

 CLINICAL AND LABORATORY STANDARDS INSTITUTE®	Bylaws
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Article I—Name

The name of this corporation is the Clinical and Laboratory Standards Institute, Inc., hereinafter referred to as CLSI.

Article II—Purposes

The purposes of CLSI shall be:

- a) To develop and promote the evaluation, approval, and implementation of standards and guidelines (collectively “standards”) for health care services and medical laboratory services
- b) To provide a mechanism for approval of standards based on a consensus of parties interested in the scope, provision, and use of such standards
- c) To maintain a forum for communication among government, industry, and health care professions as well as other entities concerned with the quality of health care services, medical laboratory services, and the relationship of standards thereto
- d) To provide education regarding the use of standards in the delivery of quality health care services and medical laboratory services
- e) To develop, modify, and implement policies, processes, and procedures consistent with these Bylaws

Article III—Membership

Section 1. Member Types

There shall be two (2) types of members—Organizational and Individual. Organizational members are entities that assign a delegate and an alternate delegate to act on behalf of the organization. Individual members are persons who are interested in the work and products of CLSI. Organizational members will fall into one of three constituencies as described below.

Individual members will self-declare a constituency based on their primary role consistent with the guidelines for Organizational members. Subcategories of each member type shall be established by the Board of Directors to permit dues structures for different levels of benefits.

Section 2. Constituencies

All members shall be placed into one of three categories, which shall collectively be referred to as the “CLSI constituencies.” The CLSI constituencies are industry, health care professions, and government/public health agencies.

- a) Industry: Industry members shall be any for-profit corporations or other for-profit organizations (except as specified in subparagraph b) whose primary function is the development, manufacture, or distribution of products and/or services, medical laboratory testing and services, or other clinical and laboratory services including laboratory information systems. These members shall include, but are not limited to, pharmaceutical companies, *in vitro* diagnostics manufacturers, publicly traded commercial laboratories, and consulting firms. This category shall also include trade associations primarily composed of the corporations and other organizations described in this subparagraph a.
- b) Health Care Professions: Health care professions members shall be any organizations whose primary function is medical laboratory services; any organizations whose primary function is the delivery of patient care services, education in the health care sciences, or academic research; accreditation organizations; and professional societies representing such interests. The following definitions apply to the health care professions constituency:
 - 1) Health care organizations shall be all hospitals as well as non-publicly traded laboratories or pharmacies.
 - 2) Professional societies and accreditation organizations shall be any not-for-profit organizations or nongovernmental accrediting bodies that are concerned with health care services or medical laboratory services. These members do not include trade associations primarily comprising representatives of for-profit corporations.
 - 3) Academic programs shall be any programs or institutions whose primary purpose is the education of individuals who provide health care services, including medical laboratory services.
- c) Government/Public Health Agencies: Government and public health agency members shall be any federal, national, state, provincial, or local agencies of government whose primary function is regulatory, accrediting, and/or public health.

Section 3. Duration of Membership

- a) Membership shall be renewed annually.
- b) Any member may resign at any time by providing notice to CLSI. However, the resigning member shall not receive a refund of any membership dues previously paid.
- c) All rights, privileges, and responsibilities of CLSI membership shall cease upon resignation.

Section 4. Suspension and Expulsion

Any member of CLSI may be suspended or terminated for violation of these Bylaws or any CLSI rule, policy, or practice; conduct found to have been unlawful; or any other conduct determined by the Board of Directors to be detrimental to CLSI. Suspension or termination shall be in accordance with the process adopted by the Board of Directors. Suspension or expulsion of a member shall require a vote by a two-thirds (2/3) majority of the Board members voting.

Section 5. Voting

- a) Each Organizational member shall notify CLSI of the person who shall serve as its official delegate and a second person, if so designated, who shall serve as its alternate delegate. Either the official or alternate delegate may represent, vote on behalf of, and act for the Organizational member.
- b) All Organizational member delegates and subcategories of Individual members eligible to vote may vote on all matters that come before the general membership of CLSI.
- c) Except as otherwise provided by law or in these Bylaws, all matters requiring a vote of the members shall be determined by a majority of the members voting. Each member eligible to vote shall be entitled to one (1) vote.
- d) All members entitled to vote may vote in person or by proxy executed by the member, or in the case of an Organizational member, its delegate or alternate delegate. Notwithstanding any other provision of these Bylaws, any copy, facsimile transmission, or other reliable reproduction of the original proxy may be substituted or used in lieu of the original proxy for any purpose for which the original proxy could be used if the copy, facsimile transmission, or other reproduction is a complete reproduction of the entire proxy. An appointment of a proxy is not valid after eleven (11) months following the date of its execution unless otherwise provided in the proxy.

Members and proxy holders who are not physically present at a meeting may, by means of remote communication, participate in the meeting and will be deemed to be present in person and voting at the meeting, provided that such members or proxy holders have the reasonable opportunity to participate in the meeting and to vote on matters submitted to the members, including an opportunity to communicate and to read or hear the proceedings of the meeting substantially concurrent with the proceedings.

Section 6. Dues

- a) The Board of Directors shall annually set the dues for each subcategory of membership.
- b) Any member who fails to pay annual membership dues in a timely fashion may have its membership revoked.

Article IV—Meetings

Section 1. Annual Meeting

The Annual Meeting of the members shall be held at a time, place, and in a manner determined by the Board of Directors. The Annual Meeting shall include annual reports on the status of the organization and the transaction of such other business as may be determined by the Board of Directors. Notice of such meeting shall be distributed to each member at least thirty (30) days in advance of the meeting.

Section 2. Special Meetings

Special meetings of the members may be called by the President or by a two-thirds (2/3) majority of the Board of Directors. The form of any special meeting shall be determined by the Board of Directors. Notice of any such special meeting shall be distributed to each member at least twenty (20) days in advance. Such notice shall indicate the time and place of the meeting and shall include a brief description of the subject or subjects to be covered.

Section 3. Quorum

- a) Ten (10) members, including at least one (1) member from each constituency, shall constitute a quorum for the Annual Meeting.
- b) Thirty (30) members, including at least one (1) member from each constituency, shall constitute a quorum for special meetings.

Section 4. Order of Business

The order of business at any meeting of the membership shall be established by the Board of Directors. The order of business may be altered or suspended by a two-thirds (2/3) majority of the members present at any meeting. The then current edition of “Robert’s Rules of Order” shall govern deliberations when not in conflict with these Bylaws.

Article V—Officers and Directors and Their Elections

Section 1. Officers and Directors

- a) The officers of CLSI shall be a President, President-Elect, Immediate Past President, Treasurer, Secretary, and the Chief Executive Officer (CEO).
- b) The Board of Directors shall consist of not less than ten (10) and not more than fourteen (14) elected directors plus the officers.

Section 2. Election or Appointment

The officers and directors shall be elected as follows:

- a) A President-Elect shall be elected biennially. That individual shall hold office as President-Elect for a two (2)-year term, shall automatically become President for a two (2)-year term immediately thereafter, and shall automatically become the Immediate Past President for a two (2)-year term thereafter.
- b) A Treasurer shall be elected every three (3) years and shall hold office for a three (3)-year term. No elected Treasurer may serve more than two (2) consecutive full terms as Treasurer.
- c) A Secretary shall be elected every three (3) years and shall hold office for a three (3)-year term. No elected Secretary may serve more than two (2) consecutive full terms as Secretary.
- d) The CEO shall be appointed, and the terms of the CEO's employment shall be determined by the Board of Directors. The CEO shall serve *ex officio* as a voting member of the Board of Directors and may serve as a nonvoting member of one (1) or more committees of the Board of Directors.
- e) There shall be an annual election of directors. The Board of Directors shall determine in advance the number of directors from each of the CLSI constituencies required to maintain a balance among the three (3) CLSI constituencies. A Call for Nominations shall be sent to the CLSI member delegates and alternate delegates and posted for public notice on the CLSI website. The Call shall be open for a period of at least thirty (30) days. The Board of Directors may also determine the need for at-large directors to fill identified skill mix requirements. The at-large director(s) shall be appointed by the President with the concurrence of the Board of Directors. To maintain a balance among the CLSI constituencies, the total number of elected officers and directors representing any one (1) constituency shall not exceed by more than one (1) the number of representatives from the other two (2) constituencies. Each elected director shall serve a term of three (3) years except where terms of lesser duration are adopted by the Board of Directors to maintain a balanced structure in succeeding elections. No director may serve more than two (2) consecutive terms as a director.
- f) Each candidate for an officer or director position, except at-large directors, shall be an employee of a member organization or an Individual member eligible to vote.
- g) Voting for officers and directors shall be in accordance with procedures determined by the Board of Directors.
- h) Ballots will be sent to the delegate and alternate delegate for each of the Organizational members and Individual members eligible to vote, allowing thirty (30) days for return thereof. Only one (1) vote per member organization is permitted. The election process shall be completed by November 30 in any given year. Election will be by majority vote of the ballots received.

- i) Officers and directors shall take office on January 1 following the election. Their terms of office shall end on December 31 of the year that their term expires.
- j) Election results shall be posted on the CLSI website and may be published in news releases and by other media.

Section 3. Vacancies

- a) Any officer or director may resign at any time by giving written notice to the President. The President may resign by giving notice to the President-Elect. Any resignation shall take effect at the time specified in the notice, or if no time is specified, at the time determined by the President or President-Elect, as appropriate.
- b) Any officer or director may be removed by three-fourths (3/4) vote of the Board of Directors.
- c) Any vacancies that may occur among elected directors, the Secretary, or the Treasurer shall be filled as an interim appointment by the President, subject to approval by the Executive Committee. In filling any vacancy, the President shall be guided by the need to ensure balance on the Board among the three (3) CLSI constituencies. Any interim appointee shall be for the remainder of the unexpired term. If the unexpired term is greater than one (1) year, the appointee shall be eligible for election to one (1) term only. In no case will the total length of service in a director position exceed seven (7) consecutive years.
- d) If the office of President becomes vacant, the President-Elect shall immediately succeed to the office of President. The President-Elect shall serve out the unexpired term of the presidential vacancy and the ensuing regular two (2)-year term as President. There shall be deemed to be a vacancy in the office of President-Elect.
- e) A vacancy in the office of the President-Elect shall be filled at the next regularly scheduled election. In the interim, the Secretary shall assume the duties and responsibilities of the President-Elect.

Section 4. Compensation

Elected officers and directors shall serve without pay and shall not receive any compensation for their services. Officers and directors from the health care professions and government/public health agencies constituencies and at-large directors may be reimbursed for reasonable expenses incurred in the performance of their duties. Officers and directors from the industry constituency are not reimbursed except upon specific approval from the President or CEO.

Section 5. Change of Status or Employment

In the event of a change in status or employment of an officer or director that results in a change in the constituency of that individual or the individual's employer who is the member of CLSI, the officer or director shall resign. The resignation may or may not be accepted at the discretion of the President.

Article VI—Powers and Duties of Officers and the Board of Directors

Section 1. Board of Directors

- a) The Board of Directors shall have supervision, control, and direction of the affairs of CLSI; shall, subject to these Bylaws, determine its policies or changes therein; and shall have discretion in the disbursement of its funds. The Board of Directors may adopt such rules, policies, and regulations for the conduct of its business as it deems necessary, and may, in the execution of the powers granted to it, appoint such agents as it deems necessary.
- b) Unless otherwise specified in these Bylaws, actions of the Board of Directors shall be taken by a majority of those voting.

Section 2. President

The President shall be the chief elected officer of CLSI, shall serve as the chair of the Board of Directors, and shall preside at meetings of the Board of Directors and the Executive Committee. The President shall see that all orders and resolutions of the Board of Directors are carried into effect. The President shall report annually to the membership on the activities and accomplishments of CLSI for the preceding year. The President may assign responsibilities not specifically prescribed by these Bylaws or the Board of Directors to any officer, agent, or employee of CLSI.

Section 3. President-Elect

The President-Elect shall perform the duties of the President in the event of the President's temporary disability or absence from meetings.

Section 4. Immediate Past President

The Immediate Past President shall have such duties as designated by the President or Board of Directors.

Section 5. Treasurer

The Treasurer shall be responsible for overseeing the development of an annual budget and for overseeing the fiscal affairs of CLSI. The Treasurer shall report to the Board of Directors regarding the financial status of CLSI according to any schedule and in such additional duties as the President or Board of Directors may designate and as specified in these Bylaws.

Section 6. Secretary

The Secretary shall keep, or cause to be kept, the membership roll and votes and proceedings of the Board of Directors. The Secretary shall perform such additional duties as the President or Board of Directors may designate and as specified in these Bylaws.

Section 7. Chief Executive Officer

The CEO shall be responsible for the management of administrative affairs of CLSI and the carrying out of Board policy. The CEO shall employ and may terminate the employment of professional and administrative staff necessary to carry out the work of CLSI. The CEO shall manage and direct all functions of CLSI, including the operation of staff and the functioning of the CLSI office. The CEO shall perform such other duties as may be specified by the Board of Directors. As provided for in Article V, Section 2d, the CEO shall serve *ex officio* as a voting member of the Board of Directors and may serve as a nonvoting member of one (1) or more committees of the Board of Directors.

Article VII—Board of Directors Meetings

Section 1. Meetings

The Board of Directors shall meet upon the call of the President at such times and places as the President may designate. The Board of Directors shall also meet upon the demand of a two-thirds (2/3) majority of the officers and directors. Any or all directors may participate in a regular or special meeting by, or conduct the meeting through the use of, any means of communication by which all directors participating may simultaneously hear each other during the meeting. A director participating in a meeting by this means is deemed to be present in person at the meeting.

Section 2. Quorum

A majority of the entire Board of Directors, including at least one (1) representative from each CLSI constituency, shall constitute a quorum.

Section 3. Voting

CLSI directors shall vote Yes/Affirmative, No/Negative, or Abstain on each motion coming before the Board of Directors. For a motion to pass, it must, unless otherwise specified in these Bylaws, receive a majority of Yes/Affirmative votes from those present in person and must also receive at least one Yes/Affirmative vote from one (1) member representing each constituency.

Article VIII—Committees

Section 1. Appointing Authority Limitations

- a) The President, subject to the provisions of these Bylaws and with the concurrence of the Executive Committee, shall annually appoint committees of the Board of Directors, and the members thereof, as may be required.
- b) The President or designee, subject to the approval by the Executive Committee, may establish, combine, or discontinue standards development committees as required to achieve the standards development objectives of CLSI.

- c) No committee, including the Executive Committee, shall have the authority to approve or recommend to members actions or proposals required by the Florida Not for Profit Corporation Act to be approved by members; fill vacancies on the Board of Directors or any committee thereof; or adopt, amend, or repeal the Bylaws.

Section 2. Executive Committee

The Executive Committee shall consist of the President, Immediate Past President, President-Elect, Treasurer, and Secretary. The CEO shall serve *ex officio* as a nonvoting member of the Executive Committee. To maintain a balance among the CLSI constituencies on the Executive Committee, the total number of officers representing any one (1) of the constituencies shall not exceed by more than one (1) the number of representatives from the other two (2) constituencies. The Executive Committee may exercise the powers of the Board of Directors when the Board is not in session, reporting to the Board of Directors at its succeeding meeting of any actions taken. Four (4) members of the Executive Committee shall constitute a quorum for the transaction of business. Meetings of the Executive Committee may be called by the President or three (3) members of the Committee.

Section 3. Consensus Council

The Consensus Council shall consist of at least nine (9) persons, in addition to the Chairholder and the President-Elect, and will include representation from each constituency. The Chairholder shall be appointed by the President, subject to the approval of the Executive Committee, and, if not a member of the Board of Directors, shall serve as an *ex officio* nonvoting member of the Board of Directors during his or her term as Chairholder.

The Consensus Council is responsible for providing reasonable assurances that standards development activities are conducted in compliance with requirements and serves as the authority responsible for project approval, prioritization, status assessment, and consensus approval for document publication where applicable.

Section 4. Nominating Committee

- a) The Nominating Committee shall consist of not more than seven (7) persons, in addition to the Immediate Past President and the President-Elect. The CEO shall serve *ex officio* as a nonvoting member of the Nominating Committee. To maintain a balance among the CLSI constituencies, the total number of members representing any one (1) constituency shall not exceed by more than one (1) the number of representatives from the other two (2) constituencies.
- b) The Nominating Committee shall recommend to the Board of Directors a slate of candidates for the next election cycle for positions eligible for election. The Nominating Committee shall issue a Call for Nominations from among CLSI members. All nominations shall be duly considered and eligible nominees will include employees of a member organization or Individual members eligible to vote. The Committee shall be authorized to consider additional qualified candidates.

Section 5. Finance Committee

The Finance Committee shall consist of the Treasurer and other members appointed by the President. The Committee is responsible for recommending to the Board of Directors for approval the annual budget, the annual financial audit, selection of an independent audit firm, investment guidelines, and a reserve fund investment policy. In addition, the Committee is responsible for developing recommendations intended to ensure the long-term financial viability of CLSI.

Article IX—Indemnification

CLSI shall indemnify each officer, director, employee, and duly appointed committee member against liability and expenses, including attorneys' fees, incurred in connection with any legal action in which the individual is named as a defendant by reason of the individual's good faith efforts on behalf of CLSI. This indemnification shall be secondary to any insurance coverage otherwise available to the individual. It does not extend to conduct deemed by the Board of Directors to have been undertaken in bad faith or contrary to any CLSI rule or policy. As a condition of receiving indemnification, the indemnified individual shall allow CLSI to appoint counsel and shall agree to a coordinated defense to the extent deemed appropriate by CLSI. Counsel appointed for the individual may, at the discretion of CLSI, be the same as counsel appointed to represent CLSI and/or other individuals. CLSI shall pay expenses (including reasonable attorneys' fees) actually and reasonably incurred in defending any action or proceeding referred to in this Article in advance of the final disposition of the action or proceeding upon receipt of any undertaking by or on behalf of the representative to repay the amount if it is ultimately determined that he or she is not entitled to be indemnified by CLSI as authorized in this Article or otherwise.

Article X—Seal

CLSI shall have a seal of such design as the Board of Directors may adopt. Such seal shall always contain the words "corporation not for profit."

Article XI—Fiscal Year

The fiscal year of CLSI shall begin on the first (1st) day of July and end on the thirtieth (30th) day of June of the subsequent year.

Article XII—Amendments

- a) Amendments to these Bylaws may be proposed by the Board of Directors or by thirty (30) or more members of CLSI in good standing. Proposed amendments shall be submitted to the Secretary. The Secretary shall transmit a copy of the proposed amendments to each Organizational member's delegate and alternate delegate and to each Individual member eligible to vote at least thirty (30) days before the meeting at which the proposed amendment is to be considered. An amendment shall be approved by a two-thirds (2/3) majority of members who vote.
- b) Amendments to these Bylaws may also be made by a three-fourths (3/4) vote of the full Board of Directors, provided that notice of a proposed amendment shall be given to each Board member by the Secretary at least thirty (30) days before the meeting at which the proposed amendment is to be considered.

Article XIII—Notice

Section 1. Written Notice

Any notice required to be given under these Bylaws to any person shall be given to the person, either personally or by sending a copy thereof:

- a) By first class or express mail, postage prepaid, or courier service, charges prepaid, to the person's postal address appearing in the records of CLSI or, in the case of Directors, supplied by the person to CLSI for the purposes of notice. Notice under this subparagraph to a member shall be deemed to have been given when deposited in the US mail or with a courier service for delivery to that person. For other notices under this subparagraph, notice is effective at the earliest date of the following: when received; five (5) days after its deposit in the US mail, as evidenced by the postmark, if mailed postage prepaid and correctly addressed; or on the date shown on the return receipt, if sent by registered or certified mail, return receipt requested, and the receipt is signed by or on behalf of the addressee.
- b) By facsimile transmission, e-mail, or other electronic communication to the person's facsimile number or e-mail address or other electronic communications supplied by the person to CLSI for the purpose of notice. Notice under this subparagraph shall be deemed to have been given to the person entitled thereto when sent.

Section 2. Waiver by Writing

Whenever any notice is required to be given, a waiver thereof that is filed with the Secretary in record form, signed by the person or persons entitled to the notice, whether before or after the time stated therein, shall be deemed equivalent to the giving of the notice. Neither the business to be transacted at, nor the purpose of, a meeting need be specified in the waiver of notice of the meeting.

Section 3. Waiver by Attendance

Attendance of a person at any meeting shall constitute a waiver of notice of the meeting except where a person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting was not lawfully called or convened.

Article XIV—Signature Authority

The Treasurer, President, and President-Elect shall have the authority to negotiate, approve, execute, and/or deliver all documents and instruments that may be necessary or desirable to open and close bank and investment accounts for CLSI and update signature authority over such accounts and to enter into contractual arrangements involving the day-to-day operations of CLSI, within the ordinary course of business, as may be necessary or appropriate from time to time, and upon such terms and conditions as shall be determined by an officer to be in the best interests of CLSI.

Article XV—Dissolution and Distribution of Assets

Section 1. Dissolution

CLSI may be dissolved by the Board of Directors or as provided for by governing law.

Section 2. Distribution of Assets

On dissolution of CLSI, any assets remaining shall be distributed to one (1) or more charitable, educational, or scientific organizations that are exempt from federal income taxation under Section 501(c)(3) of the Internal Revenue Code and that are selected by the Board of Directors.