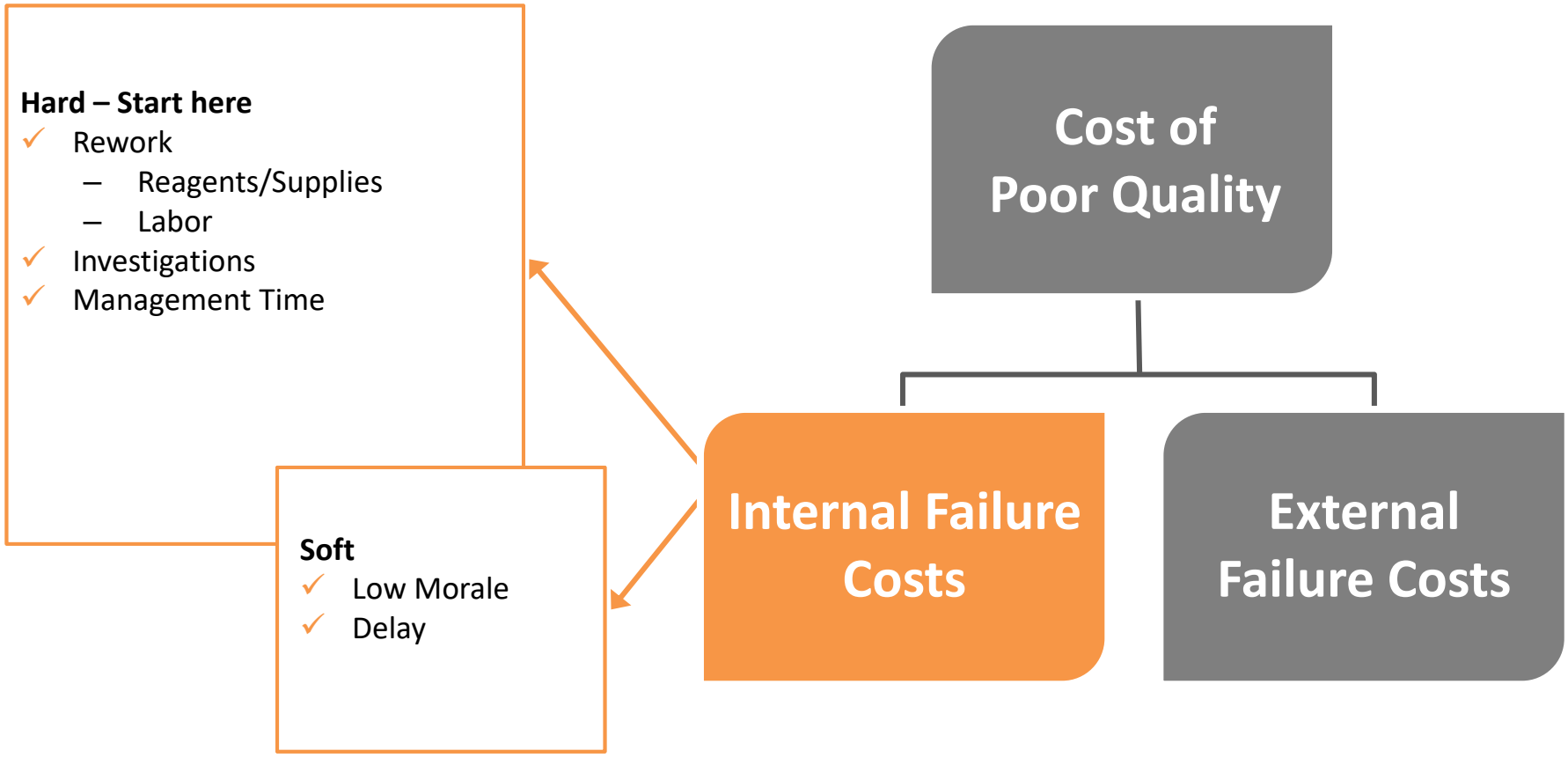
- ✓ Instrument Downtime
- ✓ Inefficiencies
- ✓ Data entry errors
- ✓ Missing samples
- ✓ Reruns
- ✓ Reagents/Supplies
- ✓ Instrument repair
- ✓ Recollected samples
- ✓ Correcting data errors
- ✓ Systematic errors
- ✓ Investigations
- ✓ Root Cause Analysis
- ✓ Corrective actions
- ✓ Management time

EXTERNAL FAILURE COSTS

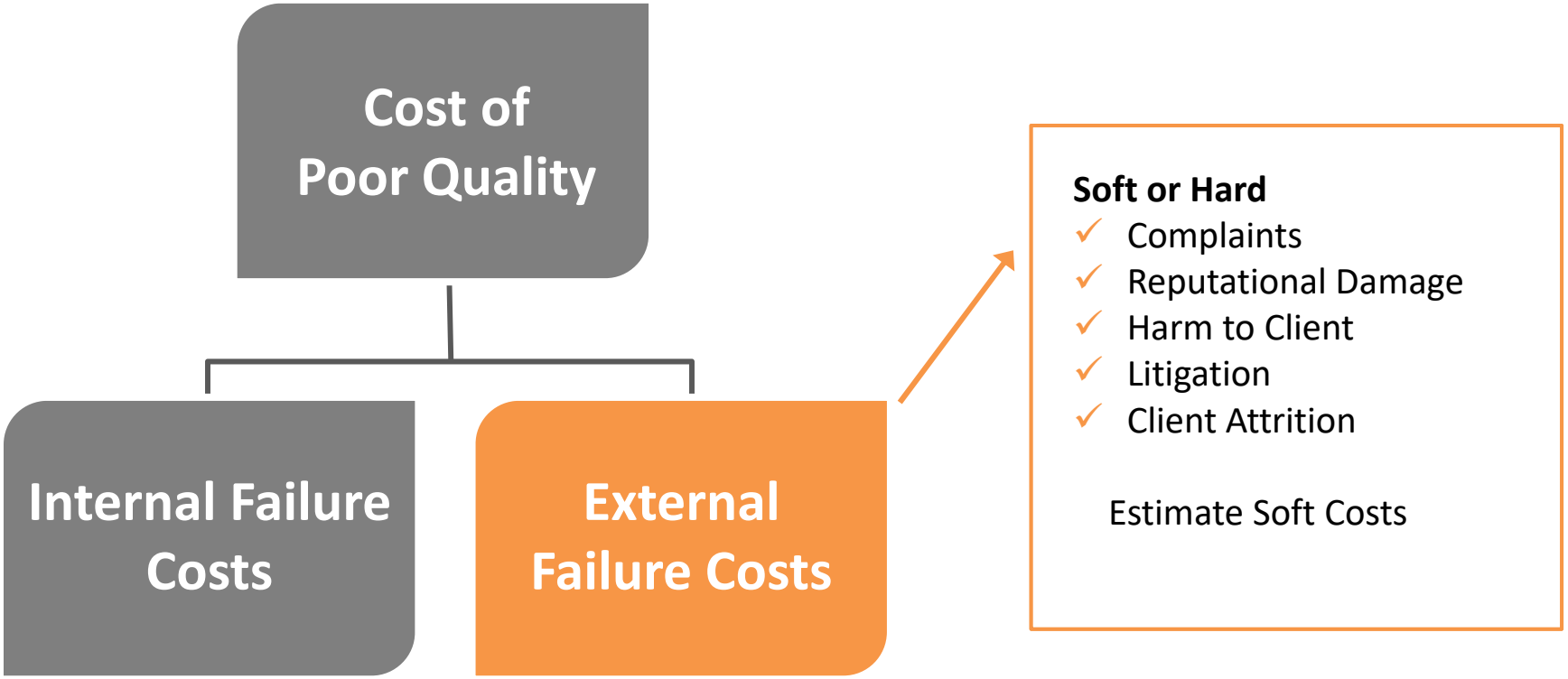
- ✓ Customer complaints
- ✓ Losing clients
- ✓ Wrong decisions made
- ✓ Missed TAT
- ✓ Harm to client’s project
- ✓ Revised reports
- ✓ Lost reputation
- ✓ Harm to public
- ✓ Lawsuits



Cost of Poor Quality – Soft vs Hard Costs



Cost of Poor Quality



Tracking CoPQ: Internal Failures – Hard Costs

Considerations	#	Units	Cost/Unit	Total
Wasted Analyst Time	2	Hours	$15.00	$30.00
Wasted Reagents	10	mL	$20.00	$200.00
SOP Revision	3	Hours	$70.00	$210.00
Management Time	3	Hours	$80.00	$240.00
Investigation	4	Hours	$50.00	$200.00
Overtime	3	Hours	$15.00	$45.00
Client Service Recovery	2	Hours	$15.00	$30.00
Rework -Failed Run	2	Runs	$100.00	$200.00
Complaint Handling	.25	Hours	$15.00	$3.75
			Total	**$1,158.75**

Tracking CoPQ – Soft Costs

via conservative estimates

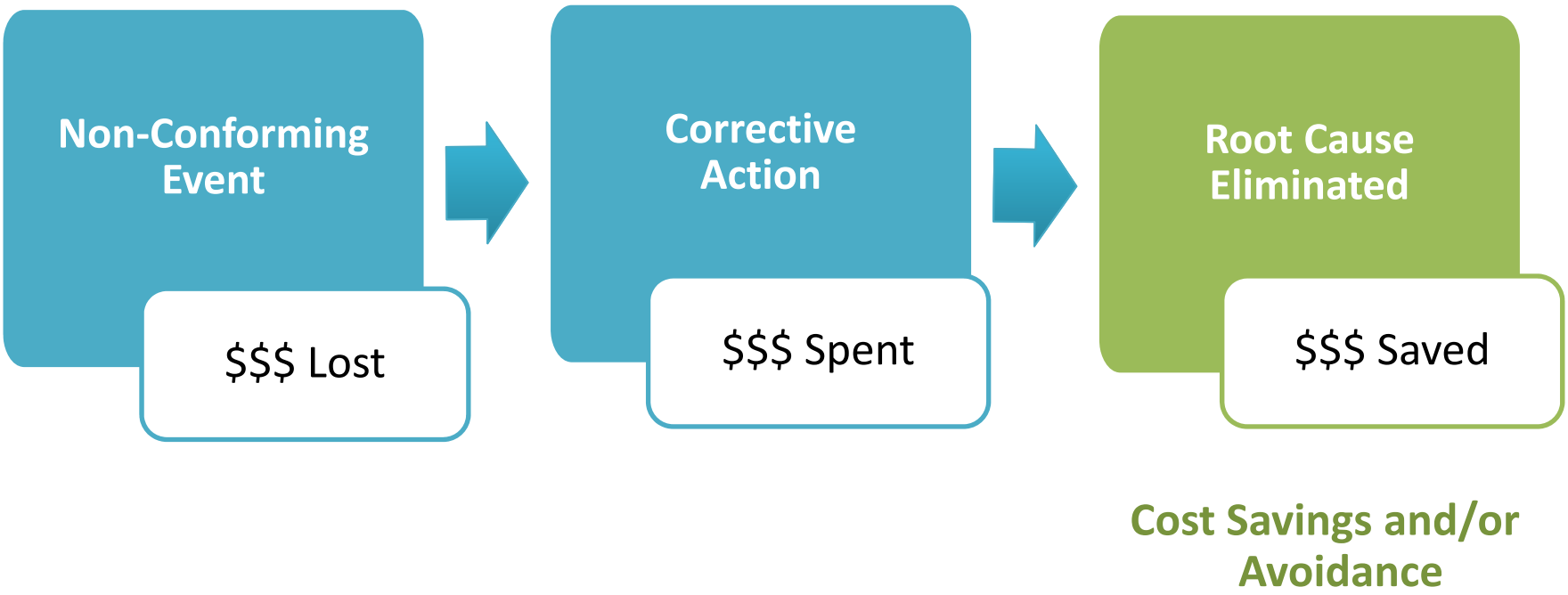
Internal Failure – Soft Costs

Considerations	$ Estimate
Low Morale	$0.00
Lost Sales	$2500.00
Equipment Downtime	$0.00
Harm to Employees	$0.00
Total	**$2500.00**

External Failure – Soft Costs

Considerations	$ Estimate
Reputational Damage	$250.00
Contractual Penalties	$1500.00
Corrected Reports	$0.00
Harm to Clients	$0.00
Total	**$1750.00**

Why does CoPQ matter?
Why does an effective and fully integrated Quality Management System matter?



Quality as a Cost Center vs Cost Savings There is Value in the Cost of Quality, including Data Review

VS

Definitions

Return on Investment (ROI)

The benefit (or return) of an investment is divided by the cost of the investment, and the result is expressed as a percentage or a ratio *(Investopedia)*

$$\text{ROI} = \frac{(\text{Gain from Investment} - \text{Cost of Investment})}{\text{Cost of Investment}}$$

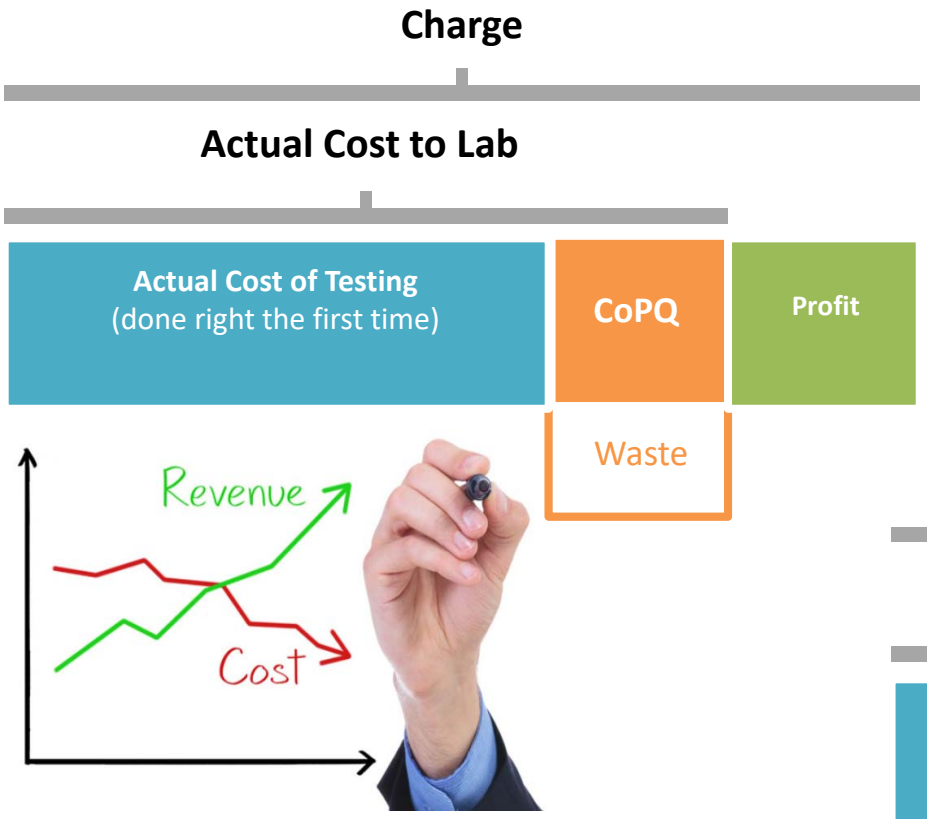
Cost Savings

Actions that lower current spending, investment or debt levels. They result in a tangible financial benefit.

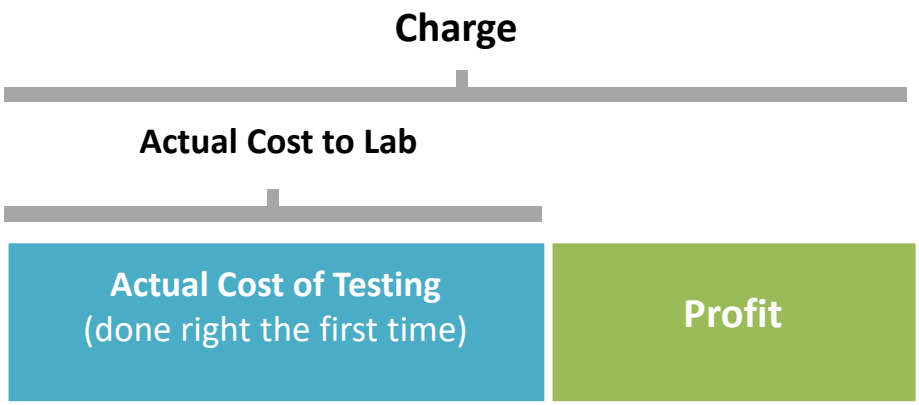
Cost Avoidance

Any action that avoids costs in the future. They represent potential increases in costs that are averted through specific preemptive actions.

Reduce CoPQ = Maximize Profits



CoPQ negatively impacts your bottom line and ***drives down profits!***



CLSI. Understanding the Cost of Quality in the Laboratory; A Report. CLSI document QMS20-R, PA: Clinical and Laboratory Standards Institute; 2014

Focus on Prevention or Lower Risk

- Eliminate problems proactively.
- Don't wait until there is a nonconformance, data is negatively impacted, money is lost or client complains or worse fires your laboratory.
- Front line employees doing the work have knowledge about things that could go wrong. If you empower your employees to report those issues and management commits to correcting them, your lab will become much more proactive and your CoPQ will be much lower.

Tip of the Iceberg

Cost of Poor Quality Calculator

Exercise: Calculating “Hard” Failure Costs

Obvious Costs: Labor, Reagent, Supplies & QC Materials

Example:

5 hours of analyst time wasted rerunning testing due to error or failed QC

5 x $24/hr = $120 = Hard internal failure cost

Exercise: Calculating “Hard” Failure Costs

Obvious Costs: Labor, Reagent, Supplies & QC Materials

Example:

1.5 vials QC material wasted due to errors or failed QC

1.5 x $100/vial = $150 = Hard internal failure cost

Example

Failing Seals

In the extractions laboratory, there are seals that are prematurely failing on instruments.

This has led to considerable CoPQ: clean up from solvents spilling on the floor, rerunning testing and significant investigation time as the cause was not known initially.

Testing was delayed by a day or longer due to rerunning samples due to these failures. It was discovered that one of the solvents being utilized was recently changed and is no longer compatible with our seals. Corrective action included an investigation into a new solvent supplier.

Example: Failing Seals

Internal Failures – Hard Costs

Considerations	#	Units	Cost/Unit	Total
Wasted Tech Time	20	Hours	$15.00	$300.00
Wasted Reagents	1	Gallons	$50.00	$50.00
Spill Kit Supplies	4	Kits	$60.00	$240.00
Occupational Health Visit	0	Visit	0	$0.00
Management Time	12	Hours	$100.00	$1200.00
Investigation	10	Hours	$50.00	$500.00
Overtime	0	Hours	0	$45.00
Client Education	0	Hours	0	$0.00
Rework -Failed Run	9	Runs	$100.00	$900.00
Complaint Handling	2	Hours	$15.00	$30.00
			Total	**$3,265.00**

Example: Failing Seals

Internal Failure – Soft Costs

Considerations	$ Estimate
Low Morale	*$0.00*
Lost Sales	*$0.00*
Equipment Downtime	*$2500.00*
Harm to Employees	*$0.00*
Total	***$2500.00***

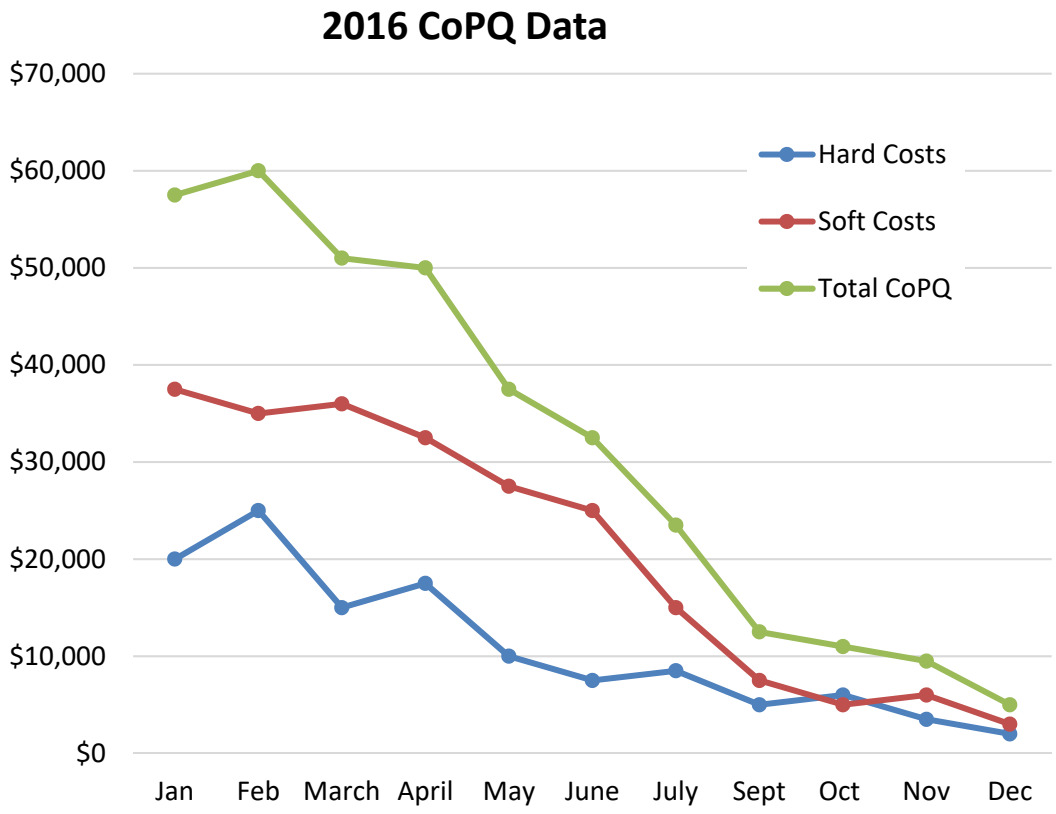
External Failure – Hard or *Soft*

Considerations	$ Estimate
Reputational Damage	*$750.00*
Litigation/Malpractice	*$0.00*
Corrected Reports	*$0.00*
Harm to Patients	*$0.00*
Total	***$750.00***

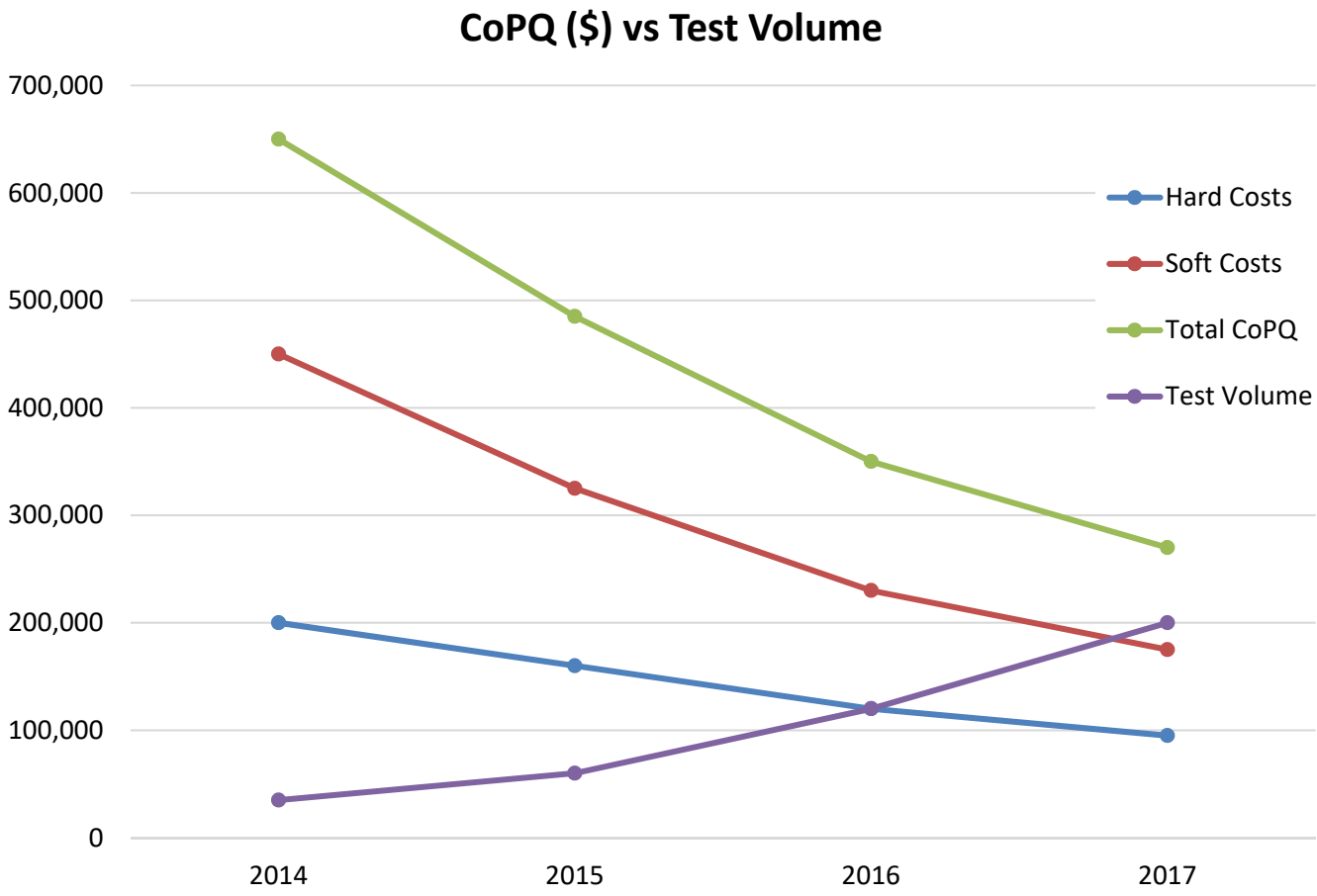
Total Hard Costs	$3,715.00
Total Soft Costs	*$3,250.00*
Total CoPQ	**$6,965.00**

Articulating the Value of Quality
Demonstrating Cost Saving and Cost Avoidance
Example - Presenting the CoPQ Data

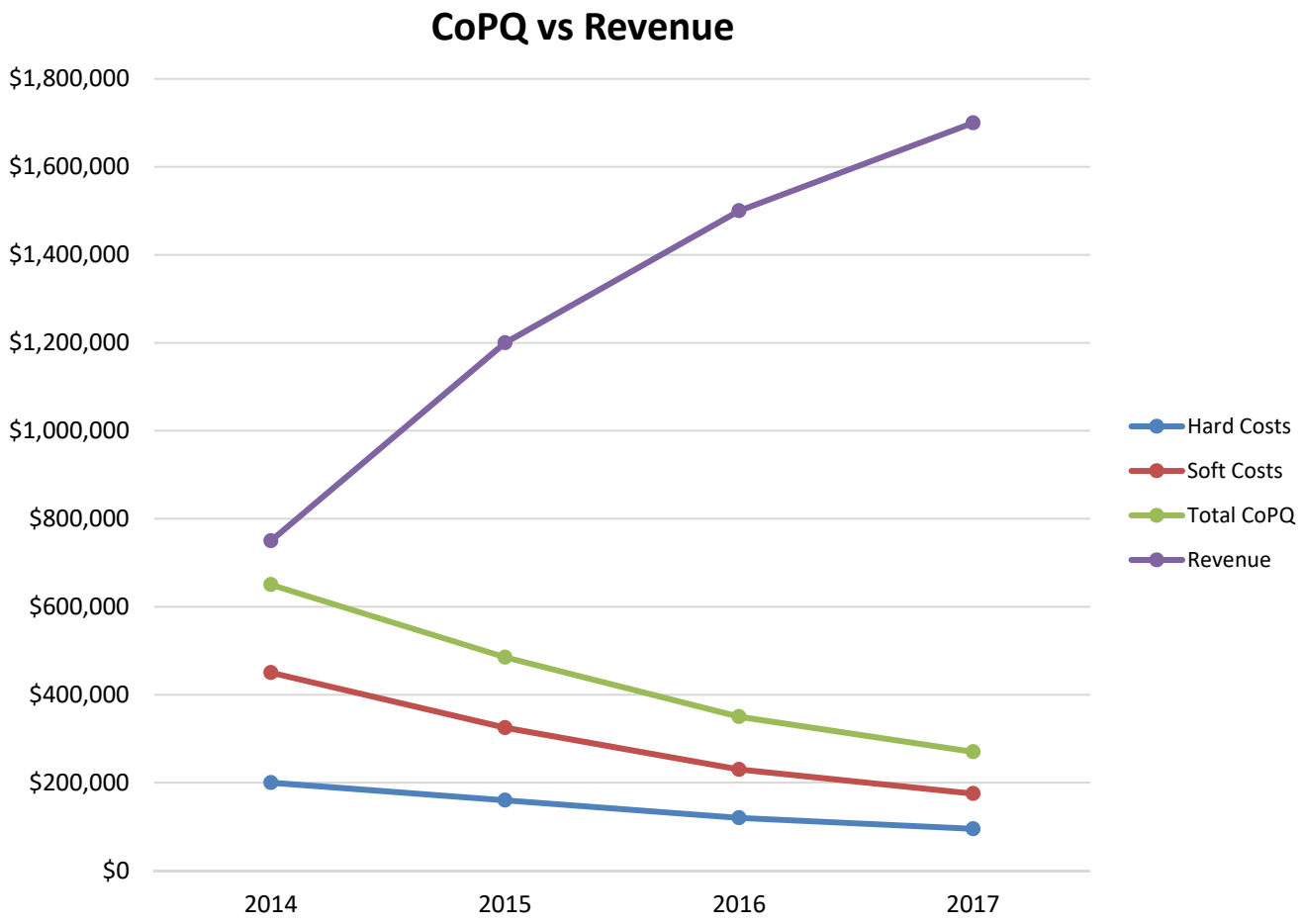
2016 CoPQ Data	
Total Hard Costs	$120,000
Total Soft Costs	$230,000
Total CoPQ	**$350,000**



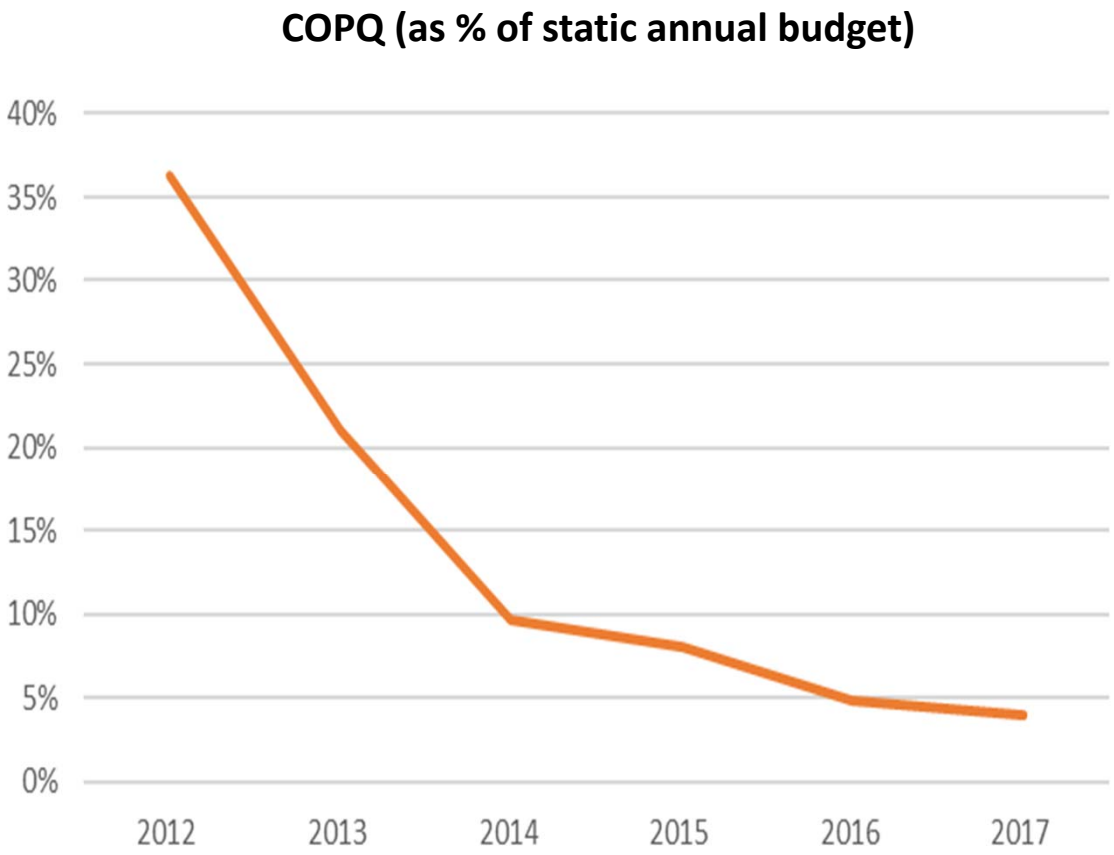
Example - Presenting the CoPQ Data



Example - Presenting the CoPQ Data



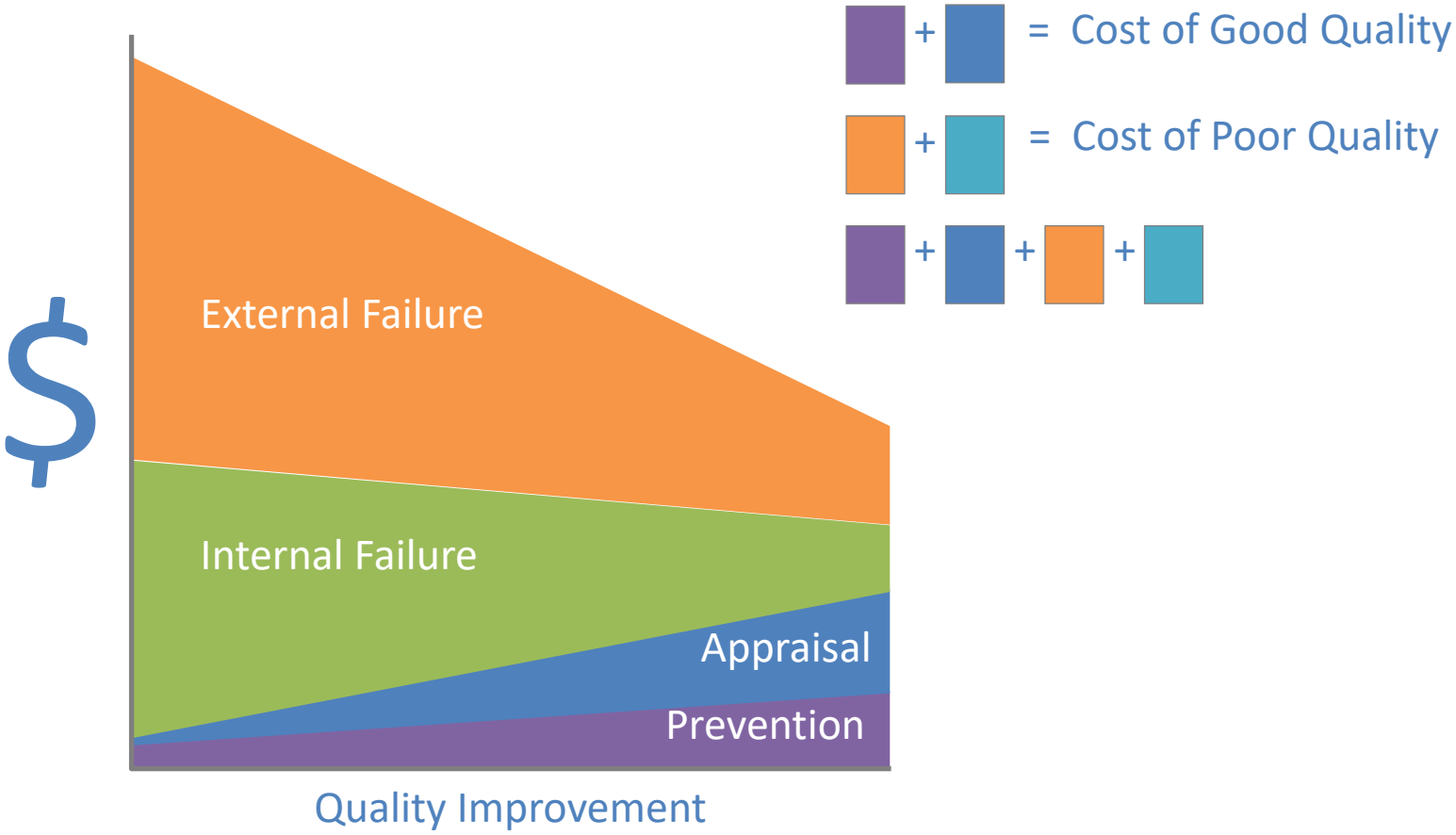
Example – Presenting the COPQ Data



2012	$2,250,000.00	36.29%
2013	$1,300,000.00	20.97%
2014	$600,000.00	9.68%
2015	$500,000.00	8.06%
2016	$300,000.00	4.84%
2017	$250,000.00	4.03%
Static Annual Budget	$6,200,000	

Typical Relationship/Progression of CoPQ

Important Diagram!



Example - Demonstrating Return on Investment (ROI)

Cost of Good Quality

Prevention

Quality 2.0 FTEs = **$150,000**

VS

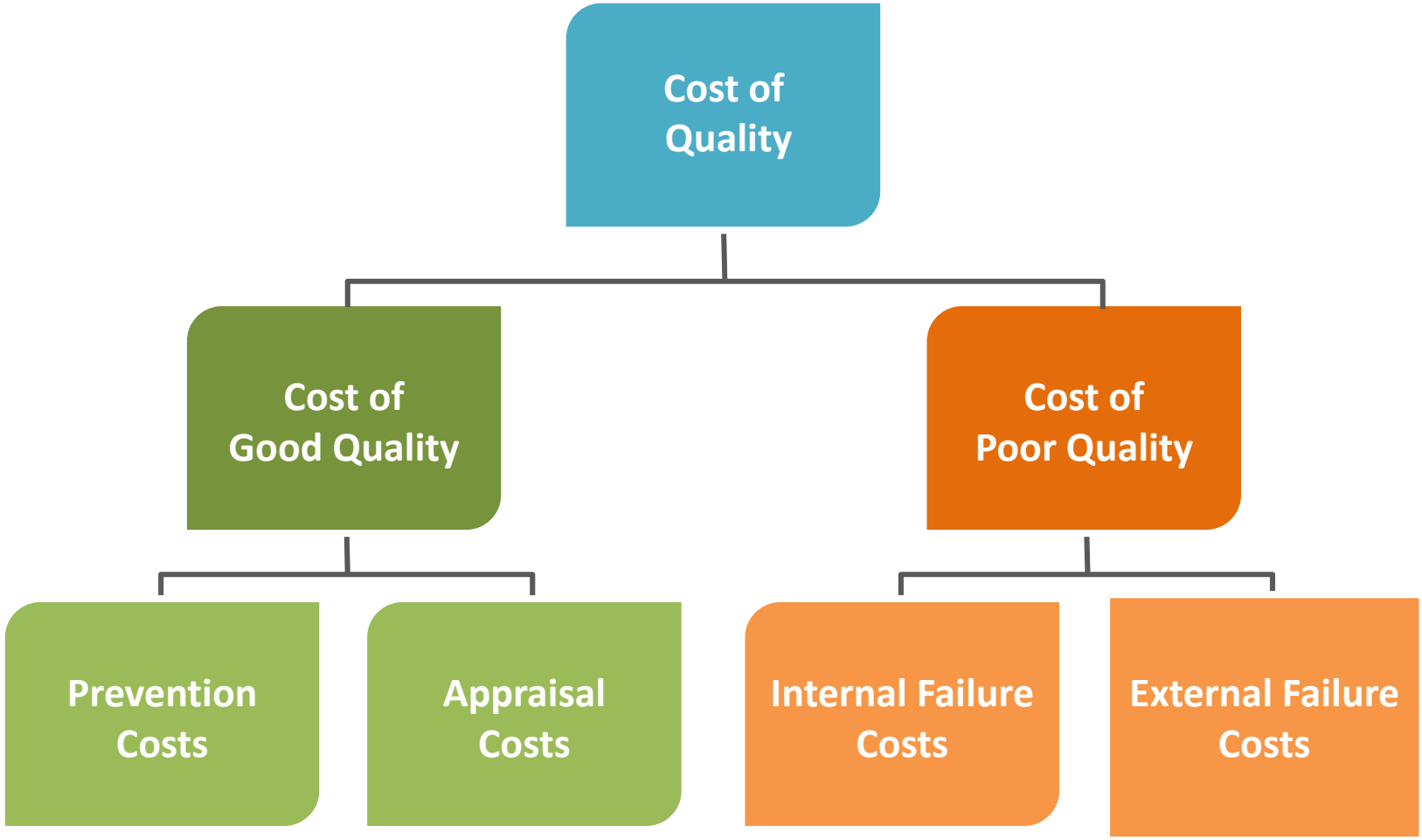
Cost of Poor Quality

Internal/External Failure Costs

~$350,000 for 2016
(very conservative estimate)

ROI in 5 months for entire year FTE devoted to quality program just considering non-conforming events

Summary: Cost of Quality Breakdown



Keep These Thoughts

- “If you don’t have the time to do it right, you must have the time to do it over.”
- If you don’t have the time to do it right,

  you must have the time to do it again,

  then do an investigation,

  a root cause analysis,

  implement corrective action, and

  follow-up with an effective check.

Thank You

QUESTIONS

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