



Instructions for voting and commenting on national and US TAG ballots conducted by AAMI

General

All committee members must return a ballot.

Negative votes **MUST** be accompanied by rationale.

If you do not use AAMI's electronic ballot and comment form:

1. To submit your vote electronically, in your email message provide:
 - a. Designation of document and ballot deadline (see ballot or comment form, p.1)
 - b. Your responses to all sections of the ballot or comment form, being sure to identify your answers by the form heading or number. In the case of check boxes, simply type the text that applies in your situation and exclude all other options.
 - c. Attach your comments, if any, or type them directly into your email message (see next item for format). If you vote "Abstain," be sure to include a brief explanation for why you are abstaining.

NOTE: AAMI uses WORD97 as its word processor. If you send comments as an email attachment and use a later version of WORD or some other software, AAMI will try to convert the document, however this may not be successful. Therefore, you also should mail or fax a copy of your comments to AAMI.

2. If you have comments, either recreate the AAMI comment table using your own word processing program, or if you are unable to set up a table, set forth your comments as follows:

Section: (identify by clause number, e.g., 1.1.2; for unnumbered sections, identify by heading text, e.g., Introduction)

Item: (if applicable, identify more specifically what part of the section you are commenting on by paragraph #, line #, table, figure, etc.)

Comment Type: ("T" for Technical, "E" for Editorial, or "G" for General)

Comment/objection:

Rationale: (ie, rationale for comment/objection)

Suggested alternative text: (ie, text that if included in the draft would resolve your comment)

Section:

Item:

Comment Type:

Comment/objection:

Rationale:

Suggested alternative text:

Etc.

NOTE: Typographical errors need only identify the page number, line, and word. Strictly editorial comments may be treated similarly.

Proof your comments carefully, especially the section number to which your comment refers. Do not submit marked-up copies of the document as your comments.

Committee Obligations to Commenters

For comments that are rejected or that are not accepted in their entirety, the committee must provide an explanation, unless the comment is of a vague, general nature and does not identify specific objections to the text; and/or the **comment** is not clear or not persuasive because it is not accompanied by rationale, suggested alternative text, or both are lacking. Negative **votes** must be accompanied by rationale, otherwise, they may be dismissed as nonpersuasive.

In summary, committees are obliged to respond to clearly stated, clearly justified concerns, not to speculate on why a commenter is concerned or on what sorts of changes would satisfy him/her. All comments and objections, whether accompanying affirmative or negative ballots, should therefore be **specific** and clearly identify the section paragraph containing the offending text, the reasons for the objection, suggested alternative text that would resolve the commenter's objection, and, in the case of substantive technical objections, a refutation of the existing rationale.

Guidelines on voting

AAMI drafts and international drafts being considered by AAMI for parallel US adoption

(excerpted from "AAMI Standards and Technical Publications Program: Policies and Procedures Manual.")

A committee member or invited reviewer should vote:

"Affirmative" if he/she endorses the document exactly as presented;

"Affirmative with comments" if his/her comments are of an editorial nature or can be resolved without substantive technical changes in the text, or if the committee member supports the document regardless of whether or not his/her comments are accepted.

"Negative" if substantive technical changes would be necessary to resolve his/her concerns; or

"Abstain."

NOTE: It is not necessary to vote negative in order to assure committee consideration of comments. Committees are obliged to seriously consider and respond to all comments, whether accompanying affirmative or negative ballots, except as qualified below.

International drafts that AAMI is developing U.S. position on (without parallel adoption as U.S. standard)

Excerpted from *Criteria for the development and coordination of U.S. Positions in the International Standardization Activities of the ISO and IEC*, by the American National Standards Institute

B6 Guidelines for determining a U.S. voting position

The development of a U.S. position with regard to voting on international documents is a matter of great complexity. Firm rules for casting affirmative votes, negative votes, or abstentions would be presumptuous and unworkable in many cases. On the other hand, efforts should be made to achieve consistency in the perceived conduct of the United States as a participant in international, non-treaty standards development. Toward that end, guidelines for determining a voting position are included herein in order to provide direction toward a consistent voting policy. These guidelines cannot cover all of the factors which must be considered in determining the U.S. vote. They do, however, represent generally accepted principles which should be applied to normal situations.

B6.1 If there is an existing U.S. national standard (i.e. an American National Standard or, in the absence of an American National Standard, another standard generally accepted within the United States) and —

1. If the national standard can be considered equivalent¹ to the requirements in the international document, vote affirmative.
2. If the international document includes different, additional, or more stringent requirements than are in the national standard and the U.S. consensus indicates that such requirements are:
 - a. acceptable and should be considered for inclusion in the national standard, vote affirmative, or
 - b. not acceptable, vote negative.
3. If the national standard includes different, additional, or more stringent requirements than are in the international document and the U.S. consensus indicates that such requirements:
 - a. should be modified in accordance with the international document, vote affirmative, or
 - b. must be maintained, vote negative, or
 - c. must be maintained, but the proposed document is considered to represent the best agreement which can be reached at the present time from an international point of view, vote Abstain with a statement that the U.S. cannot modify its national standard for stated reasons.

B6.2 If no national standard exists and —

1. If U.S. consensus establishes that the international document is:
 - a. technically acceptable and could be used as a basis for the development of a national standard, vote affirmative, or
 - b. not technically acceptable, vote negative.
2. If the international document is of little or no interest to the U.S., abstain.
3. If the international document unnecessarily creates a barrier to domestic or international trade or impedes innovation or technical progress, vote negative.

B6.3 Regardless of whether or not a national standard exists —

If no U.S. consensus has been established, abstain.

B6.4 The U.S. vote, if negative, must be accompanied by reasons and supporting information such as technical data and logical argument. Also, any known exceptions and/or additions that will be required to conform with U.S. safety practices or regulations shall be noted.

B6.5 Exceptions. Exceptions to the above stated voting guidelines should be carefully considered.

¹The word "equivalent" is intended to convey the thought that any product or procedure which meets the requirements of the national standard will also meet the requirements of the international standard and vice versa when tested for conformance by accepted means