CLSI – Voluntary Consensus Standards in Clinical and Laboratory Quality Control

Robert L. Habig, Ph.D.
President Elect, CLSI

Presented to the
Clinical Laboratory Improvement Advisory Committee
September 8, 2005 – Atlanta, GA

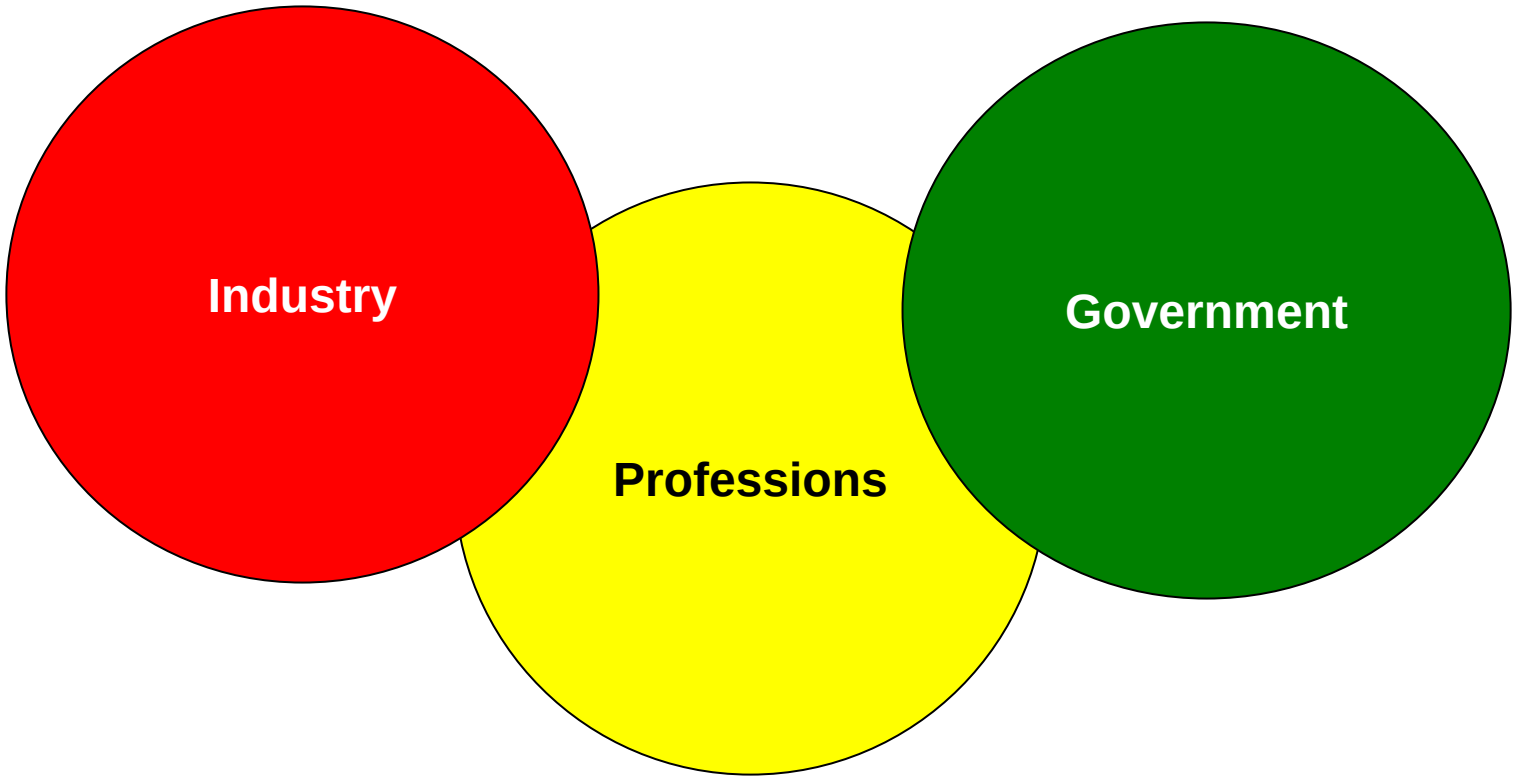
CLINICAL AND LABORATORY STANDARDS INSTITUTE ™

What is CLSI?

- An American National Standards Institute accredited consensus standards development organization
- A not-for-profit corporation
- An educational organization
- An association of organizations with balanced constituencies (Industry, Government, and Professions)
- A volunteer organization
- A global organization

CLINICAL AND LABORATORY STANDARDS INSTITUTE

CLSI Sectors



CLINICAL AND LABORATORY STANDARDS INSTITUTE

CLSI Principles and Values

Principles

- Volunteerism
- Openness
- Balance
- Structure
- Pragmatism
- Timeliness

Values

Excellence

Responsiveness

Inclusiveness

Fairness

CLINICAL AND LABORATORY STANDARDS INSTITUTE

Process for Project Selection

- Idea generation
  - Volunteer & Member Questionnaires
  - Area Committee and Subcommittee Strategic Planning
  - Website input and project proposal invitation
- Comprehensive proposal required
- Internal idea assessment completed
- External (qualitative) interest assessment
- External (quantitative) market assessment
- Subcommittee membership
- Business plan
- Authorization

Process for Document Development

- Subcommittee Formation Complete by Project Authorization Time
- Subcommittee usually has nine months to draft Proposed-level Document
- Proposed-level Document circulated widely for review and comment
- Subcommittee revises document and submits to Area Committee for Consensus Vote
- Board of Directors votes to publish
- Total time target from proposal authorization to publication of approved-level document is twenty-two months

Process for Evaluation of the Utility and Use of a Standard, Guideline, or Report

- Document Sales are monitored and analyzed by the Chairholders Council and Board of Directors
- Review of the Annual Questionnaires of Volunteers, Members, and Customers
- Comments received on each document are reviewed by subcommittee or workgroup at next document revision activity
- FDA List of Recognized Standards for use in device submissions

CLSI Documents are Used By Industry Scientists

- Evaluation Protocol Documents
  - No need to develop new material
  - Speeds up product development
  - Standardizes results across the field
  - Helps customers compare performance

- FDA Recognizes Standards for use by Industry in Product submissions
  - Currently 82 CLSI Approved Standards are recognized by the FDA

CLSI Publications Relating to Laboratory Quality

CLSI Document	Intended Audience
C24, Statistical Quality Control	Laboratorians, Manufacturers
C46, pH and Blood Gas Analysis	Laboratorians, Manufacturers, Respiratory Therapists
EP5, Precision Performance	Laboratorians, Manufacturers
EP18, Unit-Use Testing	Laboratorians, Manufacturers
H20, Differential Count/Evaluation of Instrumentation	Laboratorians

CLSI Publications Relating to Laboratory Quality (continued)

CLSI Document	Intended Audience
H26, QC of Multichannel Analyzers	Laboratorians
H38, Calibration and QC of Automated Hematology Analyzers	Laboratorians, Manufacturers, Reference Laboratories
H42, Flow Cytometry: QA and Immunophenotyping	Laboratorians
I/LA23, Assessing the Quality of Immunoassay Systems	Laboratorians
GP22, Continuous Quality Improvement	Laboratorians

CLSI Publications Relating to Laboratory Quality (continued)

CLSI Document	Intended Audience
M2/M7, Antimicrobial Susceptibility Tests	Laboratorians
M22, QC for Microbiological Culture Media	Laboratorians, Manufacturers
M24, Suseptibility Testing for Mycobacteria	Laboratorians
M23, QC Parameters for Human Antimicrobial Agents	Laboratorians, Pharmaceutical Companies

CLSI Publications Relating to Laboratory Quality (continued)

CLSI Document	Intended Audience
M27 , Antifungal Testing	Laboratorians
M31, Susceptibility Testing for Bacteria Isolated from Animals	Laboratorians
M37, QC Parameters for Veterinary Antimicrobial Agents	Laboratorians, Pharmaceutical Companies
MM2, Immunoglobin and T-Cell Receptor Assays	Laboratorians, Manufacturers

CLSI Publications Relating to Laboratory Quality (continued)

CLSI Document	Intended Audience
MM3, Molecular Diagnostic Methods for Infectious Diseases	Laboratorians, Manufacturers
MM5, Nucleic Acid Amplification Assays for Molecular Hematopathology	Laboratorians, Manufacturers
MM6, Quantitative Molecular Methods for Infectious Diseases	Laboratorians
M38, Antifungal Susceptibility Testing	Laboratorians

CLSI Publications Relating to Laboratory Quality (continued)

CLSI Document	Intended Audience
MM7, FISH Methods for Medical Genetics	Laboratorians, Manufacturers, Regulatory Agencies
MM9, Nucleic Acid Sequencing Methods	Laboratorians, Manufacturers
AST2, Point-of-Care IVD Testing	Laboratorians, Non-lab Healthcare Practitioners

EQC Option 4 Document – EP22

- Title: *Principles of manufacturer's validation of risk mitigation using quality controls*

Objectives:

- To assess definitive risk.
- To prove one's QC mitigates risk, and
- To discern which data is needed.

EQC Option 4 Document – EP22

SCOPE

- Manufacturers can determine risks associated with their product.
- Can then determine which risks can be mitigated with internal or external controls mechanisms.
- Once risks are understood, can validate effectiveness of controls.

FUNCTION

- Describes the principles, and gives procedural examples, for validation of the capability of the control mechanisms to mitigate the identified risks.

AUDIENCE

- Primarily manufacturers and government reviewers.

Status of EQC Activities

- Working group led by Greg Cooper developing EP22
  -Working Group Met on 31 Aug and 1 Sept
- Project proposal for companion document to EP22 (for laboratory users) under consideration by the CLSI Area Committee on Evaluation Protocols
- Summary of the *QC for the Future Workshop* available from CLSI (X6-R)
- Presentations from *QC for the Future* Workshop will be published in *Laboratory Medicine* in October 2005