

Laboratory Certification Intersection with Quality Management Systems

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Laboratory Certification Intersection w/ Quality Management Systems

CLIA
Regulations

Quality
Management

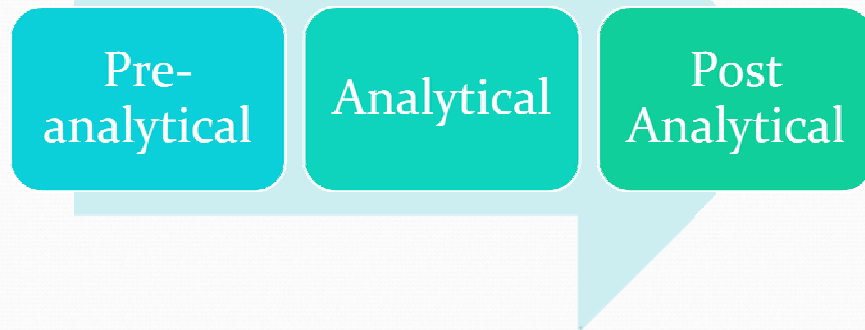
Topics for Discussion

- Concepts, Key Standards & Intent of Laboratory Certification
- What is a Quality Management System?
- How Do They Intersect?
- Benefits of Applying QMS to Achieve CLIA Compliance
- Discussion & Questions
- Resources

Concepts, Key Standards & Intent of Laboratory Certification

- CLIA requirements are organized in systems to follow a sample through the laboratory's entire testing process
 - That is, from pre-analytical to analytical & to post analytical
- Quality assessment is required for all systems
 - Ongoing plan to monitor all systems & processes
 - Problem identification & effective resolution
 - Complaints
 - Communication with employees & clients

Concepts, Key Standards & Intent of Laboratory Certification Path of Work Flow



Concepts, Key Standards & Intent of Laboratory Certification

- This facilitates a better understanding of the requirements, identification & resolution of problems & regulatory compliance
- CLIA is implemented w/ an educational approach, a quality assurance focus & a goal of continual performance improvement
- CLIA's outcome oriented survey process evaluates laboratories' test results & the systems & processes utilized to ensure accurate, & reliable testing

Concepts, Key Standards & Intent of Laboratory Certification

- Quality Control (QC)
 - Equipment
 - Procedures
 - Reagents, supplies
- Proficiency Testing (PT)
- Personnel
 - Qualifications/Responsibilities/Competency
- Records
- Quality Assessment (QA)
- Facilities

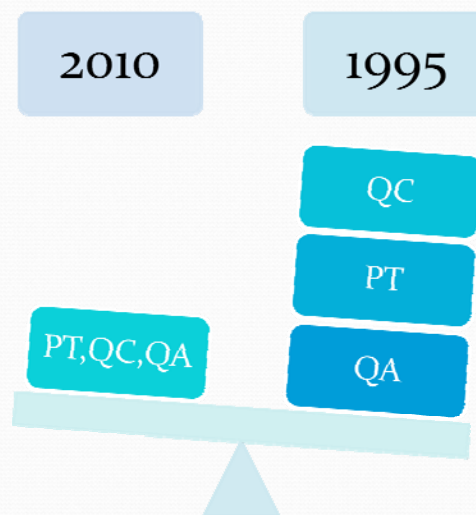
Concepts, Key Standards & Intent of Laboratory Certification

The intent of CLIA is to ensure the quality (accurate, reliable, timely & confidential) of laboratory testing using standards based on test complexity, not the location of the testing.

Outcome of Laboratory Certification

- CMS survey data reflects significantly improved performance over time
 - > 30% of labs do not meet QC in 1995
 - < 5% of labs do not meet QC in 2010
- Government Performance Review Act (GPRA) data for public budget goals demonstrates CLIA effectiveness
 - PT enrollment/performance
 - Certificate of waiver educational visits' effectiveness
 - Cytology PT MD performance

Comparison of Deficiencies Over Time



What is a Quality Management System?

- Systematic process-oriented approach to meeting quality objectives, if you look at a quality pyramid
- Management system to direct & control an organization with regard to quality*
 - Consists of 12 Quality System Essentials (QSE's)
- Quality System Management begins having [Organizational](#) support from the top down
- The quality pyramid starts at the bottom with Quality Control, & ends with Total Quality Management (TQM)

*Source: CLSI GP26-A4

Levels of Quality

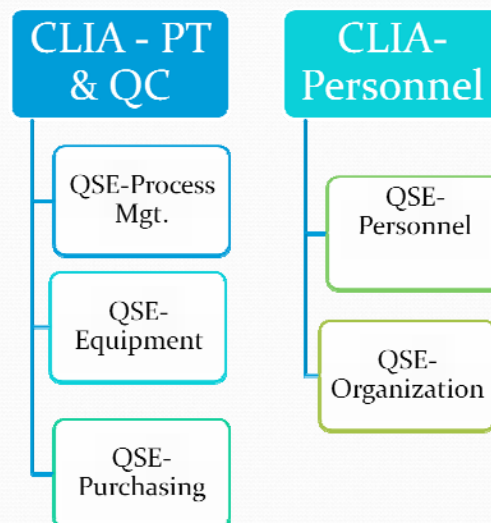


Quality System Essentials*

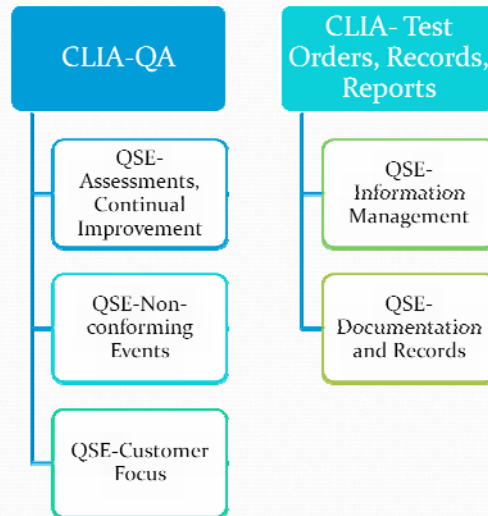
- Organization
- Customer Focus
- Facilities & Safety
- Personnel
- Purchasing & Inventory
- Equipment
- Process Management
- Documents & Records
- Information management
- Non-Conforming Event Management
- Assessments
- Continual Improvement

*Source: CLSI GP26-A4

Relationship of CLIA to QSE's



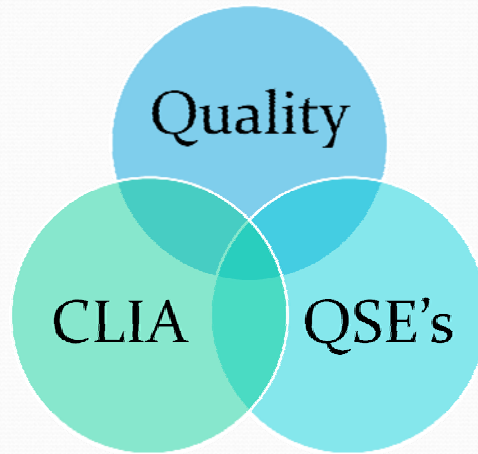
Relationship of CLIA to QSE's



Benefits of Using QSM to Achieve Regulatory Compliance

- A more effective (error correction/prevention) & efficient (process improvements) quality operation is effectuated through the adoption of quality systems management & related processes
- Improved efficiencies & quality save money & enables the lab to maximize the utilization of its resources
- Enhanced quality & reduced errors improve patient care
- CLIA doesn't prescribe how to comply

Intersection of CLIA & Quality Management Systems



Conclusion

- With overlapping standards & the same goals, laboratories should take advantage of the benefits derived from using QSM to achieve CLIA compliance & strive to improve the quality of their patients' care.

Contact Information & Resources

CMS/CLIA Web site:

www.cms.hhs.gov/clia/

Application, Guidelines, Brochures, Lab look-up

CMS Central Office—Baltimore

410-786-3531

Judy Yost's Email:

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GP26-4A

Clinical & Laboratory Standards Institute

www.clsi.org

The End!!

Thank You!

Questions??

