

# **Reality Check on the True Cost of Recurring Bad Quality in Your Lab...**



- How to Find It**
- How to Fix It**
- How to Sustain the Cost Savings**

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## Fact:

“Companies rarely have a realistic idea of how much profit they are losing through poor quality.”

Schiffauerova A, Thompson T. A review of research on cost of quality models and best practices. *International Journal of Quality and Reliability Management*, Vol.23, No.4, 647-669, 2006.

## **Fact:**

**“It’s cheaper to do the job right the first time than to recover from an error.”**

**Philip Crosby**

# **A lab that didn't “get it”...**

*Baltimore Sun, August 13, 2004*

*Lab workers warned Md. General 2 years ago*

“Laboratory workers at Maryland General Hospital warned top hospital administrators and state officials in writing nearly two years ago of serious and long-standing testing problems that put patients and employees at risk...”

**...and you know the rest of  
that multi-million dollar  
fix-it story...**

# Example: Recollected samples

- ***Paid*** the direct cost for the rejected sample
  - Labor
  - Supplies (collection, computer)
- ***Lost*** the margin from the first collection
- ***Paid*** direct cost for the second sample
- ***Need*** direct cost for the next sample



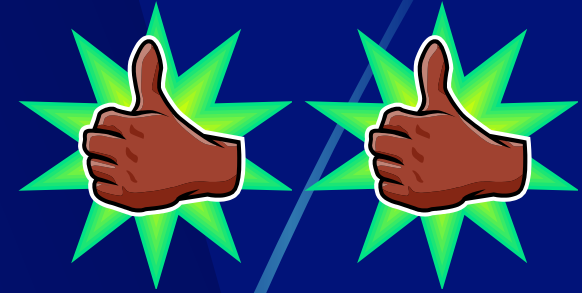
**What's the  
cost of quality  
in YOUR  
laboratory  
?**

# Four Types of Quality Costs

- Prevention
- Appraisal
- Failure
  - Internal
  - External



# Prevention Costs



- Quality planning
- Supplier capability
- Process capability
- Preventive maintenance
- Quality improvement
  - Meetings
  - Projects
  - Education
  - Training
- *Work process training*

# Appraisal Costs



- Inspections
  - Incoming
  - In-process
  - Final
- Internal Auditing
  - Sample tracing
  - Record tracing
- Competence assessment
- Equipment calibration
- Quality Control
- Proficiency testing
- Outside accreditations
- Method comparison testing

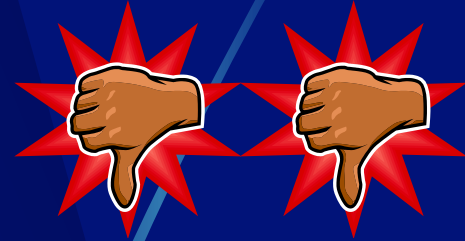
**Can you identify  
prevention and appraisal costs  
on your operating budget?**

# Internal Failure Costs (before delivery)



- Path of workflow errors and problems
- Rework
- Reinspection
- Retesting
- Repair
- Expired reagents
- Nonconforming material review
- Downgrading

# External failure costs (after customer receipt)



- Customer complaints
- Misdiagnoses
- Report recalls
- Lawsuits

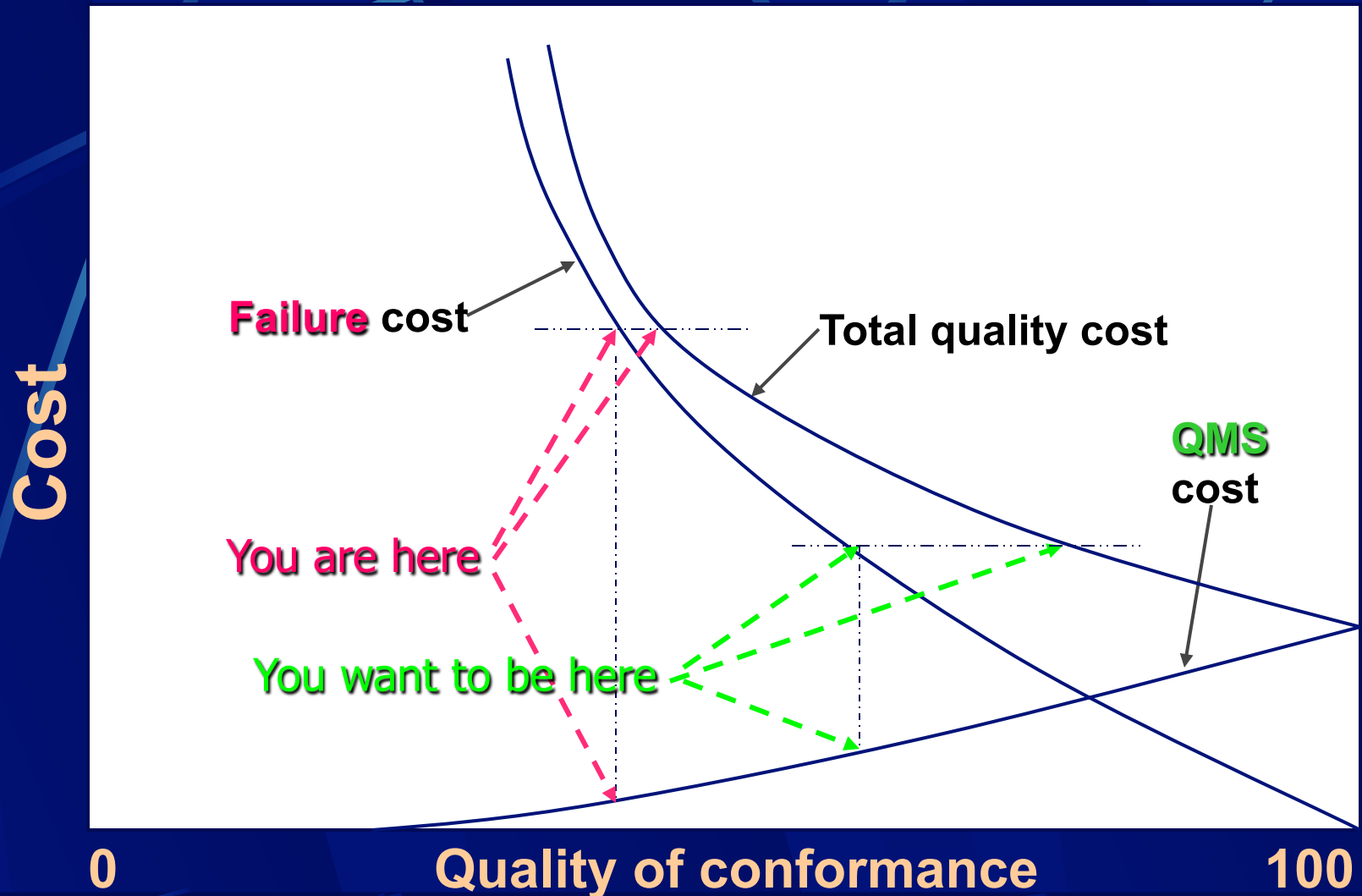
**Can you identify  
internal and external  
failure costs  
on your operating budget?**

# Cost of Poor Quality

Sigma Level	Yield	DPM	COPQ
1	31%	690,000	Not competitive
2	69.1%	308,537	Not competitive
<b>3</b>	<b>93.3%</b>	<b>66,807</b>	<b>24% to 40% of revenue</b>
<b>4</b>	<b>99.4%</b>	<b>6,210</b>	<b>15% to 25% of revenue</b>
5	99.98%	233	5% to 15% of revenue
6	99.9997%	3.4	<1% of revenue

Schiffauerova A, Thompson T. A review of research on cost of quality models and best practices. *International Journal of Quality and Reliability Management*, Vol.23, No.4, 647-669, 2006.

# The Cost of Quality



# One Hospital System's Experience

- 2 JC/CAP NPSG related to patient ID
- Goal of 50% reduction of specimen labeling errors over 18 months, through...
  - education
  - data collection and analysis
  - interhospital collaboration
- *[Every mislabeled sample needed recollection – hence, failure cost incurred]*

Reducing errors in blood specimen labeling: A multihospital initiative. Pennsylvania Patient Safety Advisory, 2011 Jun; 8{2}:47-52.

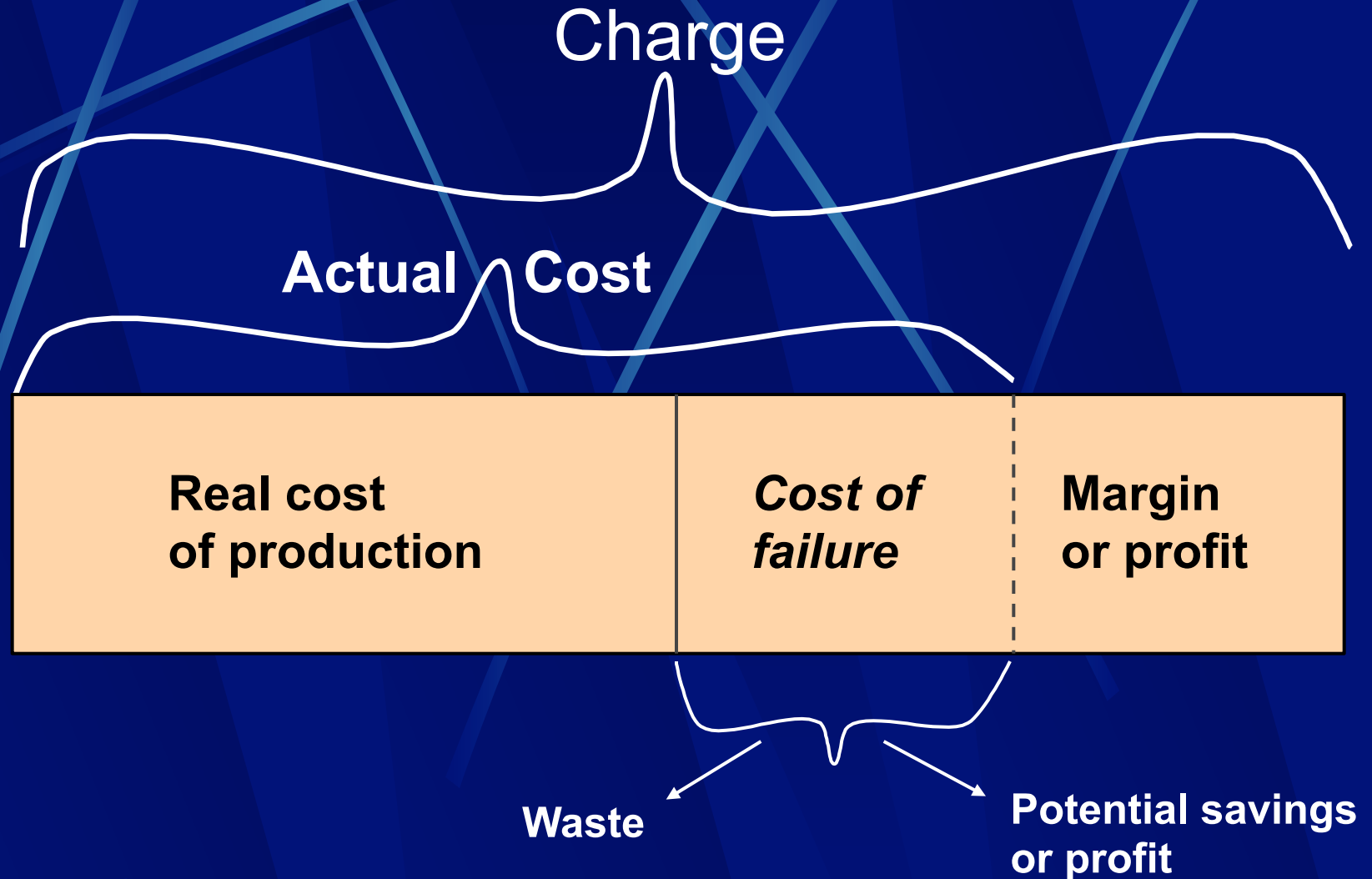
# One Hospital System's Experience 2.

- Baseline rate = 0.1 to 4.1 errors per 1000 OFE
  - With 1.3 million OFE, a range of 130 – 5330 errors
- Applying slide 7 formula:
  - at \$15.00/hr direct phlebotomy labor cost. and rate of 5 phlebotomies per hour = \$3 per phlebotomy
  - at direct supplies of about \$10 per 1-tube collection
  - assuming a margin of \$1
- Failure costs of  $\$14 + \$13 + \$13 = \$40$  each

# One Hospital System's Experience 3.

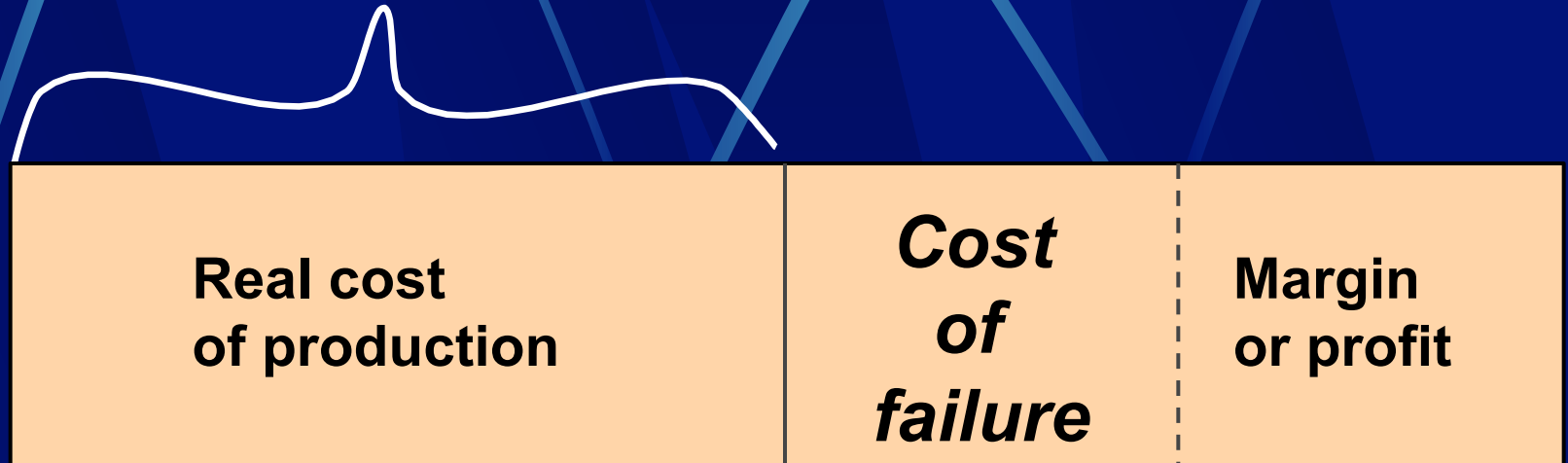
- @ \$40 failure cost per error = \$5200 - \$213,200
- A 37% statistically significant decrease in errors in the collaborative over the 18 month period
- Post intervention error rate of 0.0 to 1.3 errors
- Failure cost reduced to \$0 for one hospital!

# Total Costs



# Key to Your Lab's Survival

Reduce through better  
process management



***Eliminate THIS !!***

# Determining Failure Costs

- Use quality indicators
- Total the failure cost elements
  - direct variable costs for the failure
  - direct variable costs for the replacement
  - revenue margin foregone for the failure
  - direct variable costs used for the next sample
- Prepare failure cost reports



# Laboratory Path of Workflow Failure Costs 1.

## ● Preanalytic

- Wrong orders
- Wrong order entry
- Unacceptable samples
- Recollected samples
- Accessioning and processing errors

## ● Analytic

- Repeated tests
- Incomplete test runs (instrument issue)
- Invalid test runs (calibrator or control failures)

# Laboratory Path of Workflow Failure Costs 2.

- Postanalytic
  - Result recalls
  - Reprinted reports
  - Redelivered reports
  - Remedial action on occurrences
  - Complaint resolution
  - Lawsuits

# Management Infrastructure Failure Costs

- Forgone revenue from lost customers
- Lab safety accidents
- Staff turnover and replacement
- Expired reagents and supplies
- Overstock
- Equipment downtime
- LIS downtime
- TAT outliers
- Resolving document problems
- Confidentiality violations
- Resolving system interface issues
- Recurring NCE “corrective actions”

# Hidden Quality Costs

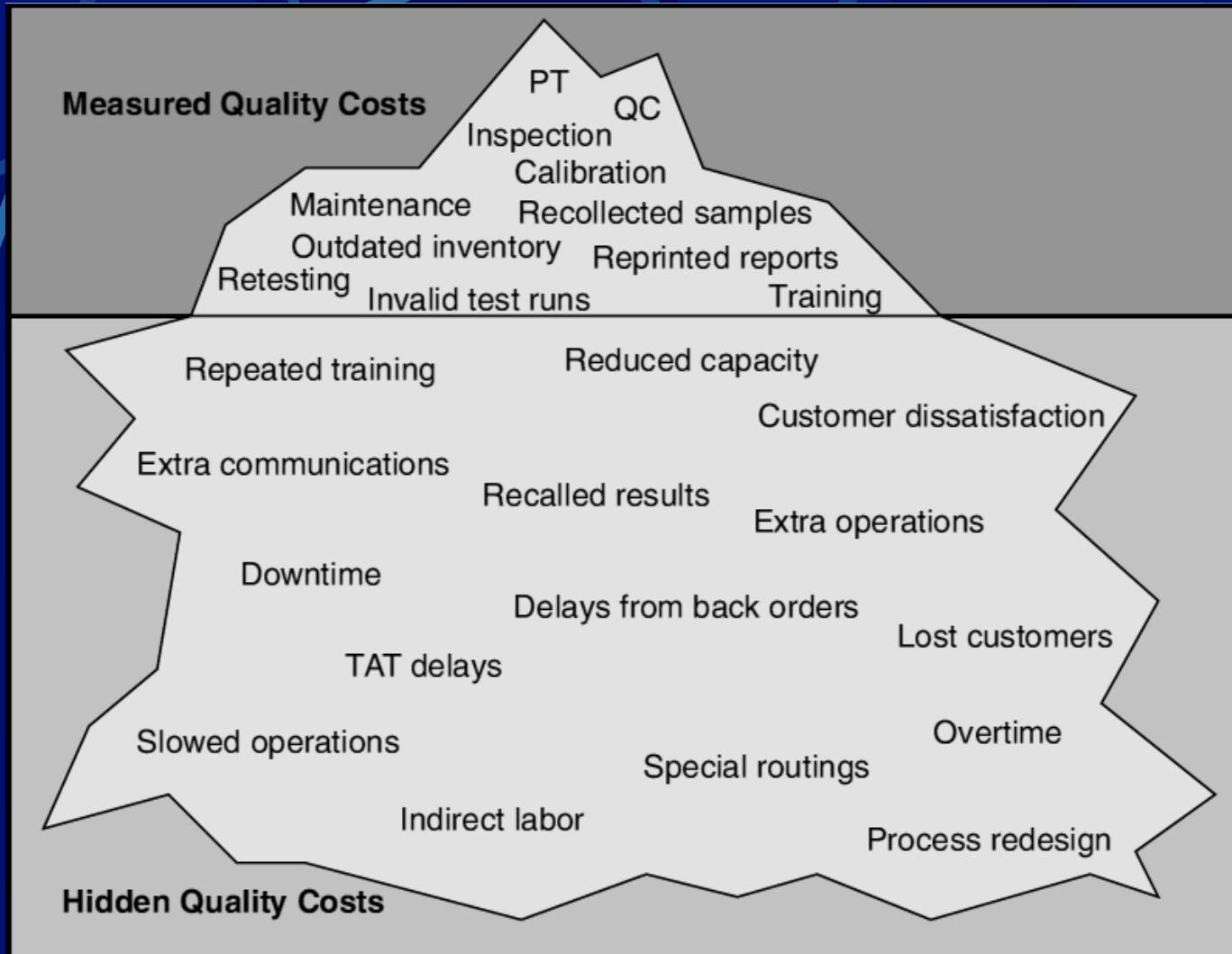


Fig. 13-3 with permission, from Harmening's *Laboratory Management Principles and Processes*, 3rd ed., 2012. 25

# Quality-Based Costing Identifies

- Non-value-added activities to be eliminated
- Waste caused by poor quality
- Areas where financial performance can be improved
- Cost justification for needed corrective actions



# Ways to Eliminate Failure Costs 1.

- Streamline processes

- Process analysis and flowcharting
- Six Sigma defect reduction, Lean, and 5S
- Automation, where possible

- Apply *prevention*

- Design Failure Modes and Effects Analysis
- Process validation – not only test methods!

# Ways to Eliminate Failure Costs 2.

- Reduce turnover
  - Training programs for *all* staff
  - Effective training
  - Effective competence assessment
- Develop and use *effective* documents
  - Process-based
    - flowcharts
    - work instructions and job aids

“For organizations that do not have a formal effort to reduce chronic and sporadic problems, operations managers often spend 30% of their time on troubleshooting.

For the supervisors reporting to these managers, the time consumed frequently exceeds 60%.”

Joseph Juran

# What's the cost of quality in YOUR laboratory ?

Good quality

Bad quality

# Take Home Message #1

**For each failure  
there is a root cause.**

**Causes are preventable.**

**Prevention is always cheaper.**

# Take Home Messages

## 2-8

- Know the 4 types of quality costs – P, A, IF, EF
- Identify P and A costs on your lab's budget.
- Calculate IF and EF costs and prepare reports
- Invest in P and A to ↓ IF + EF
- Use RCA and CI to further ↓ A
- The language of the C-Suite is \$\$\$\$\$\$

# **Final Message**

**“Costs do not exist to be calculated.**

**Costs exist to be reduced.”**

**Taiichi Ohno**

# Additional Resources

- Schiffauerova A, Thompson T. A review of research on cost of quality models and best practices.  
*International Journal of Quality and Reliability Management*, Vol.23, No.4, 647-669, 2006.
- Reducing errors in blood specimen labeling: A multihospital initiative. Pennsylvania Patient Safety Advisory, 2011 Jun; 8{2}:47-52.
- Berte LM. *The Cost of Quality*. In: *Harmening DM. Laboratory Management Principles and Processes*, 3<sup>rd</sup> ed. St. Pete, FL, DH Publishing and Consulting, Inc. 2012.
- Wood DC, mng ed. *Principles of Quality Costs*, 4<sup>th</sup> ed. Milw, WI: ASQ Quality Press, 2013.
- Wood DC. *The Executive Guide to Understanding and Implementing Quality Cost Programs*. Milw, WI: ASQ Quality Press, 2007.