Clinical and Laboratory Standards Institute

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Director, Standards, CLSI

KEYPOCC Meeting
Kennett Square, PA
June 15, 2012
Our Common Goal: Quality Health Care
Today’s Presentation

- CLSI background information
- Membership and volunteers
- Document development process
- Crosswalks with the College of American Pathologists (CAP) and The Joint Commission
- Quality management systems
- Point-of-care testing (POCT) documents and companion products
CLSI Background

• Established in 1968
• Nonprofit corporation based in the United States
• Accredited standards-developing organization
• An organization of organizations – (no individual memberships)
CLSI Organizational Chart

- CLSI Member Organizations
- Board of Directors
- Executive Committee
- Chairholders Council
- Consensus Committees
- Document Development Committees
- Subcommittees
- Working Groups
- CLSI staff (45 employees)

- 2000 member organizations; no individual memberships
- 70 active projects at a time
- 2300 active volunteers
- 75,000 documents distributed per year
- ANSI* accredited

*American National Standards Institute
CLSI Recognized Worldwide
Vision

To be the leader in clinical and laboratory standards to improve the quality of medical care.
Mission

To develop best practices in clinical and laboratory testing and promote their use throughout the world, using a consensus-driven process that balances the viewpoints of industry, government, and the health care professions.
CLSI Consensus Process

- Government
- Industry
- Professions

Balance
CLSI Consensus Process

- Meetings are open to everyone.
- Meeting materials are available to participants and interested parties.
- A balance of interests is maintained.
- Conflicts of interest are fully disclosed.
- An appeals process exists to address issues or concerns.
Standardization in the Medical Laboratory

The right laboratory test at the right time with the right result leads to quality diagnostics, improved patient care, and improved public health around the world.

- Standardized test
- Standardized procedure
- Standardized reporting
- Improved outcomes

Improved

Standardized

Improved

Standardized

Test
CLSI Products

- Standards
- Guidelines
- Reports
- Companion Products
  - Quick Guides
  - Toolkits
  - Specialty Collections
  - DVDs
  - Software
Standards and the Laboratory

- Most medical laboratory errors are caused by systems and process issues, not people.

- These are the areas where standards can help the most.
A consensus standard or guideline is a document developed to promote uniform products, materials, methods, or practices.
Membership and Volunteers

Over 600 non–North American members and volunteers from over 70 countries, and growing
CLSI Members and Volunteers

Diverse representation from three constituencies

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CLSI Consensus Committees

- Automation and Informatics
- Clinical Chemistry and Toxicology
- Evaluation Protocols
- Hematology

- Immunology and Ligand Assay
- Microbiology
- Molecular Methods
- Point-of-Care Testing
- Quality Systems and Laboratory Practices
Committee Structure

- Chairholder
- Vice-Chairholder
- Members
- Advisors
- Contributors
- Reviewers
- Project Manager/Staff Liaison (Executive Offices’ staff)
The Document Development Process

Project Idea → Published Document
Idea → Document Project

- Identified need/project idea
- Project proposal developed
- Assessment/endorsement by consensus committee
- Call for volunteers
- Document development committee (DDC) membership established
- Business plan developed
- Presentation to Chairholders Council
- Project authorization
Document Development Process

• The document development process begins with the inaugural webinar for the DDC.
• Refine expanded outline.
• Introduce draft text to support scope and outline points.
• Prepare text for submission as a preliminary draft document.
Five Voting Stages

- **Voting Stage 1:** Draft 1 for document development committee approval

- **Voting Stage 2:** Draft 2 for approval by delegates; review and comment by consensus committee, board of directors, and nonmembers
  - Replaces proposed-level documents, which are no longer published
  - Provided to member organizations at no cost
Five Voting Stages (cont’d)

• **Voting Stage 3:** Draft 3 for document development committee approval

• **Voting Stage 4:** Draft 4 for review and approval by consensus committee

• **Voting Stage 5:** Final Draft for consensus committee approval to publish
Two Timeline Tracks

Track 1 – 15-month timeline
Track 2 – 25-month timeline

Timeline determined by:
• Scope
• Complexity
• Comprehensiveness and depth
• Degree of controversy
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Document Review Schedule

Within five years after its approval, the appropriate consensus committee(s) initiates a review to determine the necessary action to reaffirm, revise, archive, or withdraw an approved consensus document.
Crosswalks with CAP and The Joint Commission
Adoption of Documents Into Accreditation Crosswalk

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† Document has been withdrawn.
‡ Noted, not referenced.
* Electronic only.
### CLSI Documents Referenced to The Joint Commission

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Quality Management Systems
The Quality Management System (QMS) provides a framework for managing and monitoring activities to address quality standards and achieve organizational goals.
Principles of high-quality laboratory testing are the same anywhere in the world.

It is one area of health care that can be, and should be, highly standardized.
CLSI and the Quality Management System

CLSI produces globally recognized QMS guidelines.

- “The Key to Quality”
There are two major models for QMS used globally.

<table>
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<tr>
<th>ISO: 15189</th>
<th>CLSI: GP26-A4</th>
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<td>• Broad-based</td>
<td>• Specific</td>
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<tr>
<td>• Overarching standards</td>
<td>• Practical implementation guidelines</td>
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<td>• 15 management requirements</td>
<td>• 12 quality systems essentials</td>
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<td>• Eight technical requirements</td>
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Both are built on the same concepts, but differ in the amount of specificity described. ISO is broader and CLSI is more specific. ISO = what to do; CLSI = how to do it.
Quality Management System

QMS is a simple, systematic approach of organizing all key work processes around the path of workflow in the laboratory.
40+ countries have implemented, or are in some stages of national adoption, of the QMS model approach to their laboratory services.

The World Health Organization has fully adopted the QMS approach on a global basis and is in the process of education and training.

In the United States, the Centers for Medicare & Medicaid Services is encouraging laboratories to adopt a QMS approach to laboratory licensure and accreditation.
POCT Documents and Companion Products
Why is Point-of-Care Testing Important?

- Point-of-care testing (POCT) includes patient self testing, physician office laboratories, and hospital-based testing.
- Estimated revenues of approximately $3 billion (USD), excluding non-IVD applications and whole blood glucose testing.
- Overall IVD market growth 6 to 7% per year.
- POCT market growth 10 to 12% per year.
- Numerous new technologies and applications entering POCT (e.g., molecular methods, MRSA).

IVD Market R. Sutherland, Jan 2010
• AST04-A2—Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition (under revision; will be published as POCT13)
• C30-A2—Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition (under revision; will be published as POCT12)
• H49-A—Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline
• POCT01-A2—Point-of-Care Connectivity; Approved Standard—Second Edition
• POCT02-A—Implementation Guide of POCT01 for Health Care Providers; Approved Guideline
• POCT04-A2—Point-of-Care In Vitro Diagnostic Testing; Approved Guideline—Second Edition (under revision)
Point-of-Care Testing Guidelines

- POCT05-A—Performance Metrics for Continuous Interstitial Glucose Monitoring; Approved Guideline
- POCT07-A—Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline
- POCT08-A—Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline
- POCT09-A—Selection Criteria for Point-of-Care Testing Devices; Approved Guideline
Guidelines in Development

- POCT06—*Guidelines on the Impact on Glucose Measurement When Different Sample Types Are Used*
- POCT14—*Point-of-Care Testing for Infectious Disease*
- POCT15—*Emergency and Disaster Point-of-Care Testing*
Potential Projects

• Noninvasive monitoring

• Oral POCT

• Cost and advantages of POCT vs testing in main laboratory (a report)
Companion Products for POCT Documents

- POCT07—Addressing errors in point-of-care testing (reference guide)
- POCT08—Quality control troubleshooting (flow chart)
- POCT08—Corrective action report (quick guide)
- POCT08—Quality control log sheet (quick guide)
- POCT09—Instrument selection (worksheet)
  - Clinical needs assessment
  - Testing system specifications
Addressing Errors in Point-of-Care Testing

This Quick Reference Guide Includes:

1. **Preexamination Considerations**
   - Patient Preparation for the Test
   - Sample Collection and Handling

2. **Examination Considerations**
   - Operator related
   - Reagent related
   - Sample related
   - Device related

3. **Postexamination Considerations**
   - Communication related
   - Data management related
POCT08 Companion Product
POCT10-A2, Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition
General Information

• Safety – personal protective equipment, hand hygiene, workspace disinfection, medical waste, and chemical safety
• Microscope – operation and maintenance
• Quality assurance – training and competency of the provider, procedure manual, QC, proficiency testing, and accreditation
Procedures Included in POCT10-A2

- Fecal leukocyte examination
- Fern test
- Nasal smears for inflammatory cells
- Pinworm examinations
- Postcoital, direct, qualitative examinations of cervical mucus
- Qualitative semen analysis
- Urine sediment examination
- Wet mount preparations and potassium hydroxide (KOH) preparations
Consistent Layout of Procedures

- Principle
- Materials
- Specimen collection
- Testing procedure
- Quality control
- Reporting results
- Limitations of the procedure
Appendixes in POCT10-A2

- Microscopic components of urine sediment
- Microscopic components in vaginal fluid and KOH preparations
- Ectoparasites
- List of figures and tables
Updates to POCT10-A2

• A reorganized and more comprehensive section (Section 14) for wet preparations, identifying differences between wet preparation for vaginal and nonvaginal procedures
• Representative pictures (or images) for as many procedures as possible, to facilitate training programs using this document as a teaching tool
• To complement the inclusion of so many images, the creation of Appendix C to help the reader identify and locate the images within the document
POCT10-A2 Companion Products
Checklists

- Cumulative training
- Employee training
• Proficiency testing exception response form
• Microscope maintenance log
Wall Charts

- Microscopic components in urine sediment
- Microscopic components in vaginal fluid and KOH preparations
- Ectoparasites
Procedures

- Fecal leukocyte examination
- Nasal smears for inflammatory cells
- Urine sediment examinations
- Wet mount and KOH preparations
Summary

• CLSI is an internationally recognized, consensus-based standards organization that produces a large number of documents and related materials.
• Document development is a highly organized, systematic process involving a balanced approach by all stakeholders.
• QMS improve laboratory practice.
• Documents are applicable in laboratory standardization, preparation for inspection and accreditation, and in improving the quality of results and patient care.
• POCT documents can provide guidance as well as tools to help create and maintain a comprehensive program.
How to Contact CLSI

• Web: www.CLSI.org
• E-mail: customerservice@clsi.org
• Customer Service: 1.610.688.0100

• David Sterry
• dsterry@clsi.org
• Phone: 484.588.5942
Thank you.