



Standards and Certification Training

Module B – Process

B8a. US TAG to International Standards Organization (ISO) Standards Development

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This Module will cover US Technical Advisory Group (TAG) participation in International Standards Organization (ISO) Standards Development.

Module B Course Outline

- B1. ASME Organizational Structure
- B2. Standards Development: Staff and Volunteer Roles and Responsibilities
- B3. Conformity Assessment: Staff and Volunteer Roles and Responsibilities
- B4. Initiating and Terminating Standards Projects
- B5. Consensus Process for Standards Development
 - B5a. Project Management
- B6. The Basics of Parliamentary Procedure
- B7. The Appeals Process
- B8. ASME International Standards Development
 - B8a. US TAG to ISO Standards Development**
- B9. ASME Conformity Assessment Programs
- B10. Performance Based Standards
- B11. Standards Inquiries, Interpretations and Cases



Module B contains thirteen modules.

REVISIONS

DATE	CHANGE
11/11/15	First Draft, content was removed from B8 and revised.



LEARNING OBJECTIVES

At the end of this module you will know...

- How ISO committees are structured
- How ISO standards are developed.
- How ASME and the US TAGs participate in the ISO standards development process.

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AGENDA

- I. ISO Organization
- II. ISO Standards Development Process
- III. US Technical Advisory Group (TAG)
Participation

These topics will be discussed during this presentation

I. ISO ORGANIZATION

This part of the module will focus on the organization of ISO, how the ISO committees are structured and the types of ISO publications.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

- Purpose
 - To facilitate the internationalization and unification of standards and related activities
- Membership
 - 162 countries, each represented by a national standards body
 - 119 member body countries each with one vote
 - ANSI is the U.S. member body
- Official languages are English, French, Russian
- Outputs
 - International standards, technical reports, etc.

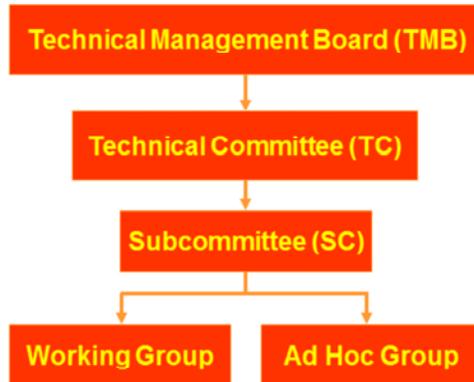
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- ISO is a private European based standards development organization (SDO) created to facilitate the internationalization and unification of standards and related activities.
- It is made up of 162 member countries, each represented by a national standards body from that country and 119 member body countries each having one vote. The one country-one vote principle sometimes causes problems as small, less industrial countries have the same vote as larger industrialized nations and, occasionally, countries may vote as a bloc to advance specific regional positions.
- ANSI, the American National Standards Institute, is the U.S. member body.
- The official languages are English, French and Russian, but ISO documents are published only in French and English.
- ISO develops international standards, technical reports and other documents.
- Participation in the ISO process is important as it may help to maintain or increase foreign market access.

ISO ORGANIZATION

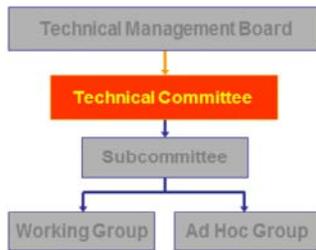


The technical work of ISO is carried out by the Technical Management Board which manages ISO's technical activities and sets policy regarding these activities. There are various Technical Committees that report to it.

This chart shows the various groups involved and their reporting structure.

Let's take a closer look at each one of these.

ISO ORGANIZATION



- **Technical Committee (TC)**
 - Responsible for a particular technical area, e.g Pipe Fittings
 - Membership: all countries
 - P = Participating (must vote)
 - O = Observer (may vote)
 - Liaisons with other TC or SC
 - TMB allocates the Secretariat role to a national body

ISO has more than 250 Technical Committees

A Technical Committee is responsible for a particular technical area, such as Pipe Fittings. Technical Committees and their scopes are established by the TMB.

- All countries may participate in a Technical Committee, but ISO provides three categories of membership to allow different degrees of participation. A country may select the category that best suits its needs and may select different categories of participation for different committees. The membership categories are: Participating, Observer and Liaison.
 - A Participating (P) member is obliged to vote on draft International Standards and, whenever possible, to participate in meetings. If a P-member consistently misses votes, it may be asked to change its category of participation to O-member.
 - An Observer (O) member attends meetings and receives and comments on drafts. An O member also has the right to vote on certain ballots, but no obligation to do so. O-member votes do not carry the same weight as P-member votes when evaluating criteria for approval of a proposed standard.
 - Liaisons are formed between TC's or SC's. Liaison representatives may attend meeting and receive documents, but do not vote.
- The TMB allocates the Secretariat role for the committee to a national body. Chairs of Technical Committees are nominated by the secretariat and are approved by the TMB.
- ISO has more than 250 Technical Committees.

THE TC SECRETARIAT

- Responsibilities
 - Provides administrative and technical support to the committee in accordance with ISO Directives
 - Examples: meeting arrangements, agendas, ballots
 - Works closely with ISO Central Secretariat
 - Must remain strictly neutral in its dealings
- ASME provides the Secretary for two ISO subcommittee.

- A Technical Committee Secretariat provides administrative services for a particular Technical Committee in accordance with ISO Directives (procedures). This includes working with a host country on meeting arrangements, distributing agendas, taking minutes and conducting ballots.
- A Secretariat must work closely with ISO Central Secretariat and must be strictly neutral in its dealings.
- While ANSI is the official organization who holds the US Secretariat role, they delegate the Secretary responsibility to other US SDO's in which the expertise for that particular committee lies. ASME provides the Secretary for TC 5/SC 10 on Flanges which relates to the ASME B16 Committee; and TC 96/SC 6 on Mobile Cranes which relates to the ASME B30 Committee. (ASME also has TC 10/SC 1 Conventions, but will be relinquishing this role.)

ISO ORGANIZATION



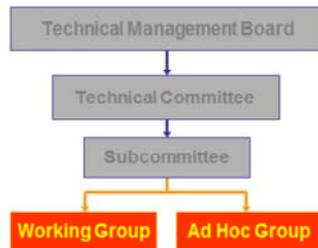
- Subcommittee

- Responsible for a specific aspect of a TC's responsibility
- P and O members
- Liaisons with other TC or SCs
- Parent TC appoints Secretariat

*NOTE: A country's Subcommittee membership category may differ from its TC category.

- A Technical Committee may create Subcommittees to deal with specific aspects of its work.
- A Subcommittee consists of P or O members only, but a country's subcommittee membership category need not be the same as its TC membership category. In other words, a country that has chosen to be an Observer at the TC level may choose to be an active Participant at the Subcommittee level.
- The parent TC appoints a national body to act as Secretariat for the Subcommittee. If more than one national body applies for the position, the Technical Management Board will decide the appointment.

ISO ORGANIZATION



- Working Group/Ad Hoc Group
 - Formed for single project
 - Collection of individually appointed experts

Working Groups and Ad Hoc Groups are created by the Technical Committee or Subcommittee, if necessary, and are usually responsible for a single project or a set of related projects. They are disbanded upon completion of those projects. Membership categories do not apply in a Working Group or Ad Hoc Group.

ISO PUBLICATIONS

- **International Standard and Amendments**
 - Requires approval of 2/3 of P-members with less than 1/4 of voting members dissenting
 - Five year review cycle (Systematic Review)
- **Technical Specification (TS)**
 - Requires only 2/3 of P-members
 - Three year review cycle
- **Publicly Available Specification (PAS)**
 - Requires only a simple majority
 - Three year review cycle

ISO publishes three types of documents which set international standards. These documents reflect different levels of international support for the norms they describe and therefore carry different weights in the international community.

- An **International Standard** is ISO's primary product. In order for a proposed standard to be accepted as an International Standard it must be approved by at least two-thirds of the P-members of the relevant Technical Committee and disapproved by less than one quarter of all voting members. International Standards must be reviewed at least every five years.
- A **Technical Specification** is also a normative document, but does not enjoy the status of an International Standard as it requires the approval of only 2/3 of the P-members voting and must be reviewed after three years. Normally, Technical Specifications are issued when the original intent was to produce an ISO Standard but, subsequently, it was discovered that there was insufficient support for the publication of a standard.
- A **Publicly Available Specification** requires even less support for approval—requiring only a simple majority—and must also be reviewed after three years.

OTHER ISO PUBLICATIONS

- Technical Report (TR)
 - Provides information only
- Industry Workshop Agreement (IWA)
 - Results from international workshop
 - Provides information only

ISO also publishes informational documents:

- A **Technical Report (TR)** provides technical information on a particular topic. It is not normative.
- An **Industry Technical Agreement (ITA)** is a document resulting from an international workshop held outside the technical structure of ISO but administered by a designated ISO national body. An ITA will always include a list of the participating organizations.

II. ISO STANDARDS DEVELOPMENT PROCESS

This part of the module will focus on the process used by ISO to develop, approve and publish their standards.

ISO STANDARDS DEVELOPMENT

Stages of Development Process



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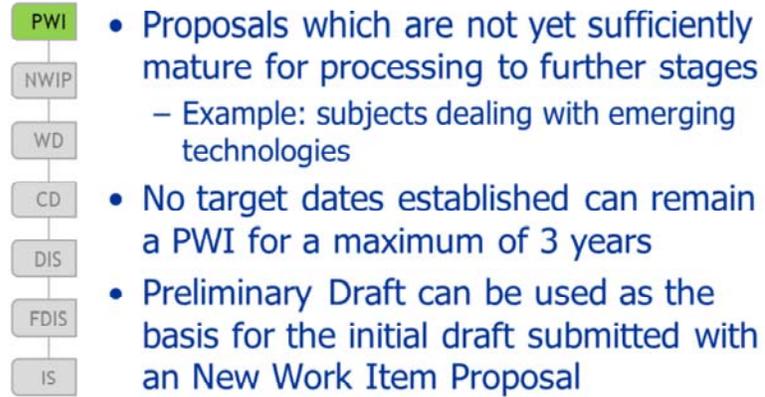
The basic stages of ISO standards development are as follows:

1. Preliminary
2. Proposal
3. Preparatory
4. Committee
5. Enquiry
6. Approval
7. Publication

These stages may vary slightly based on whether the document is new or revised, the type of document and results of the ballots or decisions taken during meetings. After the document is printed the documents are periodically reviewed to ensure that they are still valid and useful.

We will discuss each of the basic steps and the periodic review process in the next few slides.

PRELIMINARY STAGE (PWI)



Preliminary Work Items are proposals which are not yet sufficiently mature for processing to further stages. For example: subjects dealing with emerging technologies

- No target dates established, a project can remain a PWI for a maximum of 3 years
- Preliminary Draft can be used as the basis for the initial draft submitted with a New Work Item Proposal.

PROPOSAL STAGE (NWIP)



- New Work Item Proposals (NWIP) are proposals for a new standard, new part of an existing standard, ISO TS or PAS
- Ballot is submitted to relevant TC or SC for a 3 month ballot
- Approval by a simple majority of P-Membership and at least 5 Members commit to participating
- Stage not required for the revision of an existing standard if there is a resolution containing a timeline, scope and project leader and a call for experts is initiated.

Once a new work item has been developed sufficiently, it can be forwarded as a new work item proposal.

- New Work Item Proposals (NWIP) are proposals for a new standard, new part of an existing standard, ISO Publicly Available Specification or ISO Technical Specification.
- A new work item proposal (NP) ballot is submitted for vote by members of relevant TC or SC for 3 months. A committee can shorten the voting phase for a NWIP from 3 to 2 months by passing a resolution
- Approval by a simple majority of P-Membership and at least 5 Members commit to participating in the document's development. Exception - if less than 16 P-Members in the committee, only 4 Members must commit to participating.
- This stage is not required for the revision of an existing standard provided the committee passes a resolution confirming the development of a timeline, scope and project leader and a call for experts is initiated.

PREPARATORY STAGE (WD)

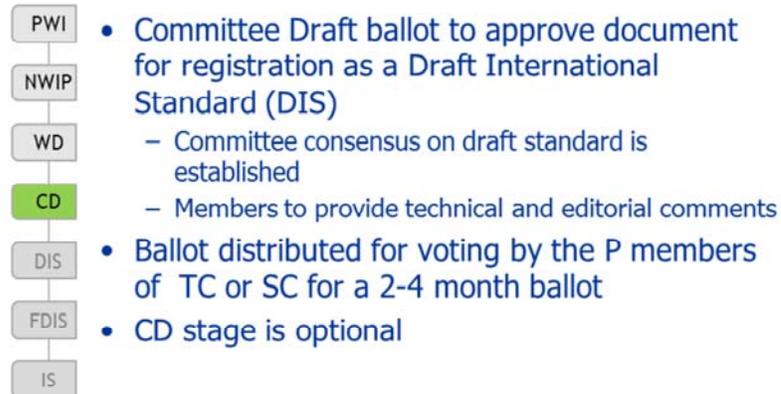


- WG or Project Team established based on experts nominated via NWIP ballot.
- Development of the Working Draft
 - Input from International Experts
 - Working Draft may undergo several revisions before moving forward to next stage of development (Committee Draft)

Once the document has been approved by NWIP ballot, the project is placed on the committee work plan and is further developed.

- During the preparatory stage the working group or project team is established from the list of experts nominated on the NWIP ballot. A project leader responsible for the work item is normally appointed to serve as the Convener (Chairman) of a working group of experts.
- Members prepare a draft (WD) to address the new work item. Sometimes it will take several drafts until the working group is satisfied with the technical content. This draft is then forwarded to the working group's parent committee and becomes the CD (Committee Draft).

COMMITTEE STAGE (CD)

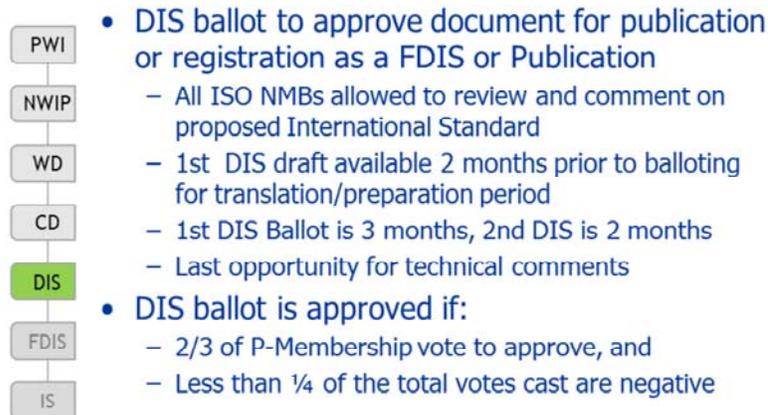


The Committee Draft (CD) ballot is distributed for voting by the P members of TC or SC. Committee Draft ballot is issued to approve the document for registration as a Draft International Standard (DIS)

- Ballot distributed for voting by the P members of TC or SC
- Default 2 month ballot; however voting length can be extended to up to 4 months
- CD stage is optional - Skipping the CD stage can be determined either by a 1 month ballot or at an international meeting
- After close of the comment period, Secretariat prepares comment compilation and, in consultation with Chairperson and/or Project Leader, determines how to proceed. Comments are considered and successive committee drafts may be considered until consensus on the technical content has been reached.

When consensus has been achieved and the text is finalized, it is submitted to ISO Central Secretariat for a Draft International Standard (DIS) vote.

ENQUIRY STAGE (DIS)



Draft International Standard (DIS) ballot is sent by ISO Central Secretariat to approve document for publication or registration as a Final Draft International Standard (FDIS) or Publication.

- All ISO National Member Bodies (NMBs) allowed to review and comment on proposed International Standard
- 1st DIS draft available 2 months prior to balloting for translation/preparation period
- 1st DIS Ballot is 3 months, 2nd DIS is 2 months
- This is the last opportunity for technical comments to be submitted.

The DIS ballot is approved if:

- 2/3 of P-Membership vote to approve, and
- Less than 1/4 of the total votes cast are negative

National bodies' comments are considered by the originating TC/SC and successive drafts may be reviewed until consensus is achieved. If the document is approved, the FDIS stage is typically bypassed unless the committee leadership decides otherwise.

APPROVAL STAGE (FDIS)



- Optional FDIS ballot to approve document as an International Standard (IS)
 - All ISO NMBs able to review and comment on proposed International Standard 2 month ballot
 - Technical Comments not acceptable at this stage
 - Any technical comments submitted will be considered during the next review of the document
 - This stage can be omitted and a document sent directly to publication if agreed to by resolution of the ISO Committee (2/3 majority of those voting)
- FDIS ballot is approved if:
 - 2/3 of P-Membership vote to approve, and
 - Less than 1/4 of the total votes cast are negative

Optional Final Draft International Standard (FDIS) ballot is sent by ISO Central Secretariat to approve document as an International Standard (IS).

- All ISO NMBs able to review and comment on proposed International Standard 2 month ballot
- Technical Comments not acceptable at this stage and any technical comments submitted will be considered during the next review of the document.
- This stage can be omitted and a document sent directly to publication if agreed to by resolution of the ISO Committee (2/3 majority of those voting)

FDIS ballot is approved if:

- 2/3 of P-Membership vote to approve, and
- Less than 1/4 of the total votes cast are negative

PUBLICATION STAGE (IS)



- Shortly after approval of FDIS, all errors shall be corrected and International Standard (IS) will be published

Shortly after approval of the document either FDIS approval or if it was agreed to bypass the FDIS and go directly to publication, all errors shall be corrected and International Standard will be published by the ISO Central Secretariat.

PERIODIC REVIEW

- All International Standards will be reviewed every 5 years
- Technical Specifications and TS / Publically Available Specifications are reviewed every 3 years
- Ballot Procedure
 - Ballot is issued by ISO CS ANSI requires a specific ballot to be filled out.
 - P members eligible to vote are asked to:
 - Confirm
 - Revise (= new project, without vote on NP)
 - Withdraw
- Decision by simple majority of P-Members voting.

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- All International Standards will be reviewed every 5 years and Technical Specifications (TS) and Publically Available Specifications (PAS) are reviewed every 3 years.
- ISO Central Secretariat issues a ballot automatically. ANSI requires a specific ballot to be filled out which includes a statement for demonstration of ongoing market relevance.
- The ballot requests that P members vote to
 - Confirm
 - Revision (= new project, without vote on NP)
 - Withdrawal
- Decision is by simple majority of P members voting.

III. US TECHNICAL ADVISORY GROUP (TAGs) PARTICIPATION

ASME currently participates in approximately 40 ISO standards development activities. This part of the module will focus on the path dealing with participation in the activities of the International Organization for Standardization, or ISO, and will explain how ASME participates in the ISO standards development process.

TECHNICAL ADVISORY GROUP (TAG)

- The means by which U.S. participates in ISO Technical Committees
- Responsible for a specific technical area
 - ANSI accredits TAG
 - Scope of TAG typically matches that of a specific ISO committee or subcommittee
- Prepares the U.S. position on issues
- Represents U.S. at committee meetings

All U.S. participation in ISO Technical Committees is through Technical Advisory Groups, or TAGs.

- ANSI accredits the U.S. TAG for a specific technical area of responsibility. The scope of the U.S. TAG typically matches the area of responsibility of a particular ISO committee or subcommittee.
- A TAG prepares the U.S. position on issues handled by its corresponding ISO committee or subcommittee and
- Represents the U.S. at committee meetings.

TECHNICAL ADVISORY GROUP (TAG)

- Specific Responsibilities
 - Determines the U.S. position on
 - ISO drafts out for ballot
 - ISO Committee agenda items
 - Designates U.S. delegations
 - Initiates and approves U.S. proposals for new work
 - Recommends the TAG membership

A TAG's responsibilities include:

- Determining the U.S. position on ISO drafts out for ballot and ISO Committee agenda items
- Designating the head and members of any delegation that will represent the U.S. at committee meetings
- Initiating and approving U.S. proposals for new work
- Making recommendations regarding TAG membership

TECHNICAL ADVISORY GROUP (TAG)

- Membership
 - Open to all U.S. national interested parties (companies, technical and trade organizations, government agencies and individuals)
 - Balanced (no single interest category has majority)
- Contributing members (optional)
 - Review and comment voting rights only

Membership in a TAG is:

- Open to all U.S. national interested parties who are directly and materially affected by the activity of the TAG. This includes technical experts from companies, technical and trade organizations, government agencies and individuals. TAG members are not required to be U.S. citizens.
- Membership of the TAG is balanced, that is, no single interest category should have a majority.

The US TAG may also have contributing members that have rights to comment on documents, but do not have approval rights. This type of membership is generally selected by members who wish to be informed of US TAG items, but do not need or want the voting privileges.

NOTE: Having the Standards Committee taking actions as the TAG is not acceptable. Although the actual membership comprising the TAG and the Standards Committee might be the same, the TAG must have a separate roster. Some Standards Committee members may not be interested in ISO activities and not want to receive ballots on ISO drafts. Others may be interested in joining the TAG, but may not be interested in or able to, because of balance requirements or other reasons, join the Standards Committee as well.

TAG ADMINISTRATION

- TAG Administrator
 - Organization is accredited by ANSI to administer a TAG
 - Provides administrative services in accordance with ANSI and ISO procedures
- TAG Secretary
 - Administrative staff for TAG, usually ASME Staff
 - Duties include meeting arrangements and minutes, agendas, ballots, etc.
 - Transmit U.S. TAG approved positions to ANSI

TAG Administrator:

- ANSI accredits an organization to administer each TAG. ASME is currently the Administrator for over forty TAGs, for example, to TC 2 on Fasteners, to TC 10 on Technical Drawings and to TC 11 on Boilers and Pressure Vessels.
- The Administrator provides administrative services for the TAG in accordance with ANSI and ISO procedures.

TAG Secretary:

- The TAG Administrator provides the actual administrative staff of the TAG. In an ASME TAG, they are usually ASME staff persons, who serve as TAG Secretaries. The Secretaries make arrangements for meetings, prepare and distribute documents related to the work of the TAG, and maintain appropriate records (including minutes of meetings and results of ballots). They also transmit proposals and positions developed and approved by the TAG to ANSI.

TAG PROCEDURES

- Operating Procedures for ASME Administered U.S. Technical Advisory Groups for ISO Activities
 - Based on ANSI Model Operating Procedures
 - Openness
 - One member, one vote
 - Balance
 - All negatives considered
 - Appeals process

 - Supplemental Procedures are required
 - ASME categories of interest

ASME has developed a set of generic procedures for use by all U.S. TAG's administered by ASME titled Operating Procedures for ASME Administered U.S. Technical Advisory Groups for ISO Activities. These procedures contain the same basic concepts as the ASME Standards Development Committee Procedures and ANSI Model Procedures to ensure:

- Openness
- One member, one vote
- Balance
- All negatives considered
- Appeals process

The TAG's shall also create a supplement to the generic procedures that contain membership categories of interest and may contain additional requirements unique to the specific TAG operation. They shall not conflict with the generic TAG procedures.

DETERMINING A U.S. POSITION

- Option 1 (2 ballots needed)
 - Draft sent to TAG for ballot
 - Consolidated position prepared
 - Consolidated position balloted
- Option 2 (1 ballot needed)
 - Draft sent to TAG for comment
 - Project Team prepares proposed position
 - Proposed position balloted

The first step in stating a U.S. position to ISO is determining what the position is. The appropriate TAG is responsible for developing a consensus position, but there are two ways it can do this.

- Option 1: In the first option, the draft is sent to the TAG for ballot. A group or individual then consolidates and refines the TAG comments into a position, which is then balloted by the TAG.
- Option 2: In the second option, a Project Team Leader is designated. The draft is distributed to the Project Team Leader who will develop a proposed US position by a specific date. That positions is then balloted by the TAG.

Since the first option is more time consuming and often the ballot timeline is short, strong consideration should be given to the second option. When using the Project Team Leader approach, try to have the Project Team Leader established early and/or participate in the early development stages.

If possible, do not submit individual comments from a review of the draft. First have a volunteer review the comments and refine them. In the past, a listing of various members' comments were sent to ISO. Since these were individual comments, they often were not consistent with each other.

GUIDELINES FOR DETERMINING A U.S. POSITION

- Appendix A of the Operating Procedures for ASME Administered U.S. Technical Advisory Groups for ISO Activities
- Positions should consider
 - If there is an equivalent national standard, are the ISO standards and national standard significantly different, is that acceptable.
 - Technical acceptability of the document.

- Appendix A of the Operating Procedures for ASME Administered U.S. Technical Advisory Groups for ISO Activities covers the Guidelines for determining a U.S. voting position.
- The guideline outlines how the US TAG should vote in certain circumstances by first considering whether or not there is an equivalent national standard and if that standard differs greatly from the proposed ISO standard.
- If there is no existing national standard, the US can vote purely on technical acceptability

SUBMITTING A U.S. POSITION

- All votes are transmitted to the U.S. Member body, ANSI, for submittal of the vote to ISO.



Once the TAG approves a position, it is sent to ANSI. ANSI then submits the U.S. vote on the ISO balloting portal.

EFFECTIVE ISO PARTICIPATION

- Guidelines/Considerations
 - Begin participation in early stages of draft development.
 - Consider being a Convener.
 - Study the ISO Directives (procedures).
 - Know how to use the ISO Template.
 - Review ANSI's Guide for U.S. Delegates to ISO Meetings.

To make your participation in ISO as effective as possible, we recommend that you follow these guidelines:

- Begin your participation in the early stages of draft development. As in any standards development project, the earlier you suggest changes, the more likely they are to be accepted.
- Consider being a Convener. The convener functions as the chairman of a working group.
- Study the ISO Directives and become familiar with the ISO Template for submitting new work items.
- Review ANSI's Guide for U.S. Delegates to ISO Meetings. These are sent to all registered participants by ANSI prior to the meetings.

NOTE: Links to the ISO Directives, ISO Template, and ANSI Guide for U.S. Delegates to ISO Meetings can be found on the references page of this presentation.

NORMATIVE REFERENCES TO ASME DOCUMENTS

- Approach

- Incorporate normative reference to U.S. and ASME Standard in other Standards Development Organization (SDO) Standards

- Advantages

- Maintain control of technical content
- No need to exert the sometimes extensive effort in creating new standard
- Users can continue to use familiar requirements

As noted in Module 8, it should be noted here that one way to ensure that U.S. standards can be used as an equivalent standard to standards developed by other standards development organizations (SDOs) and ISO standards is to incorporate a normative reference to that standard.

Example:

- An example of this approach came with the publication of ISO 15649:2001, which contained a normative reference to the ASME B31.3 Code on Process Piping, thus making compliance with B31.3 essential in order to comply with the ISO Standard.

Advantage:

- Unlike some of the other approaches to international standardization, this option allows ASME to maintain control of the technical content of the key document. If an ASME document were submitted to ISO as the basis for a standard, ASME would have no control over the technical content of the eventual standard, other than participation through the U.S. TAG as one member body of the ISO Technical Committee.
- This option also precludes the need for potentially extensive effort to create a new standard.
- Additionally, this approach would allow users of the referenced standard to continue to use familiar requirements.

MODULE SUMMARY

- ISO standards are developed using a system that allows one vote per participating country. There are 7 steps in the development process for ISO standards.
- The U.S. Technical Advisory Groups (TAGs) are the means by which U.S. participates in ISO Technical Committees. By voting on ballots and attending meetings, members of the US TAG can participate in formulating the U.S. position on ISO documents.

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- The U.S. Technical Advisory Groups (TAGs) are the means by which U.S. participates in ISO Technical Committees. By voting on ballots and attending meetings, members of the US TAG can participate in formulating the U.S. position on ISO documents.

MODULE SUMMARY

- US TAGs that are facilitated by ASME follow the Operating Procedures for ASME administered U.S. Technical Advisory Groups. This outlines the requirements for membership and approval of US TAG positions.

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REFERENCES

- Codes and Standards Policy CSP-4, International Standardization
- Operating Procedures for ASME Administered U.S. Technical Advisory Groups for ISO Activities
<https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=L01000000&Action=7609>
- ISO Standards Development site:
http://www.iso.org/iso/home/standards_development/resources-for-technical-work/support-for-developing-standards.htm
- ISO Directives, ISO Templates, Vienna Agreement and other resources for those developing ISO documents are located at:
http://www.iso.org/iso/home/standards_development/resources-for-technical-work.htm