Standards Development Policies and Processes

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

Document #/Version #: S-001/10.0 Effective Date: 29 May 2026

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 Consensus Council, expert panels, document development committees, document review working group, subcommittees, working groups, and ad hoc 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, supplements, 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 to 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 shall forward suggested policy revisions (Part A) to the Board of Directors for its consideration and action. Policy revisions are approved by the Board of Directors. Revisions shall be consistent with CLSI Bylaws and with American National Standards Institute (ANSI) accreditation requirements. The Consensus Council is responsible for approving revisions to the processes codified in these SDPPs (Part B).

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.

ad hoc working group (AHWG) - volunteer group that is typically a subunit of a working group and has an assignment limited in scope.

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 ExP 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.

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:** Consensus documents are categorized as active, reaffirmed, 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.

document review working group (DRWG) — volunteer group that has expert knowledge and experience in specific facets of expert panel's subject area and has responsibility for reviewing and recommending revisions to published documents (including limited revision); reviewing and assessing all comments received (ie, since publication and during the public comment period); developing recommendations for next action on published documents in their area of expertise; and, assisting with development of responses to comments submitted on revised documents.

due process - any party (organization, company, government agency, individual, etc.) with a direct and material interest has a right to participate by: a) expressing a position and its basis, b) having that position considered, and c) having the right to appeal.

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; **NOTE:** For purposes of voting on documents, the number of eligible voters on from one constituency on an expert panel cannot be greater than the number of eligible voters from the other two constituencies combined.

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.

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 regulatory, accreditation and/or

safety requirements; **NOTE 3:** Mandates may be indicative of a necessary step to ensure patient safety or proper fulfillment of a procedure.

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.

industry constituency — individuals employed by or retired from a manufacturing or trade organization.

reaffirmed document — a CLSI document that has been reviewed and confirmed as suitable to remain published without revision to content.

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

AHWG	ad hoc working group
ANS	American National Standards
ANSI	American National Standards Institute
BOD	Board of Directors
DDC	document development committee
DRWG	document review working group
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.

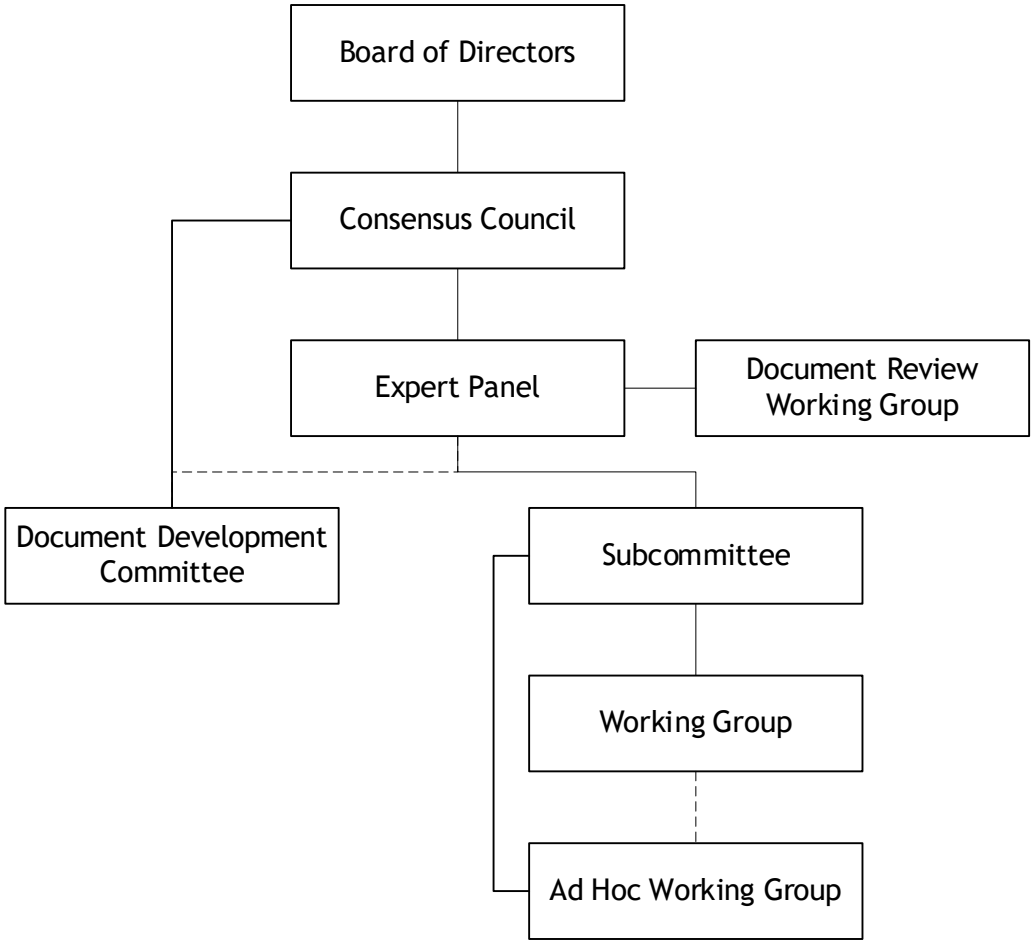


Figure 1. Relationships Between the Board of Directors and the Groups Responsible for Developing CLSI Documents and Products

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 review working group (DRWG), document development committee (DDC), subcommittee (SC), working group (WG), and ad hoc working group (AHWG) 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, secretary, 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, DRWGs, DDCs, SCs, WGs, and AHWGs 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, secretaries, 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 are categorized in one of three constituencies, ie, health care professions, government, or industry (see Subchapter 4.1 for constituency definitions).

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

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/their 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

5.4 Committee Constitution

Details regarding committee appointments are described in the following subchapters.

5.4.1 Committee Formation

Table 1 outlines responsibilities for committee formation.

Table 1. Committee Formation

Committee	Formation Approved by
CC	BOD
ExP	BOD with the advice of the CC
DRWG	ExP
DDC	CC
SC	BOD with the advice of the CC and the responsible ExP
WG	Responsible committee
AHWG	Responsible committee
Appeal panel	CC

Abbreviations: AHWG, ad hoc working group; BOD, Board of Directors; CC, Consensus Council; DDC, document development committee; DRWG, document review working group; ExP, expert panel; SC, subcommittee; WG, working group.

5.4.2 Committee Position Term Limits

Table 2 provides term limit information for each CLSI committee position.

Table 2. Committee Position Term Limits

CLSI Committee	Committee Position and Term Limits							
	Chairholder	Vice-chairholder	Secretary	Member	Emeritus member	Advisor	Contributor	Reviewer
CC	1*	1*		1	2, 6			
ExP	1*	1*		3		3, 6		
DRWG	4			4				
DDC	4	4	4, 6	4			4, 6	
SC	1*	1*	3, 6	3		3, 6		5, 6
WG	1*	1*	3, 6	3		3, 6		
AHWG	4	4		4		4, 6		

Abbreviations: AHWG, ad hoc working group; DDC, document development committee; DRWG, document review working group; CC, Consensus Council; ExP, expert panel; SC, subcommittee; WG, working group.

Key

1	• The position is appointed for a one-year term. • Individuals may continue in the appointed position for up to 4 years.
2	• The position is appointed for a one-year term. • Individuals may continue in the appointed position for up to 2 years.
3	• The position is appointed for a one-year term. • Individuals may continue in the appointed position for up to 6 years.
4	• The position is appointed for a specific purpose that has a beginning and an end. • Individuals serve in this position for the duration of the project.
5	• Individuals serve in this position until appointed to the committee in another capacity or removed by request.
6	• This is a non-voting position.

NOTE 1: All maximum timeframes listed assume the individual is able to continue to fulfill his or her duties and is reappointed by the appropriate committee (see Subchapter 5.4.3).

NOTE 2: No individual shall serve on the same committee in a voting role for more than 14 cumulative years. Years served do not need to be consecutive.

* When necessary for continuity, appointment may be extended for up to 2 years. Such extension shall not result in more than 14 cumulative years on the committee in a voting role.

5.4.3 Committee Appointments and Removals

Table 3 summarizes responsibilities for committee appointments and removals.

Table 3. Committee Appointments and Removals

Committee	Position	Appointment Approved by	Removal from Committee Approved by
CC	• Chairholder • Vice-chairholder	BOD	BOD
	• Member • Emeritus member	BOD	BOD with the advice of the CC leadership
ExP	• Chairholder • Vice-chairholder	CC	CC leadership
	• Member • Advisor	CC with the advice of ExP leadership	CC with the advice of ExP leadership
DRWG	• Chairholder • Member	ExP	ExP
DDC	• Chairholder • Vice-chairholder	CC	CC
	• Secretary	DDC leadership	DDC leadership
	• Member • Contributor	ExP leadership with the advice of DDC leadership	ExP leadership with the advice of DDC leadership
SC	• Chairholder • Vice-chairholder	ExP leadership	ExP leadership
	• Secretary	SC leadership	SC leadership
	• Member • Advisor • Reviewer	ExP leadership with advice of SC leadership	ExP leadership with advice of SC leadership
WG	• Chairholder • Vice-chairholder	SC leadership	SC leadership
	• Secretary • Member • Advisor	SC leadership with advice of WG leadership	SC leadership with advice of WG leadership
AHWG	• Chairholder	SC leadership with the advice of WG leadership	SC leadership with the advice of WG leadership
	• Member • Advisor	SC leadership with advice of AHWG leadership	SC leadership with advice of AHWG leadership

Abbreviations: AHWG, ad hoc working group; BOD, Board of Directors; CC, Consensus Council; DDC, document development committee; DRWG, document review working group; ExP, expert panel; SC, subcommittee; WG, working group.

5.4.4 Volunteer Participation Stipulations

Table 4 summarizes stipulations regarding a volunteer's participation on multiple CLSI committees.

Table 4. Volunteer Participation Stipulations

Position on	Nominated for a Position on	Decision
BOD	ExP, DRWG, DDC, SC, WG, AHWG	Permitted
CC	BOD	Not permitted with the exception of the President-Elect or Chairholder of CC
CC	ExP	Not permitted as a voting member May be excused from discussions at the discretion of CC leadership
CC	DRWG, DDC, SC, WG, AHWG	Permitted and must abstain from CC votes on related DRWG, DC, SC, WG, or AHWG matters May be excused from discussions at the discretion of CC leadership
ExP	DRWG, DDC, SC, WG, AHWG	Permitted

Abbreviations: AHWG, ad hoc working group; BOD, Board of Directors; CC, Consensus Council; DDC, document development committee; DRWG, document review working group; ExP, expert panel; SC, subcommittee; WG, working group.

A person employed by a pharmaceutical company,[a] 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.[b]

5.4.5 Committee Participation by Multiple Volunteers From the Same Member Organization

No more than two individuals from the same organization can serve on the same committee. These individuals must represent different divisions or departments, and justification must be provided and documented. Only one of those individuals can serve as a voting member. Reviewers are excluded.

[a] 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.

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

5.4.6 Committee Participant Limits

Table 5 shows the number of individuals by role permitted to participate on a committee.

Table 5. Committee Participant Limits

CLSI Committee	Number of Participants							
	Chairholder[a]	Vice-chairholder[a]	Secretary	Member[a, b]	Emeritus Member[b]	Advisor[b]	Contributor[b]	Reviewer
CC[c]	1[d]	1[d]		7	3[e]			
ExP	1	1		14		8		
DRWG	1			5 times the number of documents for review[f]				
DDC	1	1	1	12			12	
SC	1	1	1	14		28		No limit
WG	1	1	1	10		10		
AHWG	1	1		10		No limit		

[a] This is a voting position.
[b] This represents the maximum number of participants; fewer participants may be appointed. Committees are encouraged to base participation on the work to be done.
[c] The Consensus Council is required to be comprised of 7 members plus the chairholder and vice-chairholder (ie, a total of 9 eligible voting members).
[d] The chairholder and vice-chairholder shall not represent the same constituency.
[e] No more than one emeritus Consensus Council member from each constituency shall be represented.
[f] This is a suggested membership.

5.5 Voting Rules and Requirements

Voting rules and requirements are described in the subchapters below.

Rules and requirements for voting are provided in Tables 6 through 12. Information is presented by each committee's voting responsibilities. No one constituency shall have a simple majority on any given committee. Voting options at each stage are:

- Accept
- Accept with comments
- Reject with comments
- Abstain

Abstentions can be cast if the subject matter is not an area of interest and/or expertise for the eligible voter or in the case of conflict of interest.

Specific to the Subcommittee on Antimicrobial Susceptibility Testing and the Subcommittee on Antifungal Susceptibility Tests, a conflict of interest is any personal gain within 3 years or imminently expected as a result of working with a specific drug (occasionally might apply if did such work with direct competitor[s]). **NOTE:** Personal gains do not include payments only to

their institution or research funds. These need to be declared but do not require a declared abstention.

Voting is typically conducted electronically, however, because some topics (eg, proposals and appeals) require discussion, committees may conduct voting at meetings following their discussion provided a voting quorum is present.

In the case of the consensus body, ie, Consensus Council, all members have the opportunity to vote. When recorded votes are taken at meetings, members who are absent are given the opportunity to vote before or after the meeting.

Table 6. Consensus Council Voting in the Document Development Process

Process Stage	Project Proposal	Limited Revision	Final Draft	Appeal
Eligible Voters	• CC Chairholder • CC Vice-Chairholder • CC Members			
Conditions for Action	• Complete, comprehensive proposal submitted and deemed acceptable. • Responses to "thought questions" are complete and acceptable. • Chairholder and vice-chairholder nominations are submitted and acceptable for appointment.	• Complete, comprehensive proposal submitted and deemed acceptable. • Complete revisions marked in draft document. • Revisions meet the requirements for a limited revision. • Proposed revisions are needed.	• Confirm that the CLSI consensus process was followed, and the voting requirements were fulfilled. • Satisfactory and adequate response to all comments before the Final Draft is advanced for publication.	• Appeal panel is needed to arbitrate commenter concerns.
Action Requested	• {Document code} is authorized for development/ revision. • {Name} is appointed to serve as the DDC chairholder. • {Name} is appointed to serve as the DDC vice-chairholder.	• {Document code} revisions are authorized for public comment.	• {Document code} is approved for publication.	• The CC approves the appeal panel's response to commenter concerns raised on CLSI document {code}.
Voting Rules	• Two thirds of the CC eligible voters must vote affirmatively. • One member from each of the three constituencies must vote affirmatively.			

Abbreviations: CC, Consensus Council.

Table 7. Expert Panel Voting in the Document Development Process

Process Stage	Project Proposal	Limited Revision	Proposed Draft	Supplement
Eligible Voters	• ExP Chairholder • ExP Vice-Chairholder ExP Members			
Conditions for Action	• Proposal is practical, comprehensive, and complete. • Project fills an identified need.	• Complete revisions marked in draft document. • Revisions meet the requirements for a limited revision. • Proposed revisions are needed. • Revisions are accurate, practical, comprehensible, and useful.	• The document is scientifically accurate, practical, comprehensible, and exhibits overall quality and utility. • The document scope is consistent with that approved by the CC.	• The document is scientific-ally accurate, practical, comprehen-sible, and exhibits overall quality and utility.
Action Requested	• The proposal for development/ revision of {Document code} is endorsed by the ExP.	• {Document code} is approved for advancement in the consensus process.		• {Document code} is approved for advance-ment in the develop-ment process.
Voting Rules	• Two thirds of the ExP eligible voters must vote affirmatively.			

Abbreviations: CC, Consensus Council; ExP, Expert Panel.

Table 8. Document Development Committee Voting in the Document Development Process

Process Stage	Proposed Draft
Eligible Voters	• DDC Chairholder • DDC Vice-Chairholder • DDC Members
Conditions for Action	• The document is scientifically accurate, practical, comprehensive, and exhibits overall quality and utility. • The document scope is consistent with that approved by the CC.
Action Requested	• Completed Proposed Draft is suitable for progressing in the consensus process.
Voting Rules	• Two thirds of the DDC eligible voters must vote affirmatively.

Abbreviations: CC, Consensus Council; DDC, Document Development Committee.

Table 9. Subcommittee Voting in the Document Development Process

Process Stage	Proposed Draft	Limited Revision	Supplement
Eligible Voters	• SC Chairholder • SC Vice-Chairholder • SC Members		
Conditions for Action	• The document is scientifically accurate, practical, comprehensible, and exhibits overall quality and utility.		
Action Requested	• {Document code} is approved for advancement in the consensus process.		• {Document code} is approved for advancement in the development process.
Voting Rules	• Two thirds of the SC eligible voters must vote affirmatively.		

Abbreviations: SC, Subcommittee.

Table 10. Delegate Voting in the Document Development Process

Process Stage	Proposed Draft	Limited Revision
Eligible Voters	• Member organization delegates • (In the absence of a member organization delegate's vote, the alternate delegate's vote is counted.) • Individual members with full membership status	
Conditions for Action	• The document is scientifically accurate, practical, comprehensible, and exhibits overall quality and utility.	
Action Requested	• {Document code} is approved for advancement in the consensus process.	
Voting Rules	• Two thirds of those who voted and did not abstain must vote affirmatively.	

Table 11. Consensus Council Voting in the Review of an Approved Consensus Document Process

Process Stage	Reaffirmation	Withdrawal
Eligible Voters	• CC Chairholder • CC Vice-Chairholder • CC Members	
Conditions for Action	• 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.	• The document is not technically correct and/or • The document has low interest and/or • The document was incorporated into another document.
Action Requested	• Reaffirmation of {Document code} is approved.	• Withdrawal of {Document code} is approved.
Voting Rules	• Two thirds of the CC eligible voters must vote affirmatively. • One member from each of the three constituencies must vote affirmatively.	

Abbreviations: CC, Consensus Council.

Table 12. Expert Panel Voting in the Review of an Approved Consensus Document Process

Process Stage	Reaffirmation	Withdrawal
Eligible Voters	• ExP Chairholder • ExP Vice-Chairholder ExP Members	
Conditions for Action	• The document continues to adequately reflect the current practice. • 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.	• The document is not technically correct and/or • The document has low interest and/or • The document was incorporated into another document.
Action Requested	• Reaffirmation of {Document code} is endorsed.	• Withdrawal of {Document code} is endorsed.
Voting Rules	• Two thirds of the ExP eligible voters must vote affirmatively.	

Abbreviations: ExP, Expert Panel.

5.5.2 Meeting and Virtual Voting

A quorum (ie, two-thirds of a committee's eligible voters) must be present to conduct a vote at a meeting. **NOTE:** For purposes of ExPs and CC, a quorum must include one member from each constituency.

When a two-thirds majority of committee members are not present at a meeting, an electronic ballot shall be issued. A ballot and access to the meeting recording or written summary of the discussion are issued ideally within five business days of the meeting. The voting period for electronic ballots shall not exceed 10 business days and the voting rules outlined in Table 15 apply.

Voting rules in Table 15 apply to all other circumstances for which committee votes are taken.

Table 15. Minimum Number to Conduct and Pass A Vote

Total Number of Eligible Voters	Quorum (2/3 of Eligible Voters)
5	4
6	4
7	5
8	6
9	6
10	7
11	8
12	8
13	9
14	10
15	10
16	11
17	12
18	12

Chapter 6: Committee Responsibilities

The subchapters below outline the roles and responsibilities of the various groups involved in developing and approving CLSI consensus standards and guidelines, supplements, and derivative products. All committee participants are expected to devote the anticipated, required time and participation necessary for committee activities.

6.1 Board of Directors

The BOD establishes the policies that govern the Consensus Document Development and Derivative Product Development Processes and has final approval of policy changes to the SDPPs.

6.2 Consensus Council

The CC:

- Serves as the consensus body for CLSI
- Approves projects confirming consensus for project development based on medical utility, clinical relevance, and CLSI's mission
- Evaluates concerns regarding delays in project development and implements proposed intervention process as needed
- Votes on Final Draft documents to confirm adherence to their respective development processes and approves documents and products for final production
- Appoints DDC chairholders and vice-chairholders, ensuring appropriate expertise of incumbents
- Replaces an ExP/DDC chairholder and/or vice-chairholder when deemed necessary and/or appropriate

The CC consists of seven persons, in addition to the chairholder and the vice-chairholder. 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.

CC membership must be balanced among constituencies. Typically, the CC 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).

Participation on the CC is not conditional upon membership in CLSI, nor unreasonably restricted on the basis of technical qualifications or other such requirements. There shall be no undue financial barriers to participation on the CC.

The only committee in the Consensus Document Development Process for which balance is required is the CC.

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

6.2.1 Consensus Council Chairholder

The CC 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 CC, make decisions in alignment with Board-directed goals and objectives, and lead the Council to an effective outcome.

The CC chairholder is responsible for:

- Leading the activities of the CC, ensuring all responsibilities of the CC are met
- Preparing agendas for meetings
- Facilitating all CC meetings
- Actively participating in CC activities and meetings
- Reviewing and approving meeting records

The CC 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 2 for term limits.

6.2.2 Consensus Council Vice-chairholder

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

The CC 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 CC activities and meetings

See Table 2 for term limits.

6.2.3 Consensus Council Members

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

CC 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 CC and actively participate in CC activities and meetings.

6.2.3.1 Emeritus Member

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 recommended to the Board of Directors by the CC Chairholder to continue to participate in all Council activities after the expiration of the Council membership. No more than one emeritus CC member from each constituency shall be invited. An Emeritus CC member is preferably an individual who has recently rotated off the CC to ensure that their knowledge of CC projects, history and issues is current. See Table 2 for emeritus member term limits.

The emeritus member:

- Provides historical background on documents, previous decisions, procedures
- Is invited to attend all CC meetings (including face-to-face meetings) **NOTE:** CLSI pays the travel expenses of its emeritus CC members when eligible under the CLSI Volunteer Reimbursement Policy.
- Receives all CC notifications and meeting minutes
- Is not eligible to vote

See Table 5 for committee participant limits.

6.2.3.2 New Member Mentorship

To facilitate introduction of incoming CC members to CC business matters as well as CC team culture and meeting protocols, incoming CC 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 CC vice-chairholder will ensure that each in-coming Council member has an experienced Council member as a mentor. When a new CC vice-chairholder is scheduled to begin their position, the outgoing CC vice-chairholder will communicate the mentor/new Council member pairings to the new vice-chairholder to ensure a smooth transition.

6.2.4 Program Manager

The assigned program manager is responsible for serving as the communication conduit between ExPs and the CC. The program manager is responsible for reporting notable successes and/or challenges experienced by an ExP and presenting recommendations for process and/or procedural changes offered by an ExP to the CC by way of CC's staff liaison (ie, Vice President, Standards and Quality).

6.3 Expert Panels

ExPs are constituted for various technical subject areas, as determined by CLSI's Board of Directors. 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
- Create or solicit the creation of a completed Project Proposal Form (available on the Resources section of the CLSI website) for consolidating or dividing a document
- Review proposals from other sources
- Endorse project proposals and present them to CC for authorization as applicable
- Monitor progress of documents in its technical area
- 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
- Serve as advisors and subject matter experts for DDCs/DRWGs/SCs/WGs in its technical area

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

6.3.1 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 CC, 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 DRWGs, DDCs, SCs, and for providing advice regarding committee participant appointments as appropriate. (See Table 3 for specific appointment responsibilities.)

The ExP chairholder maintains close contact with DRWG, 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 DRWGs, DDCs, SCs, and/or WGs in the specific technical area.
See Table 2 for term limits.

6.3.2 Expert Panel Vice-Chairholder

The ExP vice-chairholder is responsible for assisting and supporting the ExP chairholder as needed, ensuring all responsibilities of the ExP are met. 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 CC.

See Table 2 for term limits.

6.3.3 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/their 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.

See Table 2 for term limits and Table 5 for committee participant limits.

6.3.4 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, advisors are appointed. The number of advisors can equal up to 8. 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 2 for term limits and Table 5 for committee participant limits.

6.4 Document Development Committees, Document Review Working Groups, Subcommittees, Working Groups, and Ad Hoc Working Groups

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

6.4.1 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.

6.4.2 Document Review Working Group

ExPs have the responsibility to review published documents in accordance with requirements (see Subchapter 6.3). A DRWG is formed annually to review documents scheduled for assessment in a calendar year. The DRWG can be comprised of only ExP participants or can include nonExP subject matter experts; however, at least one ExP voting member must participate in the review of each document.

DRWG members have expert knowledge and experience in specific facets of ExP's subject area and are able to devote the anticipated required time to WG activities.

DRWGs are responsible for assisting the ExP with the Scheduled Review of Approved Consensus Documents Process activities, ie:

- Reviewing and recommending revisions to published documents

- Drafting document revisions under the Limited Revision Process

- Reviewing and assessing all comments received (ie, since publication and during the public comment period)

- Developing recommendations for next action on published documents in their area of expertise

- Developing responses to comments submitted on revised documents

The number of DRWG members depends on the number of documents to be reviewed as part of the Scheduled Review of Approved Consensus Documents Process. On any given document, two to five DRWG members must be assigned to review all comments received and provide the recommendation for next action to the ExP.

See Table 2 for term limits and Table 5 for committee participant limits.

6.4.3 Subcommittees

SCs may have 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 supplements.

See Table 2 for term limits and Table 5 for committee participant limits.

6.4.4 Working Groups

A WG is typically a subunit of an SC. A WG's assignment is limited in scope and the WG may be 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

See Table 2 for term limits and Table 5 for committee participant limits.

6.4.5 Ad Hoc Working Groups

An AHWG is typically a subunit of a WG. An AHWG's assignment is limited in scope, and it is disbanded upon completion of the assignment. Short-term assignments that can be handled by AHWGs may include:

- Writing a section of a document
- Conducting a special technical study
- Responding to comments on a CLSI document or product

See Table 2 for term limits and Table 5 for committee participant limits.

6.4.6 Chairholders

The DDC/DRWG/SC/WG/AHWG 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 program manager, is responsible for:

- Proposing placement of volunteers in appropriate DDC/DRWG/SC/WG/AHWG roles and recommending the proposed membership for approval (see Table 3 for more information on committee appointments).

- Identifying a committee participant who will serve as committee secretary as applicable

- 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/DRWG/SC/WG/AHWG meetings and conference calls

- Furnishing progress activity reports, including time and expenses forecasts for completing each authorized project, to the CC, 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 when deemed necessary and/or appropriate (see Subchapter 5.4.3 for information on committee appointments and removals). 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 2 for term limits.

6.4.7 Vice-Chairholders

The DDC/DRWG/SC/WG/AHWG 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 meetings, reviewing documents, 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 CC when deemed necessary and/or appropriate (see Subchapter 5.4.3 for information on committee appointments and removals). 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 2 for term limits.

6.4.8 Members

DDC/DRWG/SC/WG/AHWG members are selected to represent 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 for Standards and Guidelines and/or Derivative Product Development Processes.

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

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

DDC/DRWG/SC/WG members who fulfill their responsibilities are regarded as the document's authors.

A member may be replaced (after appropriate consultation; see Table 3) 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 2 for term limits and Table 5 for committee participant limits.

6.4.9 Secretary

The DDC/SC/WG 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. Secretaries are voting members of the DDC/SC/WG.

See Table 2 for term limits and Table 5 for committee participant limits.

6.4.10 Contributors

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

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. Contributors are not eligible to vote.

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 2 for term limits and Table 5 for committee participant limits.

6.4.11 Advisors

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

SC/WG/AHWG advisors have expert knowledge and experience in the SC's subject area and are interested in actively supporting the SC's efforts. Advisors are not eligible to vote.

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 serve on WGs for new documents or revisions.

See Table 2 for term limits and Table 5 for committee participant limits.

6.4.12 Reviewers

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

SC reviewers are interested in and knowledgeable about the SC'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 activities. Reviewers are expected to review and comment on draft documents. Reviewers are not eligible to vote.

See Table 2 for term limits and Table 5 for committee participant limits.

6.4.13 Delegates

Each member organization names an official CLSI delegate and has the option to name one alternate delegate to serve in absence of the primary 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 Resignations From CLSI Committees

A resignation from a member's position on the CC or an ExP, DRWG, DDC, SC, WG, or AHWG may be accepted by the respective chairholder and forwarded to the CLSI office. The resignation of the CC chairholder or vice-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 CC 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 CC is prohibited from voting on consensus documents until balance is restored. Efforts to achieve balance can include a Call for Volunteers or a Presidential appointment.

6.6 Program Manager

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

6.7 Endorsement Disclaimer

Membership in CLSI indicates support of the CLSI Consensus Document Development Process for Standards and Guidelines and the Derivative Product Development Process 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.

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

Chapter 7: Committee Operations: General Information

7.1 Committee Meetings

CLSI committees conduct business at in-person meetings, virtually 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 program 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.

Virtual meetings are strongly encouraged for all 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. No meeting 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 committee chairholder, vice-chairholder, and members are the primary participants in meetings. The chairholder's, vice-chairholder's, and members' availability are given priority consideration when scheduling meetings. Other committee participants are allowed to participate and their schedules are accommodated when feasible. Participation in virtual meetings is limited by practical restrictions imposed by the ability to effectively conduct productive sessions in this medium.

7.1.2 Meeting Notice and Agenda

CLSI staff ensures that all appointed committee participants 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 program manager clarifies who is eligible to vote. See Subchapter 5.5.2 for meeting voting rules.

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

During each CC/ExP/SC meeting, the committee chairholder, secretary, and program manager are responsible for ensuring that summary minutes are kept by the committee secretary or designate or the program 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

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.

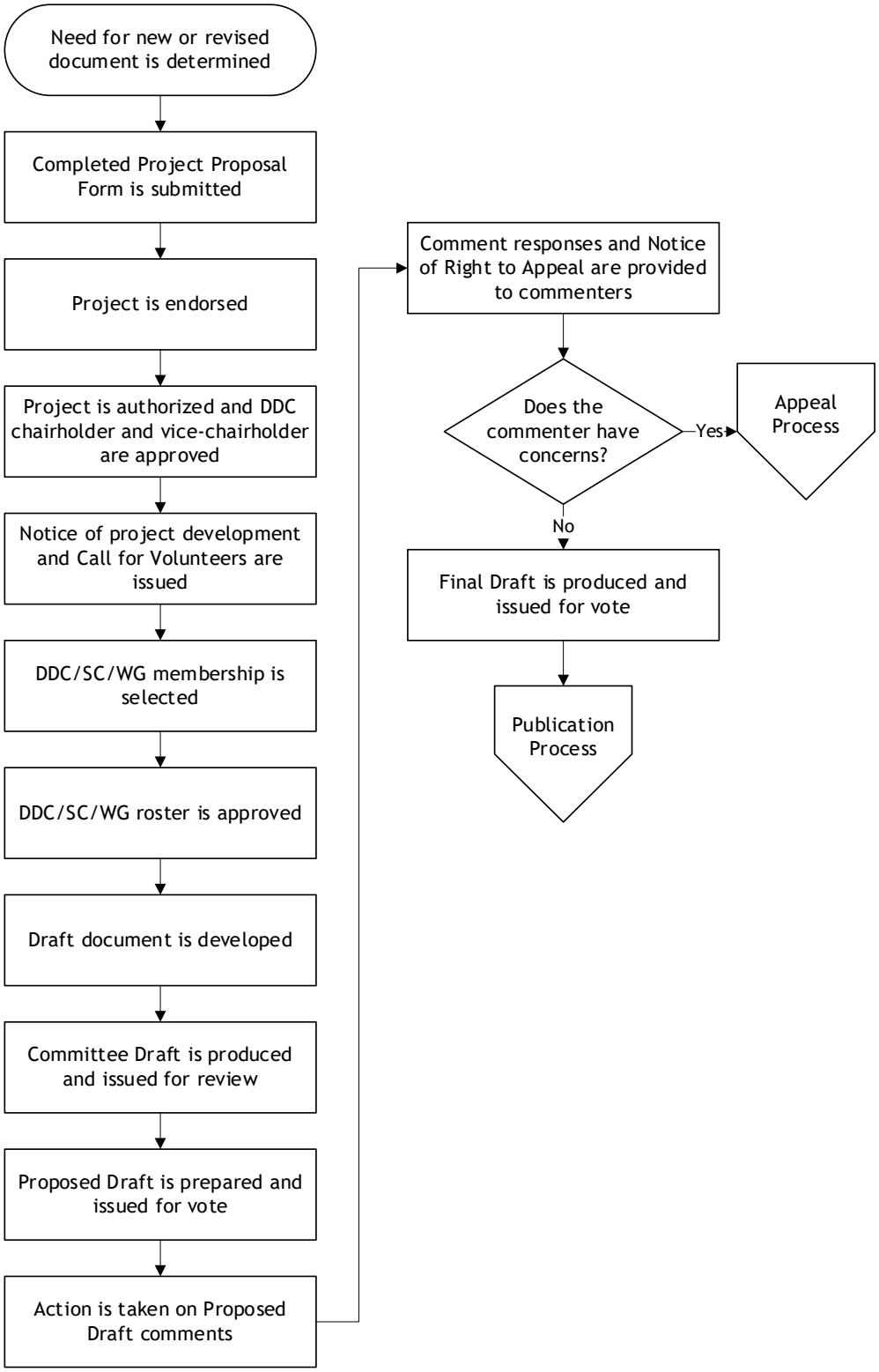
When needed and determined vital to standards development, informational surveys of a specific portion of the health care community can be performed by the CLSI office. This technique gathers valuable information committees can use when developing a CLSI document or product. The applicable committee 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 Document Development Process for Consensus Standards and Guidelines

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



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

Figure 2. High-Level View of the Document Development Process for Consensus Standards and Guidelines

8.1 Project Proposal Submission

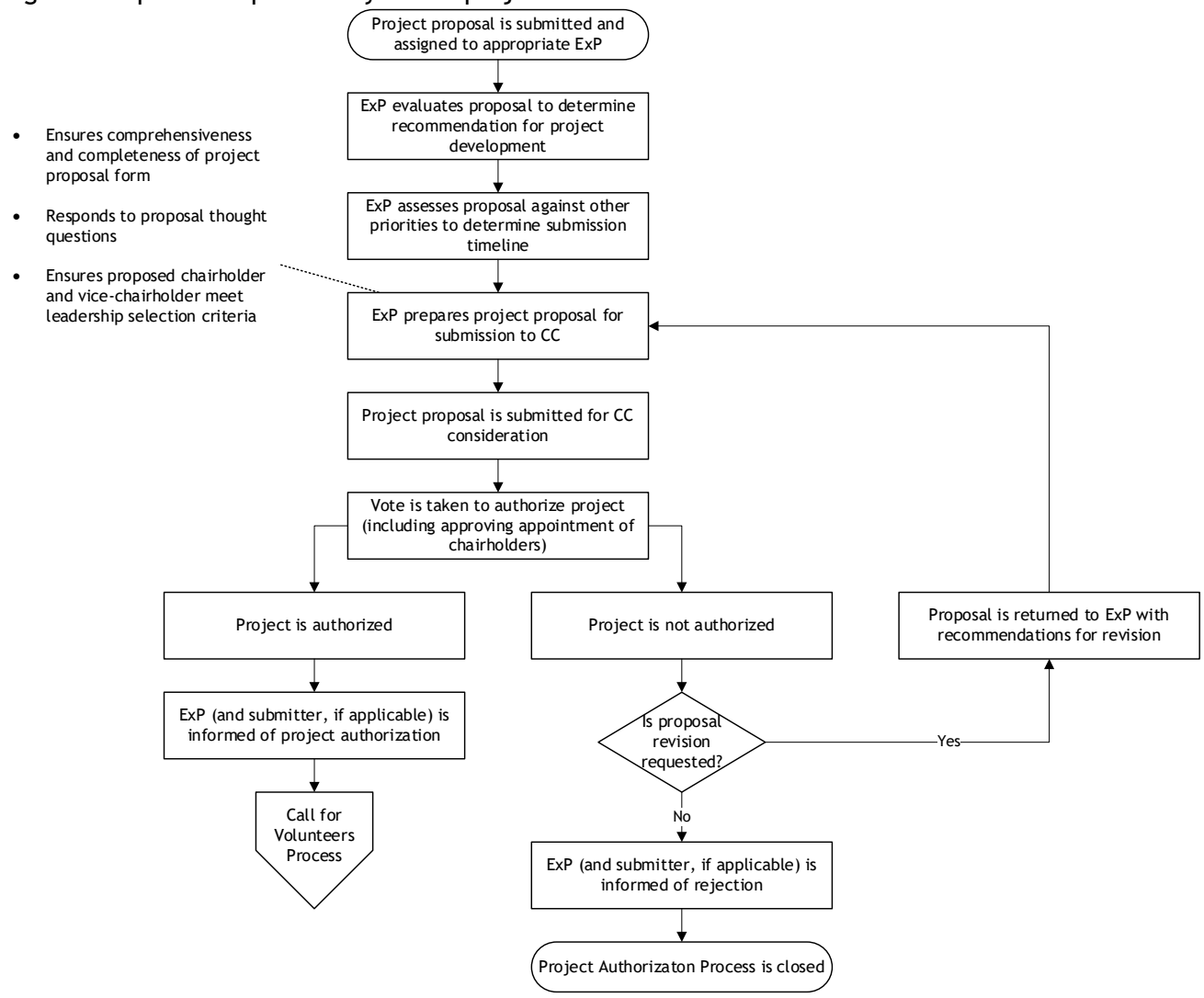
Any person or organization, including CLSI committees or committee participants, can propose a new CLSI project. All new project proposals must be submitted on a completed CLSI Project Proposal Form, which is available on the CLSI website.

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

Only completed forms will be evaluated by the responsible ExP and CC. Forms with missing or incomplete information will be returned to the submitter.

8.2 Project Endorsement

Figure 3 depicts the process by which projects are endorsed and authorized.



Abbreviation: CC, Consensus Council; ExP, expert panel.

Figure 3. Project Endorsement and Authorization Process

A proposal form is submitted to the responsible ExP for evaluation. ExP members are asked to:

- Ensure the comprehensiveness and completeness of the project proposal
- Evaluate the proposal content by responding to the thought questions posed
- Ensure the proposed chairholder and vice-chairholder meet leadership selection criteria (see Subchapter 8.2.1)
- Cast a vote on the project proposal

See Table 7 for project proposal voting conditions and rules.

8.2.1 Committee Leadership Selection Considerations

When determining DDC/SC/WG chairholder- and vice-chairholder designates, the ExP should take the following into consideration:

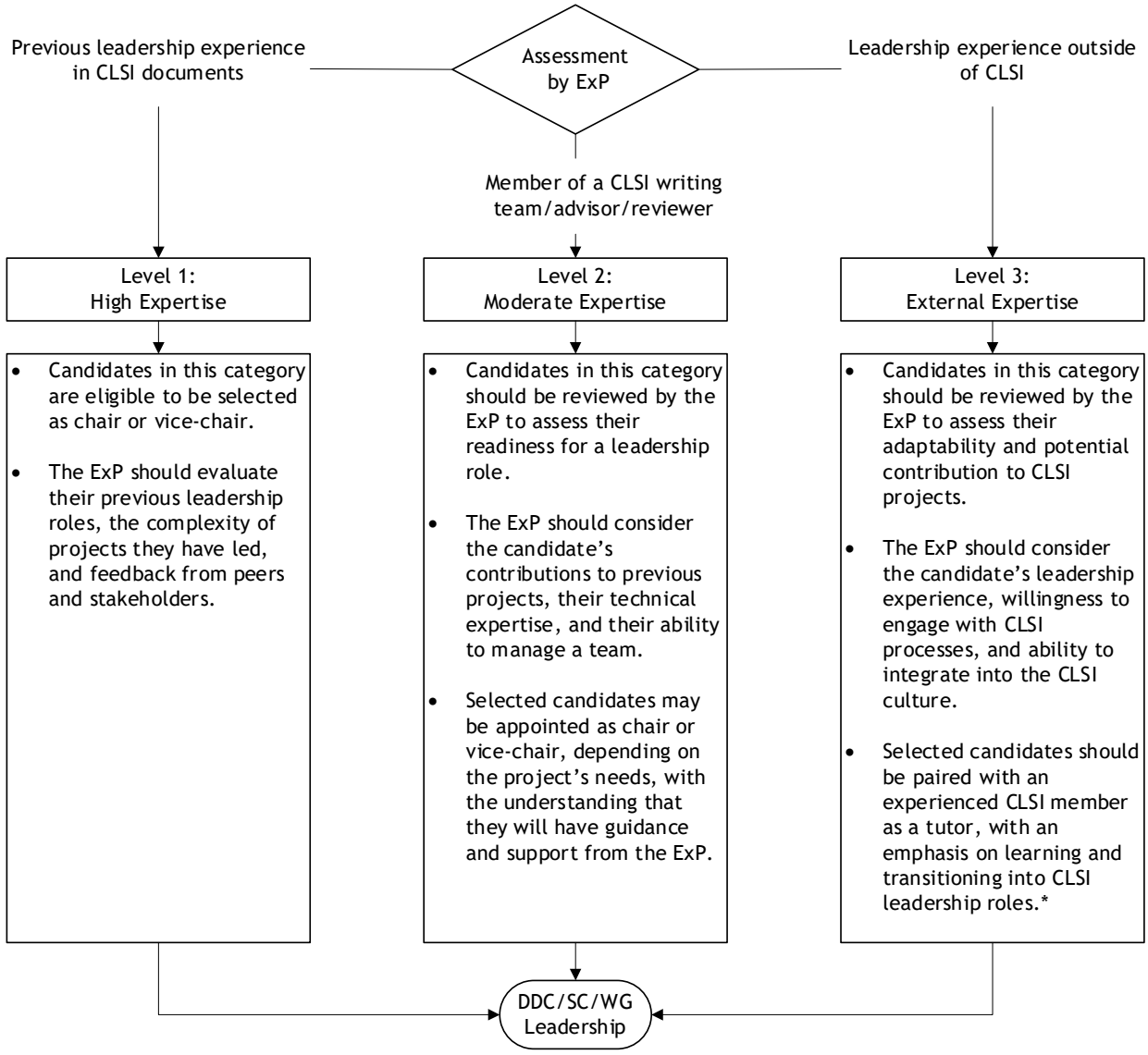
- Individuals with no leadership experience inside or outside of CLSI are ineligible to serve as a chairholder or vice-chairholder.
- Lack of familiarity with the CLSI processes can impact the document development timeline.

In accordance with Figure 4, the following combinations (in any order) for committee leadership are acceptable:

- Level 1 and level 1
- Level 1 and level 2
- Level 1 and level 3

The following combinations should be strongly justified if proposed:

- Level 2 and level 2
- Level 2 and level 3
- Level 3 and level 3



* **NOTE:** The CLSI program manager cannot serve in the capacity of tutor.

Figure 4. Committee Leadership Considerations

8.3 Project Authorization

The CC is responsible for authorizing consensus projects (see Figure 3). The CC reviews each project proposal to ensure that a proposed project is consistent with the mission and goals of CLSI and fulfills a perceived need.

Once the CC members review the proposal for completeness and comprehensiveness, confirm the ExP responses to the thought questions are acceptable, and the development committee chairholder and vice-chairholder nominees are acceptable for appointment, action is taken to authorize the proposal.

See Table 6 for project proposal voting conditions and rules.

Table 17 outlines the timeline for the Project Authorization Process.

Table 17. Anticipated Project Authorization Process Timeline

Activity	Timeframe
Project proposal is submitted and assigned to the appropriate ExP.	Month 0
ExP endorses proposal.	Month 1
CC reviews proposal; proposal is authorized (including appointment of DDC chairholder and vice-chairholder).	Month 2
Call for Volunteers is issued.	Month 2
DDC selection is undertaken.	Month 3
Proposed DDC roster is approved by ExP.	Month 4
DDC participants are notified of selection and meeting announcement is issued.	Month 4
Inaugural meeting is held.	Month 4

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

8.4 Notification of Document Development and Call for Volunteers

The initiation of new and revised 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 or revision of standards and guidelines can formally record their interest and be considered for DDC membership. (**NOTE:** Limited revisions are exempt from this Call for Volunteers Process.)

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 committee 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.

8.5 Membership Selection for Document Development Committees, Subcommittees, and Working Groups

DDC/SC/WG participants are selected from the nominations submitted through the Call for Volunteers. Committee selection is undertaken by the management team (ie, DDC/SC/WG chairholders, ExP chairholders, program manager) (see Table 3 for details). DDC/SC/WG participants are selected based on the attributes they can bring to document development.

As stated in Subchapter 6.4, balance among CLSI constituencies is not required on DDCs/ SCs/WGs.

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

8.6 Roster Approval

The responsible committee is notified of the need to review and vote on the proposed DDC/SC/WG roster. See Table 3 for details on committee appointments.

When approval is obtained, document development begins based on the prioritization schedule that is developed by staff leadership.

When a roster is not approved, the responsible committee provides the program manager with recommendations for how to proceed.

8.7 Document Development

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/SC/WG 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/SC/WG 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.

8.7.1.1 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 CC preapproval before a Proposed Draft document is submitted for voting.

8.7.1.2 Regulatory References

Terms or regulations of a specific country are not permitted as the sole justification for a recommendation in a CLSI document.[c] 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 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 CC when the project is approved.

8.7.2 Target Dates

Target dates for each milestone in the document development process are established upon project authorization as shown in Figure 5.

NOTE: Time spent on data collection and evaluation during the development of a document shall not be counted in the overall development time.

[c] 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."

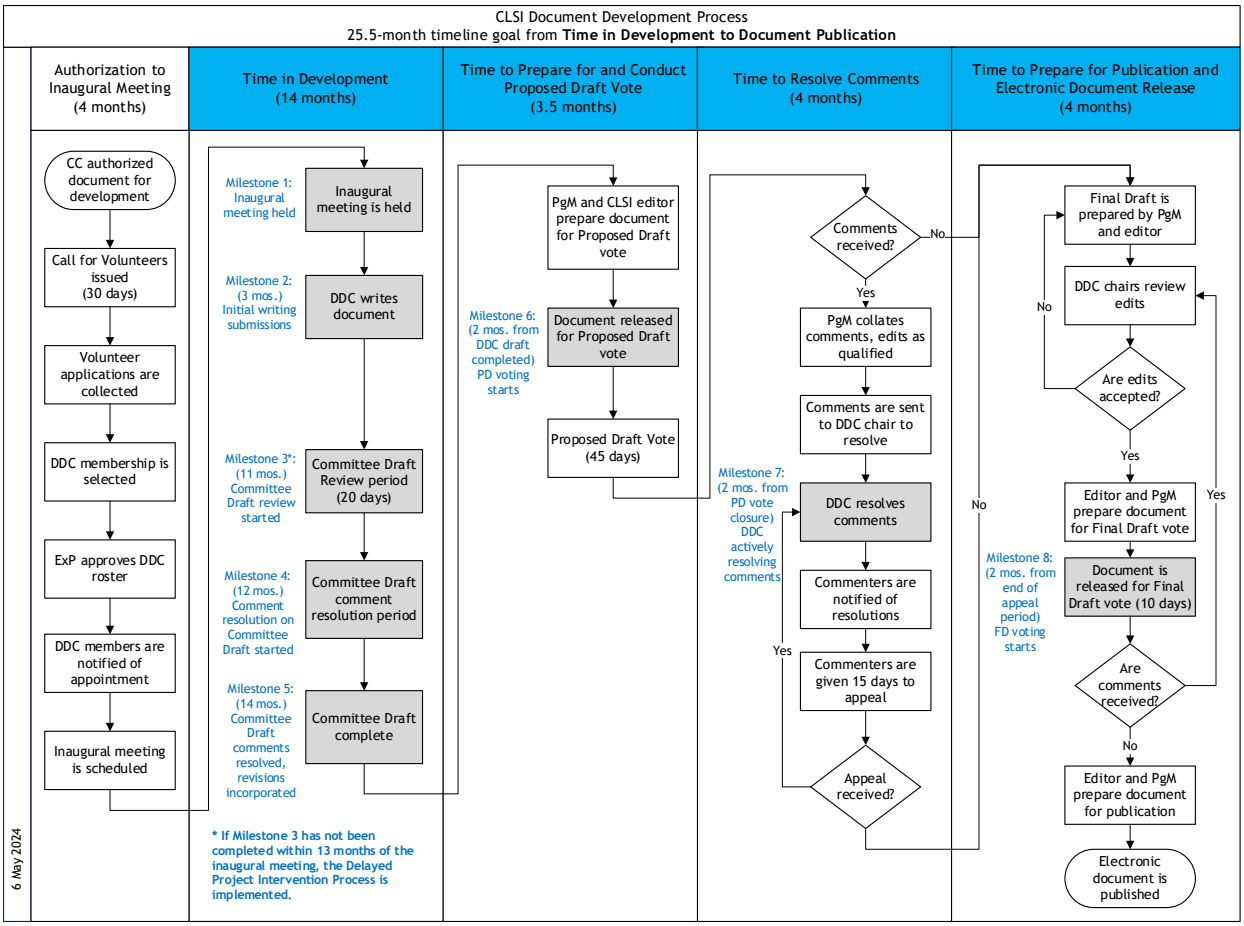


Figure 5. Document Development and Revision Process for Standards and Guidelines

Target dates are continuously monitored by staff and confirmed throughout the project's development and periodically reviewed (eg, quarterly) by the responsible ExP and the CC.

8.7.3 Delayed Project Intervention

When a project has not reached Milestone 3 (ie, Committee Draft review period) within 13 months of the committee's inaugural meeting, the Delayed Project Intervention Process is initiated. The DDC chairholder, in consultation with the ExP leadership, shall complete the Delayed Project Intervention Form and submit it to CC for consideration.

Taking the DDC chairholder's recommendation(s) into account, CC shall take one of the following options:

- Grant an extension
  NOTE: No more than 1 extension will be granted.

- Cancel the project

- Or other option as deemed appropriate by CC

NOTE: Failure to submit a recommendation within 14 calendar days of distribution of the delayed project notification will result in project cancellation.

When an extension is granted and the Committee Draft review stage (ie, Milestone 3) is not reached within the allotted timeframe, the project shall be cancelled by CC. If the document was undergoing revision, the original document is reaffirmed or withdrawn.

If an ExP recommends that a cancelled project be reinstituted, the project shall undergo the project proposal submission, endorsement, and authorization processes (see Subchapters 8.1, 8.2, and 8.3, respectively).

8.8 Committee Draft

8.8.1 Committee Draft Development

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

8.8.2 Committee Draft Commenting Period

The DDC/SC/WG conducts a technical review of the Committee Draft to determine its suitability for progression in the consensus process and submits comments on the document as applicable.

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.

The DDC/SC/WG responds to any technical or substantive issues. The program manager makes editorial changes and revises the text per the comment resolutions.

The DDC/SC/WG is responsible for delivering a Committee Draft that is appropriately sequential, technically sound, accurate, understandable, and ready to advance to Proposed Draft.

8.9 Proposed Draft

8.9.1 Proposed Draft Preparation

The CLSI program manager and editors prepare the Proposed Draft. The Proposed Draft is submitted for vote to the DDC/SC/WG, ExP, and the CLSI delegates. The document is also made available for concurrent review and comment by the CC, the Board of Directors, and the public.

CLSI posts a notice of the Proposed Draft document title, description, and voting period on its website.

8.9.2 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 8.9.3.

The ExP and DDC/SC 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/SC and ExP review needs to ensure the overall quality, utility, and readability of CLSI consensus documents and that they are technically correct and that the document scope is consistent with that approved by the CC.

The Board of Directors, the CC, and the public are invited to review and submit comments.

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

Each ExP member and DDC/SC member, casts a vote on the Proposed Draft.

Each CLSI duly named delegate or alternate casts a vote, if desired.

See Tables 7 through 10 for Proposed Draft voting conditions and rules.

8.9.3 Proposed Draft Comment Responses

After the 45-day voting and commenting period has expired, the DDC/SC/WG chairholder and vice-chairholder are informed that the comments received on the Proposed Draft document are ready for follow-up action. The DDC/SC/WG takes timely action on comments received, usually within 60 days of receiving the comment file from the program manager. Comment responses are prepared. The DDC/SC/WG chairholder and vice-chairholder prepare comment responses. Then, the comment responses are reviewed by the DDC/SC/WG.

A response to each comment is prepared by the DDC/SC/WG. 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/SC/WG member must participate in the review of and response to all comments. The DDC/SC/WG must achieve consensus on the proposed responses. When there is undue delay in completing responses to all the comments, the CC may restructure the DDC/SC/WG or cancel the project.

When a Proposed Draft document receives sufficient substantive comments that require substantial and/or significant changes to the document, resulting in the need for a second Proposed Draft vote, the CC, in consultation with the ExP and DDC/SC/WG, decides whether to rework the document and resubmit it for a new voting and commenting period or other action.

Comments received after close of the Proposed Draft review and balloting period are reviewed by the DDC/SC/WG, 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 CC may authorize a delay in document publication until appropriate action is taken.

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

8.9.5 Rejected Proposed Draft

A Proposed Draft document that does not achieve the required voting majorities is considered rejected (see Tables 7 through 10). The rejected Proposed Draft and all comments, including those supporting reject votes, are forwarded to the appropriate DDC/SC/WG for consideration and resolution. The CC~~DDC~~, in consultation with the ExP and DDC/SC/WG, decides whether to rework the document and resubmit it for a new voting and commenting period or cancel the project.

8.10 Final Draft

8.10.1 Final Draft Preparation

The DDC/SC/WG and program 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 Final Draft Voting and Commenting Period

CC members are provided with the following materials for review:

- The results of the Proposed Draft voting
- All Proposed Draft comments received and their resolutions
- A copy of the Final Draft document
- Notice of any appeals and their resolutions

During the 10-day voting period, CC members submit any questions to the CC's CLSI staff member. The staff member answers any process questions and refers any technical questions, as appropriate, to the relevant DDC. Virtual meetings or other means of communication between the CC and the DDC are conducted, when needed.

CC members vote on the Final Draft document.

See Table 6 for Final Draft voting conditions and rules.

When the CC 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 CC's concerns. The CC determines whether or not the DDC's responses to CC comments and concerns have substantially changed the document. **Significant changes to the Final Draft may trigger a new Proposed Draft review and vote.**

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

8.12 Document Development Committee or Working Group Disbandment

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

8.13 Records of Committee Draft, Proposed Draft, and Final Draft Votes, Comments, and Comment Responses

The CLSI office maintains all of the following records for the Committee Draft, Proposed Draft, and Final Draft:

- Formal votes cast by the DDC, ExP, SC (as applicable), delegates, and CC
- All comments received
- All comment responses
- Any objections to the comment responses
- Resolution to any objections
- Notice by DDC, ExP, SC (as applicable), and delegates or commenter invoking the Appeal Process

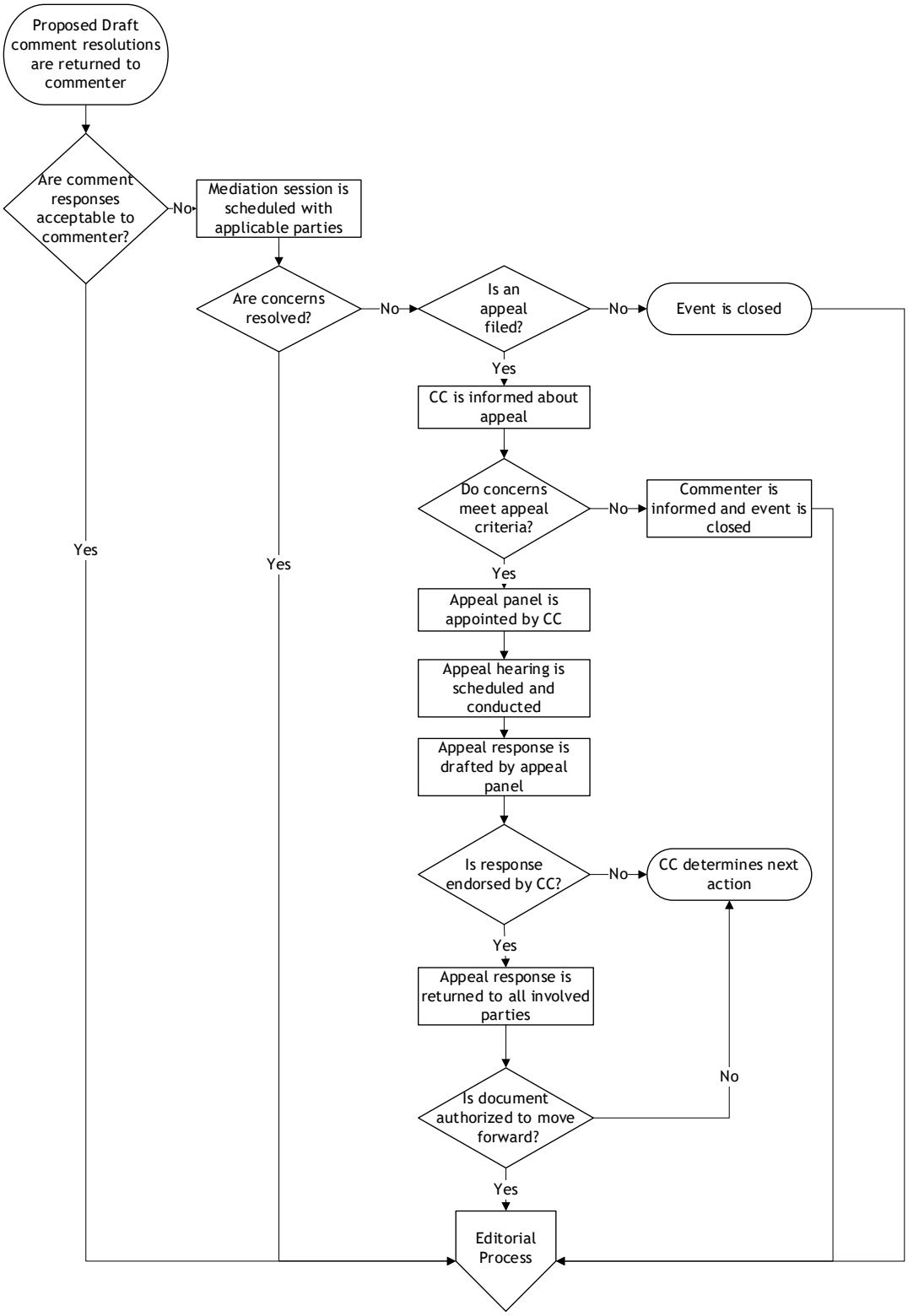
8.13.1 Evidence of Compliance

Records that demonstrate compliance with the Document Development Process for Consensus Standards and Guidelines described in these SDPPs are retained in accordance with the CLSI

Documents and Records Retention Policy and Records Retention Schedule. CLSI conducts periodic audits of selected records of consensus documents for adherence to the Document Development Process for Consensus Standards and Guidelines.

Chapter 9: Mediation and the Appeal Process

The CLSI Document Development Process for Consensus Standards and Guidelines includes a process for mediating concerns resulting from Proposed Draft comment resolution and an Appeal Process (see Figure 6).



Abbreviations: CC, Consensus Council.

Figure 6. Mediation and the Appeal Process

9.1 Mediation

Any commenter who has concerns with responses to their Proposed Draft comments shall inform CLSI within 15 days of being informed of the DDC's decision. When a commenter registers concerns with Proposed Draft comment resolutions, a mediation session is scheduled within 30 days of receipt of the concerns to discuss them. The commenter, DDC/SC/WG leadership, and CLSI project manager shall be in attendance.

If the mediation session is successful (ie, concerns are adequately addressed as determined by the commenter), the document proceeds to the editorial process. If concerns remain (as determined by the commenter), the commenter can file an appeal.

9.2 Appeal Process

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 Document Development Process for Consensus Standards and Guidelines or by substantive or procedural actions taken in the development, revision, reaffirmation, archiving or withdrawal of a CLSI consensus document may appeal to the CLSI Chief Executive Officer—in writing or by electronic communication—within 15 days of the mediation session. The appellant shall provide specific justification for the appeal (ie, a description of how the DDC's/SC's/WG's decisions will materially or adversely affect the appellant, appellant's organization, and/or public and/or identify the failure in application of CLSI's Document Development Process for Consensus Standards and Guidelines). 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.

Any 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 CC to determine if an appeal panel will be appointed. The CC appoints the appeal panel within 30 days of an unsuccessful mediation. Typically, the responsible ExP is appointed to serve as the appeal panel and may include other subject matter experts (for appeals related to document content) and/or individuals with knowledge of and proven experience in the Document Development Process for Consensus Standards and Guidelines (for appeals related to process issues). Members and/or contributors to the responsible DDC shall not be included on the appeal panel. **NOTE:** Individuals representing the same organization are permitted if they represent different divisions or departments.

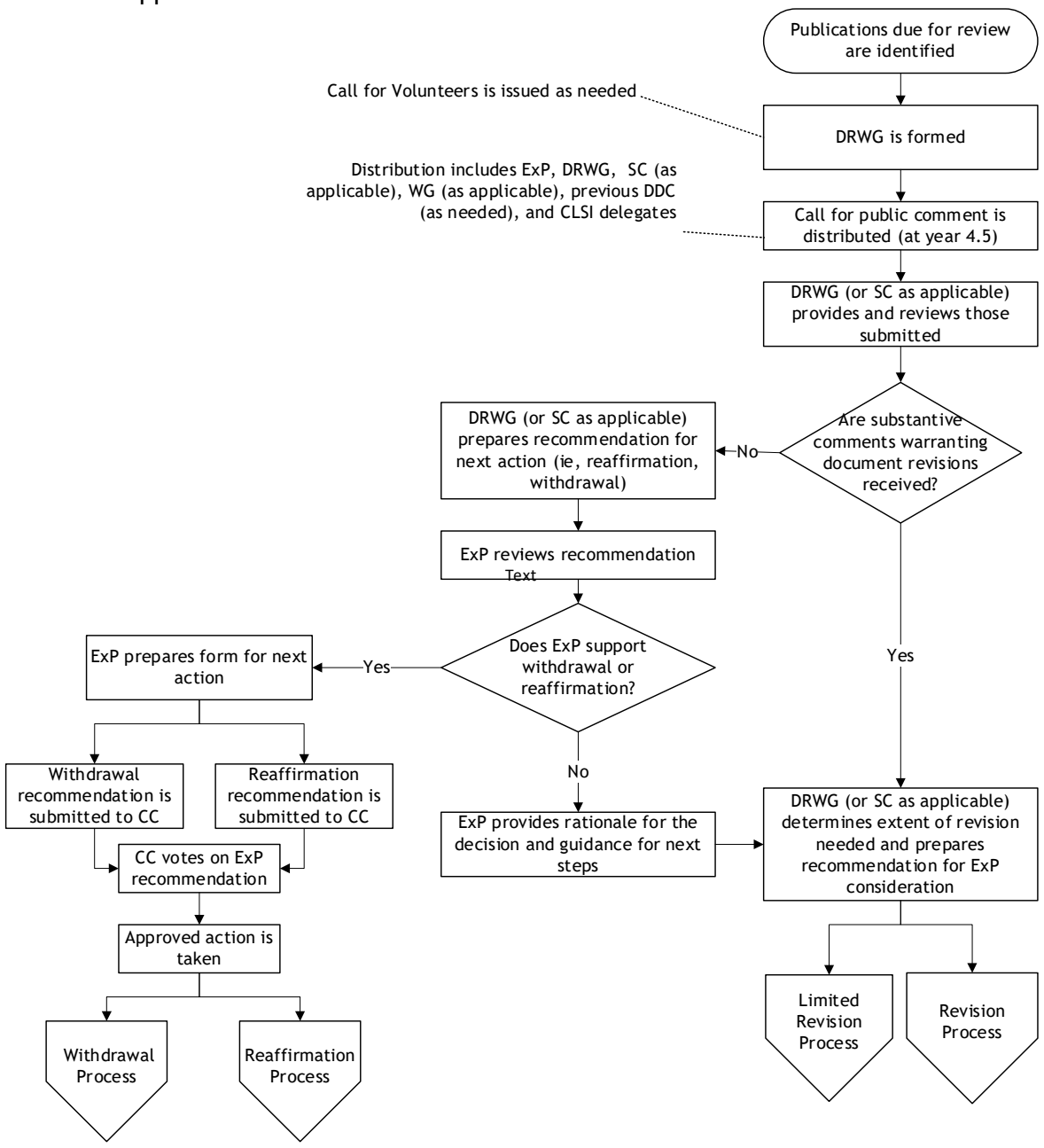
An appeal hearing is scheduled on a date mutually convenient as soon as possible for the appeal panel, the appellant, and any other interested parties. Attempts will be made to not exceed 30 days. The hearing may be conducted by face-to-face or virtual meeting.

Within 30 days of the appeal being heard, the appeal panel drafts a response which is returned to the CC for endorsement. The CC may uphold the response or recommend~~, by a majority vote,~~ to modify the response. When endorsed, CLSI promptly notifies the appellant and all involved parties in writing of the results of the appeal hearing. If the document is authorized to move forward, it proceeds to the editorial process. If the response is not endorsed or if the response is modified, the CC determines next actions.

See Table 12 for appeal voting conditions and rules.

Chapter 10: Scheduled Review of Approved Consensus Documents

All approved consensus documents undergo periodic review. Figure 7 depicts the Scheduled Review of Approved Consensus Documents.



Abbreviations: CC, Consensus Council; DRWG, document review working group; ExP, expert panel.

Figure 7. Scheduled Review of Approved Consensus Documents

Annually, the program manager identifies documents requiring review in accordance with the Scheduled Review of Approved Consensus Documents Process and informs the appropriate ExP(s) of the need to review. The ExP then constitutes a DRWG from its members by identifying the subject matter expertise needed to conduct technical review of the identified documents and makes specific document assignments. When needed, a Call for Volunteers is issued for additional DRWG members with pertinent subject matter expertise. Committee selection is undertaken by the responsible ExP leadership and the assigned program manager (see Subchapter 5.4 for information on committee constitution.) It is expected that 2 to 5 individuals (including one member from the ExP) with pertinent expertise will review each document and submit comments either supporting or not supporting the need for revision.

A 45-day call for public comment is issued for each document scheduled for review. The call for public comment is posted on CLSI's website and distributed to the ExP, SC (as applicable), DRWG (as applicable), and CLSI delegates, and can include participants from the former DDC as needed. After the close of the public commenting period, the assigned DRWG (or the SC as applicable) considers any substantive comments received after publication of the document and substantive information and/or changes received during the public commenting period and determines if revision of the document is warranted.

If revision is not needed, the assigned DRWG (or applicable SC or ExP) prepares a recommendation for reaffirmation or withdraw for the ExP's consideration. See Subchapter 10.3 for details on the process for reaffirmation and Subchapter 10.6 for details on process for withdrawal.

When the DRWG recommendation is not endorsed, the ExP provides rationale for the decision and guidance for next steps to the DRWG.

When revision is warranted, the assigned DRWG, or applicable SC determines the extent of the revisions needed and prepare a recommendation for the ExP's consideration (see Subchapter 10.2).

10.1 Revision of an Approved Consensus Document

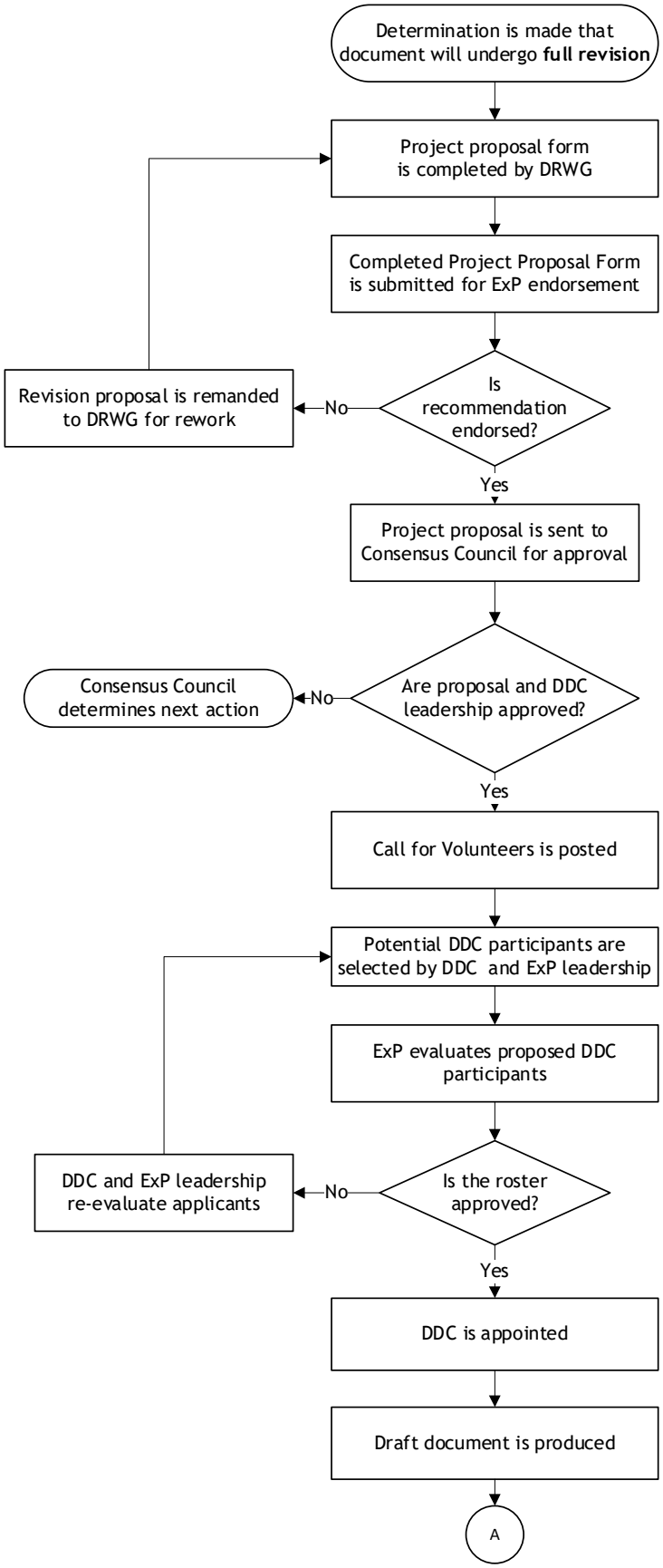
Revision or limited revision is recommended by the DRWG ~~chosen~~ when any changes in the consensus document are needed.

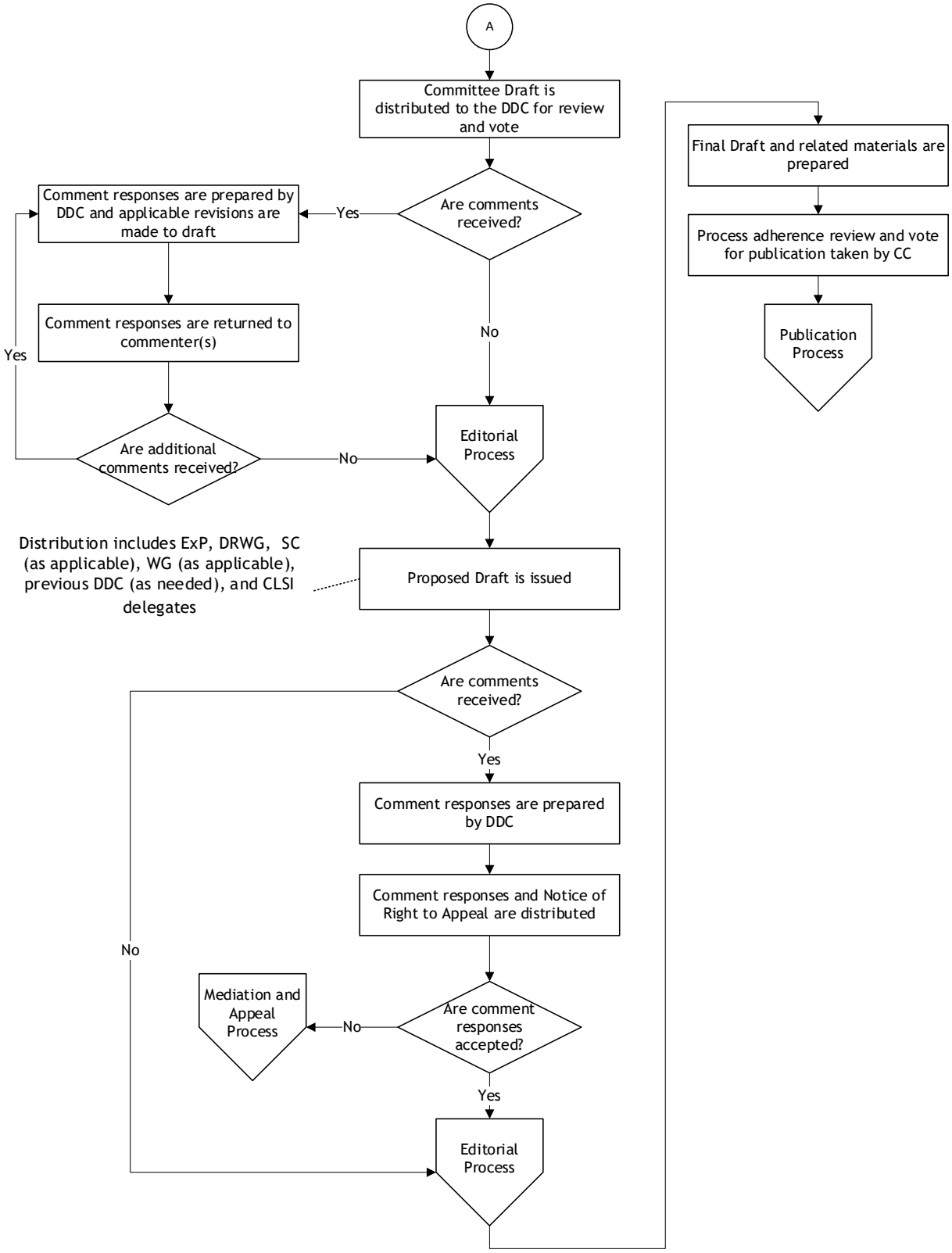
The Revision Process and Limited Revision Process are described in Subchapters 10.1.1 and 10.1.2, respectively.

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 CC reserves the right to withdraw any document that is deemed inappropriate for continued sale.

10.1.1 Revision Process

The Revision Process is outlined in Figure 9.


Determination is made that document will undergo **full revision**
Project proposal form is completed by DRWG
Completed Project Proposal Form is submitted for ExP endorsement
Is recommendation endorsed?
No
Revision proposal is remanded to DRWG for rework
Yes
Project proposal is sent to Consensus Council for approval
Are proposal and DDC leadership approved?
No
Consensus Council determines next action
Yes
Call for Volunteers is posted
Potential DDC participants are selected by DDC and ExP leadership
ExP evaluates proposed DDC participants
Is the roster approved?
No
DDC and ExP leadership re-evaluate applicants
Yes
DDC is appointed
Draft document is produced
A



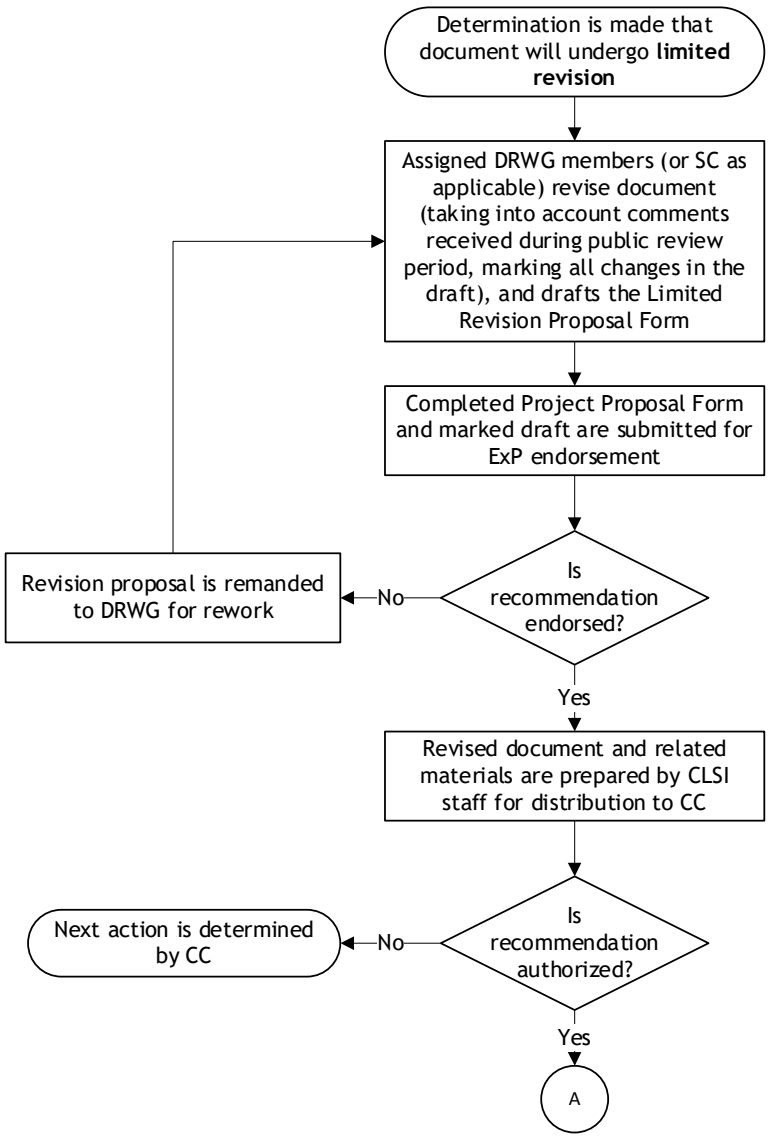
Abbreviations: DDC, document development committee; CC, Consensus Council; DRWG, document review working group; ExP, expert panel.

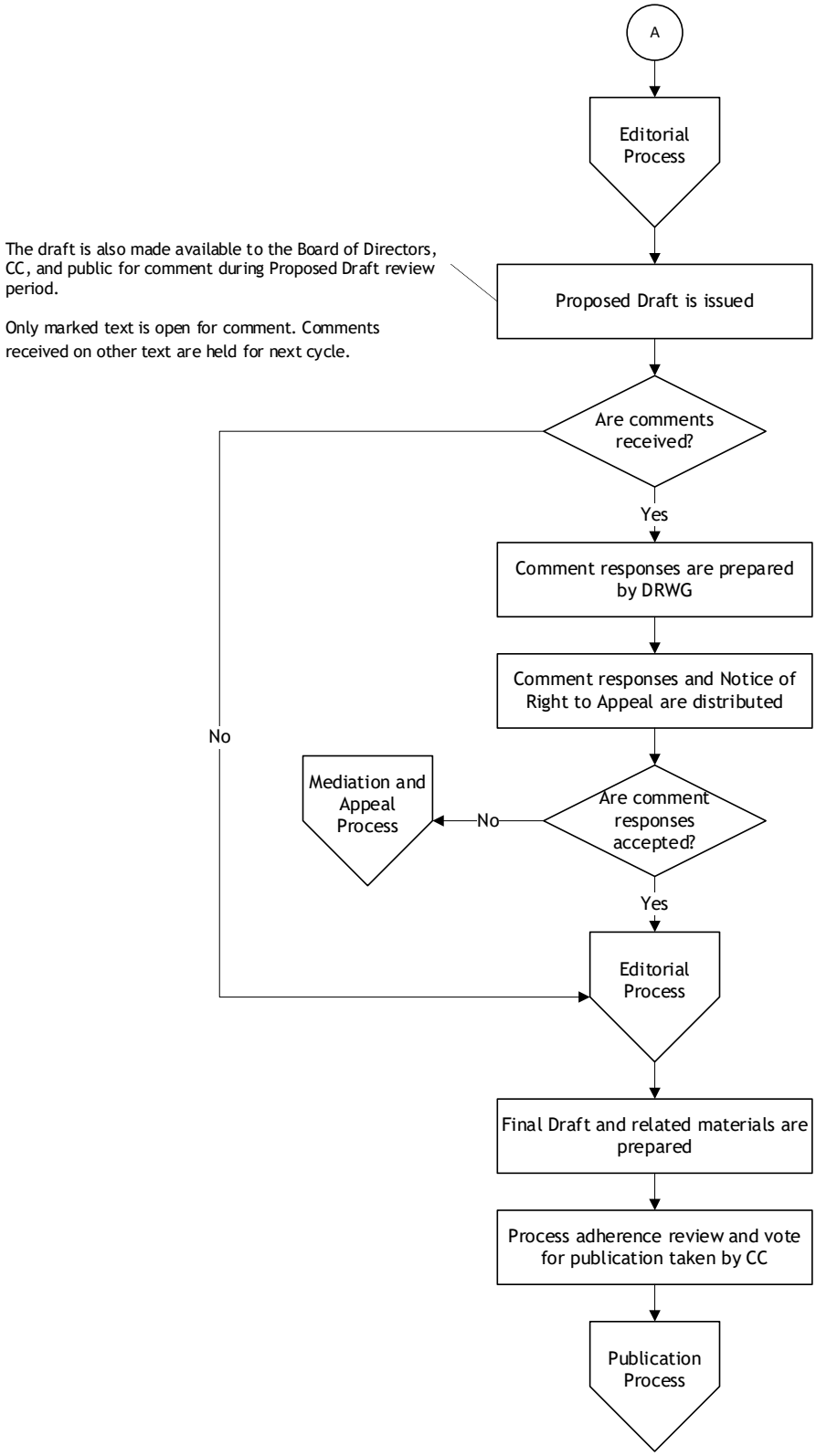
Figure 9. Revision Process

Consensus document revisions follow the activities described in Chapter 8.

10.1.2 Limited Revision Process

The Limited Revision Process is outlined in Figure 8.





Abbreviations: CC, Consensus Council; DRWG, document review working group; ExP, expert panel.

Figure 8. Limited Revision Process

The Limited Revision Process is used when the requested document updates meet defined criteria, ie, limited revisions shall not:

- Result in changes to the document's scope, purpose and/or intended audience
- Significantly affect the methodology used or application of the consensus document

Once a determination is made that the document shall undergo a limited, the assigned DRWG members mark recommended revisions—taking into account the comments received since publication and during the public review period—in the document and draft the Limited Revision Proposal Form.

CLSI staff completes the "internal use" portion of the proposal form, then routes the tracked changes version of the document and completed proposal form to the ~~appropriate~~ Expert Panel for review and vote for endorsement.

The Expert Panel vote to endorse the recommended revisions confirms that:

- Recommendation meets the requirements for a limited revision
- Proposed revisions are needed
- Revisions are accurate, practical, comprehensible, and useful

See Table 10 for limited revision voting conditions and rules.

When endorsed, the recommendation for limited revision is submitted to the CC to be authorized for Proposed Draft review and comment and vote. Once authorized, the document revisions are submitted for CLSI editorial review. During the editorial process, only the revised content is reviewed and edited. The revisions are retained as redlined text for the review period.

The Proposed Draft is issued for a 30-day comment and vote period. The Proposed Draft is made available to the CLSI delegates, the Board of Directors, Consensus Council, and public for comment during this period.

NOTE: All revisions to the draft document are retained as redlined text for the review period. The Proposed Draft announcement indicates that only the revised (redlined) text is to be reviewed and commented on, and that comments pertaining to other portions of the document (ie, those that were not revised) will be held for consideration at the next review.

After conclusion of the Proposed Draft comment and vote period, any comments received on the revised content are resolved by the assigned DRWG. Comment resolutions are distributed to the commenters with the notice of the right to appeal for a 15-day period.

The approved document is submitted to the Consensus Council for confirmation of process adherence and a vote for publication. When approved, the document proceeds to the Publication Process and is published with the next edition number.

10.2 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.

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

10.3 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.

10.3.1 Expert Panel Decision on Reaffirmation

In conformance with the Scheduled Review of Approved Consensus Documents Process (see Figure 8), the ExP recommends reaffirmation to the CC through completion and submission of the Postpublication Review Form. CLSI staff records the ExP's review and retains any comments on file.

10.3.2 Consensus Council Decision on Reaffirmation

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

See Table 13 for reaffirmation voting conditions and rules.

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

10.3.3 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.

10.4 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 Document Development Process for Consensus Standards and Guidelines
- Users
- CLSI staff

A consensus document can be withdrawn at any point in the Document Development Process for Consensus Standards and Guidelines 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 recommendation and retains any comments on file. The ExP recommends withdrawal to the CC through completion and submission of the Postpublication Review Form.

A consensus document is withdrawn by the CC when a situation needs expedited action. See Table 14 for withdrawal voting conditions and 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 in accordance with the CLSI Documents and Records Retention Policy and Records Retention Schedule.

Chapter 11: Special Considerations for Susceptibility Testing Documents

11.1 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 consensus document is determined, the Document Development Process for Consensus Standards and Guidelines described in Chapter 8 is followed without deviation.

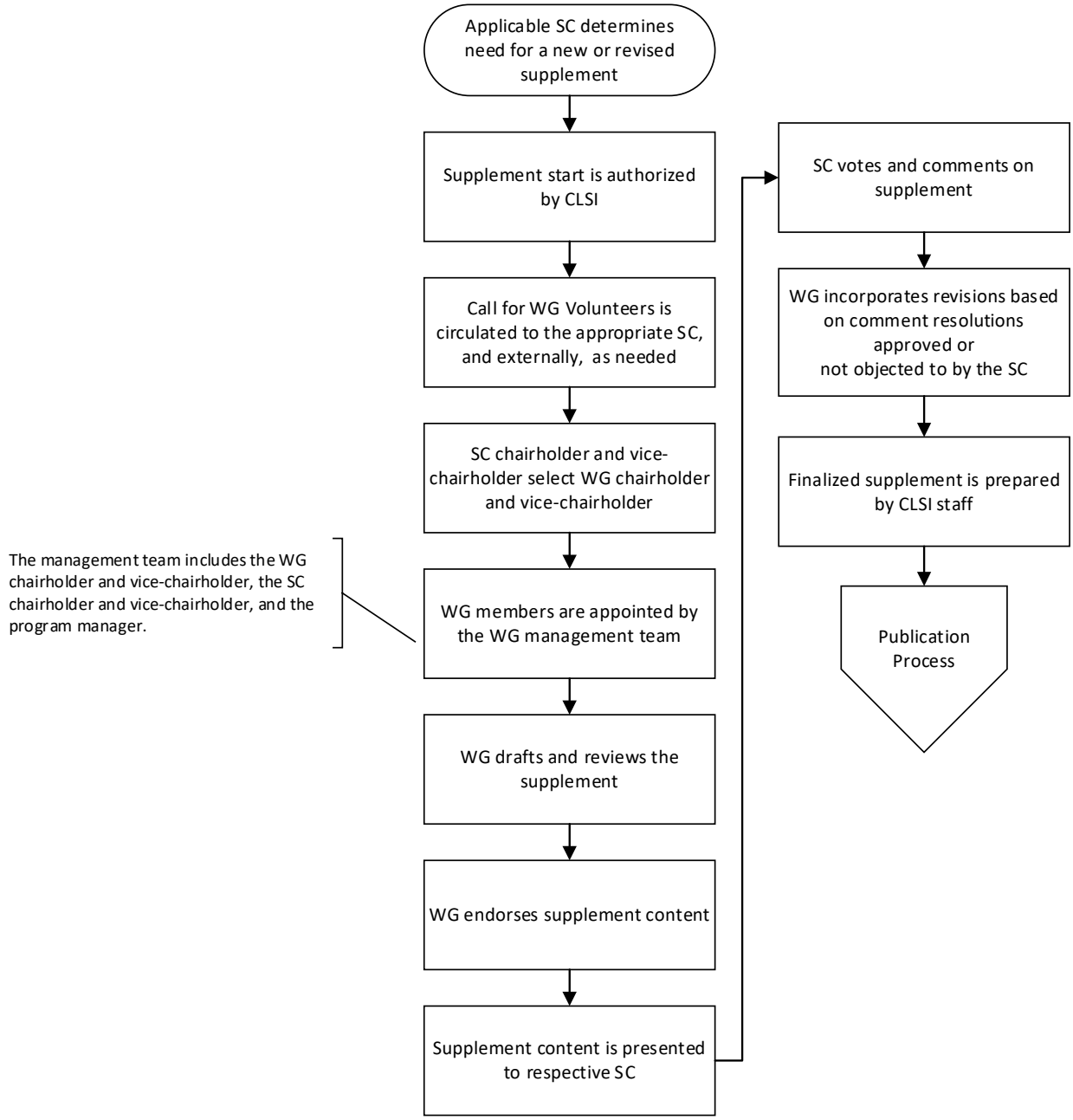
See Tables 11, Table 15, and Subchapter 5.5.2 for voting conditions and rules. **NOTE:** WGs do not conduct formal votes on Proposed Drafts. Proposed Drafts for consensus documents developed by WGs are voted on by the associated SC.

Regarding any SC/WG business for which a vote is required, including WG votes to move decisions forward to the associated SC, the conditions and rules presented in Table 15 and Subchapter 5.5.2 apply.

11.2 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 are developed through a process that has limited consensus following the process shown in Figure 9.



Abbreviations: SC, subcommittee; WG, working group.

Figure 9. Microbiology Supplement Development and Approval Process

Supplements are not submitted for CLSI delegate or CC ballot.

11.4 Process for Continual Revision of a Supplement

A recommendation for continual revision of a supplement is based on the SC's/WG'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 associated consensus document. The information is to be used only in accordance with the provisions of the approved consensus document.

See Table 11 for supplement voting conditions and rules.

Information contained in supplements supersedes previously published information.

Supplements are published and made available through established CLSI.

Chapter 12: 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 CLSI's Document Development Process for Consensus Standards and Guidelines whereas, supplements and other products (eg, 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 these other products are outside the scope of the *Standards Development Policies and Processes*; however, a high-level overview of the processes and comparison with the Document Development Process for Consensus Standards and Guidelines is provided for completeness.

NOTE: A supplement is not a derivative product. See Subchapter 11 for details on supplements.

Descriptions and examples of CLSI products are outlined in Appendix B.

Chapter 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.

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/SC/WG 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/SC/WG representatives, unless otherwise agreed upon in writing by CLSI and the cooperating organization.

CLSI appoints all additional DDC/SC/WG members following the process for establishing DDCs/SCs/WGs and develops the consensus document according to the Document Development Process for Consensus Standards and Guidelines and timelines in these SDPPs.

The cooperating organization's DDC/SC/WG representatives are responsible for obtaining the organization's input and comment during the Document Development Process for Consensus Standards and Guidelines, 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.

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 CC approves the joint project and includes it in the CLSI work plan.

The CC nominates a voting member from an existing CLSI committee with applicable expertise 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 CC votes on the cooperating organization's final draft document during the final vote conducted by the cooperating organization. The CC retains the right to also review any comments and comment resolutions received and prepared by the cooperating organization. See Table 9 ~~Subchapter 8.10.12~~ for CC voting rules.

The approved document is published by CLSI and/or the cooperating organization and includes the logos of both organizations. If CLSI rejects the document, its name and/or logo is not included on the published document.

Chapter 14: Review and Comment on Documents Developed by an Organization Other Than CLSI

14.1 Identifying Reviewers

CLSI staff, in consultation with the chief executive officer, through informal contacts and/or direct CC or BOD 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.

14.2 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.

14.3 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.

14.4 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 15: Submission of CLSI Consensus Standards to the American National Standards Institute

Based on a request and justification from an ExP or a DDC, DRWG, SC, or WG, the CC 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:

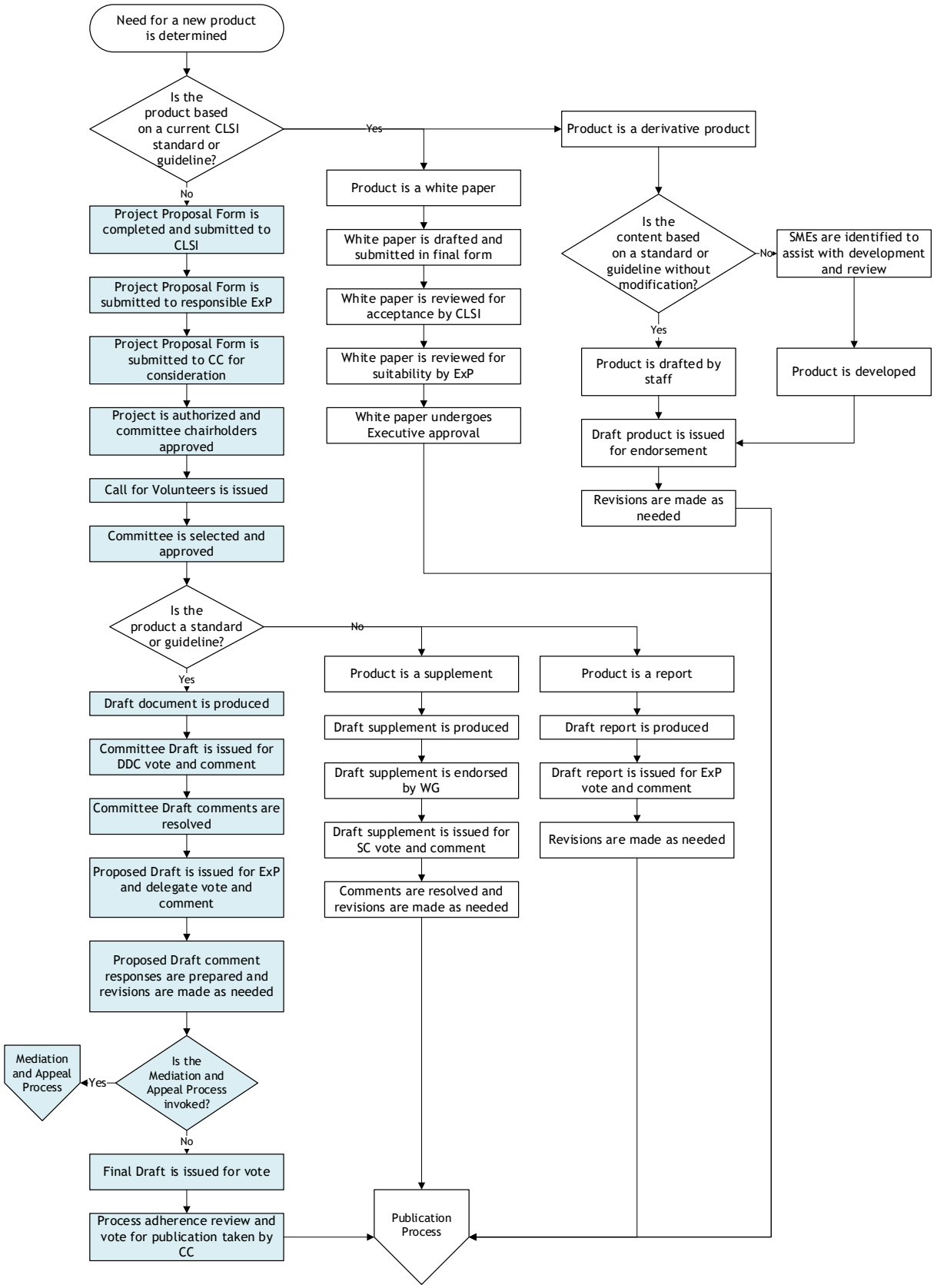
- The document is a standard, not a guideline.
- The standard is US-centric.
- The standard has little or no global applicability.

The decision to create an ANS can be made at any point in the Document Development Process for Consensus Standards and Guidelines. 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 C). 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.



Abbreviations: CC, Consensus Council; DDC, document development committee; ExP, expert panel; SC, subcommittee; SMEs, subject matter experts; WG, working group.

Appendix B. Descriptions and Examples of CLSI Products

Descriptions and examples of CLSI products are outlined below.

Table B1. 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
Supplement	• Supports the scope, purpose, methodology, and performance of the associated approved consensus document • Provides information that updates or refines use of associated consensus document
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 B1. Examples of CLSI Products

Product Type	Example (CLSI Product Code)
Standard	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeast (CLSI M27)
Guideline	Evaluation of Linearity of Quantitative Measurement Procedures (CLSI EP06)
Supplement	Performance Standards for Antimicrobial Susceptibility Testing (CLSI M100)
Report	Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities (CLSI I/LA20)
White paper	Use of Glucose Meters for Critically Ill Patients (CLSI POCT17)
Derivative Products	
Checklists	Gap Analysis Checklists (CLSI QMS01CL)
Implementation Guide	User Evaluation of Acceptability of a Reagent Lot Change Implementation Guide (CLSI EP26IG)
Templates	Instrument Selection Worksheet (CLSI POCT09AWS)
Quick guides	Quality Venipuncture Quick Guide (CLSI PRE02QG)
Workbooks	Laboratory Quality Control Based on Risk Management; Workbook (CLSI EP23AWB)
Worksheets	Instrument Selection Worksheet (CLSI POCT09AWS)
Educational Products	
Educational audioconferences	Setting up the Clinical Laboratory: What to Think About Before You Start (CLIA2WR)
On-demand Course	CLSI Overview of Risk Management for the Laboratory
Online learning program	Cost of Quality (COQOL)
Video	Making a Difference Through Newborn Screening: Blood Collection on Filter Paper (NBS01A6DVD)
Webinar	What's New in VET01S Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated from Animals (On-Demand VET01S Webinar)

Appendix C. 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).

C.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.

C.2 Coordination and Harmonization

During the development or revision of ANS, the CC 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 CC 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*.

C.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*).

C.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* 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 CC 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 CC in order to afford all members of the CC an opportunity to respond, reaffirm, or change their vote.

C.5 Evidence of Consensus and Consensus Council Vote

Consensus is determined per the voting process described in Subchapter 5.5 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 retained in accordance with the CLSI Documents and Records Retention Policy and Records Retention Schedule.

C.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.

C.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).

C.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 within 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."

C.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.

C.10 Periodic Maintenance of American National Standards

Within five years after its approval, the appropriate ExP(s) completes a review to recommend the CC reaffirms, revises, or withdraws an approved ANS. When action is not taken under periodic maintenance to reaffirm, revise, or withdraw 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 CC and ExP 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 Document Development Process for Consensus Standards and Guidelines, Supplement Development Process, Appeal Process, Derivative Product Development Process
June 2020	• Incorporated roles and responsibilities of CC Emeritus Member position
July 2021	• Clarified Derivative Products Process
January 2022	• Incorporated Board-approved policy changes (ie, ExP responsibilities to reflect process improvement project recommendations
September 2022	• Removed ExP Liaison role from CC's responsibilities; clarified that project managers serve as the communication conduit between the ExPs and CC • Added Limited Revision Process
March 2023	• Added Delayed Project Intervention Process
July 2023	• Revised CC and ExP responsibilities
February 2024	• Incorporated grammatical revisions throughout for consistency and readability
February 2026	• Revised Scheduled Review of Approved Consensus Documents • Revision of an Approved Consensus Document • Removed Archiving an Approved Consensus Document • Revised Committee Constitution • Added voting rules and requirements • Incorporated grammatical revisions throughout for consistency and readability
May 2026	• Corrected Table 2 to remove footnote "a" from secretary position (editorial error)

Abbreviations: ANSI, American National Standards Institute; CC, Consensus Council; ExP, expert panel.

NOTES

P: 610.688.0100 **Toll Free (US):** 877.447.1888 **F:** 610.688.0700

E: customerservice@clsi.org **www.clsi.org**