POCT QC Based on Risk Management: How to Develop an IQCP

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Director, Scientific Affairs

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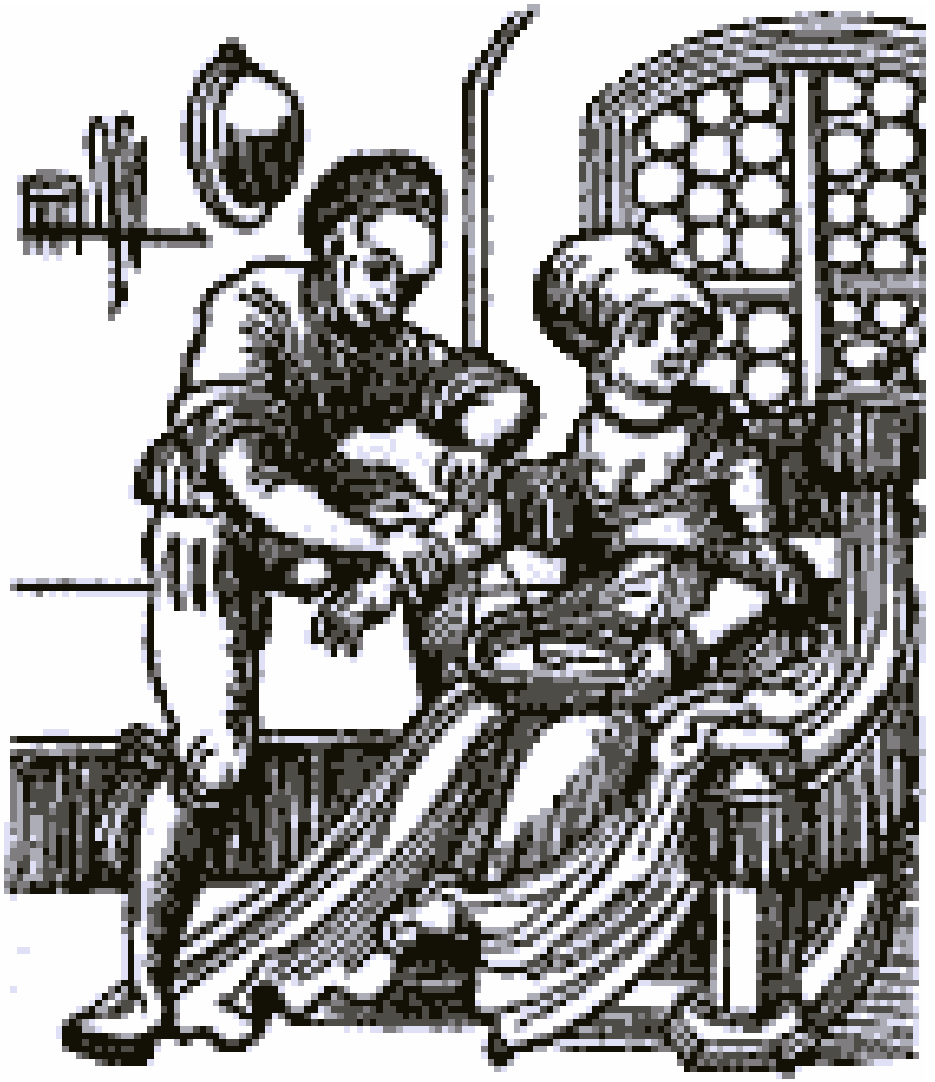
Point-of-Care Testing Characteristics

- A broad based process
- Unrestricted to location, personnel or test menu.
- A collective, multi-disciplinary effort.
- Simple to use technology
- Potentially low volume testing



The Truth about POCT

POCT introduces an additional technology

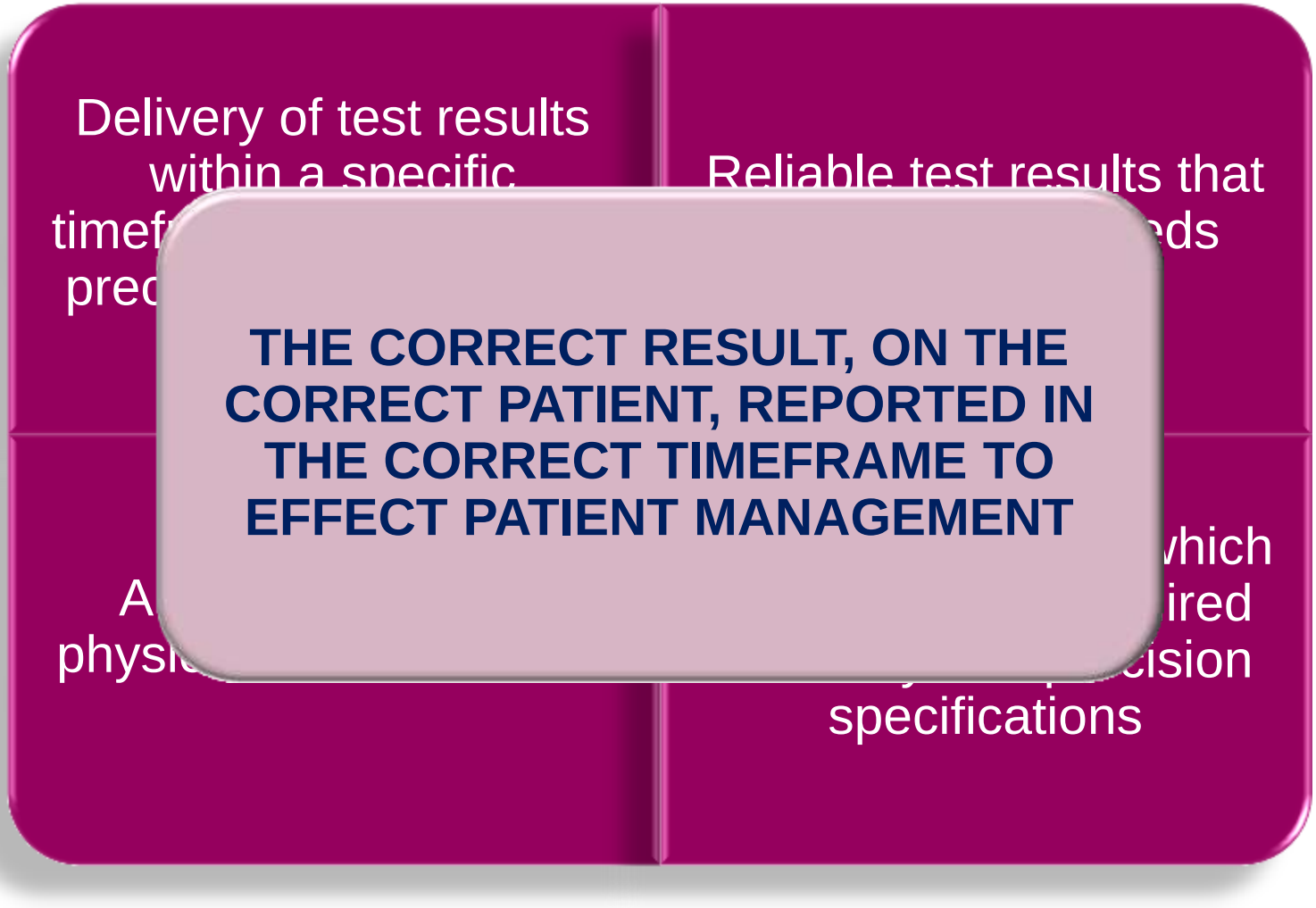
- Different precision
- Biases
- Unique Interferences

POCT results do not necessarily agree with core laboratory results

Quality concerns if manufacturers instructions and controls are not performed as required

Additional testing is ordered when POCT results do not match core lab results or questions about the quality of results present

What is Quality



Quality Issues

There is no “perfect” device, otherwise we would all be using it.

Any device can and will fail under the right conditions.

Any discussion of risk must start with what can go wrong with a test (errors).

Laboratory tests are not foolproof.

Quality System

Organizational structure, resources, policies, processes and procedures needed to implement quality management

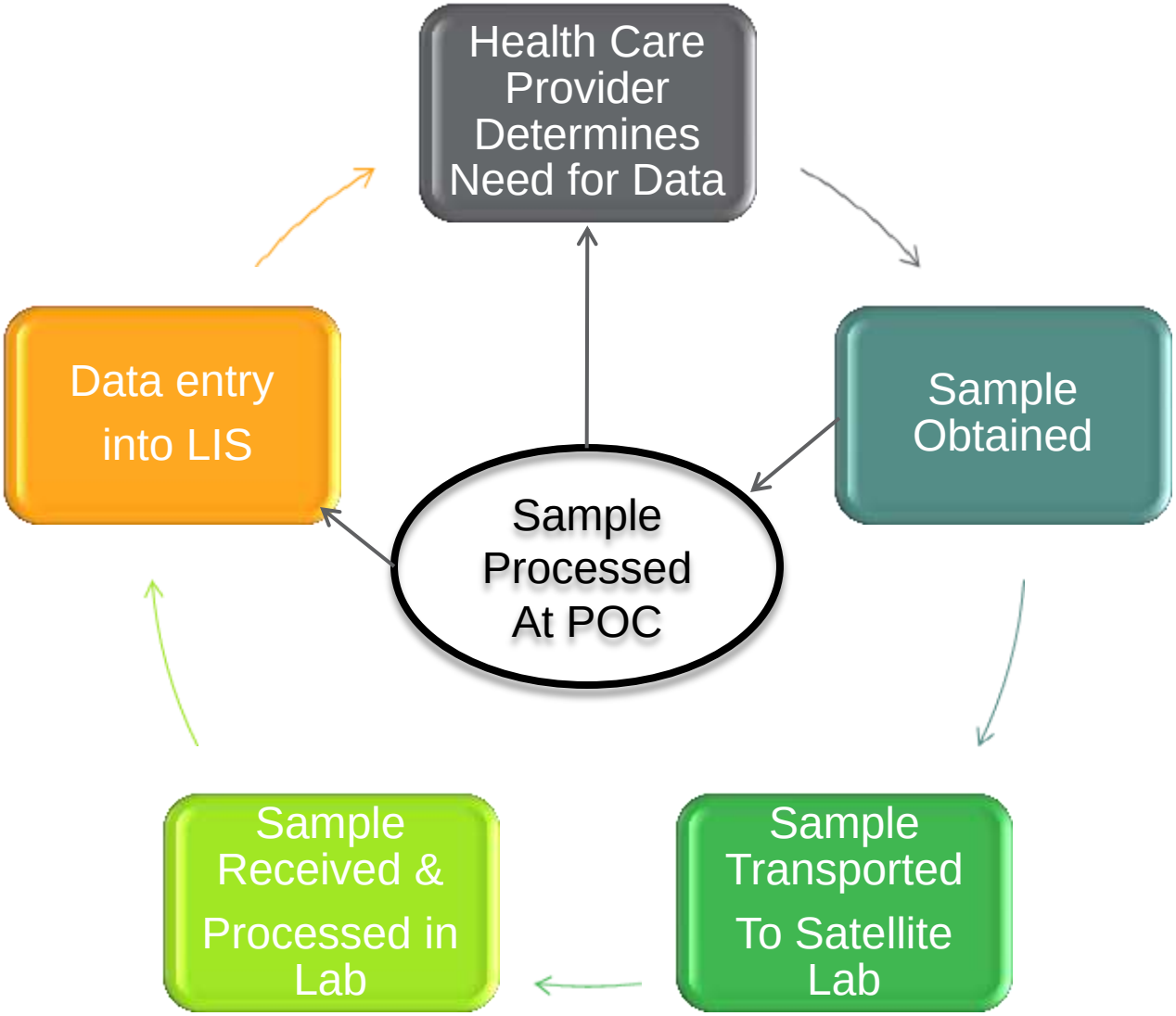
(ISO, CLSI)

In other words… all activities which contribute to quality of testing, directly or indirectly.

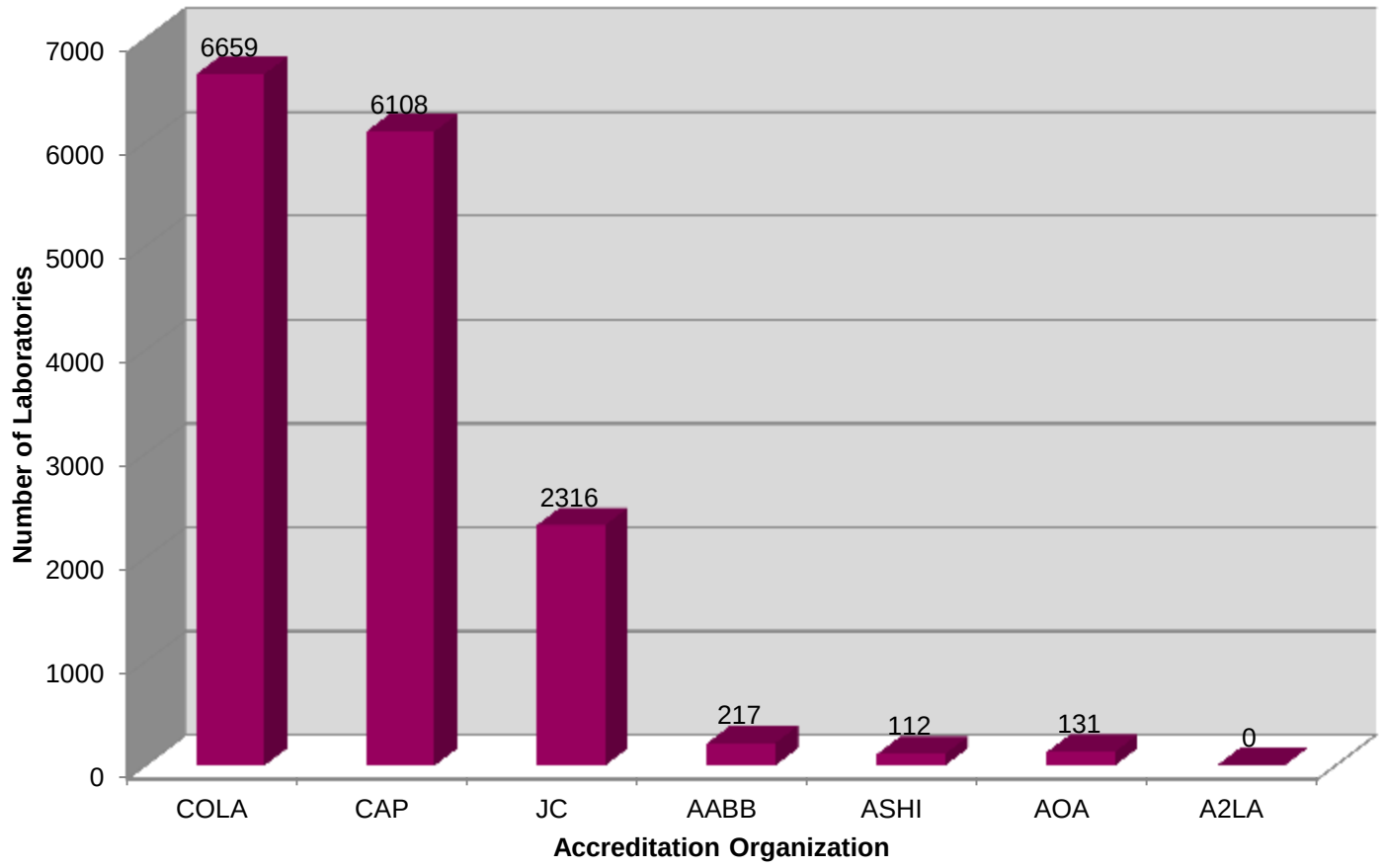
Quality Assurance

All planned and systematic actions necessary to provide adequate confidence that goods or services will satisfy the customer's needs.

POC Testing Knowledge Flow

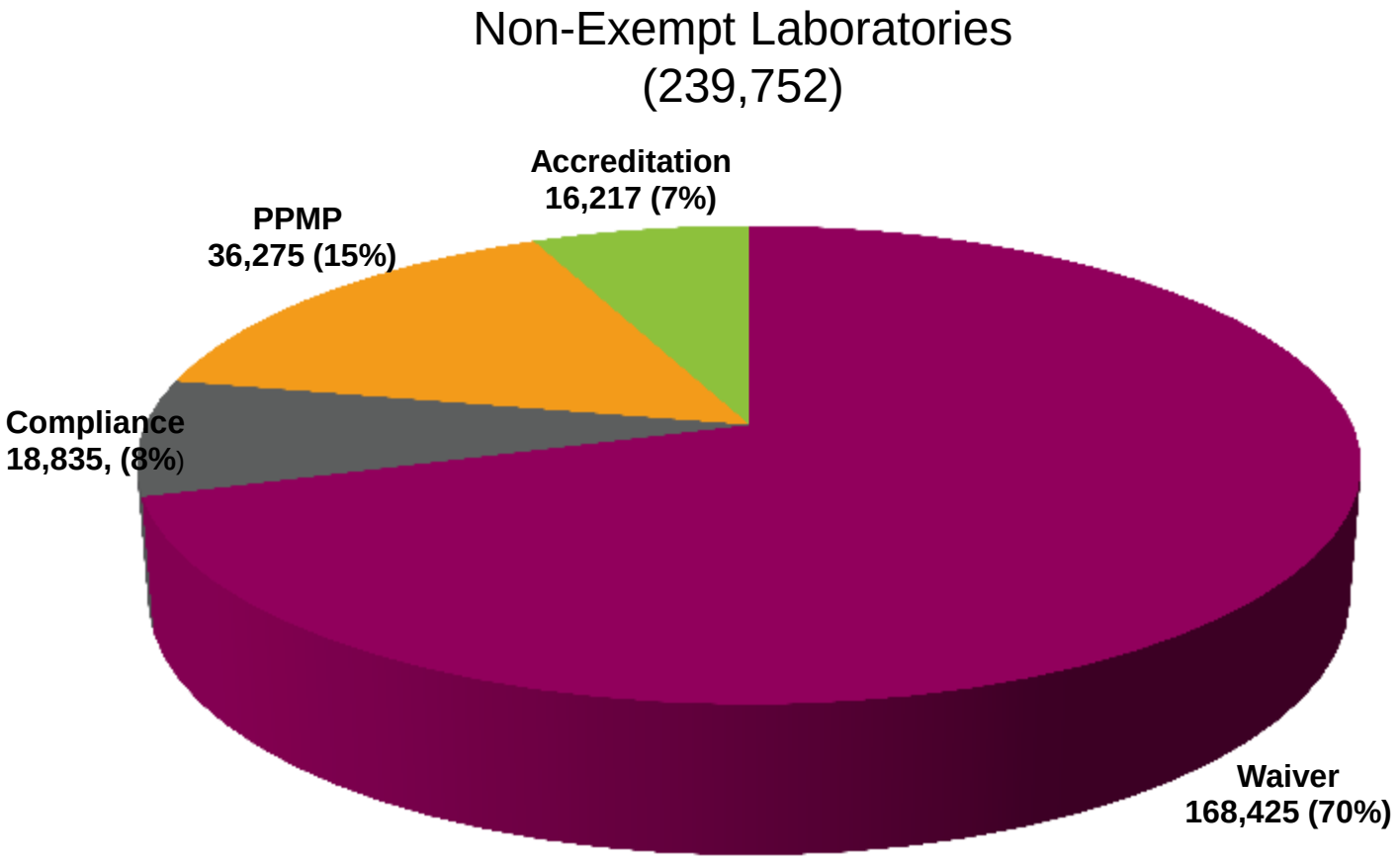


Number of CLIA Certificate of Accreditation Labs



Source: CMS CLIA database June 2014

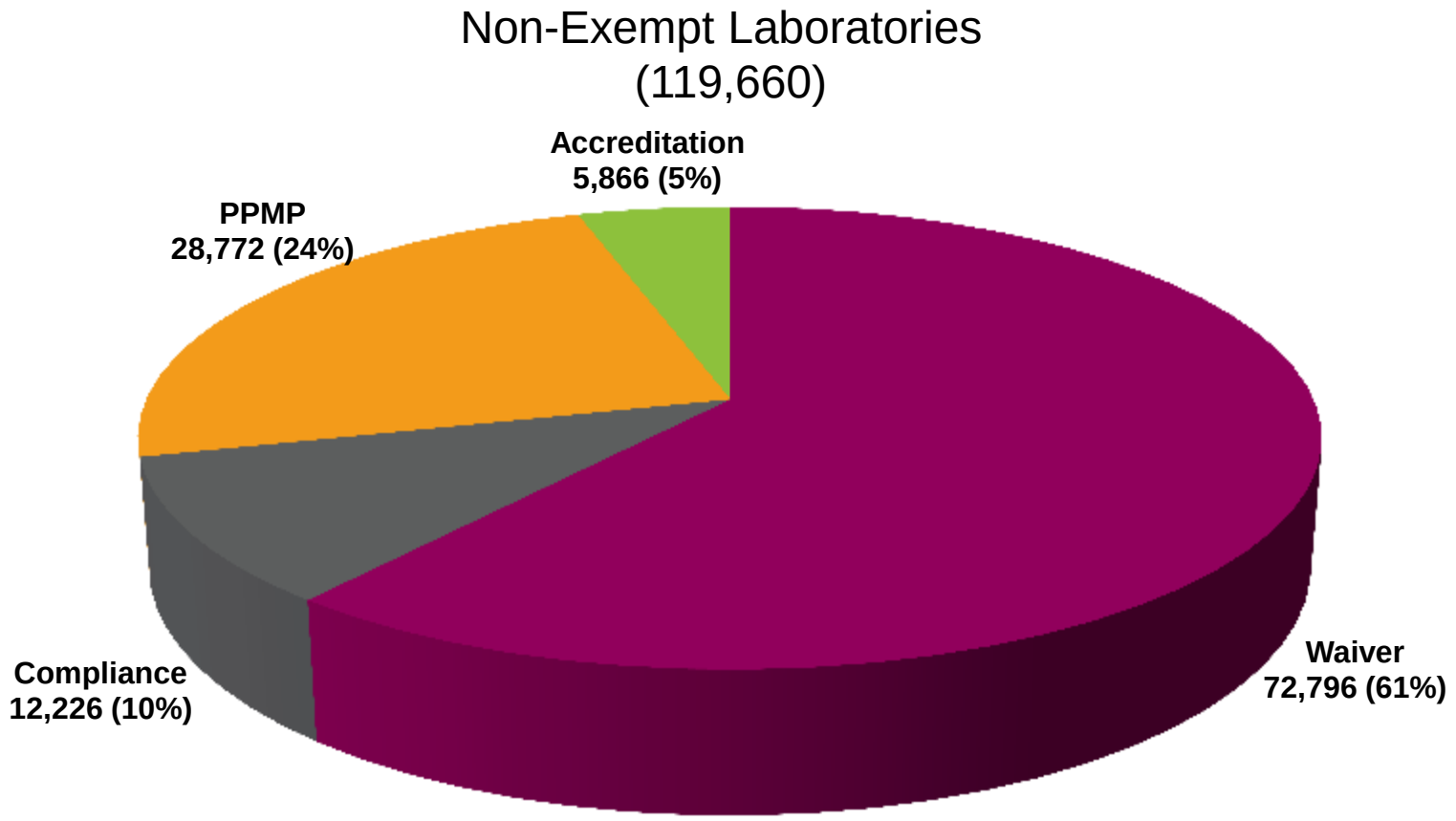
Number of CLIA Certificate of Accreditation Labs



CLIA Exempt States: NY (3,990), Washington (3,974)

Source: CMS CLIA database June 2014

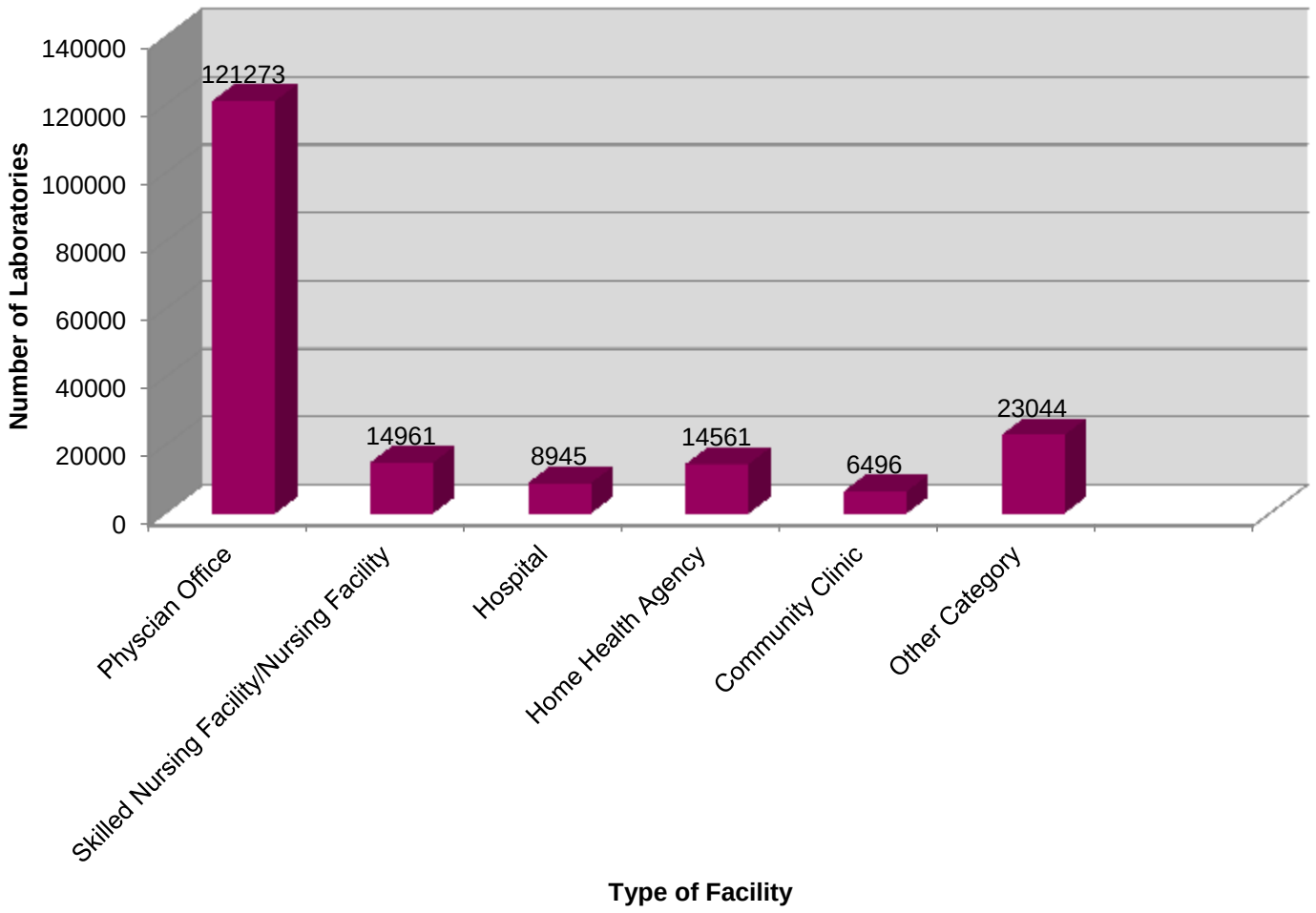
Number of CLIA Certificate of Accreditation POLs



Exempt Labs = 1,613

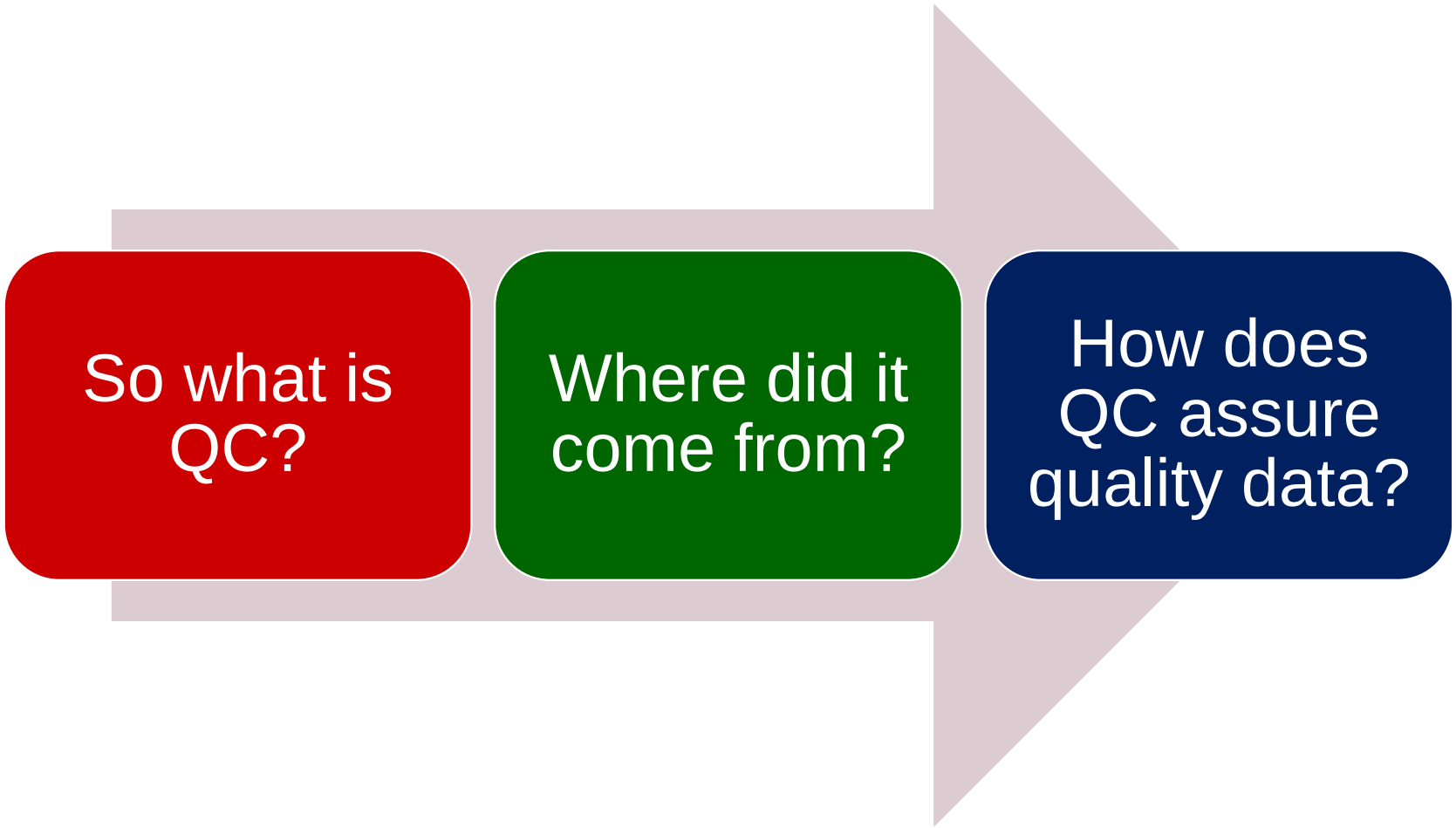
Source: CMS CLIA database June 2014

Number of CLIA Laboratory Registration Self-Selected Laboratory Types



Source: CMS CLIA database June 2014

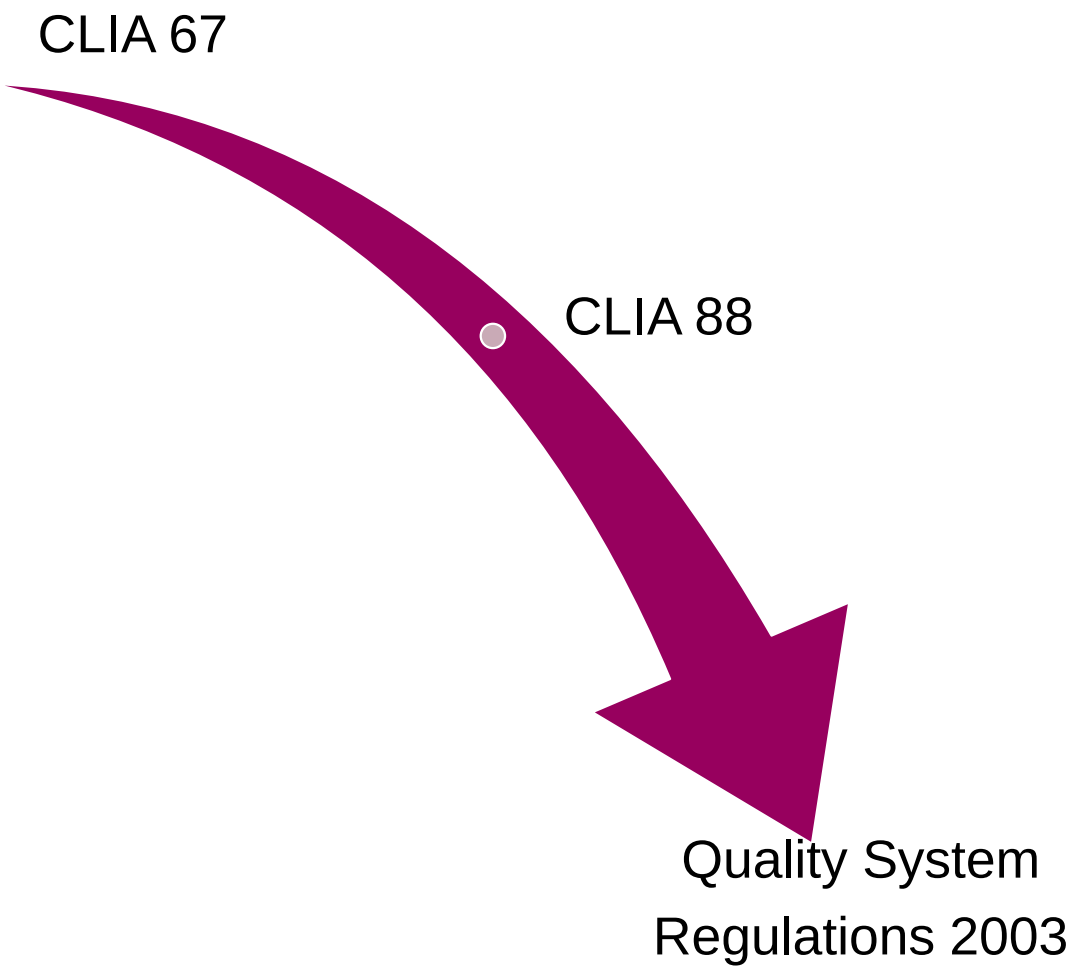
Evolution of QC Practices

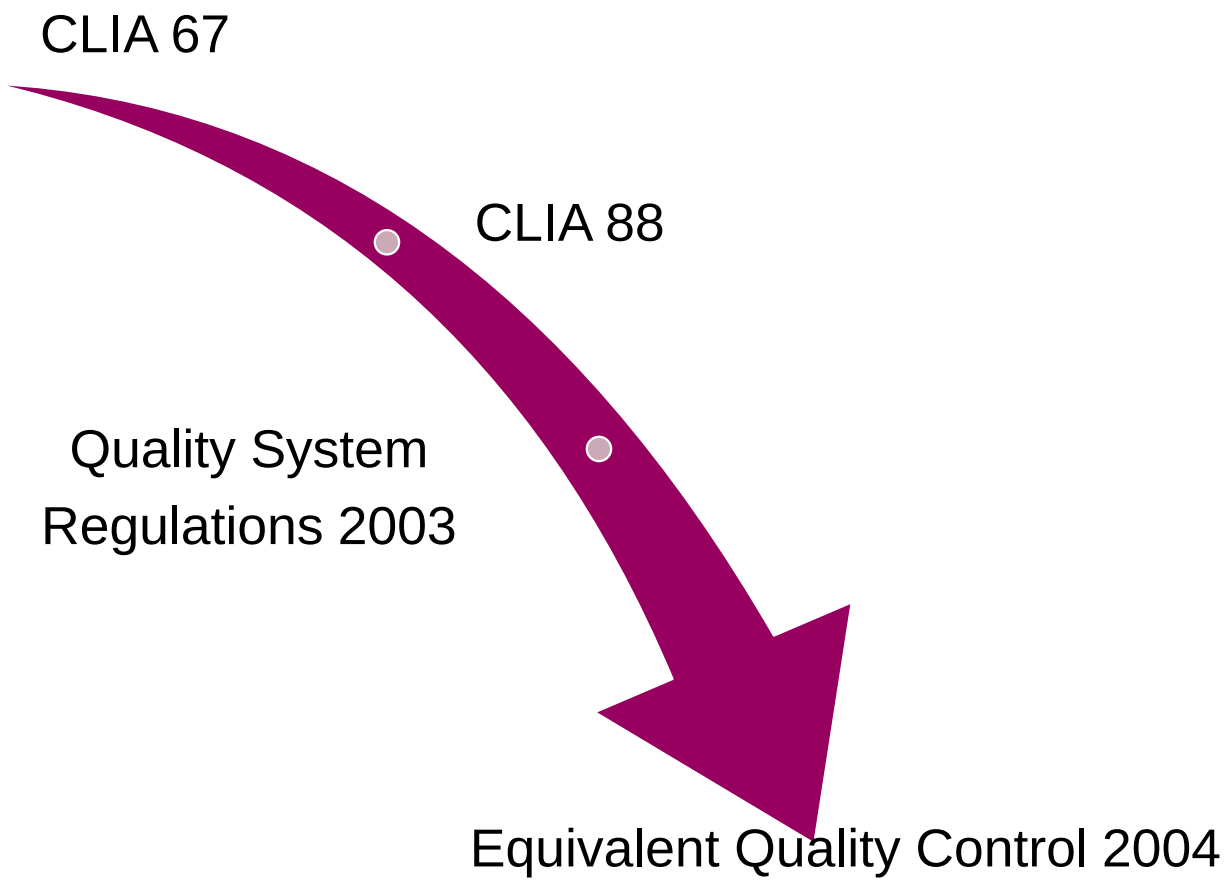


Quality Control

Operational techniques and activities used to fulfill requirements for quality (ISO)

Internal quality control (IQC) – set of procedures for continuously assessing laboratory work and the emergent results; immediate effect, should actually control release of results (WHO, 1981)





493.1256 – QC procedures

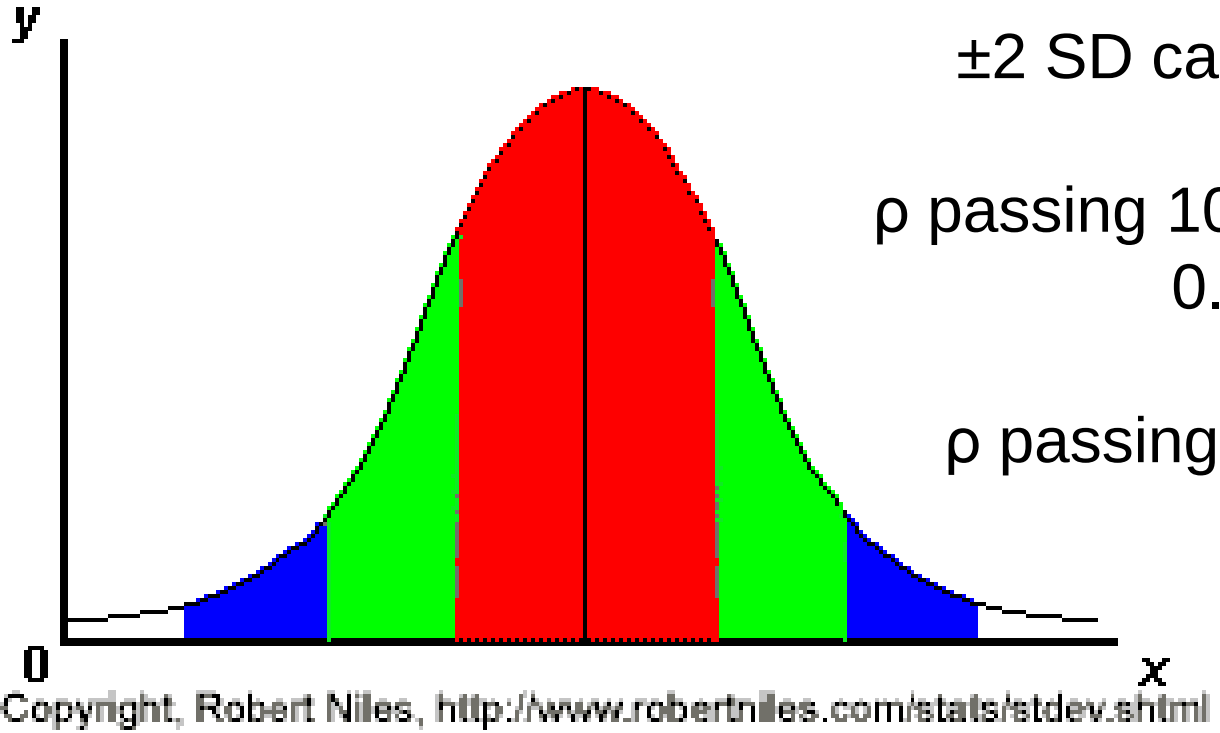
For each test system, the laboratory must test, at a minimum, two levels of external QC materials each day it performs a nonwaived test.

However, the regulations now allow the laboratory to reduce the frequency of testing external QC materials (equivalent QC procedure) for certain test systems.

EQC Evaluation

	Evaluation Process		External QC checks
Option 1 System monitors all analytic components	Daily testing with internal monitoring systems	10 consecutive days of passing external QC	At least once per month
Option 2 System monitors some analytic components	Daily testing with internal monitoring systems	30 consecutive days of passing external QC	At least once per week
Option 3 System monitors no analytic components	NA	60 consecutive days of passing external QC	At least once per week

Normal Population Distributions



±2 SD captures 95% of data (0.95).

ρ passing 10 reps = 0.95^{10}=0.598.

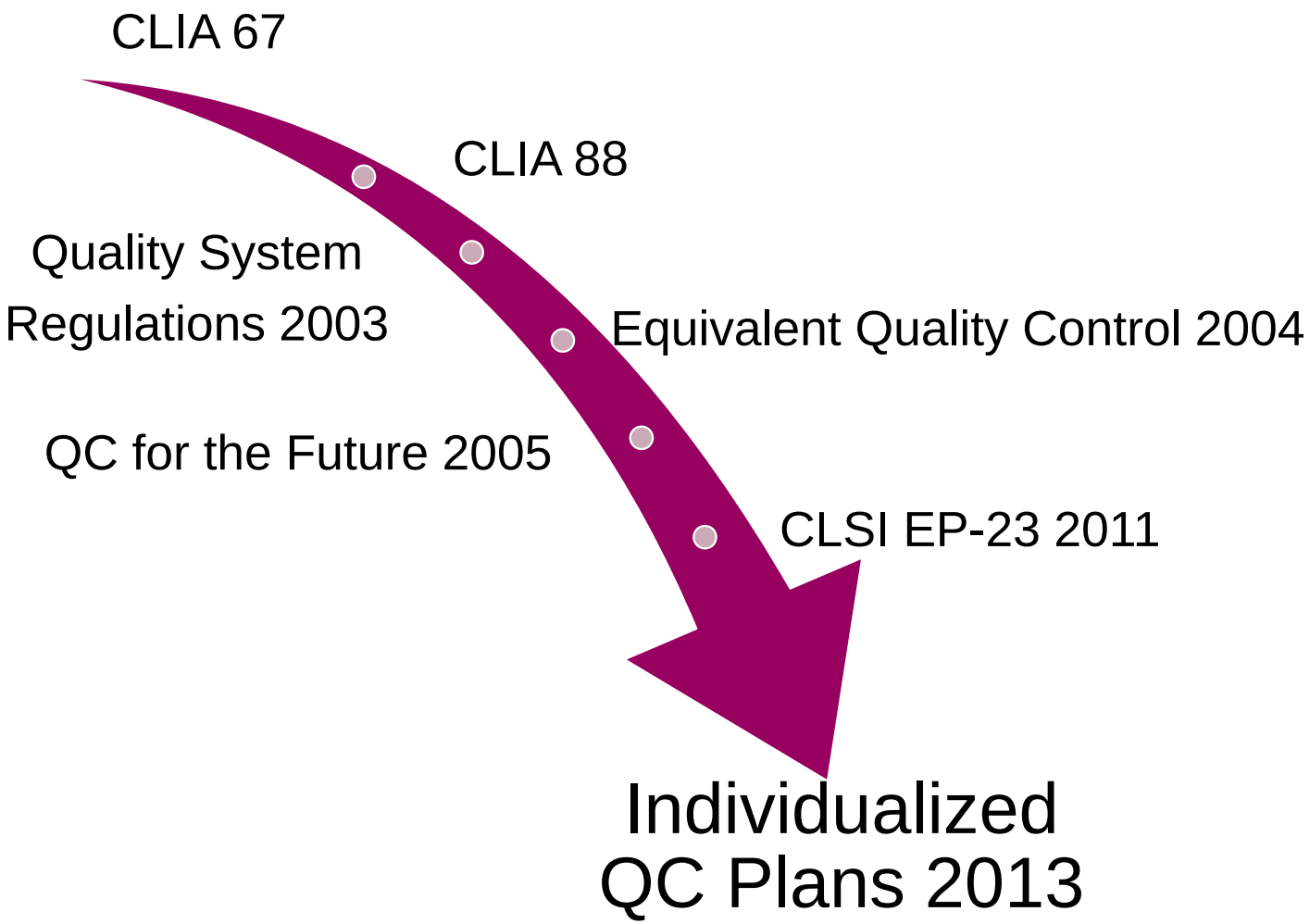
0.95^{30}=0.215

ρ passing 10/11 reps = 0.897

± 1 SD captures 68% of data

±2 SD captures 95% of data

±3 SD captures 99.7% of data



CLSI to the Rescue!!!

EP23

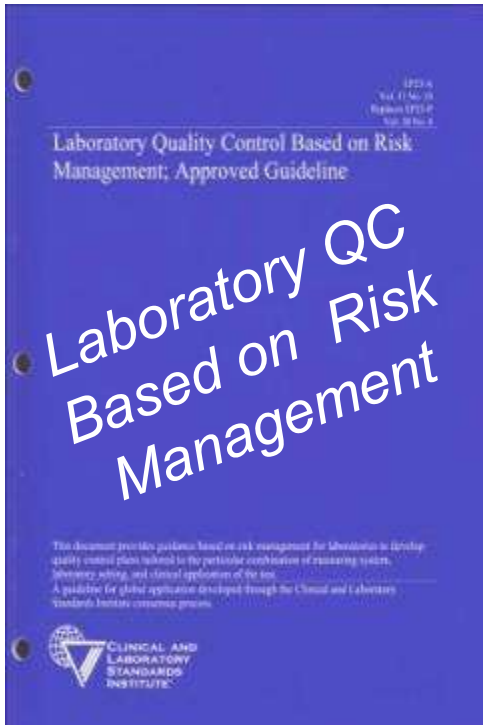
User Defined QC Protocols for *In Vitro* Diagnostic Devices Based on Manufacturer's Risk Mitigation Information and the User's Environment

EP18

Risk Management Techniques to Identify and Control Laboratory Error Sources

CLSI. *Laboratory Quality Control Based on Risk Management; Approved Guideline.* CLSI document EP23-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

CLIA's New QC Option – Jan. 1, 2016



Quality control plan development based on risk management (RM)

Systematic approach to analyze, evaluate, control, and monitor risks

CMS' *new* CLIA IQCP option incorporates RM concepts

ISO14971:2007. Application of risk management to medical devices. www.ISO.org ;
Clinical and Laboratory Standards Institute. www.CLSI.org;
http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

The Foundations of IQCP

Includes key concepts from CLSI EP-23, "*Laboratory Quality Control Based on Risk Management*"

IQCP is not EP-23

Labs are not required to incorporate EP-23

CLIA QC options

	Now	Jan. 1, 2016
Default (2-3 levels external QC/day)		
EQC (Equivalent QC)		
IQCP		

Individualized Quality Control Plan (IQCP)

CLIA

- ☑ **Customizes** QC Plan for each test in its unique environment
- ☑ **Optimizes** use of electronic/integrated controls
- ☑ **Offers** laboratories **flexibility** in achieving QC compliance
- ☑ **Adaptable** for future advancements in technology
- ☑ **Incorporates** other sources of Quality Information
- ☑ **Strengthens** Manufacturer/Laboratory partnerships
- ☑ **Formalizes** risk management data already maintained within the laboratory
- ☑ **Provides** equivalent quality testing to meet the CLIA QC regulations

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

CMS goals for IQCP

Address concerns with “built-in, quality assessment” technology in evaluating test quality

- IQCP validates, at a minimum, that manufacturer recommendations adequately **ensure analytical quality**

Ensure test result quality by eliminating significant risk in the entire testing process

Allow sites flexibility to develop quality strategies appropriate for their specific testing situation

IQCP overview

Is it voluntary?	• Yes
Who is eligible?	• All specialties *except* pathology and cytology
What is involved?	• Risk assessment • Quality control plan • Quality assessment for ongoing effectiveness

3/9/12 CMS Official Memorandum

Key concepts from EP-23 will be an acceptable alternative QC policy. The New CLIA QC policy will be entitled Individualized Quality Control Plan (IQCP)

IQCPs are a formal representation and compilation of many things laboratories currently do for quality.

IQCPs permits the laboratory to customize its QC plan according to environment, reagents, testing personnel, specimens, and test system.

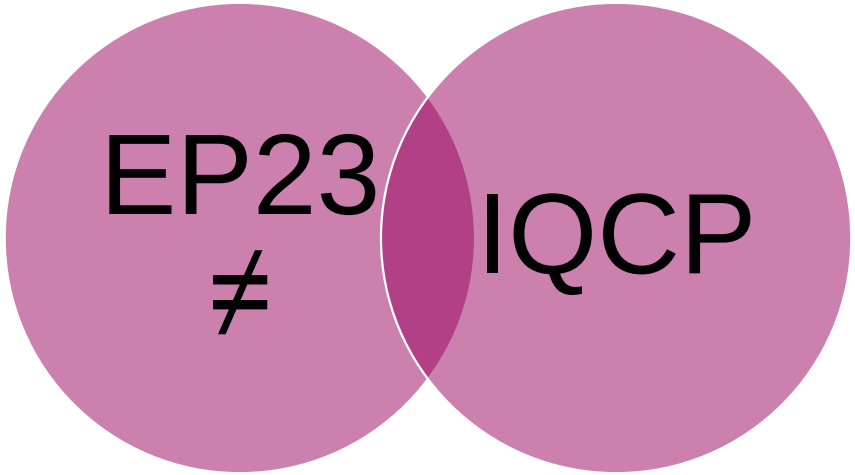
IQCP will be voluntary: Laboratories will have two choices for QC compliance: 1) Two levels of QC per day or, 2) IQCP. Package insert requirements must be met.

Education period: 1/1/14-1/1/16

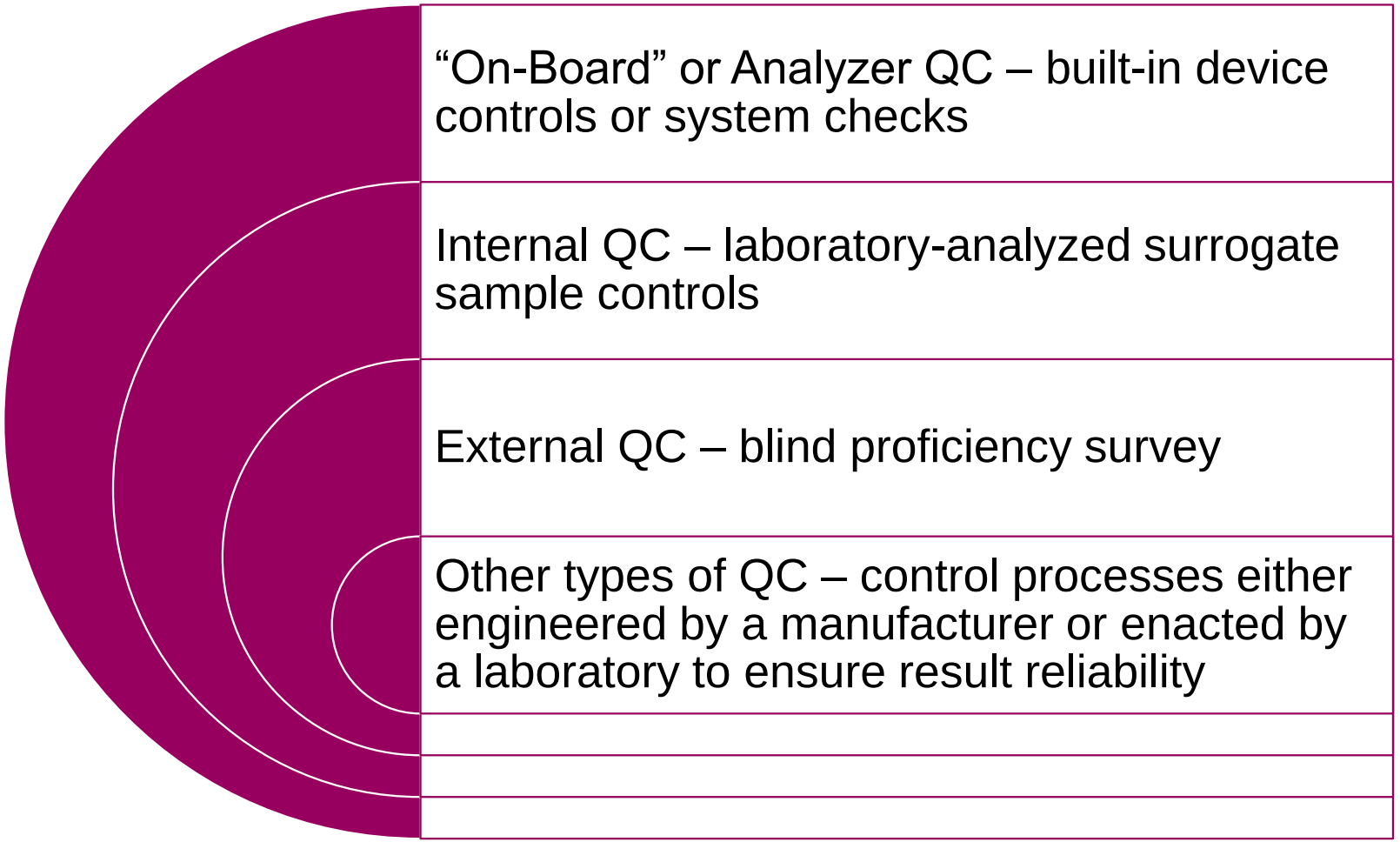
EQC will be phased out at the end of the education and transition period

Remember…

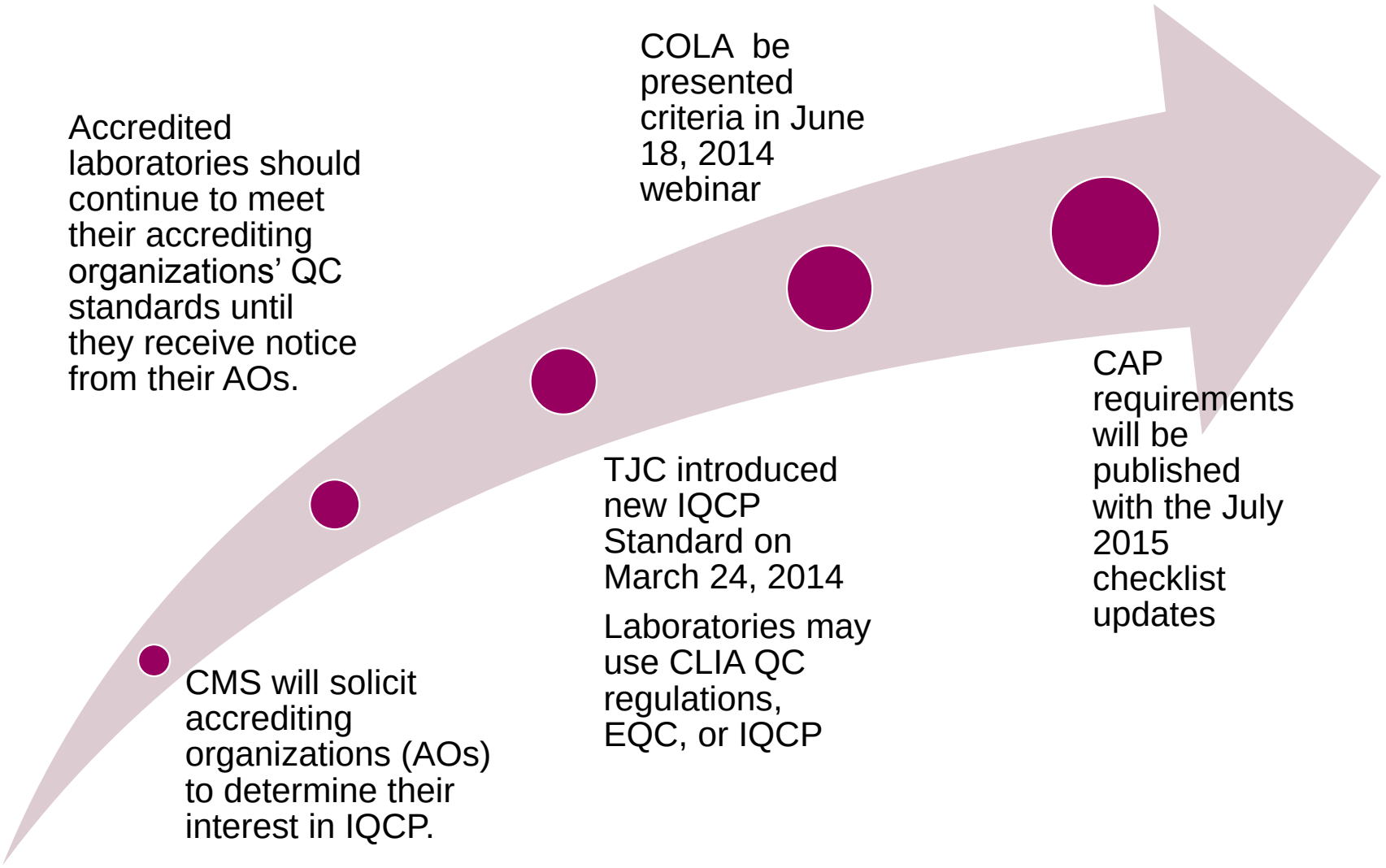
- **CMS/CLIA Website:** http://www.cms.hhs.gov/clia/
- **CMS CLIA Central Office:** 410.786.3531
- **IQCP Link:** IQCP@cms.hhs.gov
- EP23 Workbook



Types of Quality Control



Accrediting Agencies Updates



Sources of Errors in POCT

Scientific Affairs
Clinical. Technical. Educational.

Key Processes in Laboratory Workflow Path

Preexamination (Preanalytical) Processes	Examination (Analytical) Processes	Postexamination (Postanalytical) Processes
• Examination ordering • Sample collection and labeling • Sample transport • Sample receipt and accessioning • Preexamination sample processing	• Examination • Results review and follow-up • Medical review	• Results reporting • Results archiving • Sample archiving • Charging for examinations, where applicable

CLSI. *Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition*. GP02-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2006.

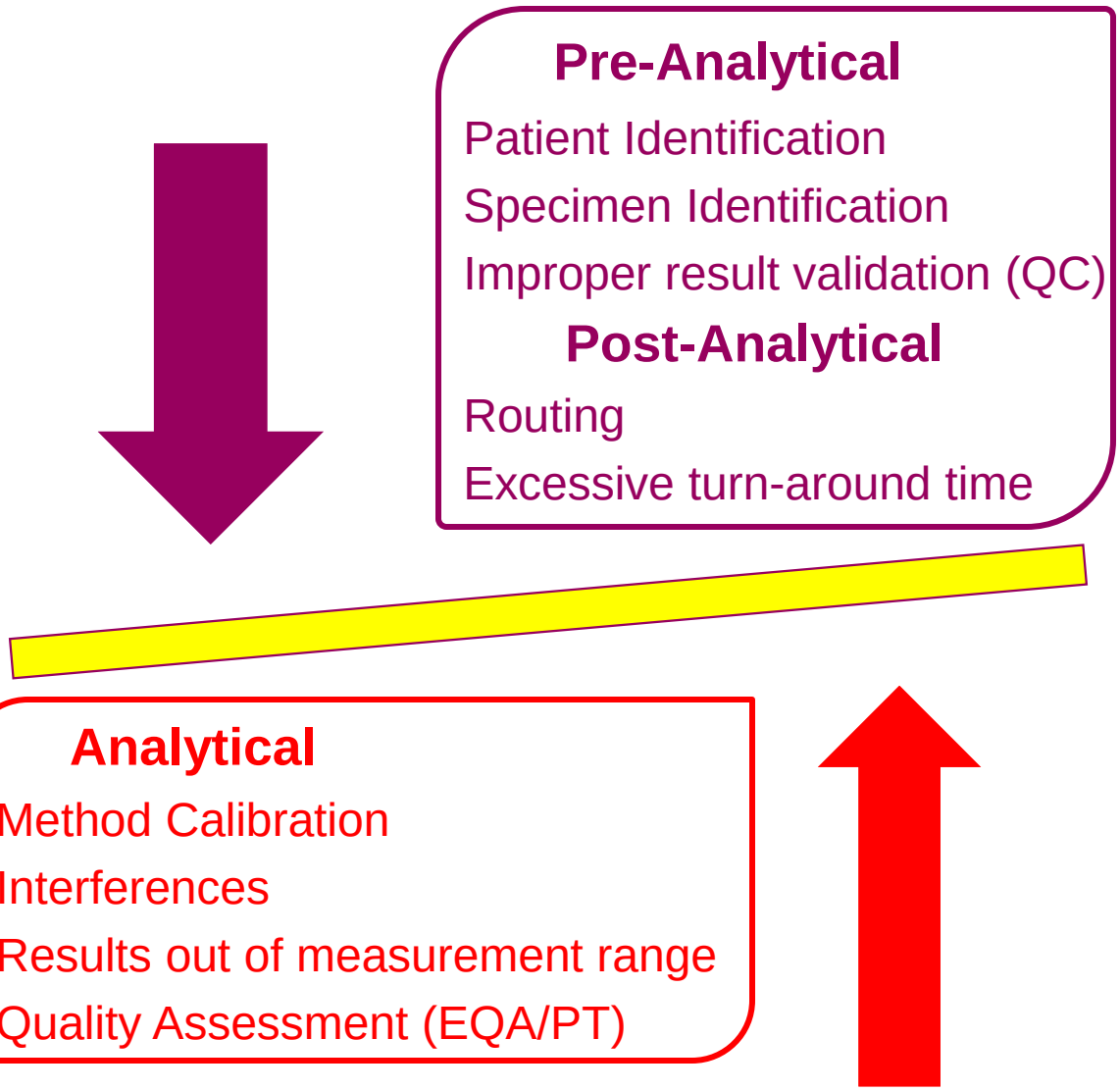
Sources of Testing Error

	1997	2007
Preanalytical	68%	62%
Analytical	13%	15%
Post-analytical	19%	23%

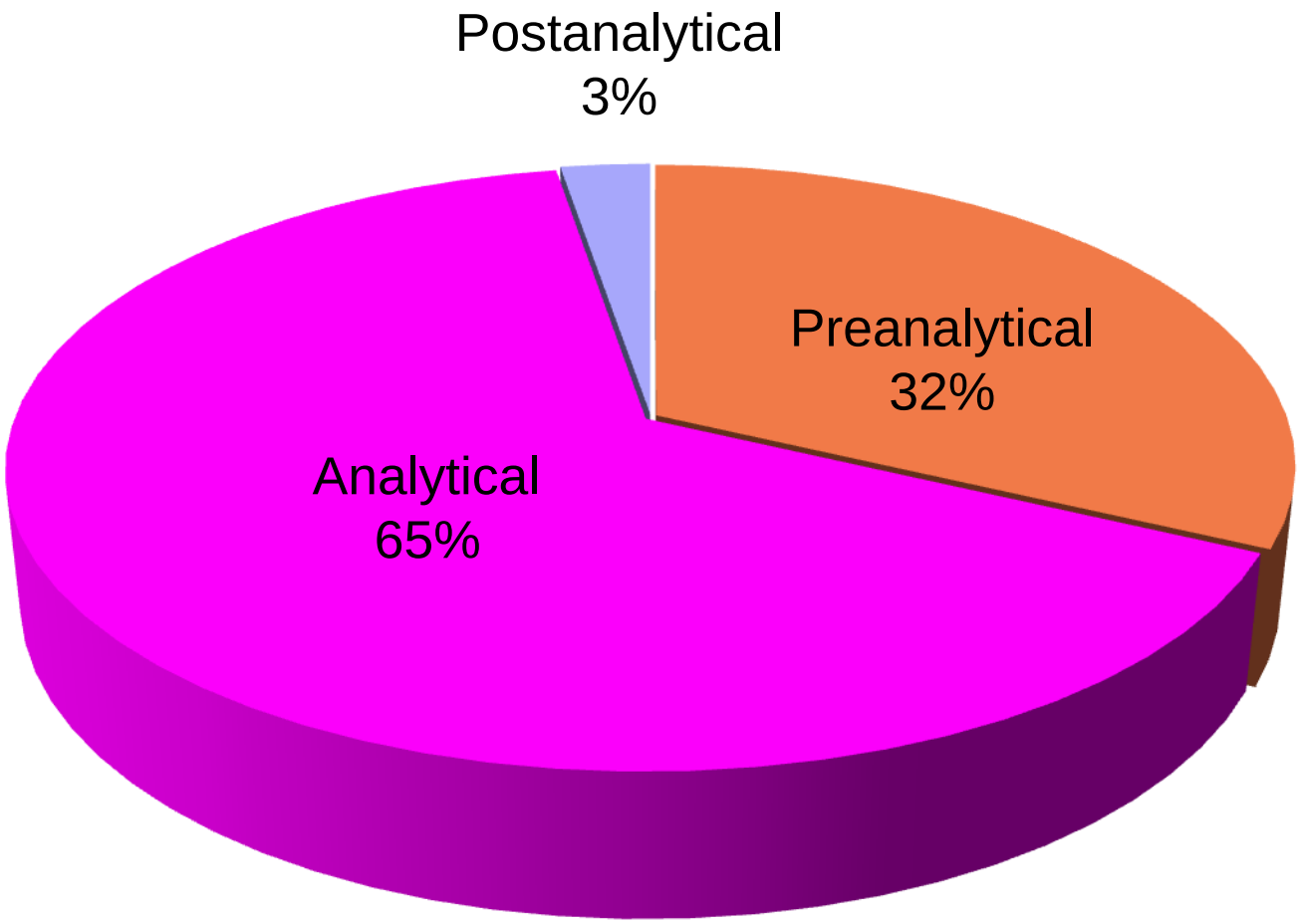
Plebani M, Carraro P, Clin Chem 1997;43:1348-1351

Carraro P, Plebani M, Clin Chem 2007;53;1338-1342

Potential Impact of POCT on Laboratory Errors



Sources of Quality Errors in POCT



N = 225

O'Kane M, et al, Clin Chem 2011;57:1267-1271

POCT Quality Errors by Test

Test Type	# of Tests	# of defects	% of defects
Blood gas/electrolytes	22,687	119	0.52
Blood gas/electrolytes/ troponin I	5,809	10	0.17
Pregnancy	8,879	14	0.158
Glucose	30,389	71	0.02
Drugs of Abuse	247	1	0.4
Hb A1c	1,236	8	0.65
Urinalysis	64,370	2	0.003
Blood Ketones	1,087	0	0

O'Kane M, et al, Clin Chem 2011;57:1267-1271

Impact of POCT Errors

Score	Acutal n (%)	Potential n (%)
1	116 (51.2)	6 (2.7)
2	109 (48.4)	175 (77.8)
3	0 (0)	3 (1.3)
4	0 (0)	33 (14.7)
5	0 (0)	8(3.6)

O'Kane M, et al, Clin Chem 2011;57:1267-1271

Managing Sources of POCT Errors

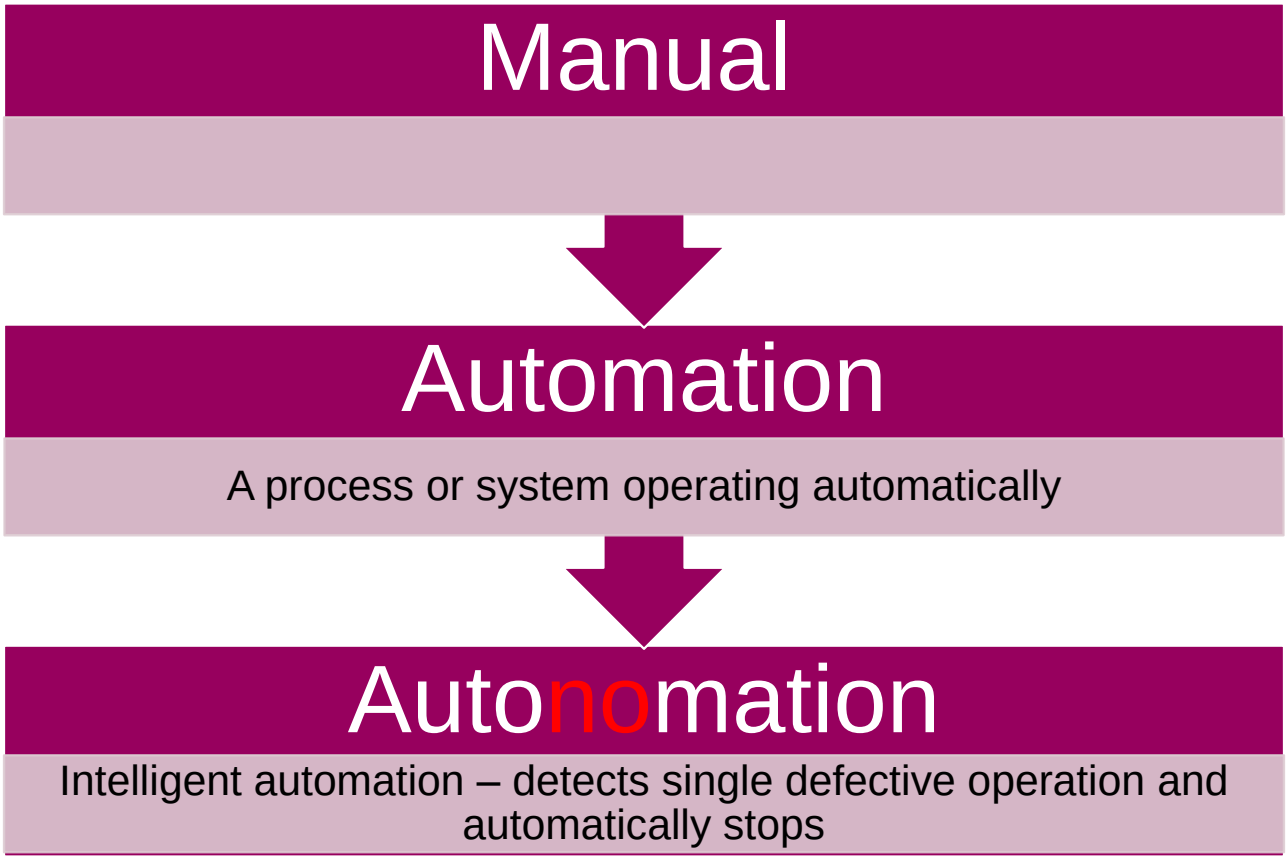
Designed out of the product

Tested for

Warned about

- monitored

Evolution of POCT



Ehrmeyer S, Lassig R. Clin Chem Lab Med 2007;45(6):766-773

Patient/Sample Identifcation

Pre-barcoded arterial syringe for positive patient identification

Establishes and maintains sample ID throughout testing process

Preanalytical Error Reduction

Reduced Analytical Risks

- Glucose-specific strip technology
- Individually foil wrapped and bar-coded strips –
  - reduces risk of contamination
  - assure fresh reagents for each test
  - only approved lots can be used

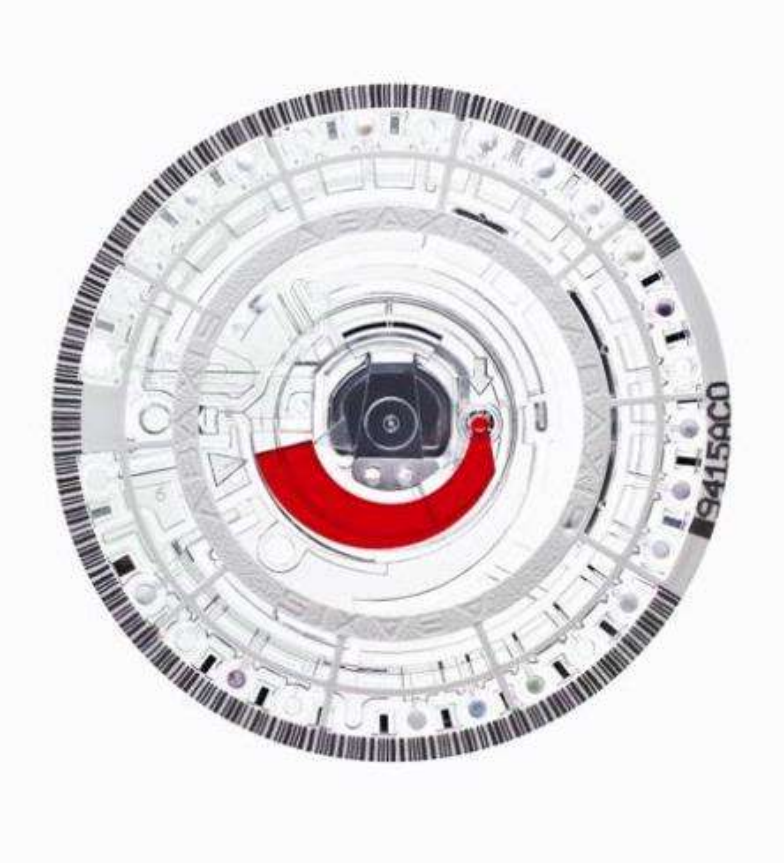
Reduced Risk of Sampling Errors

- Test begins when adequate sample is detected, reducing risk of short-sampling and over-sampling errors

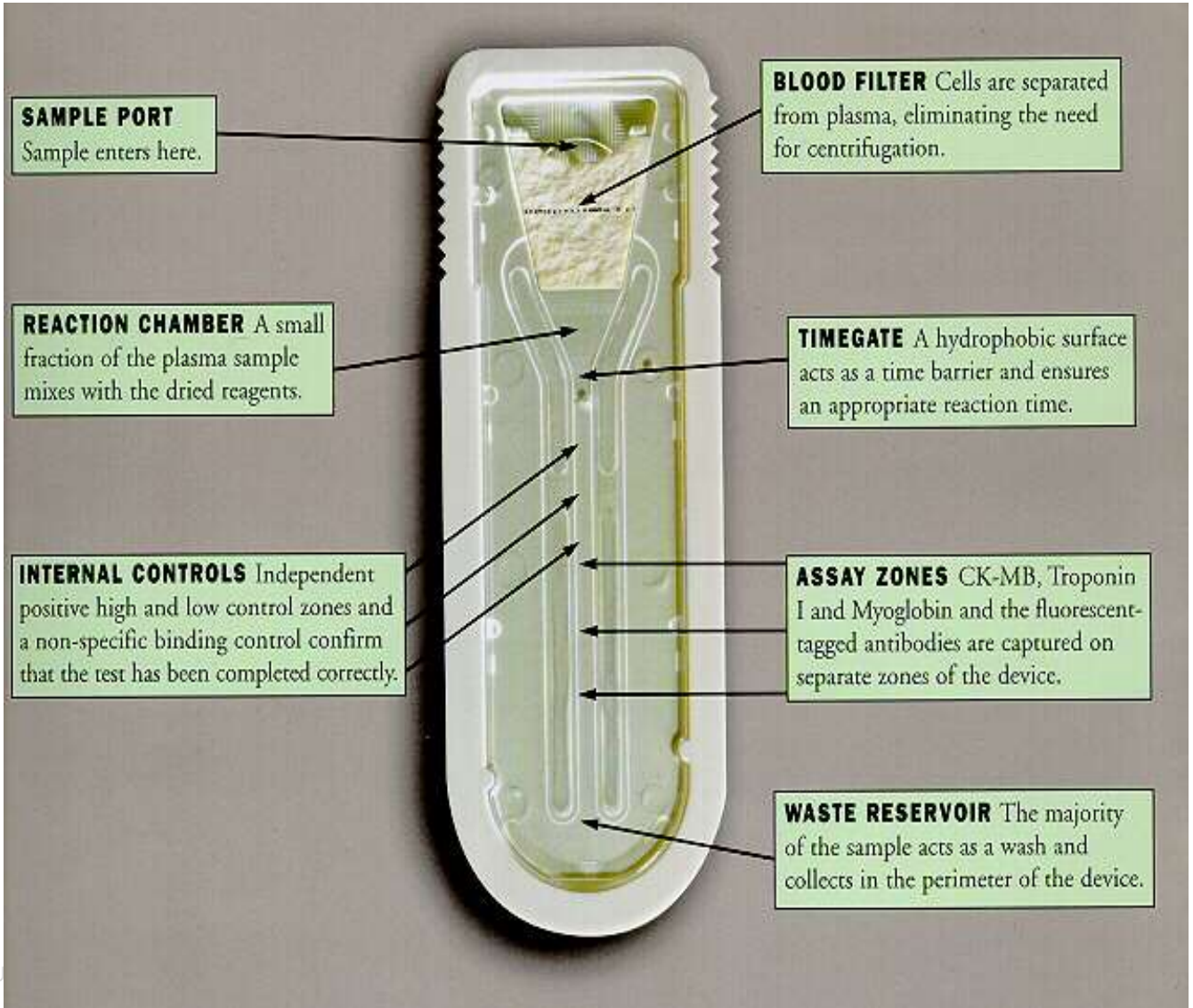
Nature of QC Procedures

- Use of electronic checks, including any instrument software features that serve as error detection or prevention mechanisms
- Use and number of surrogate samples, where appropriate, to be included as part of the QC procedure
- Testing of controls that are engineered into the test system

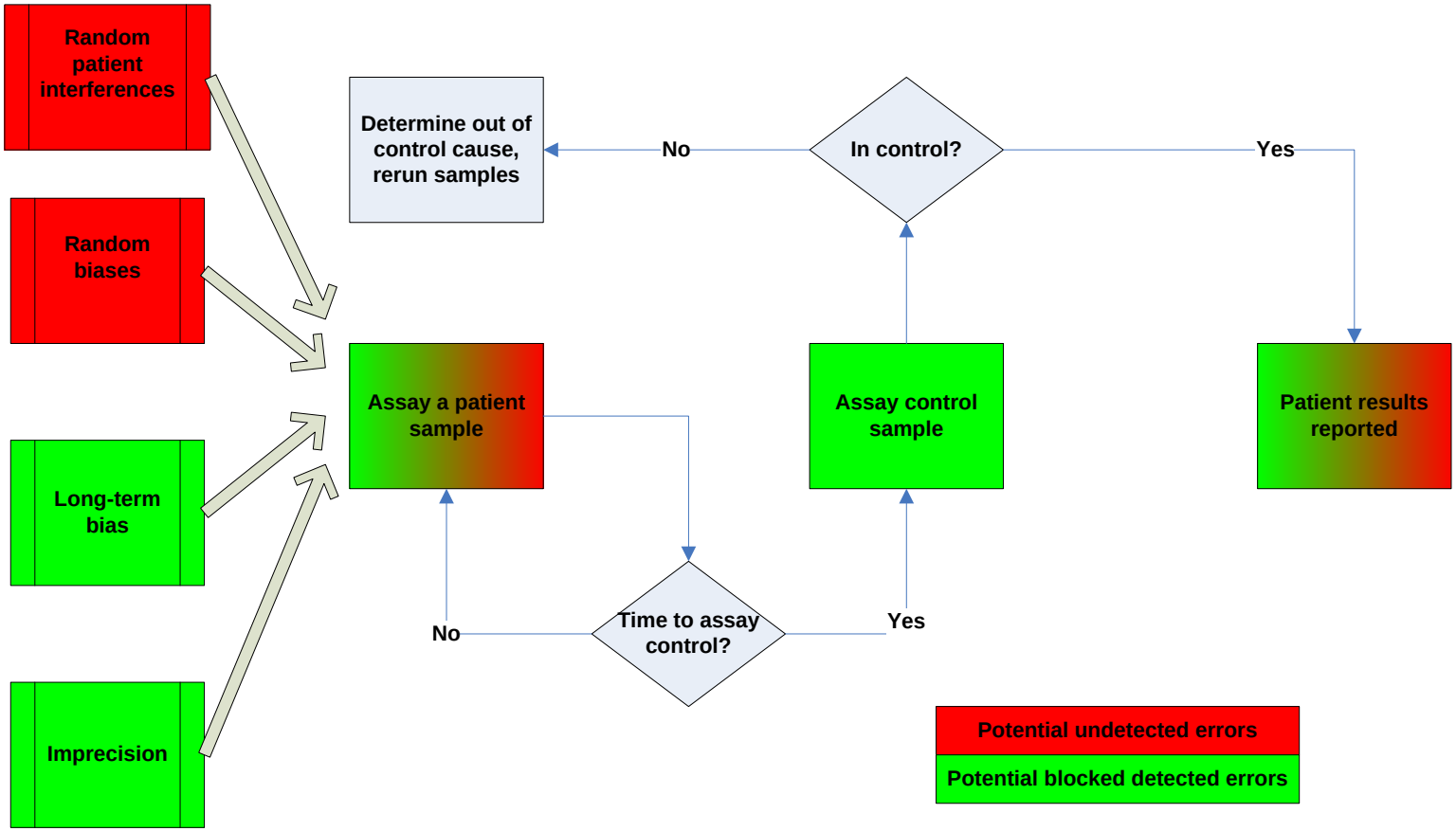
Integrated Surrogate Controls Centrifugal Analyzer



Integrated Surrogate Control Quantitative Immunochromatography



Surrogate QC doesn't detect all errors



Non-Surrogate Sample QC

Includes all forms of quality control other than the measurement of a surrogate sample, usually integrated into the device

- electronic QC (which simulates signals electronically)
- automated procedural controls (which ensure that certain steps of the procedure occur appropriately), ex. Immunochromatography test kits
- automated internal quality controls (which may, for example, ensure the quality of a raw signal)
- diagnostic pattern recognition systems

Procedural Control
Immunochromatography – Urine Dip

Internal Monitoring Systems

IMS are a collection of hardware and software that detect errors and prevent the effect of the error from occurring

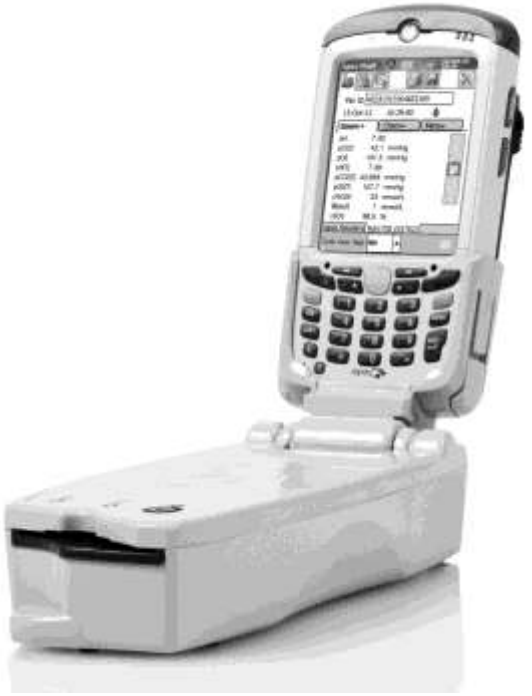
- Example: Noise in the signal of a patient sample is detected, the result is flagged and not reported

IMS are not new – although improved, they have been in systems for over 30 years

The epoc® System

epoc® BGEM Test Card	epoc® Reader	epoc® Host Mobile	epoc® Data Manager

Room temp storage
11 measured results
10 calculated results
~30 second test time



epoc™ EDM — EPOC Data Manager

Connected to : EDM DB 2.1.0 User: epocsysadmin EPOC Link @ 192.168.10.10 : 45002 ✔ DB : ✔ 2.1.0 Log Off

EPOC Manager > Tests > Blood Tests

Blood Tests QA Tests EPOC System

Blood Tests (last 7 days) - 24 tests

My Tests | Select Filter Type ... | Select Filter Value ... | From : 10/23/2008 | To : 10/29/2008 | Refresh

Date/Time	Patient ID	Operator	Host	Reader	Status	Critical	LIS
29-Oct-08 14:33		administrator	EPOC Host 0055B8C	Aldin QA Rdr	Incomplete	--	Not Sent
29-Oct-08 14:27	administrat12	administrator	EPOC Host 0055B8C	Aldin QA Rdr	iQC	--	Not Accepted
29-Oct-08 14:23		administrator	EPOC Host 0055B8C	Aldin QA Rdr	Incomplete	--	Not Sent
29-Oct-08 14:14	administrat11	administrator	EPOC Host 0055B8C	Aldin QA Rdr	Incomplete	--	Not Sent
29-Oct-08 13:48	administrat10	administrator	EPOC Host 0055B8C	Aldin QA Rdr	iQC	--	Not Accepted
29-Oct-08 13:17	administrat00	administrator	EPOC Host 0055B8C	Aldin QA Rdr	OK	yes	Not Accepted
28-Oct-08 16:13	administrator	administrator	EPOC Host 0055B8C	Aldin QA Rdr	Incomplete	--	Not Sent

epoc QC Checks

Every time the Host and Reader connect, the Reader undergoes an automatic, 2 level, electronic QC test.

This will repeat every 8 hours if needed.

The Reader monitors the testing environment:

- The operating conditions are 15°-30° C, 400-825 mm Hg atmospheric pressure and <85% humidity.
- The Reader has internal thermometers and barometers and will shut down if these ranges are exceeded.
- The internal QC checks will fail if humidity is >85

Other epoc QC Checks

An audible beep is produced when adequate sample is applied to the card.

The system will flag the following conditions and not deliver a test result when:

- Using an expired card
- Rerunning an already used test card
- Putting in too little sample
- Introducing the sample too rapidly, too slowly or sample with an air bubble.
- Introducing the sample at the wrong time

Internal Monitoring Systems

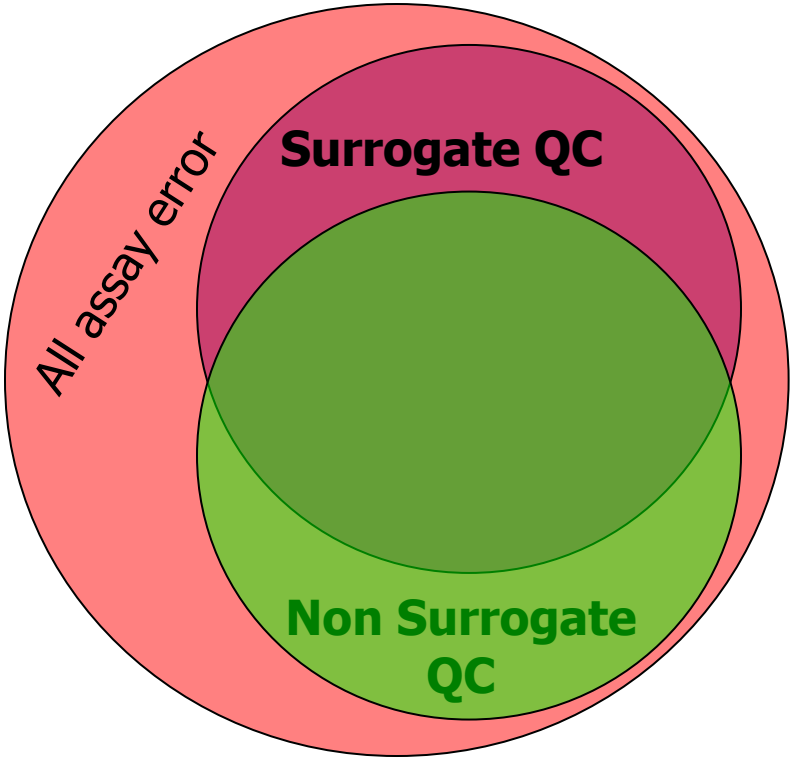
Internal monitoring systems don't detect all errors, because:

- Complexity of instrument systems prevents perfect failure mode models
- There is management pressure to release new products quickly
- There is insufficient knowledge to "design things right the first time"

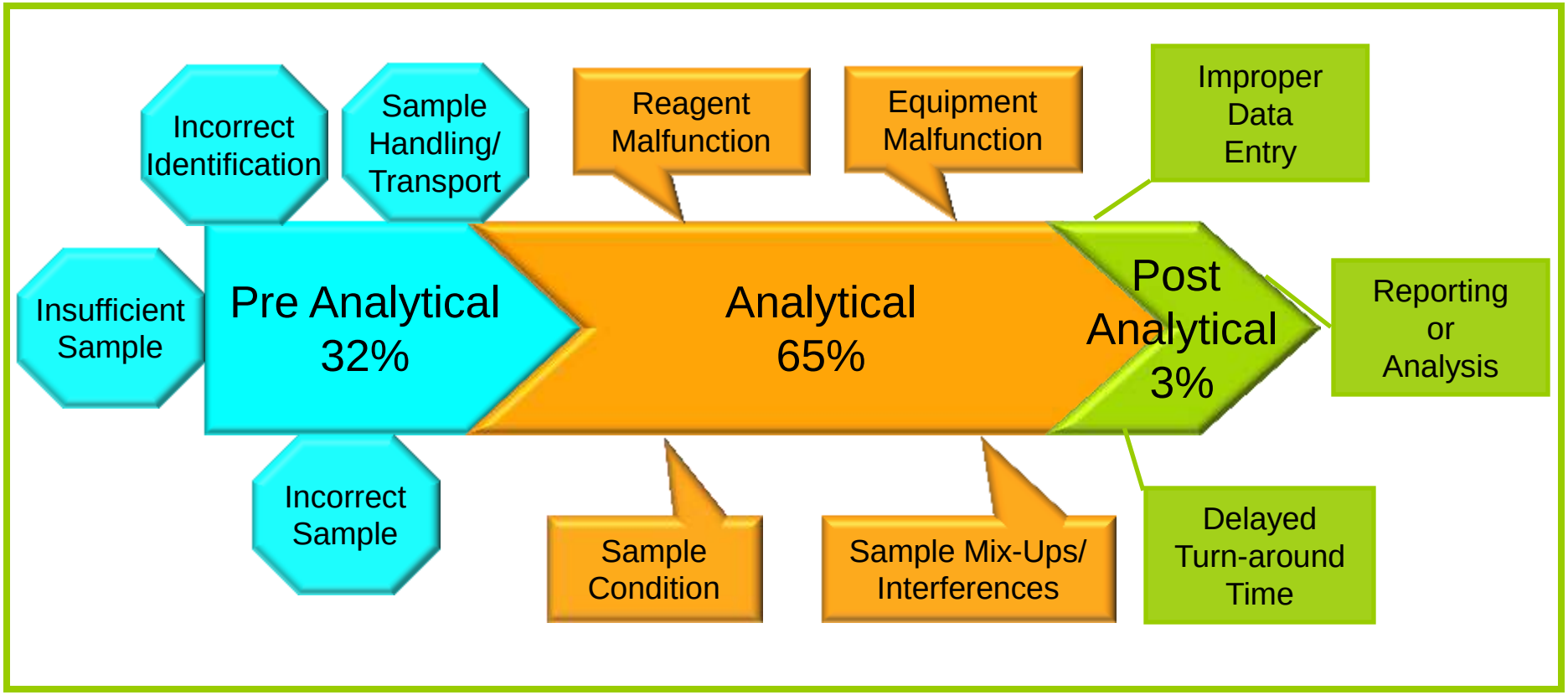
Non-Surrogate QC and QC

are not completely redundant

do not detect all errors



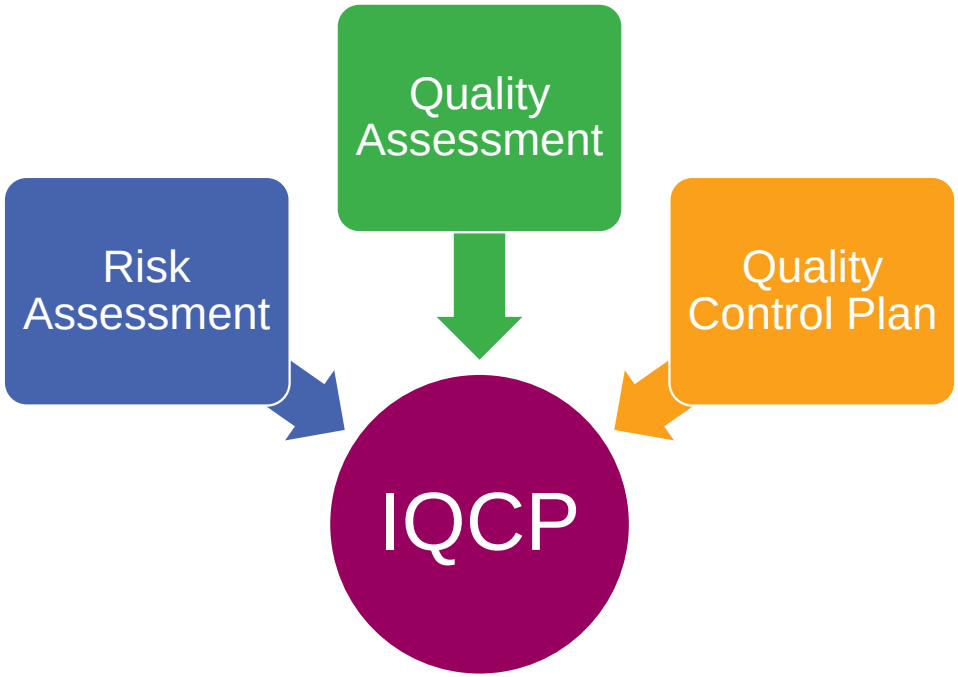
Thinking in the POCT Box



As autonomation reduces errors in the box, further reductions must occur outside the box

Developing the Quality Control Plan

Individualized Quality Control Plan



Risk Assessment

- Process to identify risks

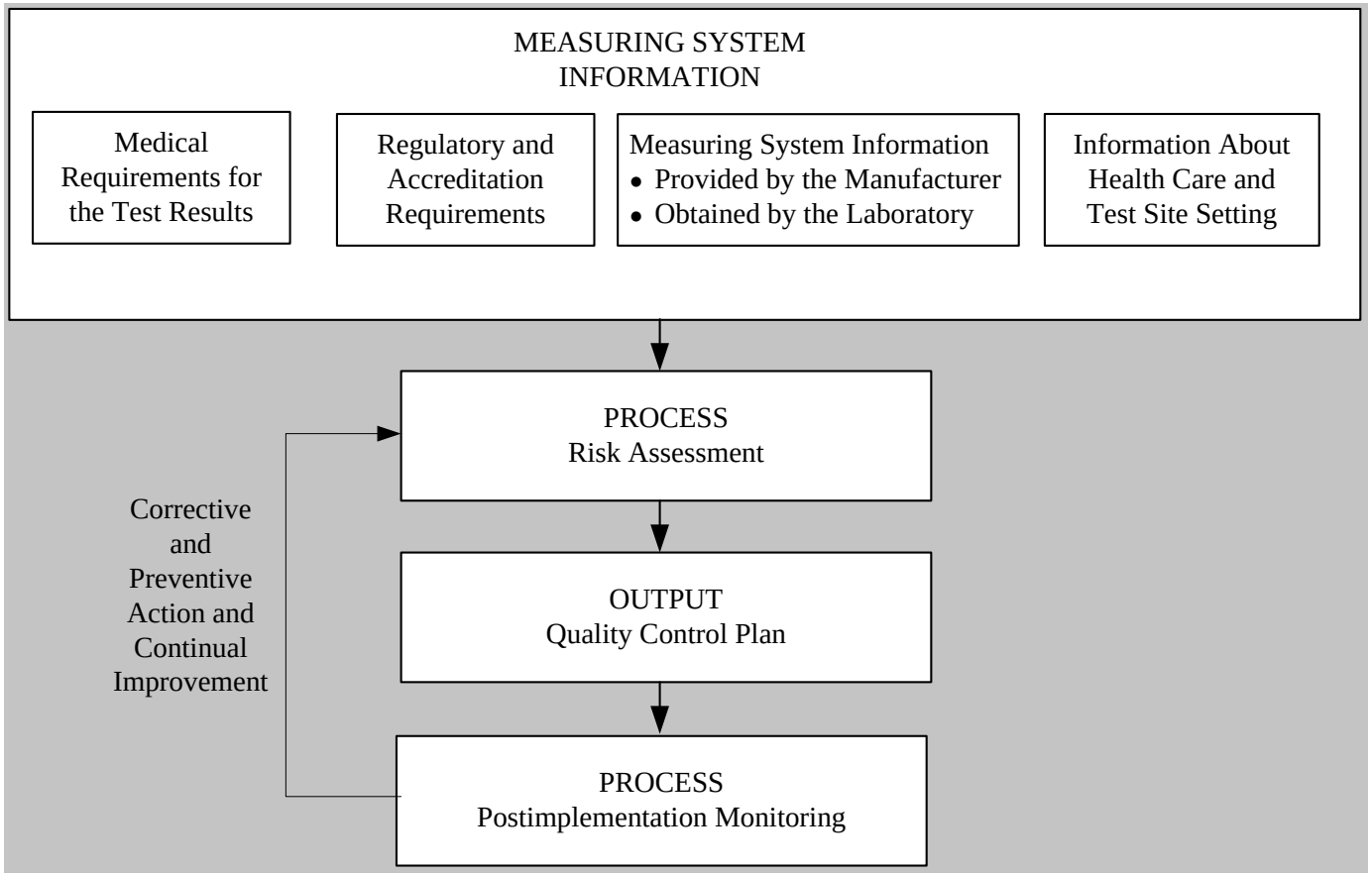
Quality Control Plan

- List of errors and actions to mitigage the risks

Quality Assessment

- Monitoring of that plan

Process to Develop and Maintain (CQI) a Quality Control Plan (QCP)



CLSI. *Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A*. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Where is the Risk Here ?

What is Risk

The chance of suffering or encountering harm or loss (*Webster's Dictionary and Thesaurus*. Ashland, OH: Landall, Inc.; 1993).

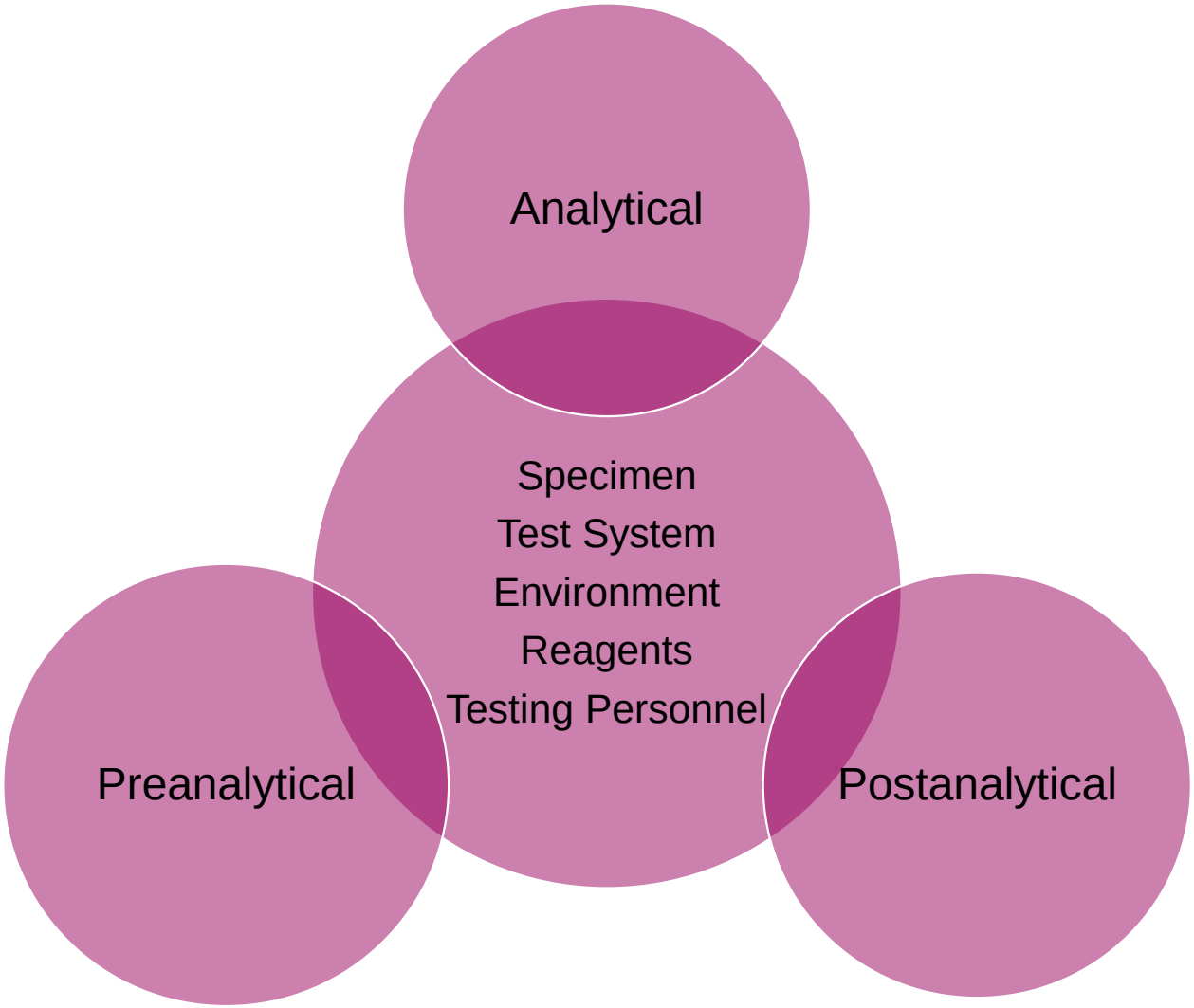
Risk can be estimated through a combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51).

The potential for an error to occur that could lead to patient/staff harm

Risk Management Definition

Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk (ISO 14971)

Risk Assessment in IQCP



Resources for Identifying Potential Errors

Manufacturer's package insert including but not limited to:

- Intended use
- Limitations
- Environmental requirements
- QC frequency
- Specimen requirements
- Reagent storage
- Maintenance
- Calibration
- Interfering substances

Resources for Identifying Potential Errors

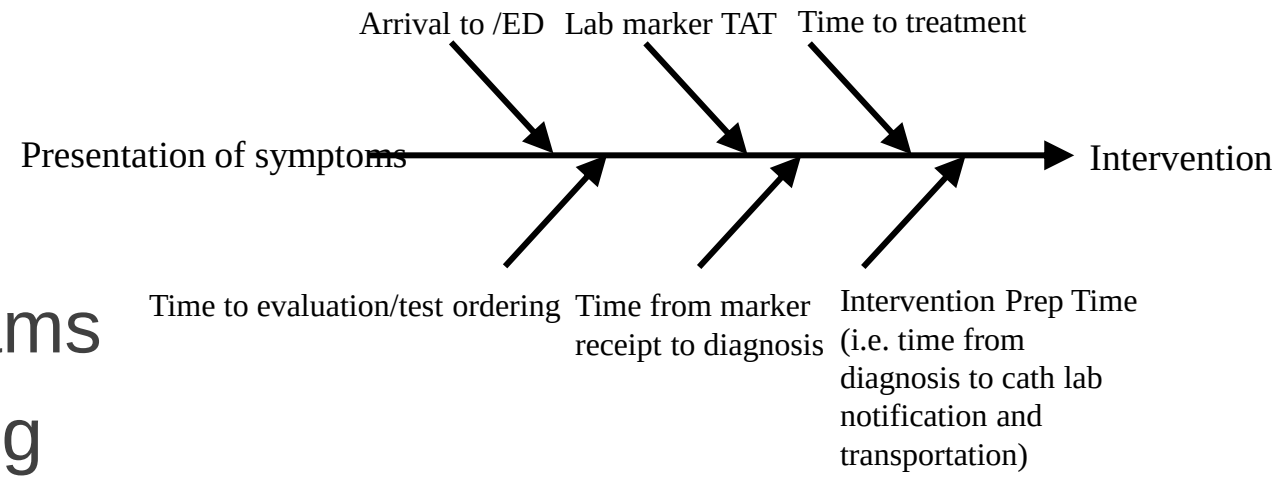
- Manufacturer's operator manual
- Troubleshooting guide
- Manufacturers' alerts and bulletins
- Verification or establishment of performance specifications
- Training manuals

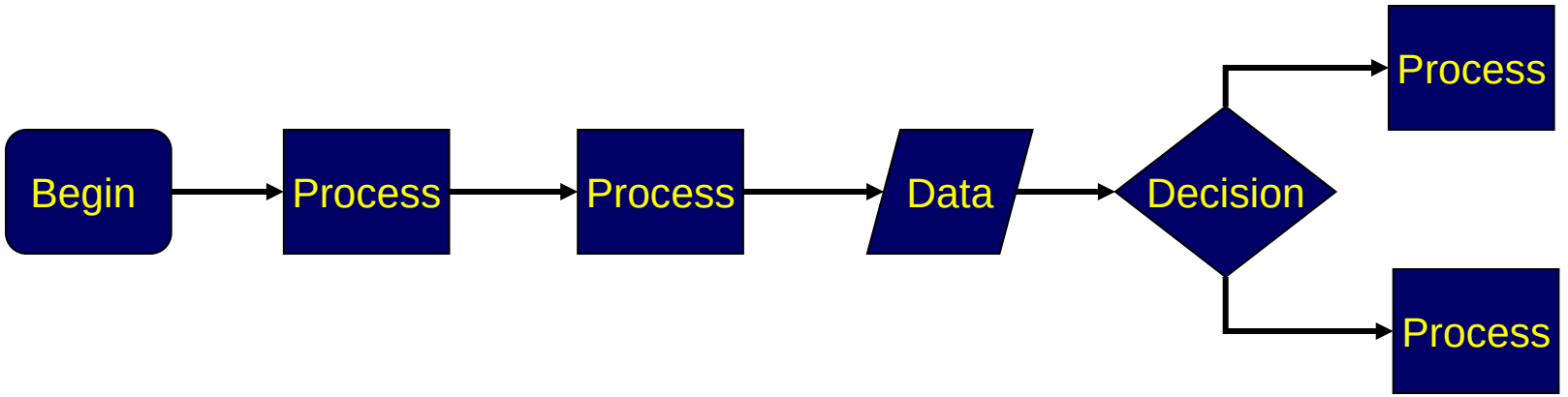
Resources for Identifying Potential Errors

- Testing personnel qualifications, training, and competency records
- QC/Proficiency testing data
- QA information including corrective actions taken
- Scientific publications/journals
- Internet/database searches
- Laboratory community/specialty forums

Risk Assessment Tools

- Brainstorming
- 5 Whys
- Fishbone diagrams
- Process mapping



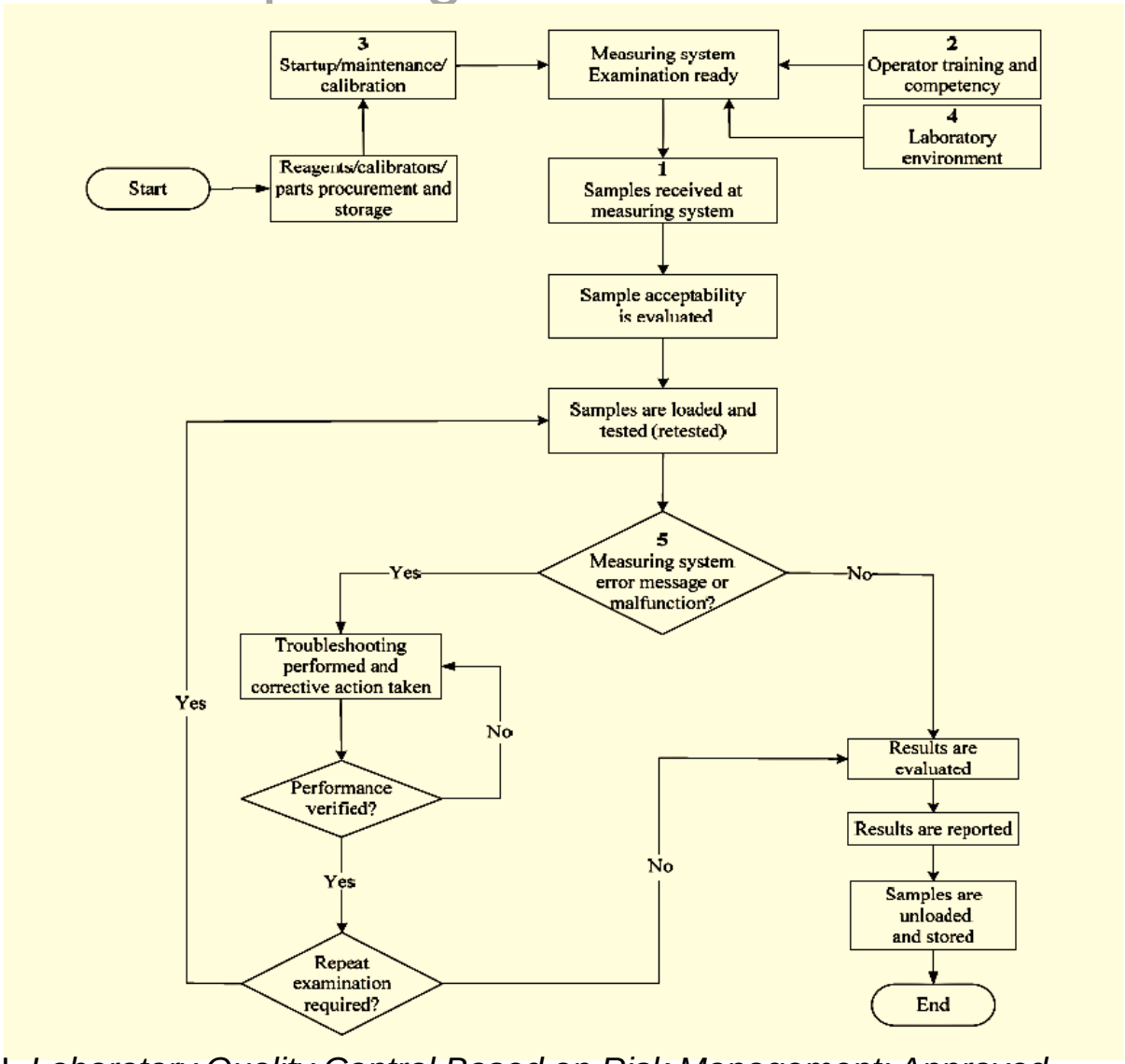


EP23 Workbook Key Process Steps

1. Operator training and competency
2. Reagent/calibrator/parts procurement and storage
3. Patient sample acceptability evaluation
4. System startup
5. System calibration
6. Loading and testing of patient samples
7. Proper device function
8. Test result review

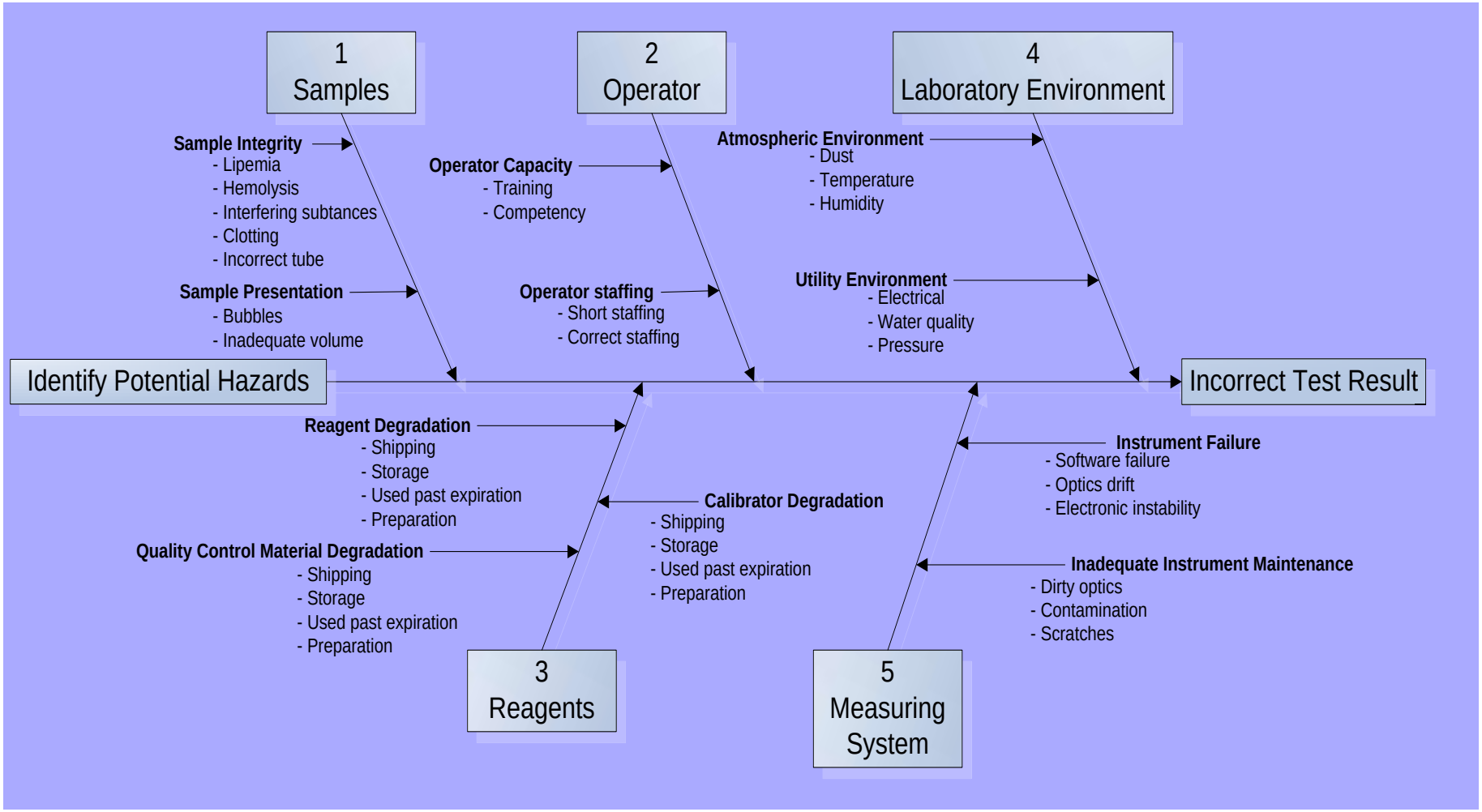
CLSI. *Laboratory Quality Control Based on Risk Management; Approved Guideline.* CLSI document EP23-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Process Map –High Level



CLSI. *Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A*. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Fishbone Diagram of Potential Failure Modes



CLSI. *Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A*. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Risk Acceptability

	Severity of Harm				
Probability of Harm	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	unacceptable	unacceptable	unacceptable	unacceptable	unacceptable
Probable	acceptable	unacceptable	unacceptable	unacceptable	unacceptable
Occasional	acceptable	acceptable	acceptable	unacceptable	unacceptable
Remote	acceptable	acceptable	acceptable	acceptable	unacceptable
Improbable	acceptable	acceptable	acceptable	acceptable	acceptable

CLSI. *Laboratory Quality Control Based on Risk Management; Approved Guideline. EP23-A*. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Frequency Scoring

Frequency Score	Description
1	Likely to occur very infrequently, on the order of once in a hundred years.
3	Likely to occur infrequently, on the order of once every five years.
5	Likely to occur with moderate frequency, on the order of once a year.
7	Likely to occur with significant frequency, on the order of once a month.
10	Likely to occur with high frequency, on the order of one or more times a day.

ISO 14971 Medical Devices – Application of risk management to medical devices, 2007

Severity Scoring

Severity Score	Description
1	Negligible = inconvenience or temporary discomfort
3	Minor = temporary injury or impairment not requiring professional medical intervention
5	Serious = injury or impairment requiring professional medical intervention
7	Critical = permanent impairment or life-threatening injury
10	Catastrophic = patient death

ISO 14971 Medical Devices – Application of risk management to medical devices, 2007

Detectability Scoring

Detectability Score	Description
1	Very easy to detect, high visibility & multiple steps in process that follows step where failure might occur, failure is virtually certain to be detected.
3	Fairly easy to detect, with moderately high visibility & several steps in process that follows step where failure might occur, significant likelihood that failure will be detected.
5	Moderately detectable, with fair degree of visibility and at least two or more steps in process that follow step at which failure might occur.
7	Moderately difficult to detect, with low visibility and only one step in process that follows step where failure might occur, low likelihood that failure will be detected.
10	Extremely difficult to detect, with process being virtually invisible to others and with not steps in process that follow step where the failure might occur, extremely no chance that failure will be detected.

Criticality Index Scoring

- CI = Frequency x Severity x Detectability

CI Score	Relative Importance
>/ 250	Significant
100 – 249	Less Important
<100	Not Important

Coler-Goldwater Specialty Hospital and Nursing Facility
FAILURE MODE, EFFECT, and CRITICALITY ANALYSIS WORKSHEET

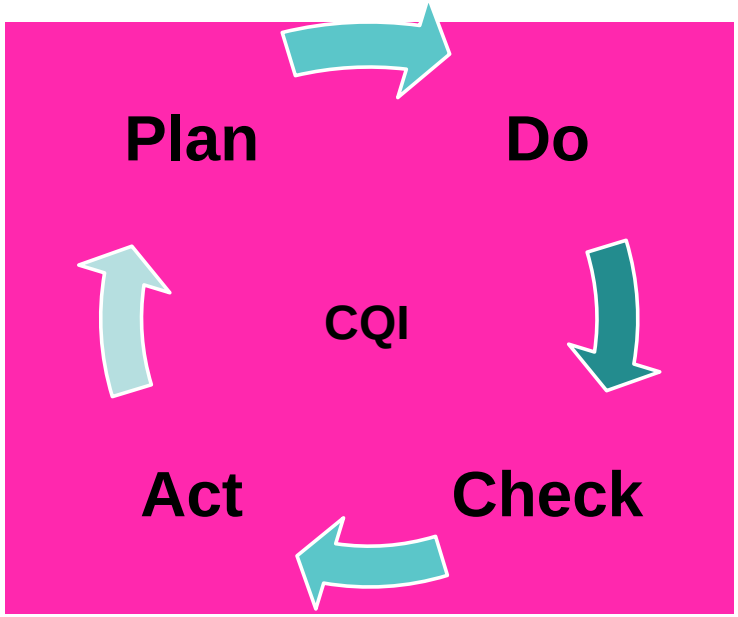
Topic-Infection Prevention and Control

Explore causes of failure and develop risk reduction strategies for steps that score 250 or higher and/or for those steps deemed necessary to address regardless of their FMECA score

(1) Step in the Process	(2) Possible Failure Mode	(3) Effect(s) of Failure	(4) Freq	(5) Severity	(6) Detection	(7) CI	(8) Causes of Failure	(9) Risk Reduction Strategies
	What could go wrong?	What are the consequences of the failure?	How likely is it that this failure will occur?	If this failure occurred, how likely is it that harm will occur?	How likely is it that this failure will be detected?		Why might this failure happen?	Actions to reduce the failure from happening
#1								
#2								
#3								
#4								
#5								
#6								
#7								
#8								
Etc.								

Is the IQCP effective?

- **Implement** the PLAN
- **Monitor, verify** and **improve** the PLAN, when needed
- **QA step is nothing new –** the process is required for all testing processes
  - Include in lab's overall QA plan



Plan-Do-Check-Act for Continuous Quality Improvement (CQI)

Critical Factors in QC Decisions

QC must be able to detect mistakes to enable immediate correction

Risks and costs must be weighed

QC is only one part of the quality control plan / quality management system

Not all laboratories have the same competencies and organization

Science and common sense must converge

Individualized QC Plan

Summarizes the potential errors for a device and how the lab will address them.

Can be high level or very detailed - depends on the device, the laboratory, and the clinical application and can vary from lab to lab.

Is scientifically based. It depends on the extent to which the device's features or actions achieve their intended purpose and the laboratory's expectations for ensuring quality test results.

Summary

Risk management is something laboratories are already doing..

An IQCP assesses the medical need for test, performance requirements, and weaknesses in the testing process as well as actions to address those risks.

Each IQCP is unique because the combination of device, setting, medical requirements and operators may differ between laboratories.

An IQCP is the industry standard. It depends upon the extent to which the device's features achieve their intended purpose in union with the laboratory's expectation for ensuring quality results.

Once implemented, the IQCP is monitored for effectiveness and modified as needed to maintain risk at a clinically acceptable level.

Additional Resources

- **CMS/CLIA Website:** http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/
- **CMS CLIA Central Office:** 410-786-3531
- **IQCP Link:** http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.htm
- **CMS IQCP Questions:** Any questions about IQCP should be forwarded to IQCP@cms.hhs.gov
- **Cause and Effect Diagrams:** Description and example - http://www.ihi.org/resources/Pages/Tools/CauseandEffectDiagram.aspx
- **CLSI Link:** http://www.clsi.org

QUESTIONS

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