



The CLSI Consensus Process: Making a Difference in Health Care

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Today's Topics and Goals

- Introduction to CLSI
- The consensus process: a primer
- Creating a consensus document
- Standards: how they impact the professions
- CLSI guidelines for POCT
- Current standards development tracts
 - Getting Involved

Who Is CLSI?





Not-for-profit



Volunteer
Membership
Organization



Vision

Quality practices for better health



Mission

Develop clinical and laboratory practices
and promote their use worldwide



Values

- **Inclusiveness**

We include the viewpoints of industry, government, and the health care professions in a consensus-driven process.

- **Excellence**

We continuously improve upon our tradition of technical excellence and superior quality.

- **Responsiveness**

We proactively identify and respond to the needs of our stakeholders in an open and timely manner.

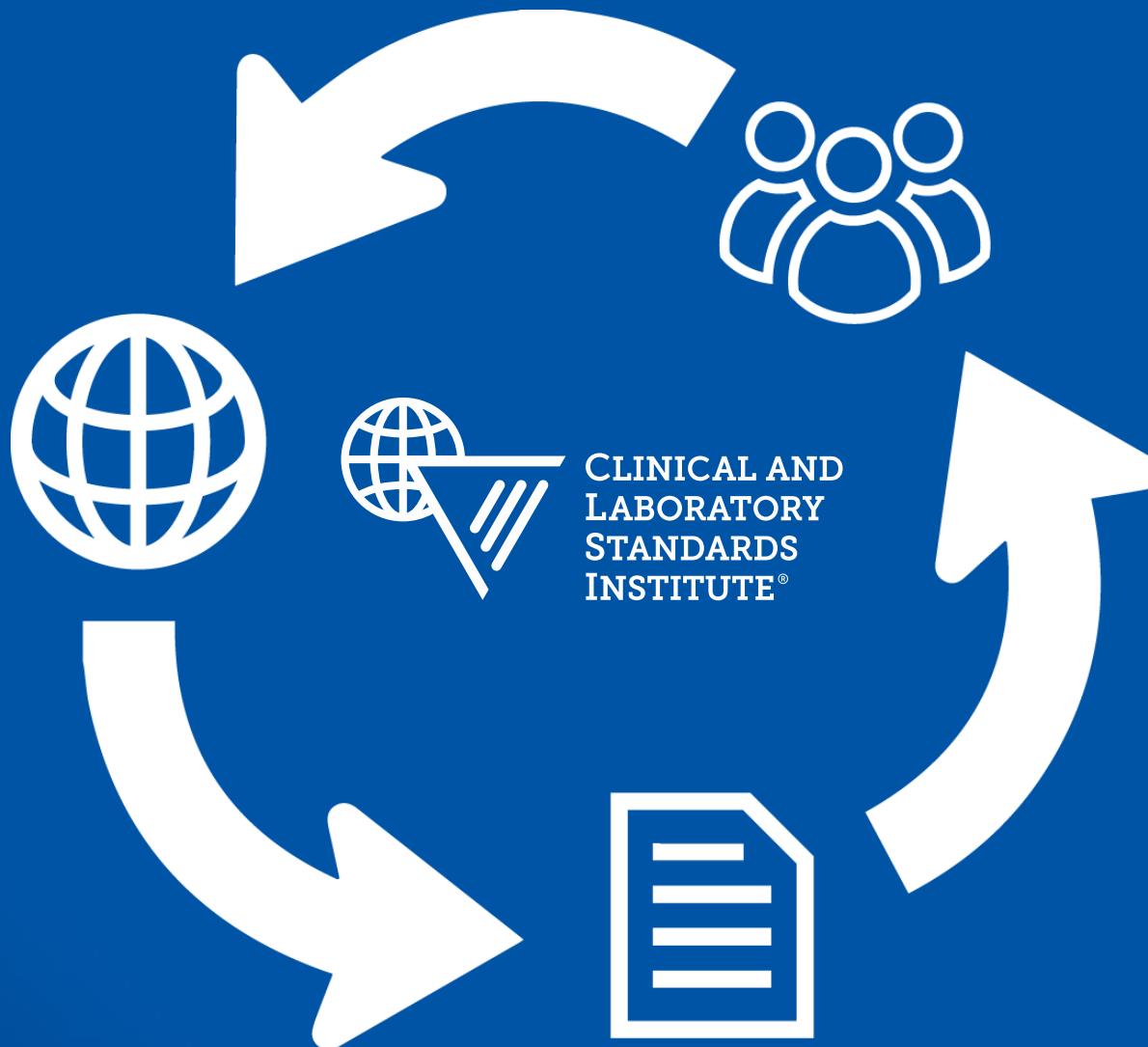
- **Integrity**

We act ethically and with fairness, trust, respect, and openness.

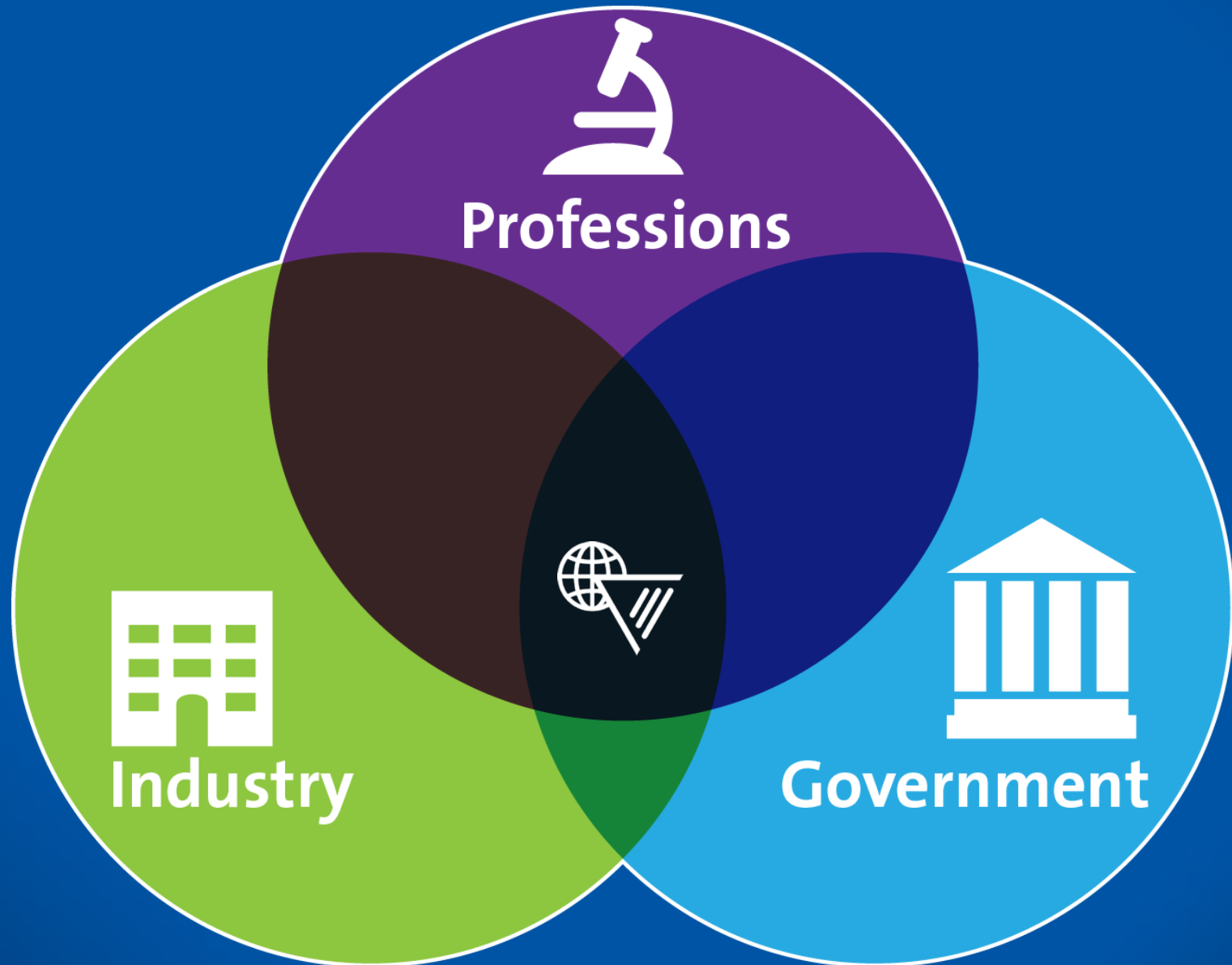
- **Teamwork**

We are committed to effective collaboration among members, volunteers, staff, and other partners.

What Do We Do?



Tripartite Constituencies





Professions Constituency



Industry Constituency



Abbreviations: IVD, *in vitro* diagnostic; LIS, laboratory information systems.

Government Constituency



Who Are Our Members?



1,700+ Members From 60+ Countries



1,400+



Hospitals




and



Independent Labs



The background of the entire image is a dark blue color. Overlaid on this background is a grid of small, light blue icons. Each icon is a stylized representation of a building or a multi-story structure with a central entrance and several windows. The icons are arranged in a regular, repeating pattern across the entire frame.

125+ Industry
Organizations



80+
Educational
Institutions





40+

Government Agencies



Why Do CLSI Standards Matter?

Why CLSI Standards Matter



Increased quality, safety, and consistency

Why CLSI Standards Matter



Increased quality, safety, and consistency

A basis for legislation

Why CLSI Standards Matter



Increased quality, safety, and consistency

A basis for legislation

Access to best practices

Why CLSI Standards Matter



Increased quality, safety, and consistency

A basis for legislation

Access to best practices

Economically improved outcomes



Application of CLSI Documents

Regulatory Compliance

- Compliance with recognized CLSI consensus documents to facilitate regulatory review of IVD devices

Professional Practice

- Implementation of CLSI best practices for accreditation preparedness

Education in Clinical Laboratory Sciences

- Building blocks for sound organizational programs
 - POCT selection and implementation
 - Quality Management Systems
 - Performance standards
 - Risk assessment

Abbreviations: IVD, *in vitro* diagnostic; POCT, point-of-care testing.



Quality System Essentials

- QSEs are the fundamental building blocks in a Quality Management System.
- Each QSE encompasses policies, processes, and procedures necessary to manage and improve your facility's work practices.
- CLSI's QSEs were developed from the integration of ISO documents, hospital standards, accreditation standards, international and national (US) standards.

Abbreviations: ISO, International Organization for Standardization; QSE, Quality System Essential; US, United States.



The Systematic Approach

- Policy: “What must we do?”
- Process: “How does it happen in our facility?”
- Procedure: “How do I do this activity?”

Library of Over 200 Standards





January 2013

POCT12-A3

Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition



This document contains guidelines for performance of point-of-care blood glucose meter systems that stress quality control, training, and administrative responsibility.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.



3rd Edition

POCT13

Glucose Monitoring in Settings Without Laboratory Support



This guideline focuses on performance of point-of-care glucose monitoring systems, with an emphasis on safety practices, quality control, training, and administrative responsibility.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.



February 2013

QMS02-A6

Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition



This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.



June 2012

GP17-A3

Clinical Laboratory Safety; Approved Guideline—Third Edition



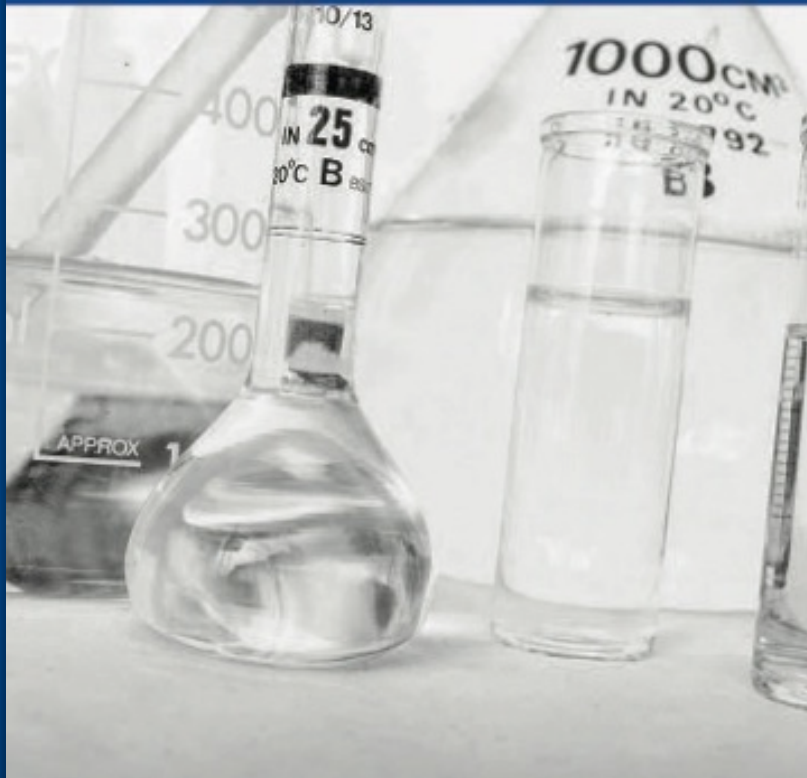
This document contains general recommendations for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.

A guideline for US application developed through the Clinical and Laboratory Standards Institute consensus process.

Quality System Regulation for Laboratory-Developed Tests



A Practical Guide for the Laboratory



WORKBOOK

EP23-A-WB: A Practical Guide for Laboratory Quality Control Based on Risk Management



QMS01 — Redesigned

4 The Quality Management System Model

A QMS can be described as a set of essential building blocks needed for a laboratory's work operations to fulfill stated quality objectives. Such a system provides the means to direct and control the organization with regard to quality.¹⁷

The QMS model in this guideline describes the management foundation of quality building blocks (ie, the QSEs) and demonstrates how the foundation supports the laboratory's path of workflow as depicted in Figure 1.



Figure 1. The Quality Management System Model for Laboratory Services. The 12 QSEs function as building blocks that are necessary to support any laboratory's path of workflow and laboratory disciplines. This example represents how the 12 QSEs support a clinical laboratory's disciplines.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. If a QSE is missing or not well implemented, problems will occur in preexamination, examination, and postexamination laboratory activities. For example, when the laboratory lacks defined processes for properly installing, calibrating, and maintaining its analyzers so that they are working effectively, there will be problems in examination processes.

NOTE:

The QSEs are simply published requirements for medical laboratories sorted into 12 generic topics.

4.1 The Quality System Essentials

For the purposes of the QMS model described in this guideline, the QSEs are:

-  Organization
-  Process Management
-  Customer Focus
-  Documents and Records
-  Facilities and Safety
-  Information Management
-  Personnel
-  Nonconforming Event Management
-  Purchasing and Inventory
-  Assessments
-  Equipment
-  Continual Improvement

REMINDER:

Laboratories can use the QSEs as a generic outline for the quality management systems required in ISO standards.

QMS01 — Redesigned

Number 15

QMS01-A4

Policy	Process	Procedure
<i>State intent and direction for:</i>	<i>Activities that transform the intent into action:</i>	<i>Examples of documented instructions for:</i>
Hazardous waste management	<ul style="list-style-type: none"> Hazardous waste disposal plan Hazardous waste management training program 	<ul style="list-style-type: none"> Identifying waste stream disposing of various types of the laboratory's hazardous waste
Fire prevention	<ul style="list-style-type: none"> Fire prevention and control plan Fire extinguisher training program 	<ul style="list-style-type: none"> Reporting a fire Taking follow-up action Recording staff participation
Emergency management: preparedness, response, mitigation, and recovery	<ul style="list-style-type: none"> Internal and external preparedness plans, including response to bioterrorism and chemical terrorism Evacuation plan Emergency preparedness training program 	<ul style="list-style-type: none"> Assigning roles and responsibilities to laboratory staff in a declared disaster Evacuating the laboratory in specific situations Conducting and recording regular evacuation drills Posting evacuation routes Executing the business recovery plan
Radiation safety, as applicable	<ul style="list-style-type: none"> Radiation safety program Radiation safety training program 	<ul style="list-style-type: none"> Using radiation safety badges properly Posting radiation signage Monitoring radiation Taking action when acceptable levels are exceeded

The requirements for QSE Facilities and Safety are:

- ▶ Allocate appropriate space for laboratory activities.
- ▶ Secure access to laboratory areas, as appropriate.
- ▶ Maintain cleanliness and monitor the environment.
- ▶ Maintain physical means of staff communications.
- ▶ Provide safety protocols and training for all of the following:
 - Biosafety
 - Occupational health, accidents, and illnesses
 - Fire protection
 - Radiation safety, as appropriate
 - Chemical hygiene
 - Hazardous waste management
 - Emergency management

Each laboratory needs to establish and maintain a facility that provides adequate space, workflow, and environmental conditions to support the quality of work and safety for all staff, in compliance with requirements. This includes the environment in which services are delivered to patients as well as nonpatient work areas.

5.3.1 Facility Design and Modification

The laboratory should work with its organization's facility planning department to develop processes for laboratory building and renovation

Volume 31

QMS01-A4

projects. The projects should ensure the best possible design for work process flow, environmental conditions, and ergonomics. The laboratory needs a means to ensure that international, national, accreditation, local, and organizational requirements for current and planned space are met.



5.3.1.1 Space Allocation, Facility Design, and Access

The laboratory's allocated space needs to be organized such that its workload can be performed without compromising the quality of work and the safety of personnel or patient care services.

The laboratory design needs to support efficient operation and quality examinations, optimize the comfort of its occupants, provide for adequate storage space, and minimize the risk of injury and occupational illness. CLSI document QMS04³⁵ provides useful information on laboratory design. CLSI document GP17³⁶ provides information on laboratory safety.

Consideration is needed for the following:

- Accommodations and access for disabled persons, comfort, privacy, and safety, as well as optimization of collection conditions
- Maintaining confidentiality of protected health information in areas accessible to patients and visitors
- Protection of patients, staff, and visitors from recognized hazards including engineering controls required for the type of examinations performed in the laboratory
- Separation of work areas when cross-contamination is possible between adjacent laboratory sections, or effective separation where there are incompatibilities. Examples include nucleic acid amplification testing, a quiet workspace without interruptions for cytopathology screening, and a temperature-controlled environment for the computer system
- Adequate emergency systems
- Laboratory-specific environmental requirements (eg, energy sources, lighting, ventilation, water, refuse disposal, microbial control)
- Adequate storage space with the required environmental conditions
- Controlled access to areas requiring biosecurity including access to supplies and patient samples
- Adequate communication system appropriate to the size and needs of the laboratory

NOTE:

Each laboratory needs to establish and maintain a facility that provides adequate space, workflow, and environmental conditions to support the quality of work and safety for all staff, in compliance with requirements.

NOTE:

The laboratory's allocated space needs to be organized such that its workload can be performed without compromising the quality of work and the safety of personnel or patient care services.

REMINDER:

CLSI document QMS04³⁵ provides useful information on laboratory design. CLSI document GP17³⁶ provides information on laboratory safety.

QUICK GUIDE

GP42-A6 QG

Technique for Skin Puncture in Adults

Skin Puncture Procedure

NOTE: Standard Precautions should be followed.

1. Prepare the accession order (test request).
2. Identify the patient.
3. Position the patient.
4. Verify the patient diet restrictions, as appropriate.
5. Verify that the patient is free of latex allergies.
6. Wash hands and put on gloves.
7. Verify the paperwork, select the microcollection device, and assemble the supplies.
8. Choose the puncture site.
9. Warm the puncture site (as applicable).
10. Clean the puncture site and allow to air dry.
11. Open a new, sterile skin puncture device within sight of the patient or guardian, inspect the skin puncture device and other equipment.
12. Notify older children and adults of the imminent puncture.



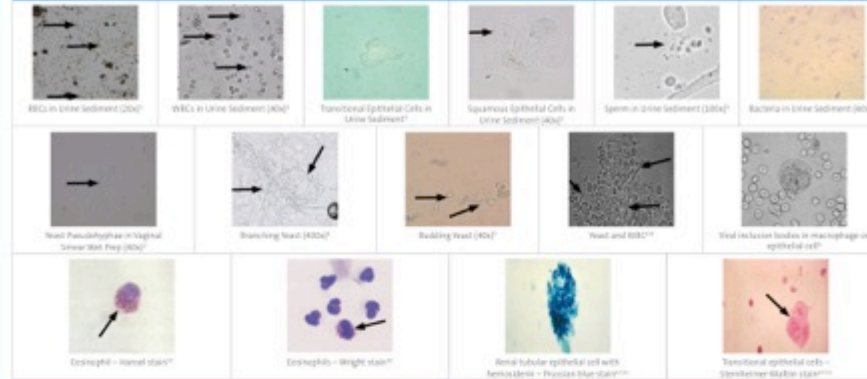
Source Documents: Procedures and Devices for the Collection of Diagnostic Capillary Blood (GP42-A6) [replaces H04-A6]

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WALL CHART Microscopic Components in Urine Sediment and Vaginal Fluid



CELLS



CRYSTALS



NONCELLULAR MATERIAL



Source Documents: Physician and Nonphysician Provider Performed Microscopy Testing: Approved Guidelines—Second Edition (POCT10-A2); and Urinalysis: Approved Guidelines—Third Edition (EP10-A3)

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Approach to Lupus Testing – Independent



Refer to the U.S. Auto Antinuclear Ab, normal. Pathologist consultation procedure, P1.

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revised | www.clsi.org

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Implementing Standards

CLSI References in the CAP Laboratory Accreditation Program Checklists



950 West Valley Road, Suite 2000, Wayne, PA 19087 | P: 610-688-0100 | Toll Free (US)

CLSI Documents Referenced to The Joint Commission Laboratory Accreditation Standards Chapters



950 West Valley Road, Suite 2000, Wayne, PA 19087 | P: 610-688-0100 | Toll Free (US) 877-441-8888 | 610-688-0100

CLSI-FDA Recognized Consensus Standards

A quick reference tool for those seeking information on FDA-recognized, CLSI consensus standards.



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Welcome!

We are happy you stopped by.



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Instructions for Homework Assignment



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See courses you are enrolled in



Resources

Browse or download resources



CLSI U Catalog

See list of available courses



Message Board

30

You have been enrolled in QSE Organization Les...

You have been enrolled in QSE Personnel Lesson

You have been enrolled in QSE Process Manage...



Key ID

Enter your Key ID for a new course





CLSI As a Global Organization

CLSI's Role in Global Standards



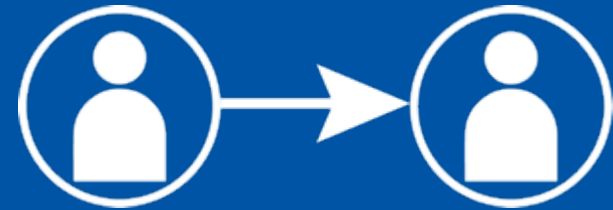
International
Organization for
Standardization

Secretariat for
ISO Technical
Committee (TC) 212

Administrator of
ANSI-accredited US
Technical Advisory
Group to ISO/TC 212



ISO: Broad,
standard
requirements



CLSI: Detailed help
and practical
guidance

Complementary, not conflicting, roles



Global Health
Partnerships





Tanzania



Azerbaijan



How Do We Create Standards?



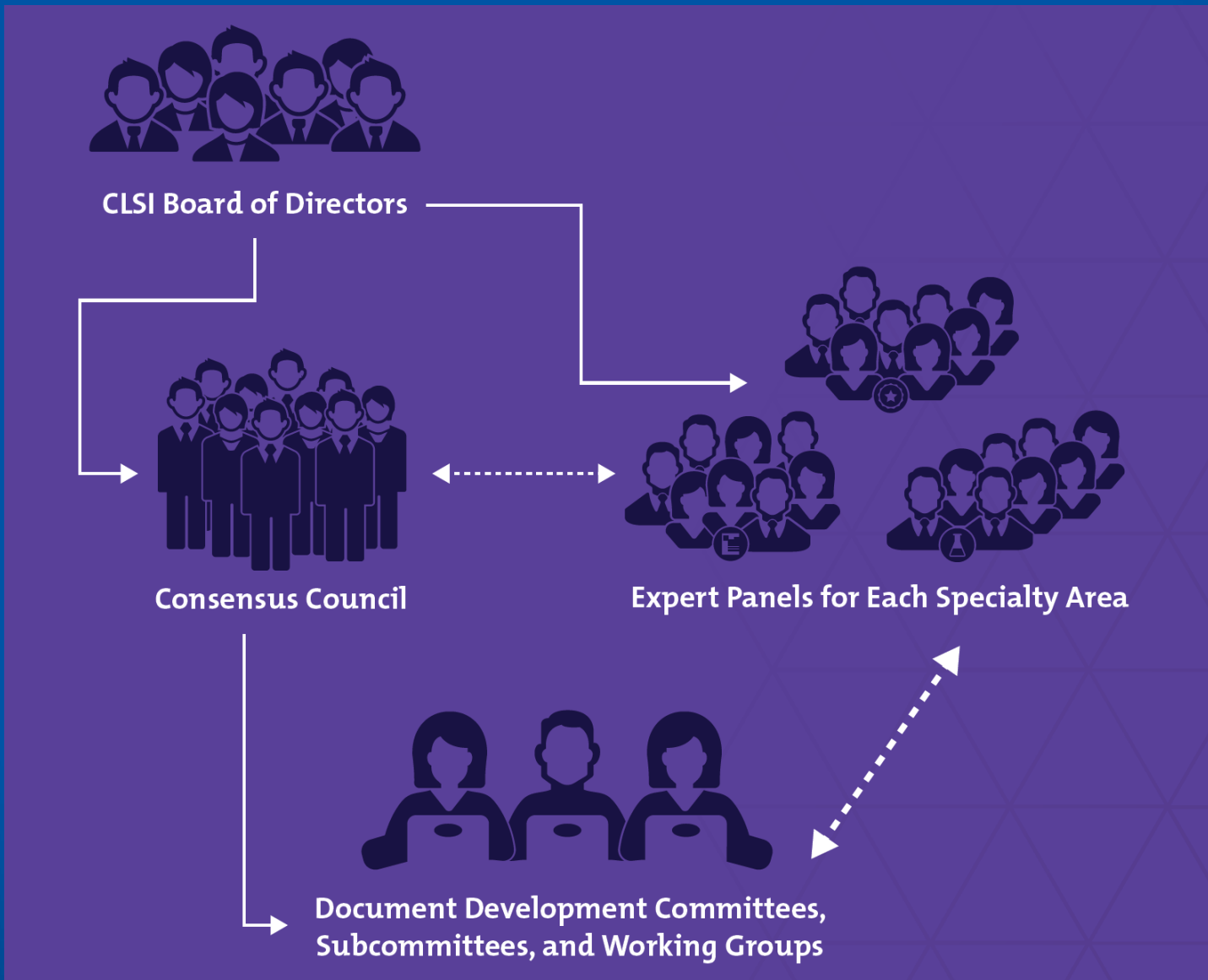
>2,000
Active Volunteers





> 75 Standards
in Development

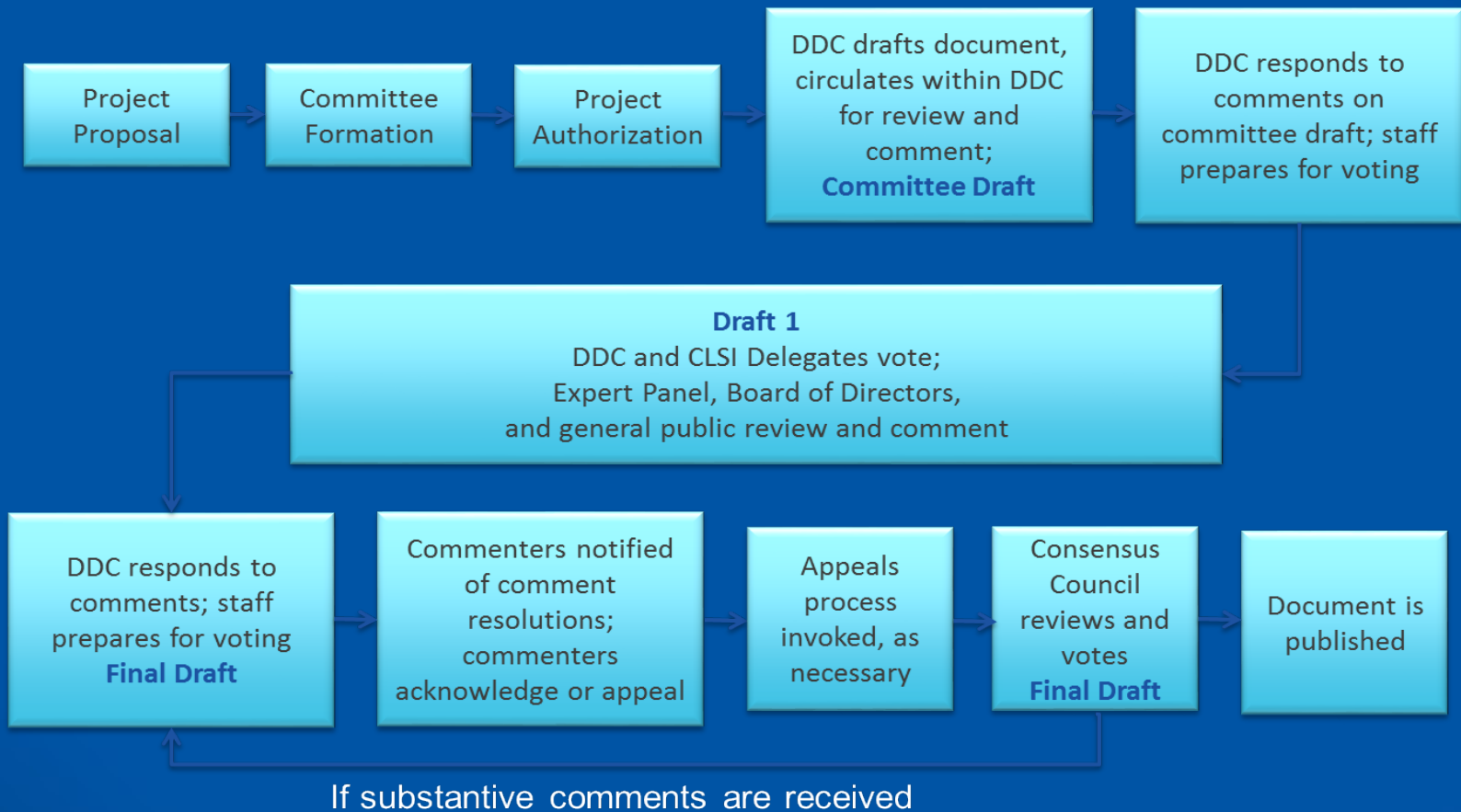
Standards Development Structure



Overview of the Process

- Proposals are generated by individuals or at the request of an Expert Panel (Project Proposal Form).
- The Expert Panel evaluates the Project Proposal and decides to move it to Consensus Council.
- Consensus Council Reviews and Authorizes Project Proposals (need and alignment across Expert Panels).
- A Call for Volunteers is issued to form a Document Development Committee.
- The Document Development Committee writes the document.
- The document moves through review and approval process.
- There are two voting stages (14- or 19-month track).
- The consensus standard or guideline is published.

Document Development Process



Abbreviation: DDC, document development committee.



Volunteer Value Proposition

- Maximizes the impact of your participation
- Expands opportunities for you
- Enables volunteers to work together
- Timely response to the critical need for standardized best medical practices worldwide



Standards vs Guidelines

- Standard
 - Specific, essential requirements
 - Used without modification
- Guideline
 - General operating practice, method, or material
 - Used as written or modified for a specific need

Point-of-Care Documents

- In Development:
 - POCT15, *Point-of-Care Testing for Infectious Diseases*; Report
 - POCT16, *Emergency and Disaster Point-of-Care Testing*; Guideline

Point-of-Care Documents

- For Revision:
 - POCT14, *Point-of-Care Monitoring of Anticoagulant Therapy; Approved Guideline* (formerly H49)
 - POCT05, *Continuous Glucose Monitoring; Approved Guideline*

Point-of-Care Documents

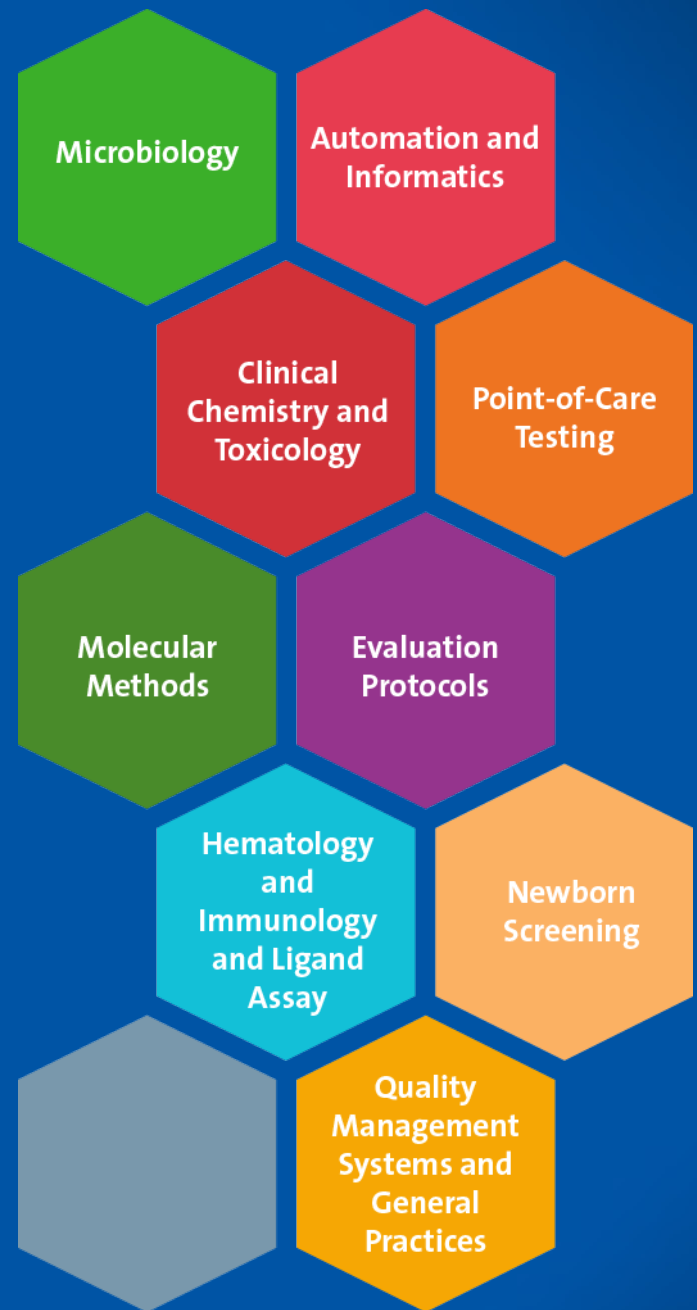
- Published:
 - POCT01-A2—*Point-of-Care Connectivity; Approved Standard*
 - POCT02-A—*Implementation Guide of POCT01 for Health Care Providers; Approved Guideline*
 - POCT04-A2—*Point-of-Care In Vitro Diagnostic Testing; Approved Guideline*
 - POCT06—*Effects of Different Sample Types on Glucose Measurements*
 - POCT07—*Quality Management Approaches to Reducing Errors at the Point-of-Care*

Point-of-Care Documents

- Published:
 - 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
 - POCT10—Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline
 - POCT12—Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline
 - POCT13—Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline



Standards Specialty Areas



Submit New Project Ideas



clsi.org/volunteer/propose-a-project/



Staying Connected With CLSI

How Do I Get Involved?

clsi.org/volunteer

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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About CLSI Standards Membership Education Global Health Partnerships Volunteer News & Events

Volunteer

- VOLUNTEERING FAQs
- STANDARDS DEVELOPMENT OPPORTUNITIES
- CALL FOR VOLUNTEERS
- GLOBAL HEALTH PARTNERSHIPS OPPORTUNITIES
- PROPOSE A PROJECT
- EXCELLENCE AWARDS

Sponsor a CLSI Project »

Call for Volunteers

View our current call for volunteers to see how you can get involved with the CLSI standards development process.

DISCOVER HOW »

Volunteering with CLSI!
Don't just follow the gold standard. Set it.

Get Involved—Volunteer with CLSI!

Don't just follow the gold standard. Set it.

CLSI offers unmatched opportunity to maximize your voice in the global laboratory health care community as you work alongside colleagues and experts from diverse sectors to improve patient care worldwide.

Through our various volunteer opportunities, you'll not only have a seat at the table with many influential members of the health care community, but have a chance to contribute your own expertise to the development and implementation of world-respected clinical laboratory testing standards.

WHY VOLUNTEER?

By donating your time and talents to improve the standards that affect your own work, you will pay

Shop Now!

How Do I Become a Member?

clsi.org/membership

The screenshot shows the CLSI website's membership page. At the top, there is a navigation bar with the CLSI logo (a globe with a stylized 'C' and 'I') and the text 'CLINICAL AND LABORATORY STANDARDS INSTITUTE'. To the right of the logo are links for 'About CLSI', 'Standards', 'Membership', 'Education', 'Global Health Partnerships', 'Volunteer', and 'News & Events'. Further right are links for 'CLSI Shop', 'My CLSI', and 'Volunteer Login', along with a 'Google Custom Search' box. Below the navigation bar is a large image of four people in a laboratory setting. On the right side of this image is a vertical yellow button that says 'Shop Now!' with a shopping cart icon. Below the image is a 'Membership' sidebar with links for 'MEMBERSHIP OPPORTUNITIES', 'MEMBER DIRECTORY', 'FAQS', and 'MY CLSI'. The main content area features a green box with a group of three people icon and the text 'A Truly Global Membership Base' and 'Advancing Clinical Laboratory Testing, Together.'. Below this is a paragraph about CLSI members and a 'Discover how.' link. A section titled 'WHO IS CLSI?' follows, with a paragraph about CLSI's mission and a paragraph about the global membership base. At the bottom, there is a paragraph about support for members. On the left side of the main content area, there are three buttons: 'Join Today' (purple), 'Renew Now' (blue), and 'CLSI by the Numbers' (green) which displays '2,000+ ACTIVE PARTICIPANTS'.

CLSI Shop / My CLSI / Volunteer Login

Google Custom Search

CLINICAL AND LABORATORY STANDARDS INSTITUTE

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Shop Now!

Membership

MEMBERSHIP OPPORTUNITIES

MEMBER DIRECTORY

FAQS

MY CLSI

Join Today

Renew Now

CLSI by the Numbers

2,000+
ACTIVE PARTICIPANTS

A Truly Global Membership Base

Advancing Clinical Laboratory Testing, Together.

CLSI members around the world are achieving greater accuracy, efficiency, and safety in their own laboratories while helping to improve patient care quality across the globe. [Discover how.](#)

WHO IS CLSI?

CLSI is an organization dedicated to developing consensus-based clinical standards that enable laboratories to fulfill their responsibilities most effectively through high-quality testing practices.

Our global membership base shares in a common mission: **to develop and promote the use of standards that are respected worldwide to improve patient care.** These members come from prestigious and innovative organizations of all sizes, and are the backbone that supports CLSI's ability to deliver timely scientific guidance for strengthening clinical laboratory processes.

In turn, we support our members with a range of invaluable products, programs, and services that help them to continually improve quality in their own work.

How Do I Buy Standards?

shop.clsi.org

The screenshot displays the CLSI Shop website. At the top left is the CLSI logo, a globe with a stylized 'C' and 'S' and the text 'CLINICAL AND LABORATORY STANDARDS INSTITUTE'. To the right of the logo are navigation links: 'Login / My CLSI', 'CLSI Shop' with a shopping cart icon, and a search bar labeled 'Search here'. Below these are more navigation links: 'About CLSI', 'Standards', 'Membership', 'Education', 'Global Health Partnerships', 'Volunteer', and 'News & Events'. The main content area features a large banner image of a laboratory setting. Below the banner, on the left, is a 'Cart Summary' section with a blue header and the text 'Your Cart is Empty' and 'View Cart:'. Below this is a 'Navigation' section with a blue header and a list of categories: 'New', 'Membership', 'Collections', 'ISO Documents', 'Electronic Products', 'Automation and Informatics', 'Clinical Chemistry and Toxicology', 'General Laboratory', and 'Hematology'. The main 'Shop' area is a grid of 12 categories, each with a title and an icon: 'New' (blue starburst with 'NEW'), 'Membership' (green icon of three people), 'Collections' (green icon of a folder and document), 'ISO Documents' (blue globe with 'ISO'), 'Electronic Products' (blue '@' symbol), 'Automation and Informatics' (blue icon of a server and cables), 'Clinical Chemistry and Toxicology' (blue icon of a test tube and flask), 'General Laboratory' (blue icon of a microscope and beakers), 'Hematology' (red and white circular icons), 'Immunology and Ligand Assay' (blue and yellow icons), 'Method Evaluation' (blue icon of a line graph), and 'Microbiology' (red and white circular icons).

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Summary

- CLSI provides the venue for consensus standards development.
- CLSI has global reach and is aligned with US and International standards.
- Point-of-care testing has relevant specific standards as well as general guidelines.
- The standards process requires active participation from all sectors.
- These documents provide guidance for practical implementation of POCT.
- These documents provide applicable performance and quality requirements for POC devices.
- Whether employed in the health care delivery, regulatory, or industry sector, CLSI standards are integral to your daily responsibilities.
- Get Involved in the process—don't be a bystander.



Questions?

Contact Us!

customerservice@clsi.org | +1.610.688.0100