
Clinical and Laboratory Standards Institute Standards Development Policies and Process

This document is effective as of October 01, 2013.

This document defines due process requirements for development of CLSI consensus documents and related activities. An understanding of these Administrative Procedures enables participants to familiarize themselves with the procedures and principles of the Clinical and Laboratory Standards Institute (CLSI), maximize their level of participation, and appreciate the significance of their individual and collective contributions.



Table of Contents

Foreword	iii
1 Introduction.....	4
2 Scope.....	5
3 Revision History	5
4 Definitions.....	5
5 Organization for Document Development.....	7
6 Committee Responsibilities	11
7 Committee Operations	20
8 The Document Drafting Process	25
9 Consensus Approval and Publication	30
10 Nonconsensus Review of Documents.....	40
11 Appeal of Action or Inaction on CLSI Consensus Documents	42
12 Submission of CLSI Consensus Documents to ANSI	43
13 Companion Products	48
14 Revision of the Administrative Procedures	50
Appendix A.1. Management of Disclosure of Interests and Conflicts of Interests	52
Appendix A.2 CLSI Disclosure of Interests Form.....	54
Appendix B. CLSI Project Proposal Form.....	54
Appendix C. CLSI Comment Summary Form.....	60
Appendix D. Example ANSI Forms.....	64

Foreword

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

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

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

Clinical and Laboratory Standards Institute Administrative Procedures

1 Introduction

The CLSI Administrative Procedures serve the following purposes:

- **To build quality** into CLSI consensus documents.
- **To consolidate the general administrative operating procedures** of the organization, the committee structure for development of consensus documents, and the consensus development process itself.
- **To ensure organizational and operational continuity** in the development of consensus documents. The procedures recognize that participation in CLSI is voluntary.
- **To ensure balanced representation** in the CLSI consensus process such that all interested parties may participate, and adequate scientific expertise is available.

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

For those in leadership roles, the Administrative Procedures assist in organizing their efforts and outlining their responsibilities for supervising and documenting the development of consensus documents.

The procedures:

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

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

2 Scope

The CLSI Administrative Policies and Procedures apply to CLSI standards, guidelines, and other materials developed within the CLSI consensus process. These procedures do not apply to marketing or other CLSI materials not intended to be consensus documents.

3 Revision History

Revision Date	Description of Change
November 2008	Updated Disclosure of Interest form and Project Proposal form; eliminated the Quality and Ethics Committee.
February 2009	Updates to the Disclosure of Interests form and the Appeals Process.
January 2011	Incorporated changes in committee structures and document development processes. Inserted description of 15- and 25-month document development timelines.
April 2012	Addressed ANSI audit findings, including more detail regarding development of American National Standards.
January 2012	Inclusion of membership administrative fee information
April 2013	Inclusion of ANSI recommended language regarding American National Standards
June 2013	Change to 2-stage document development process

4 Definitions

American National Standard (ANS) - a standard that has been submitted to the American National Standards Institute (ANSI) and reviewed through their process. CLSI standards and relevant ISO standards may be considered for ANS submittal if desired by a consensus committee and agreed by Chairholders Council (CLSI standards) or the US TAG (ISO Standards).

administrative fee – a monetary amount incurred by all committee participants that defrays the costs of committee operations. 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. No constituency may have a voting majority. For example, a committee with 4 professions members, 4 industry members, and 2 government members meets the definition for balance. A committee with 6 professions members, 3 industry members and only one government member does not meet the definition for balance. Only consensus committees are required to be balanced.

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

companion product - any item provided or sold that is intended to be utilized in conjunction with a CLSI Standard or Guideline. Examples include, but are not limited to, Quick Guides, Wall Charts, software, and templates. Companion products typically contain or refer to technical content taken directly or derived from CLSI Standards and/or Guidelines. They may sometimes be called “derivative products”.

consensus body – the group of volunteer participants who have the final vote to approve publication of a document via a vote of acceptance by at least two-thirds of the group’s voting members. This group is required to have balance, as described above. At CLSI, the consensus body is the consensus committee for each topic area.

consensus committee management team – select volunteer and staff members given authority for making decisions on behalf of a particular consensus committee; NOTE: This group consists of the consensus committee chairholder, consensus committee vice chairholder, staff liaison, and senior staff member responsible for standards development operations/activities.

consensus document - the generic term used to refer to any document published by CLSI that has been subjected to the consensus review process. An approved consensus document has achieved consensus within the healthcare community. Nonetheless, subsequent revisions of an approved consensus document should be reviewed to assess utility of the final document and attainment of consensus (ie, that comments on earlier versions have been satisfactorily addressed), and to identify additional needed consensus documents.

consensus document categorization

Categorization for Document Availability

- Category A: CLSI documents that are active in the consensus process.
- Category B: CLSI documents that are no longer reviewed as part of the consensus process but remain available in electronic format only, for informational purposes.
- Category C: CLSI documents that have been discontinued.

Categorization for Document Sales Analysis

- Core 1: CLSI documents with unit sales that meet or exceed the average CLSI document unit sales for the prior 3 – 5 year period.
- Core 2: CLSI documents with unit sales that fall between the mean and median CLSI document unit sales for the prior 3 - 5 year period.
- Core 3: CLSI documents with unit sales at or below the median CLSI document unit sales for the prior 3 - 5 year period.

constituency / interest category - All volunteers are categorized into one of three interest groups: government, industry, or professions. In determining constituency categories, the following guidelines apply:

- individuals employed by an academic institution, a healthcare delivery organization, a professional society or association, or an accreditation or certification organization in the healthcare field are considered members of the professions constituency
- individuals employed by a government, or government-funded agency, are considered members of the government constituency
- individuals employed by a manufacturing or trade organization, and consultants to any constituency are considered members of the industry constituency except that,
- an individual officially designated by an organization in any of the constituencies represents that constituency regardless of his/her employment.

These declarations are an important factor in the appointment process, and apply to committee members and the chairholder alike. Volunteers declare their constituency in writing on their Disclosure of Interests form. CLSI staff verifies the interest category for each consensus committee member.

document development committee management team – select volunteer and staff members given authority for making decisions on behalf of a particular document development committee; NOTE: This group consists of the consensus committee chairholder, consensus committee vice chairholder, document development committee chairholder, or co-chairholders, as applicable; document development committee vice chairholder, as applicable; staff liaison; project manager; and, senior staff member responsible for standards development operations/activities.

guideline - a CLSI document developed through the consensus process describing criteria for a general operating practice, method, or material for voluntary use. A guideline can be used as written or modified by the user to fit specific needs. Mandates (i.e. “must” or “shall”) are occasionally allowed in guidelines,

in cases in which the document development committee feels strongly that a particular action is either required or prohibited, or when a guideline addresses provisions based on regulations.

President – the CLSI official responsible for the overall leadership of CLSI. The President, with the concurrence of the Board of Directors, authorizes the establishment or dissolution of consensus committees, advisory committees, and special committees as are deemed appropriate. The President is also responsible for appointing special committee members and consensus committee chairholders.

President Elect – the CLSI official with overall responsibility for administering the activities of the Chairholders Council, and the various consensus committees, subcommittees, document development committees, working groups, task groups, and special reviewers in conjunction with selected CLSI staff members. The President Elect appoints consensus committee members, advisors, and reviewers.

report - a CLSI technical document that is published as a service for informational purposes only. It is not subjected to consensus review and is not a consensus document. It is reviewed in accordance with the requirements outlined in Section 10.1, Track A: Documents Developed by CLSI, and released for publication by the appropriate consensus committee. These documents have the potential to become guidelines upon revision through the consensus process.

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

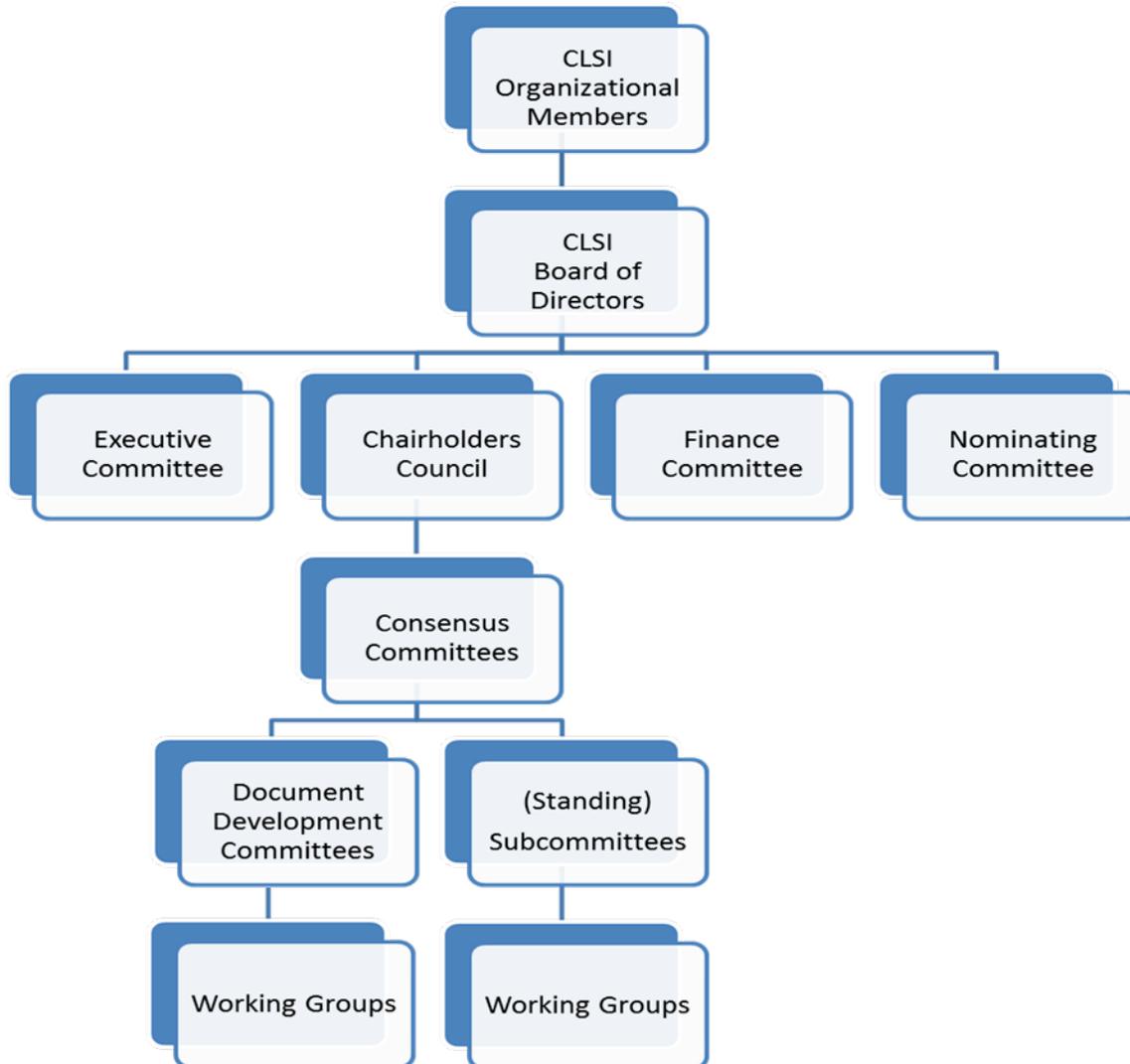
voluntary consensus - the substantial agreement by materially affected, competent, and interested parties that is obtained by following the procedures outlined in Sections 7 and 8. It does not connote unanimous agreement, but does mean that the participants in the development of a consensus document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

5 Organization for Document Development

5.1 Structure

CLSI is structured in a cascading series of volunteer committees supported by CLSI staff. Each committee is assigned specific responsibilities and accountabilities within the document development process. Each committee is discussed in detail below.

Figure 1. CLSI Committee Structure



5.2 General Requirements for all Committees

5.2.1 Eligibility

All CLSI consensus committee, document development committee, subcommittee, and working group meetings are open to any interested parties when technical matters relating to the development of standards and guidelines are to be discussed.

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

Provisions for hardship by individual members shall be considered upon request to CLSI.

If a committee determines that they need additional technical expertise, these technical experts may be invited to participate in that specific document's development without payment of the administrative fee, upon approval by the associated consensus committee management team, with agreement from the senior management of standards development for CLSI.

5.2.2 Disclosure of Interests and Copyright Assignment

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

1. Decisions made on behalf of CLSI and works published by the organization are developed by processes that allow opportunity for fair and open discussion by any interested parties.
2. CLSI must ensure that there is adequate scientific expertise represented on consensus committees, subcommittees, document development committees, and working groups.
3. To ensure adequate expertise, and to promote expression of a variety of views, individuals may participate in the process, even if they have vested interests. However, voting members of committees should be qualified experts and shall disclose all potential conflicts of interests.
4. Disclosures of interests of all participants (ie, committee chairholders, vice chairholders, co-chairholders, members, advisors, contributors, reviewers) are made upon affiliation with CLSI or at the beginning of the process of developing a consensus document. Conflicts of interests on a given project or activity may be managed in accordance with the CLSI Administrative Procedures as summarized in Appendix A.1. Disclosures of interests are available for review upon request of interested parties.

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

Volunteers participating in CLSI activity complete a Disclosure of Interests and Copyright Assignment Form (Appendix A.2) listing all interests and activities relevant to the outcome of CLSI document development at the time of nomination, and showing agreement to comply with CLSI's Code of Ethics. These forms are updated by the volunteers at least every 4 years, with each new position appointment, and with any changes in disclosed information. Volunteers who do not submit and/or update their disclosures may not continue participation in CLSI activities until the form is received in the CLSI office. The disclosure includes identification of current employer and relevant personal, professional, and financial interests. Consultancies, service as an expert witness in the particular area of expertise, and any controlling financial interest or benefit held or received should also be reported. Other interests that are reportable include faculty appointments, professional society memberships, other boards or committees, professional licenses or honors, patents, publications, grants received, and public presentations given in the past three years, relative to CLSI activities. A *curriculum vitae* may be used to supply the requested information.

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

- Personal interests in which individuals receive payment, including donations of supplies or equipment, from a company whose businesses may be directly impacted by the decisions made or the final document developed by a CLSI committee, eg, consultant fees, payment for contract work, stocks and investments in which the individual has influence on the financial management of the stockholdings versus mutual funds.
- Non-personal interests involving payment that benefits an entity for which an individual has responsibility or authority, but is not received by the individual personally, eg, fellowships, grants for supporting department operations or for a staff (not including students) position(s), and commissioned research or other studies by staff in the department.

Information on disclosed interests is kept on file at the CLSI office and is made available for review upon request. Information regarding each person's name, affiliation and interest category are provided to all participants on each CLSI committee. Disclosure of interest summaries for consensus committee members are posted on CLSI's website.

5.2.3 Undisclosed Interests

Any individual involved with CLSI in any particular area who becomes aware of an interest or activity (see Section 5.2.1) that is undisclosed must report this to the CLSI Chief Executive Officer. Such situations are reviewed and resolved by the Executive Committee of CLSI's Board of Directors. Records of such reports and their resolution are kept on file at the CLSI office. Individuals who fail to disclose interests that may contribute to a compromise in a standard or guideline are subject to removal from participation in CLSI activities.

5.2.4 Nominations and Appointments

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

Nominations describe the expertise and experience of the individual within the subject area. All nominees shall disclose financial or other interests (see Section 5.2.1) that may impact their ability to offer an unbiased view of matters that may come before the committee.

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

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

Table 1. Appointment Process

Position	Recommending Official	Appointed By	With the Advice of (as needed)
Consensus committee	Consensus committee chairholder or any interested party	President	Board of Directors
Special committee or task force	Special committee/task force chairholder or any interested party	President	Board of Directors
Consensus committee chairholder, vice chairholder, co-chairholder	Any interested party	President	Board of Directors, President Elect
Consensus committee member and advisor	Consensus committee chairholder and/or any interested party	President Elect	President, Consensus Committee Chairholder and Vice Chairholder
Document development committee	Any interested party	Consensus Committee Chairholder	Consensus Committee
Document development committee member	Document development committee chairholder and/or any interested party	Consensus Committee Chairholder	Consensus Committee
Subcommittee chairholder/vice chairholder	Any interested party	Consensus Committee Chairholder	Consensus Committee
Subcommittee members and advisors	Subcommittee chairholder and/or any interested party	Consensus Committee Chairholder	Consensus Committee
Working group chairholder, vice chairholder, co-chairholders	Subcommittee chairholder and/or any interested party	Consensus Committee Chairholder	Consensus Committee
Working group members	Subcommittee chairholder and/or any interested party	Consensus Committee Chairholder	Consensus Committee

Reviewers for consensus committees, subcommittees and working groups, and contributors for document development committees self-nominate, and are appointed by staff, consistent with CLSI’s policy of openness.

6 Committee Responsibilities

6.1 Overview

The roles and responsibilities of CLSI committees are outlined in Table 2 below. Table 3 provides a summary of the CLSI committee structure.

Table 2. Committee Roles and Responsibilities

CLSI Committee	Roles and Responsibilities
Board of Directors	<ul style="list-style-type: none"> • Establishes the policies and procedures that govern the consensus process. Specific duties in the document development process, including final approval of changes to the Administrative Procedures, are assigned to the President and the President Elect. • Has final approval of changes to the Administrative Procedures.
Chairholders Council	<ul style="list-style-type: none"> • Assembly of consensus committee chairholders, together with the President Elect and selected CLSI staff members, has overall responsibility for managing the development of CLSI consensus documents, the development process, and committee expenses versus plan. • Reviews and approves proposals for new document development.
Consensus Committee	<ul style="list-style-type: none"> • Management group that oversees development and review of consensus documents within its assigned area of responsibility • For draft documents developed by a document development committee, the consensus committee is responsible for the final review to ensure technical accuracy, conformance to CLSI document content policies, and overall quality.
Document Development Committee	<ul style="list-style-type: none"> • Primary responsibility for drafting individual consensus documents and for evaluating and addressing comments received during each phase of the consensus process • Responsible for considering scientific accuracy, practicality, and comprehensibility with the goal of creating documents of overall high quality and utility
Subcommittee	<ul style="list-style-type: none"> • Primary responsibility for drafting individual consensus documents and for evaluating and addressing comments received during each phase of the consensus process • Usually responsible for two or more related documents, for scheduled review of the documents, and/or for supplemental updates for the documents and for continuous revision of certain standards/guidelines • Typically a standing committee
Working Group	<ul style="list-style-type: none"> • Subunit of a subcommittee or document development committee • Assignment is limited in scope and it is disbanded upon completion of the assignment

Table 3. Committee Positions

CLSI Committee	Committee Position						
	Chairholder	Vice chairholder	Co-chairholder	Member	Advisor	Contributor	Reviewer
Consensus Committee	X ¹	X ²		X ¹	X ¹		X
Document Development Committee	X ³	Optional ³	Optional ³	X		X	
Subcommittee	X ¹	X ²	Optional	X ¹	X ¹		X
Working Group	X ⁴	Optional ⁴	Optional ⁴	X	Optional		X

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

² Vice chairholders of consensus committees or subcommittees are limited to serving a maximum of two one-year terms if rotating from the position of chairholder of the same consensus committee or subcommittee*

³ Appointed for a one-year term and may be reappointed in this position for the duration of the project*

⁴ Serves in this position for the duration of the project*

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

6.2 Chairholders Council

The CLSI Chairholders Council, consisting of the President Elect, appointed consensus committee chairholders, and the CLSI Vice President of Standards Development has overall responsibility for managing the development of CLSI consensus documents, and continually improving the consensus-development process. The Council recommends inter-consensus committee priorities and an overall project management plan. The Chairholders Council is responsible for setting priorities for CLSI projects based on medical utility and clinical relevance. The Chairholders Council approves all new document development activities. Upon completion of all assigned tasks, the Chairholders Council declares a document development committee or working group inactive and disbands it.

The Chairholders Council meets twice per year in face to face meetings, usually at CLSI’s annual leadership conference, and in conjunction with the fall Board of Directors meeting, and schedules teleconferences at intervals throughout the remainder of the year.

6.3 Consensus Committees

The consensus committee is the consensus body for each project within its area of responsibility, and is required to be balanced with representatives from each constituency with at least 2 members from each constituency included. The consensus committee should have approximately 10 members, including the chairholder. No one constituency may have a voting majority on a consensus committee. The consensus committee serves as a management group rather than a document-drafting committee. It identifies and prioritizes consensus-development projects and oversees the development and review of consensus documents within each area of interest.

Consensus committees are structured to ensure balanced focus on:

- consensus management
- identification of user needs
- participation of experienced and new volunteers

For draft documents developed by a document development committee, subcommittee, or working group, the consensus committee is responsible for the final technical review and approval to publish at the approved consensus level.

6.3.1 Consensus Committee Chairholders

Each consensus committee chairholder is appointed for a one-year term and may continue in this position for a total of four consecutive years upon reappointment by the President, or a designee (e.g. President Elect).

The consensus committee 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 consensus committee chairholder is willing and able to devote significant time and effort to consensus committee administration, including service on the Chairholders Council, and to guide and monitor the progress of document development committee, subcommittee, and working group activities. The chairholder also should be aware of opportunities within the technical area that are appropriate for the voluntary consensus process, and should keep CLSI informed, so that appropriate new consensus projects may be considered.

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

The consensus committee chairholder maintains close contact with document development committee and subcommittee chairholders, advising at all stages in the development of documents, emphasizing technical excellence, clarity, suitability for the user, global harmonization, and timeliness of publication.

It is the responsibility of the consensus committee chairholder to monitor the performance of consensus committee members and advisors, and to take appropriate action when required to ensure that assigned responsibilities are being met.

The consensus committee chairholder has lead responsibility for developing an annual plan of the goals and objectives of the consensus committee and for developing a project budget for each project within the consensus committee in concert with the project management team. The consensus committee chairholder is responsible for reporting progress/activity within the area of responsibility to the Chairholders Council at each meeting. Such reports indicate progress toward meeting consensus committee goals and any significant changes to the consensus committee plan that need Council, Board, or Board Executive Committee action.

6.3.2 Consensus Committee Vice Chairholder

The consensus committee chairholder recommends and the President, or a designee (e.g. President Elect) appoints a vice chairholder. Each consensus committee vice chairholder is appointed for a one-year term and may continue in this position for a total of four consecutive years upon reappointment by the President, with the advice of the President Elect and the Chief Executive Officer.

The role of each consensus committee's vice chairholder is to serve as the committee's leader and to represent the consensus committee on the Chairholders Council in the chairholder's absence. In the final year of a chairholder's eligibility for service, the vice chairholder should also be the chairholder-

designate, but planned succession to the chairholder position is neither a mandate nor a prerequisite for vice chairholder service.

6.3.3 Consensus Committee Members

Consensus committee members represent the consensus body for each topic area, and as such, vote to approve documents for publication. Members are appointed annually, and may continue in this position for a total of four consecutive one-year terms upon reappointment by the President Elect. The consensus committee chairholder determines in advance of the call for volunteers, the number of members from industry, government, or professional organizations that is required to maintain a balance of those interests on the consensus committee.

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

6.3.4 Consensus Committee Advisors

Consensus committee advisors are individuals who have expert knowledge and experience in the subject area of the consensus committee, have a working knowledge of the consensus process through experience as a volunteer with CLSI; and are interested in actively supporting the efforts managed by the consensus committee.

Advisors must agree to participate in the activities of the consensus committee, as knowledge and experience permits: ie, identify topics for consideration for new consensus documents; develop and submit new project proposals; serve as document development committee or working group chairholders or members for development or revision of consensus documents; and review and submit input on draft documents and revisions circulated to the consensus committee for approval.

Each consensus committee advisor is appointed for a one-year term and may continue in this position for a total of four consecutive years upon reappointment by the President Elect.

6.3.5 Consensus Committee Reviewers

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

6.3.6 Change in Status or Employment

In the event of a change in status or employment of a consensus committee member (including chairholders) which results in a change in the constituency category in CLSI, the consensus committee member submits a resignation which may be accepted at the discretion of the consensus committee chairholder and/or Board Executive Committee. If the criteria for balance are no longer met, the consensus committee may not vote on consensus documents until a new person is appointed and balance is restored; outreach to achieve balance is undertaken.

6.4 Document Development Committees, Subcommittees, and Working Groups

6.4.1 Document Development Committees (DDCs)

CLSI DDCs have primary responsibility for development of consensus documents, including drafting documents and editing documents in response to technical and editorial comments received during each

phase of the consensus process. Scientific accuracy, practicality, and comprehensibility are to be considered by the DDC, with the goal of creating documents of overall high quality and utility. DDC members may also participate in the development of companion products, and the presentation of document-related content in webinars and other educational sessions.

6.4.2 Subcommittees (SCs)

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

6.4.3 Working Groups (WGs)

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

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

Balance among CLSI constituencies in constituting a DDC, SC or WG is not a requirement; however, they should include representation from each constituency affected by the document.

6.4.4 Chairholders

The DDC/SC/WG chairholder may also be a participant of the consensus committee. Each DDC chairholder is appointed for a one-year term and may be reappointed in this position for the duration of a project. SC/WG chairholders are appointed for one-year terms and may continue in this position for a total of four consecutive years upon reappointment by the President (or designee), with the advice of the President Elect. The President or President Elect, in consultation with the consensus committee chairholder, maintain the right to replace a DDC/SC/WG chairholder when deemed necessary and/or appropriate.

The DDC/SC/WG chairholder should be experienced in coordinating and expediting work programs in the field. The chairholder also should have the ability to clearly communicate and understand the requirements for comment and response imposed by the consensus process.

The DDC/SC/WG chairholder is responsible for:

- Furnishing progress activity reports as requested to the consensus committee chairholder. Such reports should include forecasts of the time and expenses associated with completion of each authorized consensus effort.
- Scheduling and planning the agenda for DDC/SC/WG meetings and conference calls after consultation with the consensus committee chairholder and the CLSI staff.
- Identifying a committee participant who will serve as committee secretary and determines, based on contribution to development of a document, those individuals to be listed as contributing authors of the document.

As necessary, DDCs may have co-chairholders.

6.4.5 SC/WG Vice Chairholder

NOTE: does not apply to DDCs

Each SC/WG vice chairholder is appointed for a one-year term and may continue in this position for a total of four consecutive years upon reappointment by the President, with the advice of the President Elect. The President or President Elect, in consultation with the consensus committee chairholder and DDC/SC/WG chairholder, maintains the right to replace a DDC/SC/WG member when deemed necessary and/or appropriate.

The role of each SC's vice chairholder is to serve as the committee's leader and to represent the SC in the chairholder's absence. In the final year of a chairholder's eligibility for service, the vice chairholder should also be the chairholder-designate, but planned succession to the chairholder position is not a prerequisite for vice chairholder service prior to then, nor is it guaranteed.

6.4.6 DDC/SC/WG Members

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

DDC/SC/WG members should have in-depth knowledge in the particular area of interest. They should have the ability to communicate clearly and to understand the requirements for comment and response imposed by the consensus process.

DDC/SC/WG members, along with the DDC/SC/WG chairholder, have primary responsibility for drafting consensus documents, voting to accept the document, and evaluating and addressing comments received during each phase of the consensus process before final approval by the consensus committee.

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

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

DDC/SC/WG member status is subject to termination in the event that project-related commitments are not met (eg, submission of writing assignments, participation in committee activities). The consensus committee chairholder, with the concurrence of the President Elect, reserves the right to terminate an individual's member status when necessary and appropriate.

6.4.7 DDC/SC/WG Secretary

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

6.4.8 DDC Contributors

NOTE: does not apply to SCs or WGs

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

DDC contributors are expected to review and submit input on draft documents and revisions circulated to the DDC.

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

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

6.4.9 SC/WG Advisors

NOTE: does not apply to DDCs

SC/WG advisors are individuals who have expert knowledge and experience in the subject area of the SC/WG; have a working knowledge of the consensus process through experience as a volunteer with CLSI; and, are interested in actively supporting the efforts managed by the SC/WG.

Advisors must agree to participate and do so in the activities of the SC/WG, as knowledge and experience permits, in any of the following activities: identify topics for consideration for new consensus documents; develop and submit new project proposals; serve as working group chairholders or members for development or revision of consensus documents; and review and submit input on draft documents and revisions circulated to the SC/WG for approval.

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

SC/WG Reviewers

NOTE: does not apply to DDCs

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

6.5 Project Management Team

A project management team is composed of the DDC or WG chairholder, the SC chairholder (where applicable), the consensus committee chairholder, the staff liaison, and the project manager, if applicable. The project management team is responsible for project leadership and resolution of technical or administrative issues that arise during project development. The project management team is responsible for developing committee operating budgets in accord with the overall priorities established by the Chairholders Council, and monitoring adherence to them.

6.6 Chief Executive Officer/CLSI office

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

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

The CLSI staff coordinates all meetings of CLSI committees, including consensus committees, DDCs, SCs, WGs, task forces, and ad hoc groups.

The CLSI staff supports the activities of CLSI committees in such areas as processing of consensus documents, dissemination of documents, preparation and recording of ballots, processing of expense reports, and sale and distribution of consensus documents.

6.6.1 Staff Liaison/Senior Project Manager

The staff liaison/senior project manager is responsible for administrative support of a consensus committee and oversight of all consensus committee projects. The staff liaison/senior project manager is a member of the respective consensus committee management team and attends the Chairholders Council meetings. The staff liaison/senior project manager assists the consensus committee chairholder in the preparation of interim budget and project status reports to the Chairholders Council, the Board of Directors, and the Board Executive Committee.

6.6.2 Project Manager

Under the guidance of the staff liaison/senior project manager, the project manager provides administrative support for timely development of individual projects. The responsibilities of the project manager include:

- ensuring adherence to established CLSI policies and procedures
- organization of meetings, including face-to-face meetings, teleconferences, and electronic conferences
- announcing and confirming meetings
- collating and distributing resource information for committee members
- facilitating the preparation and distribution of draft documents
- acknowledging consensus comments

6.7 Member Organizations/Official Delegates

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

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

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

6.8 Endorsement Disclaimer

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

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

6.9 Resignations from CLSI Committees

Resignation by consensus committee, DDC, SC, or WG members may be accepted by the consensus committee chairholder and forwarded to the CLSI office. The resignation of the consensus committee chairholder may be accepted by the President or the President Elect.

In the event of a change in status or employment of a consensus committee member (including chairholders), which results in a change in the constituency category in CLSI, the consensus committee member submits a resignation which may be accepted at the discretion of the consensus committee chairholder and/or Board Executive Committee.

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

7 Committee Operations

7.1 Committee Meetings, Conference Calls and Web Meetings

CLSI committees conduct business at in-person meetings and during conference calls, by mail, and/or by electronic communication. Meeting announcements and agendas are issued from the CLSI office. Meetings of CLSI committees are open to all interested parties. However, each committee chairholder may establish procedures that ensure that the objectives of the meeting are met while accommodating the opportunity for public attendance and observation.

All consensus committee, DDC, SC, or WG meetings are scheduled in accord with the annual consensus committee budget and activities plan approved by the Chairholders Council and are in compliance with the CLSI antitrust policy.

It is the policy of CLSI to conduct all meetings in an open forum and to permit noncommittee participants to attend meetings, provided proper notice has been received so that space can be reserved to accommodate attendees.

Chairholders may schedule a conference call or web conference meeting (instead of a face-to-face meeting) especially when specific, limited discussions and decisions are needed. Draft consensus documents can often be approved and comments on consensus documents addressed and resolved through conference call or web conference meetings. They are strongly encouraged, due to the cost savings involved, when a project's workload permits this type of committee interaction.

7.1.1 Meeting and Conference Call Arrangements

All meetings and conference calls are set up by a member of CLSI's professional staff (staff liaison or project manager). No CLSI meeting or conference call may be held without the presence of a member of the CLSI professional staff, unless an exception has been granted by the Vice President, Standards Development. If an exception is granted, the chairholder is briefed on the antitrust precautions and on related information.

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

7.1.2 Meeting Notice and Agenda

CLSI staff ensures that all listed consensus committee, DDC, SC, or WG members, contributors, advisors, and reviewers are notified directly and in a timely manner of all meetings. The consensus committee chairholder should also be specifically notified about DDC, SC, or WG meetings. Notification should include all relevant information that the chairholder and staff believe should be considered in

preparation for the meeting, along with the specific time, place, date, and tentative agenda or list of subjects to be considered.

Notification should provide a mechanism for determining the number of individuals planning to attend.

7.1.3 Conduct of Meetings

Attendees must adhere to the meeting agenda. Discussions should be relevant to the purpose of the meeting as set out in the agenda. “Off-the-record” discussions should be avoided.

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

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

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

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

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

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

7.1.4 Forbidden Discussion Topics

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

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

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

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

7.1.5 Summary Minutes

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

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

The committee chairholder is responsible for ensuring that summary minutes are kept during the meeting or conference call. For meetings of a consensus committee, keeping summary minutes is the responsibility of the staff liaison/senior project manager or other CLSI staff member. For meetings of a DDC, SC, or WG, it is the responsibility of the committee secretary to keep the summary minutes (see sections 6.4.7).

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

7.1.6 Unresolved Issues

Matters (eg, minority views) that are not fully resolved by a DDC, SC, or WG deliberation on a document should be reflected in the minutes. Minority views may also be included in the Draft 2 voting document (eg, in the Foreword, Introduction, Appendix, as appropriate) at the option of the committee, with a request for comment from the broader community solicited.

7.1.7 Recorded Votes

Recorded votes are formal votes held by any CLSI body to forward a document to the next stage of development and voting, or in the case of Draft 4, to signify agreement (or disagreement) that consensus has been achieved and that the document as written represents that consensus. CLSI requires a two-thirds majority of the committee's full membership (excluding abstentions) for approval of a document, with at least one member from each constituency voting to accept the document. Any consensus body member unable to attend a meeting, conference call, or web conference where a formal recorded ballot is taken may submit a formal vote within 5 days of the meeting (before or after).

CLSI recognizes that so-called straw votes may be taken periodically within a CLSI body (DDC, SC, WG, consensus committee, or Board of Directors). These votes are considered nothing more than a part of the deliberative process and are not recorded votes.

Voting options at all stages of voting include:

- Accept;
- Accept, with comment;
- Reject, with reasons (the reasons for a rejection are given and if possible include specific wording or actions that resolve the objection); and
- Abstain.

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

7.1.8 Recorded Comments

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

All commenters submitting comments during the consensus committee review are provided, in writing, a summary of the comments and their disposition, and notification of their right to appeal.

7.2 Correspondence

7.2.1 Official Correspondence

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

No other persons are authorized to have CLSI letterhead stationery.

7.2.2 Committee Correspondence

Occasionally, it may be necessary or useful for committee members to correspond directly about committee projects. If such correspondence is intended to be included in the official record of that committee's work, a copy is forwarded to the staff liaison or project manager for appropriate marking and filing. Such correspondence may be on plain stationery or on the personal or organizational letterhead of the sender. If the sender wants this correspondence to be on CLSI letterhead, it is processed at the CLSI office.

7.2.3 Electronic Correspondence

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

7.3 Draft Documents

All draft documents are circulated to the appropriate committees by the CLSI staff. Each draft that is circulated is identified as an internal CLSI document, with each page clearly marked "Draft." The draft also has a title and an order code, which is assigned by the CLSI office. Once submitted to the CLSI office, draft documents are owned by CLSI and subject to CLSI copyright.

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

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

In addition, all Draft 2 documents bear a "DRAFT" watermark across the middle of each page, followed by "Not to be used for clinical purposes or to satisfy regulatory or accreditation requirements."

All other text that may be intended for inclusion in a draft document is considered a “preliminary writing.” All preliminary writings are treated as committee correspondence (see Section 7.2.2).

7.4 Fiscal Controls

7.4.1 Conservation of Financial Resources

CLSI adheres to strict financial budgetary controls exercised by the Treasurer through the CLSI office, with the advice and consent of the Board of Directors. These controls are consistent with the overall technical and scientific goals of the organization; the budgetary objectives adopted by the Board; and the Internal Revenue Service regulations governing a voluntary, nonprofit organization [Section 501(c)(3)].

7.4.2 Committee Budget

Each consensus committee chairholder presents a proposed consensus committee annual budget and activities plan for approval by the Chairholders Council and Board of Directors. The annual budget and activities plan includes both project objectives and the budget required to accomplish these objectives.

The management team is responsible for developing committee-operating budgets in accord with the overall priorities established by the Chairholders Council, and monitoring adherence to it.

7.4.3 Committee Accounts

The CLSI office maintains an account record for each committee. Chairholders are provided with budget status reports upon request or by a decision of the Treasurer where variances or trends require attention. Periodic audits of committee expenditures may be conducted by the Treasurer to fulfill the organization's responsibility under its nonprofit status.

7.4.4 Reimbursement for Expenses

CLSI expects member organizations to reimburse the expenses of its volunteer representatives participating in any CLSI activity, including the Board of Directors, consensus committees, DDCs, SCs, WGs, and task forces.

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

If the nominee is selected to serve as a committee member representing government or professions constituency, committee secretary, or to represent CLSI in a particular activity, CLSI reimburses that individual's expenses to participate in that activity.

Contributors, advisors, and reviewers appointed to CLSI committees are not reimbursed.

Exceptions for special circumstances (eg, need for additional expert input on a technical topic) are approved by the respective consensus committee chairholder and project manager.

Reimbursement (rather than advancement of funds) is the established policy within CLSI's Meeting and Reimbursement Guidelines. Reimbursable expenses are those necessarily associated with personal travel (by the most economical means) to and from scheduled CLSI meetings. Reimbursement may be subject to per diem limits.

7.5 Surveys

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

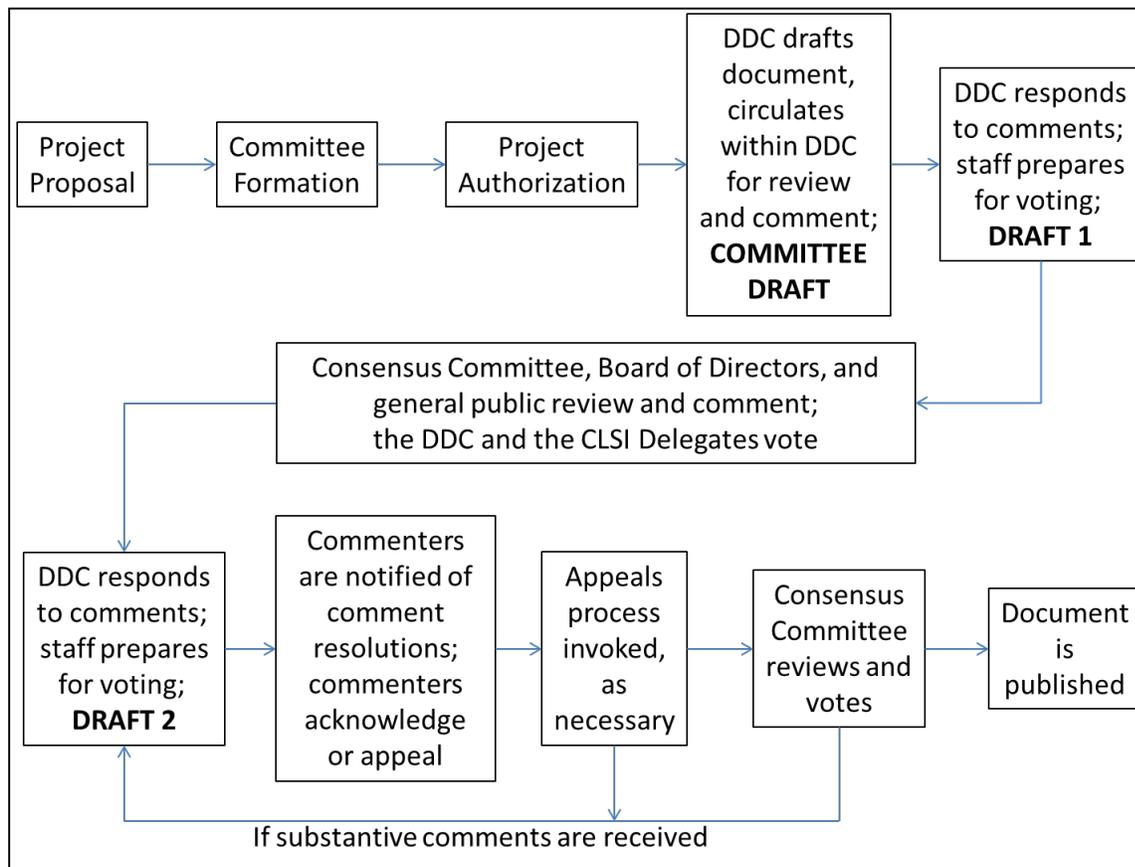
It is permissible, under appropriately controlled circumstances and procedures, for CLSI to collect data from member and nonmember companies, aggregate and blind the material as to its direct source, and distribute it to members and other recipients developing or using CLSI consensus documents.

8 The Document Drafting Process

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

During the two voting stages, the document may be reviewed by and/or voted on by members of the DDC, consensus committee, Board of Directors, CLSI delegates, and the general public. Comments received at either voting stage are fully addressed by the DDC or WG.

Figure 2. High level view of the document development process



8.1 Project Proposal and Authorization

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

8.1.1 Project Proposal Form

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

8.1.2 Elements of the Project Proposal

All project proposal forms require the following information for review by Chairholders Council:

- complete, accurate contact information of the individual submitting the proposal
- recommended title for the proposed project
- description of the type of product being proposed
- project description (see Section 8.1.2.4)
- recommended timeline for development (see Section 8.1.2.6)
- listing of all DDC participants and their constituencies
- a proposed project budget

Consensus committee review is required prior to submission of the proposal to the Chairholders Council.

8.1.2.1 Project Description

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

- project scope (see Section 8.1.2.2)
- project rationale (see Section 8.1.2.3)
- comprehensive project description (see Section 8.1.2.4)
- recommended chapter headings/topics
- additional factors for consideration (see Section 8.1.2.5)

The Chairholders Council returns a proposal to the original submitter, with a request for appropriate expansion/clarification, if the above listed information is incomplete.

8.1.2.2 Project Scope

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

NOTE: CLSI has developed a template for presentation of these elements. Refer to Appendix B for details.

8.1.2.3 Project Rationale

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

8.1.2.4 Comprehensive Project Description

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

8.1.2.5 Additional Factors for Consideration

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

8.1.2.6 Recommended Timeline

The recommended timeline (ie, Track 1 or Track 2) is provided (see Section 8.3.1). Track 1 is considered the default track and a rationale is provided to support a recommendation for Track 2, or any other expected deviation from Track 1.

8.1.2.7 Proposed DDC Membership

All project proposal submissions include a description of specific expertise required on the document development committee. This description is utilized to create a “Call for Volunteers” recruitment that solicits membership for the DDC via the CLSI website and other electronic communications. The proposed DDC chairholder, together with the consensus committee chairholder, select the proposed DDC members, considering their individual expertise and their constituency category.

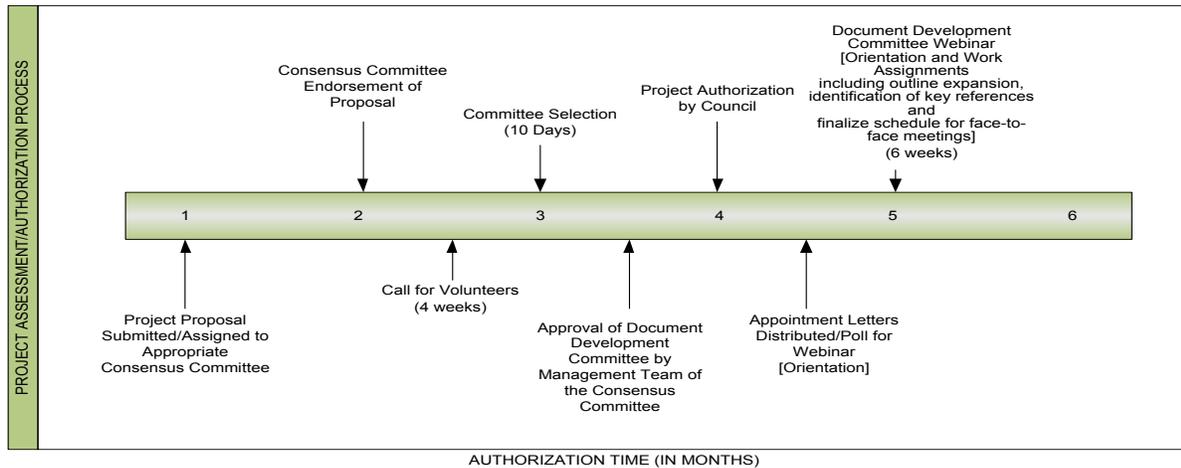
Proposals also include a description of the procedure for submission of nominations or self-nominations for consideration to serve on CLSI committees.

8.1.2.8 Proposed Project Budget

A proposed project budget is included, considering factors such as the expected number of face-to-face meetings, conference calls and/or webinars. In addition, the anticipated sales revenue of the document is included. CLSI staff may be consulted to assist with generation of these numbers.

8.1.3 Project Assessment/Authorization Process

Figure 3. Project Assessment/Authorization Process



The first stage of project assessment/authorization requires preliminary review and evaluation by the CLSI office staff and the appropriate consensus committee.

This step is intended to ensure that a proposed project is consistent with the mission and goals of CLSI, and that there is a perceived need for the project. The volunteer recruitment process also begins at this time.

When a project proposal is submitted for preliminary consensus committee review, the entire consensus committee reviews the proposal and makes a recommendation to the Chairholders Council.

The consensus committee ensures that a project’s scope is defined prior to its authorization.

The Board has delegated authority for authorization of new projects to the Chairholders Council within fiscal limits and with the concurrence of the President Elect.

The consensus committee chairholder presents the completed proposal to the Chairholders Council, or the proposal is circulated by email to all the Chairholders Council members.

- The Chairholders Council reviews and votes by electronic communication, during prescheduled conference calls, or at a face-to-face meeting. Resource allocations and capacity issues should be addressed in advance.
- The Chairholders can (1) accept the project with work commencing immediately; (2) reject; (3) in limited situations, commit to fund a project but schedule a delayed start, in which case there is recognition of the impact of that decision on the project timeline; or (4) request to discuss the proposal at the next meeting or conference call.

8.2 Notification of Standards Development

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

8.3 Organization of Effort

8.3.1 Document Development Tracks

Figures 8.3a and 8.3b depict two tracks for the development and production of CLSI documents and expected timelines.

Figure 8.3a
Track 1, 14 months

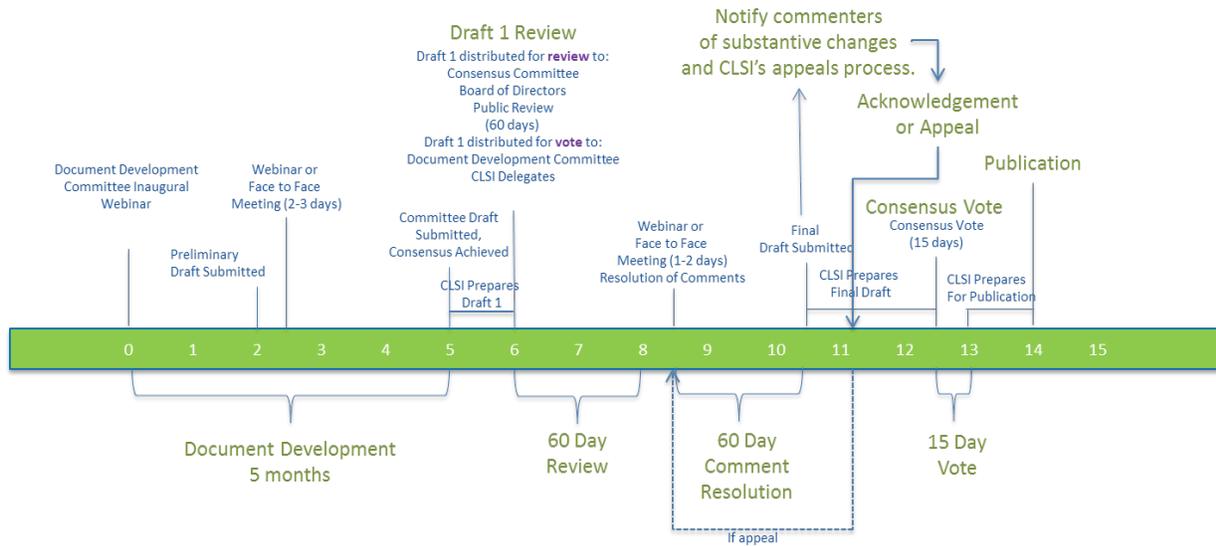
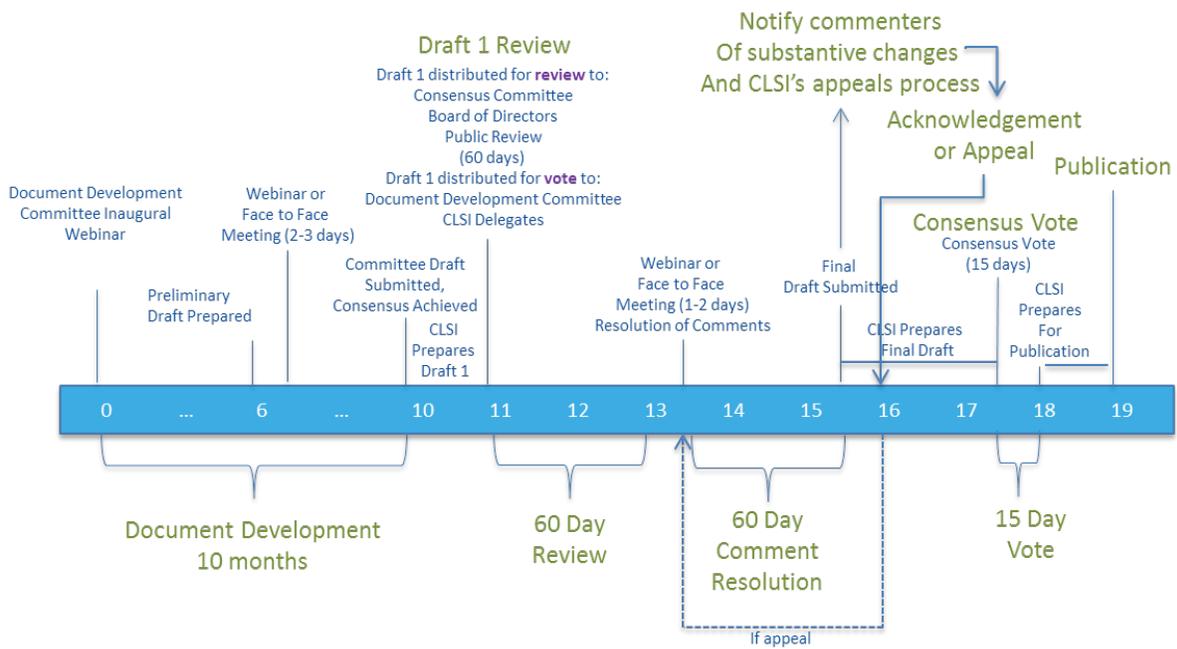


Figure 8.3b
Track 2: 19 months



The time required to develop a consensus document depends on multiple factors, including the breadth of scope, complexity of issues, comprehensiveness and depth in covering the topics, and the controversial nature of the topic. Two track options available for establishing a timeline for document development include:

- Track 1 – projects with narrow scopes dealing with noncontroversial subject areas; targeting completion in no more than 14 months
- Track 2 – projects requiring broad and/or in-depth coverage of a subject area that may deal with complex and/or controversial issues; targeting completion in no more than 19 months

Other timelines are reviewed and approved by the Chairholders Council.

Document development committee or working group communications are needed to evaluate progress and to discuss the content of various draft provisions of the consensus document. Committees use the most efficient, expeditious process possible to ensure such communications.

8.3.2 Timeline for Revisions

The timeline for completion of document revisions follows Track 1 as described in Section 8.2.1 above.

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

8.4 Style Guide

In drafting a consensus document, the DDC, SC, or WG is required to follow the guidelines established in the most recent edition of the CLSI Style Guide. The DDC, SC, or WG is encouraged to use the resources of its members for editing of documents during the drafting stage. The CLSI staff members provide limited assistance in preparation of draft documents.

8.5 Alternative Methods in Standards

An alternative procedure that is different than a CLSI method and was not used as the basis for developing the consensus document should not be included in or cited in the consensus document. If such an alternative procedure is judged by the appropriate CLSI committee to be advantageous in certain test applications, it should be either (a) the subject of a new project proposal to develop a separate CLSI consensus document, or (b) incorporated in a revision of an existing consensus document that is advanced through the consensus process.

9 Consensus Approval and Publication

9.1 Introduction

The responsible consensus committee is the official body of the organization that certifies that consensus has been reached on a consensus document, ensuring the procedures of this section have been followed.

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

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

Thus, the approved consensus document is broadly acceptable to all because it has been fairly and responsibly constructed and tested over the widest possible audience of interested parties.

An integral procedure in the consensus approval process is the mechanism through which each committee takes notice of and acts on all comments, including material objections to any provision of a consensus document. All substantive comments or objections to the content of any consensus document that are not implemented at the next level of publication in the consensus process are acted upon by a written committee response explaining the reasons for this action. The consensus committee, as reflected in the following procedures for consideration of a consensus document, ensures that there has been a satisfactory and adequate response (Section 9.2.3.4) to all comments.

For ANSs, the requirements listed in Section 12 also apply.

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

9.2 Consensus Approval Process

9.2.1 Draft 1

Draft 1 is the finalized draft standard or guideline submitted for vote to the DDC members and the CLSI delegates. At this time, the draft is also available for review and comment by the consensus committee, the CLSI Board of Directors, and the general public.

Draft 1 should receive wide and thorough technical review, including overall review of scope, approach, utility, and a line-by-line review of its technical and editorial content. This review is intended to ensure the overall quality, utility, and readability of CLSI's approved consensus documents, and that they are technically correct and reflect broad consensus.

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

For the document development processes described below, "DDC" refers to the group developing the document, whether it is actually a DDC, a WG, or an SC.

9.2.1.1 DDC Approval of Draft 1

Draft 1 is approved by the applicable DDC. A two-thirds majority approval of the DDC's members (excluding abstentions) is required for approval of Draft 1, including approval by at least one member of each constituency. If the DDC chairholder votes to reject the document, review by the project management team is required.

9.2.1.2 Delegate Approval of Draft 1

Each CLSI member organizations' duly named delegate has the responsibility to vote. In the absence of a delegate vote, the alternate delegate vote is counted. Proxy votes are not counted.

A vote to approve affirms that the document improves the quality of healthcare practices and medical testing. A document is advanced when a two-thirds majority of votes cast (excluding abstentions) is for approval.

9.2.1.3 Circulation of Draft 1 for Review and Comment

Concurrent to the DDC and delegate voting period, Draft 1 is available for review and comment by the consensus committee, the CLSI Board of Directors, and the general public. Availability of Draft 1 documents for review by nonmembers is announced on CLSI's Website. There may be a nominal charge.

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

The closing date for voting on Draft 1 is specified on the ballot and officially ends at midnight US Eastern Time on the date specified. Any ballot received after the voting deadline is not counted in the voting results.

All comments received on Draft 1 as a result of the review are compiled by the CLSI office. Comments received after the close of balloting will be evaluated by the DDC, and the DDC will determine whether to address the comment, or hold it until the next revision.

A form for submission of comments is available (see Appendix C).

9.2.1.4 Review of the Document by Selected Special Reviewers

As a result of the nature of a particular document or its subject matter, the DDC may decide that special reviewers be selected to provide an independent review of the document. This review is in addition to that of the DDC and consensus committee. Special reviewers may be asked to provide a theoretical analysis of a document or they may be asked to provide a practical, in-use test of a document, where that analysis or test may require special facilities or expertise.

The use of special reviewers is encouraged whenever appropriate. Consideration should be given to soliciting reviewers with first-hand experience at the appropriate work site. Neither membership in CLSI nor any fees are required for participation on CLSI special review committees.

9.2.1.5 Rejected Draft 1

A Draft 1 document that does not achieve the required voting majorities is considered rejected. The rejected Draft 1 and all comments including those supporting reject votes are forwarded to the appropriate DDC for consideration and resolution. The DDC, in consultation with the consensus committee (and SC for WGs), decides whether to rework the document and resubmit it to the consensus process.

9.2.1.5.1 Unresolved Objections

Unresolved objections (ie, "reject" votes), attempts at resolution of unresolved objections, and substantive changes after balloting are reported to the consensus committee and committee members have the opportunity to respond, reaffirm, or change their votes, with a minimum period of 10 days.

A Draft 1 document may highlight any unresolved technical issues as appropriate. For example, minority views not fully resolved, at the option of the committee or at the request of its individual members, may be included in the document and comment from the broader community solicited.

9.2.1.6 Handling Draft 1 Comments

The assigned document development committee or working group has responsibility for resolution of comments.

All comments on Draft 1, including unresolved voting comments, and comments submitted by the applicable consensus committee, the CLSI delegates or their alternates, the Board of Directors, and other

interested parties are kept on file at the CLSI office. The file identifies the consensus document under review, the commenter's name and affiliation, and the date received in the CLSI office.

Communications acknowledging receipt of the comments are prepared by the CLSI office and distributed to the commenter and committee chairholder(s).

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

- (1) is specific to each question/comment
- (2) includes specific support data, if requested, for each question/comment
- (3) is reviewed by the committee members
- (4) is retained on file

The DDC acts on comments received in a timely way, usually within 60 days of preparation of a comment summary. This may be done at a meeting, electronically, or by phone as long as each member of the committee is in receipt of the comments. If there is undue delay, the Chairholders Council, with the advice of the President Elect, may cancel the project at its discretion.

Comments received after close of the Draft 1 review/balloting period are reviewed by the DDC. The DDC determines whether to address the comments in the current draft, or hold them until the next revision. In the event that late comments have a significant impact (eg, raise substantive issues) on document content, the consensus committee chairholder, with the concurrence with the President Elect, may authorize a delay in document publication.

The record of disposition of comments and the DDC and consensus committee votes are documented by the CLSI office.

All commenters are provided, in writing, a summary of the comments, the disposition of the comments and the rationale therefore, as well as notification of their right to appeal. Commenters are expected to acknowledge receipt of the comment resolutions, and/or exercise their right to appeal, within 15 calendar days. If no response is received from a commenter, then it is assumed that the commenter accepts the revisions. Commenters are notified of this assumption.

A form for submission of comments is available (see Appendix C). Electronic commenting via CLSI's committee software is also acceptable.

9.2.1.7 DDC Dissolution

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

9.2.2 Draft 2

Following the Draft 1 vote, the DDC responds to the Draft 1 comments, and revises the draft as necessary. This activity usually occurs in a 2 – 3 day face-to-face meeting, but may also occur by conference calls, webinars, or other means. The choice of a meeting vs. other means is usually determined by the extent of the Draft 1 technical comments and amount of revision needed.

9.2.3 Draft 2

After resolution of all of the comments and incorporation all of the necessary revisions by the DDC, the document is now considered Draft 2, and is ready for consensus committee approval.

9.2.3.1 Consensus Committee Approval of Draft 2

All members of the consensus body (ie, consensus committee) have the opportunity to vote on the approval of the Draft 2 document. When recorded votes are taken at meetings or conference calls, members who are absent are given the opportunity to vote within 5 days of the meeting (before or after).

Two-thirds majority approval of the consensus committee's members (excluding abstentions) and approval by at least one representative of each constituency's membership is required for consensus committee approval of the Draft 2. If the consensus committee chairholder votes to reject the document, review by the project management team is required.

For the consensus committee vote, CLSI staff sends follow-up notices to consensus committee members who have not yet voted, 7 to 10 days prior to the end of the ballot period.

If the consensus committee has substantive comments (as determined by themselves), then the document is returned to the DDC to resolve the comments. Significant changes may trigger a new delegate and public review and commenting period. The consensus committee makes the determination as to whether the responses to comments have substantially changed the document, requiring a new review period.

The consensus committee, as the consensus body, is informed of all substantive comments received or changes made in the document after the consensus vote, and each member is offered the opportunity to respond, reaffirm, or change his/her vote.

After Draft 2 and its comment summary and responses are approved during the document development process, each commenter/objector is sent (electronically, if possible) a letter with the summary of comments and responses as an attachment, expressing appreciation for the comment(s). The commenter is notified of their right to appeal.

9.3 Approval of the Final Draft and Evidence of Compliance

A Final Draft is a standard or guideline that has undergone Draft 2 review/vote and has been approved by the DDC, the CLSI delegates, and the consensus committee. The Final Draft incorporates revisions reflecting resolution of Draft 2 comments as applicable.

All voting stages results are reviewed by the consensus committee chairholder and/or a designee consensus committee member. If all voting stages appear to have been conducted and documented correctly, the document is considered approved for publication.

9.3.1 Publication of Approved Consensus Document

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

9.3.2 Evidence of Compliance

Records that demonstrate compliance with all aspects of CLSI Administrative Procedures are retained in accordance with the Record Retentions Policy.

9.4 Joint Documents

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

9.4.1 Documents Developed by CLSI (also see Section 10.1)

CLSI staff informs and invites participation from the cooperating organization in proposed new projects during the external assessment stage of proposal review.

The cooperating organization nominates committee participants and covers the travel expenses of appointed representatives upon appointment.

CLSI staff authorizes, appoints committee members, and develops the consensus document according to its established procedures and timelines.

Committee participants representing the cooperating organization on the respective CLSI committee are responsible for obtaining input and comment from the cooperating organization and voting on the CLSI consensus document during the development process.

CLSI staff informs the cooperating organization when a consensus document is distributed for final vote; approval is obtained concurrently with CLSI's final consensus committee vote.

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

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

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

The respective CLSI consensus committee includes the joint project in its work plan with Chairholders Council and President Elect approval.

A representative of the consensus committee is appointed as a voting member of the responsible cooperating organization committee through the usual CLSI nomination and appointment process.

CLSI covers travel expenses of the CLSI representatives who are eligible for reimbursement under its reimbursement policy.

The CLSI consensus committee reviews, comments, and votes on draft documents at the request of the designated consensus committee representative.

CLSI staff oversees the CLSI consensus committee review and approval of joint projects, and notifies the cooperating organization about voting schedules and voting results.

The consensus committee votes on the final draft standard as the CLSI consensus body during the final approval process by the constituent bodies of the cooperating organization. A two-thirds majority approval of the consensus committee's members (excluding abstentions), and at least one representative of each constituency's membership, is required for consensus committee approval of consensus documents.

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

9.5 Withdrawn Consensus Document

A consensus document may be withdrawn by a two-thirds majority vote of the Board of Directors or a unanimous vote of the Board Executive Committee in a situation requiring expedited action. Before the withdrawal is effective, the Board or Board Executive Committee advises the responsible committee of the situation and seek its guidance.

A consensus document may be withdrawn at any point in the consensus process or after the consensus approval is achieved based on information that proves the consensus document is invalid or obsolete. Withdrawn consensus documents are referred to the appropriate consensus committee. The consensus committee decides whether to rework the consensus document and resubmit it to the consensus process. The point at which it is submitted (candidate consensus document for advancement) is determined by the consensus committee based on the status it had reached and the nature and extent of the required revision.

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

9.6 Recategorized Consensus Document

The Chairholders Council, after consultation with the appropriate consensus committee chairholder, may decide by majority vote to move consensus documents into Category B or Category C.

The consensus committee may decide to revise a Category B consensus document if it can establish sufficient justification.

Notices of recategorization are published by the CLSI office.

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

9.7 Scheduled Review of Approved Consensus Document

9.7.1 Assignment to the Consensus Committee

Within five years after its approval, the appropriate consensus committee(s) initiates a review to determine the necessary action to reaffirm, revise, or withdraw an approved consensus document. The consensus committee considers:

- any comments received after approval of the document
- any new information or changes in technology that should be included in the document
- whether the document is globally applicable, and if that is adequately reflected in the current revision
- the revision is consistent with the authorized project objectives as described in the project proposal.

9.7.2 Reaffirmation of an Approved Consensus Document

Reaffirmation is appropriate when the consensus committee(s) decides that the existing document adequately reflects the current state of the art, and that substantive changes are not necessary at the time of review. CLSI staff document the review and retain any comments on file. The consensus committee decides on an appropriate timeframe for future reviews, up to five years.

9.7.2.1 Consensus Committee Action on Reaffirmation

Two-thirds majority approval of the members (abstentions excluded) of the consensus committee(s) and at least one representative of each constituency's membership, is required for reaffirmation. The record of disposition of committee member comments and voting are documented by CLSI staff. The reaffirmation is considered approved for publication once the consensus committee has voted favorably for reaffirmation.

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

9.7.2.2 Publication of Reaffirmed Consensus Documents

When a consensus document is reaffirmed, the document is labeled as such, and the date of reaffirmation is included on the copyright page of the document. This applies to both paper and electronic versions of reaffirmed documents.

9.7.3 Amendment of an Approved Consensus Document

Amendment is appropriate when the consensus committee, after reviewing comments and considering advances in the field, decides that revision is needed but that 1) the revisions needed are editorial changes in generally recognized terminology, or minor technical changes that are unrelated to the functionality of the consensus document; and 2) the revisions do not significantly affect the scope, purpose, or methodology used in the consensus document.

9.7.3.1 Consensus Committee Action on Amendments

The consensus committee prepares appropriate revisions based on comments and/or its own initiative. A two-thirds majority approval of the consensus committee's members and at least one representative of each constituency's membership are required for approval of the amended consensus document. The record of disposition of committee member comments and votes are documented by CLSI. The amendment is considered approved for publication once the consensus committee has voted favorably for the amended document.

Amendments on CLSI documents may be presented during the consensus committee meeting or be formally distributed for a 10-day consensus committee vote and approval for publication as an "Amended Consensus Document".

9.7.3.2 Publication of Amended Consensus Documents

When a consensus document is amended, the document is labeled as such, and the date of amendment is included on the copyright page of the document. This applies to both paper and electronic versions of amended documents.

9.7.4 Revision of an Approved Consensus Document

Revision is appropriate when comments or advances in the field suggest, in addition to smaller changes, that changes in the scope, purpose, or methodology in the consensus document are needed. Such changes call for a new revision of the consensus document.

9.7.4.1 Consensus Committee Action on Revisions

The consensus committee prepares appropriate revisions based on comments and/or its own initiative. This may be delegated to a DDC or WG, and follows Track 1. All document development, comment and voting stages follow the same procedures as for new documents. Refer to Figure 2 and Section 9.2 for information on consensus document voting stages.

9.7.5 Consolidation of Approved Consensus Document

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

9.7.5.1 Consensus Committee Action to Consolidate Consensus Documents

After determining that certain consensus documents may be combined, the consensus committee prepares an integrated consensus document that includes any changes based on comments and addresses any advances in the field. A two-thirds majority approval of the consensus committee's members (excluding abstentions) and at least one representative of each constituency's membership are required for approval of the new edition of the consensus document.

The consensus committee may also recommend that the revised consensus document be submitted to selected special reviewers as in Section 9.2.2.

The record of disposition of committee member comments and voting are documented by the CLSI office.

9.7.5.2 Membership Action on Consolidated Consensus Documents

Balloting on the consolidated consensus document by the general membership follows the procedures described in Section 9.2.3.

9.7.5.3 Publication of Consolidated Consensus Documents

After a positive approval vote during the consensus process, a new edition of the approved consolidated consensus document is published.

9.8 Interim Revision

The following process is used to quickly address new information pertaining to or challenging a CLSI consensus document.

9.8.1 Assessment of New Information

The CLSI office, as the CLSI communication center, is the primary recipient of comments pertaining to CLSI consensus documents. In consultation with the management team for each project, the CLSI office routinely reviews comments pertaining to CLSI consensus documents to identify new information that may impact on the use of the consensus document.

The initial assessment of new information is the consensus committee's responsibility. The objective of the initial assessment is to consider the technical and medical significance of new information, and its impact upon the published documents. Preliminary assessment by the consensus committee may be accomplished electronically, by facsimile transmission, conference call, or web conference review of the

new information. If necessary, a meeting of the consensus committee is scheduled. A consensus committee may request outside expert input in assessing new information.

The consensus committee may recommend one of the following options:

- no action required
- routine revision, possibly earlier than scheduled (see Section 9.7.4)
- interim revision (see Section 9.8)
- supplemental revision (see Section 9.9.1)
- withdrawal (see Section 9.5)

9.8.2 Procedure for Interim Revision

A recommendation for interim revision of a consensus document is based on the consensus committee's assessment that the new information has significant medical and patient-care impact and needs to be addressed immediately.

In order for a consensus committee to recommend an interim revision of a consensus document to address new information, approval is received from two-thirds majority of the consensus committee members (excluding abstentions) and at least one representative of each constituency's membership, by consensus committee ballot. The CLSI Executive Committee has the authority to override a consensus committee decision regarding an interim revision.

The document revision process begins as soon as feasible. The CLSI office uses every available mechanism to expedite the process for interim revision.

The interim revision is made by document attachment (eg, document insert or label) or by publication of a new edition of the document.

Announcement of the interim revision is made by CLSI. The interim revision is distributed electronically or mailed to CLSI members and document purchasers.

For ANSs, an interim revision does not substantively change or result in formal revisions to the ANS.

9.9 Continuous Revision

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

9.9.1 Supplements

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

9.9.2 Process for Continuous Revision

A recommendation for continuous revision of a consensus document is based on the subcommittee's assessment that there is ongoing development of new information or refinement of existing information that requires periodic updating of an approved CLSI consensus document prior to scheduled review. The new information is consistent with the scope, purpose, methodology, and performance of the approved consensus document. The information is to be used only in accordance with the provisions of the approved consensus document.

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

- (a) Two-thirds majority approval (abstentions excluded) by the SC members, after satisfactory review of the new information.
- (b) Approval by at least one representative of each constituency's membership, after review of the SC action.
- (c) The consensus committee reviews the record for both due process and technical adequacy of the subcommittee action.

Information contained in supplements supersedes prior information but remains tentative for at least one year or pending revision of the approved consensus document.

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

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

10 Nonconsensus Review of Documents

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

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

The protocol includes two tracks:

- Track A, for review of quickly emerging, nonconsensus documents that the Board of Directors or the Board Executive Committee authorizes CLSI to prepare
- Track B, for review of documents developed by other organizations that do not require a single US position

10.1 Track A: Documents Developed by CLSI

10.1.1 Identifying Reviewers

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

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

10.1.2 Document Review

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

10.1.3 Comments

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

10.1.4 Revised Draft

CLSI staff circulates the revised draft to all of the respondents on the earlier draft, with a quick turnaround for further comment (it is usually necessary that this turnaround time be seven days or less).

10.1.5 Final Comments

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

10.1.6 Distribution

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

10.2 Track B: Other Documents Not Requiring a US Position

10.2.1 Identifying Reviewers

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

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

10.2.2 Nature of Input

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

10.2.3 Document Review

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

10.2.4 Comments

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

11 Appeal of Action or Inaction on CLSI Consensus Documents

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

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

Appeals of inaction may be filed at any time.

11.1 Process for Addressing Substantive Issues

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

Addressing all substantive issues adequately and in a timely manner is an integral part of the consensus process as a document proceeds through the draft and approval stages. At each stage, comments that include objections regarding substantive issues are actively solicited from members and other interested parties. When significant substantive comments are received on a consensus document, even an “approved” consensus document, they are evaluated for the purpose of determining whether they require immediate attention. If immediate attention is not required, the comments are collected and reviewed at the next stage in the consensus process. All substantive comments require an “adequate response” from the drafting committee. This response is reviewed by the appropriate consensus committee to ensure its technical adequacy. Each objector is advised in writing (including electronic communications) of the disposition of the objection and the reasons therefore. If resolution is not achieved, each objector is informed in writing that an appeals process exists within CLSI’s procedures.

11.2 Appeal of Substantive and/or Procedural Issues

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

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

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

If the objection remains unresolved, a CLSI Appeals Panel, established by the Board with appointments made by the President, together with the assistance of other parties the panel finds appropriate and with inclusion of the appellant's input regarding the appropriateness of the panel membership, hears the appeal on a date that is mutually convenient for the panel, the appellant, and any other interested parties.

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

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

11.3 Final Appeal

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

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

The Chief Executive Officer notifies the appellant, the chairholder of the Appeals Panel, and the affected consensus committee chairholder of the Board's decision on whether to hear the appeal. If the Board agrees to hear the appeal, the appellant, the chairholder of the Appeals Panel, and the affected consensus committee chairholder is invited to be present at the hearing on a date that is convenient to all interested parties.

The Board of Directors, having heard an appeal, may reverse the appeals action of the Appeals Panel by not less than a majority vote. If less than a majority is in favor of reversal, the action of the Appeals Panel is sustained. CLSI promptly notifies the appellant, the chairholder of the Appeals Panel, and the affected consensus committee chairholder of its decision in writing.

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

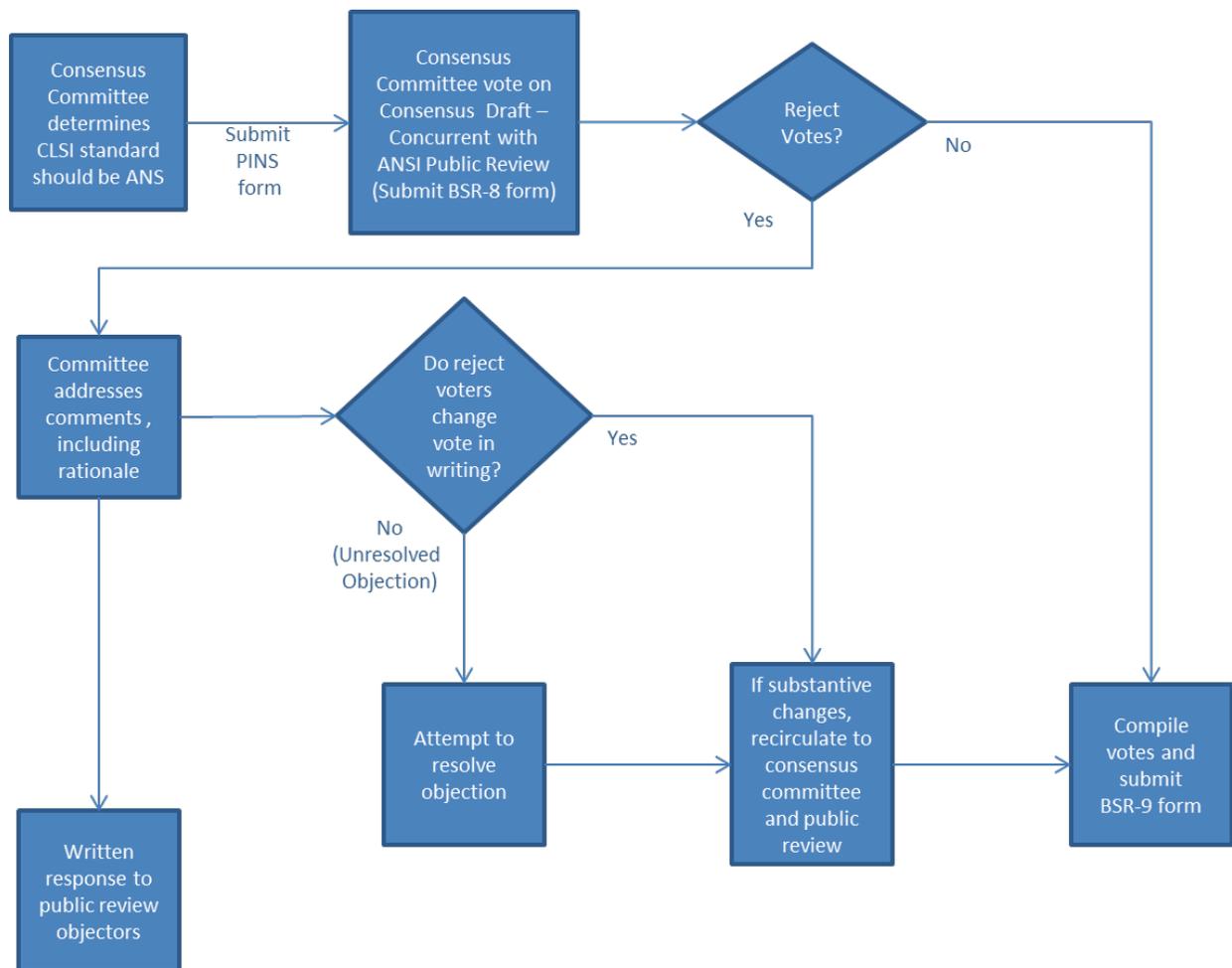
Any consensus committee may recommend a CLSI standard for adoption as an American National Standard (ANS). CLSI has established these criteria for the consensus committee to consider when evaluating the CLSI document for adoption as an ANS:

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

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

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

Figure 5. ANS Process Overview



12.1 Notification of Standards Development or Revision

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

If CLSI receives written comments within 30 days from the publication date of a PINS announcement in *Standards Action*, and the comments assert that a proposed standard duplicates or conflicts with an existing American National Standard (ANS) or a candidate ANS that has been announced previously in *Standards Action*, a mandatory deliberation of representatives from the relevant stakeholder groups is held within 90 days from the comment deadline. The deliberation is organized by CLSI and the commenter, and is concluded before CLSI submits a draft standard for public review. If the deliberation does not take place within the 90-day period and CLSI demonstrates that it has made a good faith effort to schedule and otherwise organize it, then CLSI is excused from compliance with this requirement. The purpose of the deliberation is to provide the relevant stakeholders with an opportunity to discuss whether there is a compelling need for the proposed standards project. The outcome of the deliberation is

conveyed in writing in a Deliberation Report, by CLSI to the commenter and to the ANSI Board of Standards Review (BSR) for consideration, within 30 days after the conclusion of the deliberation. Upon submission of the Deliberation Report, CLSI may continue with the submission of the draft standard for public review. If additional deliberations take place, they should not delay the submission of the draft for public review, and an updated Deliberation Report shall be conveyed within 30 days after each deliberation. Any actions agreed upon from the deliberations shall be carried out in a reasonably timely manner, but normally should not exceed 90 days following the deliberation. Subsequently, CLSI shall include all of the Deliberation Report(s) with the BSR-9 submittal to the ANSI BSR for consideration should CLSI ultimately submit the subject standard to ANSI for approval. Stakeholders who were involved in the PINS deliberation process may also file separate Deliberation Report(s) with ANSI and CLSI within 30 days after conclusion of any deliberation for consideration by the BSR, if the standard is submitted to ANSI for approval. While the outcome is not binding, participants are encouraged to develop a consensus on whether and how the standards development project should proceed.

12.2 Coordination and Harmonization

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

12.3 Patent Statements

Copies of any and all patent statements received by CLSI in connection with a proposed or existing American National Standard are forwarded to the American National Standards Institute (ANSI).

12.4 Public Review

Proposals for new ANSs and proposals to revise, reaffirm, or withdraw approval of existing ANSs are transmitted to ANSI using the **BSR-8** form (*Standards Action* Public Review Request Form), or its equivalent, for listing in *Standards Action* in order 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 one of the following:

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

This public review period is at a close-to-final stage of the document development. If the standard changes substantially after the public review, it is submitted for a new public review. Within the CLSI process, this public review occurs concurrently with the consensus committee approval of the consensus 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, and which 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 subsequent to 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 consider them in the same manner as a new proposal. Timely comments that are not related to the proposal under consideration are documented and considered in the same manner as submittal of a new proposal. The submitters of the comments are so notified.

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

12.5 Evidence of Consensus and Consensus Committee Vote

Consensus is determined as per section 9 of these procedures.

- a) 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 Board of Standards Review (BSR) as unresolved rejected votes.
- b) 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.
- c) CLSI is not required to consider reject votes accompanied by comments not related to the proposal under consideration, or reject votes without comment. CLSI indicates conspicuously on the ballot that reject votes are accompanied by comments related to the proposal, and that votes unaccompanied by such comments are recorded as "reject without comments" without further notice to the voter. Such votes are not factored into the numerical requirements for consensus. CLSI is not required to solicit comments from the rejecting voter. The reject without comment vote is reported to ANSI in the final submission to the BSR.
- d) 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.
- e) CLSI maintains records of evidence regarding any change of an original vote.
- f) All voting records are maintained by CLSI for at least one document revision cycle.

12.6 Submittal for ANS 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, Multipurpose Extension Request Form.

12.7 Designation of ANSs

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 (e.g., ANSI/CLSI CC##-A-YYYY, where CC indicates the appropriate consensus committee, ##-A indicates the appropriate document number and revision level, and YYYY indicates the year of revision or first publication).

12.8 Publication of ANSs

ANSs 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 ANSs.

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

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

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

12.9 National Adoption of ISO or IEC Standards

CLSI utilizes ANSI procedures for the national adoption of ISO or IEC standards as ANSs (*ANSI Procedures for the National Adoption of ISO or IEC Standards as American National Standards*).

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

12.10 Periodic Maintenance of ANSs

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

13 Companion Products

A companion product is any item provided or sold that is intended to be utilized in conjunction with a CLSI standard or guideline. Examples include, but are not limited to, quick guides, wall charts, software, and templates. Companion products typically contain or refer to technical content taken directly or derived from CLSI standards and/or guidelines. They may sometimes be called “derivative products”.

Companion products include alternative forms of presentation (eg, videos, computer applications) of published consensus documents, documents derived from published consensus documents that provide

implementation guidance for the user, or educational materials including, eg, teleconferences and webinars.

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

13.1 Development

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

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

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

13.2 Verification Process

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

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

13.2.1 Verification Working Group

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

In order to fulfill its role, the designated working group:

- reviews and refines the additional or clarifying content or any other pre-production content needed to create the product;
- identifies any sections of the consensus document not addressed by the product;
- if applicable, approves the preproduction product by formal vote;
- assists the staff in identifying essential supplemental information; and
- by formal vote, verifies that the final product functions as intended and faithfully represents the consensus document(s) on which it is based.

If the verification working group develops the electronic product, an additional group verifies, by majority vote, any applicable preproduction format as well as the final product. The relevant consensus committee confirms the functionality and faithful representation of the electronic product.

In the absence of a unanimous working group vote after attempting to resolve objections, the question of verifying the final product is referred to the consensus committee which, by majority vote, may approve the final product.

13.3 Reverification

A companion product based on a consensus document that has advanced to the next consensus level is reviewed for concordance with the revised document.

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

13.3.1 Minimal/Nonsubstantive Revision

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

13.3.2 Substantive Revision

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

13.4 Withdrawal and Discontinuation of Standards Application

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

As a document proceeds to the next consensus level, any related companion products are reviewed for concordance with the revised document (see Section 13). If the companion product cannot be reverified against a revised consensus document, the companion product is withdrawn. Notices of withdrawal are published by the CLSI office.

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

13.5 Supplemental Information

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

13.6 Audit

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

14 Revision of the Administrative Procedures

The Board of Directors may revise these Administrative Procedures by a majority vote of the Board taken at a duly constituted meeting or electronically. Such revisions are consistent with the requirements of the CLSI Bylaws and with accreditation requirements of the American National Standards Institute.

Appendix A.1. Management of Disclosure of Interests and Conflicts of Interests

The purpose of this appendix is to assist CLSI committees by summarizing the relevant processes described in the CLSI Administrative Procedures that can be used for managing disclosure of interests and conflicts of interests for committee activities.

The CLSI consensus process is open, inclusive and transparent. CLSI assembles experts from affected constituencies including government, industry and the professions in an open discussion forum to address specific needs and issues. Committee participants representing different constituencies may have vested interests that are important to address during the consensus process in developing a document that meets the needs of all three constituencies. The CLSI consensus process ensures balanced representation such that all interested parties may participate, adequate scientific expertise is available, and all issues are addressed.

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

It is the responsibility of CLSI committees to conduct their activities according to CLSI's Administrative Procedures, which apply to all CLSI committees and are not intended to be written prescriptively to meet the specific requirements for any one committee. In administering procedures required for obtaining, updating, and providing access for review of Disclosure of Interests forms (Section 5.2.1) committee management has flexibility to use approaches that meet the unique requirements of the committee's activities. A summary of approaches that can be used by committees in administering CLSI's procedures is provided below.

A.1.1 Reporting Disclosures of Interests

- **A completed Disclosure of Interests and Copyright Assignment Form is required from committee members, advisors, contributors and reviewers at time of appointment, upon reappointment, at least every three years and at time of relevant changes in disclosed information (Section 5.2.1).**
 - CLSI staff issues a reminder annually to committee chairholders, vice chairholders, co-chairholders, members, advisors, contributors, and reviewers to update their Disclosure of Interests forms as appropriate.
 - Prior to introductions at each committee meeting, CLSI staff asks if there is a change in disclosures of interests.
- **Access to the current Disclosure of Interests forms for chairholders, vice chairholders, co-chairholders, members, advisors, contributors, and reviewers on each CLSI committee is provided to all participants on the respective committees upon request.**

A.1.2 Summary of Appeal Process

A.1.2.1 Undisclosed Interests

Any individual involved with CLSI in any particular area who becomes aware of an interest or activity (see Section 5.2.2) that is undisclosed must report this to the CLSI Chief Executive Officer. Such situa-

tions are reviewed and resolved by the CLSI Board Executive Committee. Records of such reports and their resolution are kept on file at the CLSI office. Individuals who fail to disclose interests that may contribute to a compromise in a standard or guideline are subject to removal from participation in CLSI activities.

A.1.2.2 Procedural Issues

Any person or organization materially or adversely affected by the failure of a CLSI committee to address substantive issues or to provide “due process” in the application of the CLSI consensus process may appeal in writing, to the CLSI Chief Executive Officer (Section 11).

- An appeal on substantive issues (Section 11.1) or procedural issues (Section 11.2) submitted to the CLSI Chief Executive Officer is referred to the appropriate consensus committee for resolution. If resolution is not achieved, the appeal is forwarded to an Appeals Panel for consideration.
- Considerations of appeals are fair and unbiased and fully address the concerns expressed.
- The burden of proof to show adverse effect is on the appellant.
- A CLSI Appeals Panel hears the appeal on a date that is mutually convenient for the panel, the appellant, and any other interested parties.
- Having heard the appeal, the Appeals Panel may recommend, by a majority vote, that the CLSI Board of Directors modify the action being appealed.
- CLSI promptly notifies the appellant of the Appeals Panel decision.
- The decision of the Appeals Panel may be further appealed to the CLSI Board of Directors (Section 11.3).
 - Such an appeal is filed in writing with the CLSI Chief Executive Officer within 30 days of the Appeals Panel’s decision. It includes a statement as to why the decision should be modified.
 - The Board of Directors, having heard an appeal, may sustain or reverse the appeals action of the Appeals Panel.
 - CLSI promptly notifies the appellant, the chairholder of the Appeals Panel, and the affected consensus committee chairholder of its decision in writing.

Appendix A.2 CLSI Disclosure of Interests Form

CLSI VOLUNTEER

- Disclosure of Interests & Copyright Assignment -

Four fundamental principles govern Clinical and Laboratory Standards Institute's (CLSI) consideration of participation by individuals with vested interests:

- 1) Decisions made on behalf of CLSI and works published by the organization are developed by processes that allow opportunity for fair and open discussion by any interested parties.
- 2) CLSI must ensure that there is adequate scientific expertise represented on consensus committees, subcommittees, document development committees and working groups.
- 3) To ensure adequate expertise, and to promote expression of a variety of views, individuals may participate in the process even if they have vested interests. However, voting members of committees should be qualified experts and shall disclose all potential conflicts of interests.
- 4) Disclosure of interests of all participants (ie, chairholders, vice chairholders, co-chairholders, members, advisors, contributors, and reviewers) are made at the beginning of the process of developing a consensus document, or upon affiliation with CLSI. Conflicts of interests on a given project or activity may be managed in accordance with the CLSI Administrative Procedures as summarized in Appendix A.1. Disclosure of interests is available for review by request of interested parties.

CLSI requires that all nominees for elected office and consensus committees, subcommittees, document development committees, task forces, or working groups complete a disclosure of interests form (see Section 5.2.1 of CLSI's *Administrative Procedures*). Information on disclosed interests is kept on file at the CLSI office. Disclosed interests are part of the record as the consensus document is advanced through the CLSI committee and Board of Directors voting stages.

In addition to the above fundamental principles, CLSI believes that under no circumstances should any staff, elected officers and Board members, and volunteers appointed to any CLSI activities accept gifts, favors, discounts or anything else of value, over and above normal professional courtesies, from anyone with a vested interest or stake in the outcome of a matter being considered by CLSI.

Contributions made to a CLSI work with which I am involved are original and do not knowingly infringe on the copyright or any other right of any third party. In addition, as a copyrighted CLSI work, CLSI is the owner of any such contribution.

For Government employees, your signature represents that you participated in the development of a CLSI consensus document as part of your official duties and cannot claim or assign copyright.

I certify that I have read and understand the above CLSI Disclosure of Interests and Copyright policy. To the best of my knowledge, I have disclosed all information about my interests relevant to the subcommittee, working group, document development committee(s) or consensus committee(s) for which I am being considered. If being considered for the CLSI Board of Directors, I have disclosed information about such interests as they relate to all CLSI activities.

All volunteers are categorized into one of three interest groups: government, industry, or professions. In determining constituency categories, the following guidelines apply:

- individuals employed by an academic institution, a healthcare delivery organization, a professional society or association, or an accreditation or certification organization in the healthcare field are considered members of the professions constituency
- individuals employed by a government, or government-funded agency, are considered members of the government constituency
- individuals employed by a manufacturing or trade organization, and consultants to any constituency are considered members of the industry constituency except that,
- an individual officially designated by an organization in any of the constituencies represents that constituency regardless of his/her employment

These declarations are an important factor in the appointment process, and apply to committee members and the chairholder alike. CLSI staff verifies in writing the interest category for each consensus committee member.

Please select your constituency:

~ Government ~ Industry ~ Professions

Check all that apply and fill in specific names.

~ Working Group on _____

~ Subcommittee on _____

~ Document Development Committee on _____

~ Consensus Committee on _____

~ Board Committee _____

~ Board of Directors _____

Signature _____

Print Name _____

I understand that disclosed interests are a part of the record as consensus documents are advanced through CLSI committee and Board of Directors voting stages and that the information is kept on file at the CLSI office.

Date _____

...continued

DISCLOSURE OF INTERESTS

Name and credentials: _____
Title or Position: _____
Employer: _____
Address: _____

Phone: _____
Fax: _____
E-mail: _____

Briefly describe employer's interest in the field to be addressed by the above listed committee:

G General interest in health care/quality/standards.

G Specific interest (please describe):

Personal, Professional, and Financial Interests

Relevant to the field(s) of work^a in which I would be involved with CLSI, I list below the organizations and activities with which I participate. For example, please list any faculty appointments, professional society memberships, other boards or committees, professional licenses or honors, patents, publications, grants received and public presentations given in the past 3 years related to your CLSI activities. **(A *curriculum vitae* may be attached to supply the requested information.)** You should also list any controlling financial interest or benefit you may hold or have received, which your colleagues would need to know in order to fairly assess the basis of your position related to the CLSI activities.

Personal and Professional Interests:

Financial Interests or Benefits:

PROMPTLY NOTIFY THE CLSI OFFICE FOR ANY ADDITIONS OR CHANGES. YOU WILL ALSO BE ASKED TO UPDATE THIS INFORMATION AND PROVIDE A CURRENT CV UPON ANY REAPPOINTMENT, REELECTION OR AT LEAST EVERY THREE YEARS.

^a You need not include professional and personal interests and activities unrelated to the field in which you would be working with CLSI.

A subcommittee or document development committee participant should consider all interests and activities that relate to the specific topic under consideration by the subcommittee or document development committee. For example, if you have authored a textbook on hematology, but have been nominated for the Subcommittee on Antimicrobial Susceptibility Testing, you need not list this activity. Were you nominated to serve on the Consensus Committee on Hematology, you would list this activity. A member of a consensus committee would have to consider a broader range of interests than a document development committee member, and a member of the Board of Directors would have to consider interests and activities relevant to all CLSI activities.

Appendix B. CLSI Project Proposal Form

PROJECT PROPOSAL FORM

DATE:

SUBMITTER INFORMATION		PROPOSED PROJECT INFORMATION	
Name:		Proposed Title:	
Organization:		Anticipated product will be (check one):	
Address:		<input type="checkbox"/>	Consensus standard
		<input type="checkbox"/>	Consensus guideline
		<input type="checkbox"/>	Reference method
Telephone:		<input type="checkbox"/>	Reference material specifications
Fax:		<input type="checkbox"/>	Other (please describe)
Email:			
		Level of intended user:	
		<input type="checkbox"/>	Novice
		<input type="checkbox"/>	Intermediate
		<input type="checkbox"/>	Advanced

PART I:

PROPOSED PROJECT DESCRIPTION
<ul style="list-style-type: none"> • Provide a rationale for the project and describe its potential impact on healthcare.
<ul style="list-style-type: none"> • Describe the scope in a draft introduction section for the proposed project. This standard/guideline/report specifies requirements/recommendations for... The intended users of this standard/guideline/report are... <u>Excluded</u> This standard/guideline/report: <ul style="list-style-type: none"> • is not intended for use by...; • is not intended to provide ...; and • does not address
<ul style="list-style-type: none"> • Outline the chapter headings/topics.
<ul style="list-style-type: none"> • Provide other important factors for consideration related to the proposed project.
<ul style="list-style-type: none"> • List applicable CLSI documents that should be considered during the development of this document.

PART II:

RECOMMENDED TIMELINE FOR PROJECT DEVELOPMENT	
<input type="checkbox"/>	Track 1 (no more than 15 months)
<input type="checkbox"/>	Track 2 (no more than 25 months)
Rationale for Track 2	

PART III:

PROPOSED COMPANION PRODUCTS	
<p>Please indicate those companion products listed below that could be developed with this proposed document. The concept for potential products could be defined during the document development process. After publication of the document as an approved standard or guideline, the companion product could be prepared by CLSI staff in consultation with the committee. The objectives of developing companion products based on CLSI documents are to aid in the understanding of the documents; facilitate implementation of CLSI standards and guidelines into practice; and/or serve as handy reminders for performing and/or interpreting laboratory procedures.</p>	
<input type="checkbox"/>	Quick Guides (Handy reminders that put information at the user's fingertips) Includes: Laminated sheets, wall charts, and pocket guides
<input type="checkbox"/>	Checklists (For use in reporting completed required activities and/or assessments)
<input type="checkbox"/>	Video/DVD (Instructional video presentation)
<input type="checkbox"/>	Toolkits (Electronic templates)
<input type="checkbox"/>	Software (Includes: Databases and software for method evaluation)
<input type="checkbox"/>	Educational Presentations
<input type="checkbox"/>	Article in a professional journal(s) (List name of appropriate journals below):
<input type="checkbox"/>	Presentations/Workshops at professional meetings (List appropriate professional organizations and associated meetings below): _____ _____
<input type="checkbox"/>	Web/audio conference
<input type="checkbox"/>	Other _____

PART IV:

INTENDED USERS FOR PROPOSED PROJECT		
Please list the intended users that would find this CLSI document valuable and identify the professional organizations in which they are likely to be actively involved and the publications to which they subscribe.		
Target Audience(s) /Intended user(s)	Professional Organizations	Professional Publications

PART V:

DOCUMENT DEVELOPMENT COMMITTEE MEMBERSHIP
Describe <u>specific expertise</u> needed on a document development committee for development of this proposal.
<p>CLSI follows an established “Call for Nominations” procedure for soliciting nomination from its member organizations and the public to serve on project development committees. Nominees' supporting documentation (CV and Disclosure of Interests form) are reviewed by the new project chairholder designate, and the appropriate consensus committee chairholder. Committee formation is based upon the expertise and balanced representation required for development of the new CLSI document. The document development committee roster is reviewed and approved by CLSI's President Elect and the Chairholders Council.</p> <p>Individuals may submit nominations or self-nominate for consideration to serve on CLSI committees. More information about volunteer opportunities is available on the CLSI (www.clsi.org)</p>

PART VI: Consensus Committee Review and Recommendation

Responsible Consensus Committee:

Comment on intended users, impact on health care, and priority of project.

Consensus Committee Chairholder