Standards Development Policies and Processes

This document contains the approved policies and processes for developing CLSI consensus standards and guidelines, supplements, and derivative products.

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Contents

Foreword

Clinical and Laboratory Standards Institute consensus standards and guidelines, supplements, and derivative products are used to improve medical laboratory examinations and health care services in diverse testing settings, including:

- Manufacturers' laboratories
- Large teaching and research institution laboratories
- Hospital-based laboratories
- Physicians' offices
- Referral laboratories
- Reference laboratories

CLSI documents and products are also frequently used in other laboratory settings, such as public health, environmental monitoring, and veterinary laboratories.

To develop its standards and guidelines, CLSI uses a document development process based on consensus of viewpoints from its identified constituencies—health care professions, government, and industry. CLSI assembles volunteer experts from the three constituencies to develop these documents in an open discussion forum to fulfill specific needs and resolve problems through consensus. The CLSI Consensus Document Development Process ensures involvement of the three constituencies so that all interested parties may participate and adequate scientific and other needed expertise is available.

Through the production and publication of consensus standards and guidelines and various supplements and derivative 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 for use without modification. CLSI **guidelines** can be modified to fit a particular user's needs. CLSI **supplements** provide regularly revised information needed in applying specific CLSI documents to laboratory practice. CLSI **derivative products** provide important factual information, complement standards and guidelines, and are educational.

CLSI document development committees, subcommittees, and working groups conduct their activities by adhering to the policies and following the processes set forth in these *Standards Development Policies and Processes*.

Standards Development Policies and Processes

Chapter 1: Introduction

These CLSI *Standards Development Policies and Processes* (SDPPs):

- Provide a documented Consensus Document Development Process for creating consensus standards and guidelines that consolidates the CLSI committee structure and CLSI standards development staff activities.

- Ensure representation of health care professions, government, and industry in the CLSI consensus process such that all interested parties may participate and adequate scientific and other needed expertise is available; those who use CLSI consensus documents need confidence that the standards and guidelines were developed without undue influence exerted by any special interest group.

- Ensure that consensus documents developed by CLSI are not inappropriately vague or permissive or unduly exclusionary.

- Provide documented processes for developing CLSI supplements and derivative products.

- Ensure organizational and operational continuity in developing consensus documents and derivative products; the SDPPs recognize that participation in CLSI is voluntary.

- Build quality into each CLSI consensus document, supplement, and derivative product.

The SDPPs familiarize document and product development participants with the:

- Policies and processes for CLSI document and product development

- CLSI committee structure, positions, and associated roles and responsibilities to maximize participation in the consensus document and product development processes

- Significance of their individual and collective contributions

For those in leadership roles, the SDPPs assist in organizing their efforts and outlining their responsibilities for managing document and product development.

Chapter 2: Scope

The SDPPs apply to:

- CLSI standards and guidelines developed through the CLSI consensus document development process

- CLSI supplements for standards and guidelines developed through defined subcommittee (SC) and working group (WG) processes

- CLSI products developed through the Derivative Product Development Process (eg, reports, handbooks, white papers, quick guides, wall charts, software, templates, educational audioconferences, webinars, and online learning programs)

- Documents developed by an organization other than CLSI submitted with request for comment

The SDPPs do not apply to CLSI activities or materials created outside of the document and product development processes, eg, marketing materials.

Chapter 3: Revision of the *Standards Development Policies and Processes*

The Consensus Council may forward suggested policy and process revisions to the Board of Directors for its consideration and action. The Board may revise the policies and approve or request modification to the suggested process revisions in these SDPPs; such revisions are consistent with CLSI Bylaws and with American National Standards Institute (ANSI) accreditation requirements.

The revision history of these SDPPs is located at the end of the document.

Chapter 4: Terminology

4.1 Definitions

active document — a current CLSI standard, guideline, supplement, or derivative product that has been approved through its respective development process.

active project — a CLSI document or product that is progressing through its respective development process.

American National Standard (ANS) — a standard that has been accepted by the American National Standards Institute; **NOTE:** CLSI standards may be considered for ANS submission when requested by an expert panel and agreed to by the Consensus Council.

administrative fee — a monetary amount incurred by each committee participant that defrays the committee operations costs; **NOTE:** CLSI membership dues, whether individual or organizational, include the administrative fee.

archived document — 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 Document Development 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.

balance — having approximately equal numbers of representatives from each constituency participating as voting members on a particular committee.

consensus — the substantial agreement by materially affected, competent, and interested parties that is obtained by following the Consensus Document Development Process; **NOTE:** Consensus does not connote unanimous agreement.

consensus body — the group of volunteer participants who have the final vote to approve publication of a consensus document through a vote of acceptance; **NOTE 1:** The Consensus Council serves as CLSI's consensus body; **NOTE 2:** This group is required to maintain constituency balance.

consensus document — the generic term used to refer to any document published by CLSI that has completed the Consensus Document Development Process; **NOTE 1:** An approved consensus document has achieved consensus within the laboratory community; **NOTE 2:** Consensus documents are categorized as active, reaffirmed, archived, or withdrawn.

constituency//interest category — one of three interest groups into which all volunteers are categorized: health care professions, government, or industry.

derivative product — document and nondocument CLSI products developed through the CLSI Derivative Product Development Process; **NOTE 1:** Derivative products are not subject to consensus voting but are verified through specified review and verification processes; **NOTE 2:** A derivative product may be based on or derived from standards or guidelines.

document development committee (DDC) — volunteer group that has primary responsibility for developing a consensus document, including drafting and editing documents in response to technical and editorial comments received during the entire Consensus Document Development Process.

expert panel (ExP) — selected group of volunteers chosen for their expertise in a specific topic area that submits project proposals, reviews project proposals from other sources and advises the Consensus Council on the suitability of those proposals and reviews and comments on consensus documents and products within their area of expertise.

guideline — a CLSI document developed through the Consensus Document Development Process describing criteria and recommendations for a general operating practice, method, or material for voluntary use; **NOTE 1:** A guideline can be used as written or modified by the user to fit specific needs; **NOTE 2:** Mandates (ie, "must") are occasionally allowed in guidelines, when the document development group feels strongly that a particular action is either required or prohibited or when a guideline discusses provisions based on requirements; **NOTE 2:** Mandates may be indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure.

reaffirmed document — a CLSI document that has been reviewed and confirmed as suitable to remain published without revision to content; **NOTE:** Reaffirmed documents undergo an abbreviated consensus review and approval process.

report — a CLSI document developed through the Derivative Product Development Process that is published for informational purposes only; **NOTE 1:** Reports do not contain technical or procedural recommendations; **NOTE 2:** Reports may become guidelines through the Consensus Document Development Process.

standard — a CLSI document developed through the Consensus Document Development Process that clearly identifies specific, essential requirements for materials, methods, or practices for voluntary use in an unmodified form; **NOTE:** A CLSI standard may also contain discretionary elements, which are clearly identified.

subcommittee (SC) — volunteer group that is responsible for continual revision of selected standards, guidelines, or supplements or for overseeing creation of a series of related standards, guidelines, or supplements.

supplement — a document developed by a subcommittee and a working group(s) as an addition to a published standard or guideline.

withdrawn document — a CLSI document that has been discontinued because it is no longer relevant to laboratory practice, or it has been superseded by another document.

working group (WG) — volunteer group that is typically a subunit of a subcommittee or document development committee and has an assignment limited in scope.

4.2 Abbreviations and Acronyms

ANS	American National Standards
ANSI	American National Standards Institute
DDC	document development committee
ExP	expert panel
SC	subcommittee
SDPPs	*Standards Development Policies and Processes*
WG	working group

Part A: Policies for the Development of Standards, Guidelines, Supplements, and Derivative Products

Chapter 5: Organization for Document Development

5.1 Structure

Figure 1 depicts the relationships between CLSI's Board of Directors and the groups responsible for developing CLSI consensus documents, supplements, and derivative products (henceforth collectively referred to as "documents and products"). Each group has been assigned specific responsibilities and accountabilities in the Consensus Document Development and Derivative Product Development Processes as specified in these SDPPs.

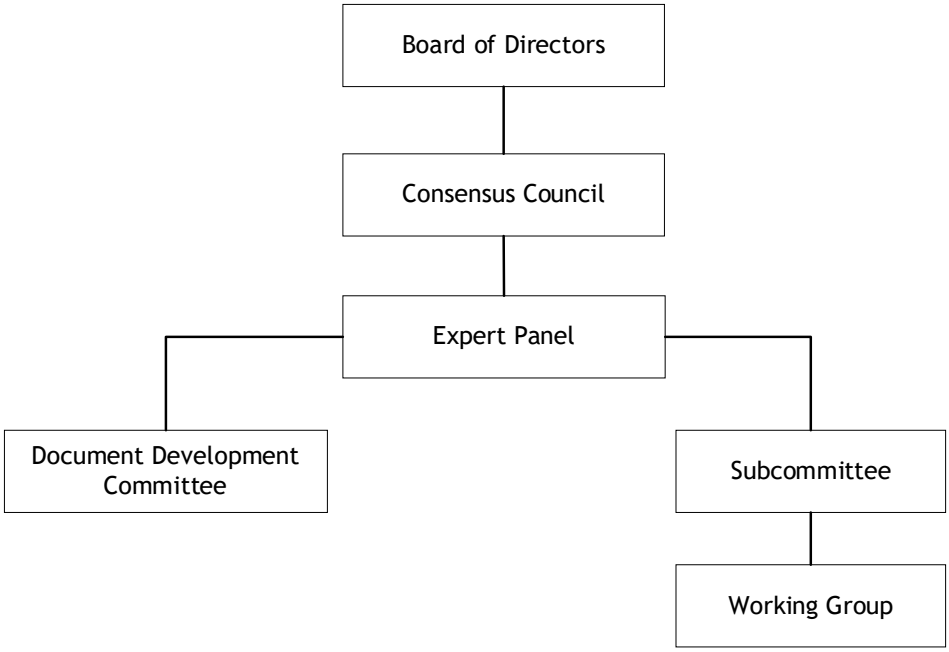


Figure 1. Relationships Between the Board of Directors and the Groups Responsible for Developing CLSI Documents and Products

5.2 CLSI's Code of Ethics

CLSI's Code of Ethics and requirements for CLSI document and product development volunteers and staff are specified in the following subchapters.

5.2.1 CLSI Values

CLSI document and product development volunteers and staff must abide by the fundamental values that guide the way CLSI operates. Specifically, these values are inclusiveness, excellence, responsiveness, integrity, and teamwork.

5.2.2 Antitrust

CLSI document and product development volunteers must adhere to CLSI's established policies and processes as specified in these SDPPs, to ensure that CLSI activities can proceed without violation of antitrust laws.

5.2.3 Confidentiality

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

5.2.4 Intellectual Property

CLSI document and product development volunteers and staff must abide by the requirements specified for CLSI's copyright in CLSI's published works (see Subchapter 5.3.5).

5.2.5 *Standards Development Policies and Processes* and Laws Adherence

CLSI document and product development volunteers and staff must abide by the SDPPs and must not knowingly violate any applicable laws or regulations.

5.2.6 CLSI's Interest

All CLSI volunteers and staff must act solely on behalf of CLSI's interests and not on any personal interests, when serving on any CLSI committee or whenever engaged in CLSI activities.

5.3 General Requirements

5.3.1 Eligibility for Participation

All Consensus Council, expert panel (ExP), document development committee (DDC), subcommittee (SC), and working group (WG) meetings are open to any interested parties when technical matters relating to developing documents and products are being discussed.

Document and product development committee participants with official committee positions (eg, chairholder, vice-chairholder, member) 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 an individual member's financial hardship shall be considered upon request to CLSI.

When a committee determines that it needs additional technical expertise, selected technical experts may be invited to participate in that specific document's development without paying the administrative fee, upon approval by the senior management staff responsible for CLSI document and product development.

5.3.2 Principles of Participation

Four fundamental principles of participation govern consideration of interested parties:

1. Decisions made on behalf of CLSI and the works it publishes must be developed through processes that allow opportunity for fair and open discussion by any interested parties.

2. CLSI must ensure that adequate scientific and other expertise is represented on ExPs, DDCs, SCs, and WGs as needed for the scopes of their respective documents and products.

3. A committee's voting members must be qualified experts and must disclose all potential conflicts of interest. However, to ensure adequate expertise and to promote expression of a variety of views, individuals may participate in the Consensus Document Development Process or Derivative Product Development Process although they have vested interests that have been disclosed (see Subchapter 5.3.4 for additional information on disclosed interests).

4. Disclosures of interests of all participants (ie, committee chairholders, vice-chairholders, members, advisors, contributors, reviewers) are made upon affiliation with CLSI or at the beginning of document and/or product development activities. Disclosures of interests are available for review upon request of interested parties.

5.3.3 Constituency Selection

Volunteers are assigned to the most appropriate constituency category (health care professions, government, or industry) based on their background. These declarations are important in the Appointment Process for chairholder, vice-chairholder, and committee members.

For the purposes of document/product development, individuals must use the following descriptions to determine their most appropriate constituency category:

- **Health care professions constituency** — Individuals employed by or retired from an academic institution, a health care delivery organization, a reference or referral laboratory, a professional society or association, or an accreditation or certification organization in the health care field

- **Government constituency** — Individuals employed by or retired from any federal, national, state, provincial, or local government agency whose primary function is regulatory and/or public health practice and research, and/or measurement standardization.

- **Industry constituency** — Individuals employed by or retired from a manufacturing or trade organization

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

Volunteers' constituency is designated on their Acceptance of CLSI Policies Form (available on the Resources section of the CLSI website). CLSI staff confirms the interest category for each volunteer.

5.3.4 Disclosures of Interest

To ensure transparency when making decisions during document and product development, volunteers must disclose any interests that could affect their objectivity, impartiality, and ability to reach consensus.

5.3.5 Disclosed Interests

Types of interests that document and product development volunteers must declare 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 could be perceived in the context of the document or product development as affecting an individual's objectivity. Representative examples of types of interests that need disclosure include:

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

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

Committee members, advisors, contributors, and reviewers must disclose their interests on an Acceptance of CLSI Policies Form at the following times:

- Appointment
- Upon reappointment
- At least every four years
- At time of relevant changes in disclosed information

Before introductions at each committee meeting, CLSI staff asks if there is a change in disclosures of interests. Changes are recorded in the meeting summary minutes. Any volunteer stating a change in disclosed interests is required to complete a new Acceptance of CLSI Policies Form.

5.3.5.1 Undisclosed Interests

Disclosures of interests submitted to CLSI are assumed to be truthful and complete. Any individual involved with CLSI document or product development who becomes aware of an interest or activity that is undisclosed and that may affect a CLSI activity must report this situation to the respective project manager. Such situations are reviewed by the Consensus Council and a recommendation is forwarded to the Executive Committee of the Board of Directors for consideration. Records of such reports and their resolution are kept on file at CLSI.

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.

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

5.3.6 Permission to Use

A person who voluntarily joins or accepts an appointment to a CLSI committee, or participates in that committee's programs, sessions, collaborations, and/or meetings, grants CLSI permission to use any contributed data and information for the purpose of discussing, analyzing, and evaluating such information as part of CLSI's Standards Development Process.

Any CLSI work that is created as the result of the Document Development and Derivative Product Development Processes belongs exclusively to CLSI. Participants in the process do not own or control any rights in or to the works by virtue of participating in the process or by virtue of CLSI synthesizing contributed information into the works. Any information provided by a volunteer shall be—to the best of his/her knowledge—accurate and does not infringe upon the rights of any other party.

CLSI has the exclusive right to publish, reproduce, and distribute the works throughout the world in all media and platforms. Volunteers shall not copy, adapt, translate, or otherwise reproduce by any means (eg, electronic, file sharing, mechanical, photocopying, recording, or otherwise), any work without prior written permission from CLSI. Likewise, CLSI shall not reproduce any specific expression of information furnished by a volunteer (eg, a chart, graph, illustration, or text) in a work without proper approval.

5.3.7 Acceptance of CLSI Policies

All CLSI document and product development volunteers must indicate that they have read, understood, and accept the policies specified in the Acceptance of CLSI Policies Form and complete the disclosure of interests. Volunteers cannot participate in any CLSI document or product development committee until this form is completed and on file at the CLSI office. A *curriculum vitae* may be used to support the information supplied. This acceptance remains part of the official records of consensus document development meetings. The elements of the Acceptance of CLSI Policies Form are:

- Code of Ethics
- Constituency selection
- Conflicts of interest disclosure
- Permission to use
- Standards development participation
- Attestation

5.3.8 Committee Appointments

Table 1 outlines responsibilities for committee formation and disbandment.

Table 1. Committee Formation and Disbandment

Committee	Formation Approved by	Disbanded by
Consensus Council	Board of Directors	Board of Directors
ExP	Consensus Council	Board of Directors with the advice of the Consensus Council
DDC	Consensus Council	Completion of the project
SC	Consensus Council with the advice of the responsible ExP	Consensus Council with the advice of the responsible ExP
WG	Responsible SC	Completion of the project
Appeal panel	Consensus Council	Resolution of appeal

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

Table 2 summarizes responsibilities for committee appointments and removals.

Table 2. Committee Appointments and Removals

Committee Position	Appointment Approved by	Removed From Committee by
Consensus Council member	Board of Directors	Board of Directors with the advice of the Consensus Council
Consensus Council emeritus member	Board of Directors	Board of Directors with the advice of the Consensus Council
ExP chairholder and vice-chairholder	Consensus Council	Consensus Council
ExP members*	Consensus Council	Consensus Council with the advice of ExP leadership
ExP advisors	ExP leadership	ExP leadership
New DDC chairholder and/or vice-chairholder	Consensus Council	Consensus Council
New DDC (members, contributors)	ExP leadership	ExP leadership with the advice of DDC leadership
Appointed DDC chairholder, vice-chairholder	ExP leadership	ExP leadership
Appointed DDC (members, contributors)*	ExP leadership with the advice of DDC or SC chairholder	ExP leadership with the advice of DDC chairholder
New SC (all participants)	Consensus Council with the advice of ExP leadership	Consensus Council with the advice of ExP leadership
Appointed SC (chairholder, vice-chairholder)*	ExP leadership	ExP leadership
Appointed SC (members, advisors, reviewers)*	SC leadership	SC leadership
New WG (all participants)	SC chairholder	SC chairholder
Appointed WG (all participants)*	SC chairholder with the advice of WG leadership	SC chairholder with the advice of WG leadership
Appeal panel	Consensus Council leaderhsip	Consensus Council leadership

* For additions to formed committees, the same selection considerations apply as for volunteer selection for new committees (see Subchapter 8.4 for details).

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

Table 3 summarizes stipulations regarding a volunteer's participation on multiple CLSI committees.

Table 3. Volunteer Participation Stipulations

Member of	Nominated for a Member Position on	Decision
Board of Directors	ExP	Permitted
Board of Directors	DDC, SC, WG	Permitted
Consensus Council	Board of Directors	Not permitted with the exception of the President-Elect or Chairholder of Consensus Council
Consensus Council	ExP	Not permitted
Consensus Council	DDC, SC, WG	Permitted and must abstain from Consensus Council votes on related DDC, SC, or WG matters
ExP	DDC, SC, WG	Permitted

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

Table 4 outlines permissibility of multiple volunteers from the same member organization participating as members of the same committee.

Table 4. Committee Participation by Multiple Volunteers From the Same Member Organization

Member of	Decision
Consensus Council	Not permitted with the exception of chairholder and vice-chairholder
ExP, SC, DDC, or WG	Permitted if individuals represent different divisions or departments; justification must be provided and documented as part of the approved by the responsible ExP's approval

Abbreviation: DDC, document development committee; ExP, expert panel; SC, subcommittee; WG, working group.

Chapter 6: Committee Responsibilities

Table 5 outlines the roles and responsibilities of the various groups involved in developing and approving CLSI consensus standards and guidelines, supplements, and derivative products.

Table 5. Committee Roles and Responsibilities

CLSI Committee	Roles and Responsibilities
Board of Directors	• Establishes the policies that govern the Consensus Document Development and Derivative Product Development Processes • Has final approval of changes to the SDPPs • Approves standards, guidelines, supplements, or derivative products projects that require funding beyond the planned budget
Consensus Council	• Together with selected CLSI staff members, has overall responsibility for managing the Consensus Document Development and Derivative Product Development Processes, and committee expenses vs Board-approved budget • Approves and prioritizes projects within Board-directed guidelines and budget • Ensures appropriate expertise on each DDC or SC • Gives final approval for publication of all consensus documents, ensuring proper process, quality, and resolution of comments • Seeks advice from ExPs and staff as needed for the preceding responsibilities
Expert panel	• Serves as technical advisor to the Consensus Council regarding new documents and products 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 • Performs additional activities as requested by the Consensus Council
Document development committee	• As its primary responsibility, drafts individual consensus documents and evaluates and responds to comments received during each phase of the Consensus Document Development Process • May be responsible for the development of derivative products as needed • Considers scientific accuracy, practicality, and comprehensibility with the goal of creating documents of overall high quality and utility
Subcommittee	• Primarily drafts individual consensus documents and evaluates and responds to comments received during each phase of the Consensus Document Development Process • Usually responsible for two or more related documents, for scheduled review of the documents, and/or for supplemental document updates, and/or for continual revision of certain standards and/or 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

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

Table 6 shows the CLSI committee structure and provides term limit information.

Table 6. Committee Positions and Term Limits

CLSI Committee	Committee Position Term Limits						
	Chairholder	Vice-Chairholder	Member	Emeritus member	Advisor	Contributor	Reviewer
Consensus Council	1	1	1	1	N/A	N/A	N/A
Expert panel	1	2	1	N/A	1	N/A	N/A
Document development committee	3	3	3	N/A	N/A	3	N/A
Subcommittee	1	2	1	N/A	1	N/A	4
Working group	3	3	3	N/A	N/A	N/A	N/A

Key

1	Appointed for a one-year term and may continue in this position for up to four consecutive terms.* Consensus Council members serve one-year terms and may be reappointed by the President for a total of four consecutive terms. When necessary to ensure continuity, a member's term may be extended for an additional 1 to 2 years.
2	Vice-chairholders of ExPs or SCs are limited to serving a maximum of two one-year terms if rotating from the position of chairholder of the same ExP or SC.*
3	Serves in this position for the duration of the project.*
4	Serves in this position until appointed to the committee in another capacity or removed by request.

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

Abbreviations: ExP, expert panel; N/A, not applicable; SC, subcommittee.

6.1 Consensus Council

The Consensus Council:

- Serves as the consensus body for CLSI
- Maintains overall responsibility for managing the development of CLSI consensus documents and products
- Identifies continual improvement opportunities in the Consensus Document Development and Derivative Product Development Processes
- Approves and sets priorities for all CLSI document and product development projects based on medical utility, clinical relevance, and CLSI's mission
- Votes on Final Draft documents to confirm adherence to their respective development processes and approves documents and products for final production
- Recommends replacement of a DDC/SC/WG chairholder and/or vice-chairholder when deemed necessary and/or appropriate

The Consensus Council consists of at least nine persons, in addition to the chairholder and the President-Elect. The chairholder is appointed by the President, subject to approval of the

Executive Committee, and, if not a member of the Board of Directors, serves as an *ex officio* nonvoting member of the Board of Directors during his or her term as chairholder.

Consensus Council membership must be balanced among constituencies. Typically, the Consensus Council members are equally distributed among the constituencies (ie, one-third health care professions, one-third industry, one-third government). Under no circumstances may a constituency have a voting majority (ie, any one constituency shall not exceed by more than one the number of representatives from the other two constituencies). The only committee in the Consensus Document Development Process for which balance is required is the Consensus Council.

When needed, the Consensus Council chairholder may recommend appointment of an at-large member to fill identified skill mix needs. The at-large member shall be appointed by the President—with the concurrence of the Executive Committee of the Board of Directors. The at-large member shall have voting right and is subject to the term limits of a Consensus Council member (see Table 6). The at-large member shall not be assigned as representative of a particular constituency.

The Consensus Council's face-to-face meetings occur during scheduled CLSI Committees Weeks, and teleconferences may be scheduled at intervals throughout the remainder of the year. Consensus Council voting may be conducted in person, electronically, or on a conference call.

6.1.1 Consensus Council Chairholder

The Consensus Council chairholder should have knowledge of CLSI, the clinical laboratory field, and the CLSI consensus document development and derivative product development processes. The chairholder is expected to lead the review and evaluation of materials submitted to the Consensus Council, make decisions in alignment with Board-directed goals and objectives, and lead the Council to an effective outcome.

The Consensus Council chairholder is responsible for:

- Leading the activities of the Consensus Council, ensuring all responsibilities of the Council are met
- Preparing agendas for meetings and conference calls
- Facilitating all Consensus Council meetings and conference calls
- Actively participating in Consensus Council activities, conference calls, and meetings
- Reviewing and approving meeting records
- Serving as the official signatory for volunteer appointment letters

The Consensus Council chairholder is willing and able to devote significant time and effort to these assigned tasks and to guide and monitor the review of all standards development activities.

See Table 6 for term limits.

6.1.2 Consensus Council Vice-chairholder

The Consensus Council vice-chairholder should have general knowledge of CLSI, the clinical laboratory field, and the CLSI consensus document development and derivative product development processes.

The Consensus Council vice-chairholder is responsible for:

- Assisting and supporting the chairholder as needed, ensuring all responsibilities of the Council are met
- Preparing agendas, together with the chairholder
- Actively participating in Consensus Council activities, conference calls, and meetings

See Table 6 for term limits.

6.1.3 Consensus Council Members

Consensus Council members should have general knowledge of CLSI and the clinical laboratory field; however, depth in a technical field is not required.

Consensus Council members should be willing to learn the CLSI *Standards Development Policies and Processes*, to review and judge materials submitted by peers, and make decisions in alignment with Board-directed goals and objectives.

Members are expected to perform the duties of the Consensus Council and actively participate in Consensus Council activities, conference calls, and meetings.

6.1.3.1 New Member Mentorship

To facilitate introduction of incoming Consensus Council members to Council business matters as well as Council team culture and meeting protocols, incoming Council members will be encouraged to develop a relationship with an experienced Council member who has greater than 24 months of Council membership experience. The purpose of these relationships is to mentor the in-coming Council members. The Consensus Council vice-chairholder will ensure that each in-coming Council member has an experienced Council member as a mentor. When a new Consensus Council vice-chairholder is scheduled to begin their position, the outgoing Consensus Council vice-chairholder will communicate the mentor/new Council member pairings to the new vice-chairholder to ensure a smooth transition.

It is recognized and appreciated that Council Members with greater than 24 months of Council membership possess knowledge of past or on-going projects and decisions that are strategic to the continued success of the Council and to CLSI. Only a select, limited number of up to three Emeritus Council members may be invited by the Consensus Council Chairholder to continue to participate in all Council activities after the expiration of the Council membership at the Chairholder's discretion. No more than one emeritus Consensus Council member from each constituency shall be invited. An Emeritus Consensus Council member is preferably an individual who has recently rotated off the Consensus Council to ensure that their knowledge of Consensus Council projects, history and issues is current. The term limit of an Emeritus Council member

shall be the same as the term limits for a Council member. The responsibilities of an Emeritus Consensus Council member are the same as the responsibilities of a Consensus Council member with the exception of voting privileges as shown in Table 7.

Table 7. Member and Emeritus Member Comparison

Primary Role	Contributor to Discussion Leading to Consensus	Attend All CC Face-to-Face Meetings	Voting Privileges	Receive All CC Notifications and Meeting Minutes
CC members	Active participants	Yes	Yes	Yes
CC emeritus members	Provide historical background on documents, previous decisions, procedures	Yes	No	Yes

CLSI pays the travel expenses of its Emeritus Consensus Council members when he or she is eligible for reimbursement under the CLSI Volunteer Reimbursement Policy.

See Table 6 for term limits.

6.2 Expert Panels

ExPs are constituted for various technical subject areas, as determined by CLSI's Board of Directors. The number of ExP participants depends on each ExP's technical needs, but should not exceed 14 in total. The ExP serves as an advisory group rather than as a document-drafting or product development committee.

ExPs:

- Identify consensus document and product development projects and propose them to the Consensus Council for action.
- Review proposals from other sources and advise the Consensus Council on the suitability of those proposals.
- Review and comment on consensus documents and products within their area of expertise during the Proposed Draft vote.
- Review documents within their area of expertise to recommend reaffirmation, revision consolidation or division, or withdrawal, or archiving.
- Creates or solicits the creation of a completed Project Proposal Form (available on the Resources section of the CLSI website) for consolidating or dividing a document.

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

6.2.1 Expert Panel Chairholder

The ExP 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 ExP chairholder serves as the panel's primary liaison to the Consensus Council, as needed.

The ExP chairholder should be aware of document development opportunities within the panel's technical area that are appropriate for the CLSI Consensus Document Development and/or Derivative Product Development Processes and should keep the ExP informed so appropriate new projects may be considered.

The ExP chairholder is responsible for recommending nominated candidates for its membership as well as candidates to chair DDCs, SCs, and WGs and for providing advice regarding committee participant appointments as appropriate. (See Table 2 for specific appointment responsibilities.)

The ExP chairholder maintains close contact with DDC, SC, and WG chairholders, advising at all stages in document development and emphasizing technical excellence, clarity, user suitability, global harmonization, and publication timeliness.

The ExP chairholder is willing and able to devote significant time and effort to these assigned tasks and to guide and monitor the review of documents and products developed by DDCs, SCs, and/or WGs in the specific technical area.

See Table 6 for term limits.

6.2.2 Expert Panel Vice-Chairholder

In the chairholder's absence, the ExP's vice-chairholder serves as the panel's leader and also represents the ExP as liaison to the Consensus Council.

See Table 6 for term limits.

6.2.3 Expert Panel Members

ExP members should be experienced individuals involved in the ExP's field of focus. ExP members are able to devote the anticipated required time to panel activities.

ExP members represent the technical expert body for each topic area and, as such, review and comment on documents and products in the respective development processes.

The ExP member should be aware of and identify document development opportunities within his/her area of expertise the panel's technical area that are appropriate for the CLSI Consensus

Document Development and/or Derivative Product Development Processes and should keep the ExP chairholder informed so appropriate new projects may be considered.

The number of ExP participants depends on each ExP's technical needs. The number of members should not exceed 14 in total.

The number of advisors appointed to an ExP can equal up to 50% of the number of members appointed. For example, if there are 10 voting members, the number of advisors may not exceed 5.

No more than 2 individuals from the same organization can hold any position on an ExP (eg, 1 member plus 1 advisor from the same organization, 2 advisors from the same organization).

See Table 6 for term limits.

6.2.4 Expert Panel Advisors

ExP advisors have expert knowledge and experience in the ExP's subject area and are interested in actively supporting the ExP's efforts.

Advisors participate, as knowledge and experience permits, in one or more of the following ExP activities:

- Identifying topics for new document consideration
- Developing and submitting new project proposals
- Reviewing and submitting input on circulated draft documents and revisions

For the purposes of obtaining or retaining expertise and experience in the CLSI Consensus Document Development and Derivative Product Processes, the ExP may choose up to 2 advisors who have volunteered to serve if chosen. ExP advisors may be selected from the ExP chairholder, vice-chairholder, or members whose term limits have expired, as well as from experienced persons who answered the Call for Volunteers.

See Table 6 for term limits.

6.3 Document Development Committees, Subcommittees, and Working Groups

CLSI standards, guidelines, supplements, and products are developed by DDCs, SCs, and WGs. Balance among CLSI constituencies in constituting a DDC, SC, or WG is not a requirement.

6.3.1 Document Development Committees

CLSI DDCs have primary responsibility for developing or revising consensus documents according to the process described in Chapter 8, including drafting the document and editing it in response to technical and editorial comments received during each phase of the Consensus Document Development Process. The DDC needs to consider scientific accuracy, practicality, and comprehensibility to create documents of overall high quality and utility. After a document is published, the DDC is disbanded.

DDC members may also participate in developing derivative products, according to the process described in Chapter 11.

6.3.2 Subcommittees

SCs have primary responsibility for drafting individual consensus documents and for evaluating and responding to comments received during each phase of the Consensus Document Development Process. SCs are usually responsible for two or more related documents, for scheduled review of the documents, and/or for supplemental document updates. SCs may also be responsible for continual revision of certain standards and/or guidelines.

6.3.3 Working Groups

A WG is typically a subunit of an SC. 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:

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

6.3.4 Document Development Committee, Subcommittee, and Working Group Chairholders

The chairholder should be experienced and effective in leading teams and/or committees and have experience in the technical area. The chairholder also should have the ability to clearly communicate and understand the requirements for expenses, timeline, comments, and responses imposed by the Consensus Document Development and/or Derivative Product Development Processes. The chairholder may also be a member of the ExP.

The chairholder, together with the appointed CLSI staff project manager, is responsible for:

- Proposing placement of volunteers in appropriate DDC, SC, or WG roles and recommending the proposed membership to the Consensus Council for approval

- Identifying a committee participant who will serve as committee secretary

- Determining (with the vice-chairholder's assistance), based on contribution to document development, the individuals ultimately listed as contributing authors

- Scheduling and planning the agendas for DDC, SC, or WG meetings and conference calls

- Furnishing progress activity reports, including time and expenses forecasts for completing each authorized project, to the Consensus Council, as requested

- Critically reviewing and commenting on the document or product at each stage in the Consensus Document Development and/or Derivative Product Development Processes

A chairholder may be replaced by the Consensus Council when deemed necessary and/or appropriate. A chairholder is also subject to termination in the event that their project-related

commitments are not met (eg, submission of writing assignments, participation in committee activities, timely project completion).

See Table 6 for term limits.

6.3.5 Document Development Committee, Subcommittee, and Working Group Vice-Chairholders

The vice-chairholder serves 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. The vice-chairholder assists the chairholder in determining, based on contribution to document development, the individuals ultimately listed as contributing authors. The vice-chairholder is also responsible for critically reviewing and commenting on the document or product at each stage in the Consensus Document Development and/or Derivative Product Development Processes.

A vice-chairholder may be replaced by the Consensus Council when deemed necessary and/or appropriate. A vice-chairholder is also subject to termination in the event that their project-related commitments are not met (eg, submission of writing assignments, participation in committee activities, timely project completion).

See Table 6 for term limits.

6.3.6 Document Development Committee, Subcommittee, and Working Group Members

DDC, SC, or WG members are selected to balance subject area expertise with consideration given to representing health care professions, government, and industry constituencies. Balance among members is not required.

These 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 expenses, timeline, comments, and responses imposed by the Consensus Document Development and/or Derivative Product Development Processes.

These members have primary responsibility for drafting standards, guidelines, and supplements, derivative products, and critically reviewing and commenting on the document or product.

DDC, SC, and WG members are also responsible for evaluating and responding to comments received throughout the Consensus Document Development and/or Derivative Product Development Processes.

Members who fulfill their responsibilities are regarded as the document's authors.

A member may be replaced (after appropriate consultation among the DDC and Consensus Council or the SC leadership and the WG chairholder) when deemed necessary and/or appropriate. A member is also subject to termination in the event that their project-related commitments are not met (eg, submission of writing assignments, participation in committee activities).

See Table 6 for term limits.

6.3.7 Document Development Committee, Subcommittee, and Working Group Secretary

The secretary is selected during the Member Selection Process. The secretary is knowledgeable in the subject area and prepares meeting summaries, including detail that supports the rationale for decisions and changes made during the meeting.

6.3.8 Document Development Committee Contributors

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

Contributors are included in the distribution of DDC announcements and agendas, meeting minutes, and draft documents for the specific DDC project. Contributors may participate in DDC meetings.

DDC contributors are expected to contribute to document content and review and submit input on DDC draft documents and circulated revisions. Contributors who develop substantial content may, at the discretion of the DDC chairholder and vice-chairholder, be listed as document authors or product developers.

See Table 6 for term limits.

6.3.9 Subcommittee Advisors

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

SC advisors have expert knowledge and experience in the SC's subject area and are interested in actively supporting the SC's efforts.

Advisors participate, as knowledge and experience permits, in one or more of the following SC activities:

- Identifying topics for new document consideration
- Developing and submitting new project proposals
- Reviewing and submitting input and approval on circulated draft documents and revisions

SC advisors can also become SC or WG chairholders or members for new documents or revisions.

See Table 6 for term limits.

6.3.10 Subcommittee and Working Group Reviewers

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

SC or WG reviewers are interested in and knowledgeable about the SC or WG's specialty areas and agree to participate in the Consensus Document Development and/or Derivative Product Development Processes, as knowledge and experience permits, in support of SC or WG activities. Reviewers are expected to review and comment on draft documents.

See Table 6 for term limits.

6.4 Delegates

Each member organization names an official CLSI delegate. Full individual members act as their own delegate.

Delegates are responsible for casting one official vote and providing comments during each document's Proposed Draft voting period.

All delegates are encouraged to suggest project ideas and, where applicable, respond to CLSI-posted Calls for Volunteers with the names of persons who could be considered as candidates for CLSI document development projects.

6.5 Endorsement Disclaimer

Membership in CLSI indicates support of the CLSI Consensus Document Development and Derivative Product Development Processes but 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 committee volunteers.

6.6 Resignations From CLSI Committees

A resignation from a member's position on the Consensus Council or an ExP, DDC, SC, or WG may be accepted by the respective chairholder and forwarded to the CLSI office. The resignation of a Consensus Council or ExP chairholder is accepted by the President or the President-Elect.

The process for finding a replacement for a resigned person is the same as the Appointment Process.

When a change in a Consensus Council member's status or employment results in a change to the member's CLSI constituency category such that constituency balance is no longer met, the Consensus Council is prohibited from voting on consensus documents until balance is restored.

The Consensus Council member submits a resignation, which may be accepted at the chairholder's or Board of Directors' or its Executive Committee's discretion. Efforts to achieve balance can include a Call for Volunteers or a Presidential appointment.

6.7 Role of the CLSI Project Manager

The project manager is responsible for moving assigned document and product development projects through the appropriate process. The project manager reports on the progress of the projects in his or her assigned areas as scheduled. The project manager is a co-leader with the DDC, SC, or WG chairholder and vice-chairholder, helping to plan and organize the volunteers' work and advise the volunteers on CLSI policies regarding writing style, content, and document organization.

Part B: Process for the Development of Standards, Guidelines, and Derivative Products

Chapter 7: Committee Operations: General Information

7.1 Committee Meetings, Conference Calls, and Web Conference Meetings

CLSI committees conduct business at in-person meetings, during conference calls, and/or by electronic communication through meeting announcements and agendas issued from the CLSI office. CLSI conducts all meetings in an open forum and permits 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 establish procedures that ensure the meeting objectives are met while accommodating the opportunity for public attendance and observation. Limitation of total participants or invocation of a registration fee may be used as needed to manage the meeting cost and logistical needs.

All face-to-face meetings are scheduled in accordance with the annual budget and activities plan approved by the Board, or when exceptional circumstances arise in reaching consensus, and are conducted in compliance with the CLSI Antitrust Policy (see Subchapter 7.1.4). Every attempt is made to schedule face-to-face meetings in conjunction with scheduled CLSI Committees Weeks. Face-to-face meetings not in the budgeted plan require approval of the senior staff leader of standards development or the chief executive officer.

Teleconference and Web conference meetings are strongly encouraged for all ExP, DDC, SC, and WG committees, as most document development work is conducted in these media in lieu of a face-to-face meeting. Teleconference and Web conference meetings are also conducted in compliance with the CLSI Antitrust Policy (see Subchapter 7.1.4).

7.1.1 Meeting Arrangements

A CLSI staff member sets up all document and product development meetings and conference calls. No meeting, Web conference, or conference call can be held without the presence of a CLSI staff member, unless an exception has been granted by a senior staff leader of standards development. When an exception is granted, the chairholder is briefed on the CLSI Antitrust Policy and related precautions.

The DDC, SC, or WG chairholder, vice-chairholder, and members are the primary participants in conference calls and Web conferences. The chairholder's, vice-chairholder's, and members' availability are given priority consideration when scheduling conference calls and Web conferences. Other committee participants are allowed to participate and their schedules are accommodated when 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) in this medium.

7.1.2 Meeting Notice and Agenda

CLSI staff ensures that all listed Consensus Council, ExP, or DDC, SC, or WG chairholders, vice-chairholders, members, advisors, contributors, and reviewers are notified directly and in a timely manner of all meetings. Notification includes all relevant information that the chairholder and staff believe should be considered in preparing for the meeting, along with the

specific time, place, date, and tentative agenda or list of subjects that will be considered and a means to determine the number of individuals planning to attend.

7.1.3 Conduct of Meetings

Meeting attendees must adhere to the meeting agenda so that discussions are relevant to the meeting's purpose, as set in the agenda. Unrelated discussions are not allowed in the meetings to avoid any perception of anticompetitive industry actions that could harm the persons involved, their organizations, and CLSI (see Subchapter 7.1.4).

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 clarifies who is eligible to vote.

When a meeting is adjourned, it is considered over in all respects and not simply in name, meaning that additional business cannot be continued outside the meeting.

7.1.4 Forbidden Discussion Topics

CLSI staff members are familiar with the organization's Antitrust Policy and will provide appropriate guidance when needed.

To avoid the appearance of tacit understanding or collusion in violation of antitrust laws, discussion of, consideration of, or action on a volunteer's organization's pricing or competitive topics is not allowed during CLSI meetings, Web conferences, conference calls, and social events associated with such meetings.

The following list of forbidden discussion topics is not all-inclusive. Forbidden discussion topics related to a volunteer's organization include:

- 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

Questions related to the appropriateness of meeting discussions must be referred to the CLSI project manager.

The chairholder and project manager are responsible for terminating improper discussions, moving ahead to subsequent agenda items, or adjourning the meeting or conference call, when necessary.

7.1.5 Summary Minutes

A designated CLSI staff member or project manager keeps and prepares summary minutes of Consensus Council and ExP meetings, respectively.

During each DDC, SC, or WG meeting and conference call, the committee chairholder, secretary, and project manager are responsible for ensuring that summary minutes are kept by the committee secretary or designate or the project manager in the absence of a formal secretary.

The summary minutes need to reflect who attended, members absent or excused, subjects discussed, decisions made, actions taken, and work products produced. Summary minutes review the discussion, the extent of agreement, and the means by which minority positions were addressed. Comments made by participants can reflect their personal perspective or reflect that of their organization. These comments are included in summary minutes as appropriate when applicable to committee decision making activities.

After the meeting, summary minutes are reviewed and finalized by the chairholder and project manager and are distributed along with any related work outcome(s).

7.1.6 Unresolved Issues

The summary minutes reflect any minority views or other matters not fully resolved by committee deliberation.

7.2 Correspondence

All official CLSI correspondence originates only from the CLSI office, from the CLSI officers, or 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.

When it is necessary or useful for committee participants to correspond directly about projects, this correspondence is included in the official record of that committee's work and a copy is forwarded to the project manager for appropriate retention.

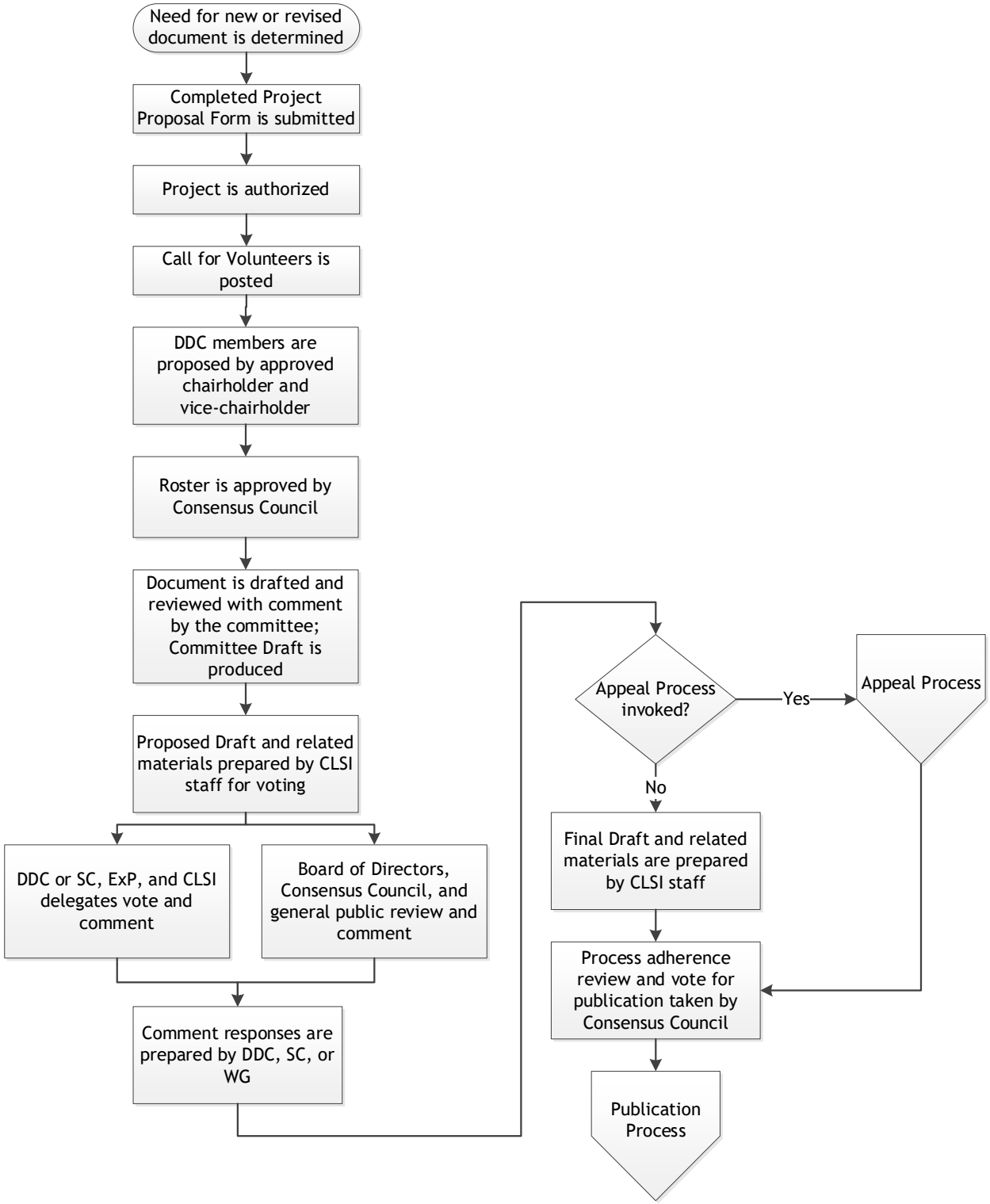
Whenever possible, CLSI staff prepares and distributes correspondence in electronic format. Appropriate safeguards are taken by CLSI staff to ensure that such transmission does not violate any restrictions related to distribution.

Informational surveys of a specific portion of the health care community are performed by the CLSI office for CLSI DDCs, SCs, or WGs. This technique gathers valuable information the DDC, SC, or WG can use when developing a CLSI document or product. The DDC, SC, or WG can be asked to supply the contact list.

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

Chapter 8: The Consensus Document Development Process for Standards and Guidelines

The CLSI Consensus Document Development Process is used specifically for developing CLSI standard and guidelines. This process incorporates consensus throughout development, commenting, voting, and comment resolution subprocesses to build quality and consensus into CLSI documents. Figure 2 overviews the Consensus Document Development Process.



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

Figure 2. High-Level View of the Consensus Document Development Process (see Subchapter 8.12.1 for development of susceptibility consensus documents)

8.1 Project Proposal Submission

Any person or organization, including CLSI committees or committee participants, can propose a new CLSI project. All new project proposals must be submitted on a completed CLSI Project Proposal Form, which is available on the resources section of the CLSI website.

The Project Proposal Form is periodically revised to reflect the criteria established and information needed by the Consensus Council to evaluate and prioritize proposals for document development.

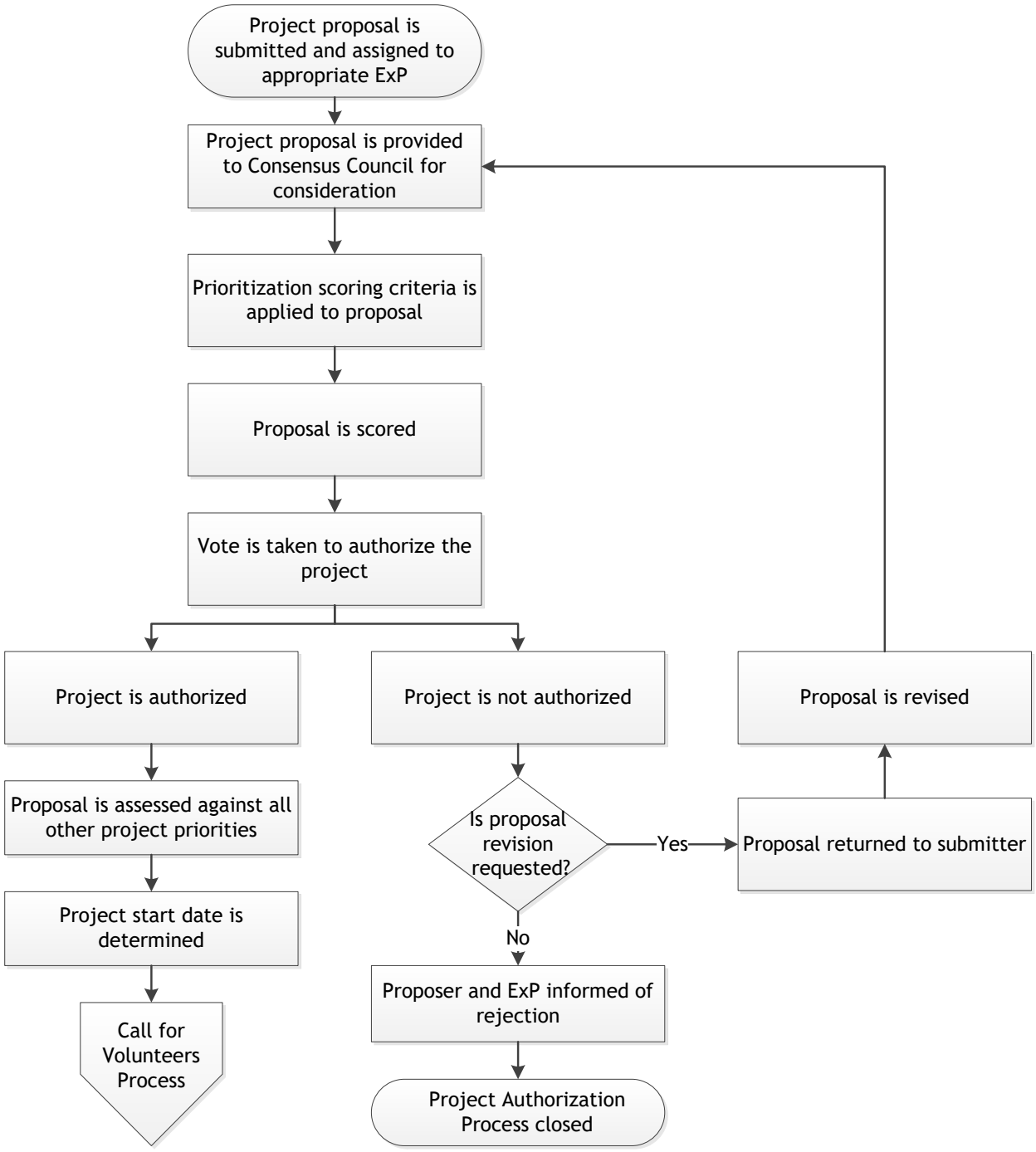
Only completed forms will be evaluated by the Consensus Council. Forms with missing or incomplete information will be returned to the submitter.

8.2 Project Authorization

The Consensus Council authorizes all document and product development projects. The Consensus Council reviews each project proposal to ensure that a proposed project is consistent with the mission and goals of CLSI and fulfills a perceived need. Then, the Consensus Council uses a set of weighted criteria to assign a priority score.

Projects expected to exceed their approved budget must be reviewed by the Consensus Council, which recommends an appropriate action to the Board.

Figure 3 depicts the process by which projects are authorized by the Consensus Council.



Abbreviation: ExP, expert panel.

Figure 3. Project Authorization Process

Table 8 outlines the timeline for the Project Authorization Process.

Table 8. Anticipated Project Authorization Process Timeline

Activity	Timeframe
Project proposal is submitted and assigned to the appropriate ExP.	Month 0
ExP endorses proposal.	Month 1
Consensus Council reviews and prioritizes proposal; proposal is authorized.	Month 2
Call for Volunteers is issued.	Month 2
DDC selection is undertaken.*	Month 3
Proposed DDC roster is reviewed by Consensus Council.	Month 4
DDC participants are notified of selection and meeting announcement is issued.	Month 4
Inaugural meeting is held.	Month 4

* The Consensus Council will consider recommendations for a chairholder and vice-chairholder submitted with the proposal, but is not necessarily bound by the submitter's recommendation.
Abbreviations: DDC, document development committee; ExP, expert panel.

8.3 Notification of Document Development and Call for Volunteers

The initiation of new standards and guidelines development activities is announced on the CLSI website and to CLSI members through electronic communications. A Call for Volunteers is included in the announcement so that parties interested in volunteering for development of standards and guidelines can formally record their interest and be considered for DDC membership.

Respondents to the Call for Volunteers must submit all required documentation, which includes:

- A current *curriculum vitae*
- A completed and signed Acceptance of CLSI Policies Form

Including a letter indicating interest in serving on the specific DDC named in the Call for Volunteers when submitting a nomination is desirable.

Instructions for submitting this documentation are provided in the Call for Volunteers website posting.

Nominees are required to remit an administrative fee to defray the costs of committee operations. **NOTE:** CLSI membership dues, whether individual or organizational, include the administrative fee.

8.4 Document Development Committee and Subcommittee Member Selection

The DDC or SC chairholder-designate, vice-chairholder-designate, ExP chairholder and vice-chairholder, and assigned CLSI project manager select the proposed members from the roster of respondents to the Call for Volunteers. As stated in Subchapter 6.3, balance among CLSI constituencies is not required on DDCs or SCs. The DDC or SC secretary may or may not be appointed as a member, depending on constituency representation and chairholder preference. DDC and SC members and the secretary are selected based on the attributes they can bring to document development.

After proposed DDC or SC member selection, the remaining respondents, if eligible (ie, CLSI individual or organizational members), are appointed as DDC contributors, SC advisors, or SC reviewers to the document.

8.5 Consensus Council Approval of Roster

The Consensus Council is notified of the need to review and vote on the proposed DDC or SC roster. When approval is obtained, document development begins based on the prioritization schedule.

When the Consensus Council does not approve the roster, it provides the project manager with recommendations for how to proceed.

8.6 Document Development or Revision

The time needed to develop or revise a consensus document depends on factors such as the breadth of scope, complexity of issues, comprehensiveness and depth of the topics covered, and the controversial nature of the topic(s). Additional development or revision time can be considered and is indicated in the project proposal. Proposals needing lengthy development or revision times can be reconsidered to limit the scope, allowing for more timely completion. The process is depicted in its entirety in Appendix A.

Table 9 provides an example timeline for developing or revising a CLSI document.

Table 9. Example Timeline for Developing or Revising a CLSI Document

Activity	Responsible Party	Duration
Hold inaugural DDC meeting.	DDC	Up to 2 days
Develop Committee Draft.	DDC	7 months
Finalize Committee Draft.	DDC	7 months
Prepare Proposed Draft	CLSI staff	2 months
Conduct Proposed Draft review and vote.	DDC, CLSI Delegates, ExP, BOD, general public	45 days
Respond to comments received on Proposed Draft and revise draft as needed.	DDC	4 months
Prepare Final Draft.	DDC chairholders; CLSI staff	1 month
Conduct Final Draft vote to verify conformance to the Consensus Document Development Process.	Consensus Council	1 month
Complete document design and layout.	DDC chairholders; CLSI staff	1 month
Publish document.	CLSI staff	1 month
Total		**25.5months**

Abbreviations: BOD, Board of Directors; DDC, document development committee; ExP, expert panel.

8.6.1 Committee Draft Development for New and Revised Documents

A CLSI document's value is reflected in the accuracy of contents, quality of writing, and practical application of the information contained. The DDC is responsible for producing a new or revised draft document that has all of the following attributes:

- Complete—with respect to the content outline or flow chart approved in the project proposal

- Correct—with accurate technical content, accurately stated reflections of requirements vs guidance, and referenced facts

- Current—with respect to the available level of information

- Compliant—with the writing requirements provided in CLSI writing instructions

The DDC is required to follow the guidance established in the most current edition of CLSI's *Essential Instructions for Writing CLSI Documents*. These instructions set requirements for document attributes such as sentence structure, terminology use (because many CLSI documents are translated into different languages), reference citations, and use of figures and tables.

The DDC members should be involved in editing during document drafting. The project manager works as co-leader with the chairholder and vice-chairholder to ensure the draft document conforms to the CLSI requirements for format and writing style as the document is assembled from the technical writing assignments of committee members.

Contributions made to documents must not knowingly infringe on the copyright or any other right of any third party. Material taken from copyrighted information must be properly referenced. DDC writers are responsible for providing complete and accurate references. Permission from the publisher is needed for use of any published figures, tables, or text excerpts; CLSI editors obtain needed permissions.

8.6.2 Implied Endorsement

CLSI documents do not endorse, either directly or implicitly, any specific commercial products, companies, organizations, or contributing persons. Therefore, trade, company, organizational, or personal names are not used in a document. The use of one or a few vendor's products (such as by inclusion in example tables, figures, or forms) is not permitted, as it implies endorsement. Acknowledging an organization as the source of an example, form, or other user aid is also not permitted because inclusion could be construed as implying endorsement of that organization as an example of best practice. Any recommendations, examples, forms, or other user aids must be presented in a generic form based on consensus scientific principles or best practices. Only very rare exceptions are granted to the Endorsement Policy; exceptions must have Consensus Council preapproval before a Proposed Draft document is submitted for voting.

8.6.3 Regulatory References

Terms or regulations of a specific country are not permitted as the sole justification for a recommendation in a CLSI document.[a] Recommendations or examples are expected to be based on consensus scientific principles or published best practices, allowing for a globally applicable document. Information in a document that is consistent with regulatory or accreditation

[a] Examples of 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 & Medicaid Services," and "Clinical Laboratory Improvement Amendments."

requirements in several countries or regions can be used with appropriately cited references. An exception can be granted when a US-centric document is intentionally developed for specific purposes and although globally applicable, is very US focused; such exceptions are authorized by the Consensus Council when the project is approved.

8.6.4 Drafts of Documents in Development

The project manager assembles the Committee Draft from the DDC/SC/WG writers' contributions. The DDC chairholder and project manager edit the Committee Draft into a cohesive sequence and uniform style. CLSI staff circulates each draft to the DDC. Each circulated draft is identified as an internal CLSI document, with each page clearly marked "Draft," and a title and a code assigned by the CLSI office. **Draft documents are owned by CLSI and cannot be used by DDC members, secretaries, contributors, or advisors for any purpose other than review and comment.**

The following legend is prominently printed on each page of a draft consensus document:

> **"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."**

8.6.5 Review and Comment on Committee Draft

The DDC reviews the Committee Draft and submits comments on the provided comment table. The DDC responds to any technical or substantive issues. The project manager makes editorial changes and revises the text per the comment resolutions.

The actions above can be repeated as needed. The DDC is responsible for delivering a Committee Draft that is appropriately sequential, technically sound, accurate, understandable, and ready to advance to Proposed Draft.

8.7 Proposed Draft Prepared for Voting

The CLSI project manager and editors prepare the draft document for Proposed Draft voting. Other materials related to voting, such as the comment table, are also readied. The Proposed Draft is submitted for vote to the DDC members and the CLSI delegates. The document is also made available for concurrent review by the appropriate ExP, the Consensus Council, the Board of Directors, and the general public.

In addition to the legend described in Subchapter 8.6.4, all Proposed Draft documents bear a watermark on each page. The watermark reads, "DRAFT Not to be used for clinical purposes or to satisfy regulatory or accreditation requirements."

8.8 Proposed Draft Vote and Comment

CLSI posts a notice of the Proposed Draft document title, description, and voting period on its website. A ballot and commenting tool are issued to voting members of the DDC and the CLSI membership. For those not eligible to vote, the commenting tool is made available.

8.8.1 Proposed Draft Voting and Commenting Period

The closing date for voting on the Proposed Draft and for submitting comments is specified on the ballot and officially ends at midnight Eastern (US) Time on the date specified.

Comments and ballots are collected electronically during a 45-day review and comment period. Any ballot received after the voting deadline is not counted in the voting results.

Comments received after the commenting deadline are managed as described in Subchapter 8.9.2.

8.8.2 Proposed Draft Document Review During the Voting Period

DDC members and the ExP are expected to thoroughly review the Proposed Draft, consisting of a line-by-line review of scope, approach, utility, and technical and editorial content, providing comments as appropriate. The DDC and ExP review needs to ensure the overall quality, utility, and readability of CLSI consensus documents and that they are technically correct.

CLSI delegates, the Board of Directors, the Consensus Council, and the general public are invited to review and submit comments.

Subject matter experts can be selected by the DDC as special reviewers who provide an independent review of a consensus document as needed. These reviewers may be asked to provide a theoretical analysis or a practical, in-use test of a document when that analysis or test may need special facilities or expertise. Neither membership in CLSI nor any fees are required for agreeing to participate when selected as a CLSI special reviewer.

Availability of the Proposed Draft documents for review by nonmembers is announced on CLSI's website.

8.8.3 Document Development Committee and Expert Panel Vote on the Proposed Draft

Each DDC and ExP member casts a vote on the Proposed Draft; the voting choices are approve, approve with comment, reject, or abstain.

Conditions for approval to advance the Proposed Draft are:

- One member from each of the three constituencies must vote affirmatively.
- Two-thirds majority of the DDC's votes must be affirmative.

Two-thirds majority of the ExP's votes must be affirmative.

8.8.4 Delegate Vote on the Proposed Draft

Each CLSI member organization's duly named delegate has the authority to vote, if desired. In the absence of a member organization delegate's vote, the alternate delegate vote is counted. When a two-thirds majority of votes cast (excluding abstentions) for approval is obtained from CLSI members, along with the required DDC votes, the document can advance to Final Draft.

When two-thirds or greater of the votes cast from a constituency are to reject the Proposed Draft, the Consensus Council decides the course of action.

8.8.5 Rejected Proposed Draft

A Proposed Draft document that does not achieve the required DDC and delegate voting majorities is considered rejected. The rejected Proposed Draft and all comments, including those supporting reject votes, are forwarded to the appropriate DDC for consideration and resolution. The DDC, in consultation with the Consensus Council, decides whether to rework the document and resubmit it for a new voting and commenting period or cancel the project.

8.9 Action on Received Proposed Draft Comments

8.9.1 Proposed Draft Comment Compilation

After the 45-day voting and commenting period has expired, the project manager compiles all comments into a single file. The comment file identifies the consensus document under review, the commenter's name and affiliation, and the date received in the CLSI office. The comment file is sent to the DDC chairholder and vice-chairholder for follow-up action.

8.9.2 Proposed Draft Comment Responses

The DDC takes timely action on comments received, usually within 60 days of receiving the comment file from the project manager. Comment responses may be prepared at a meeting, electronically, or by phone; the DDC chairholder and vice-chairholder can choose whether to prepare comment responses with their entire group, delegate comment responses to the appropriate DDC writing group(s), or draft proposed comment responses for review (and any needed discussion) by the entire group.

A response to each comment is prepared by the DDC. The chairholder may authorize the project manager to resolve simple editorial issues. An adequate response must:

- Be specific to each question or comment.
- Include specific support information, if needed, for each question or comment.
- Include a rationale for why the change offered by the commenter was not made.

Each DDC member must participate in the review of and response to all comments. The DDC must achieve consensus on the proposed responses. When there is undue delay in completing responses to all the comments, the Consensus Council may restructure the DDC or cancel the project.

Comments received after close of the Proposed Draft review and balloting period are reviewed by the DDC, which makes a determination whether to address the comments in the Proposed

Draft or hold them until the next revision. In the event that late comments raise substantive issues on the Proposed Draft's content, the Consensus Council may authorize a delay in document publication until appropriate action is taken.

8.9.3 Comment Responses Provided to Commenters

All commenters are provided with responses to their comments and notification of their right to appeal. The commenter may request a revised Proposed Draft from the project manager that incorporates all changes made from the comment resolutions. Commenters are given 15 days to acknowledge receipt of the comment resolutions and/or exercise their right to appeal (see Chapter 9). When no response is received from a commenter, it is assumed that the commenter accepts the revisions and is notified accordingly.

The Consensus Council, at its discretion, may cancel any project and/or disband a DDC in the event it determines that consensus in resolving Proposed Draft comments cannot be achieved.

8.9.4 Records of Proposed Draft Votes, Comments, and Comment Responses

The CLSI office maintains all of the following records for the Proposed Draft:

- Formal votes cast by the DDC and delegates
- All comments received
- All comment responses
- Any objections to the comment responses
- Resolution to any objections
- Notice by DDC member, delegate, or commenter invoking the Appeal Process

8.10 Final Draft Review and Vote

8.10.1 Final Draft Preparation

The DDC and project manager revise the Proposed Draft as appropriate based on the comment responses. The CLSI project manager and editors prepare the document as the Final Draft.

8.10.2 Consensus Council Vote on 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

The objective of this review is to ensure there has been a satisfactory and adequate response to all comments before the Final Draft is advanced for publication.

Consensus Council members submit any questions to the Consensus Council's CLSI staff member. The staff member answers any process questions and refers any technical questions to the

relevant DDC. Conference calls or other means of communication between the Consensus Council and the DDC are conducted, when needed.

Consensus Council members vote on the Final Draft document.

The Consensus Council vote:

- Represents its members' assessment of whether or not the CLSI Consensus Document Development Process was followed to produce the Final Draft

- Certifies that consensus was reached on a consensus standard or guideline

All of the following are required for approval to advance the Final Draft for publication:

- A quorum of 10 members is required to vote.

- One member from each of the three constituencies must vote affirmatively.

- Two-thirds majority of the Consensus Council's votes must be affirmative (ie, a minimum of seven).

When the Consensus Council has its own substantive comments or determines that Proposed Draft comments were not adequately resolved, the document is returned to the DDC to resolve the Consensus Council's concerns. The Consensus Council determines whether or not the DDC's responses to Consensus Council comments and concerns have substantially changed the document. **Significant changes to the Final Draft may trigger a new delegate and public review, voting, and commenting period.**

When the Consensus Council votes to reject a Final Draft document, no advancement of the document can be made unless the reasons for rejection are resolved. The Consensus Council revotes after resolution.

8.11 Publication Draft

The Publication Draft is a standard or guideline that has undergone Final Draft review and vote and has been approved by the Consensus Council for publication. The Publication Draft incorporates any revisions that reflect resolution of Final Draft comments. The Publication Draft is provided to the DDC chairholder for review.

Approved consensus documents are published.

8.11.1 Evidence of Compliance

Records that demonstrate compliance with the Consensus Document Development Process described in these SDPPs are retained in accordance with the CLSI Documents and Records Retention Policy. CLSI conducts periodic audits of selected records of consensus documents for adherence to the Consensus Document Development Process.

8.11.2 Document Development Committee Disbandment

A DDC is officially disbanded when the standard or guideline is published. Thank you letters are issued to the DDC, which conclude the project.

8.12 Special Considerations for Susceptibility Testing Documents

8.12.1 Development of Susceptibility Consensus Documents

CLSI's library of susceptibility testing documents are managed by three SCs, ie, the Subcommittees on Antimicrobial Susceptibility Testing, Antifungal Susceptibility Tests, and Veterinary Antimicrobial Susceptibility Testing.

When the need to develop or revise a susceptibility testing-related document is determined, the applicable SC submits a completed project proposal for each new or revised consensus standard or guideline. Approved consensus documents developed by an SC or WG follow the Consensus Document Development Process described in Subchapters 8.1 through 8.6.5 without deviation.

The Subcommittees on Antimicrobial Susceptibility Testing, Antifungal Susceptibility Tests, and Veterinary Antimicrobial Susceptibility Testing follow specific voting rules at their meetings, depending upon the number of voting members present. Per the voting rules, only SC members can vote; SC chairholders and vice-chairholders are considered nonvoting members.

WGs do not conduct formal votes. Proposed Drafts for consensus documents developed by WGs are voted on by the associated SC.

A person employed by a pharmaceutical company,[b] or a person (either self-employed or employed by a company) whose business model significantly depends on selling services to pharmaceutical companies to the extent that a conflict of interest might be reasonably perceived, is not permitted to be a voting member of an antimicrobial susceptibility testing and/or breakpoint-setting SC for humans. However, such a person is permitted to serve on an antimicrobial susceptibility testing and/or breakpoint-setting SC in a nonvoting capacity or on an antimicrobial susceptibility testing and/or breakpoint-setting WG.[c]

8.12.2 Development and Approval of Supplements

Supplements to published microbiology standards or guidelines support the scope, purpose, methodology, and performance of the associated approved consensus document by providing information that updates or refines its use.

Supplements are developed by WGs with review and comments by the applicable SC and its advisors. Due to the extremely detailed and technical nature of their contents, supplements

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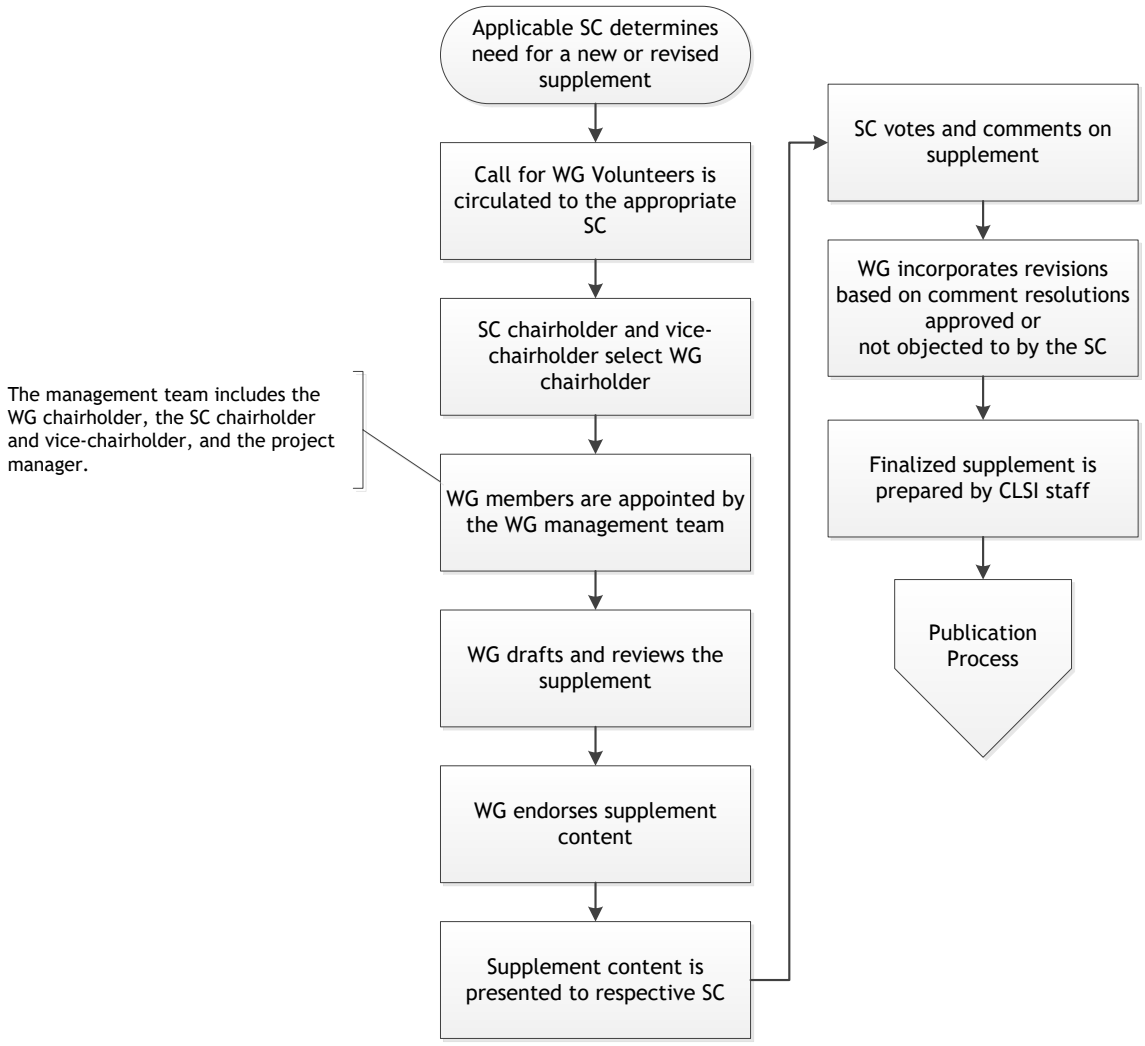
[b] For the purpose of this policy, a pharmaceutical company is defined as a company that discovers, develops, and/or sells antimicrobial drugs. Companies that engage in these activities are sometimes also identified as biotechnology companies.

[c] Note that the term "antimicrobial" in this context includes anti-infectious drugs, eg, antibacterials, antivirals, antifungals, and antiparasitics.

are developed through a process that has limited consensus following the process shown in Figure 4.



Abbreviations: SC, subcommittee; WG, working group.

Figure 4. Microbiology Supplement Development and Approval Process

Supplements are not submitted for general membership ballot.

8.13 Joint Documents

When appropriate, CLSI works cooperatively with other organizations to develop and publish jointly prepared documents. The provisions in the following subchapters apply.

8.13.1 Documents Developed by CLSI in Cooperation With Another Organization

CLSI staff informs the cooperating organization and invites their participation in proposed new document development projects.

The cooperating organization nominates DDC participants (at least one voting member and, if desired, one or two contributors). It pays the CLSI administrative fee (when the organization is

not a member of CLSI) and the travel expenses of appointed DDC representatives, unless otherwise agreed upon in writing by CLSI and the cooperating organization.
CLSI appoints all additional DDC members following the process for establishing DDCs and develops the consensus document according to the Consensus Document Development Process and timelines in these SDPPs.

The cooperating organization's DDC representatives are responsible for obtaining the organization's input and comment during the Consensus Document Development Process, voting on the Proposed Draft document, and participating in comment resolution.

The approved CLSI document is published by CLSI to include both the CLSI and cooperating organization logos.

8.13.2 Documents Developed by Other Organizations With CLSI Participation

The cooperating organization informs CLSI and invites their participation in its proposed new project. Participation by at least one representative of each CLSI constituency is encouraged.

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

The Consensus Council nominates a voting member to represent CLSI on the cooperating organization's committee.

CLSI pays the travel expenses of its representative(s) when he or she is eligible for reimbursement under the CLSI Volunteer Reimbursement Policy.

The designated CLSI voting member can request the CLSI ExP to review and comment on the cooperating organization's draft document.

Upon the recommendation of the CLSI representative(s) and the ExP, the Consensus Council votes on the cooperating organization's final draft document during the final vote conducted by the cooperating organization. The Consensus Council retains the right to also review any comments and comment resolutions received and prepared by the cooperating organization. See Subchapter 8.10.12 for Consensus Council voting rules.

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

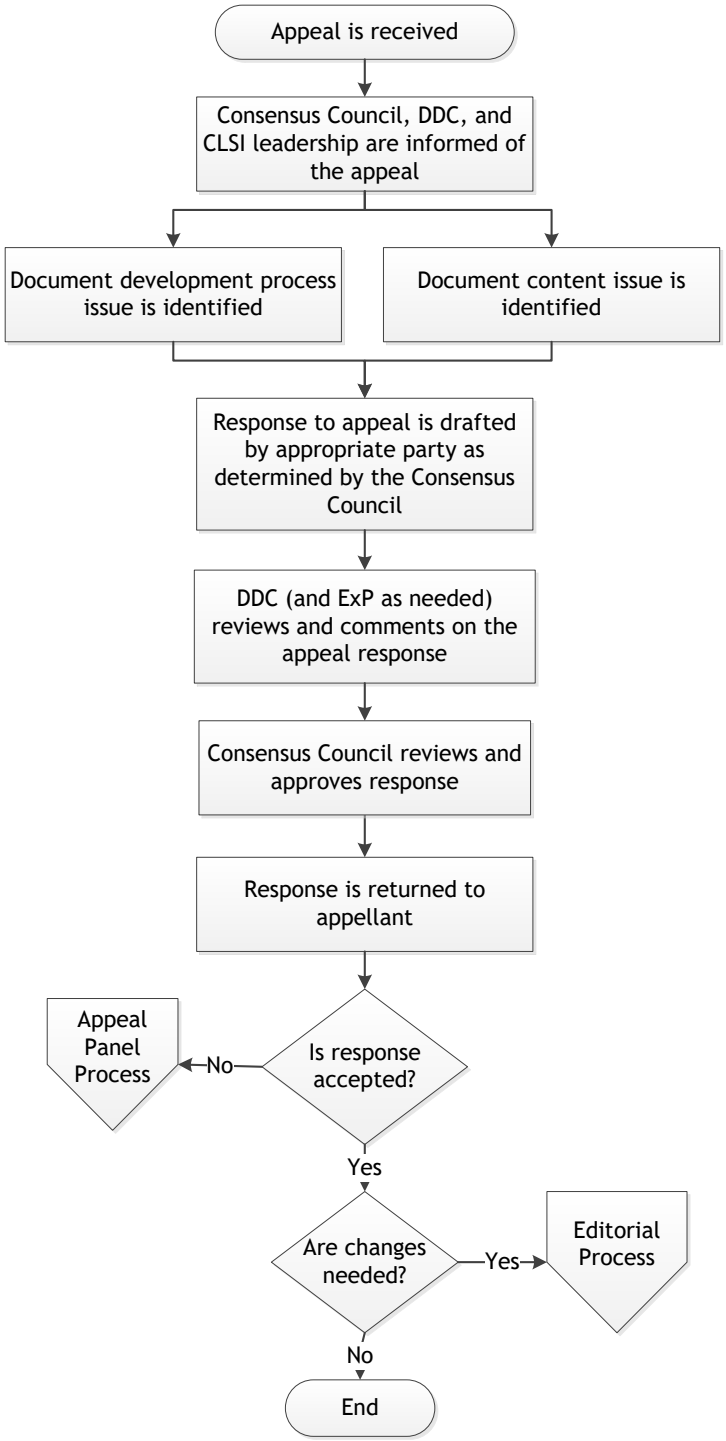
Chapter 9: The Appeal Process

The CLSI Consensus Document Development Process includes the Appeal Process (see Figure 5).

Any member or organization who believes they are or will be 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 Document Development Process or by substantive or procedural actions taken in the development, revision, reaffirmation, archiving or withdrawal of a CLSI Consensus Document Development Process may appeal to the CLSI Chief Executive Officer—in writing or by electronic communication—within 15 days of being informed of the committee's decision. Notice of the Appeal Process is provided with the comment/response summary provided to each commenter on new and revised documents.

The Appeal Process provides for participation by all parties concerned without imposing an undue burden on them. The burden of proof is on the appellant.

Figure 5 shows the flow of the Appeal Process.



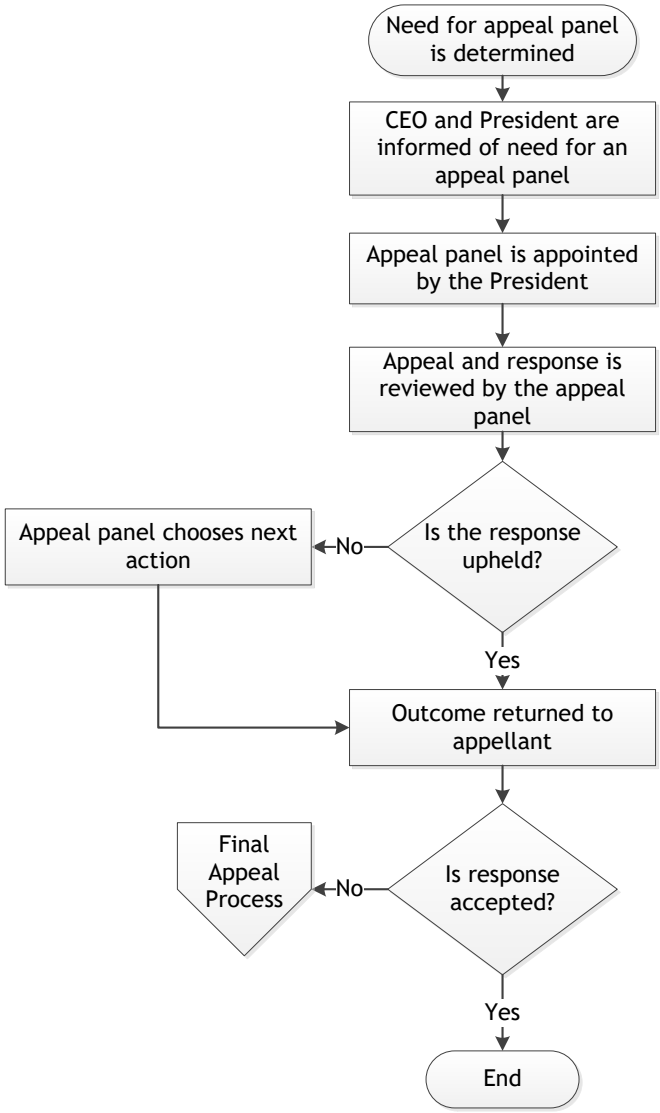
Abbreviations: DDC, document development committee; ExP, expert panel.

Figure 5. Appeal Process

9.1 Appeal Panel Process

Any CLSI Consensus Council action related to the document involved in 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 appeal.

When the objection remains unresolved, a CLSI appeal 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, the appeal panel hears the appeal on a date 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. Figure 6 show the process for arbitrating unresolved objections through an appeal panel.



Abbreviation: CEO, chief executive officer.

Figure 6. Appeal Panel Process

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

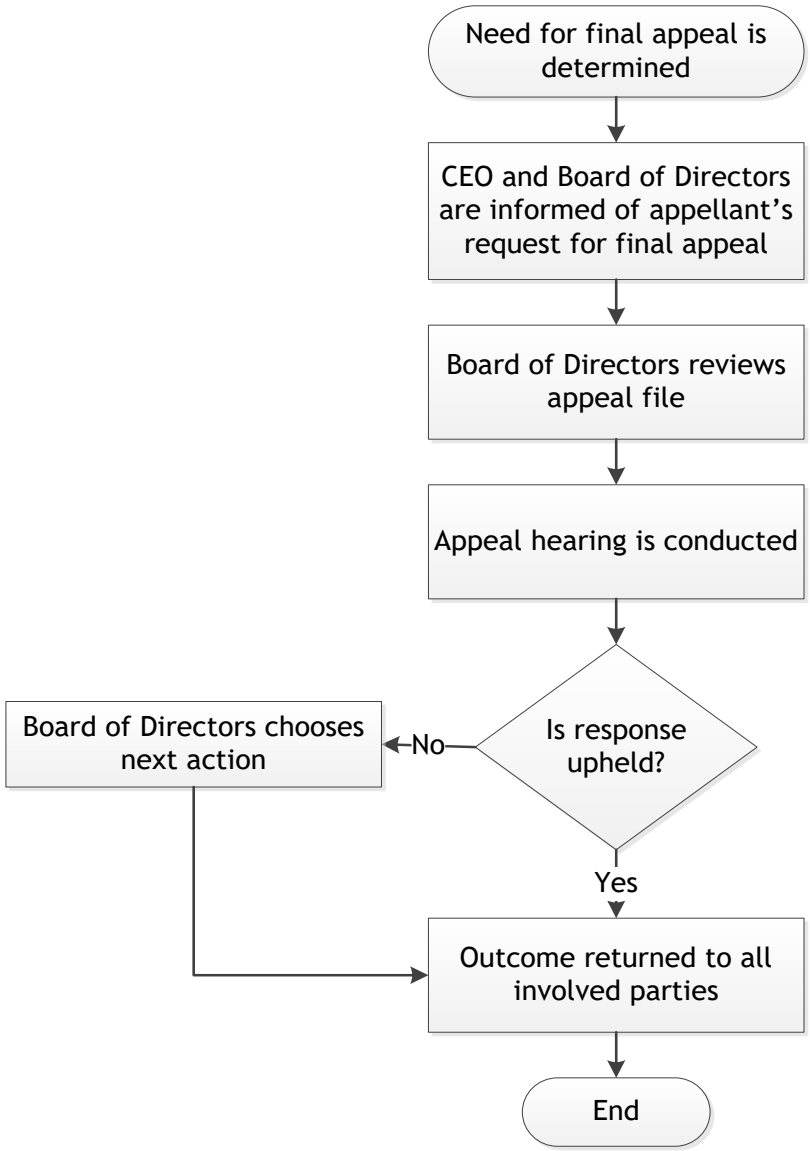
CLSI promptly notifies the appellant in writing of all results of the Appeal Panel Process.

9.2 Final Appeal Process

When the appellant does not accept the results of the Appeal Panel Process, he or she may pursue a final appeal with the CLSI Board of Directors by filing in writing with the CLSI chief executive officer within 30 days of being informed of the appeal panel decision. The final appeal needs to include a statement as to why the appellant feels the appeal panel decision should be modified.

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

The chief executive officer notifies the appellant, the appeal panel chairholder, the Consensus Council, the DDC chairholder as applicable, and the affected ExP chairholder of the Board's decision on whether it will hear the appeal. When the Board agrees to hear the appeal, the appellant, the appeal panel chairholder, the Consensus Council chairholder, and the affected ExP 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. Figure 7 depicts the Final Appeal Process.



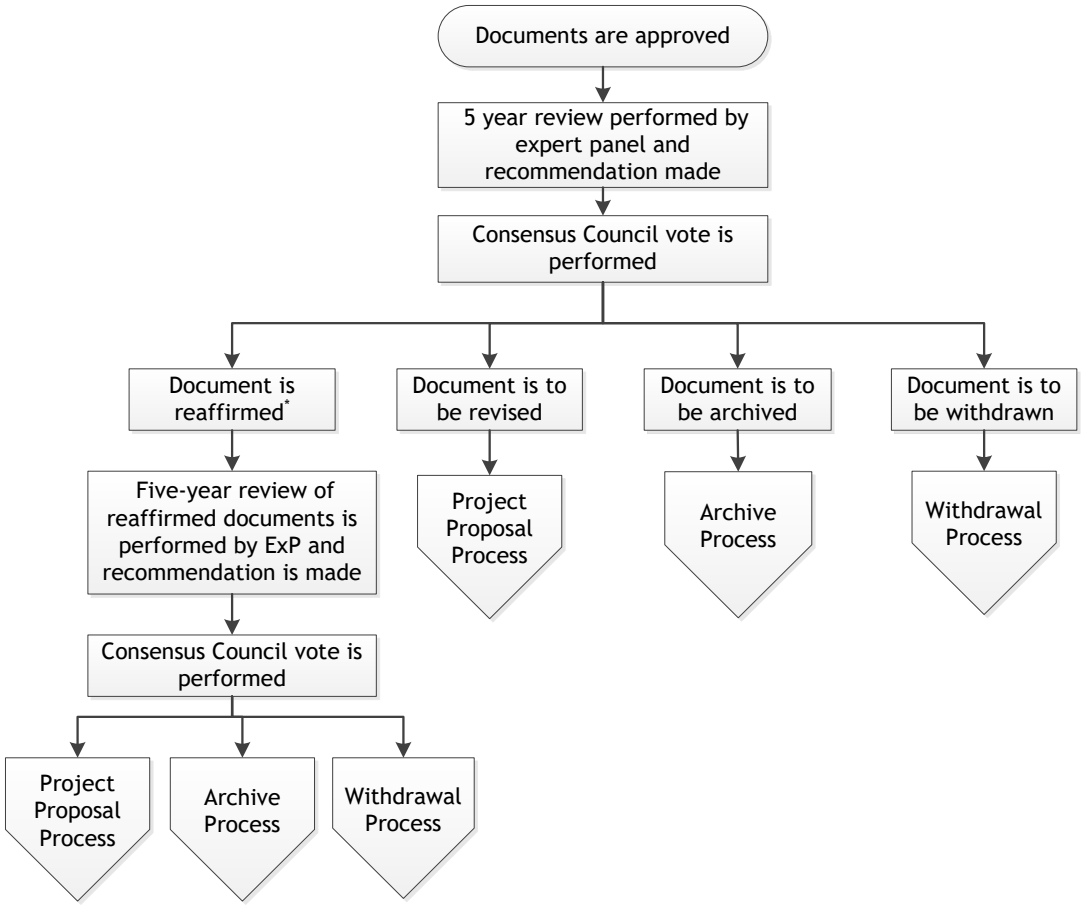
Abbreviation: CEO, chief executive officer.

Figure 7. Final Appeal Process

Having heard the appeal, the Board of Directors may reverse the appeal panel's action by a majority vote. When less than a majority is in favor of reversal, the appeal panel action is sustained. CLSI promptly notifies the appellant, the appeal panel chairholder, and the affected ExP chairholder in writing of its decision.

Chapter 10: Scheduled Review of Approved Consensus Documents

All approved consensus documents undergo periodic review. Figure 8 depicts the Five-Year Review Process.



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

Figure 8. Five-Year Review Process

10.1 Assignment to the Expert Panel

Four years after publication, the project manager informs the appropriate ExP(s) of the need to review a current document. The ExP considers:

- Any comments received after publication
- Any new information or changes in technology that should be included
- Whether the existing document is globally applicable and whether that aspect is adequately reflected in the current document

After the review, the ExP recommends to the Consensus Council to reaffirm, revise, withdraw, or archive an approved consensus document.

10.2 Reaffirmation of an Approved Consensus Document

Reaffirmation is chosen when the existing document meets all of the following requirements:

- The document continues to adequately reflect the current state of the art.
- The document's content is technically correct despite advances potentially having been made.
- Substantive changes are not needed for effective use of the document at the time of review.

10.2.1 Expert Panel Decision on Reaffirmation

In conformance with the Five-Year Review Process (see Figure 8), the ExP recommends reaffirmation to the Consensus Council through completion and submission of the Five-Year Review Form. CLSI staff records the ExP's review and retains any comments on file.

10.2.2 Consensus Council Decision on Reaffirmation

Reaffirmation on CLSI documents may be presented during a Consensus Council meeting or be formally distributed for a 10-day Consensus Council vote and approval for publication as a "reaffirmed consensus document."

See Subchapter 8.10.12 for Consensus Council voting rules.

The disposition record of Consensus Council member comments and voting is documented by CLSI staff. The reaffirmation is considered as approval for continued publication.

10.2.3 Publication of Reaffirmed Consensus Documents

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

10.3 Revision of an Approved Consensus Document

Revision is chosen when any changes in the consensus document are needed. The ExP creates or solicits the creation of a completed project proposal for revising the existing document.

CLSI staff records the ExP's review and retains any comments on file. The ExP recommends revision to the Consensus Council through completion and submission of the Five-Year Review Form.

10.3.1 Consensus Council Action on Revisions

Consensus document revisions follow the process described in Chapter 8.

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

10.3.2 Process for Continual Revision of a Supplement

A recommendation for continual revision of a supplement is based on the DDC, SC, WG, or ExP's assessment that ongoing development of new information or refinement of existing information requires that an approved CLSI supplement needs periodic updating before its scheduled review. The new information needs to be 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.

The following conditions must be met to recommend continual revision of a consensus document supplement to accommodate new information:

- Two-thirds majority (abstentions excluded) of the DDC, SC, WG, or ExP members approve continual revision, after satisfactory review of the new information.

- At least one representative of each constituency's membership approves continual revision, after reviewing the DDC, SC, WG, or ExP's action.

- The Consensus Council agrees with implementing continual revision of the supplement.

Information contained in supplements supersedes previously published information.

Supplements are published and made available through established CLSI processes for distributing consensus documents.

10.4 Consolidating or Dividing Approved Consensus Documents

Anyone can recommend consolidating a consensus document with one or more closely related consensus documents or dividing a document that is better presented in parts. The ExP creates or solicits the creation of a completed Project Proposal Form for consolidating or dividing a document.

Consolidation or division of consensus documents follows the process described in Chapter 8.

10.5 Withdrawal of an Approved Consensus Document

A recommendation for withdrawal of a consensus document can come from any of the following sources:

- Any group involved in the Consensus Document Development Process
- Users
- CLSI staff

A consensus document can be withdrawn at any point in the Consensus Document Development Process or after consensus approval is achieved, based on information that it is invalid, obsolete, or otherwise no longer needed in CLSI's active document portfolio. Reasons for withdrawal of a consensus document may include:

- The document is not technically correct.
- The document has low interest.

- The document was incorporated into another document.

CLSI staff records the ExP's review and retains any comments on file. The ExP recommends withdrawal to the Consensus Council through completion and submission of the Five-Year Review Form.

A consensus document is withdrawn by the Consensus Council when a situation needs expedited action. (See Subchapter 8.10.2 for Consensus Council voting rules.)

Notices of withdrawal are published by the CLSI office.

CLSI staff notifies ANSI when a withdrawn consensus document is also an American National Standard (ANS).

Records of decisions to withdraw a consensus document are retained for at least five years from the date of withdrawal.

10.6 Archiving an Approved Consensus Document

During the scheduled review period, the ExP may recommend archiving an approved document when the following conditions exist:

- The document is not recommended for revision, reaffirmation, or withdrawal.

- The document remains technically valid and is determined to not pose a safety risk when implemented.

Documents that are cited and/or recognized by regulatory and/or accreditation organizations are eligible for archiving.

Documents that are approved as ANS are not eligible for archiving.

CLSI staff records the ExP's review and retains any comments on file. The ExP recommends archiving to the Consensus Council through completion and submission of the Five-Year Review Form.

The Consensus Council votes on the ExP's recommendation. A consensus document is archived by the Consensus Council. (See Subchapter 8.10.2 for Consensus Council voting rules.)

An annotation is placed in the document to inform users that the document is no longer reviewed through the CLSI Consensus Document Development Process. The annotation reads,

"This archived document is no longer being reviewed through the CLSI Consensus Document Development Process. However, this document is technically valid as of [date archived]. Because of its value to the laboratory community, it is being retained in CLSI's library."

Archived documents do not undergo periodic review.

Chapter 11: Derivative and Educational Products

Derivative and educational products content is excerpted with or without modification from the standard(s), guideline(s), white paper(s), and/or report(s) on which it is based.

Standards and guidelines are developed through the Consensus Document Development Process whereas, reports, white papers, and derivative and educational products are developed and approved through other specified processes outlined in Appendix A. Details about the development and approval of reports, white papers, and derivative and educational products are outside the scope of the *Standards Development Policies and Processes*; however, a high-level overview of the processes and comparison with the Consensus Document Development Process is provided for completeness.

NOTE: A supplement is not a derivative product. See Subchapter 8.12 for details on supplements.
Descriptions and examples of CLSI products are outlined in Tables 10 and 11.

Table 10. Descriptions of CLSI Products

Product Type	Description
Standard	• Identifies specific, essential requirements for materials, methods, or practices for voluntary use in an unmodified form • May also contain discretionary elements, which are clearly identified
Guideline	• Describes criteria and recommendations for a general operating practice, method, or material for voluntary use • Can be used as written or modified by the user to fit specific needs
White paper	• Informs readers about new and emerging laboratory information
Report	• Summarizes factual information without providing specific recommendations
Derivative products (eg, quick guides, templates, handbooks, checklists, implementation guides, workbooks, software)	• Derived from or based on existing CLSI standards and/or guidelines • Contains technical content taken directly or derived from published CLSI consensus documents • May include simplified information to assist users in implementing the consensus document • May expand on information contained in a consensus document
Educational products (eg, videos, educational audioconferences, webinars, online learning programs)	• Derived from or based on existing CLSI standards and/or guidelines • Designed and organized to achieve predetermined learning objectives • Contains technical content taken directly or derived from published CLSI consensus documents • May expand on information contained in a consensus document

Table 11. Examples of CLSI Products

Product Type	Example (CLSI Product Code)
Standard	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeast (M27)
Guideline	Evaluation of Linearity of Quantitative Measurement Procedures (EP06)
White paper	Use of Glucose Meters for Critically Ill Patients (POCT17)
Report	Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities (I/LA20)
Derivative Products	
Quick guides	Quality Venipuncture Quick Guide (GP41QG)
Templates	Instrument Selection Worksheet (POCT09AWS)
Checklists	Gap Analysis Checklists (QMS01CL)
Workbooks	Laboratory Quality Control Based on Risk Management; Workbook (EP23AWB)
Educational Products	
Video	Making a Difference Through Newborn Screening: Blood Collection on Filter Paper (NBS01A6DVD)
Educational audioconferences	Setting up the Clinical Laboratory: What to Think About Before You Start (CLIA2WR)
Webinar	What's New in VET01S Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals (On-Demand VET01S Webinar)
Online learning program	Cost of Quality (COQOL)

Chapter 12: Review and Comment on Documents Developed by an Organization Other Than CLSI

12.1 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 for review and comment of the draft of a document developed by an organization other than CLSI.

The document's content determines distribution, which could be to:

- All CLSI member organizations and individual members
- Individual organizations selected through the CLSI interest inventory database
- Relevant CLSI committees or chairholders
- Individual volunteers identified as experts in the subject area

In all cases, the review process involves appropriate representation from each CLSI constituency, with a minimum of three reviewers.

12.2 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. (**NOTE:** A decision to prepare a summary is significant because of needed CLSI resources but is appropriate when the document under review is of broad significance. Having made a decision to prepare a summary, CLSI can decide to submit individual comments instead but should not do the reverse.) CLSI staff obtains representative input from the affected CLSI constituencies before deciding whether to prepare a summary, except when it is not feasible to do so because of the limited time available.

12.3 Document Review

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

12.4 Comments

After the comment deadline, CLSI staff submits the input received as a collection of individual comments from interested parties and requests a copy of the final comment resolutions and document changes.

The final comment resolutions and revised document are provided to commenters for their information.

Chapter 13: Submission of CLSI Consensus Standards to the American National Standards Institute

Based on a request and justification from a DDC or ExP, the Consensus Council may recommend to the Board of Directors that a CLSI standard be adopted as an ANS.

The criteria that need to be applied when considering a CLSI document for adoption as an ANS are:

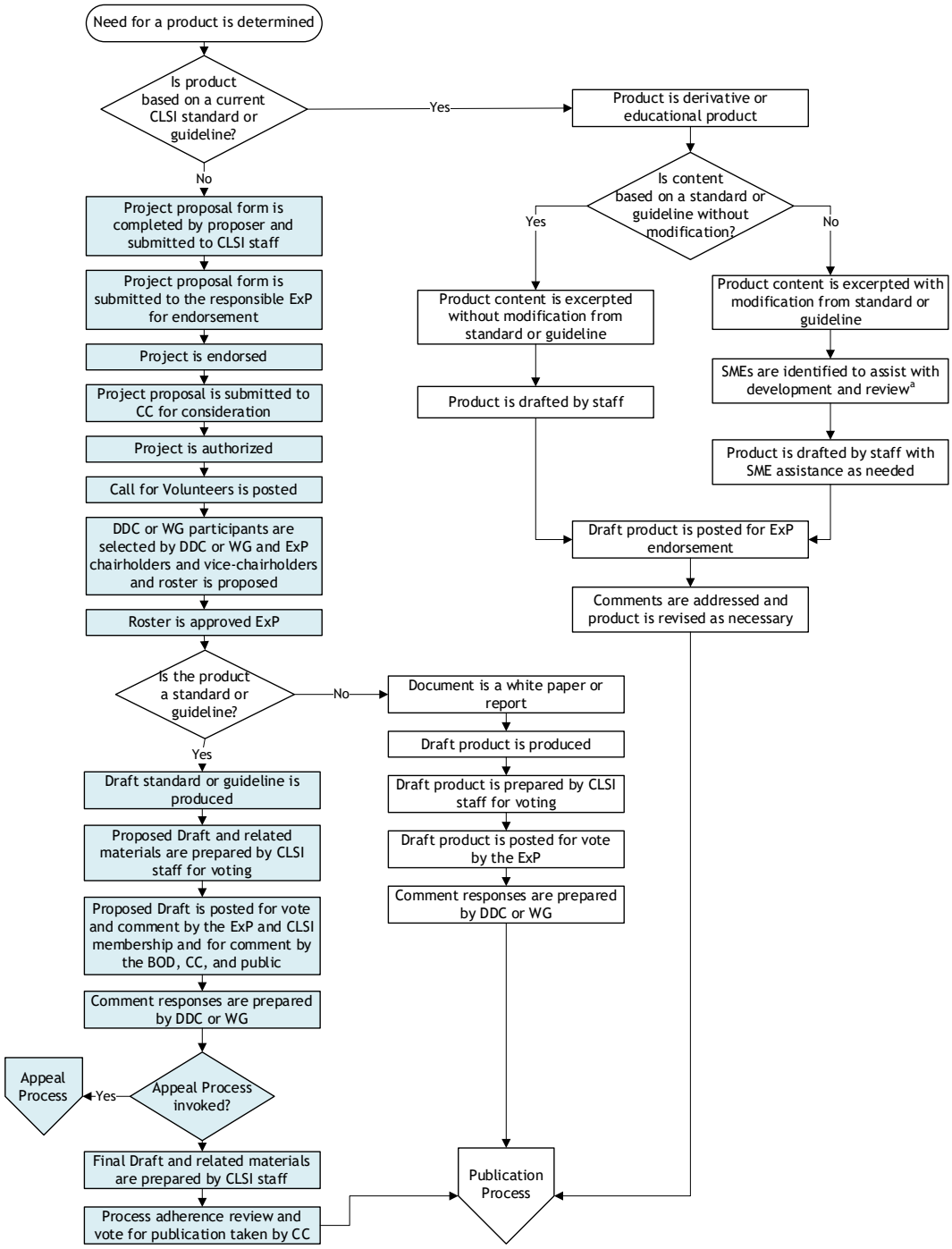
- The document is a standard, not a guideline.
- The standard is US-centric.
- The standard has little or no global applicability.

The decision to create an ANS can be made at any point in the Consensus Document Development Process. When this decision is made, notification is provided to ANSI.

Submission of a CLSI standard to become an ANS follows the ANSI-specified process (see Appendix B). For additional information on ANS adoption, refer to the *ANSI Essential Requirements: Due process requirements for American National Standards,* available on the ANSI website (www.ansi.org).

Appendix A. Overview of the Development and Approval Processes for CLSI Products

NOTE: In this figure, Consensus Document Development activities are highlighted.



[a] Subject matter experts from the DDC or WG that developed the standard or guideline on which the product is based are identified and asked to assist with product development and review if needed.

Abbreviations: CC, Consensus Council; DDC, document development committee; ExP, expert panel; SMEs, subject matter experts.

Appendix B. Development or Revision of a CLSI Document as an American National Standard

ANS American National Standard
ANSI American National Standards Institute
BSR Board of Standards Review
IEC International Electrotechnical Commission
ISO International Organization for Standardization
JTC Joint Technical Committee

The processes for development or revision of a CLSI standard as an American National Standard (ANS) are described in the sections that follow.

NOTE: Applicable ANS forms can be accessed on ANSI's website (www.ansi.org).

B.1 Notification of Standards Development or Revision

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 processes.

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:

- An explanation of the need for the project including a statement of intent to submit the standard for consideration as an International Organization for Standardization (ISO) or ISO/International Electrotechnical Commission Joint Technical Committee 1 (ISO/IEC JTC-1) standard

- Identification of the interest groups likely to be directly affected (**NOTE:** If these interest groups change during development of the standard, a revised PINS form is submitted.)

When CLSI receives written comments within 30 days from the publication date of a PINS announcement in ANSI's *Standards Action,* and the comments assert that a proposed standard duplicates or conflicts with an existing ANS or a candidate ANS that has been previously announced 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.

B.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 include—at minimum—compliance with all relevant sections of the *ANSI Essential Requirements: Due process requirements for American National Standards*.

B.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.

For any CLSI documents submitted for approval as *American National Standards*, CLSI agrees to comply with the most current version of the ANSI Patent Policy (clause 3.1 of the *ANSI Essential Requirements*).

B.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.

B.5 Evidence of Consensus and Consensus Council Vote

Consensus is determined per the voting process described in Chapter 8 of CLSI's *Standards Development Policies and Processes*.

- 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 need to be 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.

B.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.

B.7 Designation of ANS American 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).

B.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."

B.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.

B.10 Periodic Maintenance of American National Standards

Within five years after its approval, the appropriate expert panel(s) completes a review to recommend the consensus Council reaffirms, revises, withdraws, or archives an approved ANS. When action is not taken under periodic maintenance to reaffirm, revise, withdraw, or archive within five years of approval of an ANS, 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.

Revision History

Revision Date	Description of Change(s)
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 Appeal 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.
September 2017	• Separated standards development policies from related processes. • Included process flow charts for Consensus Document Development Process, Supplement Development Process, Appeal Process, Derivative Product Development Process.
June 2020	• Incorporated roles and responsibilities of Consensus Council Emeritus Member position.
July 2021	• Clarified Derivative Products Process.
January 2022	• Incorporated Board-approved policy changes (ie, expert panel responsibilities to reflect process improvement project recommendations.
April 2022	• Removed Expert Panel Liaison role from Consensus Council's responsibilities; clarified that project managers serve as the communication conduit between the expert panels and Consensus Council • Added the Limited Revision Process

Abbreviation: ANSI, American National Standards Institute

NOTES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