Cost of Quality for Lab Leaders: How to Recognize and Eliminate Sources of Recurring Bad Quality in Your Lab

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Fact:

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

Fact:

“Companies that adopt a cost of quality concept are successful in reducing failure cost and improving quality for customers.”

Premise:
Laboratories are businesses; therefore, we have no reason to believe these situations are any different for laboratories... or for all of healthcare!
Fact:

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

Philip Crosby
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.
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

<table>
<thead>
<tr>
<th>Sigma Level</th>
<th>Yield</th>
<th>DPM</th>
<th>COPQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>31%</td>
<td>690,000</td>
<td>Not competitive</td>
</tr>
<tr>
<td>2</td>
<td>69.1%</td>
<td>308,537</td>
<td>Not competitive</td>
</tr>
<tr>
<td>3</td>
<td>93.3%</td>
<td>66,807</td>
<td>24% to 40% of revenue</td>
</tr>
<tr>
<td>4</td>
<td>99.4%</td>
<td>6,210</td>
<td>15% to 25% of revenue</td>
</tr>
<tr>
<td>5</td>
<td>99.98%</td>
<td>233</td>
<td>5% to 15% of revenue</td>
</tr>
<tr>
<td>6</td>
<td>99.9997%</td>
<td>3.4</td>
<td>&lt;1% of revenue</td>
</tr>
</tbody>
</table>
Comparative Cost of Quality

Prevention

$1
Defect prevention efforts

Appraisal

$10
Inspection and testing to catch and correct defects

Failure

$100
Customer finds defects or is dissatisfied with services
Failure cost as a function of detection point in laboratory processes

The Cost of Quality

## Data from Industry

<table>
<thead>
<tr>
<th>Industry</th>
<th>COQ Basis</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telecom</td>
<td>23% ↓ 17% TOC</td>
<td>Productivity ↑ 26%</td>
</tr>
<tr>
<td>Coatings</td>
<td>4.1% ↓ 2.5% Sales</td>
<td>ROI = 1 year</td>
</tr>
<tr>
<td>Electronics</td>
<td>35% ↓ 8% TOC</td>
<td>Productivity ↑ 25%</td>
</tr>
<tr>
<td>AC / Refrig</td>
<td>13.5 ↓ 3.7% Sales</td>
<td>Factory failures ↓ 96%</td>
</tr>
<tr>
<td>Software</td>
<td>65% ↓ 15% Project</td>
<td>Rework 40% ↓ 6% Payoff = 7.5x Productivity ↑ 170%</td>
</tr>
</tbody>
</table>

One Hospital System’s Experience 1.

- 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]

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

Charge

Actual Cost

Real cost of production

Cost of failure

Margin or profit

Waste

Potential savings or profit
A Simple Solution?

Yes!

A systematic approach to quality costs!
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”
Sample Cost Structure for one failure

<table>
<thead>
<tr>
<th>$$ amount</th>
<th>Initial</th>
<th>Repeat</th>
<th>Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Margin (profit) <em>lost</em></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected return <em>lost</em></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administration costs</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fixed / miscell. cost</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirect labor cost</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indirect materials cost</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Direct labor cost</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Direct materials cost</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Hidden Quality Costs

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Fig. 13-3 with permission, from Harmening’s *Laboratory Management Principles and Processes*, 3rd ed., 2012.
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
“Costs do not exist to be calculated. Costs exist to be reduced.”

Taiichi Ohno
Ways to Eliminate Failure Costs

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

2. 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
  - 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?
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
- Further investment in P (ie, CI) further ↓ A!
- The language of the C-Suite is $$$$$$$
  - *Talk their language to get attention!*
- No laboratory COQ model and software exists!
Additional Resources


