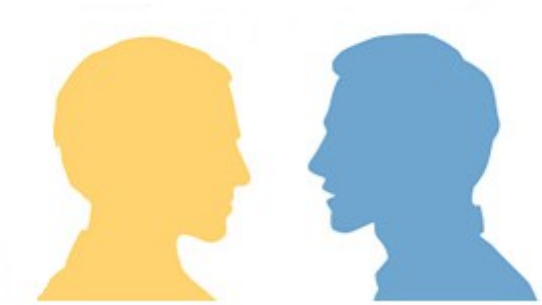
Complementary Lean-Sigma-ISO (CLSI) Quality Management in Laboratory Medicine: Crosstalk about Crosswalk



Richard Pang, PhD, FACB

3rd November 2009

Hong Kong

What is Crosstalk?

crosstalk

Show me everything on Network Performance Management

DEFINITION - Crosstalk is a disturbance caused by the electric or magnetic fields of one telecommunication signal affecting a signal in an adjacent circuit. In an telephone circuit, crosstalk can result in your hearing part of a voice conversation from another circuit. The phenomenon that causes crosstalk is called electromagnetic interference (EMI). It can occur in microcircuits within computers and audio equipment as well as within network circuits. The term is also applied to optical signals that interfere with each other.

Learn more about Network Performance Management

http://searchnetworking.techtarget.com/sDefinition/0,,sid7_gci213543,00.html

What is Crosswalk?

Answers.com®
The world's leading Q&A site

Crosswalk

Wikipedia: Crosswalk (disambiguation)

Look up ***crosswalk*** in Wiktionary, the free dictionary.

A **crosswalk** is a provision for getting across an impediment (usually a road), from one path or walkway to another. The term is common in the USA, other countries may use the term pedestrian crossing instead.

This term may also refer to:

- the way of life or "walk" of putting the needs and rights others first, even sacrificially. Where love of others is more important than love of self.
- In accounting and budget:
  - a table that shows the relationship between two other tables
  - a table used to control the allocation of funds. The analogy is that the funds get transferred (walk) from one set of balance sheets or budget to another. For example, a "Budget Crosswalk" is a term for the allocation table of budget authority to outlay amounts in a budget.

Reference US House glossary. Another example would be: Small Business Administration page 15.

http://www.answers.com/topic/crosswalk-disambiguation

Objectives

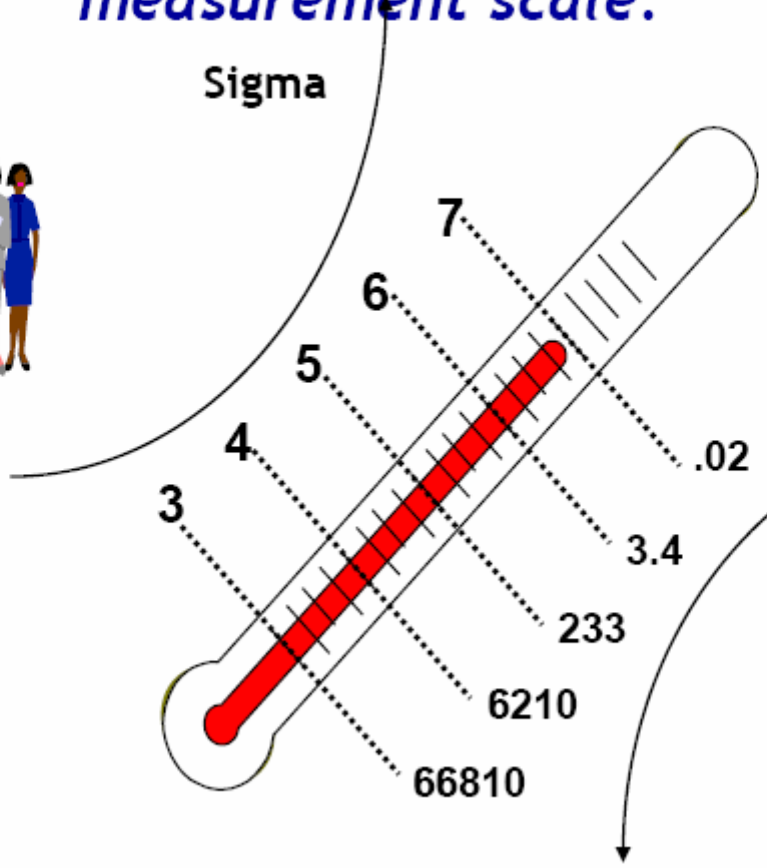
- Understand the relationships between *Lean process*, *Six Sigma* & *ISO 15189* and whether such approaches are complementary or in conflict
- Why and how to use them together in a *synchronized and complementary* way

Metrics for Laboratory Quality

... a measure of "goodness", using a universal measurement scale.

?Lean

?Sigma Metrics



?ISO 15189

?CAP

Laboratory Accreditation Newsletter

CAP Standards

June 2003 Originally published in *CAP TODAY*

International Organization for Standardization

ISO originally started as a mechanism to reduce trade barriers between countries through the publication of a broad variety of standards. The standard most applicable to the clinical laboratory is ISO 15189: Medical laboratories–particular requirements for quality and competence.

The commission has directed the checklist commissioner, Stephen J. Sarewitz, MD, to complete a cross-walk between ISO 15189 and the checklists and to develop appropriate questions to address those few specific ISO requirements not specified by the checklists. Compliance with ISO 15189 may prove to be more important for laboratories overseas than for those in the United States.

College of American Pathologists

Press Release

Posted on March 3, 2008

Released in March 2008

Sue Masaracchia-Roberts
Phone: 800-323-4040, ext. 7319
E-mail: srobert@cap.org

College of American Pathologists Offers ISO Accreditation Program for the Nation's Medical Laboratories

Northfield, IL.—A new accreditation intended to improve patient safety and reduce laboratory-related risks recently was announced by the College of American Pathologists (CAP), the leading organization in laboratory quality management. This new program accredits laboratories to conform with International Organization of Standardization (ISO) 15189:2007, and will be available to interested medical laboratories in the United States during the fourth quarter of 2008. This accreditation will be separate and distinct from the CAP Laboratory Accreditation Program (LAP), however, laboratories accredited to the ISO 15189:2007 standard will be well-positioned to rapidly respond to the changing health care environment and demonstrate measurable quality to their customers.

For more information on ISO 15189:2007 or to apply for ISO accreditation, please call 800-323-4040, option 1.

Laboratory Medicine

"*What Best Practice is the Best?*"

Bread and Butter

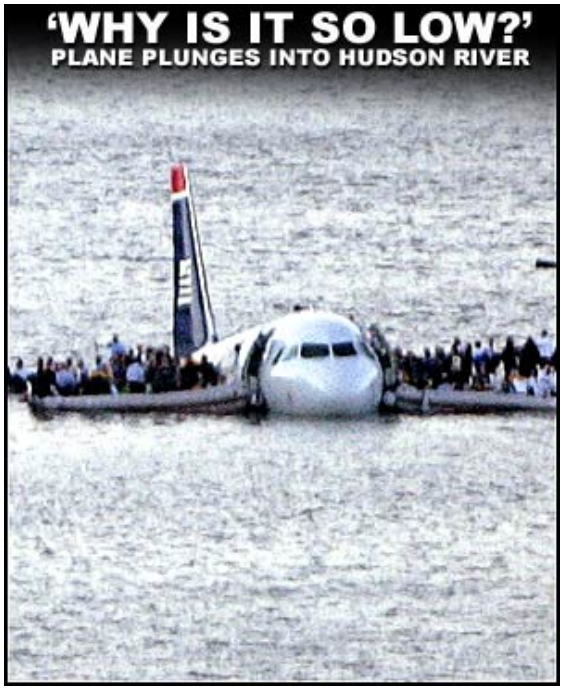
Best Practice Includes Going Back to Basics

KISS

*K*eep *I*t *S*imple and *S*mart

The pilot is such a HERO

"US Airways flight 1549 has been involved in an accident on 19 January 2009. The Airbus A320 was en route to Charlotte from LaGuardia with 150 passengers onboard that ditched into the Hudson River about five minutes after takeoff. The flight was operated with a crew of 5 (2 pilots and 3 flight attendants). Everyone onboard survived."



"…we were simply doing the job we were trained to do…"

Impacts on Quality of Laboratory Services

- Laboratories across the Asia-Pacific region are facing significant challenges in meeting demand for quality of their services despite more and more laboratories successfully complete accreditation programs.
- The international standards ISO 15189 and corresponding checklist documents for accreditation of medical laboratories are found useful in certain areas particularly in the pre- and post-examinational phases, they are considered to some extent to be insufficient in the assessment of the efficiency of the laboratory service.

?Inappropriate sample collection

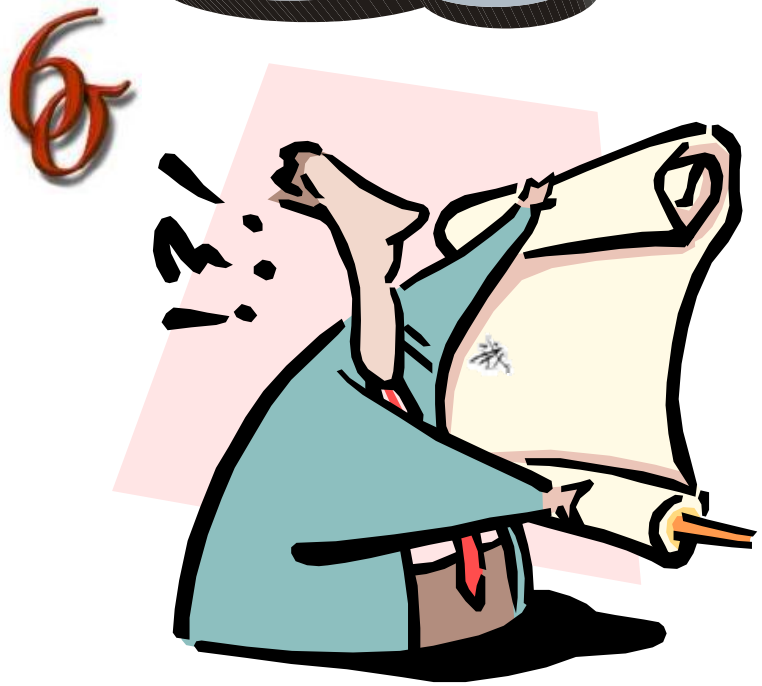
?TAT too long

?Inconsistent workflow processes

The Challenges

Improved Incident Tracking

Reduced Waste



ISO 15189

Standardized Workflows

The Solutions

High Quality

Low Cost

Pass the Inspection

Best Practice

Pass the inspection =/= Customer satisfaction

Customer Focus

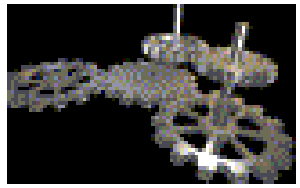
Lean and Six Sigma show how to align the organization through customer-focused measures of performance

Quality Cocktail

Be it Lean, Six Sigma and/or ISO 15189?

Core Concepts

- ISO just gives guidance regarding the types of processes you should have it does not specify the "How", and one cannot assess the adequacy of the system for delivering quality.
- Lean and Sigma define the methodologies, organizational structure, procedures, and resources that are used to improve processes. However, Lean-Sigma is not intended to define the Quality System.



Risk Management

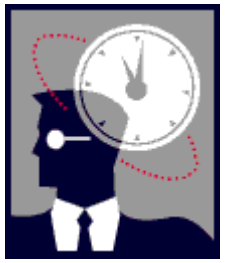
Quality Management

Quality management tools such as Total Quality Management (TQM), Continuous Quality Improvement (CQI) and Lean Six Sigma are conceptually quite similar except for their labels.

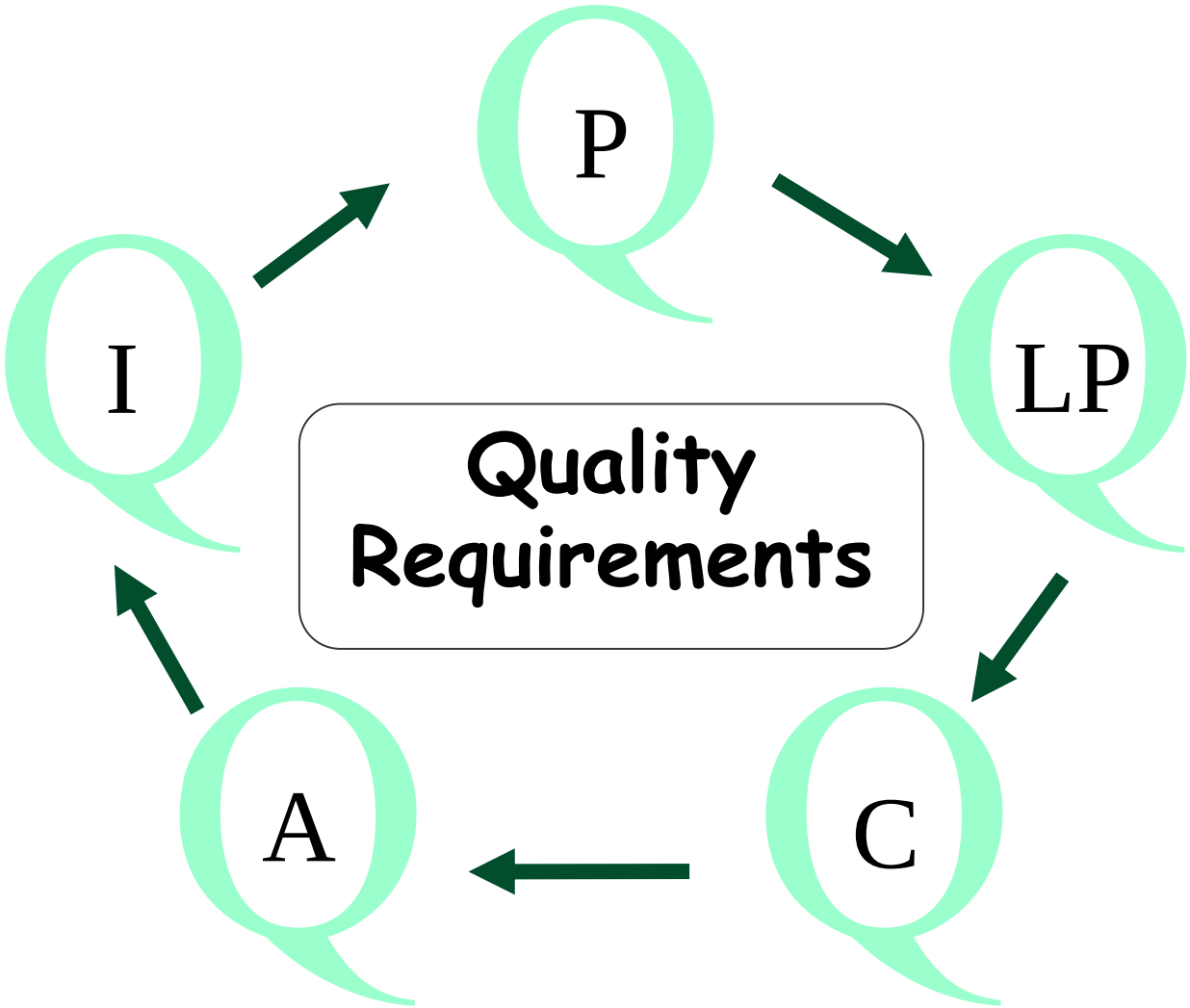
Total Quality Management (*TQM*)

Too many ***Q***uestions in my ***M***ind

Continuous Quality Improvement (*CQI*)



I ***C***annot (Can) answer the ***Q***uestion ***I***mmediately



A **Good** **Quality Management** framework showing the components of quality planning (QP), quality laboratory processes (QLP), quality control (QC), quality assessment (QA) and quality improvement (QI), and centred on laboratory quality requirements.

Quality must be designed from the front end, not tested on the back end

Fail to Plan = Plan to Fail

Certification Compliance

The New ISO 15189: 2007 Standard

ISO 15189 by itself is not a generic (**certification**) standard, but a specific one …

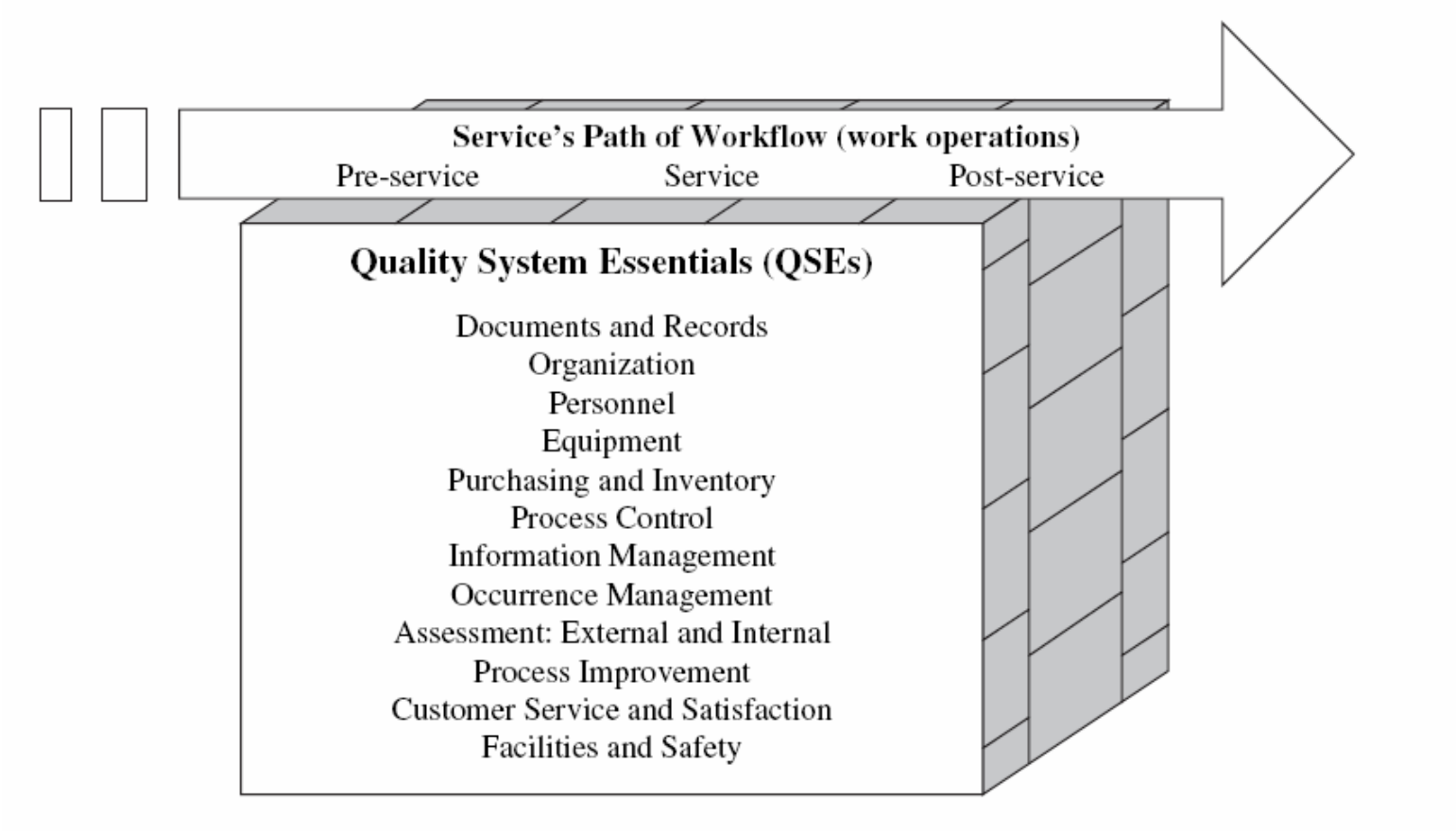
http://www.westgard.com/iso3.htm

In essence, ISO 15189 requires you to:

- Say what you do
- Do what you say
- Record what you did
- Check on the results
- Act on the deviations, if any…

Shall and Should

A Simple Generic Model for a Quality Management System



From CLSI.CLSI approved guideline HS1: a quality system model for health care. 2nd edition. Wayne (PA): 2004.

Technical Criteria for Laboratory Accreditation (ISO 15189)

- Management requirements
  - 4.1 Organization & management
  - 4.2 Quality management system
  - 4.3 Document control
  - 4.4 Review of contracts
  - 4.5 Examination by referral labs
  - 4.6 External services & supplies
  - 4.7 Advisory service
  - 4.8 Resolution of complaints
  - 4.9 Identification & control of nonconformities
  - 4.10 Corrective action
  - 4.11 Preventive action
  - 4.12 Continual improvement
  - 4.13 Quality & technical records
  - 4.14 Internal Audits
  - 4.15 Management reviews

- Technical requirements
  - 5.1 Personnel
  - 5.2 Accommodation & environmental conditions
  - 5.3 Laboratory equipment
  - 5.4 Pre-examination procedures
  - 5.5 Examination procedures
  - 5.6 Assuring quality of examination procedures
  - 5.7 Post examination procedures
  - 5.8 Reporting the results

23 QSEs

For Medical Laboratories

2007

ISO 15189

"Medical Laboratories – Particular requirements for quality and competence"

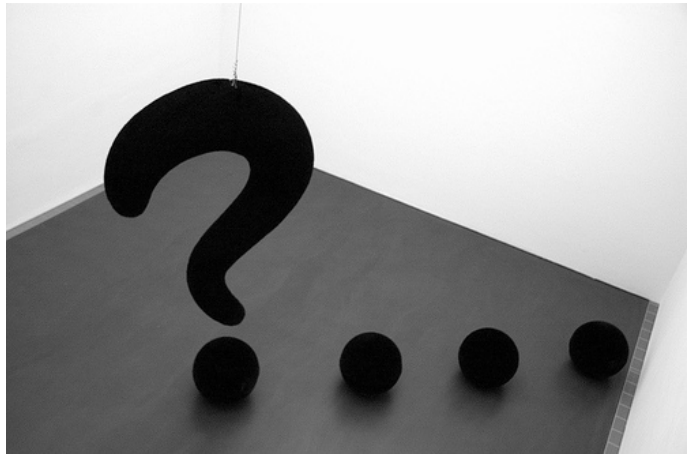
Quality Control = Quality Compliance

What Does This Mean?

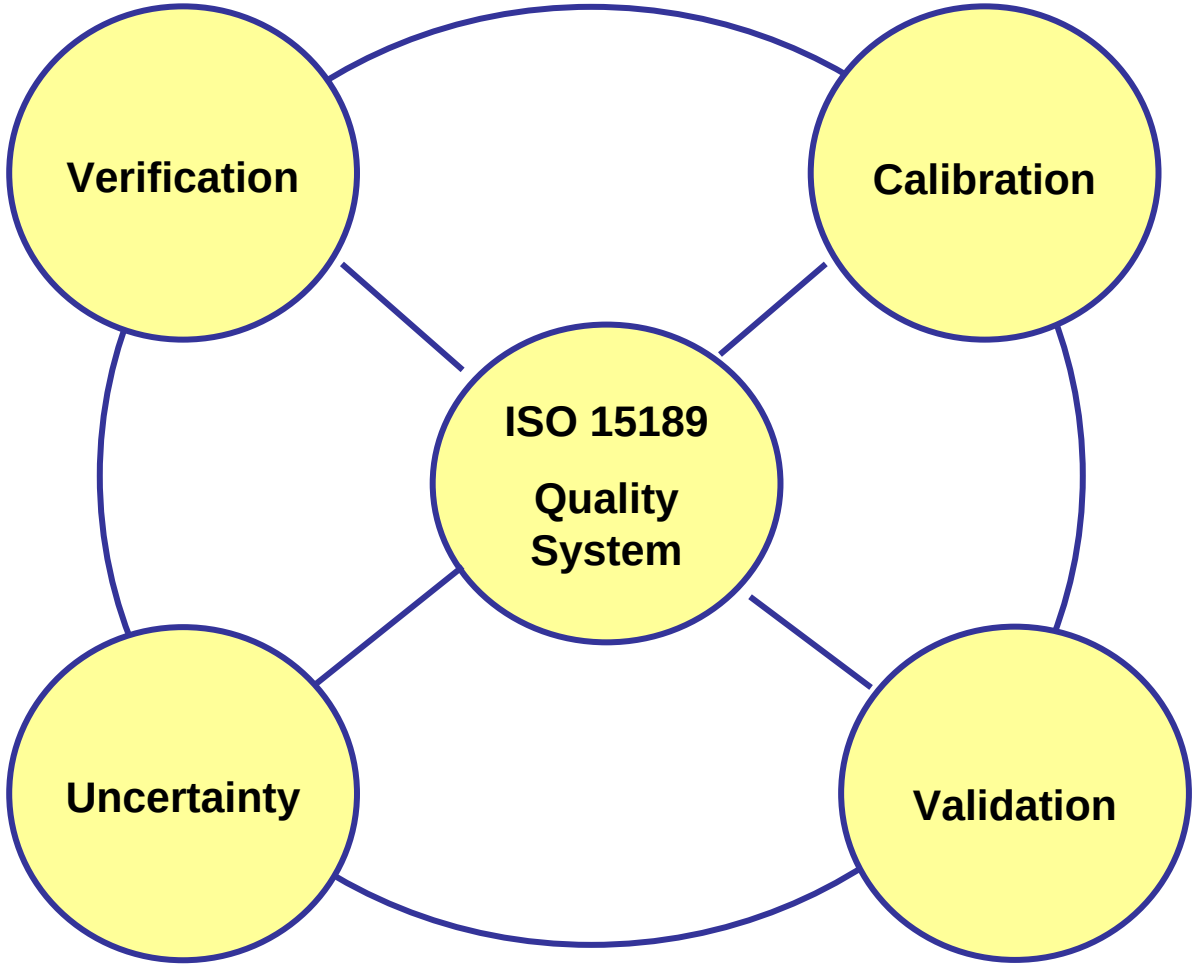
ISO 15189 5.6.1 “…the laboratory shall design internal quality control systems that verifying the **attainment** of the **intended** quality of laboratory test results…”

How Do You Do This in a Medical Laboratory?

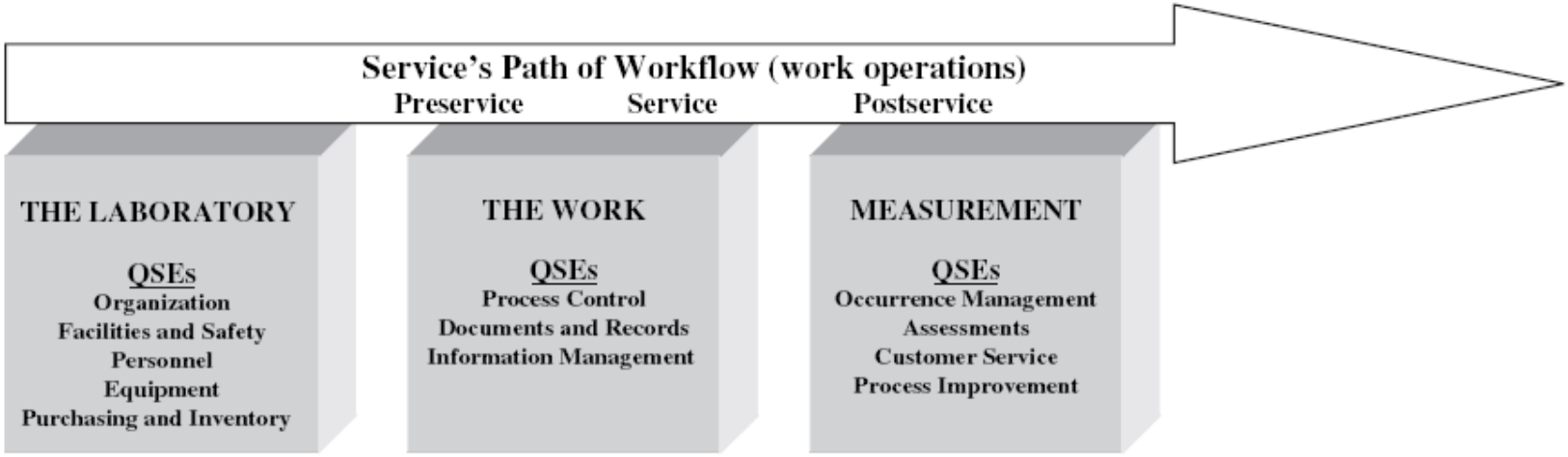
- How do you define “intended quality of results” for clinical or medical application of laboratory tests?
- How do you design IQC on the basis of that intended quality?
- How can you estimate those performance characteristics (i.e., precision and accuracy) of your analytical methods?
- How to “verify the attainment” of that “intended quality”?



Quality Standard



Arrangement of the Quality System Essentials of the QMS Model into Logical Groupings



From CLSI.CLSI approved guideline HS1: a quality system model for health care. 2nd edition. Wayne (PA): 2004.

ISO 15189 Related CLSI Documents

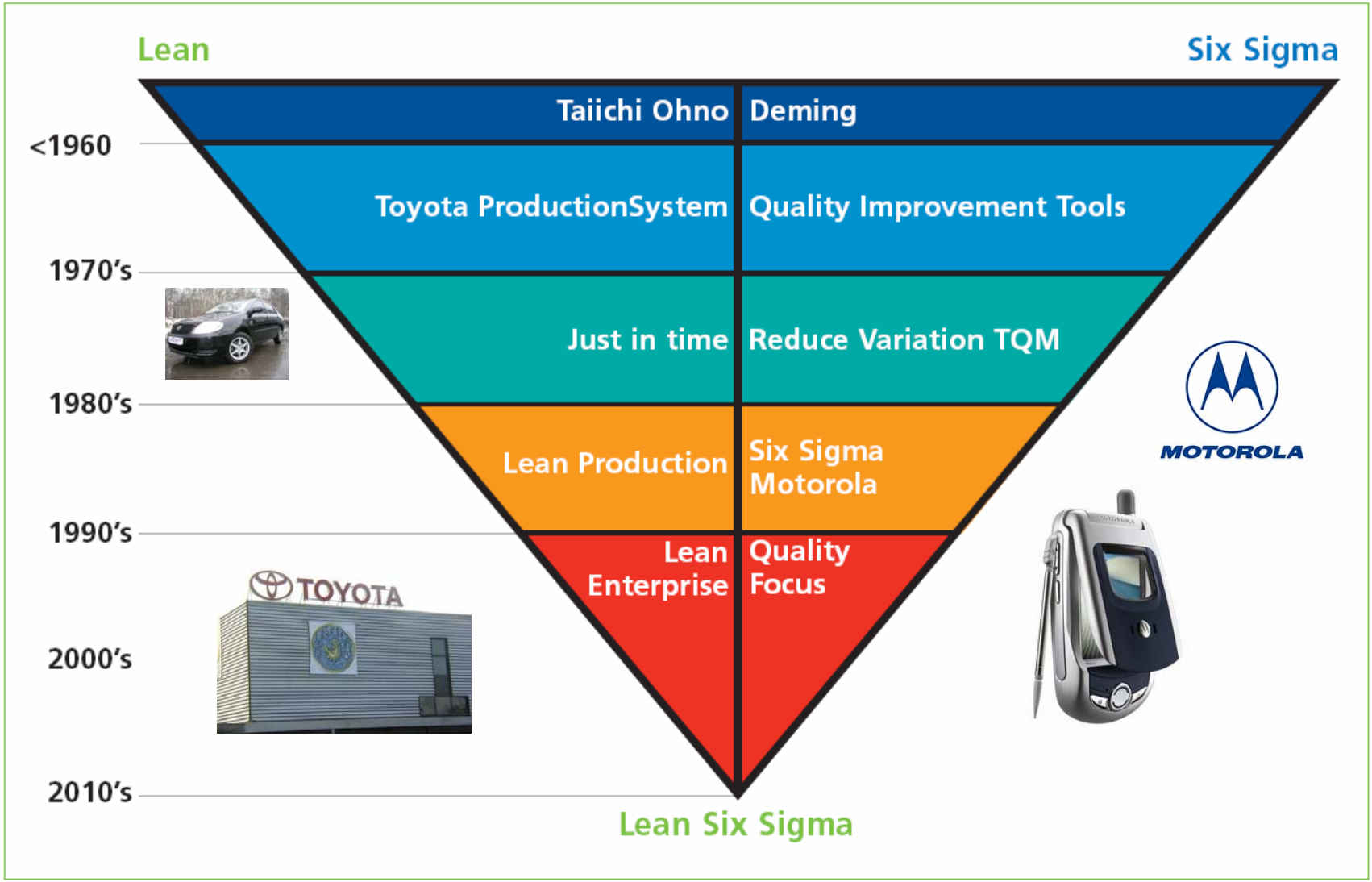
Comparison of CLSI QSEs From CLSI Documents HS1 and GP26 to ISO Documents 15189 and 9001

CLSI QSEs	CLSI HS1: A Quality Management System Model for Health Care	CLSI GP26: Application of a Quality Management System Model for Laboratory Services	ISO 15189: Medical laboratories—Particular requirements for quality and competence	ISO 9001: Quality management systems—Requirements
Organization	5.2	6.2	4.1 Organization and Management 4.2 Quality management system	4.1 General requirements 5.1 Management commitment 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority, communication 5.6 Management review 6.1 Provision of resources
Personnel	5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 Appendix F Appendix G	6.3.1	5.1 Personnel	6.2 Human resources
Equipment	5.4.1 5.4.2 5.4.3 5.4.4 5.4.5	6.4	5.3 Laboratory equipment Annex B.1 General Annex B.7 Hardware and software Annex B.8 System maintenance	7.6 Control of measuring and monitoring devices
Documents and records	5.1	6.1	4.3 Document control 4.13 Quality and technical records	4.2 Documentation requirements
Purchasing and inventory	5.5	6.5	4.4 Review of contracts 4.5 Examination by referral laboratories 4.6 External services and supplies	7.4 Purchasing

ISO 15189 Related CLSI Documents

CLSI QSEs	CLSI HS1: A Quality Management System Model for Health Care	CLSI GP26: Application of a Quality Management System Model for Laboratory Services	ISO 15189: Medical laboratories—Particular requirements for quality and competence	ISO 9001: Quality management systems—Requirements
Customer service	5.11	6.11	4.7 Advisory services 4.8 Resolution of complaints	5.2 Customer focus
Process improvement	5.10.1 5.10.3 5.10.4 5.10.5 5.10.6 Appendix M	6.10	4.12 Continual improvement	8.5 Improvement
Process Control	5.6.1 5.6.2 5.6.3 5.6.4 Appendix H	6.6	5.4 Preexamination procedures 5.5 Examination procedures 5.6 Assuring the quality of examination procedures 5.7 Postexamination process 5.8 Reporting of results Annex C.5 Examination Annex C.6 Reporting results	7.1 Planning of product realization 7.2 Customer-related processes 7.3 Design and development 7.5 Production and service provision
Occurrence management	5.8	6.8	4.9 Identification and control of nonconformities 4.10 Corrective action 4.11 Preventive action	8.3 Control of nonconforming product
Assessments—external and internal	5.9	6.9	4.14 Internal audits 4.15 Management review	8.1 General 8.2 Monitoring and measurement 8.4 Analysis of data
Information Management	5.7.1 5.7.2 5.7.3 5.7.4 5.7.5 5.7.6	6.7	Annex B.4 System security Annex B.5 Data entry and reports Annex B.6 Data retrieval and storage Annex C.3 Information Annex C.4 Consent Annex C.8 Access to laboratory records Annex C.9 Other purposes	Not addressed
Facilities and Safety	5.12	6.12	5.2 Accommodation and environmental conditions	6.3 Infrastructure 6.4 Work environment

Lean and Six Sigma Approaches



Adapted from http://www.LeanSigma.com

What is Six Sigma?

- Systematic approach to reduce the occurrence of errors or mistakes in terms of defects per million (DPM).
- Six Sigma offers to laboratories the way to make fewer mistakes in all their activities (ranging from filling in an order form to the most complicated analytical process and report delivery) by eliminating errors before they appear.
- If done properly, Six Sigma ensures that internal processes are running at optimum efficiency- it is a measure of quality i.e. DPM “before-and-after”.

偶爾的失誤才會變為過失

只有當一個人拒絕改過時

A poster from ***Galeries Lafayette***, Paris

The Higher the Sigma Value, the Better the Performance

Sigma Level	% Accuracy	Defects/Million
1	30.85	690,000
2	69.15	308,537
3	93.32	66,807
4	99.38	6,210
5	99.977	233
6	99.9997	3.4

To apply Sigma Metrics for quality assessment of laboratory processes, there are two methodologies that are useful:

- For pre-analytic and post-analytic processes, count the number of defects in a group, calculate the defects per million (DPM), then utilize a standard table to convert DPM to the sigma value.

- For analytic processes whose performance characteristics are known, i.e., whose precision (s) and accuracy (bias) can be estimated directly from experimental data, define the "tolerance limit" in the form of an allowable total error, TEa, such as specified in the CLIA proficiency testing criteria for acceptable performance, and calculate the sigma from the following equation:

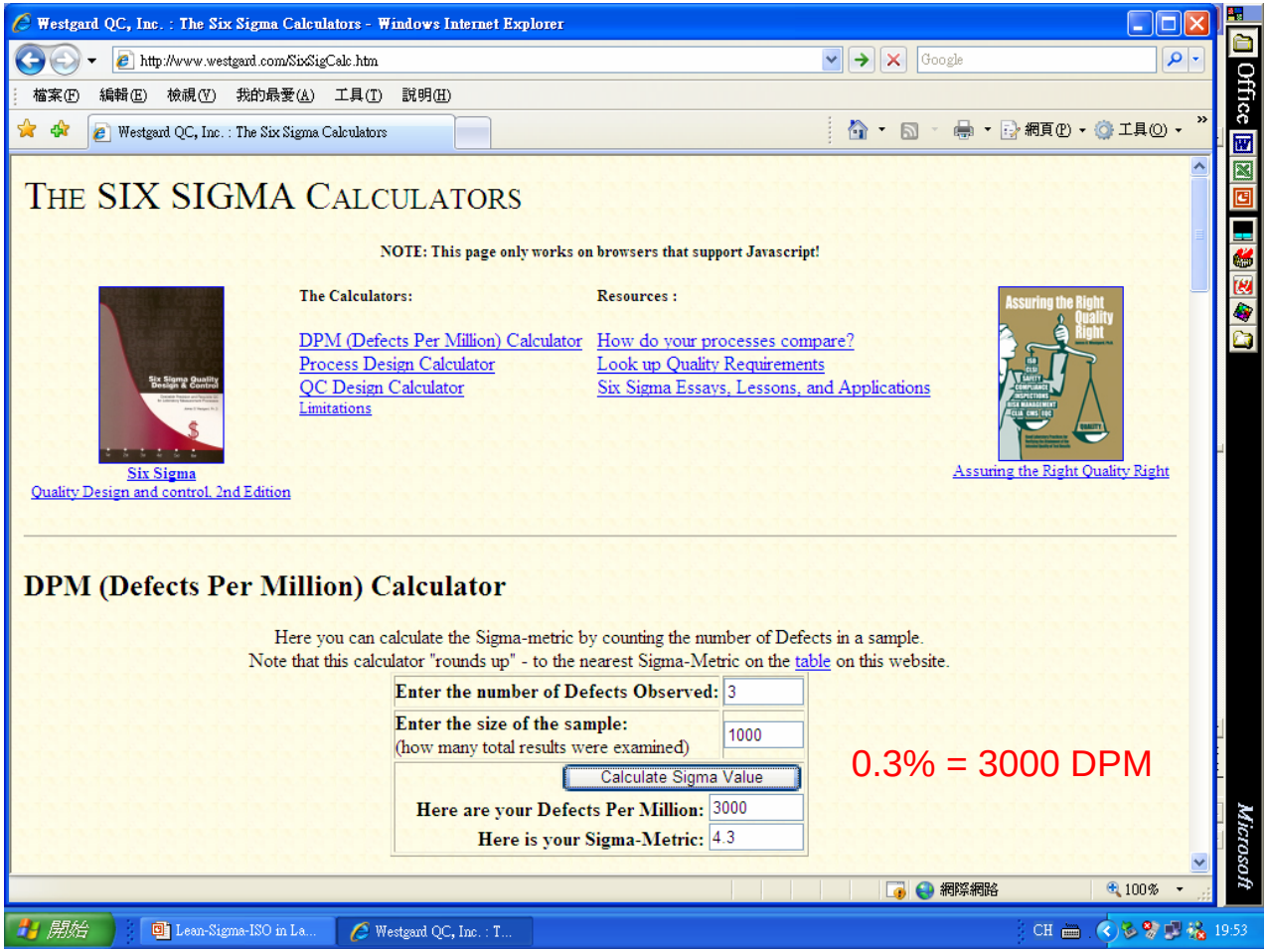
$$\textbf{Sigma} = (\textbf{TEa} - \textbf{bias})/\textbf{s}$$

Pre- and Post-analytical

- Specimen rejection rates
  - No. of specimens being rejected in the reception area per month/year
  - e.g., 3/1,000 = 3,000/1,000,000 = 4.3 Sigma
- Reporting errors
  - No. of erroneous/incorrect results being issued per month/year
  - e.g., 3/100,000 = 30/1,000,000 = 5.6 Sigma

DPM = Defects per Million

Six Sigma Calculators



http://www.westgard.com/SixSigCalc.htm

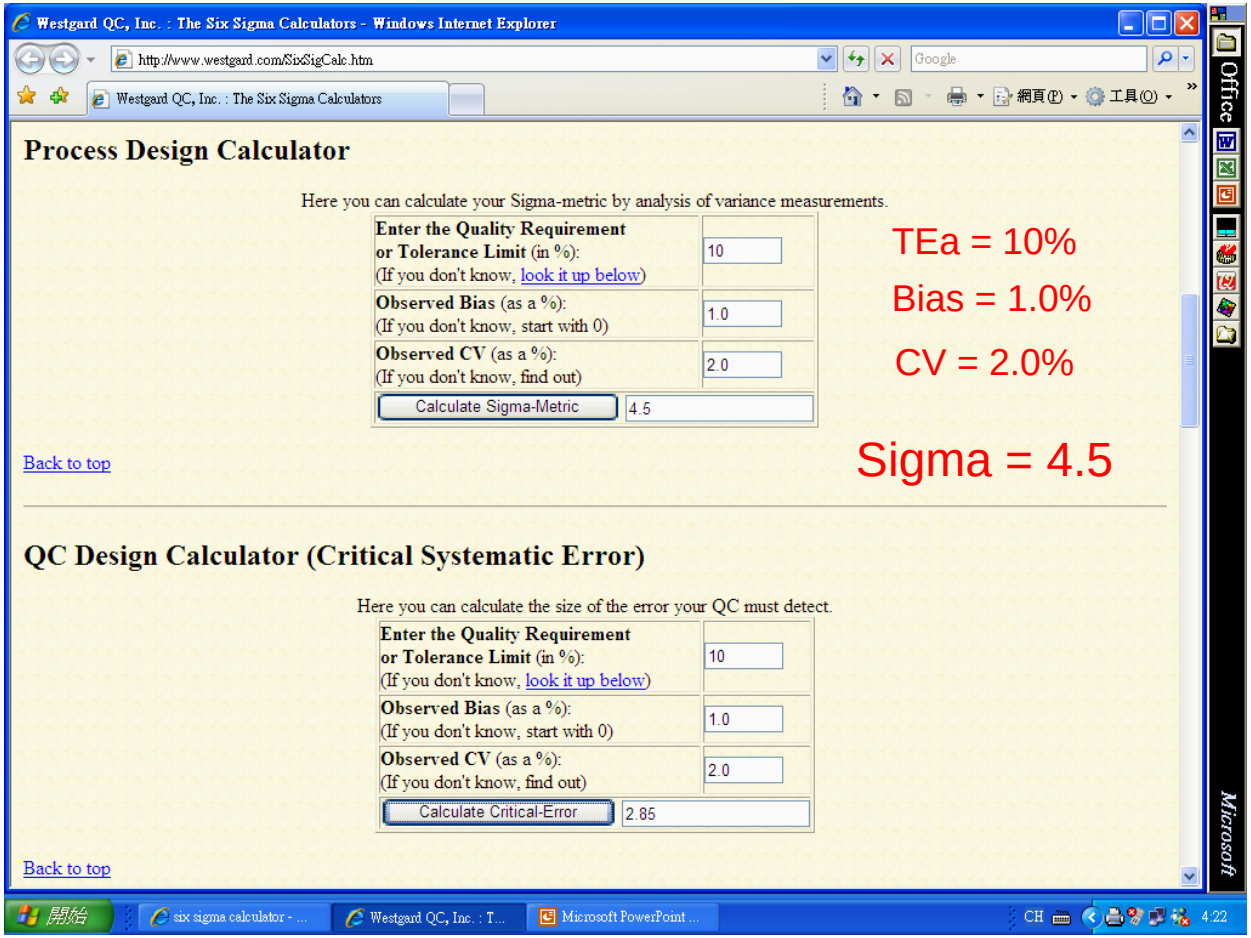
How many QCs would be sufficient?

The more, the better?

Sigma = (TEa – bias)/s

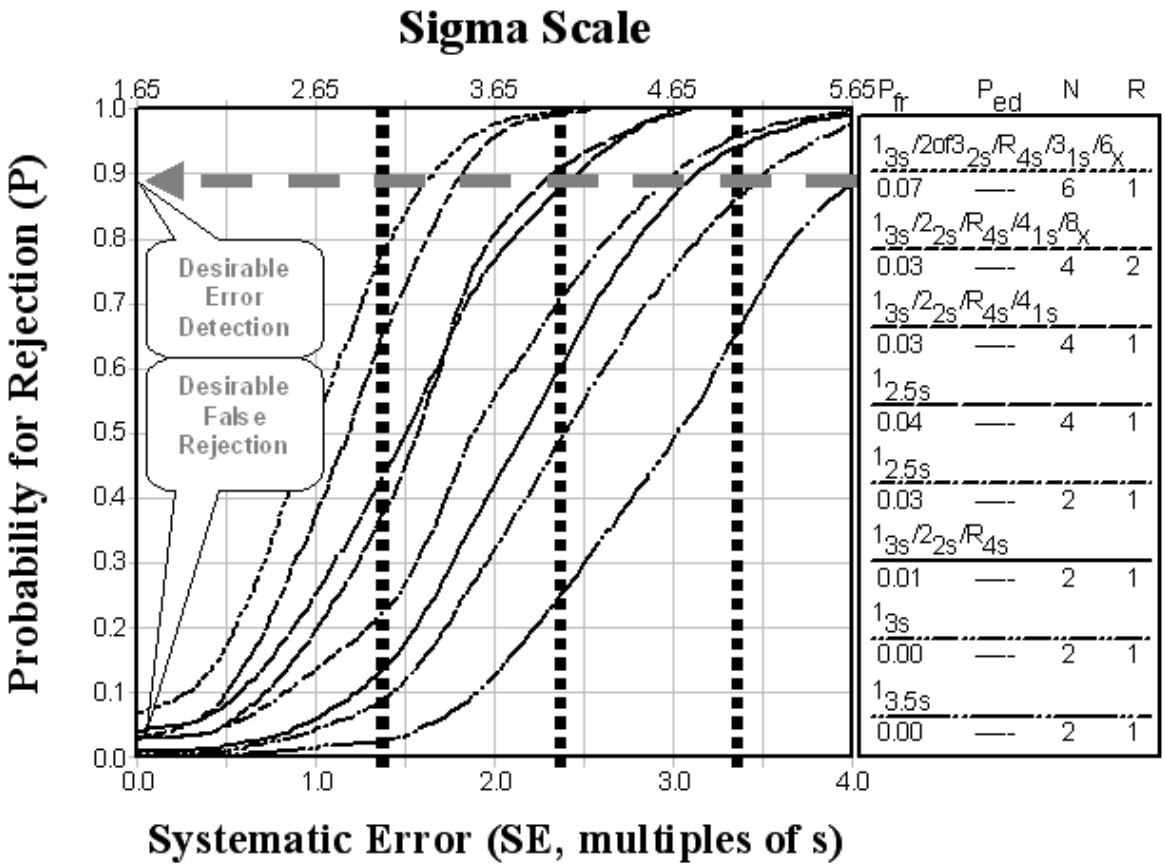
Sufficient = Not insufficient

Sigma-Metric



http://www.westgard.com/SixSigCalc.htm

Power Function Graph



$\triangle SE_{crit}$ = Sigma -z

http://www.westgard.com/essay40.htm

How many QCs would be sufficient?

- For a 6 sigma process (or higher), use 3.5 SD control limits with N=2;
- For a 5 sigma process, use 3.0 SD control limits with N=2;
- For a 4 sigma process, use 2.5 SD control limits or a multirule procedure with N=4;
- For a 3 sigma process, use a multirule procedure with N of 6 or 8.
- For less than 3 sigma, method performance must be improved before the method can be used for routine production.

http://www.westgard.com/cliafinalrule9.htm

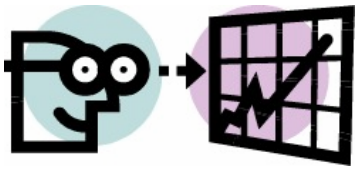
What is Lean?

- Lean is a methodology used to accelerate the velocity and reduce the cost of any process (e.g. laboratory workflow analysis) by removing waste (or muda, a Japanese word refers to a wide range of non-value-added activities).
- Lean is founded on a mathematical result known as Little's Law. Essentially the art of ‘doing more with less more efficiently’.

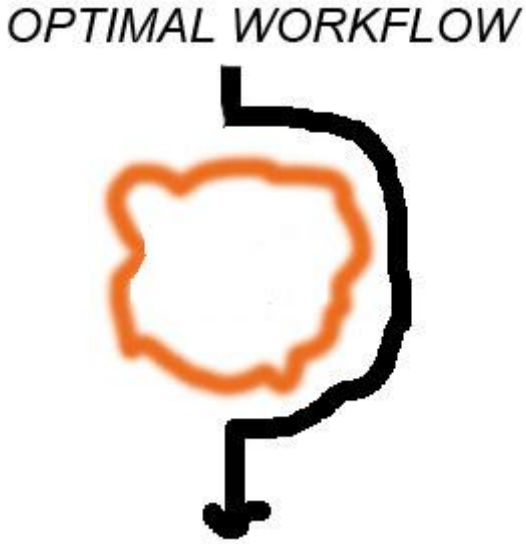
Lean Body Mass?

Financial Constraint

- With limited staff and financial resources, laboratories cannot always adopt the newest technologies and systems.
- However, laboratories have the power to change the way they perform existing tasks and such changes, say a number of process management experts, can deliver measurable service improvements.



Configuration Management



Concepts and the Rationale for its Implementation

Value Stream Mapping

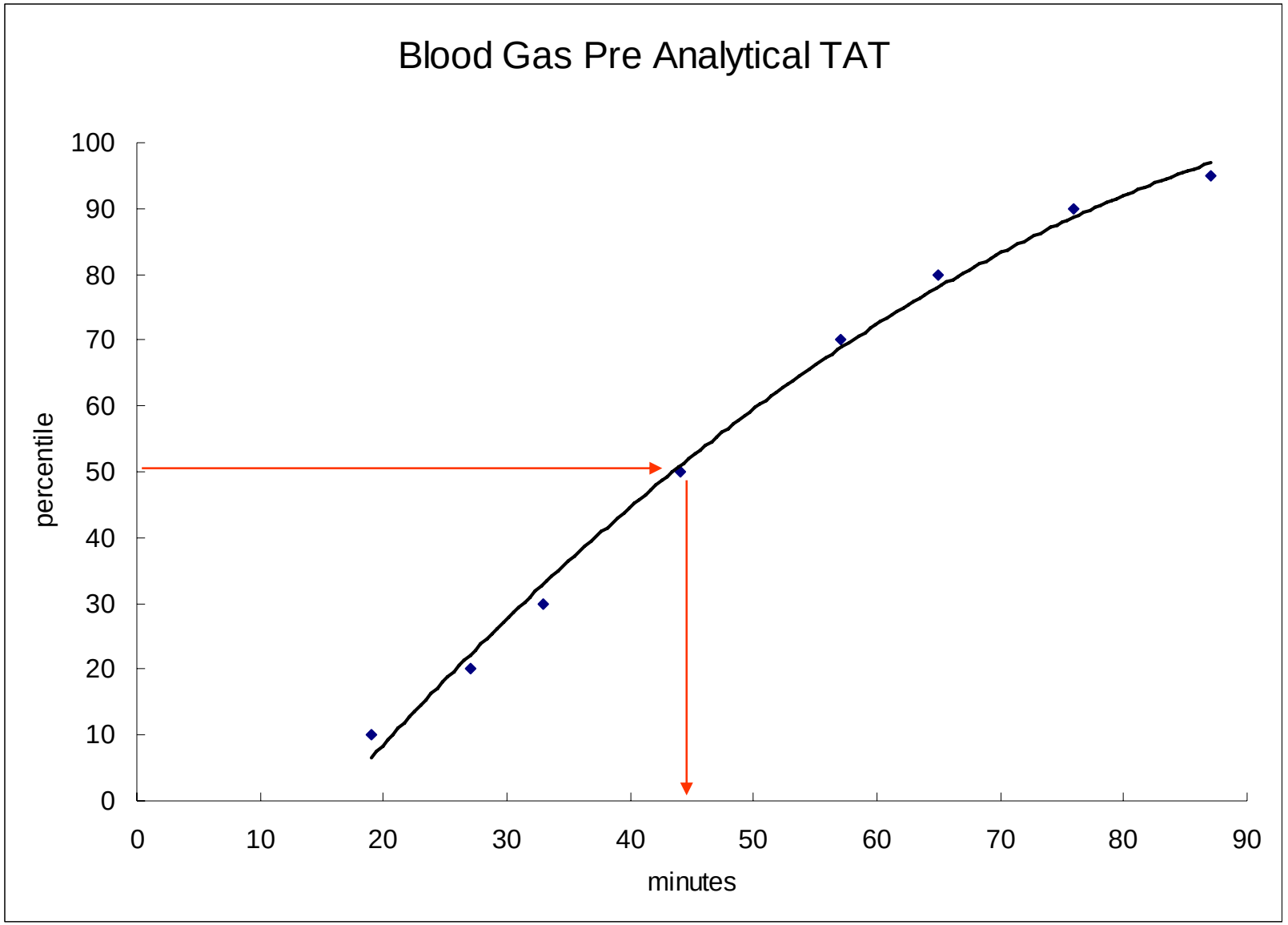
The use of the **Value Stream Mapping** to determine bottleneck priorities…

Identified and Eliminated Defects, Waste, Rework and Unnecessary Activities

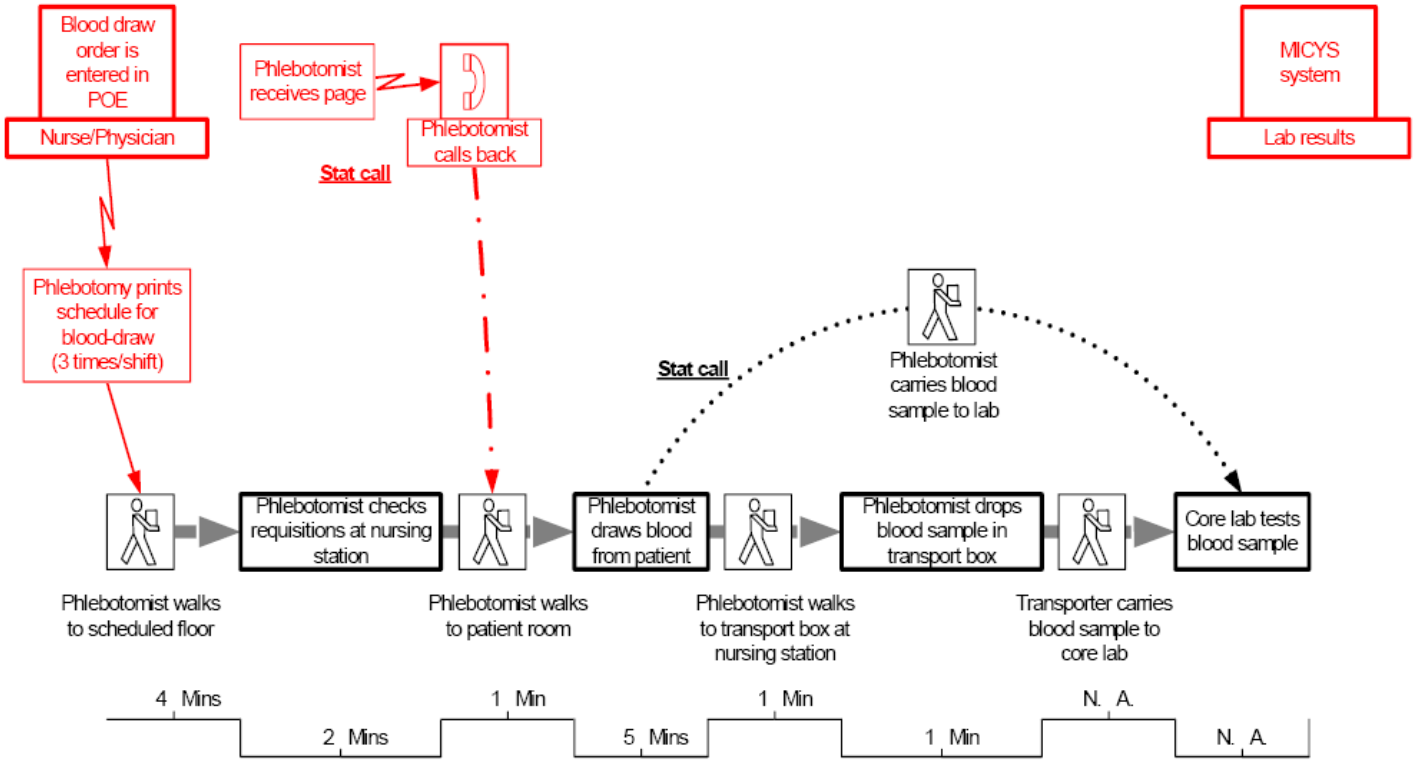
What does the process really look like?

“TR” Laboratory

By using the Value Stream Mapping in optimizing workflow it can greatly help the laboratory better utilize space, equipment and personnel, considerably upping the number of samples processes, improving processing accuracy and saving a great deal of resources.


Blood Gas Pre Analytical TAT
percentile
100
90
80
70
60
50
40
30
20
10
0
0
10
20
30
40
50
60
70
80
90
minutes

Value Stream Mapping: Phlebotomy



http://www.ahrq.gov/qual/toolkit/toolkit.pdf

Streamlining the Laboratory Workflow

- It is not just for streamlining the laboratory workflow, Lean insists on automation at every step possible, particularly for data management.

The Westgard Rules

- As anyone with experience of the 2s rule knows, there's a lot of false rejection involved. The problem with 2s violations is that laboratories get used to ignoring them.
- So that warning rule became a "warning" that was almost always ignored and people began to get used to the concept of just ignoring ALL QC flags completely.

http://james.westgard.com/the_westgard_rules/2009/02/qa-warning-rules.html

QC Rejection Characteristics

A Practical Guide to Internal Quality Control (IQC) for Quantitative Tests in Medical Laboratories

7.2.3 Summary of Rejection Characteristics:

The table below summarizes the responses of different control rules to different error conditions. Identified which other rules are most sensitive for detection of probable **False Rejection**, **Random** or **Systematic** errors.

Error Condition	Westgard Rule
False rejection	1_{2s}
Random error	1_{3s}, R_{4s}
Systematic error	2_{2s}, 4_{1s}, 10_{x}

P_{ed} vs P_{fr}

http://www.hkaml.org/flyer/Final_Printing_Version_Sept_2009_A_Practical_Guide_To_IQC_HKAML.pdf

False Error Flags!

Lead to unnecessary repeat runs!

Lead to unnecessary corrective actions!

Need for Automated Rule Selection

Real Time Quality

vs

“Too-Late-Time” Quality

"Equivalent QC" is not real-time because the QC is reduced to weekly or monthly.

For labs that feed garbage into control chart calculations, they will get garbage out.

Automated QC Rule Selection

- Reduces false rejections and desensitization to false error flags
- Saves lab time and consumables associated with the reduction of unnecessary trouble-shooting
- Improves lab test quality with optimally selected QC rules

Westgard Advisor™ online

Lean Sigma Approach

Expert QC Data Management System

1. Facilitates regulatory compliance under CLIA and/or ISO 15189
2. Recommends and implements optimum QC rules automatically with e.g. Westgard Advisor™ to help prevent false error flags
3. Provides high-quality run validation with comprehensive audit trails
4. Monitors on-going performance of QC rules with Analytical Goal options
5. Facilitates prospective and supervisory QC data review
6. Provides advanced data analysis charts and reports
7. Enables consolidation of QC management into one advanced platform
8. Enables participation in the Interlaboratory Program for external feedback on laboratory performance

The peer-comparison database service can now include recommendations for optimizing the QC procedures for individual tests in an individual laboratory based on the performance data from that laboratory, thereby facilitating the application and minimizing the work required.

Lean Sigma Approaches

"Setting up QC protocols with the aid of a QC software package which has a high probability of detecting an error together with a low rejection rate is an example of the Lean Sigma approaches in routine QC practice that could reduce unnecessary sample re-runs and unnecessary corrective actions due to QC failures".

http://www.westgard.com/essay41.htm and http://www.westgard.com/essay94.htm

The Keys for Lean Six Sigma

The keys for Lean Six Sigma are evidence-based laboratory medicine, speed and quality that work together for maximum productivity. It can give you the ideas of how to improve your workflow, reduce laboratory errors that are controllable, and better serve your clinical users.

Outcome Measures

Quality Indicators

"Outcome Measures"

Quality Indicator	DPMO	Sigma
Pre-analytical		
Missing information on Pap requisitions	100,259	2.8
Correction of errors on ordered tests	3,123	4.3
Patients without ID bands	5,625	4.1
Specimen redraws	19,053	3.6
Therapeutic drug monitoring timing	207,140	2.4
Analytical		
Laboratory testing error	726	4.7
Laboratory proficiency testing	9,000	3.9
Post-analytical		
Laboratory reporting errors	533	4.8

Arch Pathol Lab Med 2000;124:516-9

5-Phase Discipline

Implementation of Lean Six Sigma is a 5-phase discipline for improving quality laboratory processes. These phases are typically represented as **Define, Measure, Analyze, Improve and Control**

Return on Invested Capital
ROIC

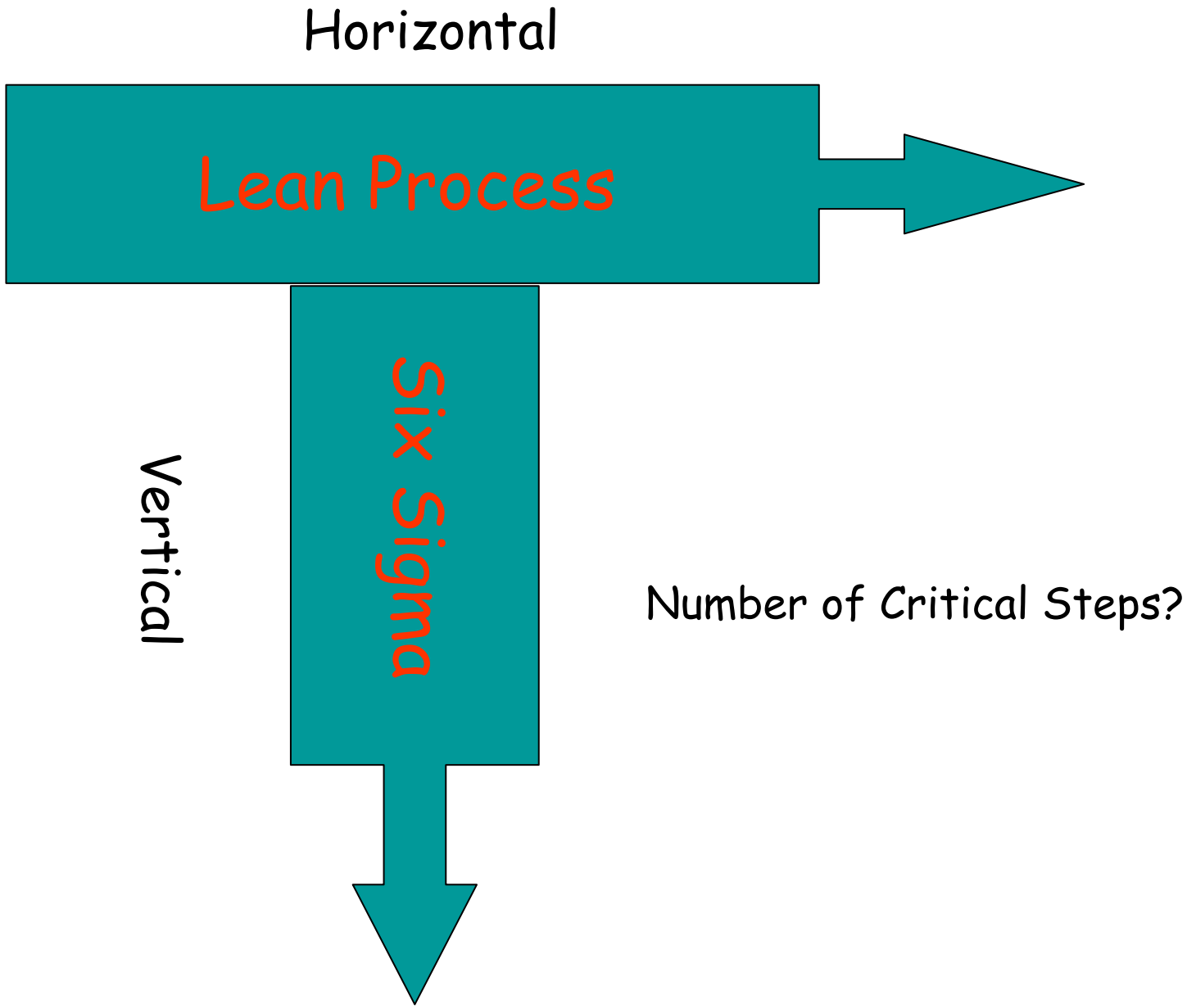
In other words, you need both Lean (speed) and Six Sigma (quality) metrics to drive improvements in Return on Invested Capital or ROIC and achieve the best competitive position.

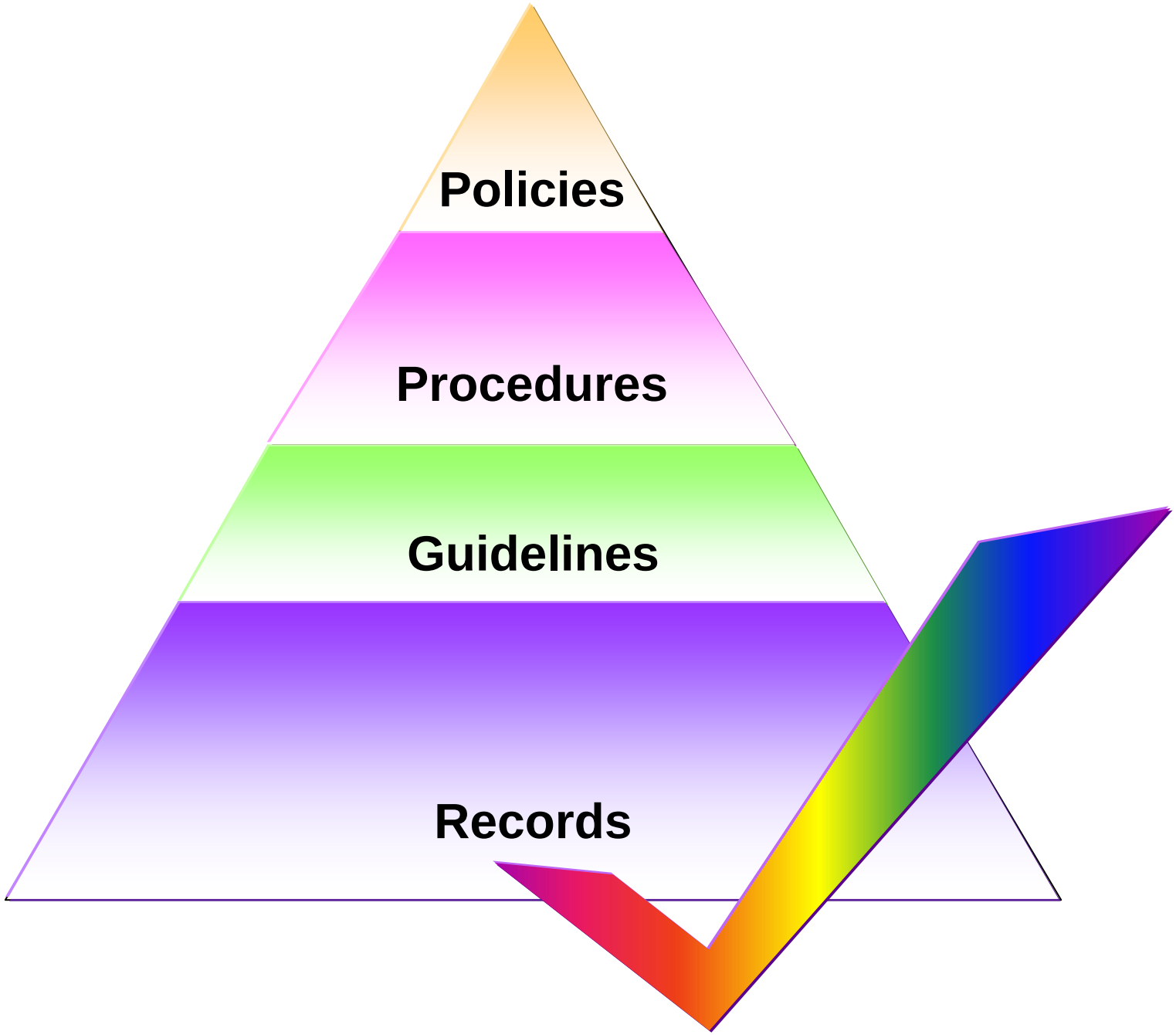
Laboratory Managers

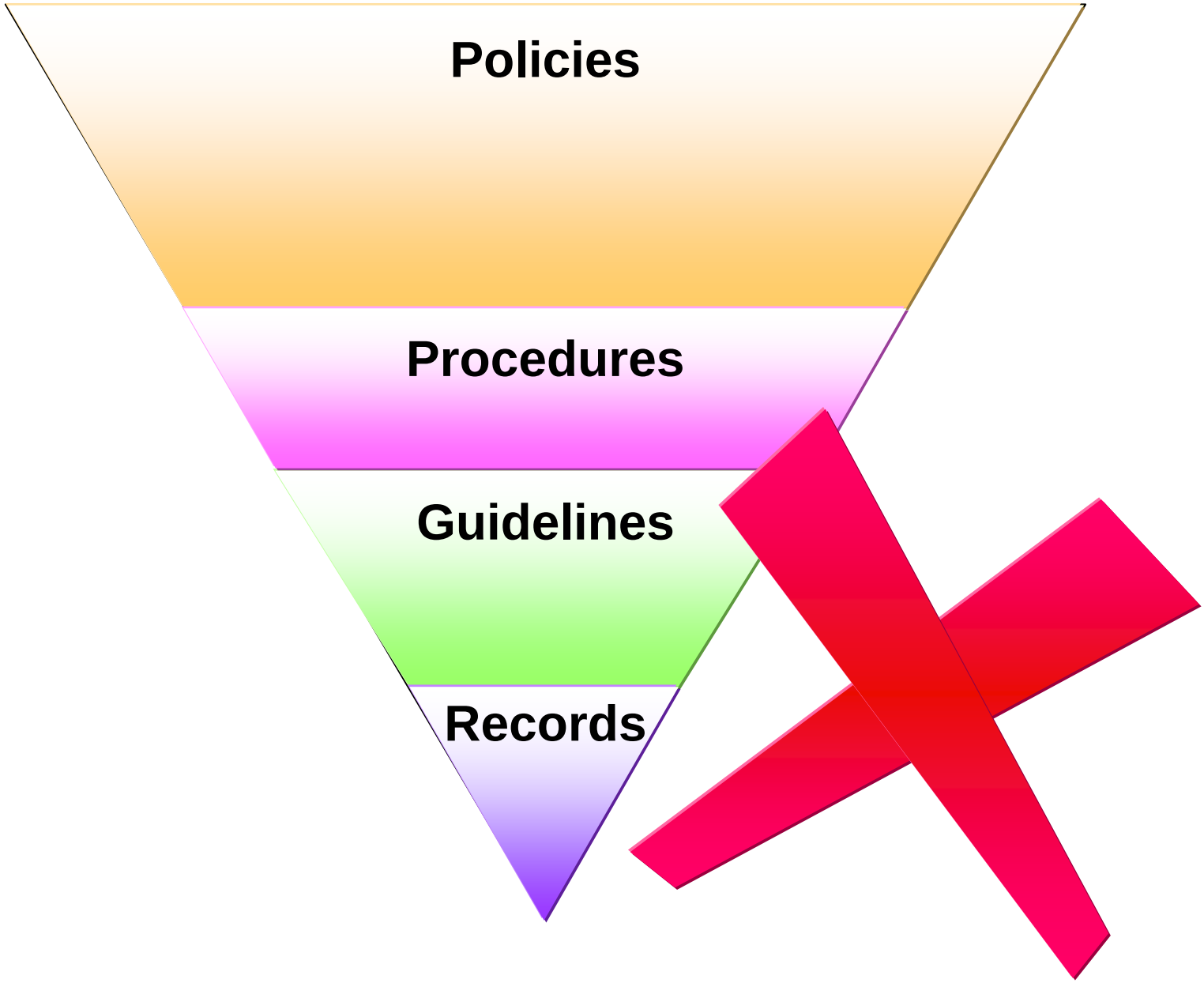
- Laboratory managers must address defect rates for quality improvement and remove inefficiencies to get the job done faster.
- The laboratory managers of today need Lean and Six Sigma for balance.

Tool and Strategic Platform

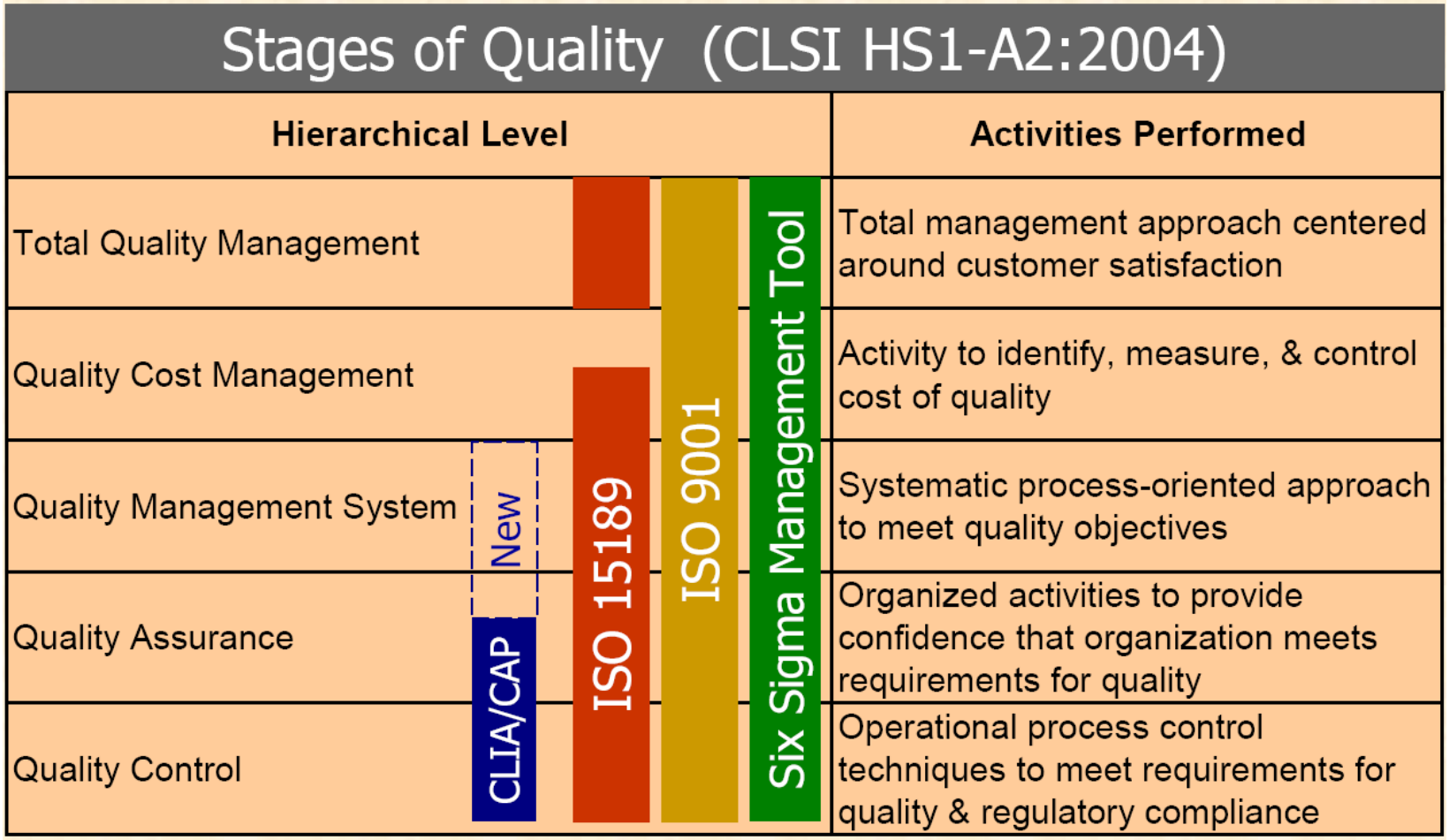
- Six Sigma is just one tool in a toolbox of continuous improvement methodologies, and some things just don't fit under Six Sigma.
- Lean is one of the strategic platforms. It is more than a tool, and total quality management is impossible without lean disciplines.
- Six Sigma and Lean should go hand in hand.


Horizontal
Lean Process
Six Sigma
Vertical
Number of Critical Steps?


Policies
Procedures
Guidelines
Records


Policies
Procedures
Guidelines
Records

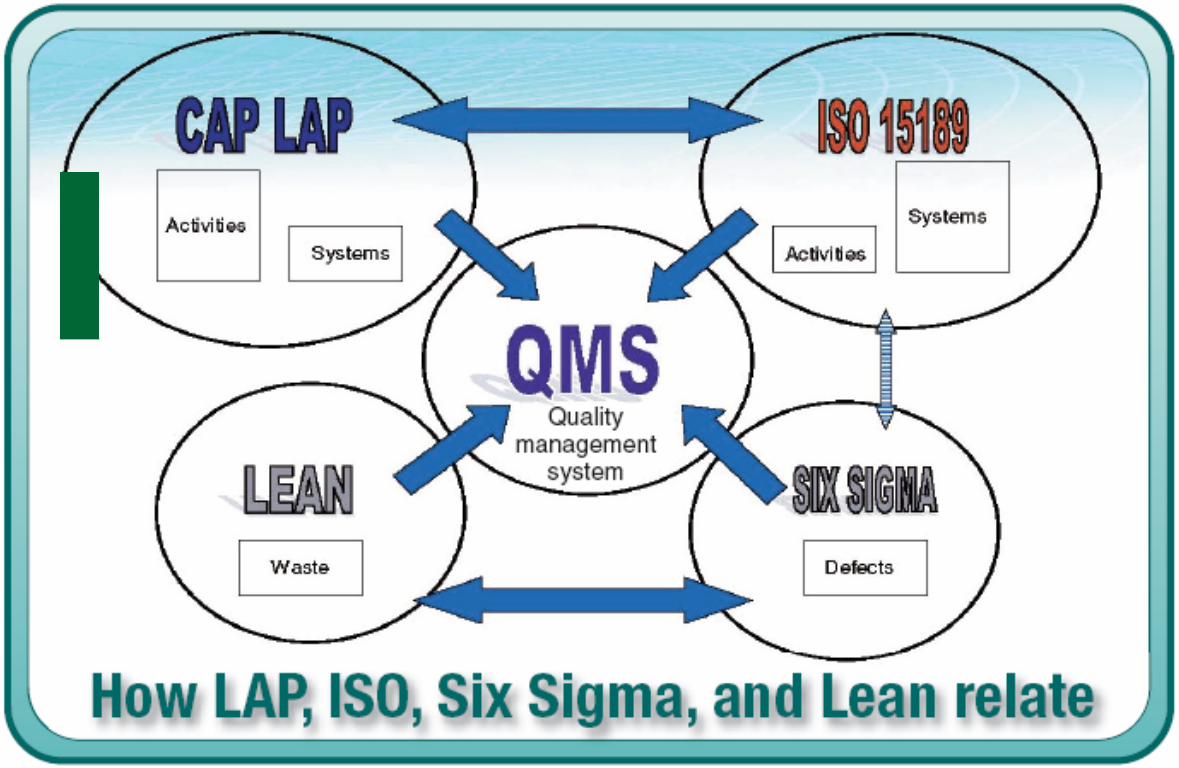
Stages of Quality (CLSI HS1-A2:2004)



CAP TODAY

College of American Pathologists

November 2008
Feature Story



http://www.cap.org/apps/docs/cap_today/1108/1108_ISO_15189_approval_02a.pdf

Cut the

Fat

Not the Quality

In Summary

- ISO is very complementary to Lean and Six Sigma
- ISO certification is a toolset to achieve bottom-line results
- Six Sigma addresses variability and reliability.
- Lean initiative creates culture change, streamlined processes and paving the way for faster and more effective Six Sigma results and, most importantly, gearing up for continuous improvement

Predicting Trends

- One cannot make predictions without the future making one look foolish.
- Things usually took five to six years to occur - three times longer than what have been expected.
- Opportunities in Laboratory Medicine are abundant, and will only increase going forward in time.
- *The next big thing in Laboratory Medicine is clearly the widespread acceptance and use of quality-management methods: Lean, Six Sigma, ISO 15189, and so forth…*

The Dark Report – November 2007 MLO www.mlo-online.com

ISO 9001/22870/15189


Quality
Improvement
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The Laboratory Has Entered a New Era of Uncertainty

- Today's Laboratory Manager faces a bewildering array of laws, guidelines, and standards. Are you going to be able to read all the CLIA Final Rules, EQC protocols and options, CLSI guidelines, ISO standards, Risk Management formulas, Patient Safety Goals and the accreditation and inspection checklists and procedures? *If you can, congratulations. You're probably the only one*.
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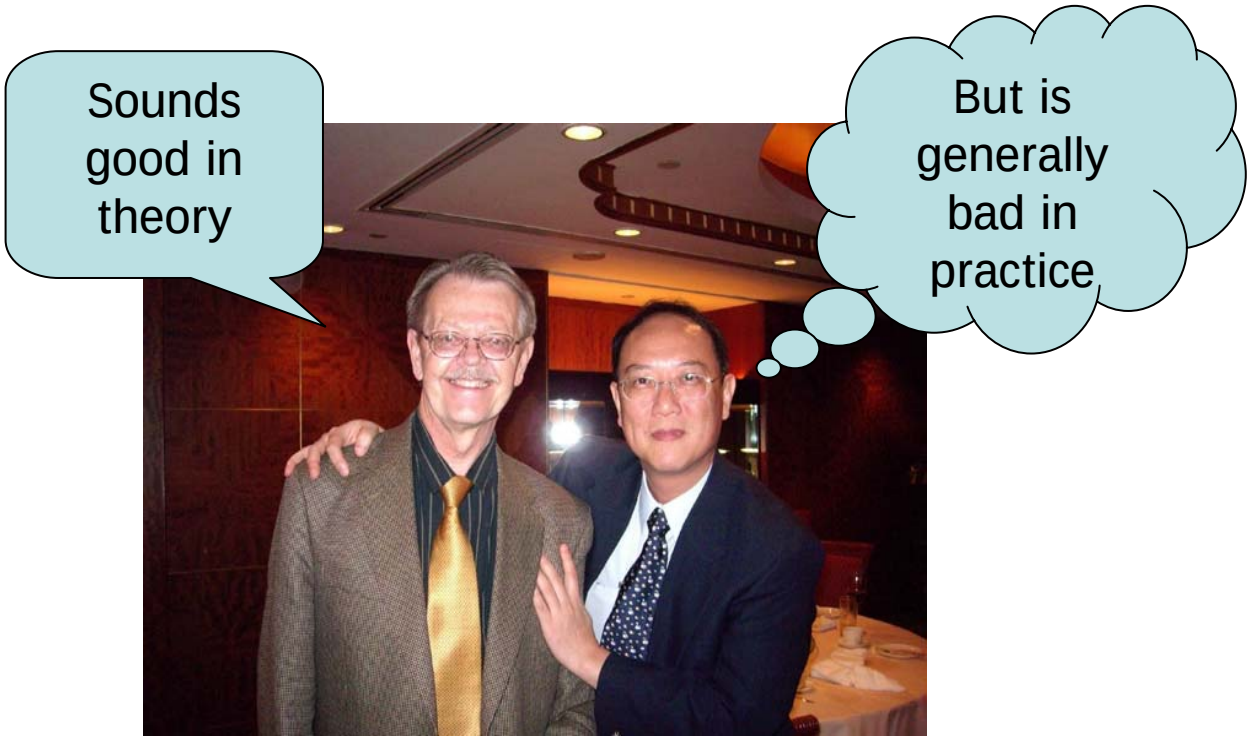
Quality Management



THANKYOU