LABORATORY QUALITY COSTS: GOOD, BAD, AND QC

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***2**do. Congreso Internationale para accreditacion en el sector salud*
24 y 25 de agusto 2017 World Trade Center CDMX

Laboratories and Costs

"***Companies*** rarely have a realistic idea of how much profit they are losing through poor quality."
"***Companies*** that adopt a cost of quality concept are successful in reducing failure cost and improvi quality for customers."

Laboratories are businesses, therefore these
situations are no different for laboratories – or for all of health care!

What to Do?

- ***Learn*** about quality costs
- ***Identify quality costs*** types on your laboratory's budget
- ***Gather data*** to defend protecting all the costs that support good quality

Quality Costs Include Those For:

- ***Preventing problems*** in laboratory services
- Measuring, controlling, and/or ***inspecting quality levels***
- ***Failing to accomplish*** *desired quality levels*
- ***Any cost*** expended ***when quality is less than what is needed***

Types of Quality Costs

Prevention

Appraisal

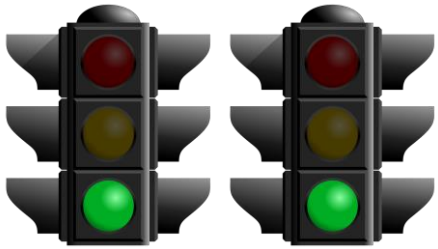
Failure

Internal

External

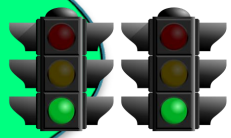
It’s cheaper to do the job right the first time than to recover from an error.

Prevention Costs



- For laboratory activities specifically ***designed to prevent poor quality*** in laboratory services
- For activities that ***prevent problems, errors, or waste*** from ***oc***curring
- ***Not*** costs incurred to keep a problem or error from ***re***curring!

Prevention



- ***Preventive maintenance***
  Maintaining your lab's instruments and equipment according to the manufacturer's schedule ensures reliable performance
- ***Quality planning***
  As the old Army saying goes, "Prior planning prevents poor performance!"
- ***Work Process Training***
  An effective new employee training program can prevent downstream errors
- ***Initial competency assessment***
  Ensures new/changed work is performed competently
- ***Quality improvement projects***
  Time spent in quality education, meetings, and projects is labor well spent

Appraisal Costs

- For ***evaluating*** quality of work ***after*** it has been performed

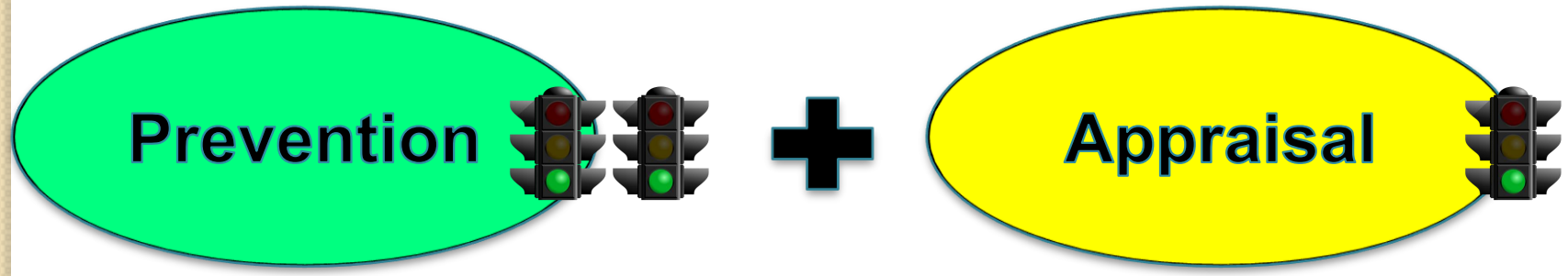
- For measuring, evaluating, and auditing
  to ***ensure conformance to requirements***

- To ***"catch and correct" problems and errors before harm*** to laboratory users and patients

Appraisal

- ***Ongoing competency assessment***
  Ensures staff maintains competence
- ***Calibration***
  Ensures accuracy of measuring equipment
- ***Inspections of samples and reagents***
  Ensures quality of inputs to testing methods
- ***Quality Control***
  Ensures that testing methods are working and results are valid
- ***Proficiency testing***
  Ensures method performance compares to peers
- ***External accreditations***
  Ensures lab performance to minimum standards

Types of Quality Costs



These costs ***support good quality***!

Educate and justify to retain these costs.

Reductions here will lead to problems.

Role of QC

- ***QC Program***: Overall policy and process for all laboratory analytes

- ***QC Plan***: Chosen levels and numbers of controls and frequency of testing QC materials for each analyte

- ***QC Materials***: Prepared or purchased materials with known quantity values for specific analytes

Make or Buy QC Materials? 1.

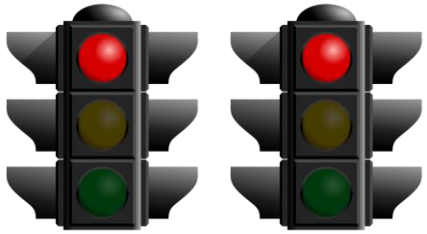
Depends on:

- Available resources for the costs of each
- Advantages vs disadvantages for each
- Need for laboratory developed tests
- Ability to save cost without sacrificing the quality of the QC material

Make or Buy QC Materials? 2.

Whichever is chosen,
this appraisal cost supports good quality!

Failure Costs

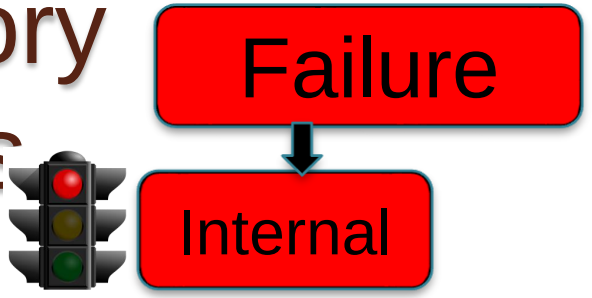


- Services that ***do not meet quality requirements the first time*** and usually need rework or correction
- ***Internal*** failure costs
  - Caught and corrected inside the laboratory
    before delivery of results or reports
- ***External*** failure costs
  - Detected outside the laboratory by users who receive faulty results, reports, or other services

Poor Quality is NOT Free!

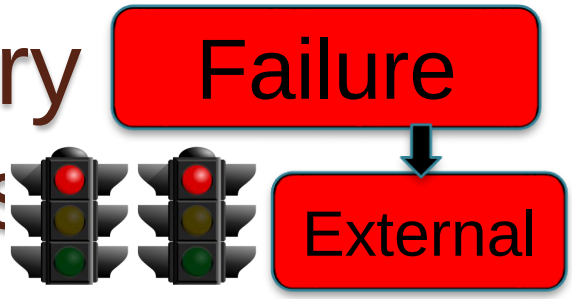
Every time work is redone, the cost of quality increases!

Examples of Laboratory ***Internal*** Failure Costs



- ***Sample problems***
  Received samples do not meet acceptance criteria and need recollection
- ***Invalid instrument runs***
  QC or calibration is out of control and results cannot be released
- ***Expired reagents or materials***
  Are not to be used in phlebotomy or
- ***Anything that causes delays in turnaround time***
  - Rework
  - Retesting
  - Repair
  - Downtime

Examples of Laboratory ***External*** Failure Costs



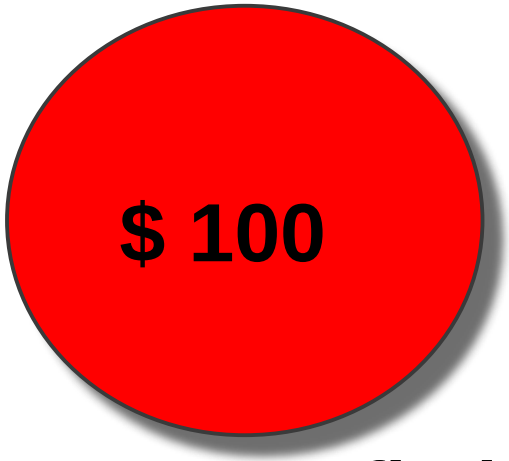
- ***Customer complaints***
  Dissatisfaction reported by any laboratory customer, user, client, or patient

- ***Report recalls***
  Erroneous results are corrected with resulting consequences

- ***Misdiagnoses***
  The cost of not receiving needed treatment and the cost of receiving treatment erroneously – not including patient distress

- ***Lawsuits***
  Uncommon, but very costly for whatever reason

Comparative Cost of Quality

Prevention	Appraisal	Failure
		
Defect prevention efforts	***Inspection and testing*** to catch and correct defects	***Customer finds defects*** or is dissatisfied with services

What is the cost of quality in YOUR laboratory?

Understanding Failure Cost Elements

Common Activities	Done Correctly, the First Time	Additional Work Due to Process Failure	Possible Additional Work for the Failure
Discovery of failure (NCE)		X	
Immediate action		X	
Preexamination	X	Depends on failure	
Examination	X	Depends on failure	
Postexamination	X	Depends on failure	
Investigation		X	
Root cause analysis			X
Corrective action			X
Report completion		X	X

Laboratory's budgets do not have a "Failure Costs" category – the expense is already included in the current operational performance.

Abbreviation: NCE, nonconforming event.

Understanding Failure Cost Elements

Common Activities	Done Correctly, the First Time	Additional Work Due to Process Failure	Possible Additional Work for the Failure
Discovery of failure (NCE)		X	
Immediate action		X	
Preexamination	X	Depends on failure	
Examination	X	Depends on failure	
Postexamination	X	Depends on failure	
Investigation		X	
Root cause analysis			X
Corrective action			X
Report completion		X	X

CALCULATING COSTS: THE BASIC WORKSHEET

Costs calculated are only for the failed process.

Do not include the cost of initial performance.

The worksheet can be used to:

- **Calculate** the exact cost of a failure or group of failures.
- **Estimate** the cost of a failure or group of failures.
- **Communicate** the financial effect of a failure or group of failures.

Reagents & Materials Costs	Reagents & Materials Item Description	Item Cost (per item)	Quantity Used	Total
	Item #1			$ -
	Item #2			$ -
	Item #3			$ -
	Item #4			$ -
	Item #5			$ -
	Item #6			$ -
	Item #7			$ -
	etc			$ -
	Reagents & Materials Subtotal			$ -

Labor Costs	Labor Item Description	Labor Cost (per Hour)	Portion of Hour in Tenths	Total
	Job title #1 (Discover)			$ -
	Job title #2 (Investigate)			$ -
	Job title #3 (Repeat Process)			$ -
	Job title #4 (Follow Up)			$ -
	etc			$ -
	Labor Subtotal			$ -

Total Costs	Cost Description	Additional Applied Factor		Total
	Basic Failure Cost			$ -
	Lost Revenue Cost	Estimated Cost:		$ -
	Lost Opportunity Cost	Estimated Cost:		$ -
	Total Failure Cost			**$ -**

When Calculating a Process Failure

- First sample collection or test run is an expected cost, included in the budget for providing the service.
- Most of the same initial costs are expended again; however, these are considered failure costs.
- Failure costs add expense to an

- *Lowest cost to perform a process is to do it correctly the first time.*
- For every repeated process, the available funds for “doing it right the first time” shrink, leading to higher expenses than budgeted.

Calculating Reagents and Material Costs for a Failed Instrument Examination

Reagents & Materials Costs	Reagents & Materials Item Description	Item Cost (per item)	Quantity Used	Total
	QC materials	$ 0.30	3	$ 0.90
	Test reagents	$ 1.25	35	$ 43.75
	Instrument supplies	$ 0.15	38	$ 5.70
	Reagents & Materials Subtotal			$ 50.35

NOTE: This example is not meant to be all-inclusive or representative of any specific laboratory; it is only an illustration of how a failed instrument examination calculation could be derived.

- **Reagents and Materials**: List each reagent and material used (individually when possible) for *repeating* the failed process (eg, gloves, disposable tubes, QC products).
- **Item Cost:** List the cost of each reagent and material.
- **Quantity Used**: List the number of items used.

Calculating Labor Costs

Labor Costs	Labor Item Description	Labor Cost (per Hour)	Portion of Hour in Tenths	Total
	Testing personnel time to perform basic troubleshooting	$ 21.00	0.5	$ 10.50
	Supervisory time to provide additional troubleshooting and documentation of resolution	$ 32.00	0.3	$ 9.60
	Testing personnel time to repeat 35 patient specimens	$ 21.00	0.2	$ 4.20
	Supervisory time to review actions	$ 32.00	0.1	$ 3.20
	Labor Subtotal			$ 27.50

- **Labor:** List each job title involved in the failed process. Include anyone involved in the initial discovery, investigation, repeated process, and follow-up.
- **Labor Cost:** List the person's wage per hour, or an average wage per hour, for that job classification. Exclude benefit costs.
- **Portion of Hour in Tenths:** List the amount of time spent in tenths of an hour—six minutes equals 0.1 hour.

Calculating Total Costs

Total Costs	Cost Description	Additional Applied Factor		Total
	Basic Failure Cost			$ 77.85
	Lost Revenue Cost	Estimated Cost:	$ 350.00	$ 350.00
	Lost Opportunity Cost	Estimated Cost:		$ -
	Total Failure Cost			**$ 427.85**

- **Lost Revenue Cost:** The organization's accounting function usually defines how to use section.

  NOTE : Some accountants have effectively argued that because the resources from the second effort are unable to produce additional revenue, the lost revenue should be included in the failure cost calculation.

- **Lost Opportunity Cost:** The organization's accounting function usually defines how to use section.

  NOTE: Some accountants have effectively argued that because resources from the second effort are taken from the total approved budget, when the expected work volume for the original budget is realized, an over budget situation results, with the extra funds for the failures "borrowed" from other resources.

Quality Quote

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

Taiichi Ohno

Quality Cost in YOUR Laboratory

- ***Identify*** prevention and appraisal costs on your laboratory's documented budget
- ***Identify*** your laboratory's most common nonconforming events such as QC failures, audit findings, PT failures, etc.
- ***Calculate*** a representative failure cost for each type of nonconforming event
- ***Improve*** processes to reduce failures and their wasted resources

Valuable Resource!

QMS20-R 2014

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