Module B - Process
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B5. Consensus Process for Standards Development

ASME

SETTING THE STANDARD
OBJECTIVES

This submodule will:
  – Explain ASME’s ANSI-accredited procedure for developing standards by consensus

Objectives

ASME administers over 700 different committees, including more than 50 consensus committees, responsible for about 500 standards.
This presentation represents ASME’s ANSI-accredited procedures for developing standards by consensus.
Many committees have supplemental requirements and administrative guidelines to suit the unique needs of their operations. Therefore, the process might vary slightly from committee to committee.
AGENDA

I. Introduction
II. Steps in the Consensus Process
III. Additional Information
Part I - Introduction

Let’s begin by looking at the process as a whole.
WHAT IS CONSENSUS?

• ASME standards are consensus standards.

• Consensus means
  – Substantial agreement by affected interest categories
  – Consideration of views, attempted resolution
  – Unanimity not required

NOTE: The Standards Committee is responsible for developing consensus on proposed standards actions.

What is Consensus?

ASME standards actions are approved by consensus. This means:
There is substantial agreement by affected interest categories on the proposed action.
All views have been considered and attempts have been made to resolve any objections from the consensus body or any other source.
Unanimity is not required. ANSI Procedures require more than simple majority approval, but not necessarily unanimity. For example, ASME’s accredited procedures require a 2/3 affirmative vote of the full consensus committee membership (exclusive of “Not Voting” and “Disapproved without Comment” responses) to proceed.

NOTE: The Standards Committee is the group responsible for developing consensus on proposed standards actions.
ASME codes and standards are developed under the consensus process. Key principles of the voluntary consensus process are openness, transparency, balance of interests, and due process.

**Openness** – Participation in the process is open to all persons who are directly and materially affected by the activity, without regard to country of citizenship or residence. Meetings for the consideration of standards actions are open to the public.

**Transparency** – Early notification of initiation of standards activities is provided in order to allow interested parties to express interest in participating. Widely available notification of status of standards activities as well as proposals is provided in order to permit review and comment by interested parties.

**Balance of Interests** – The standards development process should have a balance of interests, so that the process is not dominated by any single interest category, individual, or organization. ASME’s requirements are that not more than 1/3 of the membership of a consensus committee dealing with safety codes and standards shall come from any single interest category; and not more than ½ of the membership of a consensus committee dealing with product standards shall come from any single category.

**Due process requirements** – Due process means that any person (organization, company, government agency, individual, etc.) with a direct and material interest has a right to participate by: a) expressing a position and its basis, b) having that position considered, and c) having the right to appeal.
Standards Actions

Types:
By “standards action” we mean:
Issuance of a new standard
Revision of an existing standard
Reaffirmation of an existing standard (A Reaffirmation is a re-issue that contains no substantive changes to the main text of the standard. All non-substantive revisions must be at least noted in a foreword.)
Withdrawal of an existing standard
National adoption of an ISO or IEC standard

NOTE: If references to other standards containing requirements that are necessary to implement an American National Standard are being updated, then a Revision, not a Reaffirmation of the referencing standard, must be processed.
The Standards Development Process

Consensus requirements:

In order to ensure consensus, all standards actions require approval of the Consensus Committee, public review, Supervisory Board approval and, in most cases, ANSI approval.

Examples of cases where standards actions may be issued without ANSI approval:

Standard contains only administrative requirements – no technical requirements – as basis for conformity assessment program (e.g., QAI-1)
Appeals process for standard completed at ASME, but continued at ANSI, and need for issuance of standard is urgent.
The Standards Development Process (cont’d)

Standards Maintenance Requirements:
To ensure that standards remain current and technically relevant, the process sets these requirements:
Once a standard is approved as an American National Standard it must be reaffirmed or revised within 5 years or ANSI may administratively withdraw the standard. A standards developer may request an extension for action on the standard from ANSI. No extension of time beyond ten years from the date of approval will be granted by ANSI. ANSI approval of an American National Standard automatically expires on the tenth anniversary date of approval as an American National Standard.
In both instances, ANSI would withdraw American National Standard status without such a recommendation from the standards developer. In the first instance, it would be based on the recommendation of ANSI’s Executive Standards Council, and the standard would be withdrawn at the close of a 30-day public review notice in ANSI’s Standards Action. In the second case, ANSI will withdraw the standard and such action will be announced in Standards Action.
The Standards Development Process (cont’d)

Codes and Standards Board of Directors or Board oversight: Although the Codes and Standards Board of Directors and its Supervisory Boards may not change the wording of a standard, they may delay or suspend a standards action or act to withdraw standard without a recommendation from the Standards Committee, if they determine this is in the best interests of the Society or necessary to preserve the integrity of the standards development process.
The Standards Development Process (cont’d)

Standards Committee procedures:
ASME has procedures for developing standards which we will cover in this submodule. Some Standards Committees have supplemental requirements to suit the unique needs of their operations. Supplemental requirements must be approved by the responsible supervisory board. Any proposed deviations to the accredited procedures contained in the supplemental requirements must be approved by the board and by the Codes and Standards Board of Directors.

Administrative guidelines:
Standards committees may develop administrative guidelines that describe operational details. Such guidelines may not conflict with the procedures and don’t require approval by the supervisory board.
POP QUIZ #1

True or False?

1. A consensus standard requires approval by everyone voting on it. _____
2. Once approved, a standard remains current until specifically revised. _____
3. Consensus means consensus within the membership of the ASME committee. ____

Pop Quiz #1

Answers:

False. It requires substantial agreement, not unanimity.
False. Standards may be administratively withdrawn if not revised or reaffirmed at least every 5 years.
False. Consensus means consensus among all interested parties, including the general public.
Part II - Steps in the Consensus Process

Let’s take a closer look at each of the steps in the consensus standards development process.
The Consensus Development Process

These are the primary steps in the process for the development of consensus standards. As mentioned earlier, how and when these steps are accomplished varies among the various ASME Committees, but they are essential elements of the process.

The highlighted step is the one that will be treated in the next few slides.
The Consensus Development Process

Development of standards action:
The process begins when a committee receives a request. A request for a standards action can come from anybody—from within the committee or outside the committee. A committee may ask that such requests be submitted in a specific format (e.g., Project Initiation Form). The requestor will be asked if he or she is interested in participating in the development of a proposal.

After the committee or subordinate group appropriate to address the request has been identified, the officers assign a Project Technical Manager—an individual from the appropriate Standards Committee, Subcommittee, or working group—who has responsibility for development of proposed standards action. The pertinent Staff Secretary will normally be assigned as Project Administrative Manager, responsible for overseeing the processing of the standards action. The Project Technical Manager, Project Administrative Manager and committee officers assign members of the Project Team. Members can be members of the Standards Committee, members of a subordinate group, or other technically knowledgeable members of the public, including the requestor of the action.

The Project Technical Manager, Project Administrative Manager and Chair of the committee determine whether or not to proceed with the proposal, and if to proceed, the priority of the action. When the number of proposed changes to consider exceeds what can reasonably be considered by the committee for a given revision cycle, prioritizing proposals based on need is recommended.

For new codes and standards, and for revisions of codes and standards maintained under periodic maintenance, notice of initiation of the activity shall be provided to ANSI via the ANSI Project Initiation Notification System (PINS) form, or equivalent.

The Project Team develops draft in response to the request.
THE CONSENSUS DEVELOPMENT PROCESS

• Development of standards action (cont’d)
  – Draft made available for review and comment by interested parties
    • May be conducted concurrently with Standards Committee vote
  – Project Team considers comments; prepares responses
  – Draft accepted by Project Team submitted for Standards Committee vote

The Consensus Development Process

Development of standards action (cont’d):
After review by Project Team members and possible revision, the draft is made available for review and comment by interested parties—including members of the Standards Committee, cognizant Subordinate Groups, other affected Standards Committees, cognizant Board members and members of the public who have been identified as having an interest.

Review and comment period may be conducted concurrently with the Standards Committee recorded vote.
The Project Team considers the comments received, prepares responses to substantive comments. A summary of the comments and responses to the comments is made available. If substantive changes are made to the proposal, the proposal is distributed for another review and any additional substantive comments or responses generated are added to the summary.
When there are no further substantive changes to the proposal, the Project Team accepts the draft and submits it to the Standards Committee for a recorded vote. The Project Team will include with the proposal a brief explanation of why the action is being proposed, and a summary of substantive comments and Project Team responses from the pre-vote review by interested parties.

NOTE: All standards actions shall be forwarded to the cognizant board for review and comment, normally concurrent with the standards committee voted action.
Pop Quiz #2

Answers:
All should be checked.
The Consensus Development Process - Recorded Vote
The Consensus Development Process

Recorded vote:
The Standards Committee votes on the proposed standard in this way:
Standards actions are submitted for first consideration vote and, if necessary, subsequently for recirculation vote.
Votes shall be recorded in C&S Connect, but may take place at a meeting. Other than for unusual circumstances, members are expected to record their own votes in C&S Connect.
The normal voting period is four weeks. The voting period can be closed earlier if all votes are returned before that time. The voting period can be longer or shorter if authorized by a Standards Committee officer, but any voting period shorter than two weeks must be agreed to by the committee.
All Standards Committee participants must be given the opportunity to vote. Therefore, for instance, if the recorded vote is conducted at a meeting, but not all members are present, the participants who were not there must be given the opportunity to vote by one of the other methods.
Voting options are: Approved, Disapproved, Abstain, Not Voting.
On first consideration vote, item is considered to have passed if there are no “Disapproved” votes, and at least 2/3 of the Standards Committee (exclusive of “Not Voting” and “Disapproved without Comment” returns) has voted in the affirmative.

Let’s take a closer look at the voting options and what they mean.
The Consensus Development Process

Recorded vote (cont’d):
All “Disapproved” votes on first consideration vote must be supported by comments and, preferably, an alternative action that will resolve the vote. The committee must then attempt to resolve the disapprovals. If no comments related to the proposal accompany the vote, the committee is not required to take any action to resolve the disapprovals, but the vote must be recorded as “Disapproved without Comment” and reported to ANSI as such. A “Disapproved without Comment” response reduces the total of the committee membership for that action.
“Not Voting” shall be used by individuals who have an actual or apparent conflict of interest. A response of “Not Voting” reduces the total of the committee membership for that action.
An “Abstain” vote shall be used by individuals who feel they lack the expertise to evaluate the proposal or who have not had the time to review it. An “Abstain” vote does not reduce the total committee membership.
**The Consensus Development Process**

**Recorded vote (cont’d):**

Let’s review the actions the committee must take to attempt to resolve “Disapproved” votes. As we just said, this action is **not** required unless the Disapproved vote is accompanied by comments related to the proposal.

The Project Team must prepare a response to any substantive comments related to the proposal. This response should describe any substantive changes made in response to the comments and, if appropriate, explain why changes were not made.

Any editorial changes made to the proposal must then be submitted to the Consensus Committee for either recirculation vote or a vote at a meeting. See slide 27.

Any substantive changes made to the proposal must then be submitted to the Consensus Committee or either recirculation vote or new first consideration vote, at the discretion of the Standards Committee officers. Members are given the opportunity to change their votes, based upon the substantive changes made.

If, after consideration, any Disapproval votes cannot be resolved, they must be submitted to the Consensus Committee, along with the reasons for the Disapproved vote and the responses for recirculation vote to the Consensus Committee, along with the reasons for the Disapproved vote and the responses.

Committee members may change votes (see next slide)…
The Consensus Development Process

Recorded vote (cont'd):
Committee members may change their votes if they wish to do so on recirculation vote, either in support of any first consideration “Disapproved” votes or in disagreement with any changes introduced to the proposal.
If any unresolved Disapproved votes remain, those members shall be notified of their right to appeal the committee’s action.
If, after recirculation vote, at least 2/3 of the membership of the Consensus Committee (exclusive of “Not Voting” and “Disapproved without Comment” returns) has voted in the affirmative, the action is considered to have passed.
The Consensus Development Process

A standards action approved by the Consensus Committee may be put on hold or withdrawn by the Consensus Committee. Consideration of action to hold or withdraw approved standards action must be initiated by Consensus Committee prior to submittal of approved action for ANSI approval. Requires approval by 2/3 of total Consensus Committee membership, excluding any “Not Voting” and “Disapproved without Comment” responses. If approved standards action had already been submitted for Supervisory Board approval, action to hold or withdraw approved standards action also requires approval of supervisory board, in accordance with its procedures.
Pop Quiz #3

Answers:
Yes. Two-thirds of the voting members (66.7%) must approve.
Voting members = 21 – 3 = 18
Percentage voting approval = 13/18 = 72%
**Pop Quiz #4**

**Answer:**
21. All members must be given the opportunity to vote. The six absent members will be asked to vote via C&S Connect.
The Consensus Development Process

Approval of editorial (=non-substantive) revisions:
Editorial (i.e. non-substantive) revisions may be considered for approval using the same recorded vote process for standards actions.
Alternatively, editorial revisions may be considered for Consensus Committee approval at a meeting where a quorum is present. When approved at meetings with a quorum present, it is not necessary to give all members an opportunity to vote.
Members may vote Disapproved on the action, meaning they either disagree with the revision or believe the revision is substantive, not editorial.
When considered at a meeting, the proposal is approved if fewer than 1/5 of the committee objects. When conducted at a meeting with a quorum present, the proposal is approved when at least 2/3 of the Consensus Committee members present approve the action.
If the action is not approved, it must then be processed as a standards action.
The Consensus Development Process - Public Review
The Consensus Development Process

Public review:
- All proposed standards actions (new, revision, reaffirmation, withdrawal) must be announced for public review on the C&S Web site. ME magazine will include a notice directing interested parties to the C&S Web site for public review announcements. If the action will also be submitted as an American National Standard, it must also be announced in ANSI’s Standards Action via submittal of BSR-8 Form (BSR = Board of Standards Review).

Consideration should be given to conducting public review concurrently with the Standards Committee vote. If, by the time of the Standards Committee vote, there are expected to be no major objections, conducting public review concurrently with the Standards Committee recorded vote will save time in the development process.
The Consensus Development Process

Public review (cont’d):
The required comment period is determined by the accessibility of the details of the action. The normal public comment period is 60 days, but can be reduced to 45 days if the proposal can be accessed electronically. The comment period can be reduced further to 30 days if the complete proposal can be reprinted on the C&S Web site and in ANSI’s Standards Action. The Project Team shall respond to public comments related to the proposal and attempt to resolve them in the same way it responds to committee objections, including re-circulation of technical changes and unresolved objections to committee members. The Team must attempt to resolve all objections and must send a response to each objector detailing changes made or the reasons why changes were not made. If technical changes are made to a proposed standards action, the action must be submitted for another public review period. If, after consideration, any public review objections cannot be resolved, they must be reported to the consensus committee along with the reasons for the objection and the responses for recirculation vote, with members given an opportunity to change their votes, based on support of the unresolved objections. As with committee objectors, each objector whose objection is not resolved must be informed of their right to appeal the committee’s action.
The Consensus Development Process - Supervisory Board Approval
The Consensus Development Process

Supervisory Board approval:
After the Consensus Committee reaches consensus, the Standards Committee submits its proposed standards action to the Supervisory Board for approval. The documents submitted include the record of the Consensus Committee vote, the responses to unresolved disapproved Consensus Committee votes and Supervisory Board comments; and, upon completion of public review, any public review comments and Project Team responses.
The purpose of the Board’s review is to verify that the action is consistent with Codes and Standards policies and procedures, that the action is within the charter of the standards Committee, that the committee has followed its procedures and that comments received were adequately addressed.
NOTE: Technical comments from the Board should be submitted during the review and comment period, but not later than the Standards Committee’s recorded vote. They will be considered in same manner as comments from Standards Committee members or the public.
NOTE: If, during final Board consideration for approval, a member develops a concern where the safety, health, or welfare of the public is believed to be endangered, the concern shall be brought to the attention of the Standards Committee for consideration. The Standards Committee may withdraw the item for further consideration.
The Consensus Development Process

Supervisory Board approval (cont’d):
Boards have the option of conducting a two-week review, during which members have opportunity to express objection to the action, or conducting a traditional recorded vote. For either method, objections or Disapproved votes are provided to the Standards Committee for attempted resolution. If not resolved, they are submitted to the Board members for another review period or recirculation vote. If fewer than 1/3 of the board membership supports the unresolved objection(s), the standards action proceeds. Or, after recirculation vote, the action proceeds upon approval by 2/3 of the board voting membership (excluding “Not Voting”).
Pop Quiz #5

Answers:
a, b and d. The Board may offer comments on the technical details of the proposal for committee consideration, but they are not part of this review.
The Consensus Development Process - Appeals
### The Consensus Development Process

#### Appeals

- **ASME appeals process**
  - Covered in Submodule B7

- **ANSI appeals process**
  - Not heard until
    - Developer’s appeal process completed
    - ANSI has taken action on approval
  - May also appeal developer’s ANSI accreditation

**The Appeals Process**

Anyone who objects to an ASME standards action may appeal, at the appropriate time, to both ASME and ANSI.

**ASME appeals process:**
Submodule B7, The Appeals Process, will address the ASME appeals process in detail.

**ANSI appeals process:**
ANSI will not hear an appeal of a standards action until:
- It has taken action on approval of the action.
- Normally, the standards developer’s appeal process has been completed.
- An ANSI appeal may target a standards developer’s ANSI accreditation, rather than a specific standards action, when it is believed that the standards developer is not acting in compliance with the operating procedures against which they were accredited.
The Consensus Development Process - ANSI Approval
The Consensus Development Process

ANSI approval:
Following Supervisory Board approval, the proposed standards action is submitted to ANSI’s Board of Standards Review via BSR-9 form.

Much of the same information provided for the ASME Supervisory Board consideration for approval is provided to ANSI, e.g., the final vote of the Consensus Committee and documentation of attempts to resolve any outstanding committee Disapproved votes or public review comments. Also provided to ANSI is a committee roster indicating how each member voted.

BSR does not consider any technical issues when considering approval of a standards action.
If there are no outstanding unresolved committee Disapproved votes or public review objections, ANSI may administratively approve the proposed standards action without referring it to the BSR for a formal vote. If there are unresolved committee Disapproved votes or public review objections, the BSR must formally vote on the action.
Part III - Additional Information

In this last part of the module, we’ll find out a little more about ANSI, the organization we’ve referred to several times in the previous part. We’ll also say a few brief words about document retention.
Role of ANSI

Functions:
ANSI is responsible for overseeing the process by which American National Standards are developed. It carries out this responsibility by performing the following functions:

Any organization which wishes to develop standards that will be recognized as American National Standards must be accredited by ANSI. Accreditation is primarily based on verification that the organization’s operating procedures are consistent with the requirements of the ANSI Essential Requirements: Due process requirements for American National Standards. Any subsequent revisions to an organization’s operating procedures must be submitted to ANSI for review and possible re-accreditation.

Through the announcement of proposed standards actions, ANSI provides a public review process for standards. We discussed this earlier.

ANSI, through its Board of Standards Review (BSR), approves proposed standards actions for American National Standards. We also discussed this earlier.

Approximately every 5 years, ANSI audits accredited standards developers to verify their continued compliance with ANSI procedures, and the standards developer’s procedures and policies. To determine compliance, ANSI examines the documentation for selected standards that have completed the approval process. The first ANSI audit of ASME’s standards development activities was conducted in 1998. The most recent one was conducted in June 2003. ASME conducted internal audits prior to each ANSI audit. Standards developers must respond to any findings or recommendations from the audit; the responses are considered for acceptance by ANSI’s Executive Standards Council. Possible actions by ANSI if there are excessive substantial findings include suspension or withdrawal of accreditation.
Document Retention

Requirements:
Periodic Maintenance Standard: Records providing evidence of compliance with pertinent procedures shall be retained for one complete standards cycle, or until the standard is revised.

Periodic maintenance means the maintenance of a standard by review of, and action to approve revision or reaffirmation of, the entire document on a schedule not to exceed five years from the date of approval by the cognizant supervisory board or by ANSI in the case of American National Standards.

Continuous Maintenance Standard: Records of actions on standards, or a part of a standard shall be retained for a minimum of five years or until approval of the subsequent revision or reaffirmation of the complete standard.

Continuous maintenance means the maintenance of a standard by consideration of recommended changes to any part(s) of it according to a documented schedule for consideration and action by the standards committee. Changes to portions of standards that are approved are normally published at intervals not exceeding three years.

These requirements would apply to records such as minutes, drafts, recorded vote files, and ANSI submittals.

References:
CSP-38, Document Retention
Table CSP-38, Retention Time (Years). Refer to Table CSP-38 for retention requirements for other types of documents.
Pop Quiz #6

Answer:
False. ANSI only considers standards intended to become American National Standards.
SUMMARY

I. Introduction
II. Steps in the Consensus Process
III. Additional Information
REFERENCES

- Procedures for ASME Codes and Standards Development Committees* (Primarily Section 7)
- Supervisory Board Procedures
  - http://cstools.asme.org/csconnect/committeepages.cfm
- Codes and Standards Policy CSP-52, Policy for Consideration of Standards Actions by Supervisory Boards*
- Codes and Standards Policy CSP-38, Document Retention*


References