Clinical and Laboratory Standards Institute Standards Development Policies and Processes

This document defines due process requirements for development of CLSI consensus documents and related activities. An understanding of these Standards Development Policies and Processes enables participants to maximize their level of participation, and appreciate the significance of their individual and collective contributions.

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Foreword

The voluntary consensus process is a strong, cost-effective way to create tools that, when implemented, improve medical testing and health care services. This process provides a mechanism for bringing together the necessary resources to develop and publish high-quality consensus products for medical testing (ranging from testing in manufacturers' or large teaching and research institution laboratories to testing in physicians' offices) and other health care services. The Clinical and Laboratory Standards Institute's (CLSI's) voluntary consensus process also provides an effective means for reviewing standards developed by other organizations.

In its pursuit of quality testing and services through voluntary consensus, CLSI assembles experts from affected constituencies in an open discussion forum to address specific needs and problems. The CLSI consensus process ensures balanced participation of these affected groups so that all interested parties may participate, and adequate scientific expertise is available.

Through the publication and production of standards, guidelines, and other products, CLSI provides information to the clinical and laboratory profession and its associated stakeholders that is clearly communicated, medically relevant, and easily implemented. CLSI standards are intended to be used without modification. CLSI guidelines can be modified to fit a particular user's needs

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Clinical and Laboratory Standards Institute
Standards Development Policies and Processes

1 Introduction

The CLSI Standards Development Policies and Processes (SDPPs) serve the following purposes:

- **Build quality** into CLSI consensus documents.
- **Consolidate the general administrative operating policies and processes** of the organization, the committee structure for development of consensus documents, and the consensus development process.
- **Ensure organizational and operational continuity** in the development of consensus documents; the SDPPs recognize that participation in CLSI is voluntary.
- **Ensure balanced representation** of government, industry, and professions in the CLSI consensus process such that all interested parties may participate, and adequate scientific expertise is available.

The SDPPs enable participants to familiarize themselves with the policies and processes of CLSI document development, to understand committee structure, positions, and associated roles and responsibilities to maximize participation in the consensus process, and to recognize the significance of their individual and collective contributions.

For those in leadership roles, the SDPPs assist in organizing their efforts and outlining their responsibilities for supervising and documenting consensus document development.

The SDPPs:

- **Provide a mechanism for setting priorities** for CLSI projects based on Board-directed criteria, including medical utility, clinical relevance, and support of CLSI's mission.
- **Ensure that the consensus process is appropriately applied** to the development of consensus documents.
- **Ensure the existence of balanced representation** in the CLSI consensus process; it is essential that those who use CLSI consensus documents have confidence that they were developed without undue influence exerted by any special interest group.
- **Ensure that consensus documents developed by CLSI are not unduly exclusionary or widely permissive in their requirements;** avoidance of these extremes is essential for CLSI publications to be useful in practice.

These SDPPs cannot cover all situations. Those situations that require differing administrative control or policy decisions should be referred to CLSI's Chief Executive Officer, and CLSI staff should be consulted for guidance. CLSI has assigned certain administrative duties and responsibilities to its officers, Board of Directors, representatives of its member organizations, committee members, and staff regarding project development. Any deviations to these SDPPs must be documented, including a justification, and approved by the senior staff leader of standards development and the Chief Executive Officer.

2 Scope

The CLSI SDPPs apply to CLSI standards, guidelines, and other materials developed within the CLSI consensus process. The SDPPs do not apply to marketing or other CLSI materials not intended to be consensus documents.

3 Revision History

Revision Date	Description of Change
November 2008	Updated Disclosure of Interests form and Project Proposal form; eliminated the Quality and Ethics Committee.
February 2009	Updated the Disclosure of Interests form and the appeals process.
January 2011	Incorporated changes in committee structures and document development processes. Inserted description of 15- and 25-month document development timelines.
April 2012	Addressed ANSI audit findings, including more detail regarding development of American National Standards.
January 2012	Included membership administrative fee information.
April 2013	Included ANSI-recommended language regarding American National Standards.
June 2013	Changed to 2-stage document development process.
January 2016	Changed name throughout document to Standards Development Policies and Processes; changed to Consensus Council and Expert Panel structure; changed process to one voting and comment period followed by consensus vote.
November 2016	Introduced archived document category; revised corresponding information to accommodate addition

Abbreviation: ANSI, American National Standards Institute.

4 Definitions

American National Standard (ANS) – a standard that has been accepted by the American National Standards Institute (ANSI); **NOTE:** CLSI standards and relevant International Organization for Standardization (ISO) standards may be considered for ANS submittal if desired by an expert panel and agreed by Consensus Council (CLSI standards) or the US Technical Advisory Group (TAG) (ISO standards).

administrative fee – a monetary amount incurred by all committee participants that defrays the costs of committee operations; **NOTE:** CLSI membership dues, whether individual or organizational, include the administrative fee.

balance – having approximately equal numbers of representatives from each constituency participating as voting members on a particular committee; **NOTE 1:** No constituency may have a voting majority. For example, a committee with four professions members, four industry members, and two government members meets the definition for balance. A committee with six professions members, three industry members, and only one government member does not meet the definition for balance; **NOTE 2:** The only committee in the document development process that requires balance is the Consensus Council. However, all document development committees maintain representation from constituencies affected by the content of a document and at least one member from each affected constituency is required.

Board of Directors – the CLSI governing body consisting of the elected officers and directors, which has overall responsibility for establishing policies and procedures governing the consensus process.

companion product – any item provided or sold that includes content derived from a CLSI standard or guideline; NOTE 1: Examples include, but are not limited to, quick guides, wall charts, software, and templates; NOTE 2: Companion products typically contain or refer to technical content taken directly or derived from CLSI standards and/or guidelines; NOTE 3: Companion products may sometimes be called "derivative products."

consensus body – the group of volunteer participants who have the final vote to approve publication of a document through a vote of acceptance; **NOTE 1:** This group is required to have balance, as described above; **NOTE 2:** At CLSI, the consensus body is the Consensus Council.

consensus document – the generic term used to refer to any document published by CLSI that has been developed using the consensus review process; **NOTE:** An approved consensus document has achieved consensus within the health care community.

Document Categorization:

Categorization for document availability:

- **active:** Current CLSI documents that have been approved through the CLSI consensus process.

- **archived:** an active consensus document that is technically valid and determined to not pose safety risks when implemented, but is no longer being reviewed through the CLSI consensus process; **NOTE 1:** Any CLSI document that is adopted as an American National Standard is not eligible for archiving per *ANSI Essential Requirements*; **NOTE 2:** An archived document is retained in the CLSI library because of its value to the laboratory community.

- **reaffirmed:** active CLSI documents that have been reviewed and determined to be suitable for continued publication without revision to content; these documents undergo an abbreviated consensus process, and may be available in electronic format only

- **withdrawn:** CLSI documents that have been discontinued

Categorization for document sales analysis (units and dollars)

- **Core 1:** CLSI documents with unit sales that meet or exceed the average CLSI document unit sales for the prior three- to five-year period, or total sales of $10,000 or greater

- **Core 2:** CLSI documents with unit sales that fall between the mean and median CLSI document unit sales for the prior three- to five-year period, or total sales between $1000 and $10,000

- **Core 3:** CLSI documents with unit sales at or below the median CLSI document unit sales for the prior three- to five-year period, or total sales below $1000

constituency//interest category – one of three interest groups into which all volunteers are categorized: government, industry, or professions; **NOTE 1:** All volunteers must self-select which of the three constituency category interest groups (health care professions, government, or industry), they represent, based on their primary employment. In determining constituency categories, the following guidelines apply:

- Individuals employed by an academic institution, a health care delivery organization, a professional society or association, or an accreditation or certification organization in the health care field are considered members of the **professions** constituency.

- Individuals employed by a government, or government-funded agency, are considered members of the **government** constituency (even if they are also a health care delivery organization).

- Individuals employed by a manufacturing or trade organization are considered members of the **industry** constituency.
- An individual officially designated by an organization in any of the constituencies represents that constituency regardless of his/her employment.

NOTE 2: These declarations are an important factor in the appointment process, and apply to committee members and the chairholder alike. Volunteers declare their constituencies on their CLSI Disclosure of Interests and Policy Acceptance form. CLSI staff verifies the interest category for each Consensus Council member since they make up the consensus body for CLSI.

document development committee (DDC) – volunteer group with primary responsibility for consensus document development, including drafting and editing documents in response to technical and editorial comments received during each phase of the consensus process.

document development group (DDG) – generic term referring to a volunteer group responsible for the development of a CLSI document; **NOTE:** A document development group may be a document development committee, subcommittee, or working group.

expert panel – selected group of volunteers with expertise in a specific topic area.

expert panel management team – select volunteer and staff members given authority for making decisions on behalf of a particular expert panel; **NOTE:** This group consists of the expert panel chairholder, expert panel vice-chairholder, staff project manager, and senior staff member responsible for standards development activities.

guideline – a CLSI document developed through the consensus process describing criteria for a general operating practice, method, or material for voluntary use; **NOTE:** A guideline can be used as written or modified by the user to fit specific needs. Mandates (ie, "must" or "shall") are occasionally allowed in guidelines, in cases in which the document development group feels strongly that a particular action is either required or prohibited, or when a guideline addresses provisions based on regulations.

President – the CLSI official responsible for the overall leadership of CLSI; NOTE: The President, with the concurrence of the Board of Directors, authorizes the establishment or dissolution of the Consensus Council, expert panels, and special committees as deemed appropriate.

President-Elect – the CLSI official with overall responsibility for administering the activities of the Consensus Council, and the various expert panels, document development committees, subcommittees, working groups, task groups, and special reviewers in conjunction with selected CLSI staff members.

report – a CLSI technical document that is published as a service for informational purposes only, and does not contain technical procedural recommendations; **NOTE:** A report is reviewed in accordance with the requirements outlined in Section 10.1, Track A: Documents Developed by CLSI, and released for

publication by the Consensus Council; **NOTE 2:** These documents have the potential to become guidelines upon revision through the consensus process.

standard – a CLSI document developed through the consensus process, clearly identifying specific, essential requirements for materials, methods, or practices for voluntary use in an unmodified form; **NOTE:** A CLSI standard may, in addition, contain discretionary elements. These discretionary elements are clearly identified.

subcommittee (SC) – volunteer group that is responsible for continuous revision of certain standards or guidelines, or for overseeing creation of a series of related standards or guidelines.

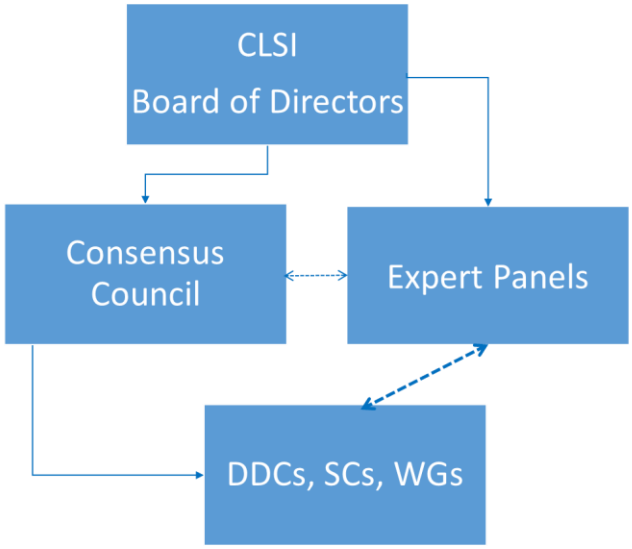
voluntary consensus – the substantial agreement by materially affected, competent, and interested parties that is obtained by following the procedures outlined in Sections 7, 8 and 9; **NOTE:** Consensus does not connote unanimous agreement, but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and are willing to accept the resulting agreement.

working group (WG) – volunteer group that is typically a subunit of an SC or DDC. A WG's assignment is limited in scope and it is disbanded upon completion of the assignment.

5 Organization for Document Development

5.1 Structure

CLSI is structured in a cascading series of volunteer committees supported by CLSI staff (see Figure 1). These committees report to the CLSI Board of Directors, and include the Consensus Council, expert panels, document development committees (DDCs), subcommittees (SCs), and working groups (WGs). Each committee is assigned specific responsibilities and accountabilities within the document development process. Each committee is discussed in detail below.



Abbreviations: DDC, document development committee; SC, subcommittee; WG, working group.

Figure 1. CLSI Committee Structure

5.2 General Requirements for all Committees

5.2.1 Eligibility for Participation

All CLSI Consensus Council, expert panel, DDC, SC, and WG meetings are open to any interested parties when technical matters relating to the development of standards and guidelines are to be discussed.

CLSI consensus process participants with official committee positions shall have paid their administrative fee, either as an individual or as included as part of a CLSI member organization.

Provisions to waive the administrative fee for financial hardship by individual members shall be considered upon request to CLSI.

If a committee determines that it needs additional technical expertise, these technical experts may be invited to participate in that specific document's development without payment of the administrative fee, upon approval of the senior management of standards development for CLSI.

5.2.2 Disclosure of Interests and Copyright Assignment

Four fundamental principles govern CLSI's consideration of participation by individuals with vested interests:

1. Decisions made on behalf of CLSI and works published by the organization are developed by processes that allow opportunity for fair and open discussion by any interested parties.

2. CLSI must ensure adequate scientific expertise is represented on expert panels, SCs, DDCs, and WGs.

3. To ensure adequate expertise, and to promote expression of a variety of views, individuals may participate in the process even if they have vested interests (see section 15 and Appendix C for additional information). However, voting members of committees shall be qualified experts and shall disclose all potential conflicts of interests.

4. Disclosures of interests of all participants (ie, committee chairholders, vice-chairholders, co-chairholders, members, advisors, contributors, reviewers) are made upon affiliation with CLSI or at the beginning of the process of developing a consensus document. Conflicts of interests on a given project or activity may be managed in accordance with the CLSI SDPPs as summarized in section 15. Disclosures of interests are available for review upon request of interested parties.

Contributions made to CLSI work must not knowingly infringe on the copyright or any other right of any third party. In addition, because CLSI works are copyrighted, CLSI is the owner of any such contributions.

Volunteers participating in any CLSI activity complete an Acceptance of CLSI Policies form (see section 15) listing all interests and activities relevant to the outcome of CLSI document development at the time of nomination. These forms are updated by the volunteers at least every three years, with each new position appointment, and with any changes in disclosed information. Volunteers who do not submit and/or update their disclosures may not continue participation in CLSI activities until the form is received in the CLSI office. A *curriculum vitae* may be used to support the information supplied.

The types of interests that are declared include personal and/or nonpersonal interests in industries and organizations relevant to CLSI committee responsibilities and specific documents in development or under revision. All interests should be disclosed that might be perceived in the context of the project as affecting an individual's objectivity. Representative examples of types of interests that are disclosed are:

- Personal interests in which individuals receive payment, including donations of supplies or equipment, from a company whose businesses may be impacted by the decisions made or the final document developed by a CLSI committee, eg, consultant fees, payment for contract work, stocks, and investments in which the individual has influence on the financial management of the stockholdings vs mutual funds.

- Nonpersonal interests involving payment that benefits an entity for which an individual has responsibility or authority, but is not received by the individual personally, eg, fellowships, grants for supporting department operations, or for a staff (not including students) position(s), and commissioned research or other studies by staff in the department.

Information on disclosed interests is kept on file at the CLSI office and is available for review upon request.

5.2.3 Undisclosed Interests

Any individual involved with CLSI in any particular area who becomes aware of an interest or activity (see Section 5.2.2) that is undisclosed must report this finding to the CLSI Chief Executive Officer. Such situations are reviewed and resolved by the Executive Committee of CLSI's Board of Directors. Records of such reports and their resolution are kept on file at the CLSI office. Individuals who fail to disclose interests that may contribute to a compromise in a standard or guideline are subject to removal from participation in CLSI activities.

5.2.4 Nominations and Appointments

Nominations for participants of all committees may be made by any interested party. Self-nominations are accepted.

Nominations describe the expertise and experience of the individual within the subject area. All nominees shall disclose financial or other interests (see Section 5.2.2) that may impact their ability to offer an unbiased view of matters that may come before the committee.

Table 1 describes the appointment process. The persons recommending, advising, and/or appointing volunteers consider the expertise, experience, and disclosure of interests of the individual when making appointments. Difficult to resolve questions may be forwarded to the Board of Directors Executive Committee for resolution.

The appointing official, with consultations as noted in Table 1, maintains the right to waive term limits when deemed necessary and/or appropriate.

Persons requesting to be added to committees after intial committee formation and roster approval are approved by the same appointing officials listed in Table 1.

Table 1. Appointment Process

Position	Appointed By	With the Advice of (as needed)
Establishment of the Consensus Council	President	Board of Directors
Consensus Council members	President	Board of Directors
Establishment of an expert panel	President	Board of Directors
Special committee or task force	President	Board of Directors
Expert panel chairholder, vice-chairholder, co-chairholder	President	Board of Directors, President Elect
Expert panel members	President Elect	President, Expert panel chairholder and vice-chairholder
DDG roster	Approved by Consensus Council, appointed by President-Elect	Expert panel chairholder and vice-chairholder
DDG roster additions to established committees	Chairholder for members (and advisors for SCs), staff for reviewers	N/A
Appeals Panel	President	Board

Abbreviations: DDC, document development committee; N/A, not applicable; SC, subcommittee; WG, working group.

6 Committee Responsibilities

6.1 Overview

Table 2 outlines the roles and responsibilities of CLSI committees. Table 3 provides a summary of the CLSI committee structure. Detailed responsibility descriptions for standards development committee positions are in Appendix B.

Table 2. Committee Roles and Responsibilities

CLSI Committee	Roles and Responsibilities
Board of Directors	• Establishes the policies and procedures that govern the consensus process • Has final approval of changes to the SDPPs • Approves standards and guidelines projects that require funding beyond the planned budget
Consensus Council	• Together with the President-Elect and selected CLSI staff members, has overall responsibility for managing the development of CLSI consensus documents, the development process, and committee expenses vs Board-approved budget • Approves and prioritizes projects within Board-directed guidelines and budget • Ensures appropriate expertise on each DDG • Gives final approval for publication of all documents, ensuring proper process, quality, and resolution of comments • Seeks advice from expert panels and staff as needed for the preceding responsibilities
Expert Panel	• Serves as technical advisor to the Consensus Council regarding new projects and documents ready for publication • Serves as advisor and subject matter expert for DDCs/SCs/WGs in its technical area • Reviews proposed draft documents in its respective technical area and provides comments
Document Development Committee	• As its primary responsibility, drafts individual consensus documents and evaluates and addresses comments received during each phase of the consensus process • Considers scientific accuracy, practicality, and comprehensibility with the goal of creating documents of overall high quality and utility
Subcommittee	• As its primary responsibility, drafts individual consensus documents and evaluates and addresses comments received during each phase of the consensus process • Usually responsible for two or more related documents, for scheduled review of the documents, and/or for supplemental updates for documents, and/or for continuous revision of certain standards/guidelines • May be a standing committee
Working Group	• Serves as a subunit of an SC or DDC • Is given an assignment that is limited in scope • Is disbanded upon completion of its assignment

Abbreviations: DDC, document development committee; SC, subcommittee; SDPPs, Standards Development Policies and Processes; WG, working group.

Table 3. Committee Positions and Term Limits

CLSI Committee	Committee Position					
	Chairholder	Vice-Chairholder	Member	Advisor	Contributor	Reviewer
Consensus Council	X	X	X[1]			
Expert Panel	X[1]	X[2]	X[1]			
Document Development Committee	X[3]	X[3]	X[3]		X	X
Subcommittee	X[1]	X[2]	X[1]	Optional[1]		X
Working Group	X[3]	Optional[3]	X			X

[1] Appointed for a one-year term and may continue in this position for a total of four consecutive years.[*]

[2] Vice-chairholders of expert panels or SCs are limited to serving a maximum of two one-year terms if rotating from the position of chairholder of the same expert panel or SC.[*]

[3] Serves in this position for the duration of the project.[*]

[*] All maximum timeframes listed assume the individual is able to continue to fulfill his/her duties and is reappointed by the appropriate official.

6.2 Consensus Council

The CLSI Consensus Council, consisting of the President-Elect, appointed volunteer members, and the CLSI senior staff leader for standards development, is the consensus body for CLSI. The Consensus Council has overall responsibility for managing the development of CLSI consensus documents, and continually improving the consensus development process. The Consensus Council is responsible for approving and setting priorities for all CLSI document development projects, based on medical utility, clinical relevance, CLSI's mission, and adherence to Board-directed priorities and budgets.

The approval to publish each document must be voted on by at least two-thirds of the members of the Consensus Council, including at least one approval vote from each constituency. The membership of the Consensus Council must be balanced among constituencies. No one constituency may have a voting majority on the Consensus Council. Consensus Council members serve one-year terms, and may be reappointed for a total of four consecutive terms upon reappointment by the President. When necessary to ensure continuity, a member's term may be extended for an additional 1-2 years.

The Consensus Council's face-to-face meetings occur during scheduled CLSI committee weeks, and teleconferences are scheduled at intervals throughout the remainder of the year.

6.2.1 Change in Status or Employment

In the event of a change in status or employment of a Consensus Council member that results in a change in the constituency category in CLSI, the member submits a resignation, which may be accepted at the discretion of the Consensus Council chairholder and/or Board Executive Committee. If the criteria for balance are no longer met, the Consensus Council may not vote on consensus documents until a new person is appointed and balance is restored. Efforts to achieve balance are undertaken, and may include a Call for Volunteers, or a Presidential appointment.

6.3 Expert Panels

Expert panels are constituted for various technical subject areas, as determined by CLSI's Board of Directors. The number of expert panel members can vary depending upon each expert panel's technical needs. The expert panel serves as an advisory group rather than a document-drafting committee. It identifies consensus development projects, proposes those projects to the Consensus Council, reviews proposals from other sources and advises the Consensus Council on suitability, and reviews and comments on consensus documents within its area of expertise.

For draft documents developed by a DDC, SC, or WG, the associated expert panel is responsible for participating in the technical review at the Proposed Draft stage.

6.3.1 Expert Panel Chairholders

Each expert panel chairholder is appointed for a one-year term and may continue in this position for a total of four consecutive years upon reappointment by the President. When necessary to ensure continuity, a chairholder's term may be extended for an additional year.

The expert panel chairholder should have in-depth knowledge and recognized expertise in the specific areas involved and/or demonstrated managerial experience in coordinating and expediting work programs in the field of interest and should be capable of managing work within the structure of a voluntary professional organization.

The expert panel chairholder is willing and able to devote significant time and effort to the assigned tasks, and to guide and monitor the review of documents developed by DDCs/SCs/WGs in the specific technical area. The chairholder also should be aware of document development opportunities within the technical area that are appropriate for the voluntary consensus process, and should keep CLSI informed so that appropriate new consensus projects may be considered.

The expert panel chairholder is responsible for recommending nominated candidates for membership on the expert panel and candidates to chair DDCs, and for providing advice regarding appointment of committee participants as appropriate. (See Table 1 for specific appointment responsibilities.)

The expert panel chairholder maintains close contact with DDG chairholders, advising at all stages in document development and emphasizing technical excellence, clarity, user suitability, global harmonization, and publication timeliness.

The expert panel chairholder serves as the primary liaison to the Consensus Council, as needed.

6.3.2 Expert Panel Vice-Chairholder

The expert panel chairholder recommends, and the President appoints, a vice-chairholder. Each expert panel vice-chairholder is appointed for a one-year term and may continue in this position for a total of four consecutive years upon reappointment by the President, with the advice of the President-Elect and the Chief Executive Officer.

The role of each expert panel's vice-chairholder is to serve as the panel's leader and to represent the expert panel as the liaison to the Consensus Council in the chairholder's absence. In the final year of a chairholder's eligibility for service, the vice-chairholder should also be the chairholder-designate, but planned succession to the chairholder position is neither a mandate nor a prerequisite for vice-chairholder service.

6.3.3 Expert Panel Members

Expert panel members represent the technical expert body for each topic area, and, as such, review and comment on documents in the consensus process. Members are appointed annually, and may continue in this position for a total of four consecutive one-year terms upon reappointment by the President-Elect. When necessary to ensure continuity, a member's term may be extended for an additional 1-2 years.

Expert panel members should be experienced individuals involved in or concerned with medical testing and/or other health care fields. Expert panel members are able to devote the anticipated required time to panel activities and they should be sensitive to opportunities in their area of technical expertise that can be aided by the voluntary consensus process.

6.4 Document Development Committees, Subcommittees, and Working Groups

6.4.1 General

CLSI standards and guidelines are developed by DDCs, SCs, and WGs. Balance among CLSI constituencies in constituting a DDC, SC, or WG is not a requirement; however, they should include representation from each constituency affected by the document.

6.4.2 Document Development Committees (DDCs)

CLSI DDCs have primary responsibility for consensus document development, including drafting and editing documents in response to technical and editorial comments received during each phase of the consensus process. Scientific accuracy, practicality, and comprehensibility are to be considered by the DDC, with the goal of creating documents of overall high quality and utility. DDC members may also participate in companion product development, and the presentation of document-related content in webinars and other educational sessions.

6.4.3 Subcommittees (SCs)

Unlike DDCs, which are formed for the purpose of creating or revising a specific document and then disbanded, SCs may be responsible for continuous revision of certain standards or guidelines, or for overseeing creation of a series of related standards or guidelines. SCs have primary responsibility for drafting individual consensus documents and for evaluating and addressing comments received during each phase of the consensus process. SCs are usually responsible for two or more related documents, for scheduled review of the documents, and/or for supplemental updates to the documents.

6.4.4 Working Groups (WGs)

A WG is typically a subunit of an SC or DDC. A WG's assignment is limited in scope and it is disbanded upon completion of the assignment. Short-term assignments that can be handled by WGs may include:

- Responding to comments on a CLSI consensus document
- Writing a single document or section of a document
- Conducting a special technical study
- Developing comments on a document created by an organization other than CLSI

6.4.5 Chairholders

The DDG chairholder may also be a participant of the expert panel. The DDC/WG chairholders are each appointed for a one-year term and may be reappointed in this position for the duration of a project. SC chairholders are appointed for one-year terms and may continue in this position for a total of four consecutive years, upon reappointment by the Consensus Council. The President-Elect, in consultation with the Consensus Council and expert panel chairholder, as needed, maintains the right to replace a DDG chairholder when deemed necessary and/or appropriate.

The DDG chairholder should be experienced in coordinating and expediting work programs in the technical area. The chairholder also should have the ability to clearly communicate and understand the requirements for timeline, comments, and responses imposed by the consensus process.

The DDG chairholder, together with his or her staff project manager, is responsible for:

- Furnishing progress activity reports, including forecasts of the time and expenses associated with completion of each authorized consensus effort, as requested to the Consensus Council

- Scheduling and planning the agenda for DDG meetings and conference calls

- Identifying a committee participant who will serve as committee secretary and determining (with the assistance of the vice-chairholder), based on contribution to document development, those individuals to be listed as contributing authors of the document

The DDG chairholder should also critically review and comment on the document at each stage in the document development process.

6.4.6 DDG Vice-Chairholders

The DDC/WG vice-chairholders are each appointed for a one-year term and may be reappointed in this position for the duration of a project. SC vice-chairholders are appointed for one-year terms and may continue in this position for a total of four consecutive years, upon reappointment by the Consensus Council. The President-Elect, in consultation with the Consensus Council, the associated expert panel chairholder, and the DDG chairholder, maintains the right to replace a DDG vice-chairholder when deemed necessary and/or appropriate.

- The role of the vice-chairholder is to serve as the committee's leader in the chairholder's absence. The vice-chairholder assumes responsibility at all times when the chairholder is not available, including conducting conference calls, document reviews, and all other tasks to move the project forward. For SCs, in the final year of a chairholder's eligibility for service, the vice-chairholder should also be the chairholder-designate, but planned succession to the chairholder position is neither a mandate nor a prerequisite for vice-chairholder service, nor is it guaranteed. The vice-chairholder assists the chairholder in determining, based on contribution to document development, those individuals to be listed as contributing authors of the document

The DDG vice-chairholder should also critically review and comment on the document at each stage in the document development process.

6.4.7 DDG Members

DDC and WG members are appointed for the duration of a project. SC members are appointed for one-year terms and may continue in this position for a total of four consecutive years upon reappointment by the Consensus Council. The President-Elect, in consultation with the Consensus Council, the associated expert panel chairholder, and the DDG chairholder, maintains the right to replace a DDG member when deemed necessary and/or appropriate.

DDG members should have in-depth knowledge in the particular technical area. They should have the ability to communicate clearly and to understand the requirements for the timeline, comments, and responses imposed by the consensus process.

DDG members, along with the DDG chairholder, have primary responsibility for drafting consensus documents, critically reviewing and voting to accept the document, and evaluating and addressing comments received during each phase of the consensus process before final approval by the Consensus Council.

DDG members, along with the DDG chairholder, generally are regarded as the authors of the consensus document, with suitable credit given in the publication.

DDG members are selected to balance expertise within the subject area with consideration given to representing industry, government, and the professions constituencies. Balance among CLSI DDG membership is not a requirement; however, formation of DDCs/SCs/WGs should include representation from each constituency affected by the document. DDCs/SCs/WGs usually consist of a maximum of nine members including the chairholder and vice-chairholder.

DDG member status is subject to termination in the event that project-related commitments are not met (eg, submission of writing assignments, participation in committee activities).

6.4.8 DDG Secretary

The DDG secretary is an individual knowledgeable in the subject area with the ability to prepare meeting summaries including detail supporting the rationale for decisions/changes made during the meeting.

6.4.9 DDC Contributors

NOTE: The description in this section does not apply to SCs or WGs.

DDC contributors are individuals who are interested in and knowledgeable in the subject area, agree to participate in the consensus process, and may be called upon for their special expertise or unique perspectives as required.

DDC contributors are expected to contribute document content, review and submit input on draft documents and revisions circulated to the DDC. Contributors who develop substantial content may be recognized as authors of a document. The chairholder and vice-chairholder are responsible for determining which contributors should be included as authors.

DDC contributors are appointed by the President-Elect based on the contributor's expressed interest and expertise, with the limitation that the operation of the DDC remains manageable.

Contributors are included in the distribution of DDC announcements and agendas, meeting minutes, and draft documents related to DDC matters. Contributors may participate in DDC meetings.

6.4.10 SC Advisors

NOTE: The description in this section does not apply to DDCs or WGs.

SC advisors are individuals who have expert knowledge and experience in the subject area of the SC and are interested in actively supporting the efforts managed by the SC.

Advisors participate, as knowledge and experience permits, in one or more of the following activities of the SC: identifying topics for consideration for new consensus documents; developing and submitting new project proposals; serving as WG chairholders or members for development or revision of consensus documents; and reviewing and submitting input on draft documents and revisions circulated to the SC for approval.

Each SC advisor is appointed for a one-year term and may continue in this position for a total of four consecutive years upon reappointment by the Consensus Council.

6.4.11 SC/WG Reviewers

NOTE: The description in this section does not apply to DDCs.

SC/WG reviewers are individuals who are interested in and knowledgeable in the specialty areas of the SC and agree to participate in the consensus process, as knowledge and experience permits, to support the activities managed by the SC/WG. Reviewers are expected to review and comment on draft documents.

6.5 Chief Executive Officer/CLSI Staff

The Chief Executive Officer is the highest ranking staff person and oversees the CLSI office and staff. The Chief Executive Officer has overall administrative responsibility for the standards development staff and the application of these SDPPs.

The CLSI staff is responsible for generating a business plan for the development, production, and marketing of consensus documents or other potential end-products of a project.

The CLSI staff coordinates all meetings of CLSI committees, including those of the Consensus Council, expert panels, DDCs, SCs, WGs.

The CLSI staff supports the activities of CLSI committees.

6.5.1 Project Manager

The project manager is responsible for assigned consensus projects. The project manager attends the Consensus Council meetings, reporting on the progress of the projects in his/her assigned areas. The project manager is a co-leader with the DDG chairholder and vice-chairholder, helping to plan and organize the work of the volunteers and to advise the volunteers regarding CLSI writing style, policies regarding content, and organization of CLSI documents. The project manager's responsibilities include:

- Ensuring completeness of project proposals

- Conducting calls for volunteers
- Assisting with committee roster selection
- Notifying selected participants
- Establishing project timelines and schedules
- Tracking adherence to the timeline
- Coordinating with chairholder and/or vice-chairholder to ensure writing assignments are completed on time and in conformance to CLSI writing instructions and all SDPP policies
- Organizing meetings, including face-to-face meetings, teleconferences, and electronic conferences
- Announcing and confirming meetings
- Collating and posting resource information for committee members
- Facilitating the collation, preparation, and posting of draft documents
- Preparing draft documents for voting, including ensuring use of CLSI style points, general readability, grammar, and layout
- Preparing draft document voting packets
- Acknowledging consensus comments
- Ensuring all comments are addressed and responses are recorded appropriately
- Ensuring adherence to established CLSI policies and procedures
- Preparing interim budget and project status reports for the Consensus Council, the Board of Directors, and the Board Executive Committee, in coordination with the DDG chairholder and/or vice-chairholder
- Escalating project delays or challenges in reaching consensus to the Consensus Council for resolution Preparing voting approval packets for Consensus Council

6.6 Member Organizations' Official Delegates

The member organization's official delegate is responsible for handling communications between CLSI and the member organization. In the interest of efficiency, the official delegate should develop a procedure within the member organization to expedite consideration of consensus documents and determination of the member's vote on CLSI matters.

Each member organization's official delegate should be responsive to requests for nominations of personnel who may be considered as candidates for CLSI scientific work.

The official delegate is encouraged to prepare and submit proposals for project development.

For each document undergoing Proposed Draft vote, the member organization's official delegate casts the vote for that organization, and provides any comments from the member organization. In the absence of a vote from the official delegate, an alternate delegate may cast the organization's vote and provide the comments. Each member organization may cast one official vote.

6.7 Full Individual Members

Full individual members act as their own delegate and have the ability to cast one official vote and provide comments on each document during the Proposed Draft voting period.

6.8 Endorsement Disclaimer

Membership in CLSI indicates support of the CLSI consensus process, but it does not necessarily imply endorsement of individual CLSI publications.

Unless specifically indicated in writing by the Board of Directors or its Executive Committee, CLSI does not endorse positions stated by individual officers, directors, or committee volunteers.

6.9 Resignations From CLSI Committees

Resignation by members of the Consensus Council, expert panels, DDCs, SCs, or WGs may be accepted by the affected committee chairholder and forwarded to the CLSI office. The resignation of a Consensus Council or expert panel chairholder may be accepted by the President or the President-Elect.

The procedure for finding replacements for persons who have resigned is the same procedure as that used for appointments.

7 Committee Operations

7.1 Committee Meetings, Conference Calls, and Web Meetings

CLSI committees conduct business at in-person meetings, during conference calls, and/or by electronic communication. Meeting announcements and agendas are issued from the CLSI office. It is CLSI policy to conduct all meetings in an open forum and to permit noncommittee participants to attend meetings, provided proper notice has been received so that space can be reserved to accommodate attendees. The project manager and the committee chairholder may establish procedures that ensure the objectives of the meeting are met while accommodating the opportunity for public attendance and observation. In some cases, it may be necessary to limit the total number of participants, or to invoke a registration fee, to manage the cost or logistical requirements for a meeting.

All expert panel, DDC, SC, or WG meetings are scheduled in accord with the annual budget and activities plan approved by the Board, and are in compliance with the CLSI antitrust policy. Teleconference and Web conference meetings are strongly encouraged for all committees. Expert panels typically do not meet face-to-face.

Most document development work will be conducted by a conference call or Web conference meeting (instead of a face-to-face meeting). Face-to-face meetings are scheduled according to the budgeted project plan or when exceptional circumstances arise in reaching consensus. Face-to-face meetings not in the budgeted plan require approval of the senior staff leader of standards development or the CEO. Every

attempt is made to schedule any face-to-face meetings in conjunction with scheduled CLSI Committee Weeks.

7.1.1 Document Development Meeting and Conference Call Arrangements

All document development meetings and conference calls are set up by a member of CLSI's staff; no meeting or conference call may be held without the presence of a member of the CLSI staff, unless an exception has been granted by the senior staff leader of standards development. If an exception is granted, the chairholder is briefed on the antitrust precautions and on related information.

The committee chairholder, vice-chairholder, and members are the primary participants in conference calls and Web conferences. The chairholder, vice-chairholder, and members' availability are given priority consideration when scheduling conference calls and Web conferences. Other committee participants' schedules are accommodated if feasible. Participation on conference calls or Web conferences is limited by practical restrictions imposed by the ability to effectively conduct productive work sessions (or meetings) by conference call or Web conference.

7.1.2 Meeting Notice and Agenda

CLSI staff ensures that all listed Consensus Council, expert panel, or DDG members, contributors, advisors, and reviewers are notified directly and in a timely manner of all meetings. The expert panel chairholder should also be specifically notified about DDG meetings. Notification should include all relevant information that the chairholder and staff believe should be considered in preparation for the meeting, along with the specific time, place, date, and tentative agenda or list of subjects to be considered.

Notifications may provide a mechanism for determining the number of individuals planning to attend.

7.1.3 Conduct of Meetings

Attendees must adhere to the meeting agenda. Discussions should be relevant to the purpose of the meeting as set in the agenda. "Off-the-record" or unrelated discussions should be avoided.

A CLSI meeting should not be used as an occasion for attendees to informally gather to discuss nonagenda topics or other related or unrelated business matters. If anticompetitive industry actions were to follow such a session, the results could be serious for the personnel involved, their companies, and CLSI.

The chairholder is responsible for ensuring that all attendees who express an interest in being heard are given the opportunity to do so before a vote is called.

Before a vote is called, the chairholder or project manager should clarify for all attendees who is eligible to vote.

It should also be made clear that participation in meeting activities and the decisions arising from a CLSI meeting are voluntary on the part of the attendees and other CLSI members.

When a meeting is adjourned, it should be over in all respects and not simply in name.

CLSI staff members are familiar with the organization's antitrust policy and can provide appropriate guidance.

7.1.4 Forbidden Discussion Topics

A prudent rule to follow at all CLSI meetings, conference calls, and social events associated with such meetings is that **no subjects relating to pricing or competitive topics should be discussed, acted upon, or even considered.** One reason for the prohibitions in this section is that while not always unlawful in and of itself, discussion of such topics among competitors can suggest or create the appearance of tacit understanding or collusion in violation of antitrust laws. The following is a list of forbidden topics. The list is not all-inclusive.

- Price or any element of price or pricing policy, including price changes, price levels, price differentials, markups, margins, profits, discounts, allowances, credit terms, etc.
- Costs, production or sales volume, capacity, facilities, inventories, or changes in such
- Sales or production quotas, territories, allocations, boycotts, or market shares
- Particular competitors or customers
- Warranties, guarantees, terms or conditions of sale, including credit, shipping and transportation arrangements, rates, or rate policies
- Bid activities or procedures, or decisions to quote or not to quote
- Product or service offerings, product plans or design, production, distribution, marketing plans, methods, or activities including proposed territories or customers
- Individual company or organizational statistics on any of the foregoing
- Matters that might have the effect of excluding suppliers or customers, or influencing business conduct toward suppliers or customers, or dealing with coercion or the exclusion or control of competition

Refer any question related to the appropriateness of the discussion to the CLSI staff project manager.

It is the responsibility of the chairholder and the project manager to terminate improper discussions, move ahead to subsequent agenda items, or adjourn the meeting or conference call, if necessary.

7.1.5 Summary Minutes

Summary minutes of all meetings and conference calls are kept by the committee secretary or designate, or the project manager in the absence of a formal secretary, reflecting who attended, members absent, the subjects discussed, actions taken, and work products produced.

Summary minutes should review the discussion, the extent of agreement, and the means by which minority positions were addressed (see Section 7.1.6).

The committee chairholder, secretary, and project manager are responsible for ensuring that summary minutes are kept during the meeting or conference call. For meetings of the Consensus Council or an expert panel, keeping summary minutes is the responsibility of the staff project manager or other CLSI staff member.

Before the summary minutes can be issued as final, they are reviewed by the committee chairholder and the project manager. After the appropriate reviews, the meeting or conference call summary minutes or other meeting work product(s) are distributed by the project manager to the meeting or conference call participants.

7.1.6 Unresolved Issues

Matters (eg, minority views) that are not fully resolved by a DDC, SC, or WG deliberation on a document should be reflected in the summary minutes. Minority views may also be included in the Proposed Draft voting document (eg, in the Foreword, Introduction, or an appendix, as appropriate) at the option of the committee, with a request for comment from the broader community.

7.1.7 Recorded Votes

Recorded votes are formal votes held by any CLSI body to forward a document to the next stage of development and voting, or, in the case of Final Draft, to signify agreement (or disagreement) that consensus has been achieved and that the document as written represents that consensus. CLSI requires a two-thirds majority of the DDC or SC's full membership (excluding abstentions) for approval of a document, with at least one member from each affected constituency voting to accept the document. For Consensus Council votes on Final Drafts, at least two-thirds of the members of the Consensus Council must vote, including at least one person from each constituency. Any voter unable to attend a meeting, conference call, or Web conference where a formal recorded ballot is taken may submit a formal vote within five days of the meeting (before or after). For documents developed by WGs, the SC conducts the formal vote.

CLSI recognizes that so-called straw votes may be taken periodically within a CLSI body (DDG, or Consensus Council,). These votes are considered nothing more than a part of the deliberative process and are not recorded votes.

Voting options at all stages of voting include:

- Affirmative
- Negative
- Abstain

CLSI shall not change a vote unless instructed to do so by the voter. Written or electronic confirmation of any vote change is required.

7.1.8 Recorded Comments

Comments may be submitted during any voting period and during public review. All comments are considered by the DDC, and an effort is made to resolve all expressed objections. Each commenter is advised in writing (including electronic communications) of the disposition of the comment and the reasons therefore. If resolution is not achieved, each commenter is informed in writing that an appeals process exists within CLSI's procedures. Comments received after the close of the voting period are assessed, and, if not critical, are retained until the next voting period or document revision.

The disposition of critical comments depends upon the status of the affected document. For documents that are in pre-publication stages, the comment is considered by the DDG and appropriate resolutions are

implemented. For published documents, one or more experts from the DDG and/or the expert panel assist staff in determining the appropriate resolution(s), which is then implemented by staff.

7.2 Correspondence

7.2.1 Official Correspondence

All official external CLSI correspondence can emanate only from the CLSI office, from the CLSI officers, and from individuals specifically designated by the President.

No other persons are authorized to have CLSI letterhead stationery or to issue official statements on behalf of CLSI.

7.2.2 Committee Correspondence

Occasionally, it may be necessary or useful for committee members to correspond directly about committee projects. If such correspondence is intended to be included in the official record of that committee's work, a copy is forwarded to the project manager for appropriate marking and filing. Such correspondence may be on plain stationery (including electronic communications) or on the personal or organizational letterhead of the sender.

7.2.3 Electronic Correspondence

Whenever possible, CLSI staff prepares and distributes correspondence in electronic format. Appropriate safeguards are taken by the CLSI staff to ensure that such transmission does not violate any restrictions related to distribution of the material.

7.3 Draft Documents

All draft consensus documents are circulated to the appropriate committees by the CLSI staff. Each circulated draft is identified as an internal CLSI document, with each page clearly marked "Draft." The draft also has a title and a code, which is assigned by the CLSI office. Once submitted to the CLSI office, draft documents are owned by CLSI and may not be used for any purpose other than review and comment.

When a draft consensus document is distributed for comment, the following legend is prominently printed on each page:

> **"DRAFT DOCUMENT.** This draft CLSI document is not to be reproduced or circulated for any purpose other than review and comment. It is not to be considered either *final* or *published* and may not be quoted or referenced. **DATE."**

In addition, all Proposed Draft documents bear a "DRAFT" watermark across the middle of each page, followed by "Not to be used for clinical purposes or to satisfy regulatory or accreditation requirements."

7.4 Fiscal Controls

7.4.1 Conservation of Financial Resources

CLSI adheres to strict financial budgetary controls exercised by the Treasurer through the CLSI office, with the advice and consent of the Board of Directors. These controls are consistent with the overall technical and scientific goals of the organization; the budgetary objectives adopted by the Board; and the Internal Revenue Service regulations governing a voluntary, not-for-profit organization [Section 501(c)(3)].

7.4.2 Committee Budget

The annual budget for CLSI activities is proposed by CLSI staff, and finalized and approved by the Board of Directors. The annual budget and activities plan includes both project objectives and the budget required to accomplish these objectives.

The Consensus Council, together with the DDG chairholder, vice-chairholder and designated project manager, is responsible for developing committee-operating budgets in accord with the overall priorities established by the Board of Directors, and monitoring adherence to them.

7.4.3 Committee Accounts

The CLSI office maintains an account record for each committee. Chairholders and vice-chairholders are provided with budget status reports upon request or by the Treasurer's decision when variances or trends require attention. Periodic audits of committee expenditures may be conducted by the Treasurer to fulfill the organization's responsibility under its not-for-profit status.

7.4.4 Reimbursement for Expenses

CLSI expects industry member organizations to reimburse the expenses of its volunteer representatives participating in any CLSI activity, including the Board of Directors, Consensus Council, expert panels, DDCs, SCs, WGs, and task forces.

Where the member organization is prohibited from providing reimbursement, or cannot afford to assume the expenses of a volunteer, the organization (or individual) advises CLSI in writing at the time of nomination. CLSI will makea determination of

When a nominee from the government or professions constituency is selected to serve as a committee chairholder, vice-chairholder, member, committee secretary, or to represent CLSI in a particular activity, CLSI reimburses that individual's expenses to participate in that activity, upon request, and in accordance with CLSI's current reimbursement policy, available on CLSI's website (www.clsi.org).

Contributors, advisors, and reviewers appointed to CLSI committees are not reimbursed, regardless of the constituency they represent.

Exceptions for special circumstances (eg, need for additional expert input on a technical topic) are approved by the Board Executive Committee.

Reimbursement (rather than advancement of funds) is the established policy within CLSI's Volunteer Meeting and Reimbursement Policy and Guidelines. Reimbursable expenses are those necessarily

associated with personal travel (by the most economical means) to and from scheduled CLSI meetings. Reimbursement may be subject to per diem limits.

7.5 Surveys

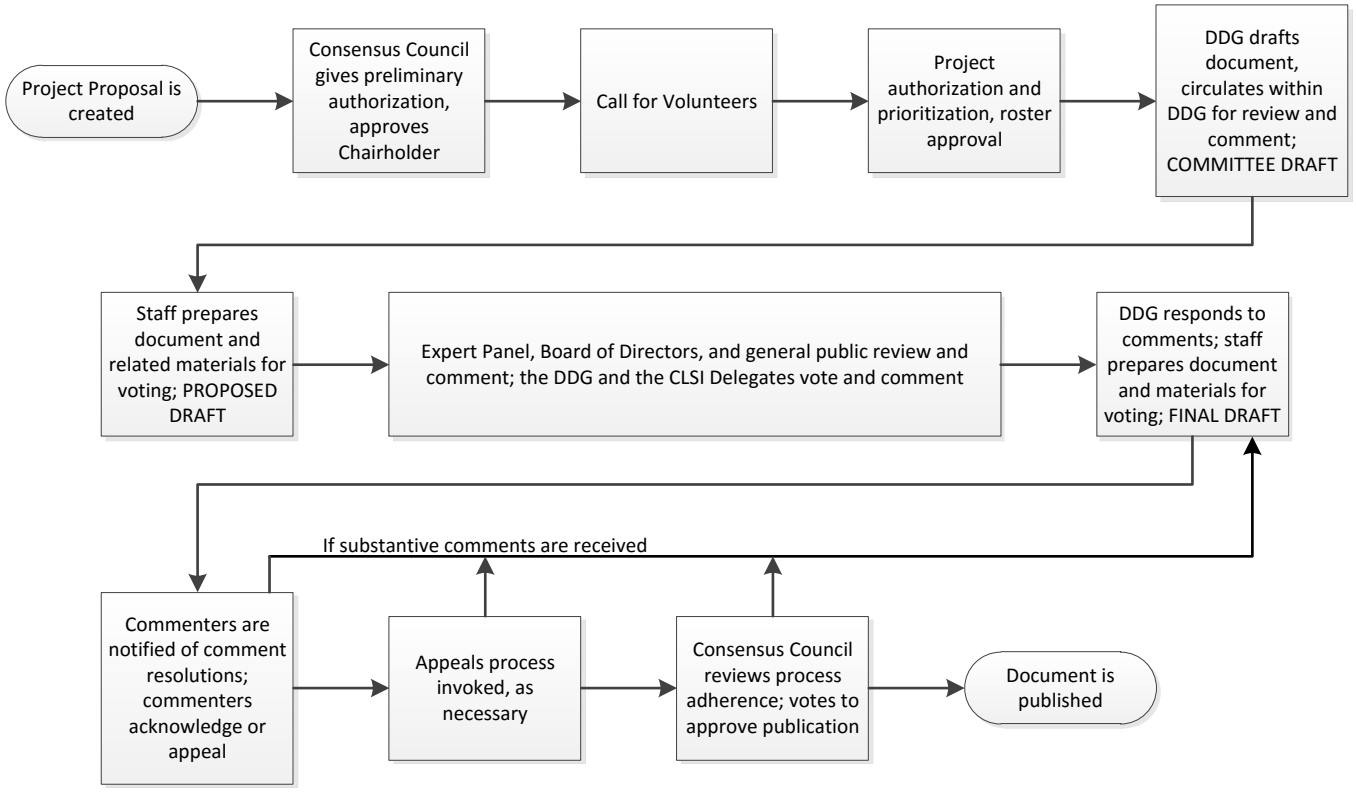
Information surveys of a specific portion of the health care community are performed by the CLSI office for any of the various CLSI committees. This technique gathers valuable information that can be used by the committee during the development of a CLSI document or other product. The committee may be requested to supply the contact list.

It is permissible, under appropriately controlled circumstances and procedures, for CLSI to collect data from member and nonmember companies, aggregate and blind the material as to its direct source, and distribute it to members and other recipients developing or using CLSI consensus documents.

8 The Document Drafting Process (Standards and Guidelines)

From a project's inception, the consensus process is intended to build quality into CLSI consensus standards and guidelines.

During the two voting stages, the document may be reviewed by and/or voted on by members of the DDC, SC, expert panel, Board of Directors, CLSI delegates, and the general public. Figure 2 displays this process. Comments received are fully addressed by the DDC, SC, or WG and reviewed by the Consensus Council, with the advice of the associated expert panel as needed.



Abbreviation: DDG document development group..

Figure 2. High Level View of the Document Development Process

8.1 Project Proposal and Authorization

Any person or organization, including CLSI committee participants or committees, may propose a new CLSI project. All proposals for new projects are reviewed through a progressive assessment/authorization process, using the Project Proposal Form (see Appendix A).

8.1.1 Project Proposal Form

A copy of the current Project Proposal Form is incorporated within these SDPPs as Appendix A. This form is regularly revised to reflect the criteria established and information needed by the Consensus Council to evaluate and prioritize proposals and the resulting documents.

8.1.2 Elements of the Project Proposal

All project proposal forms require the following information for review by the Consensus Council (NOTE: not all of this information needs to be supplied by the originator of the project proposal). The person submitting the project proposal works with the designated project manager to complete the information.

- Complete, accurate contact information of the individual submitting the proposal
- Recommended title for the proposed project
- Description of the type of product being proposed
- Project description (see Section 8.1.2.4)
- Recommended timeline for development (see Section 8.1.2.6)
- Listing of the proposed chairholder and vice-chairholder and their constituencies.
- Proposed project budget

8.1.2.1 Project Description

The project description provides the basis for the document's scope statement. The project description identifies the purpose and application (ie, intended use and users) of the standard or guideline. The project description also identifies the limitations of the document, if any.

As outlined on the project proposal form, the following information is included in all project descriptions:

- Project scope (see Section 8.1.2.1.1)
- Project rationale (see Section 8.1.2.1.2)
- Recommended chapter headings/topics
- Additional factors for consideration (see Section 8.1.2.1.4)

The project manager and/or the Consensus Council may return a proposal to the original submitter, with a request for appropriate expansion/clarification, if the above listed information is incomplete or insufficient to make an approval or prioritization decision.

8.1.2.1.1 Project Scope

The scope statement establishes a set of elements that are included in the document (ie, intended uses and users). The scope statement may also explicitly state what is not included in the document (exclusions).

NOTE: CLSI has developed a project proposal form for presentation of these elements. Refer to Appendix A for details.

8.1.2.1.2 Project Rationale

The project rationale summarizes the underlying principles to be discussed in the document, as well as a description of the document's anticipated effect on the health care arena and reasons prompting its preparation.

8.1.2.1.3 Additional Factors for Consideration

The global or national target audience of a proposed project should be described within the proposal. While CLSI is a global organization, individual projects directed at specific national or regional needs are acceptable; however, such projects and the resulting consensus documents should clearly indicate this focus.

8.1.2.2 Recommended Timeline

The project proposer selects a project development time of 4, 6, or 8 months to complete the Committee Draft. The complete timeline is added to the project proposal by the project manager (see Section 8.3.1).

8.1.2.3 Proposed DDG Membership

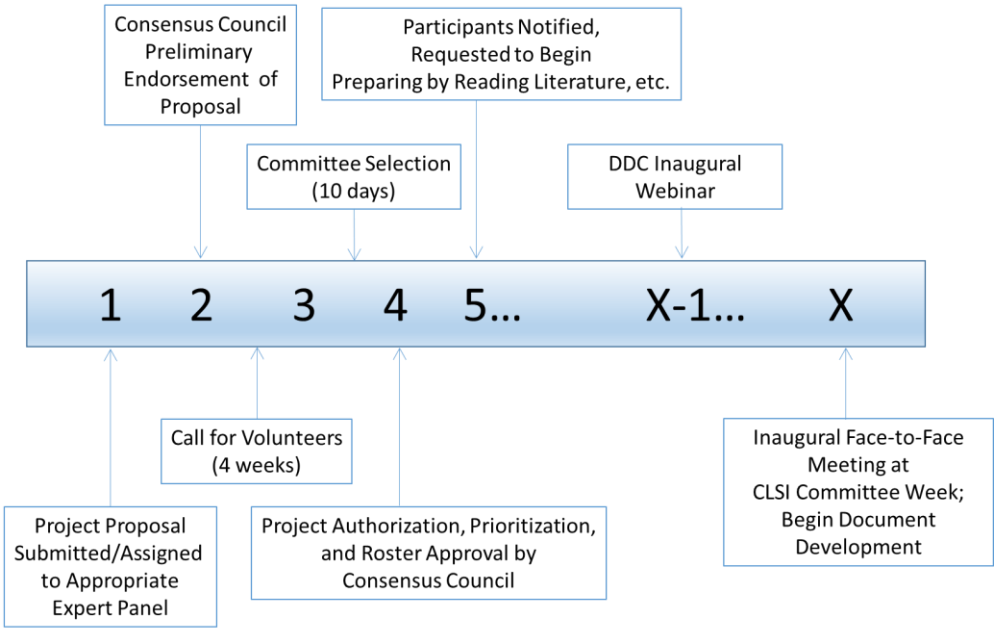
All project proposal submissions include a description of specific expertise required on the DDC. This description is used to create a "Call for Volunteers" recruitment that solicits membership for the DDG through the CLSI website and other electronic communications. The proposed DDG chairholder and vice-chairholder, together with the expert panel chairholder and the project manager, select the proposed DDC members, considering their individual expertise and their constituency categories.

8.1.2.4 Proposed Project Budget

CLSI staff will collaborate with the proposed chairholder and vice-chairholder to propose a project budget, considering factors such as the expected number of face-to-face meetings, conference calls, and/or webinars. In addition, the anticipated sales revenue of the document is estimated.

8.1.3 Project Assessment/Authorization Process

Figure 3 displays the project assessment/authorization process.



Abbreviation: DDG document development group.

Figure 3. Project Assessment/Authorization Process

The first stage of project assessment/authorization requires preliminary review and evaluation by the CLSI office staff and the Consensus Council.

This step is intended to ensure that a proposed project is consistent with the mission and goals of CLSI, that there is a perceived need for the document, and the project has a high enough priority to proceed. The volunteer recruitment process begins once the Consensus Council has given preliminary approval.

The Board has delegated authority for authorization of new projects to the Consensus Council, as long as projects remain within their Board-approved budget limits. Projects expected to exceed the Board-approved budget limits must be approved by the Board Executive Committee.

- The Consensus Council reviews and votes by electronic communication, during prescheduled conference calls, at a face-to-face meeting, or by electronic communication. Overall project prioritization, resource allocations, and capacity issues should be addressed by the Conensus Council.

- The Consensus Council can 1)accept the project; 2)reject the project; 3)in limited situations, commit to fund a project but schedule a delayed start, in which case there is recognition of the effect of that decision on the project timeline; or 4) defer discussion of the proposal to the next meeting or conference call.

- After approving the proposal, the Consensus Council prioritizes the work in relation to all other CLSI projects.

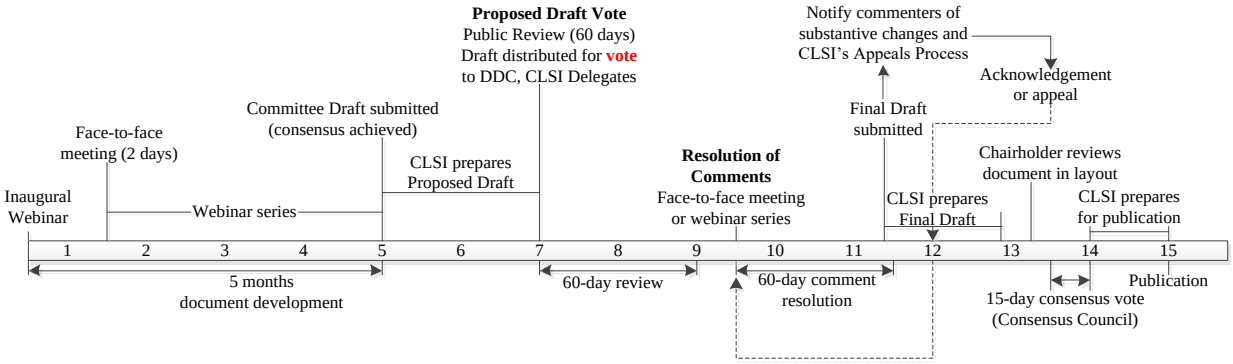
8.2 Notification of Standards Development

The initiation of new standards development activities are announced on the CLSI website and through electronic communications to CLSI members.

8.3 Organization of Effort

8.3.1 Document Development Timeline

The time required to develop a consensus document depends on multiple factors, including the breadth of scope, complexity of issues, comprehensiveness and depth in covering the topics, and the controversial nature of the topic. Figure 4 depicts an example timeline for the development and production of CLSI documents. Additional development time may be planned for and is indicated in the project proposal. Proposals requiring lengthy development times may be reconsidered to limit the scope to allow more timely completion.



Abbreviation: DDC, document development committee.

Figure 4. Example Document Development Timeline

8.3.2 Timeline for Revisions

The timeline for completion of document revisions is included in the project proposal, and reviewed and approved by the Consensus Council.

The Consensus Council reserves the right to set separate timelines for projects requiring additional time (eg, wet studies for microbiology projects).

8.4 Style Guide and Writers' Instructions

In drafting a consensus document, the DDG is required to follow the guidelines established in the most current edition of the CLSI Style Guide for Authors and Editors and the Essential Instructions for Writing CLSI Documents. The DDG is encouraged to use the resources of its members for document editing during the drafting stage. The CLSI project manager works as co-leader with the chairholder and vice-chairholder to ensure the draft document conforms to the CLSI requirements for format, writing style, and policy as the document is assembled from the technical writing assignments of committee members..

8.5 Alternative Methods in Standards

An alternative procedure that differs from a CLSI method and was not used as the basis for developing the consensus document should not be included in or cited in the consensus document. If such an

alternative procedure is judged by the appropriate CLSI committee to be advantageous in certain test applications, it should be either (a) the subject of a new project proposal to develop a separate CLSI consensus document, or (b) incorporated in the document and advanced through the consensus process.

8.6 Implied Endorsement

CLSI documents do not endorse, either directly or implied, specific commercial products, companies, organizations, or contributing persons. This requirement means that trade names are not used in a document. Implied endorsement of one or a few vendor's products (such as by inclusion in example tables, figures, or forms) is not permitted. Acknowledging an organization as the source for examples, forms or other user aids is not permitted because that practice is an implied endorsement of that organization as an example of best practice. Recommendations, examples, forms or other user aids are to be generic based on consensus scientific principles or best practices. There should be only very rare exceptions to this endorsement policy. Exceptions need Consensus Council pre-approval before a proposed draft is submitted for voting.

8.7 Regulatory References

Terms or regulations of a specific country are not permitted as justification for a recommendation in a document (examples for US-centric language include Basic Metabolic Profile as a name for a test panel, waived as a category of a test procedure, Centers for Medicare and Medicaid Services, Clinical and Laboratory Improvement Amendment). In general, recommendations or examples should be based on consensus scientific principles or best practices, so the document will be globally applicable. It is acceptable to indicate that the information in a document is consistent with regulatory or accreditation requirements in several countries or regions with citations of several in the references as supporting documentation. There may be exceptions when a US-centric document is intentionally developed for specific purposes, and although globally applicable, is very US-focused. Such exceptions will be authorized by the Consensus Council when the project is approved.

9 Consensus Approval and Publication (Standards, Guidelines, and Reports)

9.1 Introduction

The Consensus Council is the official body of the organization that certifies consensus has been reached on a consensus standard or guideline, ensuring the procedures of these SDPPs have been followed.

Approval of a consensus document entails review by both the membership and the health care community, and includes professions, industry, and government.

Consensus does not imply total agreement as to all pertinent comments and objections received.

Thus, the approved consensus document is broadly acceptable to all because it has been fairly and responsibly constructed and reviewed by a wide audience of interested parties.

An integral procedure in the consensus approval process is the mechanism through which each committee takes notice of and acts on all comments, including material objections to any provision of a consensus document. All substantive comments or objections to the content of any consensus document that are not implemented in the consensus process are acted upon through a written committee response to the commenter explaining the reasons for this action. The Consensus Council, as reflected in the following procedures for consideration of a consensus document, ensures that there has been a satisfactory and adequate response (see Section 9.2.2.1) to all comments.

For American National Standards (ANS), the requirements listed in Section 12 also apply.

CLSI staff maintains the official records that confirm that the consensus process has been followed. CLSI conducts periodic audits of selected records of consensus documents for adherence to the consensus process.

9.2 Consensus Approval Process

9.2.1 Proposed Draft

The Proposed Draft is the finalized proposed draft standard or guideline submitted for vote to the DDC members and the CLSI delegates. At this time, the draft is also available for review and comment by the applicable expert panel, the CLSI Board of Directors, and the general public.

The Proposed Draft should receive wide and thorough technical review, including overall review of scope, approach, utility, and a line-by-line review of its technical and editorial content. This review is intended to ensure the overall quality, utility, and readability of CLSI's approved consensus documents, and that they are technically correct and reflect broad consensus.

Comments and ballots are collected electronically during a 60-day review and comment period.

9.2.1.1 DDG Approval of the Proposed Draft

The Proposed Draft is approved by the applicable DDG. A two-thirds majority approval of the DDG's members (excluding abstentions) is required for approval of the Proposed Draft, including approval by at least one member of each constituency. If the DDG chairholder or vice-chairholder votes to reject the document, review by the Consensus Council is required.

NOTE 1: WGs do not conduct formal votes. Proposed Drafts for documents developed by WGs are approved by the associated SC.

NOTE 2: The Subcommittees on Antimicrobial, Antifungal, and Veterinary Antimicrobial Susceptibility Testing follow specific voting rules at their meetings, depending upon the number of voting members present. As per the voting rules, only members of the subcommittees vote; subcommittee chairholders and vice chairholders are considered non-voting members. See Appendix C for a listing of the voting rules for each of these subcommittees.

9.2.1.2 Delegate Approval of the Proposed Draft

Each CLSI member organization's duly named delegate has the responsibility to vote, if desired. In the absence of a delegate vote, the alternate delegate vote is counted. A document is advanced when a two-thirds majority of votes cast (excluding abstentions) is for approval.

9.2.1.3 Circulation of the Proposed Draft for Review and Comment

Concurrent to the DDG and delegate voting period, the Proposed Draft is available for review and comment by the applicable expert panel, the Consensus Council, the CLSI Board of Directors, and the general public. Availability of the Proposed Draft documents for review by nonmembers is announced on CLSI's website. There is a nominal charge to receive the proposed draft for non-members.

All parties have 60 calendar days from the date of circulation to submit comments to the CLSI office. Extension of the commenting period requires the approval of the Consensus Council chairholder.

The closing date for voting on the Proposed Draft is specified on the ballot and officially ends at midnight US Eastern Time on the date specified. Any ballot received after the voting deadline is not counted in the voting results.

All comments received on the Proposed Draft as a result of the review are compiled by the CLSI office. Comments received after the close of balloting will be evaluated by the DDG, and the DDG will determine whether to address the comment, or hold it until the next revision.

An electronic form for submission of comments is available on CLSI's electronic collaboration Web tool.

9.2.1.4 Review of the Document by Selected Special Reviewers

As a result of the nature of a particular document or its subject matter, the DDGmay decide to invite subject-matter experts to serve as special reviewers, in order to provide an independent review of the document. This review is in addition to that of the DDG and expert panel. For example, special reviewers may be asked to provide a theoretical analysis of a document or they may be asked to provide a practical, in-use test of a document, where that analysis or test may require special facilities or expertise.

The use of special reviewers with first-hand experience in the subject of the document is encouraged whenever appropriate. Neither membership in CLSI nor any fees are required for participation as a CLSI special reviewer.

9.2.1.5 Rejected Proposed Draft

A Proposed Draft document that does not achieve the required voting majorities is considered rejected. The rejected Proposed Draft and all comments, including those supporting reject votes, are forwarded to the appropriate DDG for consideration and resolution. The DDG, in consultation with the Consensus Council (and SC for WGs), decides whether to rework the document and resubmit it to the consensus process.

9.2.1.6 Handling Proposed Draft Comments

The DDG has responsibility for resolution of comments.

All comments on the Proposed Draft, including comments submitted by the applicable expert panel, the Consensus Council, the CLSI delegates or their alternates, the Board of Directors, and other interested parties are kept on file at the CLSI office. The file identifies the consensus document under review, the commenter's name and affiliation, and the date received in the CLSI office.

After the period for comment has expired, a summary of comments is prepared by the project manager, usually within 30 days, and forwarded to the DDG for review and action. A summary record of actions taken on all comments is prepared by the DDG. An adequate response:

- Is specific to each question/comment
- Includes specific support data, if requested, for each question/comment
- Is reviewed by the committee members
- Is retained on file

The DDG acts on comments received in a timely way, usually within 60 days of preparation of a comment summary. Comments may be addressed at a meeting, electronically, or by phone, as long as each member of the committee is in receipt of the comments and the proposed resolutions. If there is undue delay, the Consensus Council, with the advice of the President-Elect, may restructure the DDG or cancel the project.

Comments received after close of the Proposed Draft review/balloting period are reviewed by the DDG. The DDG determines whether to address the comments in the current draft, or hold them until the next revision. In the event that late comments have a significant impact (eg, raise substantive issues) on document content, the Consensus Council may authorize a delay in document publication.

The record of disposition of comments and the DDG and delegate votes are documented by the CLSI office.

All commenters are provided with a summary of their comments and all comments with commenters' names removed, the disposition of the comments and the rationale therefore, as well as notification of their right to appeal. The commenter may request a revised draft that incorporates all changes in response to comment resolution. Commenters are expected to acknowledge receipt of the comment resolutions, and/or exercise their right to appeal, within 30 calendar days. If no response is received from a commenter, then it is assumed that the commenter accepts the revisions. Commenters are notified of this assumption.

An electronic form for submission of comments is available on CLSI's electronic collaboration Web tool.

9.2.1.6.1 Unresolved Objections

Unresolved objections (ie, unresolved reasons for "reject" votes), attempts at resolution of unresolved objections, and substantive changes after balloting are reported to the Consensus Council. DDG members, and/or delegates have the opportunity to respond, reaffirm, or change their votes, within a minimum period of 10 days after being notified of the comment resolution by the DDG.

A Proposed Draft document may highlight any unresolved technical issues as appropriate. For example, minority views not fully resolved, at the option of the committee or at the request of its individual members, may be included in the document with a request for comment from the broader community.

9.2.1.7 DDG Dissolution

A DDG is officially dissolved by the Consensus Council at the completion of the project when the final draft is published.

The Consensus Council, at its discretion and with the advice of the President-Elect, may cancel any project and/or disband a DDG in the event the Consensus Council determines that consensus cannot be achieved.

9.2.2 Final Draft

Following the Proposed Draft vote, the DDG responds to the Proposed Draft comments, and revises the draft as necessary. This activity usually occurs in a one- to two-day face-to-face meeting, but may also occur by conference calls, webinars, or other means. The choice of a meeting vs other means is determined by the extent of the Proposed Draft technical comments and amount of revision needed.

After resolution of all comments and incorporation of the necessary revisions by the DDG, the document is now considered the Final Draft, and is ready for Consensus Council approval.

9.2.2.1 Consensus Council Approval of the Final Draft

Consensus Council members are provided with the following materials for review before the Final Draft vote is taken:

- The results of the proposed draft voting
- All comments received and their resolutions
- A copy of the final draft document
- Notice of any appeals and their resolutions

Any questions are to be submitted to a designated staff member. The staff member will answer any process questions, and refer any technical questions to the relevant expert panel. If necessary, conference calls or other means of communication between the Consensus Council and the expert panel are made available.

All members of the Consensus Council (the consensus body for CLSI) are expected to vote on the approval of the Final Draft document. When recorded votes are taken at meetings or conference calls, absent members are given the opportunity to vote within five days of the meeting (before or after).

At least 10 members of the Consensus Council must vote, including one member from each of the three constituencies. Two-thirds majority approval of the Consensus Council's members (excluding abstentions) and approval by at least one representative of each constituency's membership is required for Consensus Council approval of the Final Draft.

For the Consensus Council vote, CLSI staff sends follow-up notices to Consensus Council members who have not yet voted, five days before the end of the ballot period.

If the Consensus Council has substantive comments (as determined by its members), or determines that comments were not adequately resolved, then the document is returned to the DDC to resolve the comments. Significant changes may trigger a new delegate and public review and commenting period. The Consensus Council makes the determination as to whether the responses to comments have substantially changed the document, requiring a new review period.

The Consensus Council, as the consensus body, is informed of all substantive comments received or changes made in the document after the consensus vote, and each member is offered the opportunity to respond, reaffirm, or change his/her vote. Each Consensus Council commenter/objector is sent a summary of all Consensus Council comments and responses. The commenter is notified of his/her right to appeal in the event the member feels the response by the DDC was inadequate.

9.3 Approval of the Publication Draft and Evidence of Compliance

A Publication Draft is a standard or guideline that has undergone Final Draft review/vote and has been approved by the Consensus Council. The Publication Draft incorporates revisions reflecting resolution of Final Draft comments as applicable.

9.3.1 of Approved Consensus Document

Approved consensus documents are published and made available through the CLSI office. A current list of all approved consensus documents is available from the CLSI office.

9.3.2 Evidence of Compliance

Records that demonstrate compliance with all aspects of CLSI SDPPs are retained in accordance with the Records Retention Policy.

9.4 Joint Documents

When appropriate, CLSI works cooperatively with other organizations to develop and publish joint documents. The following provisions apply to joint documents.

9.4.1 Documents Developed by CLSI in Cooperation With Another Organization (also see Section 10.1)

CLSI staff informs and invites participation from the cooperating organization in proposed new projects during the project proposal review.

The cooperating organization nominates committee participants (one voting member and if desired, one or two contributors) and covers the CLSI admistrative fee (if the organization is not a member of CLSI), and the travel expenses of appointed representatives, unless otherwise agreed-upon in writing by CLSI and the cooperating organization.

CLSI appoints all additional committee members following normal procedures for establishing DDGs, and develops the consensus document according to its established procedures and timelines.

Committee participants representing the cooperating organization on the respective CLSI committee are responsible for obtaining input and comment from the cooperating organization during the document development process, voting on the Proposed Draft document, and participating in comment resolution.

The approved CLSI document is published by CLSI and includes both the CLSI and cooperating organization logos within the document.

9.4.2 Documents Developed by Other Organizations (also see Section 10.2)

The cooperating organization informs and invites CLSI participation in proposed new projects; participation by at least one representative of each CLSI constituency is encouraged.

The Consensus Council approves the joint project and includes it in its work plan.

The Consensus Council designates a voting member to represent CLSI on the cooperating organization committee through the usual CLSI nomination and appointment process.

CLSI covers travel expenses of the CLSI representative(s) who are eligible for reimbursement under the CLSI reimbursement policy.

The CLSI expert panel reviews and comments on draft documents at the request of the designated CLSI voting member.

CLSI staff oversees the CLSI expert panel review and Consensus Council approval of joint projects.

Upon the recommendation of the CLSI representative(s) and the expert panel, the Consensus Council votes on the final draft document as the CLSI consensus body during the final approval process by the constituent bodies of the cooperating organization. The Consensus Council retains the right to also review any comments and comment resolutions. Approval of consensus documents requires a two-thirds majority approval of the Consensus Council's members (excluding abstentions), with at least 10 Consensus Council members voting, and at least one representative of each constituency's membership.

The approved document is published by CLSI and/or the cooperating organization and includes the logos of both organizations.

9.5 Withdrawn Consensus Document

A consensus document may be withdrawn by a two-thirds majority vote of the Consensus Council or a unanimous vote of the Board Executive Committee in a situation requiring expedited action. Before the withdrawal is effective, the Consensus Council or Board Executive Committee may seek advice from the applicable expert panel.

A consensus document may be withdrawn at any point in the consensus process or after the consensus approval is achieved based on information that the consensus document is invalid or obsolete, or otherwise no longer needed in CLSI's portfolio. Reasons for withdrawal may include:

- The document is not technically correct.
- The document has low sales.
- The document was incorporated into another document.

The Consensus Council may decide to revise the consensus document through the consensus process if it determines that there is a technical need for the document.

Notices of withdrawal are published by the CLSI office. Records concerning withdrawn standards are retained for ten years from the date of withdrawal.

CLSI staff notifies the American National Standards Institute (ANSI) if a withdrawn consensus document is also an ANS This notification is consistent with current ANSI procedures.

9.6 Reaffirmed Consensus Document

Documents are eligible for one-time reaffirmation. Once reaffirmed, at the next review cycle, the document must be revised, archived, or withdrawn.

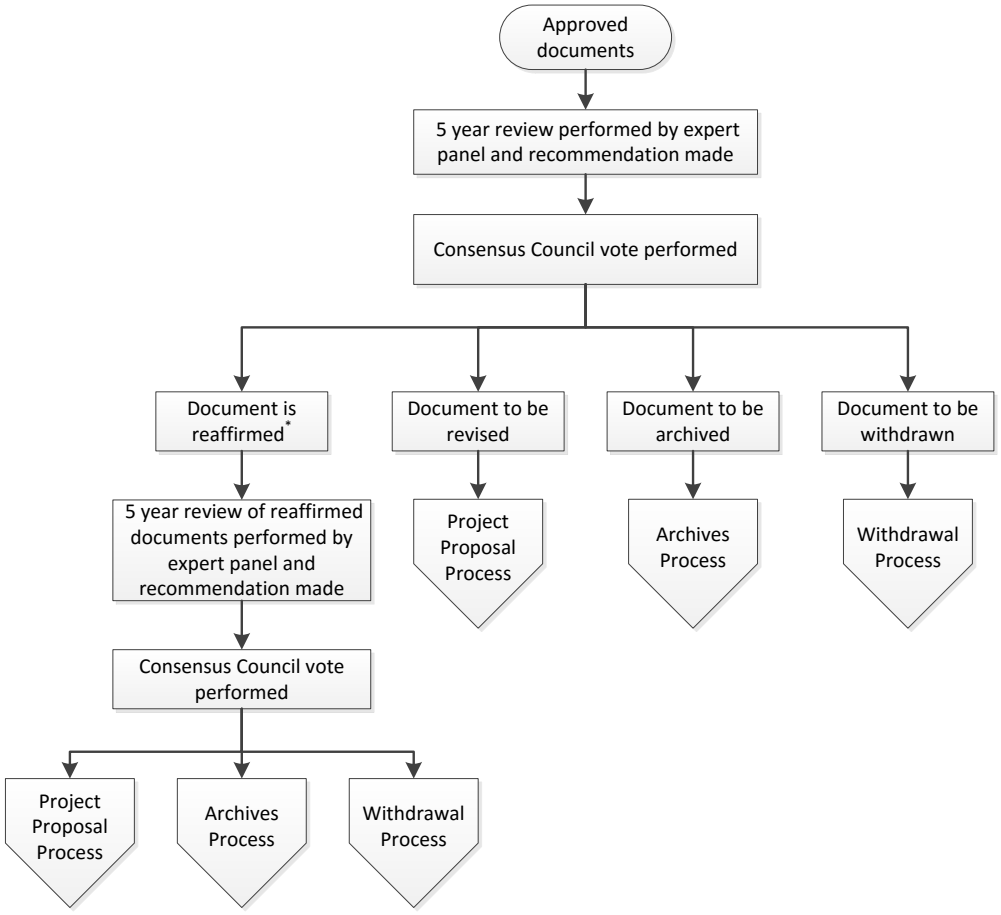
9.7 Archived Document

An archived document is an active consensus document that is technically valid and determined to not pose safety risks when implemented, but is no longer being reviewed through the CLSI consensus process. Archived documents are retained in the CLSI library because of their value to the laboratory community.

CLSI documents cited and/or recognized by regulatory and/or accreditation organizations, are eligible for archival status as applicable. Any CLSI document adopted as an American National Standard is not eligible for archiving per *ANSI Essential Requirements*.

9.8 Scheduled Review of Approved Consensus Document

Figure 5 provides an overview of the 5-year process.



*Documents are eligible for one-time reaffirmation. Once reaffirmed, at the next review cycle, the document must be revised, archived, or withdrawn.

Figure 5. Five-year Review Process

9.8.1 Assignment to the Expert Panel

At the five-year review period, the appropriate expert panel is assigned to evaluate the document.

The appropriate expert panel initiates a review of an approved consensus document within a five-year period to recommend to the Consensus Council to archive, reaffirm, revise, or withdraw the document. In determining an appropriate recommendation, the expert panel:

- Assesses that the document remains technically valid and does not pose safety risks when implemented

- Reviews comments received after approval of the document
- Considers new information or changes in technology that should be included in the document

- Determines whether the existing document is globally applicable, and if that aspect is adequately reflected in the current revision

9.8.2 Reaffirmation of an Approved Consensus Document

Reaffirmation is appropriate when the expert panel(s) decides that the existing document adequately reflects the current state of the art, its content is technically correct even if advances have been made, does not pose safety risks when implemented, and that substantive changes are not necessary for effective use of the document at the time of review. CLSI staff document the review and retain any comments on file. The expert panel decides on an appropriate timeframe for future reviews, up to five years.

9.8.2.1 Consensus Council Action on Reaffirmation

Two-thirds majority approval of the members (abstentions excluded) of the Consensus Councilwith at least 10 members voting and at least one representative of each constituency's membership, is required for reaffirmation. The disposition record of Consensus Council member comments and voting is documented by CLSI staff. The reaffirmation is considered approved for continued publication.

Reaffirmation of CLSI documents may be presented during the Consensus Council meeting, or be formally distributed for a 10-day Consensus Council vote and approval for publication as a "Reaffirmed Consensus Document."

9.8.2.2 Publication of Reaffirmed Consensus Documents

When a consensus document is reaffirmed, the document is labeled as such, and the date of reaffirmation is included on the copyright page of the document.

9.8.3 Archiving of an Approved Consensus Document

9.8.3.1 Consensus Council Action on Archived Documents

Two-thirds majority approval of the members (abstentions excluded) of the Consensus Council with at least 10 members voting and at least one representative of each constituency's membership, is required for archival. The disposition record of Consensus Council member comments and voting is documented by CLSI staff. The document is considered approved for archiving.

Recommendations for archiving CLSI documents may be presented during the Consensus Council meeting, or be formally distributed for a ~~1~~20-day Consensus Council vote.

9.8.3.2 Designating Archived Consensus Documents

When a consensus document is archived, the document is labeled as such, and the following disclaimer is applied to the document:

"This archived document is no longer being reviewed through the CLSI consensus process. However, because of its value to the laboratory community, it is being retained in CLSI's library."

9.8.4 Revision of an Approved Consensus Document

Revision is appropriate when any changes in the consensus document are needed.

9.8.4.1 Consensus Council Action on Revisions

The Consensus Council reviews a project proposal for any proposed revision. A DDG is formed to create the revision. All document development, comment, and voting stages follow the same procedures as for new documents. Refer to Figure 2 and Section 9.2 for information on consensus document voting stages.

NOTE: When a revision is determined to be necessary, the currently published version of the document continues to be available for sale until the revision is published, and then it is withdrawn. The Consensus Council reserves the right to withdraw any document that is deemed inappropriate for continued sale.

9.8.5 Consolidation of Approved Consensus Documents

During the scheduled review of any approved consensus document (by the relevant expert panel), consolidation of that consensus document with one or more closely related consensus documents may be considered if such consolidation does not compromise the scientific or technical integrity of any of the individual consensus document contents.

9.8.5.1 Consensus Council Action to Consolidate Consensus Documents

After determining that certain consensus documents may be combined, the Consensus Council constitutes a DDG to prepare an integrated consensus document that includes any changes based on comments and addresses any advances in the field. All document development, comment, and voting stages follow the same procedures as followed for new documents.

9.9 Continuous Revision

Due to the dynamic nature of CLSI project activities, continuous revision of a published consensus document may be required to address new or changing information. Continuous revision is accomplished through supplements to the approved consensus document.

9.9.1 Supplements

Supplements are developed through the consensus approval process but are not submitted for general membership ballot. The supplements support the scope, purpose, methodology, and performance of an associated approved consensus document by providing information that updates or refines use of the consensus document.

9.9.2 Process for Continuous Revision

A recommendation for continuous revision of a consensus document supplement is based on the DDG's or expert panel's assessment that there is ongoing development of new information or refinement of existing information that requires periodic updating of an approved CLSI consensus document before scheduled review. The new information is consistent with the scope, purpose, methodology, and

performance of the approved consensus document. The information is to be used only in accordance with the provisions of the approved consensus document.

In order to recommend continuous revision of a consensus document to address new information, the following requirements must be met:

- Two-thirds majority (abstentions excluded) of the DDG or expert panel members approve continuous revision, after satisfactory review of the new information.
- At least one representative of each constituency's membership approves continuous revision, after review of the DDG or expert panel action.

- The Consensus Council agrees with implementing continuous revision.

Information contained in supplements supersedes prior information.

Supplements are published and made available generally through the established CLSI mechanisms for distributing consensus documents.

Publication of supplements to approved consensus documents is broadly announced by CLSI.

9.9.3 Reports

Reports are CLSI documents that are prepared for informational purposes, but do not contain procedural information. Reports follow all of the same processes and procedures as standards and guidelines.

10 Nonconsensus Review of Documents

CLSI has established the following procedure for nonconsensus review of documents to facilitate availability while still ensuring adequate review of documents addressing quickly emerging, nonconsensus issues before publication by CLSI.

The procedure is also applicable to CLSI review of documents developed by other organizations.

The procedure includes two tracks:

- Track A, for review of quickly emerging, nonconsensus documents that the Consensus Council or the Board Executive Committee authorizes CLSI to prepare

- Track B, for review of documents developed by other organizations that do not require a single US position

10.1 Track A: Documents Developed by CLSI

Nonconsensus documents developed by CLSI may include companion products, educational products, white papers, or other informative products as authorized by the Consensus Council or the Board Executive Committee.

These products, once authorized, are developed by appropriate experts and/or staff (eg, if the material is derived from a standard or guideline).

10.1.1 Identifying Reviewers

CLSI staff, in consultation with the Chief Executive Officer, through informal contacts and/or direct Consensus Council or Board Executive Committee input, as appropriate, quickly determines the scope of circulation of the draft for review and comment.

Depending on the document's content, distribution could be to all CLSI member organizations (including individual members), to individual member organizations selected through the CLSI interest inventory database, to relevant CLSI committees or chairholders, or to individual volunteers identified as expert in the subject area. In all cases, the review process involves appropriate representation from all affected CLSI constituencies, with a minimum of two reviewers.

10.1.2 Document Review

CLSI staff circulates the draft to the review group, sets an appropriate comment deadline, and includes in the transmittal memorandum a disclaimer clearly establishing that the review process is part of the CLSI communication role and not a consensus review, and that the process includes an opportunity for participation by representatives of all affected CLSI constituencies.

10.1.3 Comments

Immediately after the comment deadline, the CLSI staff and/or a qualified volunteer collates the input and prepares a revised draft addressing the comments received, which includes divergent opinion, if it exists. No attempt is made to resolve mutually exclusive comments and weightings are not attributed to divergent views unless they are validated through the subsequent review steps in this protocol.

10.1.4 Revised Draft

CLSI staff circulates the revised draft to all of the respondents on the earlier draft, with a turnaround for further comment that is typically seven days or less.

10.1.5 Final Comments

CLSI staff, if necessary, further revises the draft to incorporate any additional input obtained from the individual respondents.

10.1.6 Distribution

The Chief Executive Officer authorizes release of the final revision as a nonconsensus document.

10.2 Track B: Documents Developed by an Organization Other Than CLSI and Not Requiring a US Position

10.2.1 Identifying Reviewers

CLSI staff, in consultation with the Chief Executive Officer, through informal contacts and/or direct Consensus Council or Board Executive Committee input, as appropriate, determines the scope of circulation of the draft for review and comment.

Depending on the document's content, such distribution could be to all CLSI member organizations (including individual members), to individual organizations selected through the CLSI interest inventory

database, to relevant CLSI committees or chairholders, or to individual volunteers identified as expert in the subject area. In all cases, the review process involves appropriate representation from all affected CLSI constituencies, with a minimum of two reviewers.

10.2.2 Nature of Input

CLSI staff determines the purpose of the review (eg, to make available to member organizations the opportunity to provide technical input; to influence the content of the document under review) and decides whether CLSI prepares a summary or submits individual comments. (A decision to prepare a summary is significant because of the CLSI resources required, but is appropriate when the document under review is of broad significance or a "US position" is required. CLSI, having made a decision to prepare a summary, can always decide to submit individual comments instead, but should not do the reverse.) Except when it is clearly not feasible to do so because of the limited time available, CLSI staff obtains representative input from the affected CLSI constituencies before deciding whether to prepare a summary.

10.2.3 Document Review

CLSI staff circulates the draft to the review group, sets an appropriate comment deadline, and includes in the transmittal memorandum a disclaimer clearly establishing that the review process is part of the CLSI communication role and not a consensus review, and that the process includes an opportunity for participation by representatives of all affected CLSI constituencies.

10.2.4 Comments

Immediately after the comment deadline, CLSI staff submits the input received as a collection of individual comments from interested parties.

11 Appeal of Action or Inaction on CLSI Consensus Documents

Appeal may be made by persons or organizations that have been or will be materially or adversely affected, or feel that laboratory medicine will be adversely affected, by substantive and/or procedural actions or inactions with regard to the development, revision, reaffirmation, or withdrawal of a CLSI consensus document. The appeals procedures provide for participation by all parties concerned without imposing an undue burden on them. Considerations of appeals are fair and unbiased and fully address the concerns expressed. These appeals procedures are consistent with the requirements of the ANSI Essential Requirements. Each objector is informed that an appeals process exists within the procedures used by CLSI. The burden of proof to show adverse effect is on the appellant.

The CLSI consensus procedure incorporates two avenues of appeal: appeal of substantive issues and appeal of procedural issues. Procedural appeals include whether a technical issue was afforded due process. Notice of this process is incorporated in the comment/response summary provided to each commenter.

Appeals of inaction may be filed at any time.

11.1 Process for Addressing Substantive Issues

The process for addressing substantive issues related to the content of CLSI documents is incorporated in the consensus development process by requiring all relevant objections to be satisfactorily addressed by the respective committee.

Addressing all substantive issues adequately and in a timely manner is an integral part of the consensus process as a document proceeds through the draft and approval stages. At each stage, comments that include objections regarding substantive issues are actively solicited from members and other interested parties. When significant substantive comments are received on a consensus document, even an approved consensus document, they are evaluated for the purpose of determining whether they require immediate attention. If immediate attention is not required, the comments are collected and reviewed at the next stage in the consensus process. All substantive comments require an "adequate response" from the drafting committee. The comment responses are reviewed by the Consensus Council who may seek advice from the appropriate expert panel. Each commenter is advised in writing (including electronic communications) of the disposition of the comment and the reasons therefore. Each commenter is informed in writing that an appeals process exists within CLSI's procedures.

11.2 Appeal of Substantive and/or Procedural Issues

The CLSI consensus procedures are designed to provide a satisfactory and complete review of all substantive issues related to a document under development or revision, ie, "due process."

Any person or organization materially or adversely affected by the failure of a CLSI committee to address substantive issues or to provide "due process" in the application of the CLSI consensus process may appeal within 30 days of being informed of the committee's decision, in writing or by electronic communication, to the CLSI office. Such appeals are addressed to the CLSI Chief Executive Officer.

Any CLSI Consensus Council action related to the subject of the appeal is suspended pending disposition of the appeal. The subject of the appeal is presented to the Consensus Council, and an attempt is made to resolve the subject of the appeal.

If the objection remains unresolved, a CLSI Appeals Panel is established by the Board with appointments made by the President. Together with the assistance of other parties the panel finds appropriate, and with inclusion of the appellant's input regarding the appropriateness of the panel membership, hears the appeal on a date that is mutually convenient for the panel, the appellant, and any other interested parties. The hearing may be conducted by face-to-face meeting, teleconference, or web conference.

Having heard the appeal, the Appeals Panel may recommend, by a majority vote, that the CLSI Board of Directors modify the action being appealed.

CLSI promptly notifies the appellant of all results of the appeals process in writing.

11.3 Final Appeal

The decision of the Appeals Panel may be further appealed to the CLSI Board of Directors. Such an appeal is filed in writing with the CLSI Chief Executive Officer within 30 days of being informed of the Appeals Panel's decision. It includes a statement as to why the decision should be modified.

The Board of Directors may agree to hear the appeal by a majority vote (in a meeting or through electronic ballot). The complete appeals action case file is made available to the Board of Directors for consideration in reaching a decision on whether or not to hear the appeal.

The Chief Executive Officer notifies the appellant, the chairholder of the Appeals Panel, the Consensus Council, and the affected expert panel chairholder of the Board's decision on whether to hear the appeal. If the Board agrees to hear the appeal, the appellant, the chairholder of the Appeals Panel, the chairholder of the Consensus Council, and the affected expert panel chairholder are invited to be present at the hearing on a date that is convenient to all interested parties. The hearing may be conducted by face-to-face meeting, teleconference or web conference.

The Board of Directors, having heard an appeal, may reverse the appeals action of the Appeals Panel by a majority vote. If less than a majority is in favor of reversal, the action of the Appeals Panel is sustained. CLSI promptly notifies the appellant, the chairholder of the Appeals Panel, the Consensus Council chairholder, and the affected expert panel chairholder of its decision in writing.

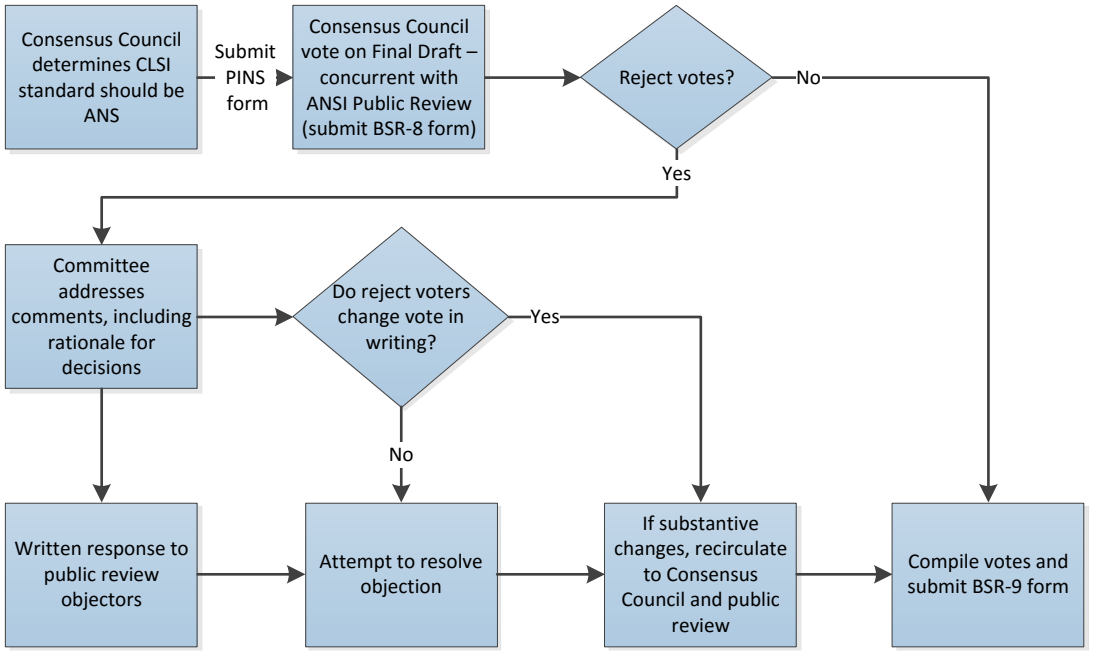
12 Submission of CLSI Consensus Documents to the American National Standards Institute

Any expert panel or the Consensus Council may recommend a CLSI standard for adoption as an ANS. CLSI has established these criteria for the Consensus Council to consider when evaluating the CLSI document for adoption as an ANS:

- The document is a standard, not a guideline.
- The standard is US-centric.
- The standard has little or no global applicability.

The decision to create an ANS can be made at any point in the document authorization and/or development process. As soon as the decision is made, notification is provided to ANSI (see Section 12.1).

Submission of a consensus document to ANSI for processing as an ANS is scheduled and implemented by the CLSI office in the manner that efficiently integrates CLSI and ANSI authorization and review procedures.



Abbreviation: ANS, American National Standard; BSR, Board of Standards Review; PINS, Project Initiation Notification System.

Figure 5. ANS Process Overview

12.1 Notification of Standards Development or Revision

At the initiation of a project to develop or revise an ANS, notification is transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for announcement in *Standards Action.* The notification includes: (a) an explanation of the need for the project, including, if it is the case, a statement of intent to submit the standard for consideration as an ISO or ISO/IEC JTC-1 (ISO/International Electrotechnical Commission Joint Technical Committee 1) standard, and (b) identification of the interest groups likely to be directly affected. If these interest groups change during development of the standard, a revised PINS form is submitted.

If CLSI receives written comments within 30 days from the publication date of a PINS announcement in *Standards Action*, and the comments assert that a proposed standard duplicates or conflicts with an existing ANS or a candidate ANS that has been announced previously in *Standards Action*, a mandatory deliberation of representatives from the relevant stakeholder groups is held within 90 days from the comment deadline. The deliberation is organized by CLSI and the commenter, and is concluded before CLSI submits a draft standard for public review. If the deliberation does not take place within the 90-day period and CLSI demonstrates that it has made a good faith effort to schedule and otherwise organize it, then CLSI is excused from compliance with this requirement. The purpose of the deliberation is to provide the relevant stakeholders with an opportunity to discuss whether there is a compelling need for the proposed standards project. The outcome of the deliberation is conveyed in writing in a Deliberation Report, by CLSI to the commenter and to the ANSI Board of Standards Review (BSR) for consideration, within 30 days after the conclusion of the deliberation. Upon submission of the Deliberation Report, CLSI may continue with the submission of the draft standard for public review. If additional deliberations take place, they should not delay the submission of the draft for public review, and an updated Deliberation Report shall be conveyed within 30 days after each deliberation. Any actions agreed upon from the deliberations shall be carried out in a reasonably timely manner, but normally should not exceed 90 days following the deliberation. Subsequently, CLSI shall include all of the Deliberation Report(s) with the BSR-9 submittal to the ANSI BSR for consideration should CLSI ultimately submit the subject standard

to ANSI for approval. Stakeholders who were involved in the PINS deliberation process may also file separate Deliberation Report(s) with ANSI and CLSI within 30 days after conclusion of any deliberation for consideration by the BSR, if the standard is submitted to ANSI for approval. While the outcome is not binding, participants are encouraged to develop a consensus on whether and how the standards development project should proceed.

12.2 Coordination and Harmonization

During the development or revision of ANS, the Consensus Council is responsible to resolve potential conflicts between and among existing ANS and candidate ANS. Conflict within the ANS process refers to a situation where, viewed from the perspective of a future implementer, the terms of one standard are inconsistent or incompatible with the terms of the other standard such that implementation of one standard under terms allowable under that standard would preclude proper implementation of the other standard in accordance with its terms. The Consensus Council makes a good-faith effort to resolve potential conflicts and to coordinate standardization activities intended to result in harmonized ANS. A "good faith" effort requires substantial, thorough, and comprehensive effort to harmonize a candidate ANS and existing ANS. Such efforts includes, at minimum, compliance with all relevant sections of the *ANSI Essential Requirements: Due process requirements for American National Standards.*

12.3 Patent Statements

Copies of any and all patent statements received by CLSI in connection with a proposed or existing ANS are forwarded to ANSI.

12.4 Public Review

Proposals for new ANS and proposals to revise, reaffirm, or withdraw approval of existing ANS are transmitted to ANSI using the BSR-8 form (*Standards Action* Public Review Request form), or its equivalent, for listing in *Standards Action* in to provide an opportunity for public comment. If it is the case, then a statement of intent to submit the standard for consideration as an ISO or ISO/IEC JTC-1 standard is included as part of the description of the scope summary that is published in *Standards Action*. The comment period shall be a minimum of:

- 30 days if the full text of the revision(s) can be published in *Standards Action*
- 45 days when the standard is available electronically and deliverable within one day of a request, and the source (eg, URL or an e-mail address) from which it can be obtained by the public is provided to ANSI for announcement in *Standards Action*
- 60 days if neither of the aforementioned options is applicable

This public review period is at a close-to-final stage of the document development. If the standard changes substantially after the public review, it is submitted for a new public review. Within the CLSI process, this public review occurs concurrently with the Consensus Council approval of the Final Draft.

Prompt consideration is given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in *Standards Action*. In connection with an objection articulated during a public comment period, or submitted with a vote, an effort to resolve all expressed objections accompanied by comments related to the proposal under consideration is made, and each such objector is advised in writing (including electronic communications) of the

disposition of the objection and the reasons therefore. If resolution is not achieved, each such objector is informed in writing that an appeals process exists within the CLSI procedures. In addition, each objection resulting from public review or submitted by a member of the consensus body that is not resolved is reported to the ANSI BSR.

When this process is completed in accordance with the written procedures of CLSI, any comments received after the closing of the public review and comment period are assessed, and, if not critical, are retained until the next voting period or document revision, or considered in the same manner as a new proposal. Timely comments that are not related to the proposal under consideration are documented and considered in the same manner as submittal of a new proposal. The submitters of the comments are so notified.

Each unresolved objection and attempt at resolution, and any substantive change made in a proposed ANS, is reported to the Consensus Council in order to afford all members of the Consensus Council an opportunity to respond, reaffirm, or change their vote.

12.5 Evidence of Consensus and Consensus Council Vote

Consensus is determined per Section 9 of these SDPPs.

- CLSI shall not change a vote unless instructed to do so by the voter. Written confirmation of any vote change is required. All reject votes that are not changed at the request of the voter are recorded and reported to ANSI's BSR as unresolved rejected votes.

- CLSI records and considers all reject votes accompanied by any comments that are related to the proposal under consideration. This includes reject votes accompanied by comments concerning potential conflict or duplication of the draft standard with an existing ANS and reject votes accompanied by comments of a procedural or philosophical nature. These types of comments are not dismissed due to the fact that they do not necessarily provide alternative language or a specific remedy to the reject vote.

- CLSI is not required to consider reject votes accompanied by comments not related to the proposal under consideration, or reject votes without comment. CLSI indicates conspicuously on the ballot that reject votes are accompanied by comments related to the proposal, and that votes unaccompanied by such comments are recorded as "reject without comments" without further notice to the voter. Such votes are not factored into the numerical requirements for consensus. CLSI is not required to solicit comments from the rejecting voter. The reject without comment vote is reported to ANSI in the final submission to the BSR.

- If comments not related to the proposal are submitted with a negative vote, the comments are documented and considered in the same manner as the submittal of a new proposal.

- CLSI maintains records of evidence regarding any change of an original vote.

- All voting records are maintained by CLSI for at least one document revision cycle.

12.6 Submittal for American National Standard Approval

Upon completion of all voting and comment resolution, CLSI completes the ANSI form BSR-9 (ANS Formal Submittal Checklist) and applies for approval of the standard as an ANS. If CLSI cannot submit

the BSR-9 form within a year following the close of the ANSI public review period, CLSI requests an extension from ANSI using the BSR-11 form, Multi-purpose Extension Request Form.

12.7 Designation of ANSAmerican National Standards

A standard approved as an ANS includes on the cover or title page an ANSI approval logo or the statement "This document has been approved as an ANS," and is identified by a unique alphanumeric designation (eg, ANSI/CLSI Code-YYYY, where "Code" indicates the appropriate CLSI document code, and "YYYY" indicates the year of revision or first publication).

12.8 Publication of American National Standards

ANS are published and made available as soon as possible, but no later than six months after approval as an ANS. CLSI retains the right to publish all ANSI/CLSI ANS.

If the standard cannot be published with six months, CLSI may request an extension of the deadline from ANSI, or the standard is subject to withdrawal.

Portions of a published document that were not approved through the full consensus process but contain information that may appear to be requirements necessary for conformance with the approved ANS are 1) clearly identified at the beginning and end of each such portion of the document, or 2) such information is overprinted on the title page. These portions of the document are marked with the following, or similar, explanatory language:

"The information contained in this (portion of a document) is not part of this ANS and has not been processed in accordance with ANSI's requirements for an ANS. As such, this (portion of a document) may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the standard."

12.9 National Adoption of International Organization for Standardization and International Electrotechnical Commission Standards

CLSI uses ANSI procedures for the national adoption of ISO and IEC standards as ANS (*ANSI Procedures for the National Adoption of ISO and IEC Standards as American National Standards).*

CLSI uses ANSI's expedited procedure for the identical adoption of an international standard, if circumstances warrant.

12.10 Periodic Maintenance of American National Standards

Within five years after its approval, the appropriate expert panels completes a review to determine the necessary action to reaffirm, revise, or withdraw an approved ANS. In the event that action is not taken to reaffirm, revise, or withdraw within five years of approval of an ANS under periodic maintenance, an extension is requested, using ANSI form BSR-11, Multi-purpose Extension Request Form. Any ANS that has not had action taken after 10 years is automatically withdrawn.

13 Companion Products

A companion product is any item provided or sold by CLSI that is intended to be used in conjunction with CLSI documents. Examples include, but are not limited to, quick guides, wall charts, software, and

templates. Companion products typically contain or refer to technical content taken directly or derived from CLSI documents. They may sometimes be called “derivative products.”

Companion products include alternative forms of presentation (eg, videos, computer applications) of published CLSI documents, documents derived from published CLSI documents that provide implementation guidance for the user, or educational materials including, eg, teleconferences and webinars.

Companion products are based on documents developed in the CLSI consensus process but are not themselves subject to the CLSI consensus process. They may include content taken directly from the consensus document (eg, templates), or they may include simplified information to assist the user with implementation of the consensus document (eg, implementation guideline). Each implementation document is verified by a designated group to ensure that it faithfully represents, communicates, and is consistent with the consensus document(s) on which it is based. Companion products that include content solely taken directly from the consensus document are published without additional review, as their content has already been reviewed through the consensus process.

13.1 Development

The CLSI office directs the development of each companion product and acts as an overseer of the verification process, when required.

Companion products are developed within the structure of CLSI (ie, by an appointed committee/WG, or by staff), and may be subject to a functionality check as described in Section 10.1.

Developers are required to submit source code for applicable software-based companion products.

13.2 Verification Process

All companion products are tested to ensure that 1) the product functions as intended and 2) it faithfully represents the document on which it is based.

Companion products developed by CLSI staff that include content lifted directly from the consensus documents are verified by an appropriate team of CLSI staff members.

13.2.1 Verification Working Group

When additional or clarifying content is created, a verification WG is formed, which includes at least two persons and represents each affected constituency. The WG is drawn from, or designated by, the DDC, SC, or WG that developed the consensus document, and it verifies that the companion product functions as intended and faithfully represents, communicates, and is consistent with the consensus document(s) on which it is based. In some cases, the DDC, SC, or WG may serve as the verification WG that performs the functionality check.

In order to fulfill its role, the designated WG:

- Reviews and refines the additional or clarifying content or any other preproduction content needed to create the product

- Identifies any sections of the consensus document not addressed by the product

- If applicable, approves the preproduction product by formal vote
- Assists the staff in identifying essential supplemental information
- By formal vote, verifies that the final product functions as intended and faithfully represents the consensus document(s) on which it is based

If the verification WG develops the electronic product, an additional group verifies, by majority vote, any applicable preproduction format as well as the final product. Representatives of the relevant expert panel confirm the functionality and faithful representation of the electronic product.

In the absence of a unanimous WG vote after attempting to resolve objections, the question of verifying the final product is referred to the Consensus Council which, by majority vote, may approve the final product.

13.3 Reverification

A companion product based on a revised consensus document is reviewed for concordance with the revised document.

The project manager and or staff liaison assesses the level of revision during the document voting process and characterizes it as minimal/nonsubstantive or substantive.

If a companion product based on a revised consensus document is developed, notice of discontinuation of the previous version of the companion product is not required.

13.3.1 Minimal/Nonsubstantive Revision

A companion product based on a document that has undergone minimal or nonsubstantive revision is verified by CLSI staff.

13.3.2 Substantive Revision

A companion product based on a consensus document that has undergone substantive revision that requires change in the consensus document application is developed and verified following the verification procedure outlined in Section 10.1.

13.4 Withdrawal and Discontinuation of Companion Products

Any companion product based on a withdrawn consensus document is withdrawn (see Section 9.5). Notices of withdrawal are published by the CLSI office.

13.5 Supplemental Information

Any essential supplemental material (other than quotations from regulations or other authoritative external documents) is reviewed under the protocol for nonconsensus review of documents (see Section 10). Under that protocol, the verification working group serves as the group that initially reviews the supplemental material and forwards it to the Consensus Council for final review.

13.6 Audit

The verification and reverification of electronic products are periodically audited by CLSI.

14 Management of Disclosures of Interests and Policies Acceptance

All CLSI volunteers are required to complete the current CLSI Disclosures of Interests and Policies Acceptance form available on the CLSI website (www.clsi.org). The CLSI consensus process is open, inclusive, and transparent. CLSI assembles experts from affected constituencies including government, industry, and the professions in an open discussion forum to address specific needs and issues. Committee participants representing different constituencies may have vested interests that are important to address during the consensus process in developing a document that meets the needs of all three constituencies. The CLSI consensus process ensures balanced representation such that all interested parties may participate, adequate scientific expertise is available, and all issues are addressed.

Because all disclosures of interests submitted to CLSI are provided on the honor system and are not verified, the honor system also applies to participants' abstentions from committee participation, including voting. Any individual involved with CLSI who becomes aware of an undisclosed conflict of interest that may affect a CLSI activity must report this to the CLSI Chief Executive Officer (see Section 5.2.2). An essential element of the consensus process is a defined appeals process (see Section 11) by which any party may submit a claim of being adversely affected by noncompliance to the consensus process, which would include any compromise in a standard or guideline resulting from confirmed conflicts of interests.

It is the responsibility of CLSI committees to conduct their activities according to these Standards Development Policies and Processes, which apply to all CLSI document development committees, and are not intended to be written prescriptively to meet the specific requirements for any one committee. In administering procedures required for obtaining, updating, and providing access for review of Disclosure of Interests forms (see Section 5.2.2), committee management has flexibility to use approaches that meet the unique requirements of the committee's activities. A summary of approaches that can be used by committees in administering CLSI's procedures is provided below.

14.1 Reporting Disclosures of Interests

- A completed CLSI Disclosure of Interests and Policies Acceptance form is required from committee members, advisors, contributors, and reviewers at time of appointment, upon reappointment, at least every three years, and at time of relevant changes in disclosed information (see Section 5.2.2).
  - CLSI staff issues a reminder annually to committee chairholders, vice-chairholders, co-chairholders, members, advisors, contributors, and reviewers to update their Disclosure of Interests forms as appropriate.
  - Before introductions at each committee meeting, CLSI staff asks if there is a change in disclosures of interests.
- Access to the current disclosure statements is provided to all participants on the respective committees at the time of appointment and upon request.

15 Acceptance of CLSI Policies

All CLSI document development volunteers shall indicate that they have read, understood, and accept certain policies, by completing the Acceptance of CLSI Policies form on CLSI's website (www.clsi.org). Volunteers may not participate in any CLSI committee until this acceptance is completed and on file at the CLSI office. This acceptance remains part of the official records of consensus document development and governance committees' meetings. The elements of the acceptance include:

- Copyright Transfer and Assignment
- Constituency Selection
- Code of Ethics

The CLSI Disclosure of Interests and Policies Acceptance form must be completed at the time of each new committee appointment or election to any new governance, standards development, or other volunteer activitiy on behalf of CLSI, and at least every three years.

15.1 Copyright Transfer and Assignment

CLSI is the sole copyright holder of every work that it publishes. Volunteers may not copy, adapt, translate, or otherwise reproduce a CLSI work by any means (eg, electronic, file sharing, mechanical, photocopying, recording, or otherwise), any CLSI work without prior written permission from CLSI.

All volunteer contributions made to any CLSI work must:

- Be original
- Not be infringing on the copyright or any orther right of any third party
- Not be defamatory
- Not be offered for an anticompetitive purpose.

All contributions are the property of CLSI, and CLSI retains all right, title, and interest to the work.

15.2 Constituency Selection

All volunteers must self-select which of the three constituency category interest groups (health care professions, government, or industry), they represent, based on their primary employment. In determining constituency categories, the following guidelines apply:

- Individuals employed by an academic institution, a health care delivery organization, a professional society or association, or an accreditation or certification organization in the health care field are considered members of the health care **professions** constituency.

- Individuals employed by a government, or government-funded agency, are considered members of the **government** constituency (even if they are also a health care delivery organization).

- Individuals employed by a manufacturing or trade organization are considered members of the **industry** constituency.

- An individual officially designated by an organization in any of the constituencies represents that constituency regardless of his/her employment.

- Individual members, not otherwise affiliated with a member organization, self-declare a constituency based on their primary role, consistent with the guidelines for organizational members.

15.3 CLSI's Code of Ethics

CLSI document development volunteers must work in a manner consistent with CLSI'a values. CLSI document development volunteers must also abide by all laws, including but not limited to antitrust, confidentiality, intellectual property, or any other applicable laws or regulations.

15.3.1 CLSI Values

CLSI document development volunteers must abide by the fundamental values that guide the way CLSI operates. Specifically, these are Inclusiveness, Excellence, Responsiveness, Integrity, and Teamwork.

15.3.2 Antitrust

CLSI document development volunteers must adhere to CLSI's established policy and procedures as specified in these SDPPs, to help assure that the activities of CLSI can proceed without violation of antitrust laws.

15.3.3 Confidentiality

CLSI document development volunteers must maintain the confidentiality, privacy, and security of information entrusted to them in accordance with legal and ethical obligations. He or she must not, without appropriate authorization, disclose to any third party any confidential information or document to which he or she obtains access by virtue of my service to CLSI. If a volunteer has any doubt about whether particular information or a particular document is confidential, he or she will not make disclosure unless he or she has first clarified the situation with appropriate CLSI officials or staff, and obtained written authorization.

15.3.4 Intellectual Property

CLSI document development volunteers must respect CLSI's copyright in the works that it publishes.

15.3.5 Standards Development Policies and Processes, and Laws Adherence

CLSI document development volunteers must abide by these standards development policies and processes, and must not knowingly violate any applicable laws or regulations.

15.3.6 CLSI's Interest.

CLSI's document development volunteers must act solely on behalf of CLSI's interests, and not on any personal interests, when serving on any CLSI committee or board, or otherwise acting on behalf of CLSI.

16 Revision of the Standards Development Policies and Processes

The Board of Directors may revise these SDPPs by a majority vote of the Board taken at a duly constituted meeting or electronically. Such revisions are consistent with the requirements of the CLSI bylaws and with accreditation requirements of ANSI.

Appendix A. CLSI Project Proposal Form

Project Submission

Date

Submitter contact information:
Name:
Organization:
Phone number:
E-mail:
Proposed Title:

Proposed product will be (check one):
Click *here* for explanation of the product types *(insert hyperlinks)*

☐ Consensus standard
☐ Consensus guideline
☐ Report
☐ Other (please describe)

Level of intended user:

☐ Novice
☐ Intermediate
☐ Advanced

Part 1A: Proposed Project

Is this proposal for a new document or a revision?

☐ New
☐ Revision
☐ Other (please describe)

Provide a rationale for the project and describe its potential impact on health care:

Please provide answers to the following:

1. How does this proposed project meet CLSI's mission? Click *here* to review CLSI's mission *(insert hyperlink)*

2. Describe why this project would be of interest to one or more of CLSI's three constituencies (government, industry, professions). Please identify the constituency along with the reason it would be of interest/value to that group.

3. Describe whether there are any related standards or guidelines already in existence or under development by another organization.

4. Describe whether there are any strategic opportunities available for the proposed document. For example, does the document fit into a strategic growth area identified in CLSI's strategic plan? (**NOTE:** The CLSI Board has identified five focus areas for the organization, which include Method Evaluation, Microbiology, Newborn Screening, Point-of-Care Testing, and Quality Management Systems.) Is this a document that could be developed in collaboration with an important partner (eg, ISO, WHO) or with funding from another group?

Provide other important factors that should be considered when evaluating this proposal:

Part 1B: Proposed Users

Check the boxes to indicate which potential users this document would apply to:

☐ Medical laboratory
☐ Veterinary laboratory
☐ Research laboratory
☐ Public health laboratory
☐ Manufacturer
☐ Regulatory or accreditation organization.
☐ Other (please describe)

Part 1C: Scope

Briefly describe what the document will and will not include.

Part 1D: Process(es) Covered in This Document

Check boxes to indicate the type of process this document will cover:

☐ *Preexamination (preanalytical) processes:* Test order through sample receipt and accessioning
☐ *Examination (analytical) processes:* Test method, validation, quality control, automated analyzer platform, laboratory results, interpretation
☐ *Postexamination (postanalytical) processes:* Reporting results, archiving results, archiving samples
☐ *Quality System Essential (QSE)* (or part of a QSE)
☐ *Information technology:* Laboratory information system, interfacing, laboratory records, etc.
☐ *Manufacturing*
☐ *Other* (please describe):

Part 1E: Existing Products

List applicable CLSI and other related publications that should be considered during the development of this document.

Part 1F: Draft Outline

Provide a DRAFT outline of the chapter headings and topics that follows the document outline template for the process(es) that will be described in this document. Click *here* for information on the document outline template. *(insert hyperlink)*

Part 2: Recommended Timeline

How much time is anticipated for completing the writing phase for a working draft for voting? *(Insert hyperlink to process timeline graphic with writing phase highlighted)*

☐ 6 months
☐ 8 months
☐ 10 months
☐ Other, justify:

Part 3: Proposed Companion Products

Check the companion products listed below that could be developed with this proposed document. Note that companion products may or may not be developed by the document writing group.

☐ Quick Guides (Handy reminders that put information at the user's fingertips, such as quick guides and wall charts)
☐ Checklists (For use in reporting completed required activities and/or assessments)
☐ Video/DVD (Instructional video presentation)
☐ Toolkits (eg, electronic document templates)
☐ Software (eg, databases)
☐ Educational presentations
☐ Article in a professional journal(s) (List names of appropriate journals)
☐ Presentations/Workshops at professional meetings (List appropriate professional organizations and associated meetings)
☐ Web/audio conference
☐ Other

Part 4: Document Attributes

Answer the following questions:

What are the key features included in this document?

☐ Updated information
☐ New methods or technologies
☐ Proven process
☐ Provision of guidance
☐ Other, describe:

Please expand on any selected items:

What are the benefits of using this document?

☐ Meet regulatory or accreditation requirements.
☐ Meet quality or organizational objectives.
☐ Satisfy customers.
☐ Other (please describe):

Please expand on any selected items:

Part 5: Document Development Committee Membership

- Describe specific expertise needed for development of this proposed document.

- Suggest possible participants and whether they have been contacted regarding potential interest.

Potential Chairholder	
Name:	Contacted? ☐ Yes ☐ No
Potential Vice-Chairholder	
Name:	Contacted? ☐ Yes ☐ No
Potential Members	
Name:	Contacted? ☐ Yes ☐ No
Name:	Contacted? ☐ Yes ☐ No
Name:	Contacted? ☐ Yes ☐ No
Name:	Contacted? ☐ Yes ☐ No
Name:	Contacted? ☐ Yes ☐ No
Name:	Contacted? ☐ Yes ☐ No
Name:	Contacted? ☐ Yes ☐ No
Name:	Contacted? ☐ Yes ☐ No

Appendix B. Committee Descriptions and Volunteer Position Descriptions

B1. Committee Descriptions

CONSENSUS COUNCIL
Purpose and Responsibilities

Reports to: CLSI Board of Directors

Purpose

The Consensus Council is the authority over all CLSI standards development activities, including project approval, prioritization, status assessment, and consensus approval for document publication. The Consensus Council serves as the consensus body for CLSI, and ensures that CLSI's standards development activities are in alignment with Board-directed organizational priorities, CLSI's mission and vision, budget, and resource availability.

Responsibilities

- Tentatively approve project proposals, including the proposed chairholder (and vice-chairholder, if known), before the Call for Volunteers for the project
- Approve, disapprove, and prioritize all standards development projects and their rosters
- Render final approval for projects, including the project roster
- Regularly review the status (progress, schedules, budgets, issues) of all projects in development; take action to keep projects on schedule, (eg, reprioritize, cancel, postpone, provide guidance, coach, make changes to personnel, enforce deadlines) as needed
- Liase, as needed, with the expert panels for technical reviews or advice on technical matters
- Render the final consensus approval for publication based on review of the following activities in the process. **NOTE:** Expert panels should be contacted if questions arise during the approval process.
  - Ensure that the CLSI *Standards Development Policies and Processes* were properly followed
  - Ensure that the comment response process was properly followed (eg, reasonably stated explanations for non-acceptance of comments)
  - Ensure all comments were appropriately resolved (with advice from expert panel chairholders, vice-chairholders, and staff project managers)
- Hear process or technical appeals and render an opinion
- Uphold the CLSI consensus process
- Use CLSI resources wisely

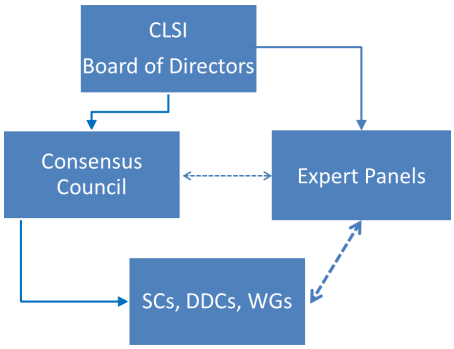


Figure 1. **CLSI Document Development Structure.** The writing groups include subcommittees (SCs), document development committees (DDCs), and working groups (WGs).

EXPERT PANEL
Purpose and Responsibilities

Reports to: Consensus Council

Purpose

Expert panels are authorized by the CLSI Board of Directors. An expert panel serves as the technical expert body for CLSI standards development activities within a technical area, including developing and endorsing project proposals; recommending document chairholders, vice-chairholders, and roster members; and reviewing and commenting on documents in development, with the purpose of ensuring the technical quality of documents. The expert panels also serve in an advisory capacity to the Consensus Council, advising on new project proposals, document development issues as they arise, and documents ready for final approval for publication.

Responsibilities

- Prepare new project proposals and advise the Consensus Council on the technical validity of project proposals submitted by other stakeholders
- Recommend chairholders, vice-chairholders, and rosters for document writing groups within the technical area
- Serve as technical advisors to the Consensus Council for document development issues, as needed
- Serve as technical advisors to document writing groups in their technical areas, as needed
- Review and comment on Proposed Draft documents within the technical area
- Serve as technical advisors to the Consensus Council for documents ready for final approval for publication, as needed
- Uphold the CLSI consensus process
- Use CLSI resources wisely

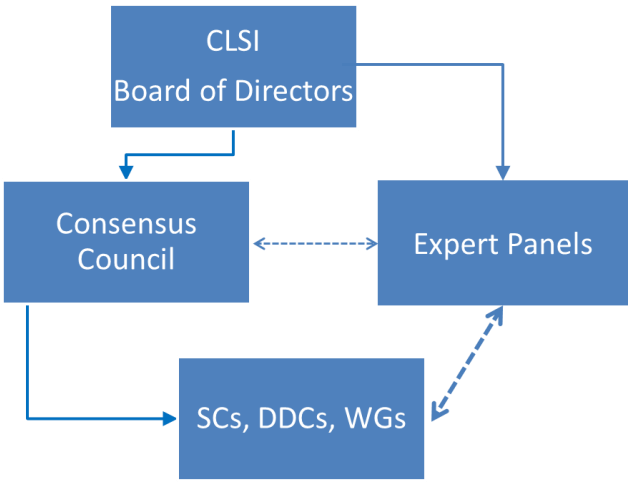


Figure 1. **CLSI Document Development Structure.** The writing groups include subcommittees (SCs), document development committees (DDCs), and working groups (WGs).

SUBCOMMITTEE
Purpose and Responsibilities

Reports to: Consensus Council

Purpose
The Subcommittee (SC) oversees the creation and revision of groups of closely-related CLSI standards, guidelines, reports, and companion products, upon approval and appointment by the Consensus Council.

Responsibilities
- Create high-quality, scientifically accurate, pertinent, and timely consensus standards, guidelines, reports, and companion products
- Understand and adhere to the CLSI *Standards Development Policies and Processes*, project goals, and timelines
- Understand and adhere to the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Uphold the CLSI consensus process
- Use CLSI resources wisely

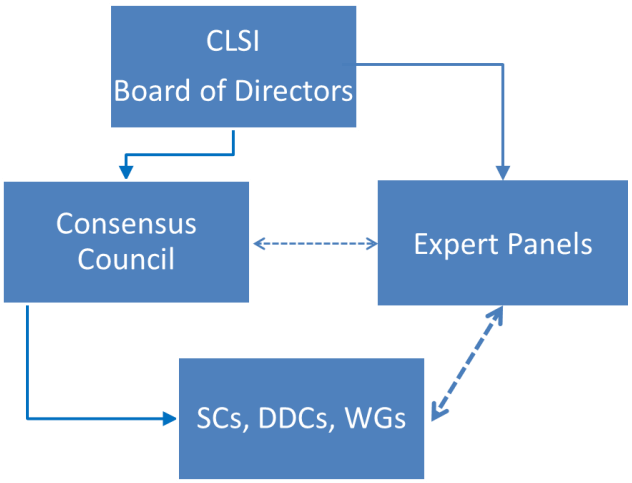


Figure 1. **CLSI Document Development Structure.** The writing groups include subcommittees (SCs), document development committees (DDCs), and working groups (WGs).

DOCUMENT DEVELOPMENT COMMITTEE
or WORKING GROUP
Purpose and Responsibilities

Reports to: Consensus Council

Purpose

The Document Development Committee (DDC) creates new and revises existing CLSI standards, guidelines, reports, or companion products, upon approval and appointment by the Consensus Council.

The Working Group (WG) prepares specific document sections, data, or other information intended to be part of a standard, guideline, report, or companion product developed by a DDC or Subcommittee.

Responsibilities

- Create high-quality, scientifically accurate, pertinent, and timely consensus standards, guidelines, reports, or companion products
- Understand and adhere to the CLSI *Standards Development Policies and Processes*, project goals, and timelines
- Understand and adhere to the requirements in the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Uphold the CLSI consensus process
- Use CLSI resources wisely

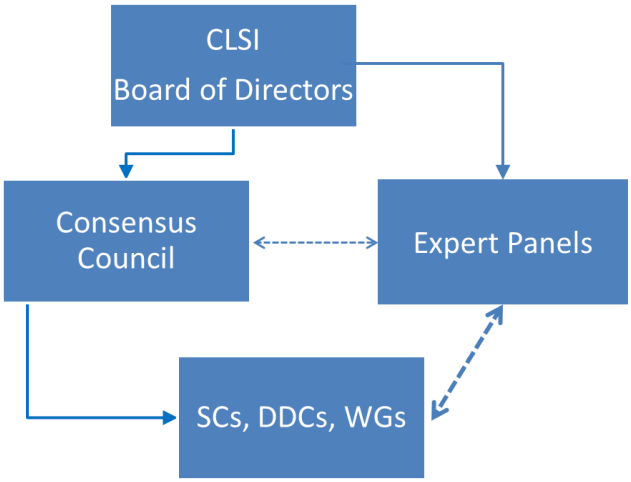


Figure 1. **CLSI Document Development Structure.** The writing groups include subcommittees (SCs), document development committees (DDCs), and working groups (WGs).

B2. Volunteer Position Descriptions

CONSENSUS COUNCIL CHAIRHOLDER (PRESIDENT-ELECT) POSITION DESCRIPTION

Position reports to: CLSI President	
Volunteer Name:	
Term Start Date:	Term End Date:
☐ First Term	☐ Second Term

Term

The Consensus Council Chairholder serves a one year term beginning 1 January and ending 31 December. The Consensus Council chairholder may serve up to two consecutive terms.

Chairholder's Essential Job Duties

- Lead the activities of the Consensus Council, ensuring all responsibilities of the Council are met
- Serve as the official signatory for volunteer appointment letters
- Prepare agendas for meetings and conference calls
- Facilitate all meetings and conference calls of the Consensus Council
- Actively participate in Consensus Council activities, conference calls, and meetings
- Review and approve meeting records

Skills and Abilities

- General knowledge of CLSI and the clinical laboratory field; **NOTE:** Depth in a technical field is not required
- Ability to lead a group of peers to an effective outcome
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to review and judge materials submitted by peers, and make decisions in alignment with Board-directed goals and objectives
- Serve in a fair, impartial manner
- Ability to read, write, and communicate effectively in English

CONSENSUS COUNCIL
VICE-CHAIRHOLDER
(Senior Standards Development Staff Person)
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Consensus Council Chairholder and CEO	
Volunteer Name:	
Term Start Date:	Term End Date:

Term
The Consensus Council Vice-Chairholder serves continuously with no term limit.

Vice-Chairholder's Essential Job Duties
- Assist and support the chairholder as needed, ensuring all responsibilities of the Council are met
- Actively monitor the standards development process and bring issues that may affect the process to the attention of the Consensus Council chairholder and members
- Facilitate the logistics of Consensus Council meetings and conference calls
- Prepare agendas, together with the chairholder
- Prepare information packages for the chairholder and members
- Actively participate in Consensus Council activities, conference calls, and meetings
- Prepare the meeting record
- Archive all meeting records

Skills and Abilities
- General knowledge of CLSI and the clinical laboratory field; **NOTE:** Depth in a technical field is not required
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Organized, efficient, and a good communicator
- Ability to read, write, and communicate effectively in English
- Experience in managing multiple projects and adjusting priorities to meet project goals

CONSENSUS COUNCIL
MEMBER
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Consensus Council Chairholder							
Volunteer Name:							
Term Start Date:				Term End Date:			
☐	First Term	☐	Second Term	☐	Third Term	☐	Fourth Term

Term
Each Consensus Council Member serves a one year term beginning January 1 and ending December 31. Council members may be reappointed for up to four consecutive terms.

Member's Essential Job Duties
- Perform the duties of the Consensus Council
- Actively participate in Consensus Council activities, conference calls, and meetings

Skills and Abilities
- General knowledge of CLSI and the clinical laboratory field; **NOTE:** Depth in a technical field is not required
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to review and judge materials submitted by peers, and make decisions in alignment with Board-directed goals and objectives
- Serve in a fair, impartial manner
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Consensus Council Responsibilities and Member's Essential Job Duties and agree to fulfill them. I understand the length of the term; and I have adequate time available to participate as a Member.

Volunteer Signature: _____

Date: _____

EXPERT PANEL
CHAIRHOLDER
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Consensus Council Chairholder							
Volunteer Name:							
Term Start Date:				Term End Date:			
☐	First Term	☐	Second Term	☐	Third Term	☐	Fourth Term

Term
The Expert Panel Chairholder serves a one year term beginning January 1 and ending December 31. The chairholder may be reappointed for up to four consecutive terms.

Chairholder's Essential Job Duties
- Lead the activities of the expert panel, ensuring all responsibilities of the expert panel are met
- Liaise with the Consensus Council to represent the expert panel for the technical quality review of documents within their technical area
- Liaise with the document development committee (DDC), working group (WG), or subcommittee (SC) chairholders regarding technical and/or quality considerations
- Facilitate all expert panel conference calls and meetings
- Prepare agendas for conference calls and meetings
- Actively participate in expert panel activities, conference calls, and meetings
- Review and approve meeting records
- Coordinate activities with the staff project manager
- May serve on SCs, DDCs, or WGs

Skills and Abilities
- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Ability to lead a group of peers to an effective outcome
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to review and comment on materials submitted by peers
- Serve in a fair, impartial manner
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Expert Panel Responsibilities and Chairholder's Essential Job Duties and agree to fulfill them. I understand the length of the term; and I have adequate time available to participate as the Chairholder.

Volunteer Signature: _____

Date: _____

EXPERT PANEL
VICE-CHAIRHOLDER
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Expert Panel Chairholder							
Volunteer Name:							
Term Start Date:				Term End Date:			
☐	First Term	☐	Second Term	☐	Third Term	☐	Fourth Term

Term
The Expert Panel Vice-Chairholder serves a one year term beginning January 1 and ending December 31. The vice-chairholder may be reappointed for up to four consecutive terms.

Vice-Chairholder's Essential Job Duties
- Assist the chairholder in organizing the work of the expert panel and in liaison with the Consensus Council, document development committees (DDCs), working groups (WGs), and/or subcommittees (SCs) within the technical area
- Assume all duties of the chairholder when that person is not available
- Actively participate in expert panel activities and conference calls
- May serve on SCs, DDCs, and WGs

Skills and Abilities
- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Ability to lead a group of peers to an effective outcome
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to review and comment on materials submitted by peers
- Serve in a fair, impartial manner
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Expert Panel Responsibilities and Vice-Chairholder's Essential Job Duties and agree to fulfill them. I understand the length of the term; and I have adequate time available to participate as the Vice-Chairholder.

Volunteer Signature: _____

Date: _____

EXPERT PANEL
MEMBER
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Expert Panel Chairholder							
Volunteer Name:							
Term Start Date:				Term End Date:			
☐	First Term	☐	Second Term	☐	Third Term	☐	Fourth Term

Term

The Expert Panel Member serves a one year term beginning January 1 and ending December 31. The member may be reappointed for up to four consecutive terms.

Member's Essential Job Duties

- Actively participate in expert panel activities, conference calls, and meetings
- May serve on subcommittees, document development committees, and working groups

Skills and Abilities

- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to review and comment on materials submitted by peers
- Serve in a fair, impartial manner
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Expert Panel Responsibilities and Member's Essential Job Duties and agree to fulfill them. I understand the length of the term; and I have adequate time available to participate as a Member.

Volunteer Signature: _____

Date: _____

SUBCOMMITTEE
CHAIRHOLDER
POSITION DESCRIPTION AND AGREEMENT (Continued)

Skills and Abilities

- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to learn the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Serve in a fair, impartial manner
- Conduct activities in a professional demeanor
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Subcommittee's Responsibilities and Chairholder's Essential Job Duties, as well as the project proposal content and timeline, and agree to fulfill these responsibilities. I understand the length of the term; and I have adequate time available to participate as the Chairholder.

Volunteer Signature: _____

Date: _____

SUBCOMMITTEE
VICE-CHAIRHOLDER
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Subcommittee Chairholder							
Volunteer Name:							
Term Start Date:				Term End Date:			
☐	First Term	☐	Second Term	☐	Third Term	☐	Fourth Term

Term

The Subcommittee (SC) Vice-Chairholder serves a one year term beginning January 1 or at project initiation and ending December 31. The Vice-Chairholder may serve up to four consecutive terms.

Vice-Chairholder's Essential Job Duties

- Assume all duties of the chairholder in his/her absence
- Assist with leading the activities of the SC, ensuring all responsibilities of the SC are met
- After project approval, assist in selecting document development committee (DDC)/working group (WG) rosters, with the chairholder and the project manager
- Assist with communication with SC, DDC, and WG members
- Assist with keeping projects on schedule
- May author document content, as desired or requested
- Review Working Draft and Proposed Draft content
- Provide writing or review assignments on time to ensure the project timeline goals are met
- Assist with ensuring the Working Drafts conform with the CLSI *Writer's Instructions* and CLSI *Style Guide for Authors and Editors*
- Serve as back-up liaison to the relevant expert panel
- Provide coaching and writing assistance as needed
- Review final layout of document

SUBCOMMITTEE
SECRETARY
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Subcommittee Chairholder							
Volunteer Name:							
Term Start Date:				Term End Date:			
☐	First Term	☐	Second Term	☐	Third Term	☐	Fourth Term

Term
The Subcommittee (SC) Secretary serves a one year term beginning January 1 or at project initiation and ending December 31. The secretary may serve up to four consecutive terms.

Secretary's Essential Job Duties
- Perform the responsibilities of the assigned role (member, advisor, reviewer)
- Complete the meeting report template, including documenting decisions made
- Collaborate with the PM to complete the meeting record

Skills and Abilities
- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to learn the CLSI *Writer's Instructions* and CLSI *Style Guide for Authors and Editors*
- Serve in a fair, impartial manner
- Conduct activities in a professional demeanor
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Subcommittee's Responsibilities and Secretary's Essential Job Duties, as well as the project proposal content and timeline, and agree to fulfill these responsibilities. I understand the length of the term; and I have adequate time available to participate as the Secretary.

Volunteer Signature: _____

Date: _____

SUBCOMMITTEE
MEMBER
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Subcommittee Chairholder							
Volunteer Name:							
Term Start Date:				Term End Date:			
☐	First Term	☐	Second Term	☐	Third Term	☐	Fourth Term

Term
The Subcommittee (SC) Member serves a one year term beginning January 1 or at project initiation and ending December 31. The member may serve up to four consecutive terms.

Member's Essential Job Duties
- Attend and actively participate in SC meetings and conference calls
- Lead or serve on document development committees and working groups as needed
- May write chapters/subchapters of documents consistent with the CLSI *Writer's Instructions* and the CLSI *Style Guide Authors and Editors*
- May contribute data or examples needed for the documents
- Review the Working Drafts and provide comments and recommendations
- Provide writing or review assignments on time to ensure the project timeline goals are met
- Vote and comment on the Proposed Draft
- Assist with comment resolution

Skills and Abilities
- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to learn the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Serve in a fair, impartial manner
- Conduct activities in a professional demeanor
- Respect the consensus process
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Subcommittee's Responsibilities and Member's Essential Job Duties, as well as the project proposal content and timeline, and agree to fulfill these responsibilities. I understand the length of the term; and I have adequate time available to participate as a Member.

Volunteer Signature: _____

Date: _____

SUBCOMMITTEE
ADVISOR
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Subcommittee Chairholder							
Volunteer Name:							
Term Start Date:				Term End Date:			
☐	First Term	☐	Second Term	☐	Third Term	☐	Fourth Term

Term
The Subcommittee (SC) Advisor serves a one year term beginning January 1 or at project initiation and ending December 31. The advisor may serve up to four consecutive terms.

Advisor's Essential Job Duties
- May attend and actively participate in SC meetings and conference calls
- May write chapters/subchapters of documents consistent with the CLSI *Writer's Instructions* and CLSI *Style Guide for Authors and Editors*
- May contribute to data and examples needed for documents
- Review Working Drafts and provide comments and recommendations
- Provide writing or review assignments on time to ensure project timeline goals are met
- Comment on the Proposed Drafts
- May assist with comment resolution

Skills and Abilities
- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to learn the CLSI *Writer's Instructions and* CLSI *Style Guide for Authors and Editors*
- Serve in a fair, impartial manner
- Conduct activities in a professional demeanor
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Subcommittee's Responsibilities and Advisor's Essential Job Duties, as well as the project proposal content and timeline, and agree to fulfill these responsibilities. I understand the length of the term; and I have adequate time available to participate as an Advisor.

Volunteer Signature: _____

Date: _____

SUBCOMMITTEE
REVIEWER

POSITION DESCRIPTION AND AGREEMENT

Position reports to: Subcommittee Chairholder							
Volunteer Name:							
Term Start Date:				Term End Date:			
☐	First Term	☐	Second Term	☐	Third Term	☐	Fourth Term

Term
The Subcommittee (SC) Reviewer serves a one year term beginning January 1 or at project initiation and ending December 31. The Reviewer may serve up to four consecutive terms.

Reviewer's Essential Job Duties
- May attend and actively participate in the meetings and conference calls
- May write chapters/subchapters of documents consistent with the CLSI *Writer's Instructions* and CLSI *Style Guide for Authors and Editors*
- May contribute data or examples needed for documents
- Review the Working Drafts and provide comments and recommendations
- Provide writing or review assignments on time to ensure the project timeline goals are met
- Comment on Proposed Drafts
- May assist with comment resolution

Skills and Abilities
- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI Standards Development Policies and Processes
- Willingness to learn the CLSI Author Writing Instructions
- Serve in a fair, impartial manner
- Conduct activities in a professional demeanor
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Subcommittee's Responsibilities and Reviewer's Essential Job Duties, as well as the project proposal content and timeline, and agree to fulfill these responsibilities. I understand the length of the term; and I have adequate time available to participate as a Reviewer.

Volunteer Signature: _____

Date: _____

DOCUMENT DEVELOPMENT COMMITTEE OR WORKING GROUP CHAIRHOLDER
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Consensus Council	
Volunteer Name:	
Term Start Date:	Term End Date:

Term

The Document Development Committee (DDC)/Working Group (WG) Chairholder serves consecutive one year terms beginning January 1 or at project initiation and ending December 31, until the project completion (ie, publication).

Chairholder's Essential Job Duties

- Collaborate with the assigned project manager (PM)
- Lead the activities of the DDC/WG, ensuring all responsibilities of the DDC/WG are met
- After project approval, select the DDC/WG roster with the vice-chairholder and the PM
- Coordinate all DDC/WG activities with the PM
- Establish the project schedule with the PM
- Communicate with DDC/WG members
- Conduct the launch meeting of a DDC/WG project per the *Chairholder's Checklist for Document Launch Meeting*
- Facilitate all DDC/WG meetings and conference calls
- Prepare agendas with the PM
- Review and approve meeting records
- Keep the project on schedule, with the PM
- Solicit volunteers to write and review subchapters
- Write, at minimum, (or designate writing of) the tagline, abstract, background, foreword, conclusion
- May write other subchapters as desired
- Provide writing or review assignments on time to ensure the project timeline goals are met
- Review and edit (or designate) the Working Draft submissions into a "common voice" document
- Ensure Working Draft conforms with the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Serve as primary liaison to the expert panel associated with the document
- Provide coaching and writing assistance as needed
- Respond to editors' questions and comments
- Propose initial comment resolutions
- Conduct consensus conference calls to resolve any comment conflicts
- Adhere to provided budget
- Review Proposed Draft after formal editing and before posting for vote
- Develop document call-outs (if applicable)
- Review final layout of Final Draft
- May be called upon to support the document after publication, by answering users' questions, delivering education, or other duties as agreed

DOCUMENT DEVELOPMENT COMMITTEE OR WORKING GROUP CHAIRHOLDER
POSITION DESCRIPTION AND AGREEMENT (Continued)

Skills and Abilities

- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI Standards Development Policies and Processes
- Willingness to learn the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Serve in a fair, impartial manner
- Conduct activities in a professional demeanor
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Document Development Committee's/Working Group's Responsibilities and Chairholder's Essential Job Duties, as well as the project proposal content and timeline, and agree to fulfill these responsibilities. I understand the length of the term; and I have adequate time available to participate as the Chairholder.

Volunteer Signature: _____

Date: _____

DOCUMENT DEVELOPMENT COMMITTEE OR WORKING GROUP VICE-CHAIRHOLDER POSITION DESCRIPTION AND AGREEMENT

Position reports to: Document Development Committee/Working Group Chairholder	
Volunteer Name:	
Term Start Date:	Term End Date:

Term

The Document Development Committee (DDC)/Working Group (WG) Vice-Chairholder serves consecutive one year terms beginning January 1 or at project initiation and ending December 31, until the project completion (ie, publication).

Vice-Chairholder's Essential Job Duties

- Assume all duties of the chairholder in his/her absence
- Assist with preparing the project proposal, working closely with the chairholder and staff project manager (PM)
- After project approval, assist with the selection of the DDC/WG roster (together with the chairholder and the PM)
- Assist with establishing the project schedule
- Assist with communication with DDC/WG members
- Assist with keeping the project on schedule
- Assist with review and edit (or designate) the Working Draft submissions into a "common voice" document, when requested
- Write document content consistent with the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Provide writing or review assignments on time to ensure the project timeline goals are met
- Review document content, ensuring the Working Draft conforms with the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Serve as back-up liaison to the relevant expert panel for the document
- Provide coaching and writing assistance as needed
- Respond to editors' questions and comments as needed
- Assist with proposing initial comment resolutions
- Review final layout of document

DOCUMENT DEVELOPMENT COMMITTEE OR WORKING GROUP VICE-CHAIRHOLDER (Continued)

Skills and Abilities

- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to learn the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Serve in a fair, impartial manner
- Conduct activities in a professional demeanor
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Document Development Committee's/Working Group's Responsibilities and Vice-Chairholder's Essential Job Duties, as well as the project proposal content and timeline, and agree to fulfill these responsibilities. I understand the length of the term; and I have adequate time available to participate as the Vice-Chairholder.

Volunteer Signature: _____

Date: _____

DOCUMENT DEVELOPMENT COMMITTEE OR WORKING GROUP SECRETARY
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Document Development Committee/Working Group Chairholder	
Volunteer Name:	
Term Start Date:	Term End Date:

Term

The Document Development Committee (DDC)/Working Group (WG) Secretary serves consecutive one year terms beginning January 1 or at project initiation and ending December 31, until the project completion (publication).

Secretary's Essential Job Duties

- Perform the responsibilities of the assigned role (member, contributor)
- Complete the meeting report template, including documenting decisions made
- Collaborate with the PM to complete the meeting record

Skills and Abilities

- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to learn the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Serve in a fair, impartial manner
- Conduct activities in a professional demeanor
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Document Development Committee's/Working Group's Responsibilities and Secretary's Essential Job Duties, as well as the project proposal content and timeline, and agree to fulfill these responsibilities. I understand the length of the term; and I have adequate time available to participate as the Secretary.

Volunteer Signature: _____

Date: _____

DOCUMENT DEVELOPMENT COMMITTEE OR WORKING GROUP MEMBER
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Document Development/Working Group Chairholder	
Volunteer Name:	
Term Start Date:	Term End Date:

Term

The Document Development Committee (DDC)/Working Group (WG) Member serves consecutive one year terms beginning January 1 or at project initiation and ending December 31, until the project completion (ie, publication).

Member's Essential Job Duties

- Attend and actively participate in the DDC/WG meetings and conference calls
- Write chapters/subchapters of the document consistent with the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Contribute to examples needed for the document such as figures, tables, and appendixes
- Review the Working Drafts and provide comments and recommendations
- Provide writing or review assignments on time to ensure the project timeline goals are met
- Vote and comment on the Proposed Draft (**NOTE:** WG votes are informal)
- Assist with comment resolutions
- DDC members may chair WGs as needed

Skills and Abilities

- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to learn the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Serve in a fair, impartial manner
- Conduct activities in a professional demeanor
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Document Development Committee's/Working Group's Responsibilities and Member's Essential Job Duties, as well as the project proposal content and timeline, and agree to fulfill these responsibilities. I understand the length of the term; and I have adequate time available to participate as a Member.

Volunteer Signature: _____

Date: _____

DOCUMENT DEVELOPMENT COMMITTEE OR WORKING GROUP CONTRIBUTOR
POSITION DESCRIPTION AND AGREEMENT

Position reports to: Document Development Committee/Working Group Chairholder	
Volunteer Name:	
Term Start Date:	Term End Date:

Term

The Document Development Committee (DDC)/Working Group (WG) Contributor serves consecutive one year terms beginning January 1 or at project initiation and ending December 31, until the project completion (publication).

Contributor's Essential Job Duties

- May attend and actively participate in the meetings and conference calls
- May write chapters/subchapters of the document consistent with the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- May contribute to examples needed for the document such as figures, tables, and appendixes
- Review the Working Drafts and provide comments and recommendations
- Provide writing or review assignments on time to ensure the project timeline goals are met
- Comment on the Proposed Draft
- May assist with comment resolution

Skills and Abilities

- General knowledge of CLSI and the clinical laboratory field
- In-depth knowledge in a technical field
- Willingness to learn the CLSI *Standards Development Policies and Processes*
- Willingness to learn the CLSI *Writer's Instructions* and the CLSI *Style Guide for Authors and Editors*
- Serve in a fair, impartial manner
- Conduct activities in a professional demeanor
- Ability to read, write, and communicate effectively in English

Agreement

I have reviewed the Document Development Committee's/Working Group's Responsibilities and Contributor's Essential Job Duties, as well as the project proposal content and timeline, and agree to fulfill these responsibilities. I understand the length of the term; and I have adequate time available to participate as a Contributor.

Volunteer Signature: _____

Date: _____

Appendix C. Voting Rules for the Subcommittees on Antimicrobial, Antifungal, and Veterinary Antimicrobial Susceptibility Testing

Only members of the subcommittees vote; subcommittee chairholders and vice chairholders are considered non-voting members.

C1 Subcommittee on Antimicrobial Susceptibilty Testing

Committee Status	"Pass" Vote
All members present and voting	12-0; 11-1; 10-2; 9-3; 8-4
One member not present or abstaining	11-0; 10-1; 9-2; 8-3; 7-4
Two members not present and/or abstaining	10-0; 9-1; 8-2; 7-3
Three members not present and/or abstaining	9-0; 8-1; 7-2; 6-3
If more than three members are not present	Chairholder's discretion to conduct vote or table until sufficient members are present, or conduct vote by mail (e-mail)

C2 Subcommittee on Antifungal Susceptibility Testing

Committee Status	"Pass" Vote
All members present and voting	11-0; 10-1; 9-2; 8-3
One member not present or abstaining	10-0; 9-1; 8-2; 7-3
Two members not present and/or abstaining	9-0; 8-1; 7-2; 6-3
Three members not present and/or abstaining	8-0; 7-1; 6-2
If more than three members are not present	Chairholder's discretion to conduct vote or table until sufficient members are present, or conduct vote by mail (e-mail)

C3 Subcommittee on Veterinary Antimicrobial Susceptibility Testing

Committee Status	"Pass" Vote
All members present and voting	10-0; 9-1; 8-2; 7-3
One member not present or abstaining	9-0; 8-1; 7-2; 6-3
Two members not present and/or abstaining	8-0; 7-1; 6-2; 5-3
Three members not present and/or abstaining	7-0; 6-1; 5-2
If more than three members are not present	Chairholder's discretion to conduct vote or table until sufficient members are present, or conduct vote by mail (e-mail)

Appendix D. Example American National Standards Institute Forms

This appendix contains the following example forms from the American National Standards Institute (ANSI):

- PINS (see D1)
- BSR-8 (see D2)
- BSR-9 (see D3)
- BSR-11 (see D4)

NOTE: Be sure to check ANSI's website, www.ansi.org, for the latest versions of these forms.

D1 Example PINS Form

Date 2/17/2012

NOTE: A record of this submittal must be retained as documentation subject to ANSI Audit.

WEB PINS FORM: STANDARDS ACTION PUBLIC REVIEW REQUEST

*NOTE: Adoptions of ISO or IEC standards require compliance with ANSI's Sales & Exploitation Policy.

*PINS Standards Action Request Form Instructions

Accredited Standards Developer Information

First Name*	Last Name of Submitter*	Organization*	Developer Acronym*
Sally	Jones	Clinical and Laboratory Star	CLSI

Address*	City*	State*	Zip*
950 West Valley Road	Wayne	PA	19087

E-Mail*	Phone*	Fax*
sjones@clsi.org	610-688-0100	610-688-0700

*** = Required Input**

PINS Standard Action Request Entry form

Please enter your data for each standard into the fields below. Fields marked with an asterisk * are required. When you have completed entering your information, hit the **ADD REQUEST** button to register the data for each standard. Each entry will be listed in the Standard Listing table below. Once you have completed entering the data for each standard and you are ready to submit to ANSI, hit the **SUBMIT ALL** button.

Designation of Proposed Standard*	Title of Standard*
ANSI/CLSI XY10-A-2012	Determination of Serum Porcelain Lev

Project Intent*	Supersedes or Affects
Create new ANS	N/A

Project Need*: Critical need for standardization of serum porcelain testing

Identify Stakeholders*: Clinical and medical laboratories, manufacturers of serum porcelain tests

Scope summary*: This document provides instructions for testing of serum porcelain levels It is intended to be used by laboratory professionals.

Identify ISO or IEC standard to be adopted	Includes text from ISO or IEC standard? *	Scope summary*
N/A	○ Yes ◉ No	This document provides instructions for testing of serum porcelain levels It is intended to be used by laboratory professionals.

Consumer Product*	Unit of Measure*	Revises a previous PINS submittal? *	Notes
○ Yes ◉ No	Metric	○ Yes ◉ No	

☑ Request an Announcement in Standards Action to Solicit New Consensus Body Members

ADD REQUEST | UPDATE REQUEST | DELETE

Standard Listing

The Standard(s) listed below will be included in your Standard Action Request. You may hit **PREVIEW ALL** button to view and **PRINT** the data entered for each standard. To edit one of the entries from below click on the Designation of the standard, make your change and then hit the **UPDATE RQUEST** button. Hit the **SUBMIT ALL** button only if you have completed all of your entries and are ready to submit to ANSI.

Designation of Proposed Standard*	Title of Standard*	Project Intent*	Supersedes or Affects

PREVIEW ALL SUBMIT ALL

D2 Example BSR-8 Form

Date 2/17/2012

NOTE: A record of this submittal must be retained as documentation subject to ANSI Audit.

WEB BSR-8/108 FORM: STANDARDS ACTION PUBLIC REVIEW REQUEST

*NOTE: Adoptions of ISO or IEC standards require compliance with ANSI's Sales & Exploitation Policy.

*BSR 8/108 Standard Action Request Form Instructions

Accredited Standards Developer Information

First Name*	Last Name of Submitter*	Organization*	Developer Acronym*
Sally	Jones	Clinical and Laboratory Star	CLSI

Address*	City*	State*	Zip*
950 West Valley Road	Wayne	PA	19087

E-Mail*	Phone*	Fax*
sjones@clsi.org	610-688-0100	610-688-0700

*** = Required Input**

BSR 8/108 Standard Action Request Entry form

Please enter your data for each standard into the fields below. Fields marked with an asterisk * are required. When you have completed entering your information, hit the **ADD REQUEST** button to register the data for each standard. Each entry will be listed in the Standard Listing table below. Once you have completed entering the data for each standard and you are ready to submit to ANSI, hit the **SUBMIT ALL** button.

Designation of Proposed Standard*	Title of Standard*
ANSI/CLSI XY10-A-2012	Determination of

Project Intent*	Supersedes or Affects
Create new ANS	N/A

Identify ISO or IEC standard to be adopted	Single Copy Price*	Public Review*	Upload 5-page (pdf file) for 30-day PR
N/A	$120.00	60	

Order paper copy from*	Consumer Product*	Unit of Measure	Scope summary*
www.clsi.org, or 610-688-010(	○ Yes ◉ No	Metric	This document provides instructions for testing of serum porcelain levels. It is intended to be used by laboratory professionals.

Order electronic copy	Includes text from ISO or IEC standard?*	
www.clsi.org, or 610-688-010(	○ Yes ◉ No	

Send comments to*	Notes
standards@clsi.org	

☑ Request an Announcement in Standards Action to Solicit New Consensus Body Members

ADD REQUEST | UPDATE REQUEST | DELETE

Standard Listing

The Standard(s) listed below will be included in your Standard Action Request. You may hit **PREVIEW ALL** button to view and **PRINT** the data entered for each standard. To edit one of the entries from below click on the Designation of the standard, make your change and then

hit the **UPDATE RQUEST** button. Hit the **SUBMIT ALL** button only if you have completed all of your entries and are ready to submit to ANSI.

Designation of Proposed Standard*	Title of Standard*	Project Intent*	Supersedes or Affects

PREVIEW ALL SUBMIT ALL

D3 Example BSR-9 Form

BSR-9 (01.08) **DATE: ____2/24/2012_____**

American National Standard (ANS) Formal Submittal Checklist

PLEASE NOTE: This document is used to transmit the final submittal of a candidate American National Standard to ANSI. A standard should only be submitted to ANSI for approval if all of the appropriate evidence of consensus accompanies it in accordance with the *ANSI Essential Requirements: Due process requirements for American National Standards (ANSI Essential Requirements.)* *NOTE: Adoptions of ISO or IEC standards require compliance with the *ANSI Policy Regarding Rights to Nationally Adopt IEC and ISO Standards or Otherwise Use IEC and ISO Material* and the *ANSI Procedures for the Adoption of ISO and IEC Standards as American National Standards.* Submittal of a standard for approval under the *Stabilized Maintenance* option requires use of a different form. When a BSR-9 is successfully received by ANSI, an acknowledgement is sent to the submitter. If you do not receive one, please contact psa@ansi.org.

1. Designation of Standard:____ANSI/CLSI Code-YYYY_____
   Year that should be included in the designation, if other than the year of approval as an ANS: _____

2. Title of Standard: Determination of Serum Porcelain Levels, Approved Standard

3. Project Intent (relates to the status of the standard in terms of ANSI only, e.g., any standard that is not an approved ANS, is a new standard):
   - X Create new ANS
   - ❑ *Adopt identical ISO or IEC standard
   - ❑ *Adopt modified ISO or IEC standard
   - ❑ ***AND** this adoption revises this current ANS
   - ❑ Revise current ANS
   - ❑ Revise and Redesignate current ANS
   - ❑ Revise, Redesignate and Consolidate current ANS
   - ❑ Revise and Partition current ANS
   - ❑ Reaffirm current ANS
   - ❑ Reaffirm and Redesignate current ANS
   - ❑ Supplement to a current ANS
   - ❑ Addenda to a current ANS under Continuous Maintenance: (this document relates to/updates the following base document that is registered under Continuous Maintenance)
   - ❑ Withdraw current ANS

4. Attach consensus body roster including interest category of each member and vote. *(See ANSI Essential Requirements 4.2.1.1.)* _X__Check here to indicate roster is attached.

5. Identify the group that is considered to be the consensus body and whose vote is included in item 13 below:
   The Consensus Council

6. Balance: The *ANSI Essential Requirements (see 1.3, 2.3)* state that participants from diverse interest categories *shall be sought* with the objective of achieving balance on a consensus body. If the consensus body associated with this submittal appears to lack balance as described in the *Essential Requirements*, please attach evidence or an explanation of outreach efforts undertaken to achieve balance. Note that if the consensus body appears to lack balance, the ANSI BSR will request evidence of outreach if it is not provided with the BSR-9, and thus, the approval process will be delayed.
   Evidence attached? __X__Yes ____ No ____N/A

7. Did a PINS deliberation take place in connection with this standard (*See ANSI Essential Requirements 2.5)*? __X__Yes ____ No ___ N/A If yes, then attach a copy of the required PINS deliberation report(s).

8. Indicate the total number of unresolved objections to the proposed action on the standard resulting from all public review period(s) **only**, including ANSI Standards Action ____0___. Attach evidence of attempted resolution. *(See ANSI Essential Requirements 2.6.) Note: do not include unresolved votes of consensus body members here unless the member also submitted public review comments. Use item 13 to report consensus body votes.*

9. Date(s) on which unresolved objections (public review/consensus body), attempts at resolution and substantive changes, were provided to the consensus body for consideration. Attach evidence of compliance with this requirement (also referred to as "recirculation" or "reconsideration".) *(See ANSI Essential Requirements 2.6.)*
   Date(s): _____ Not applicable: _X___

10. Were all unresolved objectors informed in writing of their right to appeal to the standards developer?
    Yes ___ No___ *(See ANSI Essential Requirements 2.6.)* ___X__ Not Applicable, because: ____no unresolved objections_____
    Attach documentation of written notification of the right to appeal to standards developer.

11. Did any unresolved objectors complete the appeals process available through the standards developer?
    (See ANSI Essential Requirements 2.8.)
    ____ Yes (Attach name and contact information for each) _____ No _X__Not Applicable

12. Date of Final Consensus Body Vote (i.e., date the final vote was closed): ____02/15/2012 _____

13. Evidence of Consensus, i.e., the FINAL consensus body vote tally (*See ANSI Essential Requirements 2.7*.)

SUMMARY OF CONSENSUS BODY VOTE BY INTEREST CATEGORY

Interest Category	Affirmative(s)	Negative(s)	Negative(s) without comment	Abstention(s)	Not Returned	Total
Government	2					2
Industry	4					4
Professions	4					4
TOTALS	**10**					**10**

14. State the applicable numerical requirements for consensus as established in your organization's ANSI-accredited procedures: two-thirds of Consensus Council members must vote to approve the standard (i.e., 7 members) __x__Check here to certify that these requirements have been satisfied.

15. Publication: Publication of an ANS is required within 6 months of the date of its approval as such. To request ANSI to provide publication services, please contact the ANSI Publications Department.

16. __x__ Check here if statements from patent holders (patent letters of assurance) have been received regarding this proposed ANS. Please attach a copy of all such statements.

17. **Certification Statement:** ***Please read and confirm compliance before signing and submitting to ANSI.***

I hereby declare the ANSI criteria for approval/withdrawal have been met and that the draft standard was acted on in accordance with section 4.2, Criteria for Approval and Withdrawal of American National Standards of the *ANSI Essential Requirements* and the following criteria and that evidence to this effect is enclosed or otherwise available for inspection:

- That due process requirements were met.
- That the standard is within the scope previously registered with ANSI.
- That any identified significant conflict with another American National Standard was addressed in accordance with the requirements set-forth in the *ANSI Essential Requirements*.
- That other known national standards were examined with regard to harmonization and duplication of content; if duplication exists, there is a compelling need for the standard.
- That objectors have been notified in writing of their right to appeal to the standards developer and that all appeals to the standards developer were completed.
- That any known unresolved objection as defined in the *ANSI Essential Requirements* to the approval/withdrawal of this standard as an American National Standard is documented herein.
- That no substantive changes have been made in the draft standard as listed in *Standards Action*.
- That we agree to comply fully with the *ANSI Patent Policy.*
- That we agree to comply with the *Commercial Terms and Conditions* provision contained in the *ANSI Essential Requirements*.

I agree that the evidence supporting any statement in this submittal or its attachments may be verified at any time through inspection or audit by the American National Standards Institute, either on its own initiative or upon appeal or request by any substantially concerned party. Reasonable requests for specific information that we receive directly from substantially concerned parties will be honored.

If it develops that misstatements of fact have been made in connection with this submittal, I understand that the standard in question is subject to withdrawal with appropriate public notice with reasons therefor. Furthermore, I understand that our organization may be subject to disqualification for a period of time or withdrawal of accreditation for improper submission of a standard to the Board of Standards Review.

Our organization agrees to maintain the American National Standard by reaffirmation, revision, or withdrawal within five years of the date of ANSI approval.

Submitter's Name: _Sally Jones_____ Title: __Project Manager_____
Accredited Standards Developer: __Clinical and Laboratory Standards Institute_____
Address: ___950 West Valley Road__ City: ___Wayne_____ State: __PA_____ Zip: __19087_____
E-mail/Signature: sjones@clsi.org Sally Jones_____ Fax: _610-688-0700_____

D4 Example BSR-11 Form

(BSR-11: Effective 4/03)

Multi-purpose Extension Request Form

Submit to: electronically to: psa@ansi.org or via fax to: ANSI BSR Secretary, 212-840-2298

This form, or equivalent information, is to be submitted to the Procedures and Standards Administration (PSA) Department in accordance with the requirements set-forth in the *ANSI Essential Requirements: Due process requirements for American National Standards (ANSI Essential Requirements).* If you are requesting an extension for more than one standard, please submit a table that contains the relevant information, as defined and labeled herein, in table format or tab separated text.

PLEASE COMPLETE:

Date of Submission:	**02/29/2012**
ANSI Accredited Standards Developer Name:	**Clinical and Laboratory Standards Institute**
Submitter:	**Sally Jones**
Title:	**Project Manager**
Phone:	**610-688-0100**
E-mail:	**sjones@clsi.org**
Fax:	**610-688-0700**

Please indicate the type of extension requested and provide the information listed:

	1. PUBLIC REVIEW EXPIRATION: Extension requested to submit BSR-9 more than one year after the close of the ANSI public review period.
X	**2. OVERAGE STANDARD:** Extension requested to submit candidate standard that is more than 4 years past its approval date as an ANS and for which a PINS or BSR-8 has not been submitted. (Note that the approval of an ANS as such automatically expires on the tenth anniversary date of its approval – no extensions are possible.)
	3. PUBLICATION EXTENSION: Extension requested to publish approved standard as an American National Standard.

Please provide the information requested on one of the following pages:

Multi-purpose Extension Request Form

PUBLIC REVIEW EXPIRATION.

Extension requested to submit BSR-9 more than one year after the close of the ANSI public review period in *ANSI Standards Action (SA).* Relevant clause from the *ANSI Essential Requirements*:

4.2 Approval of actions in connection with American National Standards

A proposed new American National Standard or a proposed revision or reaffirmation of an American National Standard to be approved by the BSR shall be submitted to the secretary of the BSR within one (1) year from the close of the comment period listed in *Standards Action* using the appropriate form provided by ANSI, unless the standards developer notifies the secretary of the BSR in writing of good cause for a different schedule for submittal. Failure to make the submittal within two (2) years from the close of the comment period listed in *Standards Action* shall require consideration by the BSR, i.e., withdrawal, extension for cause, or another listing in *Standards Action.*

Standard designation:	
ANSI SA public review end date:	
Duration of requested extension:	
Reason for requested extension:	

Multi-purpose Extension Request Form

OVERAGE STANDARD.

Extension requested to submit candidate standard that is more than 4 years past its approval date as an ANS. Relevant clause from the *ANSI Essential Requirements* follows. Note that the submittal of a related PINS or BSR-8 form eliminates the need for an extension request:

4.7.1 Periodic maintenance of American National Standards

Periodic maintenance is defined as the maintenance of a standard by review of the entire document and action to revise or reaffirm it on a schedule not to exceed five years from the date of its approval as an American National Standard.

In the event that a PINS or BSR-8/108 has not been submitted for an American National Standard within five years after its approval, the standards developer may request an extension of time to reaffirm or revise the standard, or shall withdraw the standard. The request for an extension of time shall be submitted to ANSI within thirty days following five years after the approval date of the American National Standard. Requests for extensions shall provide the program and schedule of work that will lead to revision, reaffirmation, or withdrawal. The extension may be granted by the ExSC or its designee.

No extension of time beyond ten years from the date of approval shall be granted for action on a standard. In no case shall a standard maintain its status as a current American National Standard beyond ten years from the date of approval. Such approval automatically expires on the tenth anniversary date of approval as an American National Standard.

In the event that an American National Standard approved by a standards developer who has been granted authority to designate its standards as American National Standards is not reaffirmed, revised, or withdrawn within five years after its approval, the standards developer shall follow its own procedures to ensure that work is proceeding and shall notify the Institute and provide the estimated time of completion. In no case shall a standard maintain its status as a current American National Standard beyond ten years from the date of approval. Such approval automatically expires on the tenth anniversary date of approval as an American National Standard.

Standard designation:	**ANSI/CLSI AB25-A-2010**
Date of approval of standard as an American National Standard:	**06/30/2007**
Duration of requested extension:	**1 year**
Reason for requested extension:	**Document is currently under revision. Revision will be completed in December, 2012.**

Multi-purpose Extension Request Form

PUBLICATION EXTENSION.

Extension requested to publish approved standard as an American National Standard. Relevant clause from the *ANSI Essential Requirements:*

4.5 Publication of American National Standards

American National Standards shall be published and made available as soon as possible, but no later than six months after approval as an American National Standard. The standards developer shall publish the standard or shall grant the right of publication to ANSI.

If an American National Standard is not published within six months following its approval, the standards developer may request an extension of this deadline from the ExSC or its designee. Such a request shall be in writing, shall supply the reason for the delay, and shall indicate a firm final date for publication. At its discretion, the ExSC or its designee may grant an additional period of time for publication.

The ExSC or its designee shall publish a notice in *Standards Action* of intent to withdraw approval if the standards developer a) fails to publish the standard or fails to grant ANSI the right to publish within six months after its approval as an American National Standard and does not request an extension of the deadline despite follow-up or b) fails to meet the extended deadline.

Standard designation:	
Date of approval as an ANS:	
Duration of extension:	
Date standard will be published:	
Reason for requested extension:	

950 West Valley Road ▼ Suite 2500 ▼ Wayne, PA 19087 ▼ USA ▼ PHONE 610.688.0100 ▼ FAX 610.688.0700
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