AAMI U.S. TAG
Policies and Procedures
for
ISO Activities

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AAMI U.S. TAG Policies and Procedures for ISO Activities

1 General

These procedures for U.S. Technical Advisory Groups (U.S. TAGs) meet the requirements for due process and coordination in the development of U.S. positions for ISO activities as given in Annex B of the ANSI Procedures for U.S. Participation in the International Standards Activities of ISO. A U.S. TAG consists of its members and its U.S. TAG Administrator. A particular U.S. TAG is related to a particular ISO committee (e.g., "U.S. TAG for ISO/TC xx.").

Subgroups of U.S. TAGs or separate U.S. TAGs may be formed to relate to subcommittees of an ISO technical committee. Where the U.S. TAG to an ISO subcommittee is not independently accredited in accordance with 2.5.4 of the ANSI Procedures for U.S. Participation in the International Standards Activities of ISO, the degree of independent authority to take actions shall be defined in writing (as part of the TAG procedures, or as a policy or agreement) and shall be approved by the parent U.S. TAG, and a copy provided to ANSI.

2 Functions and Responsibilities

The functions and responsibilities of the U.S. TAG, subject to ISO rules and limitations, are:

1. Recommend registration of ANSI as a P- or O-member (participant or observer) on an ISO committee, recommend a change in ANSI membership status on an ISO committee or recommend termination of membership as a P- or O-member on an ISO committee.

2. Initiate and approve U.S. proposals for new work items for submission by ANSI for consideration by an ISO committee.

3. Initiate and approve U.S. working drafts for submission by ANSI to ISO committees (and, where appropriate, Working Groups) for consideration as committee drafts.

4. Determine the U.S. position on an ISO draft International Standard, draft technical report, committee drafts, ISO questionnaires, draft reports of meetings, etc.

5. Provide adequate U.S. representation to ISO committee meetings, designate heads of delegation and members of delegations, and ensure compliance with the ANSI Guide for U.S. Delegates to IEC/ISO Meetings (including preparation and submission of a Head of Delegation report by the designated Head of Delegation).

6. Determine U.S. positions on agenda items of ISO committee meetings and advise the U.S. delegation of any flexibility it may have on these positions.


8. Provide assistance to U.S. secretariats of ISO committees, upon request, including resolving comments on draft international standards, draft technical reports, and committee drafts.
9 Identify and establish close liaison with other U.S. TAGs in related fields or identify ISO or IEC activities that may overlap the U.S. TAG's scope.

10 Recommend to ANSI the acceptance of secretariats for ISO committees.

11 Recommend that ANSI invite the ISO committees to meet in the United States (see 1.4 of ANSI Procedures for U.S. Participation in the International Standards Activities of ISO).


3 U.S. TAG Administrator

The U.S. TAG Administrator shall be designated by the ANSI Executive Standards Council (ANSI ExSC) upon recommendation of its designee, if any, and shall accept, in writing, the responsibilities described below:

1 Organizing the U.S. TAG and applying to ANSI for approval of the TAG Administrator and initial TAG membership list and accreditation of the TAG.

2 Submitting the U.S. TAG membership list, annual compliance form and annual report to ANSI by established deadlines for review by the ANSI ExSC or its designee.

3 Determining that the members of the U.S. TAG participate actively.

4 Providing for administrative services, including arrangements for meetings, timely preparation and distribution of documents related to the work of the U.S. TAG, and maintenance of appropriate records, including minutes of meetings and results of letter ballots.

5 Upon request by an interested party, making available, the roster of the TAG including each member’s name (or if membership is by organization, the name of the organization with a point of contact), affiliation and interest category.

NOTE “Affiliation” refers to the entity that the U.S. TAG member represents (which may or may not be that person’s employer). If the TAG member is serving in an individual capacity, then the name of the individual, that person’s employer (if employed), sponsor (if other than employer) and interest category should be available. Contact information is not required.

6 Transmitting U.S. proposals and U.S. positions, as developed and approved by the U.S. TAG, to ANSI.

7 Transmitting to ANSI U.S. delegates lists for all international meetings.

8 Establishing a procedure to hear appeals of actions or inactions of the U.S. TAG.

9 Establishing a written antitrust policy reflecting the TAG’s practice to conduct all business and activity in compliance with applicable antitrust laws.

10 Complying with the requirements associated with ANSI oversight and supervision of activities of the U.S. TAG and its administration in accordance with 2.5.5 of the ANSI Procedures for U.S. Participation in the International Standards Activities of ISO.
11 Ensuring compliance with applicable ANSI and ISO procedures.

12 Completing mandatory training offered by ANSI to support compliance with ANSI procedures governing the administration of the U.S. TAG and representation of U.S. interests at ISO.

13 Paying all relevant fees to ANSI.

14 Providing to ANSI three (3) months prior written notice if the organization that serves as the TAG Administrator is unable to continue to serve and intends to relinquish this role.

4 Officers

There shall be a chairman, and other officers if required, appointed by the U.S. TAG Administrator from the individual members of the U.S. TAG, subject to confirmation by the U.S. TAG, or if formal objections are received, to approval by a majority vote of the U.S. TAG. Each will serve until a successor is selected and ready to serve. The secretary shall be appointed by the U.S. TAG Administrator.

5 Membership

Membership shall be open to all U.S. national interested parties who indicate that they are directly and materially affected by the activity of the U.S. TAG, after being informed concerning U.S. TAG working procedures and scope of activities. There shall be no undue financial barriers to participation. Administrative fees may be charged by the TAG Administrator, but in all cases procedures for requesting a waiver of the fees must be available. Participation shall not be conditional upon membership in any organization, or unreasonably restricted on the basis of technical qualifications or other such requirements.

5.1 Application

A request for membership shall be addressed to the U.S. TAG Administrator, shall indicate the applicant's direct and material interest in the U.S. TAG's work and willingness to participate actively (see 5.8) and in accordance with the AAMI Code of Conduct, the applicant's interest category, and, if the applicant is a representative of an organization, company, or government agency, shall identify an alternate, if desired.

5.2 Recommendation

In recommending appropriate action on applications for membership, the administrator shall consider:

1 The appropriateness of the involvement of each interest in the work of the U.S. TAG

2 The potential for dominance by a single interest

3 The extent of interest expressed by the applicant, and the applicant's willingness to participate actively

The U.S. TAG Administrator may consider reasonable limits on U.S. TAG size.
5.3 Diverse Interests

If representatives from distinct divisions of an organization can demonstrate independent interests and authority to make independent decisions in the area of the activity of the U.S. TAG, each may apply for membership.

5.4 Combined Interests

When appropriate, the U.S. TAG Administrator may recommend that the applicant seek representation through an organization that is already represented by a member who represents the same or similar interests.

5.5 Observers

Individuals and representatives of organizations having an interest in the U.S. TAG's work may request listing as observers. Observers shall be advised of the U.S. TAG activities, may attend meetings, and may submit comments for consideration, but shall not vote.

5.6 Representation of Materially Affected Interests

All directly and materially affected U.S. national interested parties shall have the opportunity for fair and equitable participation without dominance by any single interest.

Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation. The requirement implicit in the phrase "without dominance by any single interest" normally will be satisfied if a reasonable balance among interests can be achieved. Unless it is claimed by a directly and materially affected person that a single interest dominated the standards activity, to the exclusion of fair and equitable consideration of other viewpoints, no test for dominance is required.

5.7 Membership Roster

The administrator shall maintain the list of U.S. TAG members and the organizations they represent.

The roster shall include the following:

1. Title and designation of the U.S. TAG
2. Scope of the U.S. TAG
3. U.S. TAG Administrator (name of organization, name of secretary, address(es), telephone number)
4. U.S. TAG officers (chairman and other officers)
5. Members:
   a. Names of the individuals and alternates (as applicable) and their addresses and business affiliations including the name of the organization they are representing on the U.S. TAG.
   b. The interest category of each individual and alternate (as applicable).
c. In addition, the member’s name (or if membership is by organization, the name of the organization with a point of contact), affiliation and interest category of each member of the TAG shall be made available to interested parties upon request.

5.8 Membership Obligations

Members are expected to participate actively by fulfilling attendance, voting, correspondence, and other obligations. Members are expected to participate in good faith and in accordance with professional standards, respectful of the rules of the TAG and the authority given to the Officers of the TAG and TAG Administrator.

5.9 Review of Membership

The U.S. TAG Administrator shall review the membership list annually with respect to the criteria of clause 5 of these procedures. Members are expected to participate actively by fulfilling attendance, voting, correspondence, and other obligations. Where a member is found in default of these obligations, the U.S. TAG Administrator shall take appropriate action, which may include termination of membership. Members are expected to participate in good faith and in accordance with professional standards and all rules applicable to members of AAMI standards committees, respectful of the rules of the TAG and the authority given to the Officers of the TAG and TAG Administrator. As appropriate, the TAG and TAG Administrator may refer to Robert’s Rules of Order, Disciplinary Procedures, for guidance.

6 Meetings

Meetings of the U.S. TAG and meetings of the U.S. delegates to international meetings should be scheduled to respond to international activities. U.S. TAG meetings shall be held, as determined by the chairman/U.S. TAG Administrator or by petition of a majority of the members. U.S. TAGs shall determine for themselves the quorum requirements. The quorum requirements shall be available in writing upon request. The quorum for an AAMI-administered U.S. TAG to an ISO TC or SC shall consist of those members present at a meeting, either in person or via telephone. For the purpose of voting on ISO documents, the quorum shall consist of those persons responding formally to a request for a voting recommendation. The voting requirements shall be in accordance with clause 7 of these Procedures.

6.1 Open Meetings

Meetings of the U.S. TAG shall be open to all members and others having direct and material interest. At least four weeks’ notice of regularly scheduled meetings should be given by the administrator and shall be announced in ANSI’s Standards Action or suitable 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.

7 Voting

7.1 Vote

Each member shall vote one position on a ballot. Voting options shall match those given for the technical question (within reason) on the ISO ballot. In all but administrative matters, the reasons for a negative vote shall be given and should include specific wording or actions which would resolve the objection.
7.2 Vote of Alternate

An alternate’s vote is counted only if the principal representative fails to vote.

7.3 Voting Period

The voting period for letter ballots shall be established to allow for timely response to international time limits. An extension may be granted at the option of the chairman or administrator when warranted (e.g., when the requirements for approval or disapproval specified by 7.5 or 7.6 are not achieved).

7.4 Authorization of Letter Ballots

A letter ballot may be authorized by:

1. Majority vote of those present at a U.S. TAG meeting
2. The chairman
3. The U.S. TAG Administrator
4. Petition of five members of the U.S. TAG or a majority of the U.S. TAG, whichever is less

7.5 Actions Requiring Confirmation or Approval by Majority

The following actions require confirmation by the U.S. TAG or, if formal objections are received, to approval by a letter ballot or an equivalent formal recorded vote with approval by at least a majority of the U.S. TAG membership:

1. Approval of officers appointed by the administrator or nominated by members of the U.S. TAG
2. Formation of a standing subgroup, including its procedures, scope, and duties
3. Disbandment of a subgroup
4. Approval of minutes
5. Other actions of the committee not specified elsewhere

7.6 Actions Requiring Approval by Two-Thirds of Those Voting

The following actions must be approved by at least two-thirds of those voting by letter ballot, excluding abstentions or, if at a meeting, by two-thirds of those present, excluding abstentions, provided that a majority of the total voting membership of the U.S. TAG is present: (If a majority is not present, the vote shall be confirmed by letter ballot.)

1. Adoption of U.S. TAG procedures, categories of interests, or revisions thereof
2. Approval of a recommendation to change the U.S. TAG scope
3. Approval of U.S. position on technical matters brought before the U.S. TAG (i.e., NP, CD, DIS, FDIS)
4. Approval of a recommendation to terminate the U.S. TAG
The TAG Administrator shall report successful ballots on items 1, 2 and 4 to the ANSI ExSC, along with its views on the action.

7.7 Consideration of Views and Objections on Letter Ballots

The administrator of the U.S. TAG shall forward the views and objections received to the chairman of the U.S. TAG, or his designee. The administrator, in consultation with the chairman, shall determine whether the expressed views and objections shall be considered by telephone, correspondence, or at a meeting.

Prompt consideration shall be given to the expressed views and objections of all participants including those commenting on a draft international standard (DIS) listing in Standards Action. A concerted effort to resolve all expressed objections shall be made, and each objector shall be advised of the disposition of the objection and the reasons therefor.

Substantive changes required to resolve objections, and unresolved objections, shall be reported to the U.S. TAG members to afford all members an opportunity within appropriate time limits to respond, to reaffirm, or to change their position.

7.8 Report of Final Result

The final result of the voting shall be reported to the U.S. TAG.

7.9 Submittal of U.S. Position

Upon completion of the procedures for voting, consideration of views and objections, and appeals, the U.S. position, which represents the U.S. consensus, shall be submitted to ANSI by the U.S. TAG Administrator. ANSI, as the official ISO member body, is responsible for providing the U.S. position to ISO.

7.10 Information Submitted

The information supplied to ANSI shall include:

1. Title and designation of the document.

2. Indication of the type of action requested (for example, approval of a new draft international standard or reaffirmation, revision, or withdrawal of an existing draft international standard, questionnaire, etc.).


A complete breakdown of all votes will be made available upon request.

8 Termination of a U.S. TAG

A proposal to terminate a U.S. TAG may be made by directly and materially affected interests. The proposal shall be submitted in writing to ANSI and to the U.S. TAG Administrator and shall include the reasons why the U.S. TAG should be terminated. The U.S. TAG shall take action in accordance with 7.6. Information regarding the termination of a U.S. TAG shall be promptly provided to the secretariat of the
associated ISO committee. In the event that the U.S. holds the secretariat for an ISO committee for which the U.S. TAG is considering termination, the organization serving as secretariat shall be informed promptly and shall submit their position regarding termination of the TAG to ANSI and to the TAG Administrator.

As a result of action taken in accordance with 7.6, should termination of the TAG be approved, notification of such action shall be announced in Standards Action. The announcement shall note that dissolution of the TAG will result in the U.S. relinquishing its P- (participant) status in the international activity. Also, if the U.S. serves as international secretariat, the announcement shall state that the U.S. will resign as international secretariat. The appropriate notification(s) shall be sent to ISO Central Secretariat regarding the change in status, and the relinquishment of the secretariat, if applicable.

9 Communications

External communications such as inquiries relating to the U.S. TAG shall be directed to the U.S. TAG Administrator for response, and members should so inform individuals who raise such questions. All replies to inquiries shall be made through the U.S. TAG Administrator.

10 Appeals

Directly and materially affected U.S. national interested parties who believe they have been or will be adversely affected by an action or inaction of the U.S. TAG or its administrator shall have the right to appeal.

10.1 Complaint

The appellant shall file a written complaint with the U.S. TAG Administrator within thirty (30) calendar days after the date of notification of action or at any time with respect to inaction. The complaint shall state the nature of the objection(s) including any adverse effects, the section(s) of these procedures or the specific actions or inactions that are 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.

10.2 Response

Within thirty (30) calendar days after receipt of the complaint, the respondent shall respond in writing to the appellant, specifically addressing each allegation of fact in the complaint to the extent of the respondent's knowledge.

10.3 Hearing

If the appellant is not satisfied with the response of the respondent, they shall so inform the U.S. TAG Administrator within ten (10) working days. The U.S. TAG Administrator shall schedule a hearing with an appeals panel on a date agreeable to all participants, giving at least ten (10) working days' notice.

10.4 Appeals Panel

The appeals panel shall be appointed by the U.S. TAG Administrator and shall consist of three individuals who have not been directly involved in the matter in dispute, and who will not be materially or directly affected by any decision made or to be made in the dispute. At least two members shall be acceptable to the appellant and at least two shall be acceptable to the respondent.
10.5 Conduct of the Hearing

The appellant has the burden of demonstrating adverse effects, improper actions, or inactions and the efficacy of the requested remedial action. The respondent has the burden of demonstrating that the committee and the U.S. TAG Administrator took all actions in compliance with these procedures and that the requested remedial action would be ineffective or detrimental. Each party may adduce other pertinent arguments, and members of the appeals panel may address questions to individuals. Robert's Rules of Order (latest edition) shall apply to questions of parliamentary procedure not covered herein for the hearing.

10.6 Decision

The appeals panel shall render its decision in writing within thirty (30) days, stating findings of fact and conclusions, with reasons therefor, based on a preponderance of the evidence. Consideration may be given to the following positions, among others, in formulating the decision:

1. Finding for the appellant and remanding the action to the U.S. TAG or the U.S. TAG Administrator with a specific statement of the issues and facts in regard to which fair and equitable action was not taken.

2. Finding for the respondent with a specific statement of the facts that demonstrate fair and equitable treatment of the appellant and the appellant's objections.

3. Finding that new, substantive evidence has been introduced and remanding the entire action to the U.S. TAG or the U.S. TAG Administrator for appropriate reconsideration.

10.7 Further Appeal

An appeal of a U.S. TAG appeals decision may be filed with the ANSI ExSC in accordance with the Operating Procedures of the ANSI Executive Standards Council.

10.8 Informal Settlement

ANSI encourages settlement of disputes at any time if the settlement is consistent with the objectives of the ANSI Procedures. Any settlement to which the parties agree in writing, that is consistent with these procedures, or an agreement to withdraw the appeal, will terminate the appeal process.

11 Antitrust Policy

U.S. positions developed by ANSI-Accredited U.S. TAGs shall be developed in accordance with applicable antitrust and competition laws and meetings amongst competitors to develop U.S. positions are to be conducted in accordance with these laws.

12 Parliamentary Procedures

On questions of parliamentary procedures not covered in these procedures, Robert's Rules of Order (latest edition) may be used to expedite due process.