CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Subcommittee Orientation Program

Your Expertise. Our Process. A Partnership for Success.

January 2014

Overview of CLSI

The Clinical and Laboratory Standards Institute (CLSI) is a widely recognized global, nonprofit, voluntary consensus organization that promotes the development and use of standards and guidelines for the health care community.

Our Vision

Quality practices for better health.

Our Mission

Develop clinical and laboratory practices and promote their use worldwide.

Our 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.

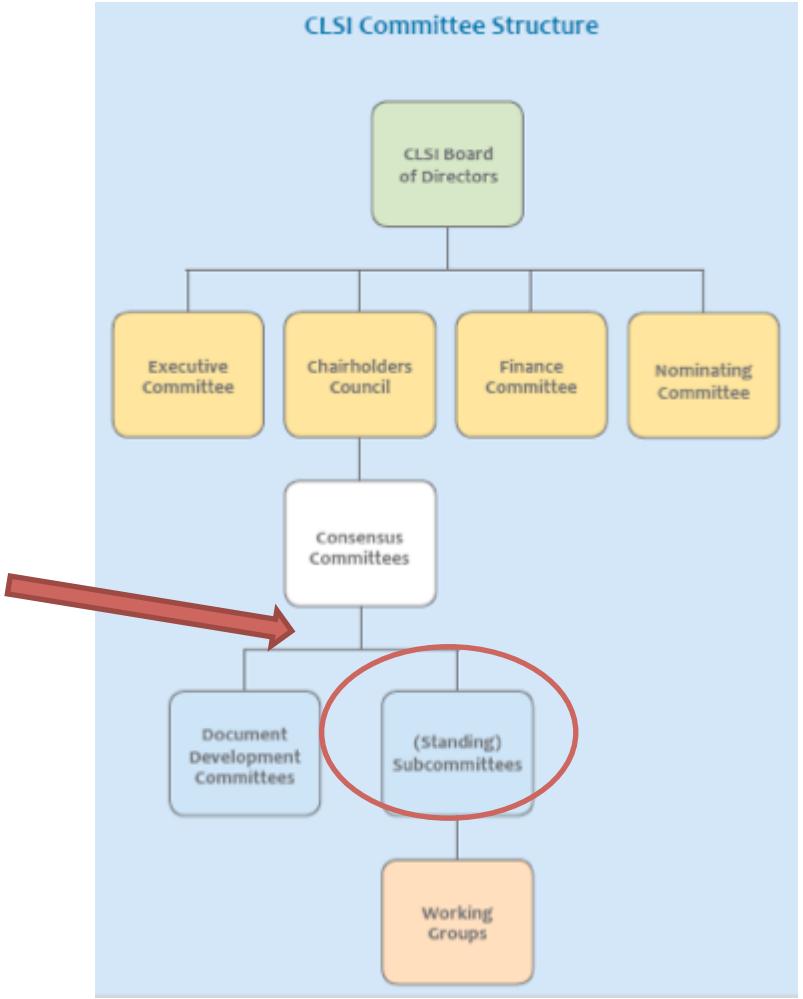
The Consensus Process

A consensus standard or guideline is a document developed, using the principles of the consensus process, to promote uniform products, materials, methods, or practices.

Organizational Structure

Consensus documents are developed within the CLSI structure.

Subcommittees continually update and revise certain standards and guidelines.



Microbiology Subcommittees (SCs)

- SC on Antimicrobial Susceptibility Testing (AST)
- SC on Antifungal Susceptibility Tests
- SC on Veterinary AST

Structure and Responsibilities

Chairholder

- Ensures that committee objectives are met and reports to the consensus committee (CC) chairholder
- Plans, monitors, and schedules the document revision process
- Moderates the discussions at face-to-face meetings
- Does not vote (except in certain situations)

Vice-Chairholder

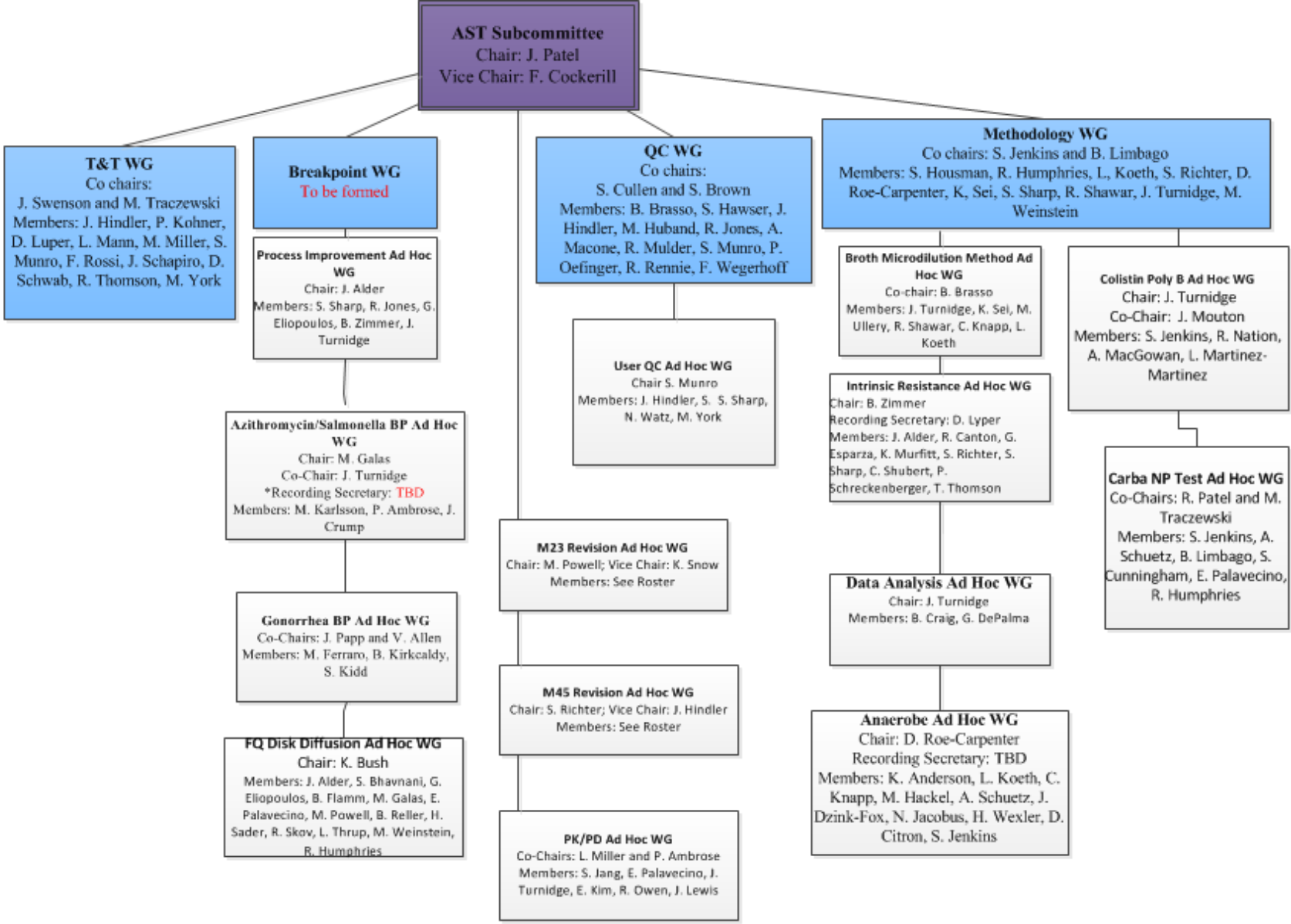
- Serves as leader in chairholder's absence
- Learns process in preparation for role as chairholder
- Does not vote

Structure and Responsibilities (continued)

- **Members**
  - Serve as authors and subject matter experts
  - Serve on working groups (WGs)
  - Vote on technical decisions
- **Advisors**
  - Provide technical expertise to the SC
  - Serve on WGs
  - Provide input on draft documents
- **Reviewers**
  - May serve on WGs and/or provide technical input
  - Review and comment on draft documents

Working Groups

- Formed as subunits of the SC
- Examples of current AST WGs
  - Text and tables
  - Methodology
  - Quality control
  - Breakpoints
- Various ad hoc WGs are formed to address certain issues and report to one of the main WGs. See next slide.



***Breakpoint Ad Hoc WGs need to select a Recording Secretary to record minutes as well as potentially draft Rationale Documents (those Ad Hoc WGs with Co-Chairs can share this responsibility if they are willing)**

Updated 12/12/2013

CLSI Staff Responsibilities

- A CLSI staff member is assigned to each SC as a project manager.
- Responsibilities:
  - Works closely with SC Chairholder and Vice-Chairholder
  - Functions as the expert on CLSI policy and the CLSI Standards Development Policies and Process document
  - Organizes and staffs full SC face-to-face meetings
  - Works with the WG recording secretaries to prepare meeting minutes
  - Manages document revisions
  - Coordinates and organizes document and meeting information
  - Disseminates SC information

Example: AST SC On-Site Meeting Schedule

Day	Session	Comment
Sunday		
8:00 AM–5:00 PM	Working Groups	Open to all (must register) Some concurrent – pick and choose Solicit comments from all “Preliminary” vote on issues*
5:30–7:00 PM	Executive session	Voting members only
7:00–8:30 PM	Reception	Open to all
Monday and Tuesday		
8:00 AM–5:00 PM	Plenary Session	Open to all (must register) Solicit comments from all Final vote on issues*

Example: Meeting Agenda Schedule

WG Schedule

MEETING AGENDA
SUBCOMMITTEE ON ANTIMICROBIAL SUSCEPTIBILITY TESTING
22-24 JANUARY 2012
THE BUTTES MARRIOTT RESORT
TEMPE, ARIZONA

Sunday, 22 January 2012

7:30 a.m. – 8:30 a.m. CLSI Orientation
(Kachina 4)

CLSI staff will provide an orientation outlining the CLSI consensus process, organizational structure, document development and revision process and consensus voting. Afterwards some AST subcommittee volunteers will give an overview of the workings of the AST subcommittee and how to actively participate as a volunteer.

Data

8:30 a.m. – 11:30 a.m. Fluoroquinolone Breakpoint Working Group **Tab E**
(Kachina 1, 2, 3) Dr. Fowler, Chairholder

The objectives of this meeting are to continue the discussion from the June meeting concerning appropriate breakpoints and the implication for susceptibility testing.

8:30 a.m. – 12:30 p.m. Quality Control Working Group **Tab I**
(Navajo) Ms. Cullen and Dr. Brown, Co-Chairholders

The objectives of this meeting are to: 1) propose QC ranges for the various submissions based on M23 Tier 2 studies; 2) review findings from a study performed to evaluate the influence of a surfactant on susceptibility testing results for polymyxins; 3) review Tier 3 QC monitoring and recommend additional actions as appropriate; and 4) review input from User QC Subgroup Chaired by Susan Munro.

8:30 a.m. – 9:30 a.m. Data Analysis Working Group **Tab H**
(Kachina 5, 6) Dr. Turnidge, Chairholder

AST SC Plenary Session 2009

Document Revision Process

- The revision process is determined by the type of document being revised
  - M100 – Revised yearly
  - M02, M07 – Ongoing revision with publication every three years
  - Procedural documents (eg, M11, M23, M39, M45) – revised after three years as needed

Document Revision Process — M100

- Revision begins with presentation of data at the January face-to-face meeting.
- Revisions are finalized and the first vote (SC) occurs at the June face-to-face meeting.
- Edits from the June meeting are made and the draft is prepared for the next voting stage.

Document Revision Process — M02 and M07

- Revision begins soon after publication of the most recent versions.
- By the June meeting in year 3, revisions are finalized.
- Documents must pass through two voting stages beginning in August.

Documents Managed by CLSI AST SC

- M02 – Disk diffusion
- M07 – Minimal inhibitory concentration (MIC) testing (aerobes)
- M11 – MIC testing (anaerobes)
- M100 – Tables (disk and MIC for aerobes and anaerobes)
- M23* – Guidance for setting breakpoints, setting quality control ranges, making recommendations in AST documents
- M39* – Antibiograms
- M45* – Fastidious organisms

*Guidelines

Thank You!

Thank you for your dedication and commitment to CLSI.