# HL7 Governance and Operations Manual

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Introduction
The Governance and Operations Manual (GOM) defines standard operating procedures and various policies created to clarify, support, and/or implement the tenets of the Bylaws. The GOM is established to assure the uniformity, equity, quality, efficiency, and compliance of administrative and organizational activities through standard methods and guidelines. GOM maintenance shall be proactive, iterative, and broadly engage the membership as defined in §17.

With the adoption of additions or revisions to the GOM, the HL7 Secretary shall add them to the manual with annotation reflecting the date adopted or revised. Additions and revisions will be posted within ten working days of the date on which they were adopted. Periodically the HL7 Secretary, using their best judgment, may call for ratification of the GOM in its entirety by the Executive Committee. Upon ratification of the GOM in its entirety it shall be posted with a new adoption date and all internal notations of addition or revision removed.

The GOM will be maintained and distributed electronically via the HL7 Web site. A hard copy of the manual is available to those without electronic access upon request. A processing fee, established by the Executive Committee, will be assessed to cover printing, postage, and handling.

Notice of Current Edition

Additions and/or Revisions Subsequently Adopted
The following additions and/or revisions, having been approved by the Executive Committee subsequent to adoption of the GOM, are included by extension. The correction of a typographical or trivial error under standing work item 001 will not be recorded as a revision in the following table; although they will appear in the mark-up version for reference. Sections that are renumbered as a result of adding or moving a section, but are not otherwise revised, are not included in the following table.

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01 The Corporation

01.01 Primary Office
As directed by the articles of incorporation and in compliance with the laws of the State of New Jersey, the Corporation shall maintain a primary office in the State of New Jersey. The Corporation may have business offices at such other places as the Board of Directors may, from time to time, designate.

01.02 Business Office
The business office of the Corporation is located at
3300 Washtenaw Avenue, Suite 227
Ann Arbor, Michigan 48104-4261 USA
(734) 677-7777 Fax (734) 677-6622

01.03 Registered Trademark
Use of any HL7 registered trademark, whether printed or electronic, to endorse, promote, foster, or criticize any commercial product, vendor, or service, or to express personal views about legislative or regulatory issues is prohibited.

01.04 Letterhead
The HL7 letterhead, be it memorandum or letter format, shall be used by Officers, other members of the Board, supporting committee or council chairs, and HL7 staff for authorized business and projects exclusively. Officers, other members of the Board and committee or council chairs shall discontinue the use of HL7 letterhead immediately upon completion of their terms or, in the case of HL7 staff or contract employees, upon termination of employment.

02 Purpose, Objectives, and Approach

02.01 Comprehensive Framework
The Modeling and Methodology Work Group shall undertake the development and maintenance of a comprehensive standards development framework to define, clarify, and delineate the processes employed by HL7. The framework shall address at least common processes, standards specific processes, and support and governance processes in sufficient detail to act as a guide to those new to the HL7 process and provide checkpoints to those involved in the process. The comprehensive framework may be promulgated as a standard in order to promote the good practices inherent in the HL7 process.

02.02 Protocol Specifications
Protocol specifications encompass the following work products developed and supported by HL7: all Versions of the HL7 messaging standard; the Clinical Document Architecture (CDA); Arden Syntax; CCOW specifications; Service Oriented Architecture (SOA) standards; any other normative standards subsequently released by HL7; various functional models, implementation guides, and Implementation Technology Specifications (ITS); the Reference Information Model (RIM); and those informative documents initiated andballoted by the various Work Groups.

02.03 Mission Statement
The mission of HL7, as approved by the Board of Directors, is:
To provide standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among all of our stakeholders, including healthcare providers, government agencies, the vendor community, fellow SDOs and patients. In all of our processes we exhibit timeliness, scientific rigor and technical expertise without compromising transparency, accountability, practicality, or our willingness to put the needs of our stakeholders first.
These efforts enable effective, efficient communication between the constituents of the healthcare community as represented by our membership, which consists of an international community of healthcare organizations, vendors, healthcare information systems developers, consultants, systems integrators, and related public and private health services agencies.

The mission of HL7 encompasses the complete ‘life cycle’ of a protocol specification – development, adoption, market recognition, utilization and adherence. Shared reference models of the healthcare and technical domains unify the HL7 specifications.

To support this mission, HL7:

a) Develops and publishes both ANSI approved normative protocol specifications and various informative documents on a timely basis.

b) Promotes the use of the protocol specifications and other documentation within the healthcare payer, provider and regulatory community, both nationally and internationally.

c) Provides education:
   i. On understanding the protocol specifications and their common usage
   ii. On implementation approaches using the protocol specifications
   iii. On protocol specification compliance and analysis approaches

d) Provides conformance certification services.

e) Provides a methodological framework for creating extensions to the protocol specifications.

f) Encourages the acceptance and usage of HL7 protocol specifications world wide through the creation of Affiliate members, and the pursuit of internationalization of the protocol specifications.

g) Collaborates with other developers of healthcare and information technology standards to leverage our respective skills, knowledge and standards.

02.04 Contract Work Process

Upon notification of the availability of a contract, either external or internal, the HL7 Executive Committee shall designate a select committee of domain experts and appropriate staff to outline the work or service to be contracted including scope of work; expected qualifications of the contractor or subcontractor; deliverables and work schedule with performance bonus and/or penalties as applicable; and a preliminary budget.

Unless the HL7 Executive Committee determines that timeliness or criticality of the project support direct award of the contract based on the recommendation of the select committee, the chair of the select committee shall provide HL7 Headquarters with the contract work announcement template. The contract work announcement shall be posted to the HL7 ContractWork list service, which is open to any individual interested in being apprised of HL7 contract work. In the event of a question or request for clarification additional information regarding the announcement may be disseminated using the ContractWork list service, but the list service shall not be used for interactive discussions among the subscribers.

Individuals interested in the announced contract work shall submit an expression of interest by the date specified via e-mail or to the fax number indicated in the announcement. All expressions of interest shall be forwarded by HL7 Headquarters to the chair of the select committee, who will convene the committee to review and discuss the submissions and develop a recommendation.

The select committee shall present their proceedings, including recommendations, to the HL7 Executive Committee who shall award the contract. Any member of the Executive Committee who is named in the recommendation or is a member of an organization or has a business relationship with an individual named in the recommendation shall be absent from any decision-making discussion and vote on the award of the contract.

HL7 Headquarters shall post the notification of award of contract to the ContractWork list service and notify the membership of the award via posting in the next edition of the HL7 eNewsletter. The award shall be entered into the HL7 Contract Register and be subject to public inspection. The HL7 Contract Register shall include at least the following elements: contract name, contract description, contract amount, contract period, date contractor selected, contractor name and contact information.
03 Membership

03.01 Establishing Membership
Membership shall become effective upon acceptance of a completed application and receipt of designated dues. The Board of Directors shall ensure that no undue financial barriers to HL7 membership exist.

03.01.01 Current Member
All types of members (Individual, Organizational, or Affiliate) shall be deemed current if dues are not in arrears or relinquished due to suspension or expulsion. Those members not deemed current shall not have access to member-only materials and documents.

03.02 Clarifying Individual Membership
The Bylaws refer to an individual member associated or not associated with an organizational member; but those terms are not otherwise defined. There are also certain restrictions placed on an individual member’s use of the HL7 Protocol Specifications (§02.02) and his or her involvement in application or systems development that deserve clarification.

03.02.01 Association with an Organizational Member
HL7 places no restrictions on the purchase of individual memberships by its organizational members who wish to extend voting privileges and provide access to the HL7 Protocol Specifications (§02.02) to their sundry divisions. Although categorized as individual members, these individuals typically list the organizational member as their employer; thus establishing an association. HL7 Headquarters is aware of these relationships and considers those individuals “additional” designated voting representatives of that organizational member. As such these extra-organizational members are extended the same privileges as the designated voting representatives allocated to that organizational member as a benefit of its membership.

03.02.02 Software Application or Systems Development
The Bylaws prohibit development of software products specific to the exchange of healthcare information or the interoperability of such information by an individual member. A software product is construed as of such complexity as to be beyond the reasonable capability of a single individual to create, enhance, maintain, and support in a commercially viable manner. The prohibition of such development by an individual member is intended to preclude an organization from developing a commercial software application or product based on access to the HL7 Protocol Specifications (§02.02) through an individual membership.

03.02.03 Implementation Services
HL7 understands that knowledge of the HL7 Protocol Specifications (§02.02) is a valuable commodity and may reasonably contribute to the earnings of an individual member. In recognition of that the Bylaws specify that individual members may engage in implementation services with the proviso that such services do not include providing access to or distribution of the HL7 Protocol Specifications. Otherwise, individual members may provide the full spectrum of implementation services.

03.02.04 Supporting In-house Operations
The development and support of an “in house” interface by an individual member is not construed in the same sense as development of a commercial application.
03.03 Classification of Organizational Members

Organizational members shall be classified in accordance with their self-characterization selected during the membership application process. HL7 Headquarters holds responsibility for screening membership classifications. If a membership classification is challenged, the HL7 Director of Membership Services shall investigate the classification and determine a resolution. In case of appeal of the decision of the Director of Membership Services, the Executive Committee shall assign the classification. Their decision shall be final. This characterization shall be for the purpose of assessing balance in the consensus group relating to normative issues.

03.03.01 Classes of Organizational Membership

03.03.01.01 Vendor/Manufacturer

An Organizational Member that produces or sells products or systems that relate to, use, or incorporate HL7 Protocol Specifications (§02.02) shall be classified as a vendor. This classification also accommodates manufacturers (medical devices, etc.).

03.03.01.02 Consultant

An Organizational Member that provides advice, support, and consultative services, but that does not sell products or systems which relate to, use, or incorporate HL7 protocol specifications shall be classified as a consultant.

03.03.01.03 Healthcare Provider/User

An Organizational Member that purchases and implements products, systems, or services which relate to, use, or incorporate HL7 protocol specifications shall be classified as a user. The user category may include, but is not limited to, organizational entities such as hospitals, physician practices, physician group practices, and academic faculty practices.

03.03.01.04 Associations/Government Agencies

A special classification created to support organizational membership by professional associations and societies, industry consortia, regulators, and government agencies.

03.03.01.05 Payer/Third Party Administrator

A special classification created to support organizational membership by health maintenance organizations (HMO), preferred provider organizations (PPO), independent practice affiliations (IPA), utilization review (UR) companies, fiscal intermediaries, third-party administrators (TPA), peer review organizations (PRO), insurers and payers.

03.03.01.06 Pharmaceutical

A special classification created to support organizational membership by pharmaceutical organizations versus a general classification as a manufacturer.

03.03.01.07 General Interest

An organization that expresses a general interest in the development, revision, reaffirmation, or withdrawal of HL7 Protocol Specifications (§02.02), but does not fit into any of the above classifications shall be classified as a general interest member.

03.04 Termination of Membership

03.04.01 Resignation

A membership may be terminated at any time by submitting a letter of resignation to HL7 Headquarters. Dues shall not be refunded upon resignation.
03.04.02 Failure to Renew
Invoices for renewal of membership are sent with sufficient lead time to allow remittance prior to membership year end. The membership of those individuals or organizations who fail to pay their membership renewal fee by the end of the membership year, as indicated on the invoice, shall be terminated. Termination of membership results in the loss of voting privileges and the individual or organization will no longer receive member benefits, including HL7 mailings, discounts, and access to member-only materials and documents. Upon receipt of a written request to waive membership termination that, in the opinion of the Executive Director, justifies a delay in dues payment the Executive Director may temporarily waive termination of membership for a period that, in their judgment, is appropriate to the situation. HL7 reserves the right to retain membership information to be used for promotional mailings.

03.04.03 Cause
The Board of Directors may, by a simple majority vote of the Board members present and voting and following a hearing on such allegations, suspend or expel any member for actions which, in the Board's considered opinion, are contrary to the practices and policies of HL7. Dues shall not be refunded or, if outstanding, collected for the year in which such action occurs. The Board of Directors may, by a simple majority vote of the Board members present and voting and following a hearing on such action, reinstate any member suspended or expelled. Reinstatement may require the remittance of dues outstanding.

03.05 Change of Membership Status due to Change of Employment
Change of membership status due to change of employment shall be declared promptly to the HL7 Director of Membership Services by telephone, facsimile, or e-mail.

03.06 Designated Voting Representative Proxy
The designated Key Representative of an organizational or Affiliate member shall hold proxy for that member’s designated voting representatives who are unable, for whatever reason, to respond to the disposition of negative comments specific to a normative issue. The Key Representative shall exercise their proxy only after a reasonable attempt to engage their respective voting representatives.

03.07 Membership Declaration
The membership application/renewal form shall include the following declaration as applicable to the membership category: “Application for or renewal of an individual HL7 membership obliges the member to abide by the HL7 Bylaws, Governance and Operations Manual, and Code of Ethics.” or “Application for or renewal of an organizational HL7 membership obliges the organization and its representatives to abide by the HL7 Bylaws, Governance and Operations Manual, and Code of Ethics.”

04 Dues, Fees, and Donations

04.01 Dues
Membership dues, as determined by the HL7 Executive Committee, shall be applicable to the year of membership based on effective date. Membership dues may change from year to year based on the needs of HL7. All dues submitted shall become the property of HL7 and be used to fund operations based on an annual budget and plan approved by the Board of Directors. Organizational members are expected to select an appropriate dues structure related to their current revenues or expenditures at the time of renewal.

04.01.01 Student
Full-time students of healthcare informatics shall be offered membership at a rate that does not preclude their participation in HL7.
04.01.02 Individual
The HL7 Executive Committee may establish different membership dues for individuals residing in North America (Canada, USA, Mexico) versus those residing elsewhere. An individual member wishing to provide additional financial support to HL7 may become an “HL7 Supporter” by doubling their annual dues. Individual member supporters shall receive appropriate recognition for their exceptional financial contribution.

04.01.03 Organizational
Organizational members classified as vendors, consultants, or other suppliers of products and services that incorporate the HL7 protocol specifications shall have their dues scaled to a range of annual revenue specific to healthcare systems, services, and/or products.

Organizational members classified as users, primarily health care provider organizations, shall have their dues scaled to a range of annual information technology (IT) expenditures. Other categories, specifically healthcare payer and clearinghouse organizations, shall have their dues scaled to a range of annual gross revenues.

Publicly traded organizations are expected to pay dues and renew membership at the level reflected by such revenues reported in their most recent annual report. Privately held companies are expected to pay dues and renew membership at the level best reflecting their actual revenues of a given type.

04.01.03.01 Supporter
Any organizational member wishing to provide additional financial support to HL7 may become an HL7 Supporter by paying double their designated annual dues. HL7 Supporters shall receive appropriate recognition for their exceptional financial contribution. No additional voting members are allocated to HL7 Supporters.

04.01.03.02 Benefactor
The Benefactor level is established within each category of organizational membership for those organizations wishing to provide exceptional financial support to HL7. All benefactor organizations are allotted 12 voting members. Benefactor organizations shall receive appropriate recognition for their exceptional financial contribution.

04.02 Fees
The Executive Committee shall determine the fees to be charged for Working Group Meetings, plenary conferences, educational sessions, publications, and other products and services HL7 may provide. All fees collected shall become the property of HL7 and be factored into the operational budget. The Executive Committee shall consider any recommendations to change established fees that arise during the review and approval of the annual budget.

04.02.01 Hardship Waiver
The Executive Director or Associate Executive Director of HL7 may, at their discretion, grant a waiver of fees to any HL7 member in good standing who has attended and paid for at least three of the last four Working Group Meetings and has encountered hardship (e.g., become unemployed) since the last meeting.

04.02.02 Student Waiver
HL7, accepting no responsibility for travel or lodging expenses, will waive registration and tutorial fees at regularly scheduled HL7 Plenary and Working Group Meetings for healthcare informatics students meeting the following criteria:
- a) Provide proof of current enrollment in an informatics curriculum (medical, nursing, or clinical informatics) at an accredited college or university
- b) Provide a letter of recommendation from an HL7 member in good standing acknowledging their sponsorship and accepting responsibility for mentoring the student to increase his/her knowledge of the HL7 organization, its procedures and Protocol Specifications (§02.02)
c) Demonstrate a commitment to HL7, as evidenced by validated activity report, though active support of a Work Group by taking meeting minutes, helping edit the HL7 Protocol Specifications, authoring or co-authoring white papers, working on the web site, or providing other assistance as requested by Work Group co-chairs, members of the Board of Directors or Executive Committee, or HL7 Headquarters staff.

d) Provide assistance with tutorials where such does not conflict with Work Group support activity, by developing and/or editing presentation slides (MS PowerPoint), developing and/or distributing printed support materials, checking attendance, or other assistance as requested by the instructor or HL7 Headquarters staff.

Students seeking a Work Group Meeting fee waiver must submit the proof of enrollment and letter from their sponsor to HL7 Headquarters not later than the close of the normal registration period. HL7 staff will match students with a Work Group based on the student’s interests and the needs expressed by Work Group co-chairs.

04.02.03 Professional Courtesy

HL7 shall extend the member rate for Working Group Meeting, including the discount rate for tutorial sessions, to ANSI-accredited SDO and other organizations that have executed an HL7 Memorandum of Understanding (MOU) or Associate Charter. It is expected that the courtesy of extending member rates shall be reciprocated by the SDO or organization throughout the term of collaboration. Such courtesies shall be suspended concurrent with the conclusion of the period of collaboration.

04.03 Donations

Any funds or property donated to further the work of HL7 shall become the property of HL7. Every effort shall be made to use donations for the purpose designated by the donor. Acceptance of donations shall require the approval of the Executive Committee. Under the provisions of Internal Revenue Code Section 501(c)(6) such donations may not be claimed as tax deductions.

05 Participation

05.01 HL7 Protocol Specification Development and Maintenance

All those present in a Work Group shall have the right to participate and cast a vote specific to development and maintenance of the HL7 Protocol Specifications (§02.02), whether in Working Group Meetings, special meetings, teleconferences, or other forums.

05.02 Work Group Co-chair Elections [effective with elections at September 2008 WGM]

Headquarters shall notify the membership of a 30-day period for nomination of co-chairs at least 60 days prior to the Working Group Meeting (WGM) when an election is to be held. Self-nominations shall be accepted. Nominees should have demonstrated an interest in the subject matter by being subscribed to the Work Group’s primary list server and attending meetings of the Work Group. Nominees shall be either a current individual member or representative of a current organizational or Affiliate member. The organizational or Affiliate member Key Representative shall confirm the status of those nominees not already designated as voting representatives of the organizational or Affiliate member. All nominees shall be contacted by Headquarters to validate their status as a candidate. Any candidate may decline nomination without question. The same criteria shall apply to write-in candidates.

At the close of the nomination period a ballot shall be prepared for each Work Group holding co-chair elections. It shall include all validated candidates for co-chair, allow for write-ins equivalent to the number of co-chairs being elected, and instruct the voter to select and/or write-in the appropriate number of names.
Current individual members and the designated voting representatives of current organizational or Affiliate members who are subscribers of a Work Group’s primary list server but who are not able to attend the WGM may submit an electronic or written absentee ballot to HL7 for the co-chair of that Work Group so long as it is received on or before the Wednesday preceding the scheduled WGM. Absentee ballots shall remain sealed and under the control of the Associate Executive Director pending the tally of the ballots. Absentee ballots shall be validated against the list server subscription lists and the WGM attendees list before being added to the tally.

Work Group co-chair elections shall be announced at each general session and shall occur on the first day a Work Group officially meets during the WGM. Work Group co-chairs are encouraged to also announce the co-chair election in their opening comments. The polls shall open immediately following that day’s general session and close at 5:30 PM the same day.

Anyone in attendance at the WGM whose badge holder, issued at registration, identifies them as Members and who are subscribers of the Work Group’s primary list server as of the Wednesday preceding the WGM may pick up and complete that Work Group’s co-chair ballot at the HL7 registration desk any time during the polling hours.

The ballots shall be controlled by reference to a list of subscriber email addresses to the Work Group’s primary list server. A polling site shall be established in proximity to the HL7 registration desk to allow voters to expeditiously complete the ballot and return it to the ballot box on the registration desk.

The ballot box shall be secured by HL7 staff when the polls close. The Associate Executive Director shall oversee the tally, including absentee ballots. The results of the previous day’s co-chair elections shall be announced during the next day’s general session, posted on the announcement board near the registration desk, and provided to the Work Groups. All ballot materials shall be retained for one month from the close of the WGM in case of a call for recount.

05.03 Administrative Ballots

Only current individual members and the designated voting representatives of current organizational members may participate in and cast a vote on administrative ballots such as the election of officers and Board members and the adoption of Bylaws. Administrative ballots are not subject to reconciliation or appeal.

05.04 Majority Rule

All formal motions made within HL7 Work Groups shall be decided by simple majority of the quorum of that Work Group, unless otherwise specified in documented Work Group decision-making practices. Work Groups may, at their discretion, adopt practices requiring thresholds higher than simple majority as long as those practices are documented and adopted by two thirds vote of the members of the Work Group present and voting at the time.

06 Governance

06.01 Board of Directors

No individual shall hold more than one position on the Board of Directors at any given time.

06.01.01 Limits to Organizational Representation

No organization, in this case the encompassing corporate entity versus a specific HL7 organizational member as defined in Bylaws §03.02.03, shall hold more than one voting position on the Board of Directors. Should change of employment or corporate acquisition during the term of office of any voting member of the Board result in a violation of this policy, that organization’s representative whose term expires first shall not stand for reelection recognizing that the Chair represents a four year commitment and shall take precedent for retention. Representatives of organizations currently holding a voting position shall not be accepted into nomination unless such nomination (1) represents the incumbent seeking a second term, or (2) is concurrent with the incumbent from said organization completing the allowable number of terms or not seeking reelection. [Effective with the election and seating of Board members for the 2009 term]
06.01.02 Officers and HL7 Directors

06.01.02.01 Nomination and Election Schedule
Nominations shall be accepted from May 1 through June 15 of each year.
Elections shall occur from July 1 through July 30 of each year.
Runoff elections, if necessary, shall occur from August 7 through August 21 of each year.

06.01.02.02 Officer Nomination Criteria and Voting Pool
Nominees for an Officer position (Chair-elect, Secretary, or Treasurer) must be a current individual member or designated voting representative of a current organizational member of HL7, Inc.
Every effort shall be made to present at least two candidates for any Officer position. HL7 Headquarters shall provide the official Officer ballot to current individual members and designated voting representatives of current organizational and Affiliate members.

06.01.02.03 HL7 Director Nomination Criteria and Voting Pool
Nominees for HL7 Director must be a current individual member or designated voting representative of a current organizational member of HL7, Inc.
All valid nominees for HL7 Director shall be placed on the ballot from which those voting will select the appropriate number of positions being filled. HL7 Headquarters shall provide the official HL7 Director ballot to current individual members and designated voting representatives of current organizational members of HL7, Inc.

06.01.02.04 Nomination and Election Process
Nomination packets shall be available on the first day of the nomination period and shall include instructions for the submission of a petition for nomination. The petition shall indicate the office being sought and include:
a) a digital image (.jpg preferred) of the candidate
b) a personal statement of goals and objectives if elected and information on HL7 leadership experience and years of participation if desired
In order to be considered “in nomination” the candidate must be named as a nominee by at least ten individuals being either current individual members or representatives of current organizational members of HL7, Inc. To ensure that no single organizational member exerts undue influence in the nomination process only the first two representatives of any given organizational member shall be counted as supporting the nomination of any given candidate.
All petitions must be submitted to HL7 Headquarters by the close of the nomination period. An individual who is nominated for more than one position must state which position he or she wishes to seek and reject other nominations. HL7 Headquarters shall validate that all nominees are current members and contact the nominees to ensure that they:
a) understand the obligations of serving on the Board of Directors (e.g., attending the Working Group Meetings, participating in Board meetings and monthly conference calls and attending the Board retreat);
b) are willing to serve; and
c) have sought and received any necessary endorsements from their respective organizations.
At the conclusion of the nomination period, the Nomination Committee shall finalize the slate including all validated candidates who petitioned for nomination. The Nomination Committee may also recruit nominees using the criteria stipulated above. The final slate shall be presented to HL7 Headquarters for preparation of the ballot at least five days prior to the start of the scheduled election period.
HL7 Headquarters shall provide the official ballots to the appropriate voting pool on the first day of the election period. The ballots shall provide for write-in candidates. However, any write-in candidates shall be validated using the criteria stipulated above before their votes are tallied.
At the conclusion of the election period the chair of the Nomination Committee shall oversee the tally of the returned ballots. Although there may be multiple nominees from a single organization, under the tenets of §06.01.01 should more than one representative of a given organization be elected only one may be seated. In such a case, the individual who received the most votes (reflecting the decision of the voters) shall serve. In the event of there being three or more candidates contending for an Office, the winner shall be deemed to be the candidate collecting the largest vote total, a plurality. The winning HL7 Directors shall be those receiving the largest vote total. In the event of a tie there shall be a runoff election. Results of the election of Officers and HL7 Directors shall be announced at the Annual Business Meeting.

The results of the tally shall remain on file for one year and shall be produced upon submission of a written request by a current individual member or a voting representative of a current organizational or Affiliate member.

06.01.03 Nomination and Election of Affiliate Directors

Using the schedule specified in §06.01.02.01 a call for nominations shall be distributed to the Affiliate chairs via electronic means. This notice shall include the duties, obligations, and term of office of the Affiliate Directors. Using their designated processes, the Affiliate chairs shall identify candidates for Affiliate Director. All nominations shall be submitted to HL7 Headquarters by the close of the nomination period. HL7 Headquarters shall contact all nominees to ensure that they

a) understand the obligations of serving on the Board of Directors (e.g., attending the Working Group Meetings, participating in Board meetings and monthly conference calls and attending the Board retreat); and

b) are willing to serve.

At the conclusion of the nomination period, HL7 Headquarters shall finalize the slate of nominees and prepare a ballot, which shall be distributed to the Affiliate chairs via electronic means. Each Affiliate is allocated a single vote for the Affiliate Director. HL7 Headquarters shall create a limited access web page to allow Affiliate chairs to submit their vote electronically. All votes must be cast within the scheduled election period. The winner shall be the candidate with the largest vote tally. In the event of a tie HL7 Headquarters shall conduct a runoff election.

06.01.04 Director Term of Office

The term of office for HL7 and Affiliate Directors shall coincide with the Calendar Year. Directors shall serve two-year overlapping terms, with half the Directors being elected in even-numbered years (term encompassing first the following odd-numbered year, then the subsequent even-numbered year) and half the Directors being elected in odd-numbered years (term encompassing first the following even-numbered year, then the subsequent odd-numbered year). HL7 and Affiliate Directors are limited to two consecutive terms of office.

06.01.05 Directors Nominated by the Chief Executive Officer

The Chief Executive Officer (CEO) shall identify suitable candidates from various sectors of the healthcare community for seats on the Board of Directors. These candidates shall be chosen based on criteria established by the CEO as necessary to meet the objectives set by the Board of Directors. The Executive Committee shall assist the CEO in assessing and validating candidates and preparing a slate of nominees. The Board of Directors shall ratify individuals from the slate of candidates by two thirds majority. These individuals shall serve a two year term and are limited to two consecutive terms. Any of these individuals may be dismissed by mutual consent of the HL7 Chair and the CEO, with the concurrence of two thirds of the Board of Directors.

06.02 Duties and Powers of the Board of Directors

The Board of Directors shall:

a) Approve the contract for an organization to provide technical and administrative services for HL7 on such terms and conditions as it may deem advisable.

b) Approve the employment or contract for such executive staff as the Board may consider necessary to support the activities of HL7, and on such terms and conditions as it may deem advisable.
c) Provide the strategic direction of the organization outlining specific goals and objectives with a proposed timeline for achievement.

d) Ratify recommended appointments for the chairmanship of councils and both ad hoc and standing committees.

e) Review and approve the annual budget.

f) Create advisory groups and councils as necessary to fulfill liaison with other organizations; and ratify the recommended appointments for representatives to those organizations.

g) Report to the membership annually regarding the goals and objectives of the organization and other such matters as are necessary and advisable.

h) Exercise its legal and constituted authority and responsibility in the direction and conduct of the affairs of HL7 in order to promote and attain the objectives of the Organization.

i) Engage in such business activities as may be in furtherance of HL7’s charitable, scientific, literary and educational purposes including, but not limited to, the pursuit of grants, the purchase and sale of real and personal property, the review of contracts with a value in excess of $150,000, and the transacting of all other affairs of HL7 not otherwise provided.

06.03 Board of Directors Meetings

a) The Board of Directors shall hold at least two meetings per year, one of which shall occur at the time of the Plenary and annual Business Meeting.

b) Other meetings of the Board of Directors may be held at the call of the Chair, or upon petition by a majority of the voting Members of the Board.

c) Any or all members of the Board may participate in a Board meeting or a meeting of a Board committee by means of a conference telephone call or by any means of communication by which all persons participating in the meeting are able to hear one another; such participation shall constitute presence in person at the meeting.

d) Robert’s Rules of Order, current revised edition, shall govern the conduct of the meetings when not inconsistent with this document or any other rules of order the Board of Directors may adopt.

e) A majority of the voting members of the Board of Directors, including at least the Chair or Vice Chair and one other officer, shall constitute a quorum for conducting official business. Unless otherwise noted, motions shall be resolved by simple majority of quorum.

f) Motions related to approval of the budget, approval of unbudgeted expenditures requiring Board approval, hiring executive staff, or contractual issues brought before the Board shall be resolved by a majority of all voting members of the Board. Those members of the Board not able to participate in a vote requiring a response from the full Board of Directors shall be contacted by the Secretary asking that they submit their vote in writing, which includes email, to both the Chair and the Secretary for inclusion in the final tally. Votes on such matters shall be recorded by name.

g) The agenda shall be distributed electronically by close of business of the third working day preceding the scheduled Board Meeting. A packet of supporting documentation, when appropriate, shall accompany the agenda. Items for the consideration of the Board that are not available when the agenda is distributed shall be expeditiously forwarded to Board members as they become available. The Chair shall rule on such matters, but where material is not made available by the day prior to the meeting the appropriate agenda item should be deferred to the next meeting or otherwise disposed.

h) In the course of a meeting members of the Board shall respect differing opinions recognizing that dissent is healthy and should not be discouraged; however, once the Board has reached a decision all members shall be of one voice supporting the decision of the Board.

i) Any action required by law to be taken at a meeting of the Board of Directors, or any other action which may be taken at a meeting of the Board of Directors, may be taken without a meeting, if a consent in writing setting forth the action so taken shall be signed by all members of the Board of Directors entitled to vote in respect to the subject matter thereof. Such consent shall have the same force and effect as a unanimous vote and may be stated as such in any document filed with the state of Michigan.
06.03.01 Observers

Board of Directors meetings convened during the Working Group Meetings shall be open to observers unless called into executive session by the Chair. Observers shall be restricted to seating on the periphery as directed by HL7 staff. Observers shall not cause distractions or otherwise interrupt the conduct of the Board Meeting. Observers shall not seek the attention of the Chair and shall not participate in Board deliberations unless specifically requested to comment by a member of the Board. Current individual members or voting representatives of current organizational or Affiliate members may individually petition to become observers during Board teleconferences. Such petitions shall be granted solely at the discretion of the Chair. Teleconference observers shall clearly announce their presence during the roll call. Teleconference observers shall be held to the same rules of courtesy and participation as expected at Working Group Meetings.

06.03.02 Board Appointed Committee Chairs

Unless serving on the Board of Directors, an appointed committee chair may attend Board meetings and/or conference calls as an observer with the express purpose of presenting the report of committee activity to the Board. Those appointed committees with co-chairs shall select a single representative to attend and render the report. The representative need not attend the Board meeting or conference call if a member of the Board serving on said committee or designated as the Board liaison is able to present the committee activity report or there is no committee activity to report.

06.04 Conflict of Interest

The purpose of the conflict of interest policy is to protect the interest of HL7 when it is contemplating entering into a transaction or arrangement that might benefit the private interest of an Officer or director of HL7 or might result in a possible excess benefit transaction. This policy is intended to supplement but not replace any applicable state and federal laws governing conflict of interest applicable to nonprofit organizations.

06.04.01 Definitions

Interested Person: any director, Officer, or member of the Executive Committee, who has a direct or indirect financial interest, as defined below, is an interested person.

Financial Interest: a person has a financial interest if the person has, directly or indirectly, through business, investment, or family:

a) An ownership or investment interest in any entity with which HL7 has a transaction or arrangement

b) A compensation arrangement with HL7 or with any entity or individual with which HL7 has a transaction or arrangement, or

c) A potential ownership or investment interest in, or compensation arrangement with, any entity or individual with which HL7 is negotiating a transaction or arrangement.

A financial interest is not necessarily a conflict of interest. Under §06.04.02.02 a person who has a financial interest may have conflict of interest only if the Board, which considers transactions or arrangements with a value exceeding $150,000 or the Executive Committee, which considers transactions or arrangements with a value up to $150,000, decides that a conflict of interest exists.

Compensation: direct and indirect remuneration including gifts or favors that exceed Internal Revenue Service guidelines.

06.04.02 Procedures

06.04.02.01 Duty to Disclose

In connection with any actual or possible conflict of interest, an interested person must disclose the existence of the financial interest and be given the opportunity to disclose all material facts to the members of the Board or Executive Committee, whichever is considering the proposed transaction or arrangement.
06.04.02.02 Determining Whether a Conflict of Interest Exists
After disclosure of the financial interest and all material facts, and after any discussion with the interested person, he or she shall leave the meeting while the determination of a conflict of interest is discussed and voted upon. The remaining Board or Executive Committee members shall decide if a conflict of interest exists.

06.04.02.03 Addressing the Conflict of Interest
An interested person may make a presentation at the meeting, but after the presentation, he or she shall leave the meeting during the discussion of, and the vote on, the transaction or arrangement involving the possible conflict of interest.

The chairperson of the Board or Executive Committee, whichever is considering the transaction or arrangement, shall, if appropriate, appoint a disinterested person or ad hoc committee to investigate alternatives to the proposed transaction or arrangement.

The Board or Executive Committee, exercising due diligence, shall determine whether a more advantageous transaction or arrangement with a person or entity that would not give rise to a conflict of interest can be obtained with reasonable effort.

If a more advantageous transaction or arrangement is not reasonably possible under circumstances not producing a conflict of interest, the Board or Executive Committee, whichever is considering the transaction or arrangement, shall determine by a majority vote of the disinterested members whether the transaction or arrangement is in the best interest of HL7, for its own benefit, and whether it is fair and reasonable. In conformity with the above determination it shall make its decision as to whether to enter into the transaction or arrangement.

06.04.02.04 Violations of the Conflict of Interest Policy
If the Board or Executive Committee, whichever is considering the transaction or arrangement, has reasonable cause to believe a member has failed to disclose actual or possible conflicts of interest, it shall inform the member of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose.

If, after hearing the member’s response and after making further investigation as warranted by the circumstances, the Board or Executive Committee determines the member has failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and corrective action.

06.04.03 Records of Proceedings
The minutes of the Board and Executive Committee shall contain:

a) The names of the persons who disclosed or otherwise were found to have a financial interest in connection with an actual or possible conflict of interest, the nature of the financial interest, any action taken to determine whether a conflict of interest was present, and the decision as to whether a conflict of interest in fact existed.

b) The names of the persons who were present for discussions and votes relating to the transaction or arrangement, the content of the discussion, including any alternatives to the proposed transaction or arrangement, and a record of any votes taken in connection with the proceedings.

06.04.04 Compensation Decisions
A voting member of the Board or Executive Committee who receives compensation, directly or indirectly, from HL7 for services is precluded from voting on matters pertaining to that member’s compensation.

A voting member of any committee whose jurisdiction includes compensation matters and who receives compensation, directly or indirectly, from HL7 for services is precluded from voting on matters pertaining to that member’s compensation.

No voting member of the Board, the Executive Committee, or any committee whose jurisdiction includes compensation matters and who receives compensation, directly or indirectly, from HL7, either individually or collectively, is prohibited from providing information to any committee regarding compensation.
06.04.05 Annual Statements
Each director, Officer and member of the Executive Committee shall annually sign a statement which affirms such person:
   a) Has received a copy of the conflicts of interest policy including current Internal Revenue Service guidelines on the value of acceptable gifts or favors,
   b) Has read and understands the policy
   c) Has agreed to comply with the policy, and
   d) Understands that to maintain its federal tax exemption HL7 must engage primarily in activities which accomplish one or more of its tax exempt purposes.

06.04.06 Periodic Review
To ensure HL7 operates in a manner consistent with its purposes and does not engage in activities that could jeopardize its tax-exempt status, periodic reviews shall be conducted. The periodic reviews shall, at a minimum, include the following subjects:
   a) Whether compensation arrangements and benefits are reasonable, based on competent survey information and the result of arm’s length bargaining.
   b) Whether partnerships, joint ventures, and arrangements with management organizations conform to written policies, are properly recorded, reflect reasonable investment or payments for goods and services, further the purposes of HL7 and do not result in inurement, impermissible private benefit or in an excess benefit transaction.

06.04.07 Use of Outside Experts
When conducting the periodic reviews as provided for in §06.04.06, HL7 may, but need not, use outside advisors. If outside experts are used, their use shall not relieve the Board of its responsibility for ensuring periodic reviews are conducted.

06.05 Code of Ethics
Members of the Board of Directors and employees of HL7 and its management organization shall act to further the best interests of HL7 in their official affairs; they shall be alert regarding relationships with third parties which might affect their independent judgment when acting for or on behalf of HL7, be alert in the conduct of the affairs of HL7 to avoid situations in which they might, directly or indirectly, profit personally, and at all times use their best efforts to enhance the reputation of HL7 for honesty, integrity, candor and lack of bias or discrimination while representing the members and the best interests of HL7.
   a) They shall avoid situations in which they personally might profit or even give the appearance of profiting from their official HL7 activities.
   b) They shall not employ the name of HL7 in seeking or accepting payment for professional services.
   c) They shall not, directly or indirectly, accept or solicit anything of significant value as a gift, gratuity or favor under circumstances that might affect, or reasonably lead others to believe such action would affect, their impartiality on behalf of HL7. This does not prohibit acceptance of reimbursement for out-of-pocket expenses while acting as an official HL7 spokesperson or of social amenities and token gifts of purely nominal value, consistent with generally accepted business practices and good taste. If there is any doubt as to the relative value of or the propriety of accepting a gift, it may be resolved by either declining to accept the gift or amenity, or obtaining the approval of the Chair or, in the case of employees of HL7 and its management organization, the Executive Director.
   d) They shall not use the HL7 name or its stationery for other than official HL7 business.
   e) They shall abide by the rule that HL7 will not endorse any product or service provided by any HL7 member or non-member. Use of the HL7 trademark by its organizational members does not imply endorsement of a specific organization, product or service.
06.06 Submitting and Resolving Motions via Email

Email processing will be used to address Board of Director or Executive Committee motions either of an urgent nature requiring immediate action that cannot be deferred until the next scheduled call/meeting or of a routine, non-controversial nature not requiring extensive debate or deserving of time on the next meeting agenda. Every effort will be made to address each motion as a separate email for tracking purposes.

Submissions shall be clearly identified by ‘MOTION’ in the subject line, e.g.: MOTION <insert text of motion>. The person seconding the motion shall append ‘SECOND’ to the end of the subject line, e.g.: MOTION <insert text of motion> SECOND. Following submission of the original motion and posting of a second, a two business day discussion period will take effect preceding a call for vote.

The discussion period shall begin at the start of business, defined as 8:00 a.m. Eastern, of the first business day following the submission of a second. No voting shall occur during the discussion period. Acceptance or non-acceptance of amendments to the original motion made during the discussion period must be acknowledged on the list by the submitter of the original motion and the individual providing a second.

When the discussion period closes, the vote will be initiated by HL7 Headquarters by placing ‘VOTE ON’ in the subject line preceding the motion; e.g., VOTE ON MOTION <text of motion>. The motion, as amended if appropriate, will be restated at the call for vote. The closing date/time of the vote will be stated in the body of the email. If a vote date limit is not set in the body of the email, the vote period shall default to 5 business days from the initial call for vote. The minimum vote period allowed shall be 2 business days.

All votes shall be submitted using “Reply All” to allow the members of the Board of Directors or Executive Committee to monitor progress. An email vote of “yes” shall be interpreted as an affirmative vote in support of the original, or amended if applicable, motion. In matters of expediency or to achieve a quorum response, members may be contacted by telephone and requested to submit their vote to the list.

A tally of vote status to include the motion, second, and count of those in favor, opposed, or abstaining shall be posted to the list by HL7 Headquarters the day before the close of the voting period using the subject line: TALLY OF MOTION <text of motion>. The number of votes cast, including abstentions shall count toward quorum. Proxy votes are not permitted. As defined in Robert’s Rules, the Chair is allowed to vote when his or her vote will materially affect the results of the vote.

06.07 Liability Insurance

The Executive Director on behalf of the Board of Directors shall contract for an appropriate form of Directors and Officers liability insurance to fund the contingent liability attendant to the referenced indemnification, to the greatest extent possible at reasonable expense.

07 Officers

07.01 The Executive Committee

The HL7 Officers shall be the Chair, the Chair-Elect or Immediate Past Chair acting as the Vice Chair, the Secretary, and Treasurer who, with the addition of the Chief Executive Officer, Chief Technology Officer, and Executive Director, shall comprise the Executive Committee. Officers must be current members. The Executive Committee shall be responsible for operations of the Organization. The Board of Directors may from time to time refer issues to the Executive Committee, whose decision shall be binding.
07.02 Chair
The Chair shall preside at all meetings of the Board of Directors, the Plenary and Business Meetings of the Membership, and with the assistance of the CEO manage liaison or affiliations with other organizations. The Chair shall report on the activities and state of HL7 at the annual business meeting. In the absence of the Chair the Vice Chair, being the Chair-Elect or the Immediate Past Chair, shall preside. The Chair shall be a member, *ex officio*, with vote, of all councils and committees including the Technical Steering Committee.

07.02.01 Term of Office
The Chair shall serve for a term of two years, ascending from the Chair-Elect serving in odd-numbered years (term encompassing first the following even-numbered year, then the subsequent odd-numbered year).

07.02.02 Representing HL7
The Chief Executive Office, or alternately the Chair, is charged with representing HL7 to other organizations or entities. This duty may be delegated, with constraints on scope and/or timeframe, to an officer, director, council, committee, or Work Group chair. The designated individual shall prepare and submit timely reports on their activities.

There are numerous situations where a member of HL7, participating in various other initiatives and venues, may wish to represent an HL7 position rather than attributing their statement to themselves or their employer. In general, any written or oral statement represented as an HL7 position must be reviewed within HL7 prior to its release. Such statements shall not appear to favor one vendor, product, or service over another. Nor shall they denigrate any individual or organization. Guidelines relative to written and oral communications regarding HL7 follow.

*Written Communications*
This policy primarily addresses position papers, statements of plans and future directions, or philosophy statements. If the communication represents information specific to the status, process, or products of an HL7 Work Group, the release of the document should be approved by the Work Group co-chairs. If an individual believes that the release of a document is inappropriately restricted, they have the right to appeal the decision to the Technical Steering Committee, whose decision shall be final. If the communication purports to represent the position of HL7, the organization, approval must be obtained from the Executive Committee.

*Oral Communications*
In the case of oral communications, the speaker should clearly state whom they are representing when making statements regarding HL7. Although anyone is free to represent an individual or employer position at will, when they are speaking on behalf of a Work Group, speakers should only represent positions that have been endorsed by the Work Group or at some higher level. If a speaker is unsure of their right to express a given position, they should refrain from responding, but commit to follow up with an answer or direct the question to the appropriate Work Group chair or a member of the Executive Committee.

07.02.03 Reimbursing Expenses of the HL7 Chair and Vice Chair
The organization supporting the individual serving as Chair is encouraged to extend its contribution to HL7 by absorbing the expenses associated with the position. HL7 shall reimburse all reasonable costs accrued by the Chair-elect (seated as the Vice Chair), the Chair, and the Immediate Past Chair (seated as the Vice Chair) associated with the conduct of HL7 business not otherwise absorbed by the individual or the supporting organization. These costs include attendance and participation at Working Group Meetings; participation in Board meetings and retreats; periodic meetings with HL7 staff; and attendance and participation at meetings, conferences, and trade shows as an HL7 representative. Other expenses shall be approved by the Executive Committee and reported to the Board of Directors at its next scheduled meeting.
07.03 Chair-Elect
The Chair-Elect shall ascend to the Chair at the conclusion of the term of the then seated Chair. The Chair-Elect shall assist the Chair and develop the operating plan for the following year. The Chair-Elect shall be a member, *ex officio*, without vote, of all councils and committees including the Technical Steering Committee. The Chair Elect shall serve as Vice Chair of the Board of Directors.

07.03.01 Term of Office
The Chair-Elect shall be elected during the first year of the term of the then seated Chair and serve for a period of one year, coincident with the second year of the term of the then seated Chair.

07.04 Immediate Past Chair
At the completion of their term the Chair shall assume the role of Immediate Past Chair. The Immediate Past Chair shall assist the incoming Chair in implementing their operating plan. The Immediate Past Chair shall be a member, *ex officio*, without vote, of all councils and committees including the Technical Steering Committee. The Immediate Past Chair shall serve as Vice Chair of the Board of Directors.

07.04.01 Term of Office
The Immediate Past Chair shall serve for a period of one year, coincident with the first year of the term of the then seated Chair.

07.05 Secretary
The Secretary shall provide or oversee the provision of general administrative support for the Board of Directors. In the absence of the Secretary, the presiding officer of the board meeting may appoint an Acting Secretary for the purpose of recording proceedings and motions and tallying votes. The Secretary, under the direction of the Board of Directors, shall accomplish or cause to be accomplished, the following tasks:

a) ensure that minutes of the various Work Groups are posted to the Web site within 30 days of a Working Group Meeting
b) record and publish Board proceedings and motions
c) create and distribute Board meeting and Working Group Meeting notices at least 30 days prior to such meetings
d) create and distribute voting items and ballots as directed by the Board
e) tally votes
f) distribute Board agendas
g) maintain the roster of Board members
h) maintain this Manual and cause updates to be posted to the Web site
i) establish and maintain appropriate archives and historical records of all official HL7 business
j) maintain any other records required by law

07.05.01 Term of Office
The Secretary shall serve for two years being elected in even-numbered years (term encompassing first the following odd-numbered year, then the subsequent even-numbered year). The Secretary shall serve no more than two consecutive terms.

07.06 Treasurer
The Treasurer shall establish orderly mechanisms for the collection of fees, dues, and assessments, and the distribution of monies owed. The Treasurer shall prepare, or cause to be prepared, all financial reports presented to the Board of Directors and to the membership. The Treasurer shall participate in the selection of a certified public accountant to conduct an annual review or audit of the records and financial statements. The selection of an auditor shall be ratified by the Board of Directors. The Treasurer shall qualify for a fidelity bond procured by the Board of Directors.
07.06.01 Term of Office
The Treasurer shall serve for two years, being elected in odd-numbered years (term encompassing first the following even-numbered year, then the subsequent odd-numbered year). The Treasurer shall serve no more than two consecutive terms.

07.06.02 Expenditure Limits
The Executive Committee shall recommend categorical expenditure limits escalating through the staff, the Executive Director, the CTO, and the CEO, which shall be presented in a matrix document for approval by the Board. Expenditure limits shall be subject to periodic review. Expenditures exceeding the established limits shall be approved by the Board.

07.06.03 Annual Budget
The Treasurer and Executive Director shall have the primary responsibility for preparing the proposed annual budget. They shall prepare a detailed, annotated budget, with guidance from the Executive Committee. It shall be the goal of the Treasurer to present the subsequent year’s budget to the Board of Directors prior to the annual business meeting.

08 Appointed Positions

08.01 HL7 Liaisons
The Chair, with the approval of the Board, shall appoint representatives to various and appropriate standards development organizations (SDO) and other groups or organizations, as necessary, to represent the interests of HL7. As a general rule travel and other expenses related to liaison activities will not be reimbursed. Requests for travel and/or other reimbursement related to these liaison activities shall be handled on a case-by-case basis. Every effort will be made to appoint individuals already associated with and participating in the meetings/activities of the SDO or group in question as the liaison. Liaisons shall report on their activity in a timely manner to the HL7 Board of Directors.

09 The Working Group
Collectively the various Work Groups established by the Technical Steering Committee to focus on particular aspects of the HL7 protocol specifications shall be know as The Working Group.

09.01 The Technical Steering Committee (TSC)
A Technical Steering Committee (TSC) shall be established to facilitate the coordination and activities of the Working Group. It shall be comprised of a representative and alternate from each of the four Steering Divisions (SD), two Affiliate representatives, the Chief Technology Officer (CTO), a representative of the Architecture Review Board (typically the ARB chair), and appropriate HL7 staff. Should the TSC identify an imbalance or the need for specific expertise, they may vote to include an ad hoc member to correct the situation. The TSC shall elect its chair from among its members; excluding the CTO, chair of the ARB, and the ad hoc member if seated. The TSC shall be responsible for product project approval and management oversight including:

a) Establishing and maintaining an HL7 Architecture, development methodologies, and work processes to be used by The Working Group in developing HL7 protocol specifications
b) Ensuring that the efforts of The Working Group to produce protocol specifications proceeds at a reasonable pace
c) Ensuring that The Working Group collaborates smoothly and covers the scope of work in a consistent manner.

09.01.01 TSC Elections
The election of TSC representatives shall be held prior to the annual plenary meeting with two of the four steering division representatives and one of the two Affiliate representatives elected each year. The results of the election shall be announced during the plenary meeting with the representatives taking office the following January.
09.01.01 TSC Chair
The TSC shall select its chair following the plenary meeting in odd numbered years from among those members currently seated or those recently elected. The selected member shall take office in January of the following even numbered year.

09.01.02 Steering Division Representatives
During a nomination period of at least 30 days, nominations for Steering Division (SD) representatives shall be accepted from the co-chairs of the Work Groups comprising the SD. The nominees should be either current or past co-chairs of one of the Work Groups comprising the SD. It is felt that level of experience is necessary to be an effective member of the TSC. Service on the TSC requires a commitment of at least two hours a week. HL7 staff will contact nominees to verify their willingness to stand for election, and to solicit a brief statement for distribution. Individuals who are nominated to represent more than one SD will be asked to choose which nomination they wish to accept, thereby rejecting the other(s).

An election period of at least 30 days shall follow the nomination period. Votes shall be cast by the Work Groups in the SD, using their normal decision-making practices. Each Work Group shall cast votes for two of the candidates, and will be asked to state a preference for one as their primary representative. The candidate receiving the most votes will be named the representative for that SD. The candidate receiving the next higher number of votes will be named the alternate representative. Tie votes will be resolved by tallying the primary representative preferences for the candidates involved in the tie. If this tally also results in a tie, the decision will be made by drawing lots, unless one of the candidates involved wishes to defer to the other. Both the elected representative and alternate shall be named co-chairs of that SD.

09.01.03 Affiliate Representatives
An Affiliate representative shall be elected each year to serve a two year term. During a nomination period of at least 30 days, nominations for Affiliate representative shall be accepted from the Affiliate chairs. Nominees should be prepared to commit at least two hours a week to the TSC, if elected. HL7 staff will contact nominees to verify their willingness to stand for election, and to solicit a brief statement for distribution.

An election period of at least 30 days will follow the nomination period. Votes will be cast by the allotted voting representatives of the Affiliates, using their normal decision-making practices. Each Affiliate will vote for their candidate of choice. The candidate receiving the most votes will be named the Affiliate Representative. Tie votes will be resolved by drawing lots, unless one of the candidates involved wishes to defer to the other.

09.02 Term of Office
The CTO and ArB chair are ex officio members of the TSC and as such are not subject to a term of office beyond that prescribed by their offices.

09.02.01 TSC Chair
The TSC Chair shall serve a term of two years without term limits; the only criteria being current membership in the TSC. Should the TSC member selected to serve as the TSC Chair only have a year remaining of their term as an SD or Affiliate representative, and is not subsequently elected to another term, the second year of their term as TSC Chair shall be served as an ad hoc member of the TSC.

09.02.02 Representative Members
SD and Affiliate representatives shall serve a term of two years without term limits.

09.02.03 Ad Hoc Member
An ad hoc member serves at the pleasure of the TSC, but in no case should their term exceed two years subject to reappointment.
09.01.03 Vacancies
Members no longer able to fulfill their responsibilities shall resign from the TSC.

09.01.03.01 TSC Chair
Upon the resignation of the chair, the TSC shall select another member to fill the remaining term of office.

09.01.03.02 SD Representative
Upon the resignation of an SD representative, the alternate shall assume the primary role for the remaining term of office with the position of alternate remaining vacant until the next regular election.

09.01.03.03 Affiliate Representative
Upon the resignation of an Affiliate representative, the Affiliate Council shall designate an individual to complete the remaining term of office.

09.01.04 Meetings
Interim to the Working Group Meeting, the TSC shall convene via teleconference on a schedule established by the TSC Chair. The TSC Chair shall convene the TSC at least once during each Working Group Meeting.

09.01.05 Observers
TSC meetings held during a Working Group Meeting shall be open to observers unless called into executive session by the TSC Chair. Observers shall be restricted to seating on the periphery as directed by HL7 staff. Observers shall not cause distractions or otherwise interrupt the conduct of the TSC meeting. Observers wishing to contribute to the meeting shall seek the attention of the TSC Chair and wait to be recognized.

09.01.06 Interpretation of the HL7 Protocol Specifications
The TSC is responsible for official interpretation of all HL7 Protocol Specifications (§02.02). The TSC Chair or CTO, in collaboration with the TSC, shall respond in kind to written requests for interpretation. These written interpretations shall be published in the next edition of the HL7 newsletter, retained on file, and made available electronically.

09.02 Work Groups

09.02.01 Establishing a Work Group

09.02.01.01 Criteria
Individuals interested in establishing a new Work Group shall schedule time with the TSC Chair and the CTO to establish their conformance to the following criteria:

a) There is a demonstrated need for the creation of a Work Group such as a government mandate, the results of “gap” analysis, or a stakeholder imperative and such need is of a scope that precludes it being addressed as a project by an existing Work Group.

b) The expressed need is within the scope of HL7 and creation of the proposed Work Group shall facilitate HL7 accomplishing its mission and objectives.

c) There are a minimum of five HL7 members who have agreed to active participation in the proposed Work Group and they possess the necessary expertise and commitment to accomplish its goals.

If the TSC Chair and CTO concur on the creation of a new Work Group they shall advise on appropriate collaboration with existing Work Groups and designate the SD to which the proposed Work Group shall be assigned. Otherwise, the TSC Chair and CTO shall recommend the appropriate Work Group for the interested individuals to approach with a project proposal.
09.02.01.02 Process
With the concurrence of the TSC Chair and the CTO, the individuals proposing a new Work Group shall complete and submit a Work Group Proposal Template to the designated SD co-chairs who shall distribute it to the co-chairs of all existing Work Groups across the various SD. Within 30 days of receipt of the template the designated SD co-chairs shall convene a conference of the co-chairs of all assigned Work Groups for the purpose of accepting or rejecting the proposal. Concurrent with the conference to consider the proposal the co-chairs of other SD Work Groups shall report any instances of overlap with the focus or intent of the proposed Work Group to the designated SD co-chairs.

The proposal shall be moved to the TSC for consideration upon a two-thirds affirmative vote by those Work Group co-chairs placing a vote with at least sixty percent of the Work Groups within the SD returning a vote. Failure to achieve quorum (60%) shall result in the proposal and record of votes cast moving forward to the TSC for consideration. Given quorum, failure to receive a two-thirds affirmative vote shall cause the proposal to be rejected. A rejected proposal may be appealed to the TSC up to thirty days from the date of rejection. The TSC shall resolve an appeal within thirty days of submission.

Upon approval by the designated SD, the SD co-chairs shall immediately submit a request for review of the proposal to the TSC Chair who shall advise the TSC members of the intent to review the proposal within thirty days. The TSC shall address the Work Group proposal under the tenets of its documented decision making practices. If approved, the TSC Chair shall inform the Board of the creation of a new Work Group, suggest that the HL7 Director of Communications consider a press release announcing the formation of a new Work Group, and notify the Associate Executive Director to initiate all necessary infrastructure activity appropriate to the creation of a new Work Group. A TSC decision to reject the proposal may be appealed to the HL7 Executive Committee within thirty days of the TSC rejection. The Executive Committee shall set a date to resolve the appeal and notify the appellant.

09.02.02 Dissolution of a Work Group
Given a majority vote of its members, the co-chairs of a Work Group may petition the TSC Chair and CTO for dissolution of the Work Group. Reasons for considering dissolution include lack of interest or expertise as evidenced by participation consistently falling below five members or achievement of the objectives of the Work Group. The petition should seek to identify those Work Groups that might assume the work of the dissolving Work Group. The TSC Chair and CTO may propose and seek alternatives to dissolution.

With the concurrence of the TSC Chair and CTO, the dissolving Work Group co-chairs shall seek the approval of the appropriate Work Group(s) to assume responsibility for their work products. The Work Group(s) shall confirm consent by a two-thirds affirmative vote of their members casting a vote. The dissolving Work Group co-chairs shall complete and submit the Work Group Dissolution Template to the parent SD co-chairs. The results of the attempt to achieve consent for the assumption of work products shall be reported on the template.

The parent SD co-chairs shall distribute the template to all other Work Group co-chairs and schedule a vote of the parent SD Work Group co-chairs to consider the request for dissolution within 30 days of submission. If appropriate, all Work Group co-chairs shall petition their Work Group members for candidates to join the affected Work Group in an effort to forestall its dissolution. Should sufficient members come forward, the request to dissolve the Work Group is moot.

Upon an affirmative vote by two-thirds of the parent SD Work Group co-chairs casting votes with at least 80% of the Work Groups returning a vote, the parent SD co-chairs shall submit the template to the TSC Chair who shall advise the TSC members of the intent to review the request for dissolution within thirty days. The TSC shall address the request to dissolve under the tenets of its documented decision making practices. Upon approval, the TSC Chair shall notify the Board of the dissolution of a Work Group and the disposition of that Work Group’s work products, and request that the Associate Executive Director take the appropriate actions to effectively remove the Work Group from the organization.
09.02.03 Work Group Co-Chairs
Each Work Group shall have a minimum of two co-chairs to ensure leadership in the event that one or the other is unable to attend a Working Group Meeting (WGM) with the actual number of co-chairs determined by majority vote of the Work Group. A decision by the Work Group to increase the number of co-chairs shall result in the subsequent call for nominations and an election for those positions at the next WGM. The Work Group may designate an individual to fill the additional position interim to the next WGM.

The co-chairs are responsible for the conduct of the Work Group in the development of the HL7 protocol specifications in the designated domain; for collecting and publishing the minutes of meetings; for ensuring that the portion of the protocol specifications for which they are responsible is properly balloted; for resolving all negative normative ballot comments appropriately; and for reporting compliance with established procedures to the TSC.

Co-chairs shall serve two year terms without term limits. Terms shall commence upon validation of election results. Terms shall be staggered to ensure continuity of leadership, with half the co-chairs of a Work Group being elected in even numbered years and half elected in odd numbered years. Upon establishment of a new Work Group, an appropriate number of co-chairs shall be elected to an initial one year term to establish staggered terms.

09.02.04 Decision Making Practices
All HL7 Work Groups shall follow a documented set of decision-making practices. The practices in effect in each Work Group shall be adopted by majority vote of that Work Group and shall not conflict with the HL7 Bylaws, this manual or the current edition of ANSI Essential Requirements. Working sessions of each Work Group shall be governed by the rules set forth in their decision-making practices. Meetings hosted jointly shall follow the practices of the host Work Group.

There is no requirement for Work Group proceedings to be overly formal; although situations may arise that require such formality. In the event that a situation occurs that mandates the use of formal procedures or for situations not otherwise addressed in a Work Group’s documented decision making practices, Robert’s Rules of Order shall govern. As situations demand, a Work Group may force the institution of this formality through a majority vote of the Work Group.

10 Committees and Councils

10.01 Advisory Council
The Advisory Council shall be comprised of industry, regulatory, and public sector leaders at the senior executive level selected for their specific expertise to provide the Board of Directors an independent, external perspective on HL7 and its stakeholders. The Advisory Council shall elect its chair, who shall serve a term not to exceed two years with no more than two consecutive terms, from among its members. The chair shall serve for the remainder of their term on the Advisory Council and may be reelected if reappointed to the council. The HL7 Chair and the CEO shall confer on identifying and selecting appropriate individuals to participate. Members of the Advisory Council shall serve two year renewable terms. The Executive Committee shall interact with the Advisory Council.

10.02 Affiliate Council
The Affiliate Council shall be the collective leadership of the Affiliate members. The Affiliate Council shall elect its own leadership. It shall coordinate the activities of the Affiliates and advise the Board of Directors on matters of interest to the Affiliates. The Affiliate Council shall approve expenditures of those funds allocated to it in the annual budget with subsequent notification of such expenditures to the Executive Committee. The HL7 Chair shall represent the United States on the Affiliate Council.
10.03 Finance Committee
The Finance Committee shall consist of a chair, appointed with the concurrence of the Board, a representative appointed by the Affiliate Council, and a representative appointed by the Executive Committee who is a current individual member or representative of a current organizational member; all of whom shall serve a two year term limited to two consecutive terms. The HL7 Vice Chair and Executive Director shall be members ex officio with vote. The HL7 Treasurer shall be a member ex officio without vote.

The Finance Committee shall review all financial statements and budgets to be presented to the Board of Directors. It shall be responsible for reviewing the annual audit of HL7 financial records. Should the auditor raise serious concerns in the course of the annual audit regarding HL7 finances or related procedures, the Finance Committee may, with the concurrence of 75% of its members, recommend to the Executive Committee that an additional audit of HL7 finances and procedures is warranted.

The Finance Committee shall recommend to the Executive Committee policies regarding the receipt and expenditure of funds. It shall assist the Treasurer in the preparation of a detailed budget for the coming year to be submitted to the Board of Directors at the Annual Business Meeting. The Finance Committee shall consider and make recommendations to the Executive Committee regarding opportunities to generate additional revenues for HL7.

10.04 Governance and Operations Committee
The Secretary, Associate Executive Director, and such other members as the Secretary shall designate will comprise the Governance and Operations Committee (GOC), which shall be responsible for maintenance of this manual as defined in §17.

10.05 Marketing Council
The Marketing Council shall consist of a chair, appointed with the concurrence of the Board, the Marketing Director, the Director of Communications, a representative selected by the Affiliate Council, and at least two (2) other individuals who are current individual members or representatives of current organizational or Affiliate members selected by the chair. The chair shall serve for two years with a limit of two consecutive terms.

The Marketing Council shall have responsibility for developing a marketing strategy for increasing HL7 visibility and advancing HL7 Protocol Specifications (§02.02) in the global marketplace and implementing plans to achieve that strategy. The Marketing Council shall work with the Affiliate Council to promote both a global perspective and global distribution of HL7 marketing materials. The Marketing Council shall advise the Finance Committee of any opportunities it identifies for gifts, grants, or contributions that will further the objectives of HL7. The Marketing Council shall seek opportunities with both HL7 organizational members and those organizations associated with HL7 through memoranda or charter to jointly promote the HL7 Protocol Specifications or their implementation.

10.06 Nomination Committee
A Nomination Committee shall be convened by the close of the second Working Group Meeting of each year to oversee the nominations process for Officers and HL7 Directors; collect and validate petitions of nomination from amongst the membership; actively recruit, if necessary, to ensure a viable, balanced slate of candidates; and prepare the slate for ballot. The Nomination Committee shall also collaborate with staff to identify and recommend individuals deserving of special recognition, honors, or awards to the Board of Directors.

10.06.01 Composition
The Nomination Committee shall consist of:

a) Up to four representatives, who meet the criteria for participation, elected from amongst current individual members or representatives of current organizational members

b) Up to two representatives selected by the Technical Steering Committee

c) The Advisory Council may select one representative, if it so chooses.
d) The Board of Directors may select one representative, if it so chooses.
e) The Executive Director shall be an ex officio member and shall appoint an HL7 staff member to support the committee

10.06.01.01 Elected Representatives
A four week nomination period for member candidates seeking a seat on the Nomination Committee, to start the second Monday following the close of the first Working Group Meeting, shall be announced during the Tuesday general session of the first Working Group Meeting of each year. All petitions for nomination will be validated against HL7 membership roles to ensure that the nominee has completed at least two years of active participation. If there are four or fewer validated candidates, they shall be accepted as selected by acclamation.

If there are more than four validated candidates, HL7 Headquarters shall prepare a ballot containing all validated candidates for release to current individual members and the voting representatives of current organizational members by the second Monday following the close of the nomination period. The ballot shall be open for thirty days. HL7 Headquarters shall tally the vote. The four candidates receiving the most votes shall be the membership representatives on the Nomination Committee. A tie vote impacting the fourth position shall be resolved by a run off ballot of two weeks duration to be initiated the second Monday following the close of the initial ballot.

10.06.01.02 Advisory Council and Board Representatives
The Advisory Council and Board of Directors shall, if they so choose, select their representatives prior to the start of the second Working Group Meeting of each year.

10.06.01.03 TSC Representative
The TSC shall select its representatives during the second Working Group Meeting of each year.

10.06.02 Announcement
The members of the Nomination Committee shall be announced via the HL7 list server within one week of the close of the second Working Group Meeting of the year.

10.06.03 Selecting a Chair
The Nomination Committee shall elect its own chairperson, who shall not be the Advisory Council or Board of Directors representative if present.

10.07 Organizational Relations Committee
The Organizational Relations Committee shall consist of a chair appointed with the concurrence of the Board and at least two (2) other members. The chair shall serve for two years with a limit of two consecutive terms. The CEO shall be an ex officio member.

The Organizational Relationship Committee shall be responsible for initiating and/or managing, under the direction of the Executive Committee, the relationship between HL7 and various other organizations, associations, and consortia. The Organizational Relations Committee shall draft appropriate memoranda of understanding (MOU) and associate charters addressing these relationships for the consideration and approval of the Board of Directors.

10.08 Process Improvement Committee
The Process Improvement Committee (PIC) shall have a chair appointed with the concurrence of the Board, who shall select the members of the committee. A co-chair, or co-chairs at the discretion of the chair, shall be elected from among the members of the committee. The chair and any elected co-chairs shall serve a two year term with a limit of two consecutive terms. The PIC shall monitor HL7 process and collect membership input with the objective of making recommendations for improvement to HL7 operations. The PIC shall assist the GOC with maintenance of this manual.
11 Conferences, Meetings, and Educational Programs

11.01 Meeting Notice
Members shall be notified of all meetings and valid assemblies a minimum of 30 days prior to the scheduled date by postings to the HL7 list server and via the HL7 Web site.

11.02 Meetings in Conjunction with HL7
Any organization wishing to convene a meeting in conjunction with an HL7 Working Group Meeting may do so given the following conditions.

a) The HL7 Executive Committee approves the request.
b) The purpose of the proposed meeting is one of the following:
c) To coordinate with HL7
d) To share in educational opportunities with HL7
e) To jointly develop standards
f) The members of the organization pay HL7 registration fees and register as Working Group Meeting attendees.

The HL7 member discount on registration fees will be extended to all members of the organization meeting jointly. These individuals shall receive all goods and services (e.g., lunches, breaks, handout materials, etc.) typically provided to Working Group Meeting attendees.

HL7 will be responsible for providing meeting space and reasonable audiovisual equipment for joint sessions during the Working Group Meeting.

Priority in scheduling will be given to:
a) Other ANSI accredited standards developing organizations
b) Professional societies and organizations
c) Consortia and user group organizations

11.03 Tutorials
Tutorials to be presented at Working Group Meetings (WGM) and/or Education Summits shall be scheduled sufficiently in advance to allow for review and discussion by the Education Committee during the WGM that precedes their occurrence.

Proposed tutorials should meet the following criteria:
a) The topic should be of broad interest to the Working Group or to one of its Work Groups
b) The topic should be of interest to all classes and types of HL7 members
c) The format should be limited to a single meeting space and normal A/V support

Special requests must be presented as a formal proposal to the Education Committee for recommendation. The Education Committee will promptly review and make a recommendation on the proposal, presenting it to the Executive Committee for final endorsement. Special requests include tutorials that use paid trainers, a broader meeting room format, outside sponsorship, etc. Considerations for special requests will include: the importance to advancing the broad goals of HL7; conflicts with the regular meetings of The Working Group; cost; benefits to HL7 such as increasing attendance; and financial risk.

11.04 Special Meetings
Any Work Group or other duly recognized body of HL7 may propose to the Executive Committee convening a special meeting; e.g., a meeting occurring interim to the regularly scheduled Working Group Meetings. The purpose of such special meetings may be educational or promotional, to permit extended work on issues to be returned to the larger group for action, to develop a course of action to be presented to the larger group, or to take advantage of circumstances to promote interest in and work on material for HL7. Proposals shall be submitted to HL7 Headquarters sufficiently in advance to allow for a decision by the Executive Committee and still accommodate the required thirty days prior notice. Proposals will include:
a) The purpose of the meeting
b) Expenses to be borne by HL7, if any
c) The name of the individual(s) in charge of the meeting
d) The meeting location, date and time or frequency if the requested meeting is recurring

The Executive Committee shall take action to approve or disapprove the special meeting proposal at its next meeting or conference call whichever comes first. If the special meeting is approved and HL7 funding has been requested, the Executive Committee shall stipulate the amount of funding to be provided. No special meeting shall represent itself as an official HL7 meeting without the express written approval of HL7.

Approved special meetings must be generally announced to the membership, via list server and/or other means, at least thirty days prior to the meeting. Special meetings being held in conjunction with meetings of another organization may publish the meeting notice as part of the other organization’s program announcement. A co-chair of the group or their duly appointed representative must attend any special meeting. A recording secretary shall be appointed for the meeting and minutes returned to HL7 Headquarters and distributed to the membership of the broader group no later than thirty days following the special meeting.

Approval for recurring special meetings shall be in effect:
   a) Until the series is completed, or
   b) Until the receipt by HL7 Headquarters of a statement that such special meetings are no longer necessary, or
   c) Until the sponsoring group is disbanded, or
   d) Until the sponsoring group fails to hold two consecutive special meetings according to its schedule.

Any deviations from the original request shall require a separate approval from the Executive Committee. The requesting group shall supply an agenda, meeting dates, times and locations for all such regularly-scheduled special meetings to HL7 Headquarters at least thirty days in advance of the meeting for posting on the HL7 website and via HL7 list servers. Groups should attempt to schedule special meetings more than ninety days in advance to facilitate member planning.

12 Electronic Ballots

All HL7 ballots, be they administrative, review, or normative, shall be conducted electronically. Electronic ballots shall provide, as appropriate:
   a) The means to form a consensus or review group and provide necessary notifications.
   b) The means to capture the vote and associated comments.
   c) A method for resolving negative comments and reconciling the normative ballot.

12.01 Alternative to Electronic Ballot Format

An alternative paper ballot shall be provided upon written request to any individual not having access to appropriate technology or demonstrating that using the electronic process constitutes a substantial hardship. A nominal fee, established by the Executive Committee, shall be assessed to cover postage and handling.

12.02 Consideration of Recommended Actions

Prompt consideration shall be given to proposals made for developing new or revising existing HL7 protocol specifications. The TSC shall approve recommendations for all actions pertaining to approval or adoption of HL7 protocol specifications, or any portion thereof, prior to submission for ballot.

12.03 Ballot Content Naming Conventions

The naming convention for Version 2 documents slated to become normative shall be:
   HL7 Standard Version 2.[release number]: An Application Protocol for Electronic Data Exchange in Healthcare Environments

The naming convention for Version 3 documents slated to become normative shall be:
   HL7 Version 3 Standard: [Name of Document], Release #, Date [month and year balloted]
Normative Material, Informative Documents and DSTU:
The Work Group proposing a new document title, or a change to an existing document title, shall obtain approval from the TSC prior to the document moving to ballot.

Other Documents:
The Work Group proposing a new document title or a change to an existing document title, for other documents published as official HL7 documents (carrying an HL7 copyright and logo) shall obtain approval from the TSC as early as possible, preferably before the document is circulated widely for review.

Documents in Progress
The TSC may require a change to the title of documents already in progress, in ballot, or in technical editing after ballot for conformance with an established convention.

13 Review Ballots
A review ballot shall be used to review and validate the content of informative documents, the subject matter of proposed draft standards for trial use (DSTU), and other items that, after due consideration of the TSC, are not yet deemed appropriate for a normative ballot.

13.01 Informative Documents
An Informative Document is the product of a Work Group that is not currently deemed normative, but nonetheless is intended for general publication. It explains or supports the structure of the HL7 Protocol Specifications (§02.02), or provides detailed information regarding the interpretation or implementation of an HL7 Protocol Specification. The TSC shall approve the issuance of an informative document ballot.

Following approval of the informative document the submitting Work Group may, with the concurrence of the TSC, submit the document to a normative ballot for subsequent consideration as an American National Standard.

13.01.01 Initiation
The TSC, in compliance with its defined processes, may initiate the ballot of an informative document. Once initiated, the ballot shall remain active until such time as the subject matter of the ballot has been approved or withdrawn from consideration.

13.01.02 Forming the Review Group
All current members shall be notified of the intent to form a review group and ballot an informative document not less than thirty days prior to the opening of the ballot. This notification shall occur via the various HL7 newsletters and member list servers and shall include the date that enrollment in the review group shall open. Members shall indicate their interest by enrolling in the review group via the HL7 Ballot Desktop during the enrollment period which shall end one week prior to the ballot closing date.

13.01.03 Ballot Package
The ballot package shall be available to all members of the ballot group for thirty days following the opening of the ballot period. Participants are encouraged to provide constructive comments for improving the content or language of the subject matter under review.

13.01.04 Handling Comments
At the close of the ballot the responsible Work Group shall consider all comments with the intent of improving the quality and clarity of the informative document. While not on a par with a normative reconciliation package, the results of the Work Group’s consideration of the comments submitted shall be posted to the Ballot Desktop.
The process of consideration of the comments is not synonymous with nor shall it assume the rigor of normative reconciliation. There is no requirement to resolve negative comments and seek withdrawal of the negative; however, an agreement that the negative comment is persuasive, resulting in change to the subject matter, will most likely result in the submitter changing their ballot to affirmative which may affect the outcome of the ballot.

The issue of substantive change shall not be applicable to an informative document. In the instance of an approved informative document with substantive change resulting from review, it is left to the discretion of the responsible Work Group to either submit to another ballot or move forward with the revised informative document.

If the informative document fails to be approved, it again falls to the discretion of the responsible Work Group, after appropriate revision if necessary, to either submit to another review ballot, withdraw the document from consideration, or repackage the content and submit it to the TSC for consideration of submission to a normative ballot.

13.01.05 Approval

There is no quorum required for an informative document. The informative document shall be considered approved if, following ballot review, sixty percent (60%) of the combined affirmative and negative votes cast are affirmative.

Upon approval the informative document may, with the concurrence of the TSC, be released for publication. An informative document may, at the request of the TSC, be registered with ANSI as a Technical Report. While registering the document with ANSI does not infer any status on the document, it does ensure notification of the availability of the informative document to a broad audience.

13.01.06 Registration as an ANSI Technical Report

HL7 develops materials that are useful in conjunction with American National Standards. These mainly take the form of informative documents and give methods for application of an American National Standard. Registration of such documents with ANSI is undertaken to encourage widespread use and acceptance, not only of the Technical Report, but also of the related American National Standard. However, nothing precludes a standards developer from developing, approving and disseminating its own reports or other publications.

All material contained in a Technical Report that has been registered with ANSI is informational in nature. Technical reports may include, for example, reports of technical research, tutorials, factual data obtained from a survey carried out among Standards Developers and/or National Bodies, or information on the "state of the art" in relation to standards of National or International bodies on a particular subject. Technical reports may not to be used as a way to circumvent the regular consensus process for approval of an American National Standard.

13.01.06.01 Criteria for Registration

To be registered as a Technical Report a document shall be entirely informative in nature and shall not contain information implying that it is a standard. It shall clearly explain its relationship to aspects of the subject that are, or will be, dealt with in related American National Standards. All Technical Reports registered with ANSI must be in compliance with the ANSI Patent Policy.
13.01.06.02 Required Foreword

When a document that has been registered as a Technical Report with ANSI is published, the following text shall be included in the foreword. “Publication of this document that has been registered as a Technical Report with ANSI has been approved by the Health Level Seven, Inc. (HL7), 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104-4261. This document is registered as a Technical Report according to the Procedures for the Registration of Technical Reports with ANSI. This document is not an American National Standard and the material contained herein is not normative in nature. Comments on the content of this document should be sent to HL7, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104-4261 or [appropriate email address].” In addition, the foreword should include a rationale for the publication of the document registered as a Technical Report with ANSI.

13.01.06.03 Procedures for Approval and ANSI Registration

The decision to publish a document as a Technical Report that is registered with ANSI (or as a Supplement to a currently registered Technical Report) shall require approval by the TSC using its own procedures and the procedures stipulated by ANSI as well as compliance with §13.01 Informative Documents. HL7 assumes responsibility for assuring that policies and procedures are followed in the development and approval of a Technical Report that is registered with ANSI. At the time of the submittal of the technical report for registration, HL7 shall certify that it has complied with its own and ANSI procedures.

Technical Reports that are registered with ANSI need not be subjected to consensus by public review before approval action is taken by HL7. In addition, no approval by ANSI's Board of Standards Review, the Executive Standards Council, or any other ANSI body is required prior to registration of the Technical Report with ANSI; however, ANSI reserves the right to deny registration of any Technical Report, for legal reasons, upon advice of its counsel, or where it is shown that publication of the Technical Report is contrary to the public interest.

Prior to registration of the Technical Report with ANSI, a 30-day announcement of the intent to register said report shall be placed in Standards Action. Parties interested in further information will be instructed to contact HL7. Immediately following the close of the announcement of the intent to register, the technical report shall be registered with ANSI. A PSA-01 form shall be used to initiate both the announcement in Standards Action and ANSI registration. An Accredited Standards Developer may choose, at any time, to issue a supplement to a Technical Report that has been registered with ANSI. The issuance of a supplement to a Technical Report that has been registered with ANSI shall require adherence to the same procedures as for registration of a Technical Report with ANSI.

Each Technical Report (with any supplements) registered with ANSI is subject to review by the responsible Accredited Standards Developer, following its own procedures. Reaffirmation, revision or withdrawal of a Technical Report that is registered with ANSI is determined by the responsible Accredited Standards Developer and the results of this determination are transmitted to ANSI for registration and publication action, as appropriate. Any Technical Report that has not been reaffirmed, revised or withdrawn by the tenth anniversary of its registration will be withdrawn administratively and a notice of same placed in Standards Action.

13.01.06.04 Designation and Publication

A document that has been registered with ANSI as a Technical Report shall have its cover or title page marked with the words "a Technical Report prepared by Health Level Seven (HL7) and registered with ANSI". The words "an American National Standard" shall not be used on any Technical Report. The date of registration shall be included in the published Technical Report, preferably on the cover. A Technical Report registered with ANSI shall be identified by a unique alphanumeric designation that shall include: (1) a Technical Report Identifier of HL7 TR and (2) a designation assigned by the HL7 and registered with ANSI such as HL7 TR 1-2008.

Technical Reports that are registered with ANSI shall be published and made available within three months of registration, if possible. In no case shall publication take longer than six months. HL7 shall publish the Technical Report or shall arrange for publication by another entity.
13.01.06.05 Challenging the Registration of a Technical Report

Developers of Technical Reports that are registered with ANSI shall establish and adhere to procedures that afford materially affected interests the opportunity to challenge the decision to register a technical report with ANSI. Materiaally affected interests wishing to initiate such a challenge at ANSI shall first exhaust all methods of challenge at the Accredited Standards Developer's level prior to submittal to the ANSI Appeals Board.

The only basis upon which such a challenge shall be filed is failure of HL7 to follow either its own procedures or any other provisions contained in the Procedures for the Registration of Technical Reports with ANSI. The burden of proof shall be on the challenger. An announcement regarding the challenge will appear in Standards Action. There will be no suspension of the registration of the document with ANSI as a Technical Report during the challenge process.

Materially affected interests shall deliver their challenge including all appropriate contact information to the HL7 business office (§01.02) addressed to the attention of the Associate Executive Director. Upon receipt the Associate Executive Director shall immediately notify the Executive Committee of the submission of a challenge by providing them a copy of the correspondence. The Executive Committee shall identify a disinterested third party, who may or may not be a member of HL7, and instruct them to conduct an audit of the process and records related to the publication being challenged. The individual conducting the investigation shall prepare a report for the consideration of the Executive Committee, who shall resolve the challenge. The challenger may appeal the decision of the Executive Committee to ANSI.

13.02 Draft Standard for Trial Use (DSTU)

ANSI allows Accredited Standards Developers broad latitude in defining their process for managing the development and release of a DSTU. The two stipulations found in Annex B: Draft American National Standards for trial use of ANSI Essential Requirements: Due process requirements for American National Standards are:

a) A DSTU shall not be used to meet the need for an emergency standard; and
b) The issuance of a DSTU shall only proceed with the understanding that the draft standard will, following a suitable period for evaluation and comment, either be moved to ballot as a normative document or expeditiously incorporated into a fully balloted and accredited version of the standard.

HL7 has taken the position that a DSTU shall be used to provide the basis for proof of concept pilot projects and objective assessment of the viability of implementation of the proposed standard. The TSC is empowered to approve the development and subsequent release of a DSTU. There is no ANSI requirement for due process regards a DSTU, implying the option of simply preparing, registering, and releasing a DSTU. However, given the requirement to ultimately make the content of the DSTU normative, it seems prudent to validate the content by subjecting it to review prior to registering it as a DSTU. Should the content of the proposed draft standard not be approved, for whatever reason, it may simply be withdrawn from consideration given that the DSTU has not yet been registered with ANSI.

Following a successful review the content, in the appropriate form, shall be presented for release and HL7 Headquarters shall file a Request to announce the availability of a Draft Standard for Trial Use with ANSI. In the event of a challenge of the intent to release a DSTU, the TSC shall review and seek resolution of the challenge. The only viable basis for a challenge is the contention that HL7 did not follow its documented process for initiating and releasing a DSTU.

13.02.01 Initiation

The TSC, in compliance with its defined processes, may initiate the review of the subject matter of the proposed draft standard. Once initiated, the review ballot shall remain active until such time as the subject matter of the proposed draft standard has been approved or withdrawn from consideration.
13.02.02 Forming the Review Group

All current members shall be notified of the intent to form a review group and ballot the content of a proposed draft standard not less than thirty days prior to the opening of the ballot. This notification shall occur via the various HL7 newsletters and member list servers and shall include the date that enrollment in the review group shall open. Members shall indicate their interest by enrolling in the review group via the HL7 Ballot Desktop during the enrollment period which shall end one week prior to the ballot closing date. The minimum review group shall be ten current members representing at least three organizational members.

13.02.03 Ballot Package

The ballot package shall be available to all members of the review group for thirty days following the opening of the ballot period. Reviewers are encouraged to provide constructive comments for improving the content or language of the subject matter under review.

13.02.04 Handling Comments

At the close of the review ballot the responsible Work Group shall consider all comments with the intent of improving the quality and clarity of the proposed draft standard. While not on a par with a normative reconciliation package, the results of the Work Group’s consideration of the comments submitted shall be posted to the Ballot Desktop.

The process of consideration of the comments is not synonymous with nor shall it assume the rigor of normative reconciliation. There is no requirement to resolve negative comments and seek withdrawal of the negative; however, an agreement that the negative comment is persuasive, resulting in change to the subject matter, will most likely result in the submitter changing their ballot to affirmative which may affect the outcome of the ballot.

The issue of substantive change shall not be applicable to a proposed draft standard. In the instance of an approved draft standard with substantive change resulting from review, it is left to the discretion of the responsible Work Group to either submit to another ballot or move forward with the revised content of the draft standard.

If the proposed draft standard fails to be approved, it again falls to the discretion of the responsible Work Group, after appropriate revision if necessary, to either submit to another review ballot, withdraw the document from consideration, or repackage the content and submit it to the TSC for consideration of a normative ballot.

13.02.05 Approval

The proposed draft standard shall be considered approved if sixty percent (60%) of the combined affirmative and negative votes cast are affirmative.

Upon approval the proposed draft standard, with the concurrence of the TSC, shall be registered as a DSTU and released for publication.

13.02.05.01 DSTU Front Matter

The front cover of a DSTU shall include the following statement.
“Publication of this draft standard for trial use and comment has been approved by Health Level Seven, Inc. (HL7) Distribution of this draft standard for comment shall not continue beyond [indicate the number of months allocated for evaluation and review, not to exceed 24] months from the date of publication. It is expected that following this [the number of months shown above] month period, this draft standard, revised as necessary, will be submitted to the American National Standards Institute for approval as an American National Standard. A public review in accordance with established ANSI procedures is required at the end of the trial use period and before a draft standard for trial use may be submitted to ANSI for approval as an American National Standard. This draft standard is not an accredited American National Standard. Suggestions for revision should be directed to [include contact information for the submission of comments].”

The use of the ANSI logo or trademark on a DSTU is strictly prohibited; however, the DSTU may be referred to as a Draft American National Standard for Trial Use given conformance to the above processes.

13.02.06 Results of the Trial Use Period
Where the evaluation and comment period results in a need for substantive changes to the draft standard, the resulting normative HL7 Protocol Specification (§02.02) may embody such changes or a revised DSTU may be released for further evaluation without recourse to a review ballot. In either case, given the need for substantive changes, the normative HL7 Protocol Specification or the subsequent revised DSTU is not bound to maintain compatibility with the initial draft standard.

Under such circumstances, given that the intent of a draft standard is to improve the viability of the subsequent normative HL7 Protocol Specification, it is the obligation of the responsible Work Group to select enhancement over compatibility. Conversely, recognizing the commitment and investment involved in implementing a DSTU for evaluation and comment, a DSTU implementation shall be accepted as viable for up to two years after its publication or for up to six months after the publication of a subsequent revised DSTU or the release of the normative HL7 Protocol Specification resulting from the draft standard, whichever is longer.

13.03 Comment-only Ballot
A Work Group, with the concurrence of the TSC, may submit proposed content or requirements documents, such as a Domain Analysis Model (DAM), to comment-only review. The intent is to gather input from members outside of the Work Group on the viability and clarity of the proposed content or requirements document. The review of proposed content or requirements documents does not seek a vote, per se, but will capture all comments.

A TSC decision to reaffirm an HL7 American National Standard (ANS) (§15.04.01) shall be submitted to a Comment-only Ballot to allow interested parties to express their opinion by supporting reaffirmation, suggesting revisions to update the ANS, or providing reasons to withdraw the ANS.

13.03.01 Initiation
The TSC, in compliance with its defined processes, may initiate a comment-only review of proposed content and requirements documents. At its discretion, the TSC may allow a Work Group to conduct multiple comment-only review cycles.

13.03.02 Forming the Review Group
All current members shall be notified of the intent to form a group for comment-only review not less than thirty days prior to the opening of the review period. This notification shall occur via the various HL7 newsletters and member list servers and shall include the date that enrollment in the review group shall open. Members shall indicate their interest by enrolling in the review group via the HL7 Ballot Desktop during the enrollment period which shall end one week prior to the review closing date. Nonmembers who wish to be part of the comment-only review group may do so at no cost, but must register their intent with HL7 Headquarters during the stated enrollment period by mail, telephone, or email.
13.03.03 Ballot Package
The ballot material shall be available for thirty days following the opening of the comment-only review period. Participants are encouraged to provide constructive comments for improving the content or clarity of the ballot material.

13.03.04 Results of the Review
At the close of the comment-only review period the responsible Work Group shall consider all comments with the intent of improving the quality and clarity of the submitted content before seeking the approval of the TSC for submission to a subsequent ballot. The Work Group shall post the results of their consideration of the comments submitted to the HL7 Ballot Desktop.

There is no requirement to respond to any comment or advise any submitter of the disposition of their comments. Given that this is a comment-only review, the issue of substantive change is moot.

14 Normative Ballot
A normative ballot is undertaken with the approval of the TSC. It is intended to process and validate those protocol specifications intended for submission to ANSI for consideration as American National Standards. The normative ballot process shall adhere to the tenets of ANSI Essential Requirements: Due process requirements for American National Standards. Under normal circumstances the subject matter of a normative ballot will have at some point been subjected to a review ballot; however, there are a number of scenarios where material may need to move directly to normative ballot, such as the need to respond to government mandate or to resolve a critical issue raised by a stakeholder or noted in an existing American National Standard.

14.01 Normative Ballot Content

14.01.01 Proposed Normative Content
A Work Group may, with the concurrence of the TSC, submit proposed normative content to a normative ballot.

14.01.02 Moving an Informative Document to Normative Ballot
An Informative Document, representing the consensus of the issuing Work Group on a given subject area, may be submitted for normative ballot by the issuing Work Group co-chairs with the concurrence of the TSC. The Work Group co-chairs shall present the TSC with the following documentation: (1) the publication date of the document, which must be at least six months prior to the request; (2) a log of any post publication comments and subsequent resolution, if such occurred; and (3) the rationale for moving the contents to normative ballot. Subsequent to the successful completion of a normative ballot, the Work Group co-chairs shall issue a statement through HL7 Headquarters withdrawing the Informative Document with reference to the corresponding normative HL7 Protocol Specification (§02.02). In the event the Informative Document was registered with ANSI, this statement shall cause HL7 Headquarters to notify ANSI of the withdrawal of the Technical Report.

14.01.03 Moving a Draft Standard to Normative Ballot
Following the close of the trial use period and the application of revisions resulting from comments received and practical experience gained during the trial use period, if any, the subject matter of a draft standard, appropriately formatted and named as a normative document may, with the concurrence of the TSC, be submitted to a normative ballot.
14.01.04 Normative Ballot Resulting from External Requirements

In order to provide timely compliance with regulatory or other governmental mandates and/or a timely response to industry or market demand, a Work Group may, with the concurrence of the TSC, issue a normative ballot without first conducting a review ballot. Although the content may represent a new HL7 Protocol Specification (§02.02), generally the content of the normative ballot resulting from an external requirement will be restricted to those changes and/or additions to an existing HL7 Protocol Specification necessary to address the specific requirement.

14.01.05 Components Labeled “For Comment Only”

Certain components of a normative ballot may be labeled as “reference material” or “informative content” and are not considered normative content. Such components may be included in normative ballot material “for comment only.” The objective of the submitting Work Group is to gather input from the membership on the appropriateness and accuracy of the material in question. There is no vote per se on such material and comments are not subject to reconciliation.

14.01.06 Confirmation of Previous Ballot Reconciliation

A normative ballot shall not include content from a previous normative ballot that has not been fully reconciled. The responsible Work Group must ensure the completeness of required documentation for all previous normative ballot cycles of the same content. The required documentation includes:

a) Reconciliation packages uploaded to the ballot site
b) The ballot site reflecting that all negative voters have been notified of the dispositions of their negative votes
c) The ballot site reflecting that all negative voters have been notified of the right to appeal (§14.12)
d) The ballot site reflecting that an email has been sent to those negative voters who have verbally agreed to withdraw their negative vote. This email shall seek confirmation of the voter’s decision and allow the voter five days in which to respond. Further, the email shall indicate the date on which this verbal agreement occurred which shall be documented in the Work Group minutes for future reference. During the subsequent five day period the negative voter may either confirm the withdrawal or state that the negative stands.

e) The ballot site reflecting that quorum was achieved and affirmative votes were handled appropriately.

The deadline for completing required documentation is the Supporting Content Deadline which is scheduled two weeks prior to ballot opening. At least two weeks prior to the Ballot Announcement Date HL7 Headquarters shall provide a list of outstanding reconciliation items by ballot cycle to the TSC. Any required documentation that is “outstanding” material for ballots that took place before the creation of the ballot site shall be sent to the Associate Executive Director.

14.02 Notice of Normative Ballot

Notice of a normative ballot shall be provided to the membership, the headquarters or secretariat of cooperating ANSI Accredited Standards Developers (ASD), and the general public via the HL7 Newsletter, ANSI Standards Action, press releases, e-mail announcements or special mailings as appropriate. This notice will be released at least thirty (30) days prior to the start of the ballot period.

14.03 Forming the Consensus Group

A normative ballot shall be open to all interested and materially affected parties; however, quorum shall be defined relative to the number of HL7 members in the consensus group. The consensus group shall have no constraints on or requirements for participation of non-members other than the assessment of an administrative processing fee to be established by the Executive Committee, but in no case to exceed the individual membership fee.

14.03.01 Member Participation in the Consensus Group

The notice of normative ballot [§14.02] shall serve as the mechanism by which HL7 shall canvass its membership to identify those members willing to participate in the consensus group for an initial normative ballot; an initial normative ballot being the first iteration of a normative ballot for a new or revised HL7 protocol specification.
The notice of normative ballot shall include the date that enrollment in the consensus groups will be available. Members may indicate their intent to ballot by enrolling in the appropriate consensus groups via the HL7 Ballot Desktop found in the Members Only section of the website. Enrollment shall remain open and available until one week prior to the close of the initial normative ballot period.

Any member who does not have access to the Internet or who can demonstrate that using the electronic process creates a substantial hardship may request that the ballot be conducted by paper through the mail.

The TSC shall be informed of any normative ballot where, within two weeks of the closing of the ballot period, the consensus group includes fewer than ten (10) members. The TSC may, at its discretion, postpone the ballot until an adequate number of members join the consensus group. Quorum shall be determined by those members submitting a ballot response.

14.03.02 Nonmember Participation in the Consensus Group

A nonmember, defined as a person not currently a member of HL7 either individually or as a representative of an organizational or Affiliate member, who is directly and materially affected by a ballot proposal may request to join the consensus group specific to the initial normative ballot of a given specification. Nonmembers shall contact HL7 Headquarters by mail, telephone, or email providing information supporting their status as non members; as being directly and materially affected and full contact information including name, address, telephone, and email address if appropriate. Nonmember participation is by definition at the individual level; there shall be no instances of organizational nonmember participation. A nonmember may seek to join the consensus group at any time up to one week prior to the close of the initial normative ballot period.

Upon validation of status the nonmember shall be provided a ballot package, either electronically or through the mail. They shall be notified that participation in the ballot implies adherence to the tenets of the HL7 intellectual property policies (§16), which shall be extracted and included in the nonmember’s ballot package. Nonmembers must adhere to all ballot instructions and respond by the ballot closing date.

At the discretion of the TSC, nonmember comments may be declared duplicative and removed from the ballot pool. Those nonmembers whose comments are so declared will be notified of such decision by the most appropriate means. The first occurrence of a given nonmember comment subsequently duplicated shall be annotated to reflect the number of duplicate comments received, but shall count as a single ballot response.

HL7 shall assess an administrative fee for the processing, handling, and shipping of the ballot package for nonmembers. Said fee, to be determined by the Executive Committee, shall not exceed the fee associated with an individual membership in HL7. The fee, at the discretion of HL7 Headquarters, may be requested in advance. The fee shall support and provide for participation in all subsequent ballots specific to the initial issue. Nonmember administrative fees may be applied to membership in the year collected, but are not refundable.

14.03.03 Seeking Balance in the Consensus Group

Within one week of the opening of the initial normative ballot period for a given specification, HL7 Headquarters shall review the consensus group to ascertain if a single interest category constitutes a majority of the group. If a disparity is found, HL7 Headquarters shall engage members of underrepresented interest categories through electronic means seeking their participation in the consensus group. A record of such action, if it proves necessary, shall be part of the ballot record.

14.03.04 Consensus Group for Subsequent Normative Ballots of the Same Content

The consensus group for subsequent normative ballots of the same content, that being an iterative ballot of material specific to the project defined by the Project Initiation Notification System (PINS) form submitted to ANSI, shall consist of those individuals, members or nonmembers, who submitted a ballot by the close of the ballot response period; whether affirmative, negative, or abstain. No additional fees shall be assessed for nonmembers who qualify to participate in subsequent normative ballots of the same content.
Citing exceptional circumstances and with the approval of three quarters of those in session when the motion is addressed, a Work Group may petition the TSC to announce open enrollment in the consensus group of a subsequent normative ballot of the same content. If approved by the TSC, the notice of normative ballot [§14.02] announcing the subsequent normative ballot of the same content shall prominently declare open enrollment in the consensus group which shall include those members of the original consensus group who cast a ballot.

Those registrants, be they member or nonmember, who do not return a ballot shall be removed from the consensus group and shall not participate in any subsequent normative ballot of the same content subject to their electing to reenroll in the consensus group of a subsequent normative ballot of the same content that is opened by decision of the TSC.

14.04 Issuing a Normative Ballot

14.04.01 Authority
The TSC is empowered to initiate and conduct a normative ballot on those items properly submitted by a Work Group.

14.04.02 Return Date
The ballot shall indicate a return date, which shall not be less than 30 days after the date that the ballot commences or opens.

14.04.03 Reason
The ballot shall include the information supporting the submission of the item to ballot.

14.04.04 Instructions
The ballot package shall include clear and conspicuous instructions that negative responses submitted without comment or with inappropriate comments or comments of no relevance to the ballot proposal will not be factored into the numerical requirements for consensus and will be recorded as “negative without comment” without further notice to the submitter.

14.04.05 Cooperating ANSI ASD
Normative ballots shall be routinely provided to the headquarters or secretariat of cooperating ANSI ASD.

14.05 Approval
A 75% affirmative response of the combined affirmative and negative votes cast by members of the consensus group shall be required for approval with not less than 60% of the consensus group returning ballots and representative of at least 60% of the HL7 members in the consensus group.

14.05.01 Achieving the Necessary Ballot Response Level
Seven (7) calendar days prior to the close of a normative ballot, HL7 staff shall issue a reminder email message to those members of the consensus group who have not yet submitted a ballot response. On or about three (3) working days prior to the close of a normative ballot, at the convenience of HL7 staff, the Work Group co-chairs having jurisdiction shall be notified of the status of the consensus pool response.

If the required 60% response level has not been achieved or the response level is not inclusive of the required 60% of HL7 members registered in the consensus group, the Work Group co-chairs having jurisdiction may choose to:
a) execute a single extension of the normative ballot closing date for a period not to exceed two (2) weeks (fourteen (14) calendar days) with the objective of achieving the required 60% response level and/or 60% response of the registered HL7 members; or
b) close the normative ballot on the date originally stipulated and declare the ballot “for comment only” if the required response levels have not been achieved by that date.
In the event that a normative ballot is closed with a declaration of “for comment only,” HL7 staff shall inform the consensus group of that decision by email message stipulating the failure to achieve the required response levels. The Work Group co-chairs having jurisdiction shall consider revising the materials involved in the normative ballot based on any comments received from the consensus group, but is not required to conduct ballot reconciliation. Said materials, whether revised or not, may be submitted for the next normative ballot cycle. Information regarding closing date extensions shall be included in the ballot report.

14.05.02 Abstentions
Abstentions shall be counted as a valid ballot for the purpose of meeting consensus requirements of not less than 60% response, but shall be construed as noncommittal for the purpose of ballot approval and not included in the tally.

14.05.03 Unresolved Negatives
Submission to ANSI for consideration as an American National Standard is not contingent on the withdrawal of all negative ballots. The existence of unresolved negatives shall not preclude the submission of a protocol specification that meets the approval criteria.

14.05.04 Approved Components
Those components of a normative ballot which receive approval and are easily delineated and shown to not adversely affect any other component of the same ballot, may, with the concurrence of the TSC, be moved forward by the Work Group having jurisdiction to publication and submission for consideration as an American National Standard regardless of the approval or disapproval of other components of the same ballot.

14.06 Accompanying Statements

14.06.01 Retraction
The submitter may, of their own volition, retract an accompanying statement, whether associated with a negative or affirmative ballot, at any time by providing written notice of such action in a letter, memorandum, or e-mail. A retracted statement shall be considered to have been submitted in error and shall not be retained as part of the ballot.

14.06.02 Affirmative Ballots
All statements accompanying affirmative ballots shall be considered by the appropriate Work Group.

14.06.03 Negative Ballots

14.06.03.01 Submission of Comments
Statements accompanying negative ballots should be submitted as an attachment to the ballot and clearly reference the particular ballot item(s) to which it pertains.

14.06.03.02 No Comments or Inappropriate Comments
Negative ballots not accompanied by comments or accompanied by inappropriate comments or comments of no relevance to the ballot proposal shall not be considered. Such ballots will be recorded as a “negative without comment” for the purposes of establishing a quorum and reporting to ANSI. However, these ballots shall not be factored into the numerical requirements for consensus. No effort shall be made to solicit comments from the submitter of a negative without comment.

14.07 Notification of Discussion of Responses
All participants in the consensus group, and specifically those who submitted negative ballots, shall be notified of the time and place where negative ballots will be considered. Such notification may be included in the normative ballot, as part of a meeting agenda, or by other appropriate means.
14.08 Negative Ballots Not Previously Considered  
All negative ballots not disposed in an earlier normative ballot cycle shall be considered by the Work Group having jurisdiction.

14.08.01 Motions for Handling Negative Ballots  
All motions for handling negative comments shall include an explanation of the reason for the action.

14.08.01.01 Not Related  
A negative response should be considered not related if it deals with issues or functionality that is beyond the scope of or is, in the considered opinion of the Work Group, clearly not related to the ballot subject matter. Approval of a motion to declare a negative response not related shall require an affirmative vote of at least sixty percent (60%) of the combined affirmative and negative votes cast by the Work Group during reconciliation. Negative responses declared not related shall be recorded and reported to ANSI as a “negative without comment” and shall not impede progress of the ballot. Those items declared not related shall become recommended actions for the development of new or revision of existing protocol specifications. The submitter of a negative response declared not related shall be advised of the disposition of their response and the reasons therefore. No further action is required.

14.08.01.02 Not Persuasive  
A negative response should be considered not persuasive if it deals with processes or issues not in the purview of the Work Group responsible for ballot content; suggests the use of alternate methodologies or solutions; or questions the validity of the approach or the expertise of the developers. Approval of a motion to declare a negative response not persuasive shall require an affirmative vote of at least sixty percent (60%) of the combined affirmative and negative votes cast by the Work Group during reconciliation. The submitter of a negative response declared not persuasive shall be advised of the disposition of their response and the reasons therefore. The submitter may choose to withdraw their negative in favor of an affirmative or abstention; otherwise, the response shall be recorded and reported to ANSI as an unresolved negative.

14.08.01.03 Persuasive  
Where the Work Group effecting reconciliation agrees without objection that the position expressed by the negative response is persuasive, the changes recommended by the comment shall be incorporated into the specification as reasonable and necessary revisions. The submitter may choose to withdraw their negative in favor of an affirmative; if not, the response will be recorded and reported to ANSI as a resolved negative given that the submitter’s concern has been satisfied by the adoption of their recommended solution.

14.08.02 Confirmation of Withdrawn Negative Ballot  
Those negative ballots recorded as resolved and withdrawn at the request of the submitter during a working group reconciliation session or teleconference will be affirmed via email. No response to the email within five working days will be considered a de facto affirmation of withdrawal.

14.08.03 Effect of Withdrawn Negative  
A negative ballot withdrawn at the request of the submitter shall be recorded as an affirmative vote.

14.08.04 Substantive Change  
Substantive change is classified as any change that materially affects the intent or content of the HL7 Protocol Specification (§02.02) as balloted; e.g., alters the information content of a message, the circumstances under which it would be sent, or the interpretation of its content. A negative response deemed persuasive and resulting in a substantive change shall necessitate a subsequent normative ballot of the same content; allowing the consensus group (§14.03.04) to reaffirm or change their vote due to the substantive change.
14.09 Negative Ballots Previously Considered
When a negative response to a normative ballot raises virtually the same issues as those contained in
a negative response disposed as not related or not persuasive in a previous normative ballot cycle of
the same subject matter, the Work Group co-chairs may move that the negative ballot be given no
further consideration and cite the results of the previous reconciliation action. Approval of this motion
shall require an affirmative vote of at least sixty percent (60%) of the combined affirmative and
negative votes cast by the Work Group during reconciliation.

14.10 Notification of Disposition of Negative Ballots
With the exception of those negative ballots submitted without comment, those individuals submitting
negative ballots or negative comments in the course of public review shall be notified as to the
disposition of their negative ballots or comments. Notification of the disposition of negative comments
submitted during the ballot or public comment period shall be in writing which includes electronic
communications.

14.10.01 Fulfilling Notification of Disposition Requirements
If the attempt to notify an organization or Affiliate member representative of the disposition of their
negative comments via the Ballot Desktop is unsuccessful, the responsible co-chair will notify HL7
Headquarters who shall forward such notification to the organization or Affiliate’s Key Member fulfilling
the requirement of notification.

If the attempt to notify an individual member of the disposition of their negative comments via the
Ballot Desktop is unsuccessful, the attempt shall be considered reasonable and prudent and shall
fulfill the requirement of notification of disposition.

14.10.02 Execution of Organizational or Affiliate Representative Proxy
In the event that a voting member is unable, for whatever reason, to respond to the disposition of a
negative ballot, the Key Member of that organization or Affiliate shall execute their proxy (§03.06).

14.11 Re-circulation of Unresolved Negative Comments
In the case of a normative ballot reconciled by the Work Groups with no substantive change and
otherwise receiving approval, all unresolved negative comments (those declared not persuasive, but
not withdrawn) shall be reported back to all members of the consensus group, allowing them the
opportunity to change or reaffirm their original vote based on the content of the unresolved negative
comments. The report of unresolved negative comments shall be an amalgamated ballot
reconciliation spreadsheet including only those negative comments declared not persuasive and not
withdrawn and documenting any attempts at resolution.

The re-circulation period shall not exceed two weeks and is solely for the purpose of allowing those
participating in the ballot to reconsider their original vote in light of the content of the unresolved
negative comments. While there is no requirement to include comments for votes that are changed
from negative to affirmative or from either negative or affirmative to abstain, participants who choose
to change an affirmative to a negative must cite the unresolved negative comment that prompted that
decision. At the close of the re-circulation period, the votes shall be tallied and the results of the ballot
reported to the membership. The results of the recirculation ballot shall constitute the final tally of the
normative ballot.

14.12 Appeal
Any individual who has been or will be adversely affected by any procedural action or inaction by HL7
with regard to the development and subsequent approval by normative ballot of a proposed American
National Standard or the revision and subsequent approval by normative ballot of an existing
American National Standard, shall have the right to appeal. The burden of proof to show adverse
effect shall be on the appellant. Appeals of actions shall be made within sixty (60) days of the
purported infraction; appeals of inactions may be made at any time.
The appellant shall state their case in writing and deliver the appeal including all appropriate contact information to the Organization’s business office (§01.02) addressed to the attention of the Associate Executive Director. Upon receipt the Associate Executive Director shall immediately notify the Executive Committee of the submission of an appeal by providing them a copy of the appellant’s correspondence. The Executive Committee shall identify a disinterested third party, who may or may not be a member of HL7, and instruct them to conduct an audit of the process and records related to the action or inaction in question.

If the investigation shall take longer than sixty (60) days, the Associate Executive Director shall inform the appellant of the reason for a delay and the expected date of response. The individual conducting the investigation shall prepare a report for the consideration of the Executive Committee, who shall resolve the appeal. The appellant may appeal the decision of the Executive Committee to ANSI.

14.13 Discontinuance of a Standards Project
The TSC may discontinue a project involving a new HL7 Protocol Specification (§02.02) or revision to an existing HL7 Protocol Specification (a standards project) if the initiating Work Group has been:

a) unable to reach consensus necessary to bring the HL7 Protocol Specification to normative ballot within a year of project initiation; or

b) unable to successfully complete a normative ballot and move the HL7 Protocol Specification to publication within a year of initiation of a normative ballot

Given approval by three quarters of those in session when the motion is addressed, a Work Group may petition the TSC to discontinue a standards project regardless of its current status. The Work Group has the discretion to take this action for whatever reason it deems appropriate. The TSC shall have the final decision on a request to discontinue a standards project.

All records related to a discontinued standards project, including a written justification for the discontinuance, shall be retained for a period of sixty (60) days beyond the date of the final action; being the announcement of discontinuance by ANSI. During this period, the justification for discontinuance shall be provided to those submitting a written request for such information.

15 Submission of American National Standards
Having previously reported project initiation and upon approval by normative ballot, the TSC shall cause the subject protocol specifications to be submitted to ANSI as a candidate for acceptance and acknowledgment as an American National Standard in compliance with then applicable ANSI requirements. Subsequent public review comments received in response to announcements in the media shall be addressed in writing in a timely fashion and shall be subject to the ANSI procedures for handling such comments.

15.01 Prerequisites for Submission

15.01.01 PINS Form
A PINS form shall be submitted to ANSI at the initiation of each new project.

15.01.02 BSR-8 Form
A BSR-8 form will be submitted to ANSI concurrent with the initiation of each normative ballot of the subject HL7 Protocol Specification (§02.02).

15.01.03 Adherence to ANSI Patent Policy
HL7 shall adhere to the ANSI patent policy relevant to the submission of American National Standards as defined in the current edition of ANSI Essential Requirements: Due process requirements for American National Standards.
15.01.04 Adherence to ANSI Metric Policy
HL7 shall adhere to the ANSI metric policy relevant to the submission of American National Standards as defined in the current edition of *ANSI Essential Requirements: Due process requirements for American National Standards*. HL7 recognizes the International System of Units (SI) as the preferred units of measure in American National Standards.

15.01.05 Exclusion of Commercial Terms and Conditions
HL7 shall adhere to the restrictions on the use of Commercial Terms and Conditions stipulated in the current edition of *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

15.01.06 Records Retention as Evidence of Compliance
Records related to new, revised, or reaffirmed American National Standards shall be retained for one complete cycle, or until the HL7 Protocol Specification (§02.02) is subsequently revised.

15.02 Required Information
HL7 Headquarters shall be responsible for the timely submission of the required information to ANSI:

a) Title and designation of the proposed American National Standard

b) Indication of the type of action requested

c) Two copies of the final proposed American National Standard

d) A declaration that the accredited procedures were followed

e) A declaration that the proposed standard is within the scope of the Work Group

f) A declaration that there are no identified significant conflicts with another known American National Standard

g) A declaration that other known American National Standards have been examined with regard to harmonization and duplication of content

h) A statement that the proposed American National Standard has been provided to the administrator(s) of the appropriate USA Technical Advisory Group(s)

i) A declaration that all appeal actions related to approval of the proposed standard have been completed

j) A summary of the voting, including abstentions and unreturned ballots in each interest category which HL7 defines as either membership category (Affiliate) or membership classification (vendor/manufacturer, consultant, healthcare provider/user, associations/government agencies, payer/third party administrator, pharmaceutical, or general interest)

k) Identification of all unresolved negative views and objections, names of objector(s), and a report of attempts toward resolution

15.02.01 BSR-9 Form
The BSR-9 form will be submitted to ANSI upon approval of the subject HL7 Protocol Specification (§02.02) via normative ballot and the close of the 60-day public comment period initiated by the BSR-8 form submitted concurrent with the initiation of the normative ballot, but not more than 6 months following the close of said public comment period.

15.03 Submission of HL7 American National Standards for ISO Approval
The submission of HL7 American National Standards (ANS) to ISO must be reviewed by the HL7 ISO liaison and approved by TSC. The recommended HL7 Protocol Specification (§02.02), in ISO-acceptable format, and the appropriate ISO forms must be submitted electronically to HL7 Headquarters, which will forward them to the ISO liaison. The ISO liaison will either return the documentation to the submitter for additional action or forward it to the Secretary of the Board with a recommendation for action.
15.04 Maintenance of HL7 American National Standards

HL7 American National Standards (ANS) shall be kept current and relevant by means of timely review and revision. Procedures shall be established which ensure a process in which requests for change are received and dealt with in a timely fashion. In the event that no revisions are issued for a period of four years from its publication as an ANS, the TSC shall decide during the fifth year, barring any subsequent revisions, whether to reaffirm or withdraw the HL7 ANS.

15.04.01 Reaffirmation of an HL7 American National Standard

An HL7 ANS subject to reaffirmation shall be submitted to a Comment-only Ballot (§13.03); allowing those parties with an interest in the ANS to record their position on the decision to reaffirm the ANS. The results of this ballot shall validate the decision of the TSC, propose revision of the ANS, or propose that the ANS be withdrawn rather than reaffirmed.

Upon validation of the decision to reaffirm the ANS, HL7 Headquarters shall notify ANSI. Should revision of the ANS be the consensus of the review group; the TSC shall recommend that the appropriate Work Group initiate a project for that purpose which will result in HL7 Headquarters filing a PINS form with ANSI thereby resolving the issue of reaffirmation.

15.04.02 Withdrawal of an HL7 American National Standard

Upon a decision by the TSC to withdraw an HL7 ANS, either of its own volition or as a result of a Comment-only Ballot for reaffirmation, HL7 Headquarters shall notify ANSI of the withdrawal. The HL7 ANS shall be withdrawn concurrent with an announcement in ANSI Standards Action. No further action is required.

15.05 Maintenance of ANSI Membership

The Associate Executive Director shall ensure timely remittance of all dues necessary for maintenance of ANSI membership.

16 Intellectual Property

HL7 acknowledges that a participant’s knowledge of intellectual property and possible infringement is limited to his or her own personal knowledge and does not include knowledge or constructive knowledge of any other member or non-member.

16.01 Copyright

All HL7 Protocol Specifications (§02.02) are protected under the provisions of US and International copyright law. Rights are granted based on type of HL7 membership. Those HL7 Protocol Specifications publically available for distribution may be distributed, in whole or in part, by current HL7 members without concern for violation of the prohibitions expressed in the Bylaws under §02.03.02 Individual Membership or §02.03.03 Organizational Membership.

16.01.01 Copyright Protection

The HL7 Protocol Specifications (§02.02) are an evolving and expanding body of work prepared by the members of HL7. They are protected as works of copyrightable authorship under applicable US and international copyright principles. Consistent with these principles, HL7 asserts and holds domestic and international copyrights to the HL7 Protocol Specifications. Recognizing that the HL7 Protocol Specifications are the work product of the membership of HL7, and that HL7 is the collective representative of all of the member’s interests, these copyrights are asserted and held by Health Level Seven, Inc. in its capacity as the representative of its total membership. All members of HL7 have and will continue to possess the usage rights to the HL7 Protocol Specifications as authorized by the HL7 member agreements and International Affiliate agreements.
As an ANSI accredited standards developer (ASD) for health care related electronic data interchange, HL7 is responsible for assuring that the HL7 Protocol Specifications remain accurate and their integrity is maintained. This duty is consistent with the mandate of a standard making organization to assure that the emerging standard is consistently presented and its evolution fully documented. Copyright secures to its owner the exclusive right to authorize certain uses of the copyrighted material. HL7’s objective in asserting and enforcing copyrights in the HL7 Protocol Specifications is to assure that the public and end-users of the HL7 Protocol Specifications may rely upon HL7 to be an official source of the most current and accurate versions of the HL7 Protocol Specifications. To achieve the twin objectives of 1) assuring the integrity of the HL7 Protocol Specifications, and 2) guaranteeing that users may secure from a reliable source a verified version of a particular HL7 Protocol Specification, HL7 has and will continue to enforce the copyrights it holds in the HL7 Protocol Specifications. As dissemination and implementation of the HL7 Protocol Specifications continues, it is imperative that HL7 have a method to assert and enforce its role to maintain the official editions of the HL7 Protocol Specifications. Copyright provides this enforcement and protection mechanism.

16.01.02 Commitment
All those contributing to the HL7 Protocol Specifications (§02.02), be they members or non-members, grant a free, irrevocable license to HL7 to:
(a) incorporate any contributions regardless of media or form, and any subsequent modifications thereof, in the creation or maintenance of HL7 Protocol Specifications;
(b) copyright in HL7’s name any Protocol Specification even though it may include portions of said contributions; and
(c) permit others, at HL7’s sole discretion, to reproduce in whole or in part the resulting Protocol Specifications.

All contributors further acknowledge that, to the best of their personal knowledge, all contributions are free of encumbrance as it relates to the intellectual property rights of others.

16.01.03 Previously Copyrighted Material
The use of previously copyrighted material in HL7 Protocol Specifications (§02.02) is discouraged; rather the material should be referenced by name and source including any known licensing requirements. However, if such material is deemed sufficiently important to merit insertion the appropriate Work Group chair shall petition HL7 Headquarters to seek formal authorization for its use, both in the HL7 Protocol Specifications and by the membership. A note citing the copyright and authorization for use shall be included in the HL7 Protocol Specifications; without such authorization the material may not be inserted in the HL7 Protocol Specifications.

16.01.04 Independently Developed Specifications
The submission of independently developed specifications for consideration as a potential HL7 Protocol Specification (§02.02) or to serve as the basis for HL7 Protocol Specification development is encouraged. In order to ensure unencumbered development a written release of unrestricted world rights to use a specification as the basis for development of an HL7 Protocol Specification and for all future revisions and editions of that HL7 Protocol Specification is required. The copyright to the original text and its future development outside of HL7 is not forfeit as a result of giving permission to use the specification as the basis for an HL7 Protocol Specification; however, the results of such development outside of HL7 shall not be referred to as an HL7 Protocol Specification. The original copyright of the base specification will be cited in the front matter of the approved HL7 Protocol Specification.

16.01.05 Negotiated Use of HL7 Copyrighted Material
HL7 is willing to negotiate with any organization wishing to reproduce, embed and/or distribute HL7 copyrighted materials within their proprietary documentation (hardcopy and online) and within their commercial applications.

In all cases, such use requires a written contract; to be provided if and only if: (a) HL7 is clearly identified as publisher of the Protocol Specifications and holder of the copyright of the material, and (b) any modifications to the HL7 Protocol Specifications are clearly identified to end-users.
16.01.06 Academic Access to HL7 Copyrighted Materials

HL7 copyrighted materials shall be made available on a by-request basis to faculty of accredited educational institutions that are members of HL7 for the purpose of teaching for-credit courses in healthcare informatics or related subjects. Non-member faculty making such requests will be advised of the benefits of membership and encouraged to join HL7. If the faculty member declines membership, limited access to only those materials appropriate to the course in question will be granted for a period not to exceed the duration of such course in the approved curriculum. In all cases faculty will attribute such material to HL7 and notify students that reproduction of HL7 material is expressly prohibited.

16.01.07 Public Access to HL7 Copyrighted Vocabulary Tables

The content of HL7 Version 2 and Version 3 Vocabulary Tables will be made available free for use electronically. HL7 reserves the copyright on all vocabulary content, but allows its use and distribution subject to the provisions of the licensing agreement shown in Addendum A. The codes and text may be used without further license in all applications, databases, and derivative works except those that seek to circumvent, competes with or replace the HL7 Vocabulary table values.

HL7 shall provide the capability to download the HL7 Vocabulary Tables via the HL7 Web site. Electronic media distribution of the HL7 Vocabulary Tables will be made available for a nominal handling fee, initially set at $50. The Executive Committee shall periodically reassess the reasonableness and viability of the handling fee.

16.02 Trademarks

The use of trademarks or service marks, other than those registered by HL7, in HL7 Protocol Specifications (§02.02) is discouraged; however, when used the first occurrence of the mark will be indicated by the appropriate symbol and the name of the trademark owner will be annotated in the front matter of the HL7 Protocol Specification.

16.03 Patents

Participant’s knowledge of any essential patent claims or outstanding patent applications that may be applicable to the HL7 Protocol Specifications (§02.02) is not contingent on having conducted a patent search nor is a patent search a requirement for contributions by the participant.

16.03.01 Commitment

All participants shall identify to HL7 Headquarters, through the issuance of a letter of assurance, any patents or patent applications felt to be applicable to the HL7 Protocol Specifications (§02.02). This assurance shall be provided without coercion and shall take the form of either:

(a) A general disclaimer to the effect that the patent holder will not enforce any of its present or future patent(s) that would be required to implement the proposed HL7 Protocol Specifications relevant to any person or entity using the patent(s) to comply with the HL7 Protocol Specifications, or

(b) A statement that a license will be made available without compensation or under reasonable rates, with reasonable terms and conditions that are demonstrably free of any unfair discrimination. This assurance shall apply, at a minimum, from the date of the HL7 Protocol Specification’s approval to the date of the HL7 Protocol Specification’s withdrawal, being irrevocable during that period.

16.03.02 Essential Patent Claims

“Essential Patent Claims” means claims of a patent or patent application (if issued) that would necessarily be infringed upon by implementation of the HL7 Protocol Specification (§02.02). A claim is necessarily infringed hereunder only when it is not possible to avoid infringement because there is no commercially plausible non-infringing alternative for implementing the HL7 Protocol Specification, including the protocols, application program interfaces, and/or data structures disclosed with particularity in the HL7 Protocol Specification in order to enable products to interoperate, interconnect or communicate as defined within the HL7 Protocol Specification.
Notwithstanding the foregoing, Essential Patent Claims shall not include any claims other than as set forth above even if contained in the same patent as essential claims; or that, if licensed, would require a payment of royalties by the licensor to unaffiliated third parties. Moreover, essential patent claims shall not include:

(i) any enabling technologies that may be necessary to make or use any product or portion thereof that complies with the HL7 Protocol Specification but are not themselves expressly set forth in the HL7 Protocol Specification (e.g., compiler technology, existing high-level application programs, basic operating system technology, and the like); or
(ii) the implementation of other published standards developed elsewhere and merely referred to in the body of the HL7 Protocol Specification, or
(iii) any portions of any product and any combinations thereof the purpose or function of which is not required for compliance with the HL7 Protocol Specification or that read solely on any implementations of any portion of the HL7 Protocol Specification that are not required by the HL7 Protocol Specification.

16.03.03 Withdrawal and Survival of Commitments for Essential Patent Claims

Upon a member’s notice of withdrawal from membership or termination of membership for any reason pursuant to §03.04, the commitments of the withdrawing or terminating member stipulated under §16.03.01 shall survive, but only with respect to (1) any HL7 Protocol Specification (§02.02) adopted by normative ballot within 60 days after notice of withdrawal or effective date of termination, and (2) any contribution of that member that has been, or that later is, incorporated in any HL7 Protocol Specification by normative ballot.

16.03.04 Disclaimer
HL7 is not responsible for either identifying patents for which a license may be required to implement an HL7 Protocol Specification (§02.02) or for conducting inquiries into the legal validity or scope of those patents that are brought to its attention. HL7 Headquarters shall notify the membership via email of any patent claims leveled against the HL7 Protocol Specifications.

16.04 Material in the Public Domain
The public domain is that body of knowledge and innovation to which no person or other legal entity can establish or maintain proprietary interests. Material from the public domain included in the HL7 Protocol Specification (§02.02) shall, whenever possible, include annotation citing source as evidence of its status.

17 Maintenance
The Governance and Operations Manual (GOM) shall be a dynamic document with proactive, iterative, and participatory maintenance designed to keep the manual current with HL7 operational requirements and ANSI Essential Requirements: Due process requirements for American National Standards.

17.01 Membership Participation
The membership shall be an active participant in maintenance of the GOM. They will be engaged through
a) a GOM suggestion box on the registration/information desk at each Working Group Meeting (WGM)
b) an open forum at each WGM to collect comments and recommendations for maintenance of the GOM,
c) an email address [goc@hl7.org] for the submissions of comments and recommendations for maintenance of the GOM interim to the WGM, and
d) peer review of all proposed revisions to the GOM.
17.02 During the Working Group Meeting

The GOM revisions adopted by the Executive Committee at their meeting prior to the WGM will be announced to the membership during the Monday general session; followed by an announcement of the GOM work items ratified by the Executive Committee (being those items to be resolved for adoption at the next WGM).

To ensure that all members are aware of current GOM revisions, an extract of the table of “Additions and/or Revisions Subsequently Adopted” reflecting the results of the most recent revision cycle shall be sent to all subscribers of the HL7 list server within two weeks of the announcement at the WGM.

On either Tuesday or Wednesday of the WGM, the Governance and Operations Committee (GOC) shall conduct an Open Forum of at least one quarter duration inclusive of the mid-morning or mid-afternoon break, as appropriate. GOC members will be available during the open forum to:

a) Answer any questions related to those revisions to the GOM announced at that WGM
b) Capture input on the GOM work items ratified by the Executive Committee
c) Capture input for future work item proposals to be considered by the Executive Committee

The GOC may, based on input gathered during the WGM, seek approval from the Executive Committee to add items to the work items list. The final work item list shall be distributed to the membership via the HL7 eNews within two weeks of the close of the WGM.

17.03 Concurrent Processes Interim to Working Group Meetings

17.03.01 Developing the GOM Revisions

The GOC shall prepare documentation with markup reflecting the proposed revisions identified in the work item list. This documentation shall be submitted to a peer review process. While a particular revision may dictate additional peer review resources, generally peer review will engage the following HL7 member lists: Board of Directors, Affiliate Chairs, Technical Steering Committee, and Process Improvement Committee (PIC).

The peer review period shall be open for thirty days and close at least thirty days prior to the opening date of the next WGM. Following the close of the peer review period, the GOC and PIC shall jointly resolve the comments received such that the GOC can finalize the revisions for consideration and adoption by the Executive Committee prior to the opening of the WGM.

17.03.02 Exception Work Item Requests

Exceptional work items may result from ongoing process review or the comments received during the peer review of work items ratified for the current revision cycle. The GOC shall assess the criticality of the exceptional work item request. If deemed necessary and given sufficient time to conduct a focused peer review of at least two weeks duration, the GOC may seek the approval of the Executive Committee to include the work item in the current revision cycle. Otherwise, the work item shall become a candidate for the next revision cycle.

17.03.03 Developing the Work Item List for the Next Cycle

Three weeks prior to the start of the next WGM, the GOC shall consolidate all comments and recommendations collected during the previous WGM and received via email since the last WGM into a work items list for ratification by the Executive Committee. The work item list shall also include a standing item to capture correction of any typographical or other trivial errors; any recommendations submitted by the PIC; any items addressing ANSI audit reports; and any items resulting from changes to ANSI Essential Requirements. This work items list, as ratified by the Executive Committee, will be presented at the next WGM. Any work items not ratified by the Executive Committee will be reworked for consideration in the next cycle or, if so directed, removed from the list and not further considered.
17.04 Executive Committee Action
The Executive Committee shall have two standing agenda items for those meetings held just prior to a WGM: Ratification of the GOM Work Items List and Adoption of Proposed Revisions to the GOM. The Executive Committee proceedings shall include notice of those revisions subsequently adopted. Those revisions not adopted shall be returned to the GOC for additional work during the next cycle of revisions.

17.05 Effective Date
Revisions to the GOM shall be effective on the date stipulated upon adoption by the Executive Committee. An updated GOM shall be posted to the HL7 Web site within ten working days of the closing date of each WGM.

17.06 ANSI Review and Accreditation
HL7 Headquarters shall establish a schedule for periodic review and accreditation of the GOM by ANSI. In no case should a year elapse since the last revision without an ANSI review.
**17.07 Process Flow Chart**

**GOM Maintenance Process**

- **EC Adopts Revision**
  - Yes: Announce GOM Revisions during WGM
  - No: Return as Work Item

- **Announce GOM Revisions during WGM**
  - Conduct Peer Review with PIC
  - PIC/GOC Reconciliation

- **Membership Participation**
  - NLT 3 Wks before WGM

- **Prepare revisions using markup**

- **EC Ratifies Work Item**
  - Yes: Capture Input for Next Cycle during WGM
  - No: Return as Work Item

- **Capture Input for Next Cycle during WGM**
  - PIC Recommendations

- **Membership input via email**

- **GOC Consolidates comments and recommendations**
  - 1 Wk before EC meeting

- **GOC Prepares Work Item List**

- **Yes**
  - EC meeting prior to WGM
  - PIC/GOC Reconciliation

- **No**
  - GOM Revisions put in EC packet

- **Return as Work Item**

- **Post revised GOM to HL7 Site**

- **Work items start here**
18 Externally Developed Implementation Guides

HL7 may choose to either endorse or adopt an externally developed implementation guide (IG). In either case the IG must be in the HL7 standard template for implementation guides and adhere to the style guide developed by the Publishing Committee.

18.01 Endorsement

If HL7 elects to endorse an externally developed IG and the developer is an accredited standards development organization, both HL7 and the developer may release their own version of the IG under separate copyright; otherwise the IG will be released by HL7 under joint copyright should the developer prefer to retain copyright. If a previously endorsed IG released under joint copyright is revised, updated, or otherwise changed from the original distribution it shall be resubmitted to HL7 for endorsement.

18.02 Adoption

If HL7 elects to adopt an externally developed IG, the document shall become the property of HL7 and be released under an HL7 copyright. Once adopted, the IG shall be updated, enhanced, and generally maintained as HL7 intellectual property.

18.03 Process

The Technical Steering Committee (TSC) shall identify the appropriate Work Group to process the IG. Representatives of the developing organization shall meet with the Work Group to develop a project plan that adheres to HL7 project initiation requirements, is consistent with the Work Group’s mission and charter, and falls within the Work Group’s scope. The Work Group will ensure that copyright and distribution rights are understood; which may include obtaining a release from the developing organization.

If deemed critical to the success of the project, the Work Group shall designate an HL7 member to serve as liaison to the developing organization. The Work Group shall ensure, to the satisfaction of the HL7 Project Management Office (PMO), that the following roles are filled by HL7 members, representatives from the developing organization, or consultants provided by HL7 or the developing organization:

a) Project Manager/Facilitator
b) Publication Facilitators, one of whom must be an HL7 member
c) Document Editor
d) Reconciliation committee members, with at least two from the developing organization and two from HL7 with HL7 representatives being the majority

The Work Group shall, with the concurrence of the TSC and following review and, if necessary, revision, submit the IG to ballot. The type of ballot chosen will determine process and approval requirements; however, in every case 60% of those participating and submitting a ballot for an externally developed IG must be HL7 members. Nonmembers may participate in the ballot subject to an administrative fee, which entitles them to a copy of the document upon completion of the ballot process.

18.04 Associated Fees

Typically fees are associated with accelerating the process of endorsement or adoption, not to be confused with fees associated with participating in a ballot. The developing organization may be assessed such a fee by the HL7 Executive Committee. The amount of the fee shall depend on negotiations between the developing organization and an individual designated by the Executive Committee to include consideration of:

a) Whether the process will require resources beyond those provided by current HL7 volunteers and project support provided by the developing organization.

b) That portion of the fee, if any, to be paid to HL7 members acting as project managers/facilitators, publishing facilitators, document editors, or members of the reconciliation committee. Such fees may be offset by resources in kind from the developing organization.
c) That portion of the fee, if any, to offset expenses for HL7 members to maintain an ongoing presence at meetings of the developing organization to ensure adoption or endorsement of the IG.

d) The costs of publication and distribution.

18.05 Distribution

Once approved the IG shall be processed through normal HL7 distribution channels. If the developing organization is an organizational member of HL7, they are entitled to all the rights of distribution granted to that member category. If the developing organization is a US government agency, they may choose to negotiate with HL7 for distribution of the IG via a public access .GOV web site.

18.05.01 Dependence on a Base Specification

The distribution of an externally developed IG does not imply, nor shall it include, the distribution of any underlying specifications or documents; e.g. the Clinical Document Architecture or some version of an HL7 Protocol Specification (§02.02). HL7 members have access to the various HL7 Protocol Specifications; others must acquire the underlying documentation from HL7.
Addendum A – HL7 Vocabulary Copyright and License

HL7® (Health Level Seven, Inc.) Vocabulary Copyright and License

HL7 is a registered trademark of Health Level Seven, Inc. The HL7 Version 2 Vocabulary Codes, Tables and Database, and the HL7 Version 3 Vocabulary Codes, Tables, and Database (jointly termed "the HL7 Vocabulary database") are copyright © 1989-2008, Health Level Seven, Inc. All rights reserved.

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1. HL7 creates and maintains codes used in data exchange messages and other health related standards as needed to fulfill its mission. To prevent the dilution of the purpose of the HL7 Vocabulary database of providing a definitive standard for identifying information in electronic messages and standards, users shall not use the HL7 Vocabulary database for the purpose of developing or promulgating a competing standard for use in data exchange messages or other health related standards.

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4. HL7 codes and other information from the HL7 Vocabulary database may be used in electronic messages, without the need to include this Health Level Seven, Inc. Vocabulary Copyright Notice and License or a reference thereto in the message (and without the need to include all fields required by Section 6 hereof).

5. Users may make and distribute an unlimited number of unmodified copies of the HL7 Vocabulary database. Each unmodified copy of the HL7 Vocabulary database must include this Health Level Seven, Inc. Vocabulary Copyright Notice and License, and must include the version number of the database. This Health Level Seven, Inc. Vocabulary Copyright Notice and License must appear on every printed copy of the HL7 Vocabulary database. Where the HL7 Vocabulary database is distributed on a fixed storage medium (such as diskette or CD-ROM), a printed copy of this Health Level Seven, Inc. Vocabulary Copyright Notice and License must be included on or with the storage medium, and a text file containing this information also must be stored on the storage medium in a file called "HL7_license.txt". Where the HL7 Vocabulary database is distributed via the Internet, this Health Level Seven, Inc. Vocabulary Copyright Notice and License must be accessible on the same Internet page from which the HL7 Vocabulary database is available for download.

6. Subject to Section 1, and the other restrictions hereof, users may incorporate portions of the HL7 Vocabulary database into another vocabulary database or software program for distribution outside of the user's corporation or organization, provided that any such database or software program includes the following fields reproduced in their entirety from the HL7 Vocabulary database:
   - VCS_concept_designation.codeSystemId,
   - VCS_concept_designation.conceptCode, and
   - VCS_concept_designation.designation.
Every copy of the HL7 Vocabulary database incorporated into or distributed in conjunction with another database or software program must include the following notice:

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8. An unlimited number of copies of the HL7 Vocabulary Users' Guide may be made and distributed. This Health Level Seven (HL7) Vocabulary Copyright Notice and License must appear verbatim on every electronic or printed copy of the HL7 Vocabulary Users' Guide. The HL7 Vocabulary Users' Guide may not be modified, nor may derivative works of the HL7 Vocabulary Users' Guide be created, without the prior written permission of Health Level Seven, Inc. Please contact HL7 by e-mail at HQ@HL7.ORG to request written permission using Subject: HL7 Vocabulary Users' Guide. HL7 retains the right to approve any modification to, or derivative work of, the HL7 Vocabulary Users' Guide.

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