Understanding Why "PROCESS" is the Essential Key for Lean and Other Quality Tools to Continually Improve Your Lab's Efficiency, Cost Effectiveness, and Profitability

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Has your lab "Leaned" anything ?

If so, which process(es) ?

Why that one (those) ?

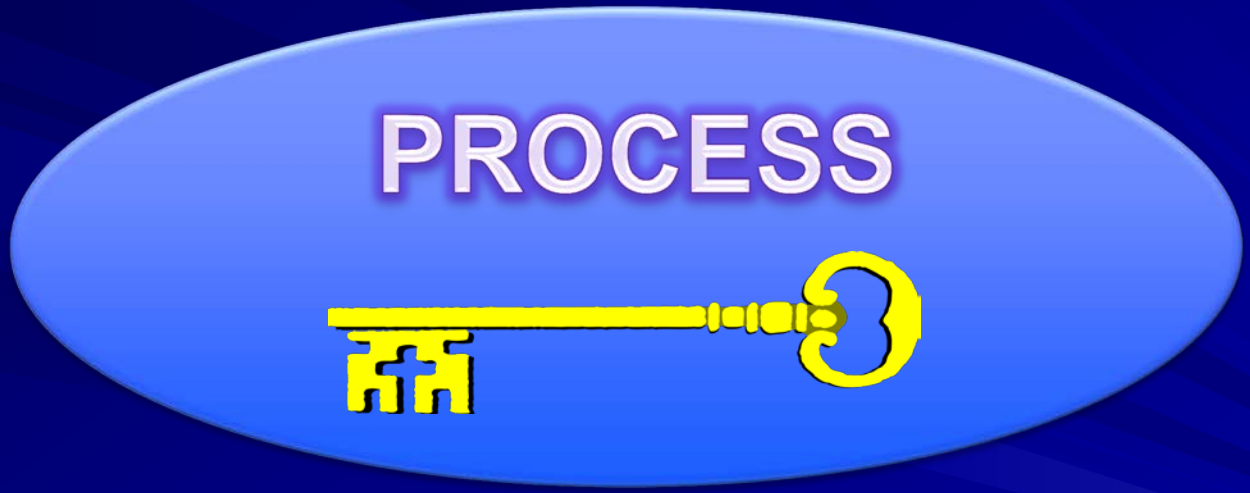
Replication?

Has your lab replicated Lean to other processes?

If so, why ?

If not, why not ?

Why This One Word?



Reasons Why “Process”

- All work is sequential ***processes***
- ISO 9001 and CLSI QSEs ***process***-based QMSs
- *Lean*: Reduce ***process*** waste
- *Six Sigma*: Reduce ***process*** variation
- Engaging with practitioners: Through the test ordering and results interpretation ***processes***
- Change leadership: ***Process*** and cost thinking

Understand

Document

Train to,
Assess

Measure,
Monitor

Improve

“Everyone doing his best is not the answer. It is first necessary that people know what to do.”

W. Edwards Deming

Understand

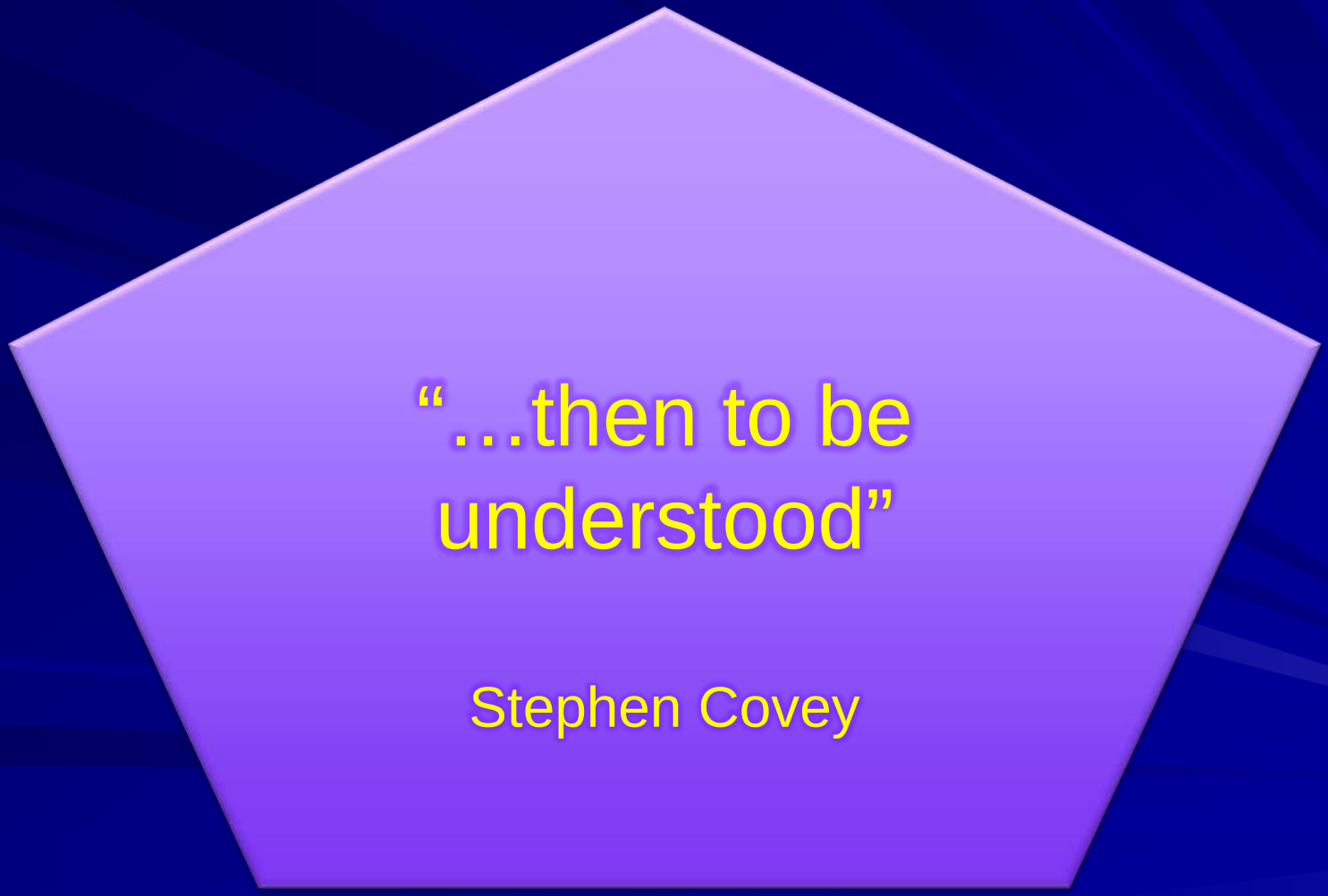
"Seek first to understand…"

Stephen Covey

Understand

- The sequence of *"Who does what, and when"*
- All preexamination, examination, post-examination processes
- All management (ie, QMS) processes
- The role of persons outside the laboratory
- Who is the process owner
- Process versus Procedure as *concepts*

Document



Document

- Difference between process and procedure as *documents*
- Banishment of lengthy, incomplete SOPs
- Use of flow charts, process maps, tables
- Responsibility assigned for each process activity
- Connections (ie, “handoffs”) between processes

Train to, Assess

"Training turns good intentions
into good results."

Thomas Berry

Train to, Assess

- Process-based training (“Telling Ain’t Training”)
- Train to the process flow chart and work instructions (ie, *work does not happen in alphabetical order*)
- The way the work happens – people work the process!
- Assess how people perform the process and what they do when it doesn’t work

Measure, Monitor

"To manage quality,
you must
measure it."

Steven George

Measure, Monitor

- Quality Assurance (QA) = *process* performance
- What aspect of this process can be measured to show it is working – or not?
  NOTE:
  QC measures <u>only</u> method performance!
- Collect raw data and turn it into information
- What is the information revealing?

Improve

"The people don't need to change; the process needs to be changed."

A. Donald Stratton

Improve

- All processes can be improved
- Find and remove the redundancies, dead ends, and bottlenecks in every technical and management process
- Personnel know and can point out process problems
- Automate where possible

Does Process Make Quality Better?

- A 17 year old patient was to receive a heart and lung transplant at a prestigious hospital.
- The organs were blood group A.
  The patient was blood group O.
- The patient is transplanted and had a massive rejection.
- Group O organs are obtained and transplanted. The patient dies anyway.
- 2 sets of organs were wasted.

What went wrong???

There Was No Documented *Process*

- Everyone thought he/she knew what to do
- No one knew what the others were doing
- We were not trained to think “process”
- The Joint Commission said the root cause was *“lack of communication”*

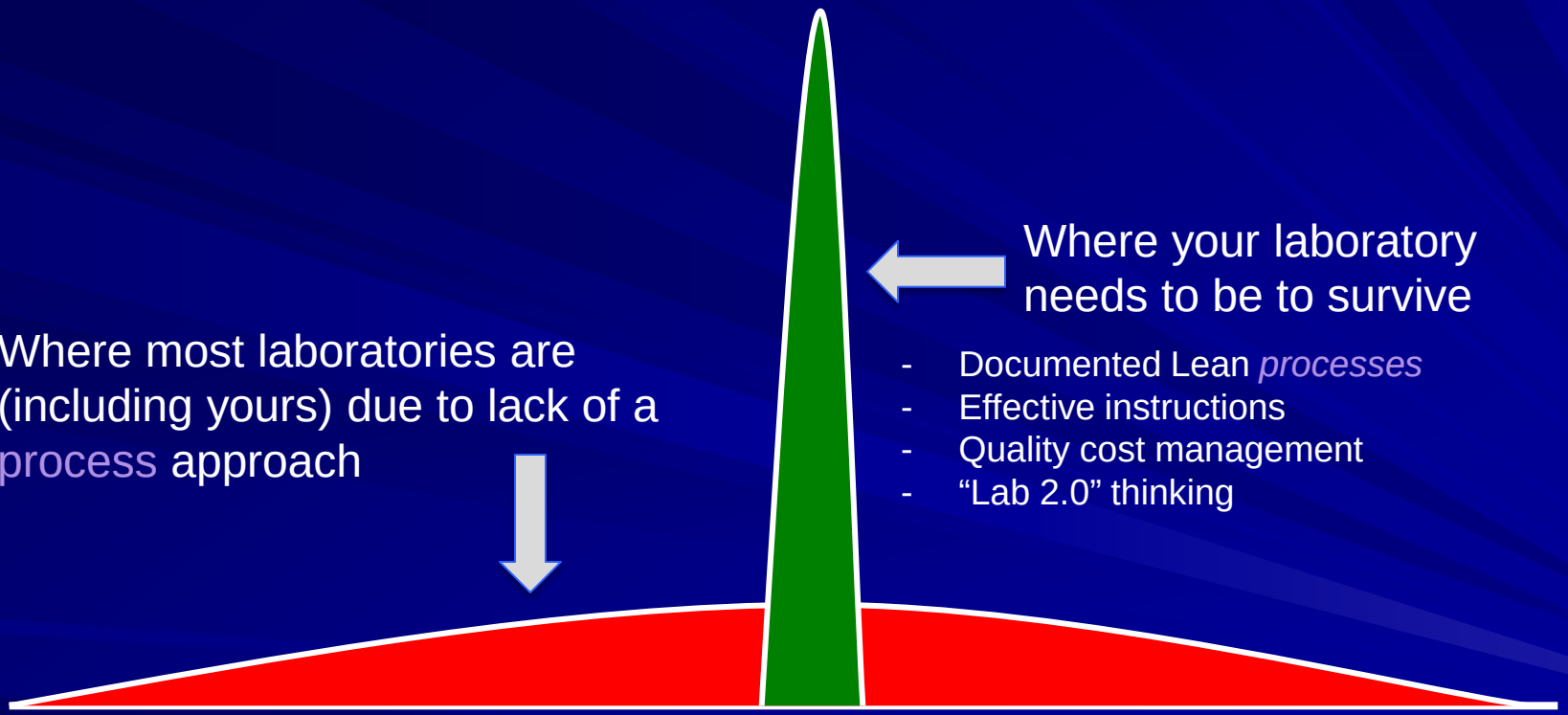
“Medical error is a failure of process.”

US-IOM *To Err is Human*…1999

“If the process is right, the results will take care of themselves.”

Takashi Asada

Quality is Lack of Variation



“To succeed we must disturb the present.”

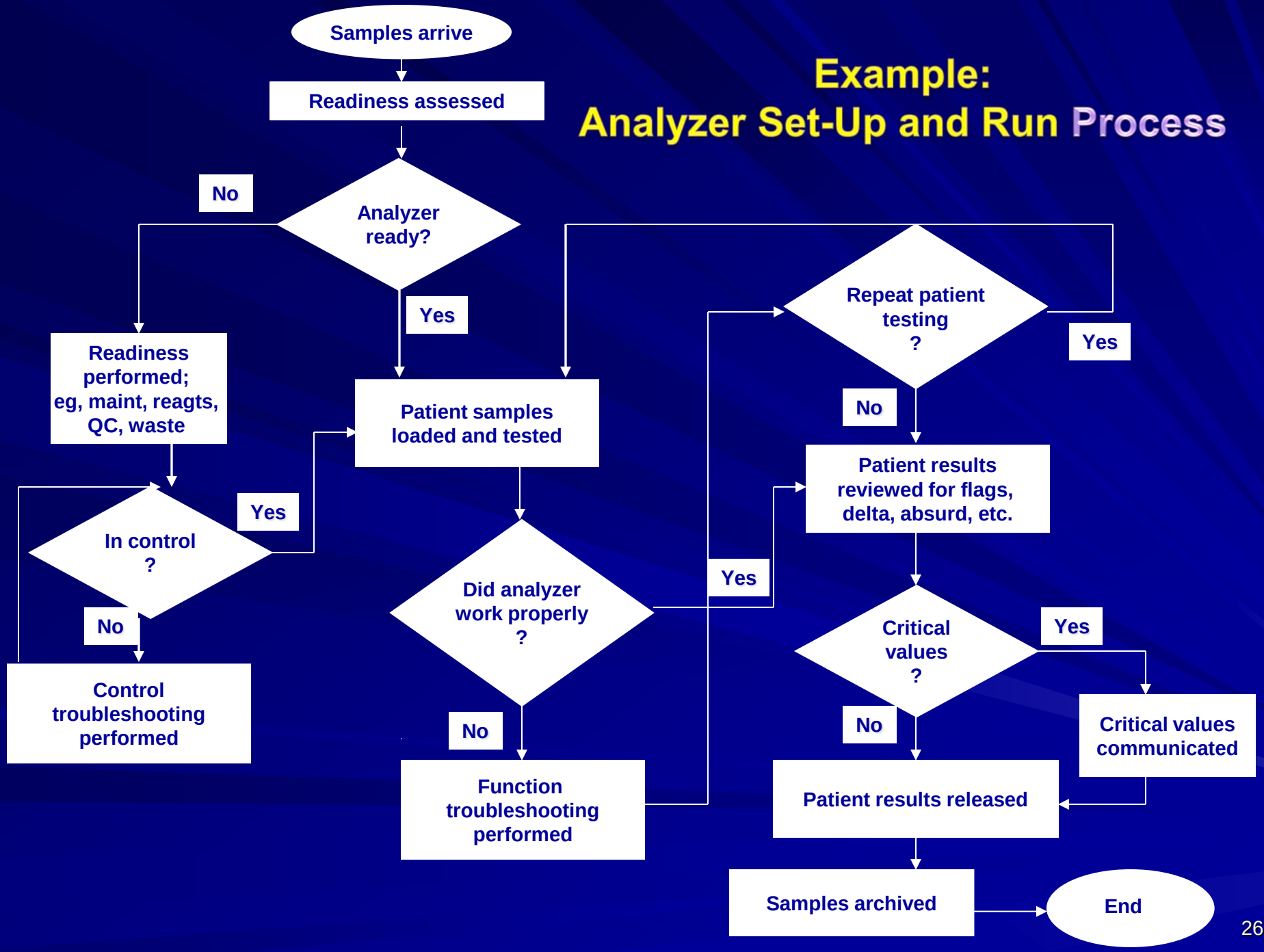
Roberto Goizueta

Look at Old Things in a New Way

Old Things  New Way

“SOPs”	**Process flow charts**

Example: Analyzer Set-Up and Run Process



Old Things → New Way

“SOPs”	**Process flow charts**
One SOP per analyte	**Analyte Attribute Tables**

Analyte Attribute Table(s) for Automated Processes

	Protime	PTT	Thrombin Time
Clinical utility			
Sample Type			
Min sample volume			
Method limitations			
Reference range			
Critical values….			

Old Things → New Way

“SOPs”	→	Process flow charts
One SOP per analyte	→	Analyte Attribute Tables
Procedures in alpha order	→	Instructions in process order

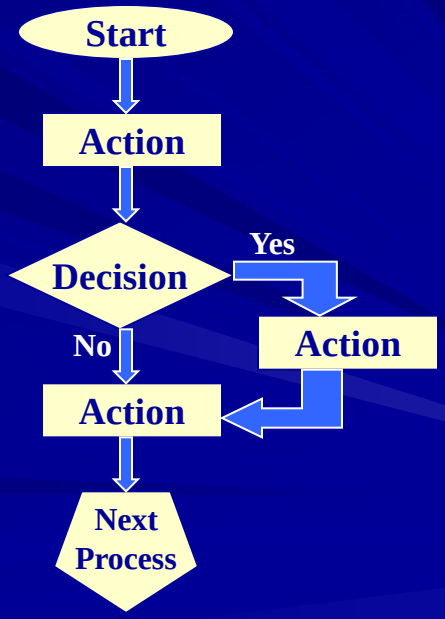
Suggested Table of Contents for Procedures Manuals for Automated Instruments

For paper or electronic manuals:

- *Process flowchart*
- Operations Procedures
- Analyte Attribute Table(s), where needed
- Quality Control Plan section
- Calibration section
- Maintenance section
- Troubleshooting section
- Examples of properly completed forms
- Other? As needed

A Quality Process Approach

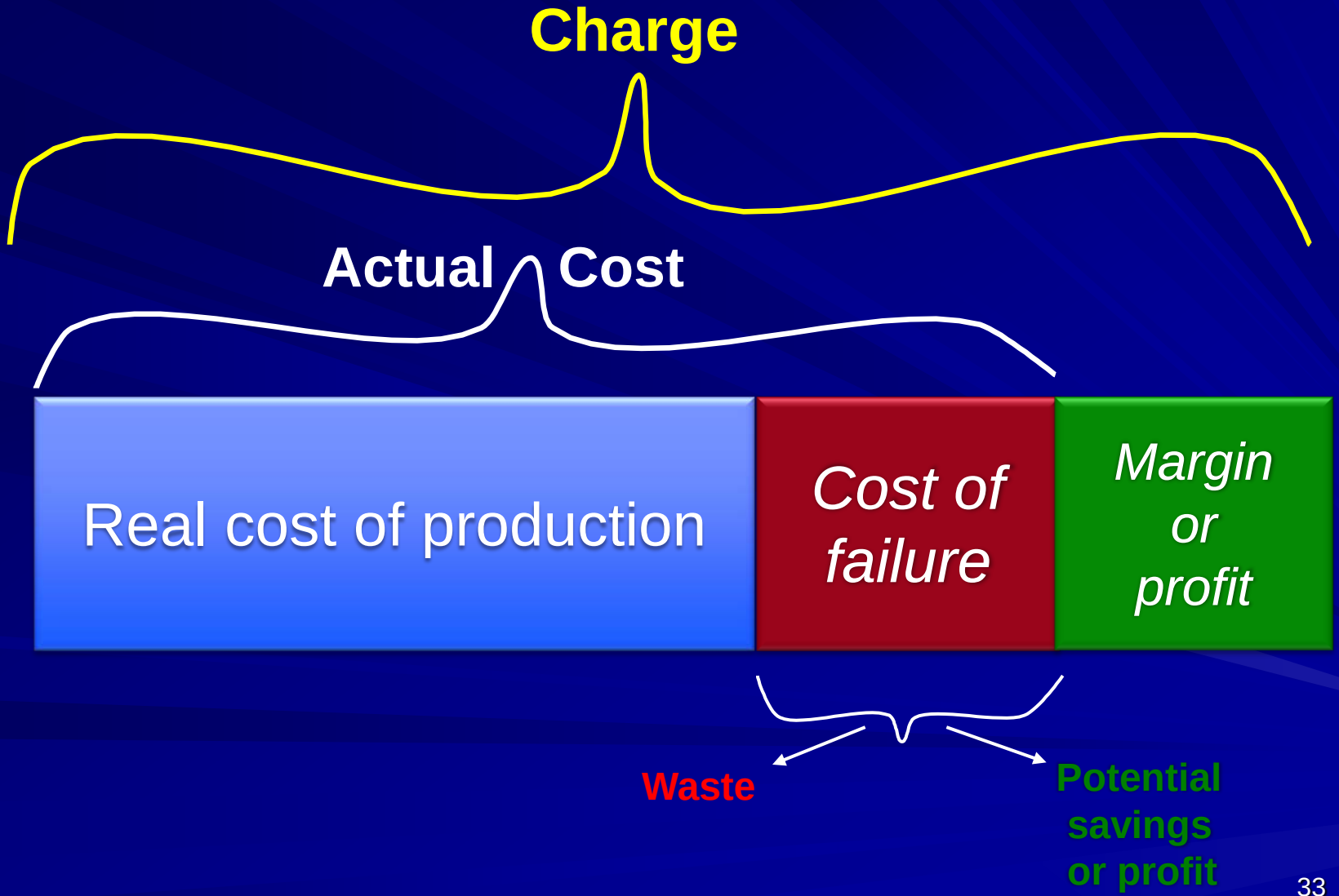
- Work processes are designed such that requirements are met *while doing the job*
  - Regulatory and accreditation
  - Customer
- Work processes are
  - Controlled
  - Measured and monitored
  - Improved



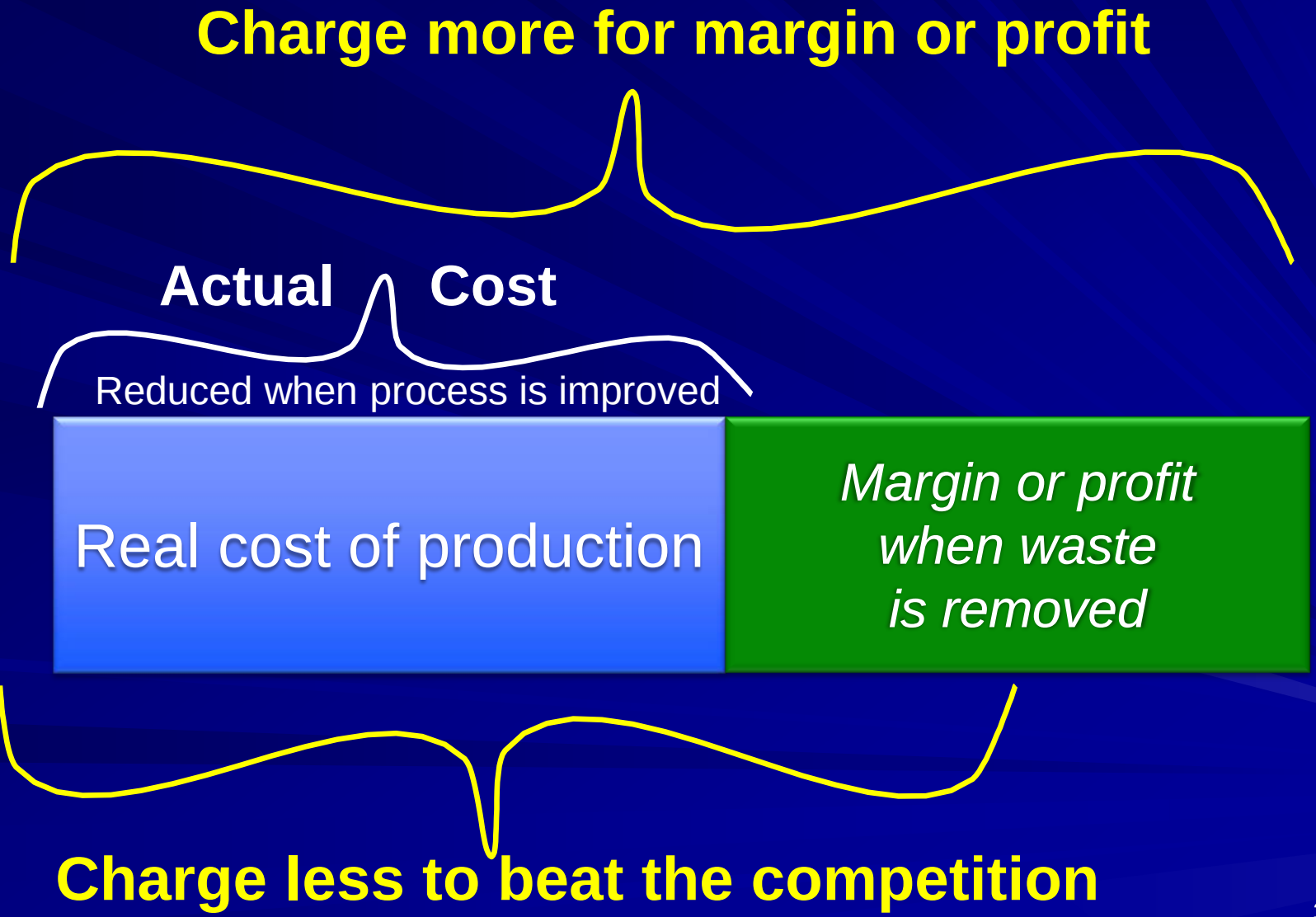
“It is always, only, and ever about money.”

Luci B

Quality, Cost, and Profitability 1.



Quality, Cost, and Profitability 2.



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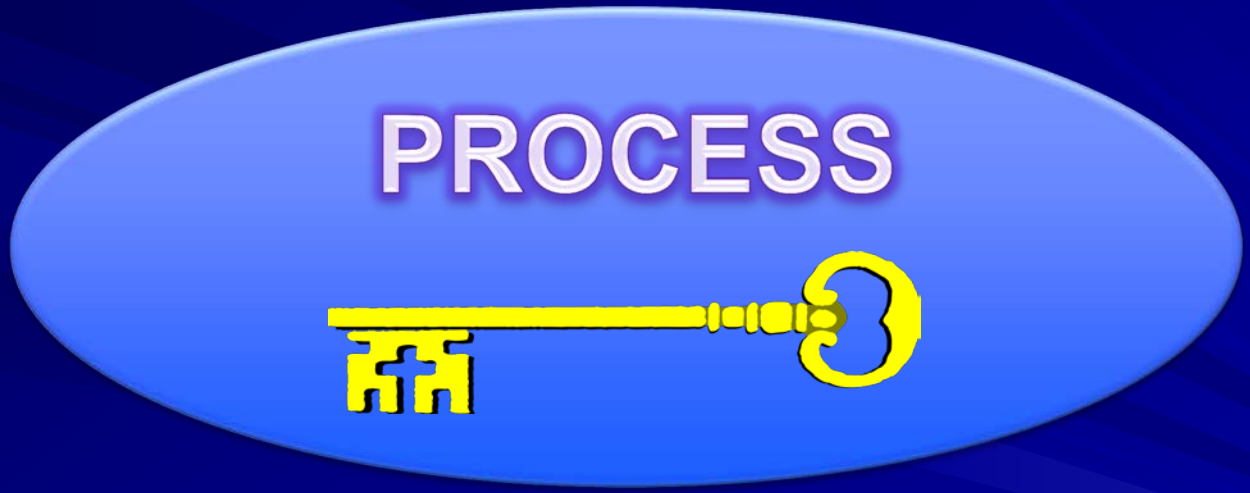

“If we don’t change our direction we’re going to wind up where we’re headed.”

Native American proverb