

Healthcare Organization Management

This document defines the procedures for developing Healthcare Standards Institute (HSI) Healthcare Organization Management Standards. Document Number: HSI-1 Version 12 (12/09/2022)

Procedures for the Development of American National Standards

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Foreword

The Healthcare Standards Institute (HSI) Procedures for American National Standards Development (Procedures) provide specific guidance for HSI standards activities including: project justification and initiation of new standards; approval balloting; requirements for balance, consensus, and due process; procedures for revision, reaffirmation and withdrawal; criteria for processing requests for interpretations; intellectual property and patent policy guidance; and HSI's appeals process.

These Procedures govern the development of all standards published exclusively by HSI and jointly with other Accredited Standards Developers (ASD). All HSI standards development activities shall be conducted in accordance with these Procedures.

These Procedures also provide guidance that allows for the submittal of a candidate HSI standard for approval as American National Standards including the option of International Organization for Standardization (ISO) standards.

These Procedures have been approved by the ANSI Executive Council effective October 16, 2019.

For additional information on HSI's standards program, please contact HSI, 1452 Hughes Road, Suite 200, Grapevine, TX 76051

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Healthcare Standards Institute (HSI) STANDARDS PROCEDURES MANUAL

1.0 SCOPE				
1.1 Standards Program Scope	Constraint and constraint and constraint the constraint and the constraint and constitution that the constraint			
1.2 Applicability	The procedures apply to activities related to the development of consensus for approval, revision, reaffirmation, and withdrawal of candidate American National Standards Institute/HSI (ANSI/HSI) standards. These Procedures are compliant with the normative American National Standards policies and administrative procedures.			
1.3 American National Standards	After approval by the standards consensus body, these standards may then be submitted to ANSI for consideration as American National Standards. When a standard is designated an "American National Standard," it means that all of ANSI's requirements for consensus, due process, public review, and ANSI review have been met.			
1.4 Committee Procedures	HSI committees and subcommittees that are responsible for standards development may also maintain written procedures addressing individual committee organization, scope, membership, and conduct. These procedures shall not be amended by individual committee procedures or procedures developed for joint committee activities.			
1.5 Legal Issues	Questions regarding intellectual property issues such as copyrights, trademarks, or patents shall be directed to the HSI Standards department. That office will refer these matters to the HSI CEO. The ASD (HSI) is recognized as a legal entity in the State of Texas.			
ISO/IEC requirements set forth in the ANSI Procedures for the Na		An adoption of an ISO/IEC standard shall comply with the requirements set forth in the ANSI Procedures for the National Adoption of ISO or IEC Standards as American National		
		Standards.		

Amendment	An amendment is a document that describes limited substantive changes to a standard or bulletin. Substantive changes made in an amendment do not require revision of the parent document. However, the parent document shall process, approve and incorporate any amendments into its next revision in accordance with the requirements of these procedures. Amendments can be submitted to ANSI if the parent document is an ANS.
ANSI	American National Standards Institute, the U.S. national accreditation body (<u>www.ansi.org</u>).
ANS	American National Standard. A document exclusively designated as a national standard by ANSI
BSR	The Board of Standards Review is the ANSI body responsible for the approval of American National Standards (with the exception of those proposed American National Standards submitted by ANSI Audited Designators).
Bulletin	Bulletins are documents that are informative in nature and shall not contain any normative requirements. Bulletins shall not be included as normative references in standards. A bulletin may be called a "guideline," a "recommended practice," a "bulletin," or something similar.
Conflict	A situation where, viewed from the perspective of a future implementer, the terms of one standard are inconsistent or incompatible with the terms of the other standard such that implementation of one standard under terms allowable under that standard would preclude proper implementation of the other standard in accordance with its terms.
Consensus	Consensus is established when substantial agreement has been reached by directly and materially affected interests. Substantial agreement means more than a simple majority but not necessarily unanimity. Consensus requires that all views and objections be considered, and that an effort be made toward their resolution. Consensus is achieved through a process of discussion, correspondence, draft contributions, and revision, all leading to the final result. For the purpose of these Procedures, consensus shall be defined as a majority of those eligible to vote shall have voted <u>and</u> approval by at least two-thirds (2/3rds) of those voting, after excluding abstentions.
Consensus Body	The group that approves the content of a standard, and whose vote demonstrates evidence of consensus. The Members of an HSI Standards committee (SC) or subcommittee (SSC) that are eligible to vote is a consensus body.

Editorial	Editorial changes are changes that correct arrays or
Editorial Changes	Editorial changes are changes that correct errors or inconsistencies in a manuscript. Editorial changes have no effect on the way the standard is used or applied.
Errata	An <i>errata</i> is a document that describes substantive errors in a standard or bulletin that were clearly not the intent of the committee or subcommittee that adopted the document. It also describes the corrections for these errors. An <i>errata</i> shall not be used as a means to update a document, it shall only be used to correct things that were clearly mistakes.
Essential Patent	A patent that is or may be required for compliance with the normative elements of a standard.
IEC	International Electrotechnical Commission (http://www.iec.ch/).
IP Proffer	A statement from a patent holder in the form set forth in Annex B (Normative).
ISO	International Organization for Standardization (http://www.iso.org/iso/home.html).
Liaisons	Individuals designated by the Chair of a group or subgroup to join another group or subgroup to participate in information sharing about common content related matters. Liaisons have no voting rights in the accepting group. Observers can serve as liaisons.
Meeting	Includes documented, face-to-face meetings, audio-, video-, or web teleconferences as outlined in this Procedure.
	NOTE - In instances where requirements differ based on the type of meeting, those differences are specified.
Meeting Vote	A vote on a standard or bulletin intended for final approval that is conducted at a meeting.
Member	An organization or individual that has fulfilled the requirements to participate in the HSI Standards Program. See Section 6.0.
Normative Elements	Elements that describe the scope of the document and which set out its conformity requirements.
Other Documents	White papers, technical reports, and other documents can be approved by committees and subcommittees to provide technical information as needed.
Representative	An individual appointed by a Member that participates in a committee, subcommittee or subgroup. An individual cannot represent more than one (1) Member in any one (1) committee, subcommittee, or subgroup meeting. A Member

	may also be his/her own representative. A Member may have multiple representatives on a standards committee, subcommittee or other subgroup. If the Member is eligible to vote on a technical item, only one representative may vote for that Member on a committee, subcommittee or other subgroup.
Shall vs. Should ¹	The use of "shall" and "should" in HSI standards conveys the following meaning: 1. Shall: As used in a standard, "shall" denotes a minimum requirement in order to confirm to the standard. 2. Should: As used in a standard, "should" denotes a recommendation or an approach that is advised but not required to conform to the standard.
Standard	Standards are documents that describe technical requirements for equipment design, processes, procedures or practices. Generally, a standard should contain at least one normative requirement. A standard shall not include a bulletin as a normative reference. A standard may be called a "standard," a "specification," or something similar.
Technically Substantive Changes	A substantive change in a proposed standard or bulletin that directly and materially affects the use of the standard. Examples of substantive changes are below: • "shall" to "should" or "should" to "shall"; • addition, deletion or revision of requirements, regardless of the number of changes; • addition of mandatory compliance with referenced standards.

3.0 References

3.1 Normative Reference List

These procedures contain provisions that, through reference in the text, constitute normative references of these procedures. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on these procedures are encouraged to investigate the possibility of applying the most recent editions of the standards listed in this section.

¹ In some cases, third parties or authorities having jurisdiction may choose to incorporate HSI standards by reference and may mandate compliance with all requirements and recommendations. All uses of the words "should" and "shall," therefore, must be based on sufficient information of the standard's current and potential future use.

ANSI:

- · ANSI Essential Requirements, most current edition
- · ANSI Procedures for the National Adoption of ISO or IEC Standards as American National Standards, most current edition

NIST

· NIST Special Publication 811, 2008 Edition, Guide for the Use of the International Systems of Units (SI).

Robert's Rules:

· Robert's Rules of Order (Newly Revised, most current edition)

3.2 Normative Reference Acquisition

ANSI:

American National Standards Institute, New York, NY Internet: http://www.ansi.org/

HSI:

- Healthcare Standards Institute, 1452 Hughes Road, Suite 200, Grapevine, TX 76051. Phone: (833) 721-1475
- · Internet: https://www.HSIhealth.com/. For more information, email suggestions@hsihealth.com

Robert's Rules of Order:

http://xn--www-rp0a.robertsrules.com/

4.0 HSI Standards Program Technical Guidance

4.1 HSI Executive Standardization Board (HSIESB)	The HSI Executive Standardization Board is solely an advisory group that is responsible for providing guidance to the ASD's Secretary about HSI's standards administration. The HSIESB will have no governing authority. This section describes only the HSIESB membership criteria and its organizational structure.
4.2 HSIESB Membership	The HSIESB shall consist of the HSI CEO or her designate, the chairs of each HSI standards committee (consensus body), the HSI-appointed chairs of each joint committee and the HSI Standards Secretary. Individuals serving on the HSIESB should have technical backgrounds and be able to advise HSI on technical and standards policy matters.
4.3 HSIESB Organization	The HSIESB shall have a chair who is the HSI CEO or her designee. The designee shall serve at the pleasure of the HSI CEO.
4.4 Standards Committees	HSI standards committees (consensus bodies) will be defined and established by the HSIESB.

5.0 Appointment and Election of Officers

5.1 Nomination Committee	A nomination committee will be appointed by the chair of the standards committee and approved by the standards committee for a period of two (2) years unless removed by ballot beforehand. The members of the nominating committee shall be approved at the first standards committee meeting in any given calendar year. The nomination committee is responsible for:	
	 Recommending to the Secretary for submission to the HSI CEO, or his/her designee, those candidates for the position of standards committee chair; 	
	Recommending to the ISSC standards committees candidates for the position of subcommittee chair;	
	 Recommending candidates for chair of special task groups or other groups to the standards committees as deemed necessary. 	
5.2 Consensus Body Chair	There shall be a chair appointed by the HSI CEO, or his/her designee, from the individual members or representatives of each consensus body, subject to approval by majority vote of the consensus body. Each will serve three (3) year appointments unless removed by ballot beforehand renewable for one (1) additional term for a maximum of a six (6) year term. The secretary shall be appointed by the HSI CEO or designee.	
5.3 Subcommittee Chair	If the consensus body divides into subcommittees, the chair of the subcommittee shall be recommended by the chair of the parent committee and HSI Standards department and requires approval by a majority vote of the consensus body. There are no limits on the length of time an individual can serve as a subcommittee chair, except for removal by ballot of the subcommittee.	
5.4 Working Group Chair	In the event that subcommittees are further divided into working groups, the chair of the working group shall be appointed by the respective standards subcommittee secretary with approval by the standards subcommittee chair. Appointments are based upon recommendations of the subcommittee chair.	
5.5 Other Notes on Officer Appointment and Election	Candidates for these appointments and elections should be selected from consensus body members with an active voting status who are participants in the respective committee, subcommittee, or working group. Candidates should demonstrate a high level of activity consistent with the committee, subcommittee or working group scope. In limited cases, the ISSC, in consultation with the HSI Secretary responsible for standards activities, may elect to consider other candidates for committee appointments and elections, and the chair of the parent (consensus) body and staff may elect to do so for subcommittee or working group appointments.	
	The chair of a committee, subcommittee, or working group is responsible for adhering to these procedures and acting consistent with the group's scope. Additionally, each committee chair is responsible for overseeing subcommittees and working groups operations under a committee's auspices. Appointment or	

	election as chair attaches to a specific individual rather than to an organizational member.
5.6 Working Group Secretary	To facilitate the working group's projects, the working group chair should appoint a secretary from its membership.
6.0 Committee N	lembership
6.1 Consensus Body Outreach	The size of a consensus body meeting the requirements of this section shall be appropriate to the standard being discussed, and should typically consist of at least five (5) members. In the event that there are insufficient consensus body members identified, or the requisite interest categories are not adequately represented, HSI shall make efforts to contact organizations or individual deemed appropriate for consensus body membership and document those efforts.
6.2 Membership Criteria	Committee membership, and membership on any subcommittee, working group or sub-group, is open to anyone with a direct and material interest in the committee's subject matter. Representatives should have a technical background relating to administration and declare their affiliation
	Neither employment with HSI nor membership in any organization affiliated with HSI is a requirement for membership on standards developing committees.
	Members of the consensus body shall consist of organizations (preferably regional or national in scope), companies, government agencies, individuals, etc., having a direct and material interest in the activities of the consensus body. The immediate past chair shall be an ex officio member of the consensus body.
	The selection and addition of members, along with their interest category, shall be subject to approval by a majority vote of the consensus body after the application has been processed. The termination of members shall be subject to approval by majority vote of the consensus body after a review of the matter by the membership.
	An individual participant may be retained by the Standards Committee in the event that this individual's original organizational member has dissolved, or if the relationship between the representative and their designated organization is otherwise severed. The participant must be in good standing with the consensus body for a period of five years or more, and/or be a demonstrated expert on a topic pertinent to the committee's standards work. This participant serves the consensus body as an Observer with no voting rights. Applications of this kind are subject to the approval by the consensus body. The consensus body, by majority vote, decides to provide this individual participant voting rights in accordance with Section 7.1.
6.3 Membership Application	A request for membership on a particular consensus body shall be addressed to the HSI Standards department and shall indicate the applicant's direct and material interest in the standards committee's work, qualifications and willingness to participate actively. In addition, if the applicant is an organization,

	organization, or government agency, it shall identify a representative (and an alternate, if desired). Representatives serve at the pleasure of their sponsoring organization. It shall be permissible for an individual to be a representative on more than one (1) consensus body.
6.3.1 Membership Application Review	In recommending appropriate action to the consensus body about an application for membership, the HSI Secretary shall consider the: a) Need for active participation by each interest; b) Potential for dominance by a single interest category; c) Extent of interest expressed by the applicant and the applicant's willingness to participate actively; d) The representative identified by the applicant organization, organization, or government agency.
6.3.2 Multiple representatives	An organization may have multiple representatives subject to a majority approval of the consensus body and provided the balance of interests is maintained as specified in Sections 6.4 and 6.3.1.
6.3.3 Combined Interests	When appropriate, the Secretary may recommend that the applicant seek representation through an organization that is already a member and represents the same or similar interest.
6.3.4 Review of Membership	The Secretary shall review the consensus body membership list annually with respect to the criteria of Section 6.2 and 6.3.1. Members are expected to fulfill obligations of active participation. Where a member is found in habitual default of these obligations, the Secretary shall direct the matter to the consensus body chair for appropriate action, which may include termination of membership.
6.3.5 Observers and Individual Subject Matter Experts	Individuals and organizations having an interest in the standard committee's work may request listing as observers. The consensus body may also select individual experts to assist it. Individual experts shall serve the same terms as members of the standards committee. Observers shall be advised of the standard committee's activities, may attend meetings, and may submit comments for consideration, but shall have no vote. An Observer in a parent committee shall only be an observer in a subordinate group. A consensus body voting member may be an Observer in a subordinate group.
6.4 Balance and Interest Categories	All appropriate interests that are directly and materially affected by the standards activity of the standards committee shall have the opportunity for fair and equitable participation without dominance by any single interest. Members from diverse interest categories shall be sought with the objective of achieving balance. Each member shall propose its own interest category as appropriate and in accordance with the consensus body's established categories. The interest categories shall be established or revised by a vote of the consensus body. The interest categories shall be included in the consensus body ballot and submitted to ANSI as part of the accreditation requirements. The total number of Members with voting rights on a standards committee or subcommittee who belong to any particular interest category should be less than a majority (<50%) of the total number of members with voting rights on the

committee. If the interest category changes during their participation, the Member shall notify HSI Standards department of the change.

- Producer: Producers are organizational members who use the standards, bulletins or other documents in question to develop products or implement services.
- **User:** Users are members who acquire from Producers equipment or services to which the standards, bulletins, or other documents apply.
- General Interest: General Interest members are neither Producers nor Users. This category may include regulatory agencies (state and federal), researchers, other organizations and associations, and consumers.

Other interest categories such as the following may be established within a standards committee in order to insure adequate levels of representation.

- · Government: Federal, state, and other regional regulatory body
- · Legal or Consultants: Legal organizations and consultancies
- Academia: College or university affiliated expert.
- Association: Professional society, trade association, or nongovernmental authority
- Patient or Patient Advocacy: Groups representing patient interests
- Non-Governmental Observer (NGO): Labor, consumer interest

6.5 Membership Roster

The Secretary shall maintain a current and accurate consensus body roster and shall distribute it to the members and their consensus body representatives at least annually and otherwise on request. The roster shall include the following:

- a) Title of the Standards Committee and its designation;
- b) Scope of the Standards Committee;
- c) Secretary's name of organization, name of secretary, and address(es);
- d) Officer: chair:
- e) Members: name of organization or agency, its representative, point of contact, and alternate (as applicable), addresses, and business affiliations; or name, address, and business affiliation of individual member(s):
- f) Classification of each member;
- g) Tally of classifications: total of full voting members, observers and subtotals for each interest category;
- h) For each subgroup: title, chair, and names and addresses of all members.

6.6 Liaisons

Committees and subcommittees may establish liaisons with other groups.

7.0 VOTING

7.1 Voting Rights

Standards committee or subcommittee members may earn and then retain voting rights by participating in committee or subcommittee meetings. For a

Member to obtain voting rights on a committee or subcommittee any Representative of the Member must attend two (2) out of four (4) consecutive meetings and will be eligible to vote at the conclusion of the second of these meetings attended. Missing two (2) out of four (4) consecutive meetings results in a loss of voting rights, after which voting rights may be regained by attending two (2) out of three (3) consecutive meetings again.

Voting rights are assigned to organizational members and not individual representatives. If a representative of a member with voting rights changes jobs and begins representing a Member that does not have voting rights, new voting rights must be earned. Voting rights do not transfer with the individual. This same principle applies to independent consultants who begin representing new clients. The attendance record in each set of meeting minutes shall serve as the official basis for acquiring, retaining and losing voting rights.

The consensus body vote shall be conducted and reported in accordance with the rules set forth herein. Votes for the approval of a document or portion thereof as a candidate ANS may be obtained by letter, fax, recorded votes at a meeting or electronic means. All members of the consensus body shall have the opportunity to vote. When recorded votes are taken at meetings, members who are absent shall be given the opportunity to vote before or after the meeting.

7.2 Voting

For a committee or subcommittee to approve an HSI standard, bulletin, *Errata* or amendment, at least two thirds (2/3rds) of those voting Members casting "yes," "yes with comment" or "no with comment" votes must vote "yes" or "yes with comment." Abstentions are not included. For a committee or subcommittee to approve any other action a simple majority of those voting Members casting "yes," "yes with comment" or "no with comment" votes must vote "yes" or "yes with comment."

Whenever any vote is taken the total number of "yes" votes plus the total number of "yes with comment" votes plus the total number of "no with comment" votes plus the total number of abstentions must meet the quorum requirement in Section 8.3.

All votes shall be conducted on a one (1) Member / one (1) vote basis.² It is the responsibility of a Member with multiple Representatives on a committee to coordinate the voting activities of its Representatives.

7.3 Actions Requiring Approval by a Majority

The following actions require approval by a majority of the membership of the consensus body either at a meeting or by letter ballot:

- a) Confirmation of officers;
- b) Removal of officers:
- c) Formation of a subgroup, including its procedures, scope, and duties;
- d) Disbandment of subgroups:
- e) Addition of new consensus body members and designation of their interest categories;

² The one (1) Member one (1) vote rule does not apply to situations where an at-large member is from the same organization as a committee or subcommittee chair because committee and subcommittee chairs represent the interests of their committees and subcommittees and not the interests of their companies.

- f) Granting or withdrawing voting rights to individual participants;
- g) Approval of withdrawal of an existing standard.

7.4 Actions Requiring Approval by TwoThirds of Those Voting

The following actions require a letter ballot or an equivalent formal recorded vote by a majority of those eligible to vote shall have voted and approval by at least two-thirds (2/3rds) of those voting, after excluding abstentions.

- a) Adoption of consensus body procedures, interest categories, or revisions thereof;
- b) Approval of a new standard or reaffirmation of an existing one:
- c) Approval of revision or addendum to part or all of a standard:
- d) Approval for submission to ANSI of change of the consensus body scope.

8.0 MEETING MANAGEMENT

8.1 Calling Meetings

Consensus body (committee) meetings shall be held, as decided upon by the consensus body, the chair, the secretary, or by petition of one-third (1/3rd) of the membership, to conduct business, such as making assignments, receiving reports of work, considering draft standards, resolving differences among subgroups, and considering views and objections from any source. Meetings of subgroups may be held as decided upon by the members or chair of the subgroup.

This section describes the requirements for distribution of meeting notices for committees, subcommittees, working groups, and other groups. A meeting notice is a written communication of the time, date, and place of a meeting.

8.2 Open Meetings

Meetings of the consensus body and all subordinate bodies shall be open to all members (voting and observer) and others designated by the Chair as having a direct and material interest. At least four (4) weeks' notice of regularly scheduled meetings of the consensus body shall be given by the Secretary in media designed to reach directly and materially affected interests. The notice shall describe the purpose of the meeting and shall identify a readily available source for further information. An agenda shall be available and shall be distributed in advance of the meeting to members and to others expressing interest. The Secretary may maintain a mailing list of other interests.

8.3 Quorum

Fifty-one percent (51%) or greater percentage of standards committee or subcommittee members in attendance constitutes a quorum. 51% is defined as greater than or equal to (≥.51) of the membership are present during the meeting. If a quorum is not present, actions shall only be taken subject to subsequent confirmation by letter ballot or vote at a future meeting.

8.4 Timely Notice to Committees and subcommittees

Meeting notices for face-to-face and electronic meetings of committees and subcommittees shall be distributed at least four (4) weeks before the meeting.

8.5 Timely Notice to Working groups and other subgroups	Meeting notices for face-to-face meetings of working groups and other subgroups shall be distributed at least four (4) weeks before the meeting. Meeting notices for electronic meetings of working groups and other subgroups shall be distributed at least one (1) week before the meeting.
8.6 Meeting Agendas	A preliminary agenda shall be distributed with each meeting notice. Agenda items related to voting on standards and bulletins shall comply with the notice requirements in Sections 8.4 and 8.5.
8.7 Meeting Minutes or Notes	Minutes or notes shall be taken for each committee or subcommittee meeting by a designated member of that committee or subcommittee. The content and structure of minutes and notes will be defined by the Secretary and per these Procedures.
8.8 Meeting Conduct	All meetings shall be conducted in compliance with these procedures. Committee and subcommittee meetings shall be conducted in compliance with the current edition of Robert's Rules of Order.
8.9 Meeting Recording	Recording of meetings, teleconferences, or web conferences via audio/video or electronic means shall not be permitted during committee, subcommittee, or working group meetings without the prior unanimous consent of all Members at the meeting. This does not preclude written note taking or capturing an occasional screen shot during the meeting for personal use.

9.0 COMMUNICATIONS

9.1 Formal Internal Communication	If correspondence between subcommittees or between working groups of different subcommittees involves issues or decisions (i.e., non-routine matters) affecting other subcommittees, copies shall be sent to all affected subcommittee chairs, the secretary, and the consensus body officers.
9.2 External Communication	Inquiries relating to the Standards Committee should be directed to the Secretary, and members should so inform individuals who raise such questions. All replies to inquiries shall be made through the Secretariat.
9.3 Requests for Interpretation of Standards	Written inquiries requesting interpretation of the HSI' approved American National Standards shall be responded to in accordance with the Standards Interpretation Policy found in Appendix D of these procedures. Revisions to the standard resulting from requests for interpretations shall be processed in accordance with these procedures.
9.4 Committee Communications to Outside Parties	All communications from a committee or subcommittee to people or organizations outside of the committee or subcommittee shall come from the ISSC chair, consensus body chair, from the appropriate HSI staff person, or through an appropriate liaison representative. Formulation of positions related to standards shall be approved by the consensus body. Liaison communications shall not conflict with formal HSI positions. Communications, including article, news reports, and speaking requests from organizations outside the standards setting effort shall be referred to the

	Secretary for review and action. The Secretary may seek guidance from the ISSC or the appropriate Chair for resolution. Members and any other party involved in standards meetings shall seek approval the HSI Standards department for all external communications before representing this work to outside parties. The Secretary recognizes the benefits of public communication and seeks to manage these exchanges in a productive manner.
9.5 Joint Standardization	HSI standards committees may engage in joint standardization efforts with other organizations. Before such work begins, an agreement between the ANSI Accredited Standards Developer (HSI) and the other organization(s) shall be established in an official Memorandum of Understanding (MoU). The MoU shall include the synchronization of process and approval by HSI CEO. HSI standards committees working jointly with other accredited standards developing organizations shall maintain written procedures addressing joint committee structure, scope, membership and operations.
9.6 With ANSI Accredited Standards Developing Organizations	If the other organization is accredited by ANSI, then a determination shall be made upon initiation of the effort concerning which organization's standardization procedures shall govern, which organization shall be responsible for maintaining committee membership information, and which organization shall provide other Secretariat services for the effort. As an alternative, HSI and the other organization may agree to rotate responsibility in these areas. Agreements on these matters shall be documented in an official MoU. The MoU shall include the synchronization of process and approval by the HSI CEO.
9.7 With SDOs Not Accredited by ANSI	For standards developing organizations not accredited by ANSI, and if the standard is intended to be an ANS, HSI's shall only agree to use its accredited procedures to manage the development of these standards. HSI will be solely responsible for the complete and effective execution of these accredited procedures. Agreements on these matters shall be documented in an official MoU.
9.8 With Organizations That Are Not SDOs	If the other organization is not an accredited standards developing organization then the standardization activity shall be conducted in accordance with the procedures described in this document. Agreements on these matters shall be documented in an official MoU. The MoU shall include the synchronization of process and approval by the HSI CEO.
9.9 Coordination and Harmonization	As an ASD, HSI shall make a good-faith effort to resolve potential conflict and to coordinate standardization activities intended to result in harmonized American National Standards. A "good faith" effort shall require substantial, thorough and comprehensive efforts to harmonize a candidate ANS and existing ANSs. Such efforts shall include, at minimum, compliance with all relevant sections of these procedures. HSI shall retain evidence of such efforts in order to demonstrate compliance with this requirement to the satisfaction of the appropriate ANSI body.

10.0 SUBGROUPS CREATED BY THE CONSENSUS BODY

10.1 Subcommittees and Working Groups	When one or more subgroups (subcommittees, working groups, etc.) are formed to expedite the work of the consensus body, their formation (and later disbandment) requires approval by a majority vote (>50%) of the consensus body and appropriate public notice. The scope and duties delegated to the subgroup shall be approved at the time it is formed, and subsequent changes in scope or duties shall also require approval by the consensus body. The charge to the subgroup shall clearly state whether:
	 The subgroup is responsible for developing the definitive content of one or more standards and for responding to views and objections thereon.
	 The subgroup is responsible for assisting the consensus body (e.g. drafting all or a portion of a standard, drafting responses to comments, drafting positions on international standards, or other purely advisory functions).
10.2 Chair and Members of Subgroups	The consensus body shall review the scope, duties, and membership of all subgroups annually.
10.3 Subcommittees	Subcommittees have the same operational requirements as committees, except that their formation (and later disbandment) requires approval by a majority vote of the consensus body and appropriate public notice. Subcommittees may create their own working groups and ad hoc groups.
10.4 Working Groups	Working groups may be established by committees or subcommittees for specific purposes. When a working group is established, the group that creates it shall approve a scope for it. The chair of the group that creates it, in consultation with the HSI Secretary responsible for Standards activities and staff, shall appoint a working group chair.
	Working groups develop recommendations to their parent group by consensus and do not take formal votes as part of the consensus building process. Therefore there are no voting rights in working groups and no voting maintenance requirements. Straw polls may be used to gauge consensus in a working group. It is up to the chair of each working group to determine when consensus has been reached.
	Informal meeting reports shall be produced for each working group meeting. Formal minutes are not required.
10.5 Ad Hoc Groups	Committees, subcommittee and working groups may form their own <i>ad hoc</i> groups by consensus. <i>Ad hoc</i> groups shall have chairs, appointed by the chair of the parent group. They shall also have scope statements and report to the parent group on a regular basis. <i>Ad hoc</i> groups are formed to address specific short terms tasks and shall be disbanded when their task is complete.
10.6 Discovery Groups	Discovery Groups are short-term groups created and dissolved by a committee or subcommittee or by the ISSC as needed to explore new areas of standards development such as new technologies or new product areas. Discovery groups should complete their evaluation within six (6) months of their first

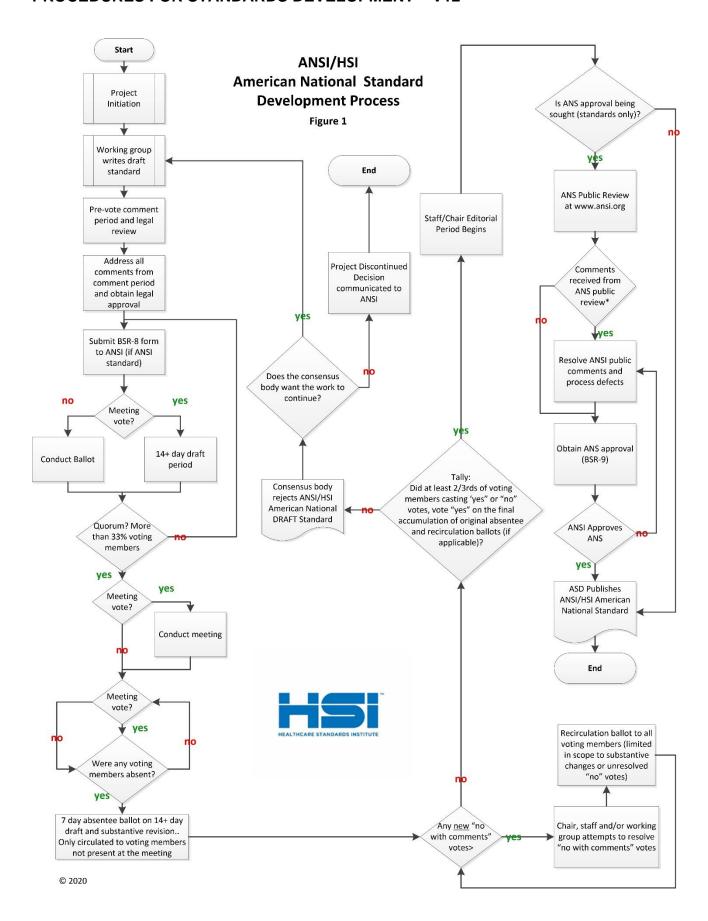
	meeting. Membership is open to anyone with a direct and material interest in the subject matter.
10.7 Approval of	Draft standards and any substantive change in the content of a standard
Draft Standards	proposed by a subgroup shall be referred to the consensus body for approval.
11.0 DOCUMENT	DEVELOPMENT STAGES
11.1 Document	This section describes requirements for the document development process.
Development	Figure 1 (informative) illustrates the process.
and Publication	
11.1.1 Investigation and Justification Stage	Before a project is formally initiated by a committee or subcommittee, an investigation may be conducted by a committee, subcommittee, working group, ad hoc group or discovery group. The investigation stage could include the creation of use case scenarios, requests for proposals or information (RFPs or RFIs), and decisions regarding the scope of the proposed project.
	The appropriate committee or subgroup shall review the need for the proposed activity, the time frame for completion, and the amount and type of resources required to complete the project. Actual work on drafting or revision of a standard shall not begin until the appropriate consensus body approves the project.
	The following factors will be considered when analyzing the justification for a standards project.
11.1.1.1 Industry or Sector Practices	To the extent possible, HSI standards will reflect current minimally effective metrics and practices in the industry and encourage best practical environmental, quality of care, and safety performance throughout the industry. The impact of new and emerging technologies should be considered.
11.1.1.2 Regulatory Impact	During the development of HSI standards, it should be recognized that they may be adopted or incorporated by authorities having jurisdiction. See Footnote 1.
11.1.1.3 Effect of Not Initiating the Standards Activity	The effect of not initiating the standards activity may be characterized in terms of cost to the incentive industry or by other means.
11.1.1.4 Other Standards	The impact of other organizations' standards on the proposed standard or the potential overlap of other organizations' standards with the proposed standard should be considered.
11.1.1.5	HSI standards should meet broad incentive industry needs. Potential demand
Document	for a new standard or for a proposed revision may be evaluated based on
Demand	customer/consumer demand data.
11.1.1.6 ANSI/ISO	The value to industry of submitting the standard to ANSI for processing as an American National Standard should be evaluated. Likewise, the value to

industry of submitting a standard to ISO for potential adoption as an Candidate international standard should be considered. The HSI Standards department Standards will develop a process that shall be utilized to determine the level of support and interest an HSI committee may have in participating and supporting the submission of an HSI standard as the base document for an ISO standard. When a standards idea is presented to the appropriate committee for 11.1.2 Project consideration, the project shall be accompanied by a proposed timeline that Planning and includes a target initiation date for work on the standard to begin and a target Initiation balloting date for the standard. A project is any action that results in a new, revised, reaffirmed, stabilized or withdrawn HSI standards document (Standard, Bulletin, Amendment or Errata). All projects shall be initiated by majority vote (>50%) of a committee or subcommittee along with an accompanying title and scope statement. In between meetings, a committee or subcommittee chair may initiate a project, but the initiation of the project must then be approved by the committee or subcommittee at its next meeting. The types of projects that may be initiated include Standards, Bulletins, Errata, and Amendments. The committee chair after consultation with the ISSC and with the support of the HSI Secretariat, upon review of open projects, may discontinue a project when necessary. Reasons could include lack of activity, a decision by the committee to move in a different direction, or a safety hazardrelated or legal issue. A disagreement with a standards project or negative feedback from external stakeholders shall not be sufficient justification to discontinue a project. The standards activities below shall be announced in a suitable manner in order 11.1.3 to provide an opportunity for participation by all direct and materially affected Notification of parties. Such announcements may be in the form of notices or copies of Standards committee notices, to know interested parties or announcements in suitable Activities media, including electronic, appropriate for the known affected interests. a) Meetings of standards committees b) Intent to develop, revise, reissue, or withdraw standards. c) Availability of draft standards and readily available sources for further information d) Availability of ballots for approval of new or revised standards, reaffirmation or withdrawal of existing standards or national adoption of international standards. e) Meaningful description of the purpose of the proposed activity

11.1.3.1
American
National
Standards
Publication
Decision

Activities related to HSI standards that are intended for submittal and/or processing through ANSI shall be announced in *ANSI Standards Action*. The decision to submit an HSI standard to ANSI for approval shall be determined by the standards committee responsible for the document in consultation with the HSI Standards department. HSI shall maintain ownership of all copyrights and other rights to such HSI standards, but may license ANSI to distribute the standard.

11.1.3.2 Submittal of PINS Form	At the initiation of a project to develop or revise an American National Standards, notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for announcement in <i>Standards Action</i> . Comments received in connection with a PINS announcement shall be handled in accordance with these procedures. A statement shall be submitted and published as part of the PINS announcement that shall include: (a) an explanation of the need for the project, including, if it is the case, a statement of intent to submit the standard for consideration as an ISO, IEC or ISO/IEC JTC-1 standard; and (b) identification of the stakeholders (e.g., telecom, consumer, medical, environmental, etc.) likely to be directly impacted by the standard. If the response to sub-section (b) changes substantively as the standard is developed, a revised PINS shall be submitted and published. PINS exceptions shall be managed in accordance with clause 2.5.1.1 of the ANSI Essential Requirements, most current edition. Assertions of conflict or duplication shall be managed in accordance with clause 2.5.1.2 of the ANSI Essential Requirements, most current edition. PINS Deliberation Reports shall be managed in accordance with clause 2.5.1.3 of the ANSI Essential Requirements, most current edition.
11.1.3.3 BSR-8 Forms	Proposals for new ANSI/HSI standards, proposals to revise, reaffirm, or withdraw approval of existing ANSI/HSI standards and proposals to nationally adopt a candidate ISO standards shall be transmitted to ANSI using a BSR-8 form for listing in <i>Standards Action</i> in order to provide an opportunity for public comment. Submission of the BSR-8 form should be concurrent with final balloting. Prompt consideration shall be given to the written views and objections of those individuals commenting as a result of the public review.
11.1.3.4 BSR-9 Form	Following the resolution of comments and objections a BSR-9 form shall be submitted requesting BSR approval. In the event of an outstanding, unresolved objection, the objectors shall be advised to their right to appeal, and there shall be a thirty (30) calendar day waiting period to allow the appeals filing period to elapse prior to submitting the BSR-9.
11.1.3.5 BSR-11 Form	In the event that a BSR-9 cannot be filed within a year following the ANSI review period, an extension may be requested using the ANSI BSR-11 form.
11.1.3.6 HSI Intellectual Property License Agreement	Prior to publication or distribution of any HSI standard or derivative works based on any HSI standard by any other organization, HSI and the other organization must execute an intellectual property agreement on a form approved by HSI's CEO.



11.4 Pre-vote Comments

A pre-vote comment period is required before a draft document may be submitted to a committee or subcommittee for vote. During this pre-vote comment period, the committee or subcommittee Members shall be asked to submit written comments accompanied by suggested alternative language.

A document may have multiple pre-vote comment periods. The first comment period shall always be initiated at least fourteen (14) calendar days before the deadline for submitting comments. Subsequent pre-vote comment periods shall last at least seven (7) calendar days. The day the email is sent shall not be considered part of the fourteen (14) calendar day or seven (7) calendar day periods.

When it is intended to submit a standard for consideration as an American National Standard this intention shall be noted when the document is distributed for pre-vote comments.

11.5 Response to Pre-vote Comments

All pre-vote comments that are received shall be reviewed by the group that drafted the document. If a comment is accepted and reflected in a subsequent draft of the document, then this is sufficient acknowledgement of the comment. If a comment is rejected, then the commenter shall be notified and provided with a brief reason for the rejection.

All pre-vote comments shall be reviewed and either accepted or rejected before a document may proceed to the next stage of the development process. A comment chart of all comments received and their respective resolutions shall be kept.

11.6 Votes and Recirculation Votes on Drafts

Except in regard to votes on new work item proposals, membership and officerrelated issues, each member shall vote one of the following positions:

- · Yes: This indicates approval of the document.
- Yes, with comment: This indicates approval of the document and includes an accompanying comment. Approval of the document shall not be contingent on acceptance of the comment.
- No with comment: This indicates disapproval of the document. All no votes should be accompanied by a comment indicating the reason(s) for the no vote and if possible should include specific wording or actions that would resolve the objection);.
- Abstain: This indicates acknowledgement of the vote and expresses no opinion concerning the outcome of the vote.

For votes on new work item proposals, membership and officer-related issues, the yes/no/abstain method of voting shall be followed. Votes with regard to these issues need not be accompanied by reasons and need not be resolved or circulated to the consensus body.

When a "No, with comment" vote is received the committee or subcommittee shall attempt to resolve the comment and advise the commenter of his right to appeal. The comment is resolved if the commenter's vote changes to something other than "No, with comment" in writing. This may happen because of changes to the document or without changes to the document. "No, without comment" votes do not require resolution nor do they require recirculation votes. "No without comment" votes shall be recorded as such on the BSR-9 form during submittal to ANSI.

A recirculation vote is required if substantive (non-editorial) changes are made to a document after it is released for vote. A recirculation vote is also required if attempts to resolve a "no with comment" vote are unsuccessful. Recirculation votes shall be limited in scope to any substantive changes that are made after the document is released for vote, and to the reasons for which any "no with comment" votes remain unresolved. In cases of an unresolved "no with comment" the "no with comment" shall be distributed with the recirculation vote material, along with a description of the efforts to resolve the "no with comment" vote.

Recirculation votes may be conducted via meeting vote or ballot at the discretion of the committee or subcommittee chair and staff. Voting options during a recirculation vote are the same as during an initial vote. Members with voting rights who do not vote during a recirculation vote shall have the original votes that they cast on the initial vote (or the most recent previous recirculation vote, if applicable) recorded for the recirculation vote.

For a document to be approved a quorum must be achieved and at least two thirds (2/3rds) of the voters voting "Yes," "Yes, with comment," or "No, with comment" shall have voted "Yes" or "Yes, with comment." Because of the recirculation vote requirement described above, a document for which a "No, with comment" vote is received cannot be approved on its initial vote. When a recirculation vote is required, the document shall be considered approved if no new "No, with comment" votes are received during the recirculation vote and the two thirds (2/3rds) threshold described above is met. If new "No, with comment" votes are received during the recirculation vote, then the committee or subcommittee shall attempt to resolve them and conduct another recirculation vote following the procedure described above.

If, during the initial vote, more than one third of the voters voting "Yes," "Yes, with comment," or "No, with comment" vote "No, with comment", then the vote fails and attempts to resolve the "No, with comment" votes are not required. When a vote fails, it is up to the committee or subcommittee chair to decide whether to continue or terminate the project.

The consensus body vote shall be conducted and reported in accordance with the rules set forth herein. Votes for the approval of a document or portion thereof as a candidate ANS may be obtained by letter, fax, recorded votes at a meeting or electronic means. All members of the consensus body shall have the opportunity to vote. When recorded votes are taken at meetings, members who are absent shall be given the opportunity to vote before or after the meeting.

11.7 Meeting Vote

When a vote on a standard or bulletin intended for final approval is to be conducted at a meeting it should be listed on the meeting agenda as early as

	possible. If it is not listed on the earliest version of the agenda it shall be listed on a subsequent, revised agenda that is circulated to the committee or subcommittee Members at least fourteen (14) calendar days before the scheduled vote. The day the email is sent shall not count toward the fourteen (14) calendar day period. If a standard is proposed to become an ANSI/HSI standard then this shall be indicated on the agenda. ANSI public review should be initiated at this time if the standard is intended to be an ANSI/HSI standard.
11.8 Vote of alternate	An alternate's vote is counted only if the principal representative fails to vote and the alternate's ballot is cast within the prescribed voting period.
11.9 Single vote	Generally, no representative shall have more than one vote. However, if two or more organizations appoint the same individual to represent each of them, that individual may cast a separate vote for each organization represented. The organizations shall confirm in writing to the Secretary that they are aware of and will accept the results. Additionally, representation of more than one organization by the same individual shall require approval by a majority of the consensus body, excluding the vote of that individual.
11.10 Fourteen (14) Day Draft	A draft of the proposed document highlighting revisions made after it was last circulated to the committee or subcommittee for pre-vote comments shall be distributed to the committee or subcommittee at least fourteen (14) calendar days before the scheduled vote. This draft is called the "14-day draft." The day the email is sent shall not be considered part of the fourteen (14) day period although the day of the meeting vote is.
11.11 Voting period	The voting period for letter ballots shall end four (4) weeks from the date of issue or as soon as all ballots are returned, whichever comes earlier. Ballots shall have a minimum response time of twenty-eight (28) calendar days. At the discretion of the committee or subcommittee chair, a thirty (30) calendar day extension may be granted to achieve quorum.
	A follow-up letter requesting immediate return of the ballot shall be sent, as appropriate, to members and alternate members whose votes have not been received ten calendar days prior to the ballot deadline.
11.12 Absent Voter Ballot	Members with voting rights who are not present at the time of a vote on a document shall be given an opportunity to vote after the meeting. HSI Standards Department shall notify the absent Members' Representatives via email of any substantive changes made to the standard subsequent to its last distribution to the committee or subcommittee, and shall advise the absent Members' Representatives of the deadline for submitting their absentee ballots. This deadline shall be at least seven (7) calendar days after the notification of the deadline by HSI staff. The day the email is sent shall not be included in the seven (7) calendar day period. Absent voting Members who do not respond to the absentee ballot shall be listed as "no response," which shall have the same effect as an abstention when determining if the standard is approved or not.
	Participation in an absentee ballot shall not count as meeting attendance for the purposes of maintaining voting rights. The results of a meeting vote shall be documented in the minutes of the meeting. The minutes shall also include a

	note describing the outcome of the subsequent absentee ballot in those cases when an absentee ballot is required.
11.13 Balloting	Ballots shall be distributed to all Representatives of a committee or subcommittee. Votes shall be accepted from Members with voting rights only. If a standard is proposed to become an ANSI/HSI standard then this shall be indicated on the ballot. ANSI public review should be initiated at this time if the standard is intended to be an ANSI/HSI standard.
	Ballots shall have a minimum response time of twenty-eight (28) calendar days. At the discretion of the committee or subcommittee chair, a ballot period may be extended for up to fourteen (14) calendar days in order to achieve a quorum.
	A new ballot may be considered if quorum was not reached or a large number of substantive changes are made after a previous ballot or meeting vote. If quorum cannot be reached, it is up to the committee or subcommittee chair to decide whether to continue or terminate the project. A ballot shall be closed at its designated closing time. Votes on ballots can be changed up until ballot deadline.
	HSI staff shall acknowledge receipt of ballots either to individual voters as they are received or to the committee or subcommittee as a whole after the ballot closes. In the event of a dispute concerning receipt of a particular ballot, it is up to the voter to provide evidence that the ballot was submitted before the ballot period expired.
	The results of the ballot vote shall be reported to the committee or subcommittee. For a document to be approved a quorum must be achieved and at least two thirds (2/3rds) of the voters voting "Yes," "Yes, with comment," or "No, with comment" shall have voted "Yes" or "Yes, with comment."
	If, during the ballot, more than one third of the voters voting "Yes," "Yes, with comment," or "No, with comment" vote "No, with comment", then the ballot fails and attempts to resolve the "No, with comment" votes are not required. When a ballot fails, it is up to the committee or subcommittee chair to decide whether to continue or terminate the project.
11.14 Optional Reballoting	In some cases it may be desirable to reballot an entire document or reballot a portion of a document in lieu of recirculation. The decision to use the reballot option shall be made by the committee chair in consultation with the HSI Standards Department. If a decision to re-ballot a proposed ANS is made, then this should be communicated to any unresolved objector
11.14.1 Reballoting an Entire Draft Document	When the decision is made to reballot an entire document, the ballot should clearly explain the reason for the reballot. When an entire document is reballoted, the results of that ballot shall supersede the previous ballot and shall be the results which are reported to the committee and included with the BSR-9 submission in the event that the document is submitted for ANSI approval.
11.14.2 Reballoting a	When a decision is made to reballot a portion of the document in lieu of recirculation, the comments are considered in accordance with section 10.16. The results of the reballot shall be included with the BSR-9 submission in the event that the document is submitted for ANSI approval.

Portion of a Document	Documentation of all comment resolution decision including consideration given to all negative ballots shall be recorded on the comment registry provided by HSI and submitted to HSI prior to proceeding to publication.
11.15 Authorization of Letter Ballots	 A letter ballot shall be authorized by any of the following: a) Majority vote of those present at a consensus body meeting; b) The chair; c) The Secretary; d) Petition of one-third (1/3rd) or more members of the consensus body.
11.16 Disposition of Views and Objections	When the balloting has been closed, the secretary shall forward the ballot tally to the chair of the consensus body or, if appropriate, of the subgroup; the chair shall determine whether the expressed views and objections shall be considered by correspondence or at a meeting. Prompt consideration shall be given to the expressed views and objections of all participants, including those commenting on the listing (if applicable) in <i>Standards Action</i> . An effort to resolve all expressed objections shall be made, and each objector shall be advised in writing of the disposition of the objection and the reasons therefore. In addition, each unresolved objector shall be informed in writing that an appeals process exists within procedures used by the standards developer. All substantive changes and unresolved objections, along with attempts of resolution, shall be reported to the consensus body members in order to afford all members an opportunity to respond to, reaffirm, or change their votes on the first ballot and all recirculation ballots within four (4) weeks. Any and all comments, regardless the source, that result in substantive changes to the draft standard shall initiate a Public Review in accordance with these procedures. This Public Review process shall repeat until there are no new substantive changes made to the draft standard. When the above process is completed, in accordance with procedures of the standards developer, the standards developer may consider any comments received subsequent to the closing of the public review and comment period, or shall consider them in the same manner as a new proposal. In cases of objections to any other issue not covered in Actions Requiring Approval by a Majority or Actions Requiring Approval by Two-Thirds (2/3rds) of Those Voting, the Secretary shall defer the matter to the chair for resolution.
11.17 Report of Final Result	The final result of the voting shall be reported, by interest categories, to the consensus body.
11.18 Public Review initiation	Standards that are intended to become American National Standards shall be submitted for public review.
	In addition, proposals for new American National Standards and proposals to revise, reaffirm, or withdraw approval of existing American National Standards shall be transmitted to ANSI using the BSR-8 form, or its equivalent, for listing in <i>Standards Action</i> in order to provide an opportunity for public comment. If it is the case, then a statement of intent to submit the standard for consideration as an ISO, IEC or ISO/IEC JTC-1 standard shall be included as part of the

description of the scope summary that is published in *Standards Action*. The comment period shall be one of the following:

- A minimum of thirty (30) calendar days if the full text of the revision(s) can be published in *Standards Action*;
- A minimum of forty-five (45) calendar days if the document is available
 in an electronic format, deliverable within one (1) calendar day of a
 request, and the source (e.g., URL or an E-mail address) from which it
 can be obtained by the public is provided to ANSI for announcement in
 Standards Action: or
- A minimum of sixty (60) calendar days, if neither of the aforementioned options is applicable.
- Such listing may be requested at any stage in the development of the proposal, at the option of the standards developer, and may be concurrent with final balloting. However, any substantive change, regardless the source, subsequently made in a proposed American National Standard requires listing of the change in *Standards Action*.³

11.19 Public Review Comments

Responsible HSI staff shall receive, collect and acknowledge receipt of all public review comments, regardless of their nature. Editorial, technical and scope-related comments shall be forwarded to the responsible committee or subcommittee for review and response. Comments addressing legal concerns shall be forwarded to HSI CEO for review and response. Comments addressing the HSI standards development process shall be addressed by responsible HSI Standards Department. Vague comments shall be returned to the commenter with a request for expeditious clarification. Comments received during ANSI public review are comments only, they are not votes.

Regardless the source, when addressing substantive (non-editorial) comments, the committee or subcommittee shall conduct a recirculation vote and a second ANSI public review if substantive (non-editorial) changes are made to the document. If a public review comment remains unresolved and no substantive changes are made as a result, a recirculation vote shall be conducted but a second public review shall not be necessary. After a response to an ANSI public review comment has been developed, responsible HSI staff shall provide the response to the commenter in writing and shall include with this response a description of the HSI and ANSI appeals process. The commenter shall be given fourteen (14) calendar days after response to accept or reject the response. If no response is received from the commenter, responsible HSI staff shall send a final written response to the commenter noting the lack of response. The commenter's comments shall then be recorded as unresolved and circulated to the committee or subcommittee. HSI staff shall retain all correspondence related to the comment, the response, and the commenter's response (or lack thereof) and provide this information to ANSI when seeking approval for the standard.

³ Although a 60-day public comment period is not required in all instances, a number of provisions in the *ANSI Essential Requirements*, when read in combination, satisfy the WTO's 60-day rule. Before adopting a standard, ANSI-Accredited Standards Developers shall allow a period of at least 60 calendar days in total for submission of comments on the draft standard if requested by an interested party within the territory of a Member of the WTO. Exceptions outlined in the rule are permitted due to issues of safety, health or environment. (See *WTO Agreement on Technical Barriers to Trade (TBT), Annex 3 Code of Good Practice for the Preparation, Adoption and Application of Standards (CGP) Substantive Provision L.)*

11.20 Request for ANSI Approval	After approval by the HSI committee or subcommittee, and once the ANSI public review period for the standard has closed and any comments received during this period have been addressed, the responsible HSI staff person shall request approval of the standard as an American National Standard by ANSI.
	Evidence of attempts to resolve unresolved public review comments and unresolved "no with comments" votes shall be submitted as needed.
	The information supplied to ANSI by the secretary shall include all relevant material required by ANSI as outlined in clause 2.2 of the Essential Requirements: Due process requirements for American National Standards.
11.21 Other Review	Proposals for new candidate American National Standards or reaffirmation, revision, or withdrawal of existing American National Standards shall be transmitted to ANSI for listing in <i>Standards Action</i> for comment using the BSR-8 form. If it is the case, then a statement of intent to submit the standard for consideration as an ISO, IEC, or ISO/IEC JTC-1 standard shall be included as part of the description of the scope summary that is published in <i>Standards Action</i> .
	The Secretary shall determine whether listing of proposed standards actions shall be concurrent with the final consensus body letter ballot and whether announcement in other suitable media is appropriate. The Secretary shall transmit a copy of the proposed new, revised, or reaffirmed standard to the administrator(s) of the appropriate US Technical Advisory Group(s) at the same time.
	Views, objections, and substantive changes from any source shall be dealt with in accordance with these procedures Any substantive change made in the proposed American National Standard shall be relisted in accordance with these procedures.
11.22 Response from ANSI	If the ANSI Board of Standards Review approves the document responsible HS staff will be notified and may then move forward with the rest of the publication process.
	If the ANSI Board of Standards Review does not approve the document for process-related reasons then responsible HSI staff shall address the ANSI comments. If the ANSI/BSR does not approve the document for reasons related to comment resolution then the responsible committee or subcommittee shall address the ANSI comments.
	If the ANSI/BSR comments are resolved and the document is approved responsible HSI Standards Department may then move forward with the rest of the publication process. If the ANSI/BSR comments cannot be resolved the document shall be returned to the responsible committee or subcommittee for further ANSI comment resolution or cancellation. The committee or subcommittee may appeal the actions of the ANSI/BSR.
11.23 Editorial Privilege Revision	The committee or subcommittee chair, the chair's designated representative, and HSI staff shall have authority to make editorial revisions to the document without further review by the committee or subcommittee for a period of thirty

without further review by the committee or subcommittee for a period of thirty

	(30) calendar days after the final vote on the document. For a meeting vote, this date shall be thirty (30) calendar days after the date of the meeting. For a ballot (full ballot or recirculation), it shall be thirty calendar (30) calendar days after the ballot closing date.
11.24 Legal Review	Standards shall not be considered final until the HSI CEO has reviewed and approved the document.
11.25 Document Maintenance	All published documents other than stabilized and reaffirmed ones shall be reaffirmed, revised or withdrawn by the committee or subcommittee responsible for them not more than five years from the date of publication. Reaffirmed documents shall be reaffirmed, revised, stabilized or withdrawn not more than five (5) years from their date of publication or most recent reaffirmation. Stabilized documents shall be reaffirmed, revised, stabilized or withdrawn not more than ten (10) years from their most recent date of stabilization. Documents should be:
	 Reaffirmed if their content is valid and it is believed they should be reviewed again in five (5) years;
	 Revised if their technical content is valid but needs to be updated or otherwise revised;
	 Stabilized if they have been reaffirmed at least once and at least ten (10) years have passed since their approval or last revision, and if their technical content is valid, addresses mature technology or practices, is not likely to require revision, is not safety related, and is required for use in connection with existing implementations or for reference purposes; or
	 Withdrawn if their technical content is no longer valid.
	If a recommendation is made at any time by a materially affected and interested party that a standard or bulletin maintained under the stabilized maintenance option requires revision or should be withdrawn, then that recommendation shall be considered in the same manner as a new proposal but within a maximum of sixty (60) calendar days from receipt. A recommendation should include rationale to begin a revision, and shall not be dismissed due to the fact that it does not necessarily suggest a specific revision. The submitter of such a recommendation shall receive a written response within sixty (60) calendar days of the receipt of the recommendation and shall be advised of the decision relative to the maintenance status of the standard or bulletin.
	A standard or bulletin that is maintained under the stabilized maintenance option shall include a clear statement of the intent to consider requests for change, and information on how to submit such requests. The procedural requirements for reaffirming, revising, stabilizing or withdrawing a document are the same as for creating a new document.
11.26 Record Retention	Records associated with standards development shall be maintained as described in this section.

11.26.1 New, Revised, or Reaffirmed Documents	These procedures fully adopt the requirements for reaffirmation in the ANSI Essential Requirements current edition, 4.2.1.2 Reaffirmation of an American National Standard Records shall be retained for a minimum of five (5) years or until approval of the subsequent revision or reaffirmation of the complete document.
11.26.2 Stabilized Documents	Records shall be retained until the document is reaffirmed, revised, or subsequently reviewed in connection with its stabilized maintenance.
11.26.3 <u>Criteria</u> for Withdrawn <u>Documents</u>	These procedures fully adopt the requirements of Section 4.2.1.3, Criteria for withdrawal in the ANSI Essential Requirements, current edition. This adoption includes all subsections: Administrative withdrawal (4.2.1.3.1), Withdrawal by ANSI-Accredited Standards Developer (4.2.1.3.2), Discontinuance of a standards project (4.2.1.3.3), and Withdrawal for Cause (4.2.1.3.4)
11.26.4 Adoption of ISO or IEC Standards as ANS	As an Accredited Standards Developer, if HSI wishes to adopt an ISO or IEC standard as an American National Standard, we shall comply with the requirements set forth in the ANSI Procedures for the National Adoption of ISO or IEC Standards as American National Standards.
12.0 Appeals 12.1 Appeals	Once the voting process is complete, HSI documents should not be published until the window for filing appeals has closed. Whenever attempts to resolve "no with comment" votes or public review comments are unsuccessful, the commenter shall be notified in writing of the right to appeal.
12.1.1 Right of Appeal	Persons with a direct or material interest in an HSI document who have been or will be adversely affected by the document may appeal substantive or procedural actions or inactions taken during the HSI standards process. In the case of an appeal to ANSI of an HSI action or inaction on an ANSI/HSI standard. However, ANSI will not normally hear an appeal of an action or inaction by HSI until the HSI appeals process has been completed. Appeals to ANSI shall be directed to ANSI in accordance with the procedures of the appropriate ANSI entity (e.g., Board of Standards Review, Executive Standards Council, etc). If an appellant chooses to forego the HSI appeals process for any reason, the HSI Standards Department shall maintain all documents pertaining to HSI attempts to resolve the matter at hand. These documents may be used in any further appeals proceedings
12.1.2 Appeal Initiation	Appeals shall be written and filed with the HSI staff member who is responsible for standards activities within twenty-eight (28) calendar days after the date of the action being appealed or at any time with respect to inaction. The appeal

shall state the nature of the objection(s) including the adverse effects on the appellant, the section(s) of these procedures or the standard(s) at issue, action(s) or instances of inaction at issue, and the specific remedial action(s) that would satisfy the appellant's concerns. Previous efforts to resolve the objection(s) and the outcome of each shall be noted.

12.1.3 Response to an Appeal

Upon receipt of an appeal, the relevant committee or subcommittee chair, or a representative of the HSI Standards Department, shall first attempt to informally resolve the appeal within fourteen (14) calendar days. If this is successful, then the relevant committee or subcommittee chair, or a representative of the HSI Standards Department, shall respond to the appellant in writing addressing each allegation of fact in the appeal within twenty-eight (28) calendar days of receipt of the appeal.

If the appeal cannot be resolved informally, then HSI Standards Department shall schedule a hearing with an appeals panel on a date agreeable to all participants that is within forty-two (42) calendar days of the date the appeal was received, giving at least ten (10) calendar days' notice.

12.1.3.1 Composition of Appeals Panel

If an appeals panel is necessary, it shall consist of three (3) individuals who have not been directly involved in the matter in dispute, and who (knowingly in good faith) will not be materially or directly affected by any decision made in the dispute. At least two (2) individuals shall be acceptable to the appellant and at least two (2) shall be acceptable to the HSI Standards Department. In the event the appellant does not wish to select a panelist or a third panelist cannot be agreed upon, the HSI Standards Department shall appoint these individuals to the panel (noting this action in the findings) in order to hold a hearing.

12.1.3.2 Conduct of Hearing

If an appeals panel is necessary, it shall convene at HSI's offices unless another mutually agreed site is selected. The appeals panel shall select a presiding officer from among the panel. The appellant has the burden of demonstrating adverse effects, improper actions or inactions, and the efficacy of the requested remedial action. The HSI Standards Department has the burden of demonstrating that the HSI entity in question took all actions in compliance with its operating procedures and that the requested remedial action would be ineffective or detrimental. Each party may make other pertinent arguments, and members of the appeals panel may address questions to the appellant and HSI representatives.

12.1.3.3 Appeals Panel Decision

An appeals panel shall render a written decision within twenty-eight (28) calendar days following the close of the hearing. This decision shall state findings of fact, conclusions, and the reasons for the conclusions. Decisions shall be determined by a two-thirds (2/3rds) majority of the appeals panel. A record of the appeal shall be kept by HSI and made available to the involved parties.

If the appeals panel finds for the appellant, it should describe with specific facts how fair and equitable action was not taken and remands the matter to the Standards Department with an explanation of the recommended corrective action.

If the appeals panel finds for the respondent, it should describe with specific facts how fair and equitable action was taken with respect to the appellant and the appellant's objections.

If the appeals panel finds that new, substantive evidence has been introduced, it should describe this evidence and remand the matter to the responsible HSI entity for appropriate reconsideration. HSI shall not publish a document for which there is an unresolved pending appeal.

12.2 Appeals

Materials associated with the conduct of appeals shall be retained for a minimum of five years, or until such time as the document that was the subject of the appeal has been withdrawn, whichever is longer

13.0 Termination

13.1 Termination of a Standards Committee

A proposal to terminate a standards committee may be made by a directly and materially affected interest. The proposal shall be submitted in writing to the HSI and shall include at least the following:

- a) Reasons why the standards committee should be terminated;
- b) The name(s) of the organization(s) that will assume responsibility for maintenance of any existing American National Standard(s) that is(are) the responsibility of the consensus body.

If it appears, after discussion among the proponent of the action and HSI, that the desired objectives can best be reached by termination, the proposal and supporting documentation shall be submitted to the committee with a letter ballot to terminate the committee and transfer responsibility, as appropriate, for the affected standards

14.0 Legal Issues

14.1 Legal Issues and Intellectual Property Rights (IPR)

All committees and subcommittees shall adhere to the general rules applicable to all HSI activities, noting specifically Intellectual Property Rights (IPR) in accordance with HSI Legal Guidelines for standards development in all matters pertaining to HSI and its standardization programs. When developing an ANSI/HSI standard ANSI's legal guidelines in the ANSI Essential Requirements shall be followed.

The HSI Legal Guidelines for standards development shall govern all standards development activities conducted by HSI Standards committees and subcommittees. Annex A contains the HSI Legal Guidelines for Standards Development.

14.2 Disclosure of Essential Patents

There is no objection in principle to drafting a proposed HSI standard or American National Standard in terms that include the use of an essential patient claim (one whose use would be required for compliance with that standard), if it is considered that technical reasons justify this approach. Participants in the ASD/ANSI standards development process are required to bring patents with claims believed to be essential to the attention of the ANSI-Accredited

Standards Developer (ASD). If an ASD, the committee or subcommittee receives notice that a proposed, revised or approved ANS may require the use of such a patient claim, the procedures in clause 14.4 shall be followed.

The standards development and approval process is made more efficient if the existence of essential patents (and essential pending patents) is made known as early as possible in the development work.

Conversely, the discovery at the final stages of standards development of an essential patent (or pending patent) that is not available for licensing under reasonable terms and conditions may result in the loss of years of committee or subcommittee effort. It is therefore required that committee and subcommittee Representatives disclose any knowledge they may have of existing essential patents (or an intent to patent items whenever appropriate) affecting the work. Chairs and HSI staff should remind committee and subcommittee Representatives of this responsibility.

14.3 General Patent Policy Guidelines

Discussion of a pending or existing patent does not constitute an acknowledgment of the validity of the patent since validity is based on prior art and determination of who first made application or discovered the technique or process. Discussion, if any, shall concern whether the patent's technical content is suitable for, or applies to, the standardization effort at hand.

By its terms, the HSI patent policy applies with equal force to situations involving:

- (1) the discovery of essential patents that may be required for use of a standard subsequent to its adoption, and
- (2) the initial issuance of an essential patent after adoption. Once disclosure is made, the holder is obligated to provide the same assurance to HSI as is required in situations where essential patents exist or are known prior to approval of a proposed standard as an HSI standard.

Thus, if notice is given of a patent that may be required for use of an already approved HSI standard, HSI may wish to make it clear to all Representatives that the HSI procedures require the patent holder to provide the assurances contained in the patent policy or suffer the withdrawal of HSI approval of the document as an HSI standard and ultimately as an American National Standard.

14.4 HSI and ANSI Patent Policies

These Procedures welcome in principle to drafting an American National Standard (ANS) in terms that include the use of an essential patent claim (one whose use would be required for compliance with that standard) if it is considered that technical reasons justify this approach.

If HSI receives a notice that a proposed ANS or an approved ANS may require the use of such a patent claim, the procedures in this section shall be followed.

Reasonable efforts shall be made to notify member representatives that they are required to identify essential patents at the earliest point in standards development. The proffer should be provided no later than seven (7) calendar days prior to the vote to approve. These efforts shall include a call for

intellectual property (IP) proffers (assurances) on all draft standards. In addition, calls for disclosure may be made during meetings.

While committee and subcommittee representatives are obligated to disclose knowledge they may have of essential patents, they are not obligated to conduct a patent search for such patents. Requirements in HSI standards that are known to call for use of an essential patent claim or process may not be knowingly considered by committees and subcommittees unless the responsible chair and HSI Standards Department have received a statement from the patent applicant, holder or a party authorized to make assurances on its behalf, in written or electronic form, either:

- a) assurance in the form of a general disclaimer to the effect that such party does not hold and does not currently intend holding any essential patent claim(s); or
- b) assurance that a license to such essential patent claim(s) will be made available to applicants desiring to utilize the license for the purpose of implementing the standard either:
 - i. under reasonable terms and conditions that are demonstrably free of any unfair discrimination; or
 - ii. without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination.

Such assurance shall indicate that the patent holder (or third party authorized to make assurances on its behalf) will include in any documents transferring ownership of patents subject to the assurance, provisions sufficient to ensure that the commitments in the assurance are binding on the transferee, and that the transferee will similarly include appropriate provisions in the event of future transfers with the goal of binding each successor-in-interest.

The assurance shall also indicate that it is intended to be binding on successors-in-interest regardless of whether such provisions are included in the relevant transfer documents.

The statement from the patent holder should be stated in Annex B (Normative). HSI will not accept statements which are conditional, or which reveal the terms of licensing. Notwithstanding the foregoing, IP owners are under no duty to license their IP or to license on reasonable terms and conditions that are demonstrably free of any unfair discrimination.

Statements from the patent holders shall be submitted to the HSI CEO for review. HSI does not have the expertise to evaluate each patent, application or license, and relies on the applicant's or holder's statement. In addition, HSI shall not be responsible for identifying any patents for which a license may be required by an HSI or ANSI/HSI standard, or for conducting inquiries into the legal validity or scope of those patents that are brought to its attention. The Secretary will provide a copy of the patent holder statement to ANSI within sixty (60) calendar days of receipt and retain the original statement on file.

In general, HSI and ANSI have similar patent policies. Both HSI and ANSI patent policies were designed to balance the rights of the patent holder to exploit its legal monopoly in connection with its technology and the rights of

readers of the standard to have access to technology that is essential to implement the standard. HSI and patent holders both have responsibilities in connection with HSI's and ANSI's patent policies. HSI shall respond to any assertion by a patent holder, request that the holder by some date certain state definitively whether the holder's technology is "essential", and if so, ask the holder if it is willing to license the technology on reasonable terms and conditions demonstrably free from unfair discrimination.

When an HSI standard is developed for submission to ANSI as an American National Standard, the *ANSI Essential Requirements* shall control to the extent there is any inconsistency with HSI's rules and procedures. Each HSI or ANSI/HSI standard shall carry the following notification in its "Notice":

Standards and Publications are adopted by HSI in accordance with American National Standards Institute (ANSI) patent policy. By such action, neither HSI nor ANSI assume any liability to any patent owner, nor do they assume any obligation whatever to parties adopting the Standard or Publication. Neither HSI nor ANSI take any position with respect to the validity of any claimed patent rights relating to this standard. Neither HSI nor ANSI are responsible for identifying patents for which a license may be required in order to comply with any HSI standard or American National Standard.

When the committee or subcommittee receives an assurance from a patent holder, the standard shall include a note as follows:

NOTE—The reader's attention is called to the possibility that compliance with this standard may require use of an invention covered by patent rights. By publication of this standard, no position is taken with respect to the validity any such claim(s) or of any patent rights in connection therewith. If the patent holder has filed a statement of willingness to grant a license under these rights on reasonable and nondiscriminatory terms and conditions to applicants desiring to obtain such a license, then the details may be obtained from HSI.

If the patent holder chooses not to make its technology available and the technology is essential to implementation of the HSI or ANSI/HSI standard, then it may be necessary to revise or withdraw the standard. A copy of all identified statements from patent holders received by HSI shall be forwarded to ANSI.

14.5 Copyrighted Material

If, in developing a document, a committee or subcommittee proposes to incorporate verbatim material from a publication copyrighted by a non-Member such as another organization then a committee or subcommittee Member or HSI staff shall obtain written permission from the owner of the copyright for HSI to reprint the material and include an appropriate reference to such permission in the standard as a footnote.

The following copyright statement shall be provided for any written contribution intended for inclusion in an HSI document (for which the contributor possesses a copyright): The contributor grants a free, irrevocable license to HSI to incorporate text or other copyrightable material contained in this contribution and any modifications thereof in the creation of an HSI document; to copyright and sell portions of this contribution; and at HSI's sole discretion, to permit

others to reproduce in whole or in part such contributions or the resulting HSI document.

The contributor will grant licenses under such copyrights to third parties on reasonable, nondiscriminatory terms and conditions, if appropriate, including the right to develop derivative works by HSI and implementers of the HSI document that incorporates this text.

Reference to such permission shall be noted in the standard. If a committee or subcommittee proposes to incorporate verbatim material, in whole or in part, from an ISO/IEC standard, the chair shall consult appropriate HSI Standards Department staff member for appropriate procedures and further details.

14.6 Committee Member Contributions

Committee, subcommittee, and working group Members agree that, as a condition of their participation, copyright of any new material created during the course of an HSI meeting will be held by HSI.

Representatives who contribute material to be used in an HSI document agree to provide a free, irrevocable license to use the contribution in any HSI publication. (Where the information is not subject to copyright protection, no license is necessary.)

Contributions made by anyone participating in HSI standards activities shall be free of "proprietary," "organization confidential," or other similar claims.

14.7 Commercial Terms and Conditions

Except as otherwise permitted by these HSI Procedures, ANS shall not include terms or conditions that are primarily contractual or commercial in nature, as opposed to technical, engineering or scientific in nature. Thus, for example, an ANS shall not include contractual requirements (ANSI Essential Requirements 3.2.1); endorse or require the use of proprietary products or services (ANSI Essential Requirements 3.2.2); or endorse or require the use of particular conformity-assessment bodies, testing facilities or training organizations (ANSI Essential Requirements 3.2.3).

Refer to the ANSI Essential Requirements, current edition, for specific requirements and obligations.

14.8 Review of International Standards

It is the policy of the U.S. National Committee (USNC) of the International Electrotechnical Commission (IEC) to work toward commonality between IEC Standards and U.S. National Standards. Commonality between IEC Standards and HSI standards shall also be an objective. During the development of an HSI standards proposal, the HSI committee or subcommittee should conduct a review and compare the standards proposal with any similar IEC or ISO standard. When similar IEC or ISO standards exist, a determination should be made regarding the extent to which the HSI standards proposal is based on an existing international standard. When similar IEC or ISO standards do not exist, it shall be recognized during the development of the HSI standards proposal that the resulting standard may represent a basis for a U.S. position in the development of an international standard.

14.9 Exploitation Rights

HSI holds the copyrights to all HSI standards and technical reports and claims exploitation rights and entitlement to all royalties from the sale of published HSI standards and technical reports, or licensing arrangements with third parties for

the publication/distribution of HSI standards and technical reports in either print or electronic media. Revenues are used to help defray a portion of the administrative costs incurred by the Secretariat in conjunction with the performance of its responsibilities and duties to the HSI community and to ANSI during the development, processing, publication and distribution of HSI standards and technical reports.

14.10 Anti-Trust Policy

American National Standards shall be developed in accordance with applicable antitrust and competition laws and meetings amongst competitors to develop American National Standards are to be conducted in accordance with these laws.

Annex A: Legal Guidelines for Standards Development (Normative)

PART I: GENERAL GUIDES APPLICABLE TO HSI STANDARDS DEVELOPMENT ACTIVITIES This Part I includes general guides applicable to HSI standards development activities. They are required to be read and followed by all members of the HSI Standards Department, chairs, and members of all committees, sections, divisions, and other HSI-sponsored groups involved in the development of standards.

Section A. IMPROPER ACTIVITIES AND PROGRAMS

HSI standards activities or programs relating to any of the following subjects are improper and are not permitted:

- (1) Restraint of Trade Agreements. The establishment of prices, production quotas, or uniformity of conduct, the allocation of customers or markets, standard terms or conditions of sale, boycotts, or other competitive restraints are improper activities. Therefore, any activities within, or in conjunction with, HSI standards meetings relating to any of these matters are improper and committee chairperson, staff and participants should take affirmative action to assure that no such discussions are initiated or pursued.
- (2) Prices and Pricing Policies. Any consideration or discussion of product prices or industry pricing policies is improper and therefore not permitted. This applies to all discussions and casual remarks relating to individual organization prices, changes in prices, or general price levels whether involving formal or informal exchanges between participating representatives. Such discussions are improper and must be avoided.
- (3) Terms and Conditions of Purchase and Sale. Any discussion at, or in conjunction with, HSI standards meetings of terms and conditions of purchase and sale, including but not limited to warranty and warranty periods, discounts, allowances, or terms of credit, or the formulation of uniform or standard terms and conditions of purchase for sale, uniform basing points or zoning prices, or the recommendation thereof for voluntary use by the membership also is improper and is prohibited. It is usually proper, however, to discuss and propose comments and recommendations to Government agencies relating to general contract

- provisions, or modifications thereof, or other procurement practices or policies proposed or adopted by such agencies.
- (4) Costs. Programs or activities involving the exchange of information relating to individual organization costs of production or distribution and any formulas for computing such costs are improper. Discussions at HSI standards meetings of industry costs are normally not permitted.
- (5) Future Plans. Programs involving the exchange of organization information relating to future plans affecting the design, research and development, production, and distribution or marketing of products and services are also improper. Any discussions at HSI standards meetings relating to such programs are not permitted.
- (6) Boycotting Customers or Products. Any activity involving the blacklisting or boycotting of customers, competitors, suppliers, or others or establishment of patterns of uniform dealing is improper. Therefore, there shall be no activities relating to any form of boycotting or any activity which may be interpreted as such.

Section B.
PROCEDURES
FOR
CONDUCTING
ACTIVITIES

- (1) Notices and Agendas. Notices and agendas for HSI standards meetings shall be prepared in advance and distributed prior to the date of the meeting. Agendas shall not include any subjects which are stated as improper for consideration or discussion under the rules established in these Legal Guidelines. Whenever feasible, background information which would be helpful in the consideration of items on the agenda should be distributed in advance of meetings.
- (2) Conduct of Meetings. All meetings shall be conducted in such a way as to assure ample opportunity and freedom in the exchange of ideas and an equal voice in all decisions. Committee chairperson and HSI staff personnel shall make sure that all actions and discussions at meetings are kept within the bounds of proper HSI standards activity. Committee chairperson should immediately rule out of order discussion deemed improper or questionable under the policies set forth herein until the propriety of such discussion has been determined by the CEO. If any doubt exists concerning the propriety of a program, either from a legal or policy point of view, it shall not become final or effective until after review by the CEO. Committee chairperson should follow the published agenda and not depart therefrom except for a good and legitimate reason, in which event the minutes should record the reasons for such departure.
 - (a) Voting in Committees. All Committees shall adopt rules consistent with these Guides to insure that each organization represented shall be entitled to vote in a manner that will give equal weight to the vote of each organization represented on the Committee, regardless of the number of representatives from any one (1) organization, if there should be more than one.
- (3) Preparation and Review of Minutes. Detailed minutes of all meetings shall be taken and recorded. Minutes shall include the time and place of the meeting, a list of all committee members and non-members

- attending, a statement of all matters discussed and actions taken with appropriate reasons therefore, and a record of all voting.
- (4) Duty of Good Faith. HSI standards members and committee, discovery group and working group participants, especially members of any Board, have a duty of good faith to HSI. This duty extends to maintaining confidentiality and disclosing any non-obvious conflicts of interest. Members have a duty to avoid specific interests that might prevent progress by HSI sponsored groups and, if a conflict of interest arises, each member has a duty to disclose the conflict to the other members of the group and to HSI staff.
- (5) Duty of Confidentiality. HSI standards members have a duty to keep information that is disclosed in HSI meetings in confidence. Confidential information is any visual, oral or written information that is designated as confidential or that a reasonable person would understand from the context to be confidential. HSI standards members must not disclose confidential information to any non-member or third-party, including the media. Issues discussed and agreed upon in HSI meetings should be disclosed to media only through HSI Standards department.

Annex B: Patent Holder Statement (Normative)

STATEMENT FROM PATENT HOLDER		
Date: Reference Document: (refer to ANSI/HSI or HSI standard/bulletin or title) (One form per document)		
Patent or Patent Application Number(s):		
Organization Name:		
Address:		
Contact		
Phone		
Email		
With respect to any essential patents held or controlled by the organization, pending or anticipated to be filed necessary to implement the above document (mark with an "X" those applicable):		
The organization states:		

	It does not hold and does not anticipate holding any patented invention the use of which would be required for compliance with the proposed HSI Standard/Bulletin
	or
	The organization states one of either:
	(i) A license will be made available without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination to applicants desiring to utilize the license for the purpose of implementing the proposed HSI Standard/Bulletin;
	or
	(ii) A license will be made available to applicants under reasonable terms and conditions that are demonstrably free of any unfair discrimination.
	and
	Finally the organization states that:
	as the patent holder (or third party authorized to make assurances on its behalf) will include in any documents transferring ownership of patents subject to the assurance, provisions sufficient to ensure that the commitments in the assurance are binding on the transferee, and that the transferee will similarly include appropriate provisions in the event of future transfers with the goal of binding each successor-in-interest. This assurance is intended to be binding on successors-in-interest regardless of whether such provisions are included in the relevant transfer documents.
	Agreed, on behalf of the above organization:
	(Signature)
	(Name printed)
	(Date)
Annex C: Statement from Copyright Holder	Contact Person regarding patents and intellectual property matters:
	(Name Printed)
	Title:
(Normative)	Telephone: Fax:

E-mail:
On behalf of the above organization, and being authorized by the organization to make such representations, we indicate the following:
(Organization Name, hereinafter "organization")
hereby grants a free, irrevocable license to the HSI to incorporate text or copyrightable material contained in any organization contributions and any modifications thereof in the creation of an HSI standards publication; to copyright and sell in HSI's name any HSI standards publication even though it may include portions of the contribution; and at HSI's sole discretion to permit others to reproduce in whole or in part such contributions or the resulting HSI standards publication. The organization will also be willing to grant licenses under such copyrights to third parties on reasonable, non-discriminatory terms and conditions.

Appendix D: Standards Interpretation Policy Official interpretations concerning the material in HSI or ANSI/HSI documents shall be made by the committee or subcommittee responsible for the document, using the same procedures that are used to approve an HSI or ANSI/HSI standard or bulletin. HSI staff shall arrange legal review prior to issuing the interpretation. Interpretations shall be made available upon written request. Interpretations on file should be considered during the next revision of the standard.

Requests for interpretation of standards shall be made in writing and addressed to the Director, Standards department, HSI, 10231 Kotzebue St., San Antonio, TX 78217. Under no circumstances is a committee or working group member authorized to interpret HSI standards. Interpretation includes officially responding on behalf of HSI as to whether a specific, named service, practice, metric, product or class of services, practices, metrics, or products meets the requirements of an HSI standard or whether procedures, metrics, and practices not addressed in an HSI standard are acceptable. Official interpretations of HSI Standards shall be made in writing by the HSI or its designee (i.e. appropriate standard committee or subcommittee). No person shall have the authority to issue, an interpretation of an American National Standard in the name of the American National Standards Institute or the HSI.

Due to the complex nature of the interpretation request, HSI cannot guarantee a turnaround time for responding to requests, and all inquirers will be advised of this at the time the request for interpretation is taken under consideration.

In the event that the HSI Standards Department determines that there is insufficient expertise or resources available to respond to the interpretation request in a timely manner in accordance with the Procedures, the inquirer shall be notified in writing that HSI cannot provide an interpretation.

Completed interpretations will be sent to the inquirer and the appropriate HSI committee, and periodically published or made available electronically.

Appendix E:
Standards
Metric Policy

Units of the International System of Units (SI), the modernized metric system, are the preferred units of measurement in HSI and ANSI/HSI standards and bulletins

In order to maintain consistency between the various ANSI/HSI Standards, all HSI Standards include SI units as defined in NIST Special Publication 811, 2008 Edition, *Guide for the Use of the International Systems of Units (SI)*.