



ATCC® POLICIES AND PROCEDURES MANUAL
FOR THE DEVELOPMENT OF
AMERICAN NATIONAL STANDARDS

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INTRODUCTION

The American Type Culture Collection (ATCC) is a global not-for-profit BioResource Center (BRC) and research organization that provides biological products, technical services and programs to private industry, government and academic organizations around the world. Our mission is to acquire, authenticate, preserve, develop and distribute biological materials, information, technology, intellectual property and standards for the advancement, validation and application of scientific knowledge. In response to the needs of our industry, ATCC has formed a standards development organization to assure the development of nationally and internationally accepted standards for biomaterials that meet International Standards Organization (ISO) guidelines for standards development.

This document defines the operating policies that the ATCC Standards Development Organization (SDO) will use to comply with the essential requirements of the American National Standards Institute for ANSI standard developers. These policies and procedures reference corresponding ATCC corporate policies that will be adhered to in implementing this program. ATCC reference documents comprise Section 23 of this manual.

Requirements for these policies and procedures are defined in *ANSI Essential Requirements: Due process requirements for American National Standards* (www.ansi.org/essentialrequirements). Where the ATCC SDO Operating Principles and Procedures are silent on an issue, the American National Standards Institute's Essential Requirements document referenced above shall serve as the precedent document. The *ANSI Essential Requirements* is therefore considered as a companion to this manual and as the principal reference document for these operating policies and procedures. When operating outside of the *ANSI Essential Requirements* procedures, ATCC SDO forums, meetings and committees shall follow the operating procedures for ATCC SDO forums, meetings and committees that are included in Section 23 of this manual.

Valid consensus standards must meet national and international guidelines for quality, openness, balance and fairness. The policies and procedures contained in this manual, together with the *ANSI Essential Requirements* and relevant ATCC corporate policies are intended to assure the national and international standards community that the ATCC Standards Development Organization embraces the ANSI/ISO guidelines for consensus standards development. Through due diligence in carrying out these policies and procedures, ATCC will produce American National Standards worthy of the stakeholder community it serves.

SECTION	1.0	ATCC SDO CONSENSUS STANDARDS DEVELOPMENT
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The ATCC SDO consensus standards development process incorporates and defaults to key elements of the *ANSI Essential Requirements* including:

- Due process
- Openness
- Lack of dominance
- Balance
- Notification of standards development and coordination
- Consideration of all views and objections
- Consensus vote
- Appeals
- Written procedures
- Compliance with normative American National Standards policies and administrative procedures

In particular, noted separately below are the ANSI definitions for due process and written procedures as found in their respective sections of the *ANSI Essential Requirements*.

1.1 Due Process

ANSI Essential 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. Due process allows for equity and fair play. The following constitute the minimum acceptable due process requirements for the development of consensus.”

1.2 Written Procedures

ANSI Essential Requirements: “Written procedures shall govern the methods used for standards development and shall be available to any interested person.”

SECTION	2.0	MEMBERSHIP
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The ATCC Consensus Standards Partnership (CSP) shall serve as the consensus body of the ATCC SDO. The Steering Committee (SC) is selected from the CSP membership and consists of high-level stakeholders that are responsible for providing guidance on overall strategic direction (Oversight Committee).

Voting membership on the Consensus Standards Partnership is not conditional to and does not require membership in ATCC or any specific organization consistent with the *ANSI Essential Requirements: Due process requirements for American National Standards*.

Participation in the ATCC SDO CSP and its subcommittees is open to primary and alternate CSP members. Eligibility for primary and alternate membership is extended to all members of the biomaterials stakeholder community.

Membership in the ATCC SDO is not a requirement for participation on an ATCC SDO Standards Development Workgroup (WG). WG members may elect to join the ATCC SDO at their discretion or may elect to transition from being an alternate member to becoming a primary member of the ATCC SDO as a result of WG participation.

All classes of membership in the CSP are open to private and public sector individuals, companies and organizations considered stakeholders in the biomaterials community.

2.1 Primary Membership

Primary membership in the CSP is open to any member of the biomaterials stakeholder community. Each primary member may designate one alternate member. Primary members are allotted one vote.

Individuals who are not members of the ATCC SDO but participate on ATCC SDO Standards Development Workgroups may elect at their discretion to become members of the ATCC SDO.

2.2 Alternate Membership

Alternate membership in the CSP is open to any member of the biomaterials stakeholder community. Alternate members must be designated by a primary member and may attend all CSP meetings and functions. Alternate members have no vote but may vote instead for their primary member when so designated by the primary member in writing.

2.3 Lack of Dominance

Unless challenged by a member of the biomaterials stakeholder community who is directly and materially affected and claims that a single interest category dominated the standards development process, no test for dominance is required.

2.4 Balance

The CSP shall serve as the representative of the biomaterials stakeholder community. Therefore, the CSP must be sufficiently diverse to ensure reasonable balance. The ATCC SDO will do everything possible to prevent any individual interest category from exceeding more than a 50% majority of the membership of any CSP working group dealing with standards. The ATCC SDO will ensure that there is

appropriate outreach made to achieve balance, and that evidence of this outreach is retained and made available to ANSI as required.

2.5 Leaving Membership

Organizations may vacate either their primary or alternate ATCC SDO Consensus Standards Partnership (CSP) membership. An organization that elects to vacate their CSP primary membership may still participate in the ATCC SDO or its subcommittees on a non-voting basis. If the ATCC SDO experiences costs that are directly attributable to non-member participation in the ATCC SDO or its subcommittees the ATCC SDO reserves the right to recover those costs from participating non-members.

Steering Committee members are either reaffirmed or succeeded every 3 years. If an ATCC SDO Steering Committee member vacates their position prior to the 3-year mark, they surrender their membership on the Steering Committee but may retain their membership in the Consensus Standards Partnership (CSP). Before assuming Steering Committee roles and responsibilities, a candidate must first submit their credentials to the SDO Office of the Director for review and approval.

2.6 Membership Roster

The roster, with the name, affiliation and interest category of each member of the consensus body must be available to interested parties upon request as stated in the *ANSI Essential Requirements*.

See the Glossary of Acronyms and Terms, **Section 25.0**, for ATCC SDO working definitions for manufacturers and marketing.

Membership rosters documenting the classification of all committee members shall be maintained.

2.7 Termination of Membership

The ATCC SDO Office of the Director shall be authorized to terminate membership for any member of the CSP for non-participation and per request of the CSP member.

Causes for termination include inactivity and/or failure to pay appropriate fees as levied by the ATCC SDO.

A CSP member shall be considered inactive and dropped from the roster for one of the following:

- Failure to return or to respond to three (3) consecutive ballots issued during a calendar year.

- Failure to attend or otherwise participate in at least one CSP meeting during a calendar year.
- After three (3) attempts to contact the member without a response.

The ATCC SDO Office of the Director shall be authorized to terminate membership for the following:

- Request in writing from member to be voluntarily removed.

CSP members and members of all CSP committees shall submit a new application following their removal from the CSP roster if continued membership is desired.

2.8 Notification of Member Changes

CSP members and members of all CSP committees shall notify the ATCC SDO Office of any changes in employment affecting interest representation, and ensure that all contact information is correct and accurate in their member record.

Should the reported change in employment affect the member's interest representation, that change will be made in the member's record on the SDO website for balloting purposes, and to continually monitor balance in the SDO.

SECTION	3.0	CONSENSUS BODY AND SDO ORGANIZATION
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3.1 Consensus Body

The CSP will serve as the "consensus body" for the purpose of documenting consensus on all American National Standards proposed by the ATCC SDO.

3.2 Steering Committee

The SDO Steering Committee is selected from CSP membership and oversees the work of the CSP and its workgroups, recommending final actions for standards development to the ATCC SDO Office of the Director.

3.3 ATCC SDO Office of the Director

The ATCC Office of the Management Representative for Standards and Certification shall serve as the Office of the Director for the ATCC SDO.

3.4 Openness, Balance and Due Process

All ATCC SDO committees and committee structures must comply with the ANSI requirement for openness, balance and due process. These requirements are detailed in the appended *ANSI Essential Requirements*.

SECTION	4.0	RECORDS
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4.1 Definition

Records are documents that provide evidence that an activity has been accomplished or that an event has happened.

Records refer to all written, recorded, or electronic information that captures data.

4.2 Requirements

Each ATCC SDO committee and every ATCC department is responsible for defining and keeping his or her own records. See **Section 23.0** of this manual, ATCC “SOP–Record Control” procedure that is supported by ATCC.

4.3 Retention

4.3.1 Records retention requires, as a minimum, that records concerning new, revised or reaffirmed American National Standards be retained for one complete development cycle or until the standard is revised.

4.3.2 Records concerning withdrawn standards shall be retained for at least five (5) years from date of withdrawal.

4.4 Presentation, Integrity, Reliability, Accessibility and Quality

ATCC maintains policies to improve presentation, integrity, reliability, accessibility and quality of information in support of ATCC operations, customer service and the planning and decision processes of management.

The ATCC “SOP–Record Control” procedure serves to define the controls for managing departmental records. The document applies to records/documentation generated in compliance with ISO9001:2008 and will be a model for ATCC SDO records control.

SECTION	5.0	OPERATING COSTS
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5.1 Fees

With appropriate notice and committee approval, appropriate and necessary fees to offset services provided in support of committee activities will be requested.

5.2 Assessment

The ATCC SDO shall request payment of reasonable fees directly relating to the support provided and activities of a given committee. These fees may be assessed only with the approval of both the committee being supported and the ATCC SDO Office of the Director.

SECTION 6.0 INTEREST CATEGORIES

For purposes of assuring balanced community representation when developing American National Standards members of ATCC SDO CSP members shall be classified as belonging to one or more of the following categories: Industry, Government/Regulatory, Academia, and Other (General Interest).

Each potential CSP members should review the category definitions listed on the Representation/Stakeholder page of the ATCC SDO website, on the paper application, or in this policy and procedure manual before applying for membership. Should the potential member still have any questions, he/she should contact the ATCC SDO directly.

Each CSP member determines which interest group they best represent. See below for detailed information of each interest group.

6.1 Industry

This category includes commercial entities such as manufacturers and marketers. Please refer to Glossary of Acronyms and Terms, **Section 25.0** for ATCC SDO working definitions for manufacturers and marketers.

6.2 Government/Regulatory

This category includes entities of national, state or local governments, and entities that exercise a regulatory role, such as the US Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). This also includes similar agencies from other countries.

6.3 Academia

This category includes entities that are or are a part of an educational institution.

6.4 Other (General Interest)

General Interest members include those not classified as Industry, Government, Academia or Regulatory. Examples include, but are not limited to, journals and other publications or any individual or organization that is affected by or interested in the need for and application of biomaterials and related processes.

SECTION	7.0	COMMERCIAL TERMS AND CONDITIONS/BUSINESS CONDUCT AND ETHICS
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7.1 Business Terms and Conditions

ATCC agrees to comply with the most current version of the *ANSI Commercial Terms and Conditions* policy given in the *ANSI Essential Requirements*.

7.2 Business Conduct and Ethics

ATCC takes all appropriate measures to comply with U.S. antitrust laws and foreign competition laws in all of its business activities. ATCC’s SDO develops consensus standards under ATCC’s general corporate policies on proper business conduct and ethics.

ATCC maintains policies to guide employees with respect to standards of conduct expected in areas where improper activities could damage the company’s reputation and otherwise result in adverse consequences to the company and to the employees involved.

Please refer to **Section 23.0**, ATCC Reference Policies and Procedures, “Corporate Policy–Business Conduct and Ethics” ATCC policy number 100-020.

7.3 Disclosure of Interest and Copyright Use

The ATCC SDO requires that all nominees for committees, subcommittees, task forces, or working groups complete a disclosure of interests and copyright assignment form (see **Appendix 26.1**). Decisions and contributions made on behalf of the ATCC SDO and works published by the organization must be developed promoting the opportunity for fair and open discussion by any interested parties. In addition, any contributions made to the ATCC SDO must not knowingly infringe on the copyright or any other right of any third party.

SECTION	8.0	COMPUTER-BASED CORPORATE INFORMATION ASSETS
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As stated in **subsection 4.4**, ATCC maintains policies to improve presentation, integrity, reliability, accessibility and quality of information in support of ATCC operations, customer service and the planning and decision processes of management.

Please refer to **Section 23.0**, ATCC Reference Policies and Procedures, “Corporate Policy–Computer-based Corporate Information Assets” ATCC policy number 100-016.

SECTION 9.0 MEETINGS

ATCC SDO meeting policy is to inform members of substantial matters related to the activities and policies of the ATCC SDO.

9.1 Frequency

The CSP will meet as necessary.

9.2 Notification

Notifications for meetings of the CSP are made in writing utilizing email, the SDO website, and various meeting requests applications.

9.2.1 Face-to-face Meetings

These meetings shall be announced via email and the ATCC SDO website four (4) weeks prior to the meeting date.

9.2.2 All Other Meetings

All other meetings, including virtual meetings and conference calls, will be announced via email and may be posted to the ATCC SDO website as well.

9.2.3 Special Exceptions

Special exceptions for extraordinary circumstances may be made on an as-needed basis. When an exception for extraordinary circumstances is necessary, the committee leadership will announce the meeting as soon as practicable.

9.2.4 Agendas

9.2.4.1 Draft Agendas

ATCC SDO draft agendas shall be prepared and distributed prior to the meetings.

9.2.4.2 ATCC SDO Final Agendas

ATCC SDO final agendas will be provided when meetings are called to order.

9.3 Open Meetings

All meetings of ATCC SDO committees shall be open and attendance by any interested party shall be welcome, subject to any relevant membership requirement

and the individual policy of each committee regarding registration, minimum attendance levels, etc.

9.3.1 Voting

9.3.1.1 Committee Members

All primary committee members shall have the right to one vote.

9.3.1.2 Non-committee Members

Non-committee members shall not have the right to vote.

9.4 Quorum

A majority of the members of a committee shall constitute a quorum for conducting business at a meeting.

Matters shall be deemed approved by the affirmative vote of a majority of the members present. If a quorum is not present, actions on agenda items may be taken but shall be subject to ratification by a letter ballot of the committee.

9.5 Parliamentary Procedures

For any procedural issues not covered under these procedures, *Robert's Rules of Order Newly Revised* shall apply on questions of parliamentary procedure.

SECTION 10.0 NOTIFICATION OF STANDARDS DEVELOPMENT

10.1 How Notification Shall Be Announced

Notification of standards activity shall be announced in suitable media as appropriate to demonstrate opportunity for participation by all directly and materially affected persons.

Efforts will be made to consult any relevant international or regional guides that may impact the proposed standard and alert the relevant ANSI-Accredited U.S. TAG(s) if the standard is intended to be submitted for consideration as an ISO, IEC or ISO/IEC JTC-1 standard.

10.2 When Notification Shall Be Given

Notification will be given at the initiation of a project to develop or revise a standard.

10.3 How Notification Shall Be Transmitted

Following the recommendation and balloting of the SDO Steering Committee, notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form for listing in the ANSI Standards Action. Notification is made at

the initiation of a project to develop an American National Standard, and/or at the initiation of a project to revise an American National Standard 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.

10.3.1 PINS Exceptions

A PINS is not required for revisions of an American National Standard that is maintained under continuous maintenance and (1) is registered as such on the ANSI website, (2) has a notice in the standard that the standard is always open for comment and how to submit comments, and (3) has information on the developer's website that the standard is under continuous maintenance and how to submit comments. A PINS is also not required in connection with the decision to maintain an ANS under the stabilized maintenance option. A PINS form may be submitted, but is not required, at the initiation of a project to reaffirm or withdraw an American National Standard.

10.3.2 Assertions of conflict or duplication

If a developer receives written comments within 30 days from the publication date of a PINS announcement in *Standards Action*, and said comments assert that a proposed standard duplicates or conflicts with an existing American National Standard (ANS) or a candidate ANS that has been announced previously (or concurrently) in *Standards Action*, a mandatory deliberation of representatives from the relevant stakeholder groups shall be held within 90 days from the comment deadline. Such a deliberation shall be organized by the developer and the commenter and shall be concluded before the developer may submit a proposed standard for public review. If the deliberation does not take place within the 90-day period and the developer can demonstrate that it has made a good faith effort to schedule and otherwise organize it, then the developer will be excused from compliance with this requirement. The purpose of the deliberation is to provide the relevant stakeholders with an opportunity to discuss whether there is a compelling need for the proposed standards project

10.3.3 PINS Deliberation Report

The outcome of a PINS deliberation shall be conveyed in writing (the "Deliberation Report") within 30 days after the conclusion of the deliberation by the developer to the commenter and to ANSI. Upon submission of the Deliberation Report, the developer may continue with the submission of the proposed standard for public review. If additional deliberations take place, they should not delay the submission of the proposed standard for public review, and an updated Deliberation Report shall be

conveyed within 30 days after each deliberation. Any actions agreed upon from the deliberations shall be carried out in a reasonably timely manner, but normally should not exceed 90 days following the deliberation. Subsequently, the developer shall include all of the deliberation Report(s) with the BSR-9 submittal to the ANSI Board of Standards Review (BSR) for consideration should the developer ultimately submit the subject standard to ANSI for approval. Stakeholders who were involved in the PINS deliberation process may also file separate Deliberation Report(s) with ANSI and the developer within 30 days after conclusion of any deliberation for consideration by the BSR, if the standard is submitted to ANSI for approval. In the case of ANSI Audited Designators, the Audited Designator shall provide a Deliberation Report to the commenter and to ANSI within 30 days after each deliberation. The Audited Designator shall review the results of the deliberation prior to designating a standard as an ANS. While the outcome is not binding, unless binding provisions are agreed to by the developer, participants are encouraged to develop a consensus on whether and how the standards development project should precede. *See also 4.3 of the ANSI Essential Requirements*

10.3.4 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 *Standards Action* 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 days if the full text of the revision(s) can be published in *Standards Action*;
- A minimum of forty-five days if the document is available in an electronic format, deliverable within one 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 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 subsequently made in a proposed American National Standard requires listing of the change in *Standards Action*.

10.4 Comments on PINS Announcement(s)

Comments on a PINS announcement will be resolved by the procedure given in the *ANSI Essential Requirements*.

SECTION 11.0 SUBSTANTIVE CHANGES

A substantive change in a standard is a change that directly and materially affects the use of the standard. Examples of substantive changes:

- Changing “shall” to “should” or “should” to “shall”.
- The addition, deletion or revision of requirements, regardless of the number of changes.
- The addition of mandatory compliance with referenced standards.

SECTION 12.0 VOTING PROCEDURES

12.1 Letter Ballots

The letter ballot process will be used for documentation of balloting associated with the development of American National Standards. This includes balloting at all levels of the organization, including balloting by the SDO Steering Committee, the Consensus Standards Partnership, and individual standards development workgroups.

Letter ballots include:

- Ballots sent through the public mail system
- Ballots sent by special delivery and/or private courier services
- Ballots sent electronically, such as by email or via a secure website

12.2 New Proposed American National Standards

All new proposed American National Standards and reaffirmations of all standards shall be reviewed, prioritized, and approved first by the Steering Committee via letter ballot.

12.3 Substantive Changes to Existing American National Standards

Substantive changes to and interpretations of all standards shall be approved by letter ballot of the CSP.

12.4 Voting

Written or electronic ballots shall provide the opportunity for each member of the committee or workgroup to vote in accordance with one of the following positions that shall be on every letter ballot:

- Affirmative

- Abstain
- Affirmative with comment
- Negative with reasons

If possible, the negative ballot shall include specific actions that will resolve the negative. This will be done in writing.

12.5 Voting Rights

Every vote shall be cast by a member of a committee or a member's alternate.

12.6 Alternate Member Votes

Alternate members may vote instead for primary members. Such votes are not considered as proxy votes. The member's alternate representative shall cast that member's vote only if the member is unable to vote. Notification by the primary member shall be made in writing before the alternate's vote is added to the final tally.

12.7 Voting Period

12.7.1 Closure Date

The closure date for letter ballots shall be at least thirty (30) days from the date of the issuance of the ballots for all ballots of the SDO Steering Committee and the Consensus Standards Partnership.

Closure dates for letter ballots issued on behalf of standards development workgroups shall be at least ten (10) days from the date of the issuance of the ballots.

12.7.2 Extensions

The ATCC SDO Office of the Director shall be authorized to grant an extension of the voting period if deemed necessary.

12.8 Approved Actions

12.8.1 Approvable Actions

- Approvals of standards
- Approvals of substantive changes to standards
- Approvals of reaffirmations of standards
- Approvals of interpretations of standards
- Approvals of actions taken by standards development workgroups

12.8.2 Conditions of Approval

Actions shall be considered approved when all of the following conditions have been met:

- At least fifty percent (50%) of the members have returned their letter ballot.
- At least seventy-five percent (75%) of the votes cast, excluding abstentions and negatives without reasons, are affirmative.
- All negative votes with reasons have been addressed in accordance with **Section 12.10** below.

12.9 Reporting Votes

The results of each vote on all standards are reported to the SDO Director, and the applicable working group. Results shall be reported as follows:

- Number of members
- Number of members voting affirmatively
- Number of members voting negatively with reasons
- Number of members voting negatively without reasons
- Number of members abstaining
- Number of members not returning ballots

12.10 Negative Votes

- Negative ballots shall be accompanied by a reason and should include specific wording or actions that would resolve the objection.
- Negative ballots not supported by a reason are not required to be re-circulated. They shall be recorded as a negative without comment.
- For the purpose of establishing a quorum, the ballot shall be counted as returned.

12.11 Consideration of Views and Objections

Workgroups shall use the following procedures in attempting to resolve negative votes:

- a. All negative ballots and comments will be forwarded to the work group that drafted the proposed standard for response and resolution.
- b. Work Group officers (with other work group members as necessary) will draft the response on behalf of the full workgroup.
- c. All comments are given a comprehensive response in writing.
- d. Unresolved objections along with attempts at resolution will be provided to the consensus body in order to afford all members the opportunity to respond, reaffirm, or change their vote.

- e. In the case of public review comments, which are not votes, these comments with the accompanying responses, will be circulated with each ballot.
- f. Unresolved public review objections, along with attempts at resolution, will be re-circulated to the consensus body to give all members an opportunity to respond, reaffirm, or change their votes, as required by the *ANSI Essential Requirements*.
- g. In cases where negative comments remain unresolved or substantial revisions are made to the standards, in an attempt to resolve remaining negatives, all members of the consensus body, or the standards specific workgroup, when appropriate, will be given the opportunity to respond, reaffirm, or recast their votes based upon the resulting revised version.
- h. All substantive changes shall be submitted to ANSI via the BSR-8 document for further public review.
- i. All SDO voting members or public review participants who have unresolved negative votes (comments) shall be notified of their right to appeal and of the appeals process in writing.

SECTION	13.0	INTERPRETATIONS
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13.1 Processing Interpretations

13.1.1 Requests for Interpretations

Requests for interpretations of standards shall be submitted in writing to the ATCC SDO Office of the Director and shall be forwarded by the said office to the CSP.

13.1.2 Proposed Interpretations

Proposed interpretations may be prepared by any CSP member with particular expertise on the subject in question. All proposed interpretations shall be prepared in writing, and shall be submitted to the ATCC SDO Office of the Director for final action.

13.2 Notification of Interpretations

13.2.1 Notification to the Requestor

Notification of approved interpretations shall be sent in writing to the requestor.

13.2.2 Notification to Other Users

Notification shall also be given to other users of the standards via the appropriate CSP email list(s) and posted on the ATCC SDO website.

SECTION 14.0 METRIC POLICY

In accordance with the *ANSI Essential Requirements*, ATCC SDO accepts ANSI's Metric Policy, which states: "Units of the International System of Units (SI), the modernized metric system, are the preferred units of measurement in American National Standards."

SECTION 15.0 PUBLIC REVIEW AND COMMENT

Proposals for new standards or reaffirmation, revision, or withdrawal of existing standards shall be transmitted to ANSI for listing in the ANSI Standards Action for comment.

The ATCC SDO Office of the Director shall determine whether listing of proposed ATCC standards actions in ANSI's Standards Action shall be concurrent with the ballot to the CSP, and whether announcement in other suitable media is appropriate.

All comments that are received shall be considered by the CSP and the commenter shall be notified, in writing, of the committee's decision/response in accordance with the *ANSI Essential Requirements*.

SECTION 16.0 PATENT POLICY

The ATCC SDO agrees to comply with the ANSI Patent Policy as outlined in the most current version of the *ANSI Essential Requirements*.

SECTION 17.0 CORRESPONDENCE

Guidance on ATCC SDO correspondence from existing ATCC corporate policy may be found in:

- "Corporate Policy–Submissions For Publications" ATCC policy number 100-009.
- "Corporate Policy–External Media Protocol" ATCC policy number 100-011.

17.1 CSP Correspondence

Correspondence from a CSP member to the entire membership shall be forwarded to the ATCC SDO Office of the Director for screening and distribution.

All official CSP correspondence, including meeting notices, agendas, reports and letter ballots, shall be distributed by the ATCC SDO Office of the Director.

Copies of all other correspondence between CSP members, relating to ATCC SDO standards activities, shall be forwarded to the ATCC SDO Office of the Director.

17.2 External Correspondence

All official CSP correspondence to external parties must be approved by the CSP or its delegated representative and distributed by the ATCC SDO Office of the Director. Inquiries relating to the CSP and standards shall be directed to the ATCC SDO Office of the Director.

CSP members should advise individuals who contact them that responses to all inquiries are handled by the ATCC SDO Office of the Director.

SECTION 18.0 PROCEDURAL APPEALS

18.1 Procedural Appeals Submission Process

Persons who have been or may be affected by any CSP action or inaction shall have the right to appeal such action or inaction.

The appellant shall file a written complaint with the ATCC SDO Office of the Director within thirty (30) days after the date of notification of any action, or at any time with respect to inaction. The complaint shall state:

- The nature of the objection
- The procedures or the sections of the standards that are at issue
- The action or inaction at issue
- The specific remedial action(s) that would satisfy the appellant's concerns

Previous efforts to resolve the objections and the outcome of each shall be noted.

18.2 Response

Within thirty (30) days after the receipt of the complaint, the ATCC SDO Office of the Director shall respond in writing, to include electronic mail, to the appellant, specifically addressing each allegation in the complaint to the extent possible. The ATCC SDO Office of the Director shall attempt to informally resolve the complaint of the appellant.

18.3 Appeals Panel and Hearing

If the ATCC SDO Office of the Director is unable to informally resolve the complaint, it shall appoint an appeals panel to hold a hearing on a date agreeable to all participants, with at least fifteen (15) working days' notice.

The appeals panel shall consist of three (3) individuals who have not been directly involved in the dispute and who will not be materially affected by any decision made in the dispute.

At least two (2) members of the panel shall be acceptable to the appellant and at least two (2) shall be acceptable to the ATCC SDO Office of the Director.

Person who have been or may be affected by any CSP procedural action or inaction shall have the right to appeal.

18.4 Conduct of the Hearing

The appellant has the responsibility of demonstrating improper action or inaction, the adverse effects that may derive and the efficacy of the requested remedial action.

The ATCC SDO Office of the Director has the responsibility to demonstrate that the appeals panel took all actions in question in compliance with these procedures.

18.5 Decision

The appeals panel shall render its decision in writing within thirty (30) days of the hearing, based upon a preponderance of the evidence. The panel shall state its findings of fact and conclusions, with reasons and cite the evidence.

The ATCC SDO Office of the Director shall notify the appellant and the committee of the decision of the appeals panel, which shall be final and binding on all concerned.

SECTION 19.0 REVISIONS TO PROCEDURES

These operating procedures are maintained by the ATCC SDO Office of the Director. Proposed revisions to these operating procedures may be submitted in writing by any ATCC SDO member, CSP member, or workgroup member to the ATCC SDO Office of the Director along with a supporting rationale for the proposed change.

The ATCC SDO Office of the Director will present the proposed revisions to the ATCC SDO Steering Committee for review and comment. The revised procedures are then to be submitted to ANSI for review and approval.

Any approved revisions to these operating procedures shall be effective upon publication. The ATCC SDO Office of the Director shall be responsible for the interpretation of these operating principles and procedures.

SECTION 20.0 CRITERIA FOR APPROVAL AND MAINTENANCE OF AN AMERICAN NATIONAL STANDARD
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The CSP and or Work Group must determine that:

- The type of action requested is clear, e.g., approval of a new American National Standard or reaffirmation, revision, or withdrawal of an existing American National Standard.
- The proposed standard is within the scope of the ATCC SDO.
- The standard was developed according to the ATCC SDO policies and procedures of this manual.
- Due process was followed, consensus was achieved, and an effort was made to resolve any objections to the standard.
- Any appeal to the standards developer with respect to the standard was completed.
- Notice of the development process for the standard was provided to ANSI in accordance with PINS.
- Any identified conflict with another American National Standard was addressed in accordance with the procedures outlined in the *ANSI Essential Requirements*.
- Other known national standards were examined with regard to harmonization and duplication of content and if duplication exists, there is a compelling need for the standard
- A clear title and designation of the proposed American National Standard was provided.
- ANSI's patent policy is met, if applicable.
- ANSI's policy on commercial terms and conditions is met, if applicable.
- The ATCC SDO provided the following or evidence of:
 - i. title and designation of the proposed American National Standard;

- ii. indication of the type of action requested (that is, approval of a new American National Standard, or
- iii. reaffirmation, revision, or withdrawal of an existing American National Standard);
- iv. a declaration that applicable procedures were followed;
- v. a declaration that the proposed standard is within the scope of the previously registered standards activity;
- vi. a declaration that conflicts with another American National Standard have been addressed in accordance with these procedures in the *ANSI Essential Requirements*;
- vii. a roster of the consensus body that indicates the vote of each member including abstentions and unreturned ballots, if applicable; the interest category of each member; and a summary thereof;
- viii. a declaration that all appeal actions related to the approval of the proposed standard have been completed;
- ix. a declaration that the criteria contained in the ANSI patent policy have been met, if applicable; and
- x. identification of all unresolved negative views and objections, with names of the objector(s), and a report of attempts toward resolution.

If the ANSI Board of Standards Review (BSR) determines, based on the weight of the evidence presented, that the above-stated criteria have been satisfied, the standard shall be approved as an American National Standard. The BSR shall deny approval, if, based on the weight of the evidence presented, the BSR determines that the American National Standard:

- a) is contrary to the public interest;
- b) contains unfair provisions;
- c) is unsuitable for national use; or
- d) that the ASD has failed to make a good faith effort to resolve conflicts.

Standards approved as American National Standards shall be designated, published, and maintained in accordance with the procedures contained herein. A substantive change that has not been afforded due process in accordance with these procedures may not be made in an approved American National Standard.

Standards approved as American National Standards shall be kept current and relevant by means of a timely revision, a reaffirmation, or an action to stabilize. Standards that are no longer relevant, obsolete, or expired shall be withdrawn. The exception to this is when an ISO and IEC standard has been nationally adopted as an American National Standards. In this case, the maintenance provisions contained in the ANSI Procedures for the National

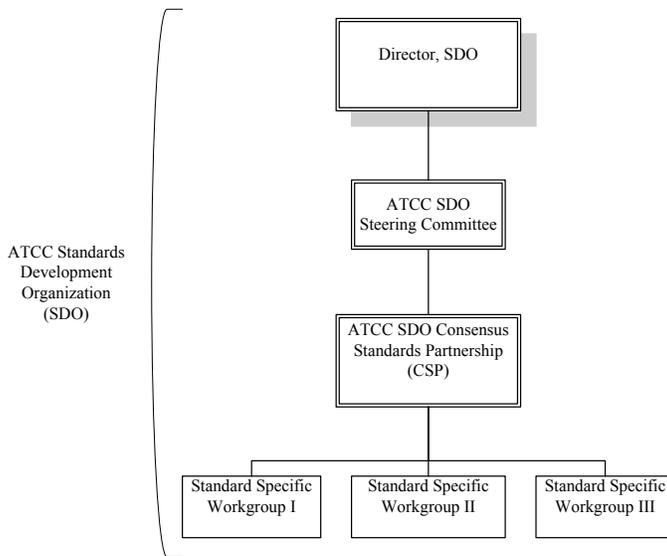
Adoption of ISO or IEC Standards as American National Standards shall apply. Refer to **Sections 4.5** through **4.7.3** of the *ANSI Essential Requirements*.

The ANSI Board of Standards Review (BSR) shall not approve standards that duplicate existing American National Standards unless there is a compelling need.

Notice of the BSR's final action on all standards shall be published in *Standards Action*.

SECTION 21.0 ATCC SDO ORGANIZATIONAL CHARTS

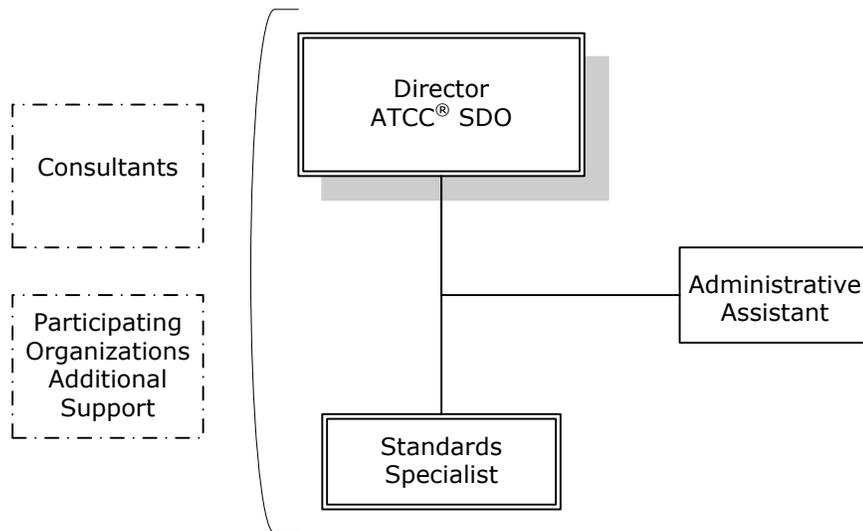
21.1 ATCC Standards Development Organization (SDO)



21.2 ATCC SDO Office of the Director

Staff:

1. Director
2. Standards Specialist
3. Administrative Assistant
4. In kind support from participating organizations
5. Consultants (as needed)



SECTION 22.0 ATCC SDO PROVISIONAL AMERICAN NATIONAL STANDARD AND WITHDRAWAL PROCEDURES

22.1 Provisional American National Standard (ANS) or a Provisional Amendment to an ANS

The ATCC SDO agrees to comply with the ANSI Procedures for the Development of a Provisional American National Standard (ANS) or a Provisional Amendment to an ANS located in Annex B of the ANSI Essential Requirements: Due process requirements for American National Standards ANSI Essential.

22.2 Criteria for WithdrawalAdministrative withdrawal

An American National Standard shall be withdrawn five years following approval:

- if the standard has not been revised or reaffirmed
- unless an extension has been granted by the Executive Standards Council or its designee
- if the ANS is withdrawn without a CSP vote

An American National Standard that has not been reaffirmed or revised within the five-year period and that has been recommended for withdrawal by the Executive Standards Council or its designee shall be withdrawn at the close of a 30-day public review notice in *Standards Action*. American National Standards that have not been revised or reaffirmed within ten years from the date of their approval as American National Standards shall be withdrawn and such action shall be announced in *Standards Action*.

22.2.2 Withdrawal by the ATCC SDO

The ATCC SDO may withdraw a standard following a written recommendation from the director of the SDO, and a consensus vote by the ATCC SDO Steering committee. The ATCC SDO shall notify ANSI immediately and the standard shall be withdrawn as an ANS and announced in *Standards Action*.

22.2.3 Discontinuance of a standards project

The ATCC SDO may decide to abandon the processing of a proposed new or revised American National Standard or portion thereof at its own discretion and without a vote of the consensus body. The ATCC SDO must notify ANSI immediately of such actions that will be announced in the Standards Action.

SECTION	23.0	ATCC REFERENCE POLICIES AND PROCEDURES
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- 23.1** Amended and Restated Bylaws of American Type Culture Collection, adopted May 2004, amended December, 2004
- 23.2** Bylaws of the International BioResources Group
- 23.3** Corporate Policy–Business Conduct and Ethics, ATCC policy number 100-020, effective December 2015
- 23.4** Corporate Policy and Procedure–Submissions for Publications, ATCC policy number 100-009, effective October 2014
- 23.5** Corporate Policy–Computer-based Corporate Information Assets, ATCC policy number 100-016, effective September 2013
- 23.6** Corporate Policy–Use of Company Resources, ATCC policy number 100-004, effective July 2013
- 23.7** Corporate Policy–External Media Protocol, ATCC policy number 100-011, effective February 2016
- 23.8** ATCC Quality Manual–Management Responsibility
- 23.9** Corporate Policy–Information Security, ATCC policy number 100-012 effective July 2013

- 23.10 Corporate Policy–Workshops, Seminars and Professional Meetings, ATCC policy number 100-008, effective October 2014
- 23.11 Corporate Policy–Confidentiality and Release of Public Information, ATCC policy number 100-001, effective October 2013
- 23.12 SOP–Record Control, ATCC procedure
- 23.13 Corporate Policy–Federal Awards Conflict of Interest, ATCC policy number 200-010, effective March 2013

SECTION 24.0 POSITION REGARDING ANSI ESSENTIAL REQUIREMENTS

The *ANSI Essential Requirements* is considered as a companion to and part and parcel of this manual.

The material contained in the *ANSI Essential Requirements: Due process requirements for American National Standards* and its recommendations shall provide guidance whenever such guidance is required and when necessary or appropriate shall supersede all other policies and procedures stated in other sections of this manual.

Decisions of policy and procedure based on policies and/or procedures not yet developed by the ATCC SDO organization but necessary to support ATCC SDO business will be guided by the *ANSI Essential Requirements: Due process requirements for American National Standards* until such time that the ATCC SDO shall develop its own replacement policy or procedure consistent with and approved by ANSI.

SECTION 25.0 GLOSSARY OF ACRONYMS AND TERMS

ACRONYM/TERM

Academia

DEFINITION

This category includes entities that are or are a part of an educational institution.

ANSI-Accredited Standards Developer (ASD)

In order to maintain ANSI accreditation, standards development organizations are required to consistently adhere to a set of requirements or procedures known as the “ANSI Essential Requirements: Due process

requirements for American National Standards,” that govern the consensus development process.

ANSI Board of Standards Review (BSR)

The ANSI Board of Standards Review is responsible for the approval and withdrawal of American National Standards and for other responsibilities that may be delegated to it by the Board of Directors.

ANSI Executive Standards Council (ExSC)

The ANSI Executive Standards Council (ExSC) is responsible for coordination of the overall national and international standards activities of the American National Standards Institute as well as the accreditation of U.S. TAGs to ISO.

ANSI Standards Action

As stated on the American National Standards Institute's (ANSI) website, “Standards Action is the Institute’s key public review vehicle. Published weekly, it provides members and the public with timely, accurate information and enables effective participation in the standards development process—both in this country and internationally.”

ATCC

The ATCC (American Type Culture Collection) is a global not-for-profit bioresource center and research organization that provides biological products, technical services and programs to private industry, government and academic organizations around the world.

ATCC Mission

ATCC is a global nonprofit bioresource center and research organization that provides biological products, technical services and educational programs to private industry, government and academic organizations. Our mission is to acquire, authenticate, preserve, develop and distribute biological materials, information, technology, intellectual property and standards for the advancement and application of scientific knowledge.

ATCC Vision	The ATCC vision is to use its resources and experience as a BRC to become the world leader in standard biological reference materials management, intellectual property resource management and translational research as applied to biomaterial development, standardization and certification.
ATCC SDO CSP	ATCC Standards Development Organization Consensus Standards Partnership
Biomaterials	Biomaterials include, but are not limited to bacteria, fungi, yeasts, cell lines, toxins, protozoa, viruses and molecular products (DNA, etc.). Biomaterials may be biosafety level (BSL) 1, 2 or 3.
Biomaterials Stakeholder Community	This includes individuals and entities concerned or involved with biomaterials and processes related to their development, identification, authentication, production, storage, distribution and transfer. Stakeholders come from industry, federal agencies, leading research organizations and universities.
Consensus	Consensus means directly and materially affected interests have reached substantial agreement. This signifies the concurrence of 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 Body	The group that approves the content of a standard and whose vote demonstrates evidence of consensus.
Consumer	An individual or entity that uses any biomaterial or is in any way involved in processes related to biomaterials including development, identification, authentication, production, storage, distribution and transfer.

CSP	Consensus Standards Partnership that functions as the ATCC SDO.
Government/ Regulatory	This category includes entities of national, state or local governments, and entities that exercise a regulatory role, such as the US Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA). This also includes similar agencies from other countries.
Industry	This category includes commercial entities such as manufacturers and marketers.
Life Science Sector Manufacturers	Biological science and technology sector. An entity that produces and/or provides biomaterial products and/or biomaterial related processes and/or services or information.
Marketers	An entity that purveys biomaterials and/or biomaterial-related processes and/or services or information.
Membership Roster	List of primary or alternate members formally maintained by the ATCC SDO and available as public information. The membership roster will be maintained electronically.
National Standards	The Consensus Standards Partnership (CSP)
Other	General Interest members include those not classified as Industry, Government/ Regulatory, or Academia
General Interest	Examples include, but are not limited to, journals and other publications or any individual or organization that is affected by or interested in the need for and application of biomaterials and related processes
PINS	ANSI Project Initiation Notification System.
Enterprise resource planning (ERP)	ATCC's business process management

Qualtrax	<p>software that allows the use a system of integrated applications to manage business and operations functions.</p> <p>Online, web-based document management software providing electronic document approval, review and publishing, as well as complete document history.</p>
Record	<p>Written, recorded, or electronic information that captures data and may include a signature and date of an individual. Records are documents that provide evidence that an activity has been accomplished or that an event has happened. Records are used to provide information on the condition (such as conformity or nonconformity) of a product. Each department is responsible for defining and keeping their own records.</p>
Records Control	<p>The ATCC SDO will maintain records control through use of online software detailed in ATCC records control policy.</p>
Work Group	<p>Interdisciplinary collaboration of researchers working together toward a common goal. These activities would be difficult to develop under traditional funding mechanisms (e.g. federal agencies). The lifespan of a Work Group (WG) is anywhere between a few months and several years. WG goals to be achieved may include creation of an informational document or creation of a consensus standard.</p>
TAG	<p>Technical Advisory Group (TAG) advises on issues involving a standard, method, and/or procedure.</p>
Steering Committee	<p>A group of high-level stakeholders that are responsible for providing guidance on overall strategic direction, abbreviated as SC.</p>

Appendix 26.1

**ATCC® SDO Volunteer Disclosure of Interest and Copyright Assignment Agreement****ATCC® SDO Volunteer Role**

Name of SDO Volunteer: _____
Specific Workgroup Title: _____

The ATCC® Standards Development Organization (SDO) is accredited by the American National Standards Institute (ANSI) and governed by policies published in the *ANSI Essential Requirements: Due Process Requirements for American National Standards* (ANSI Requirements), as interpreted by ATCC. As an accredited SDO, we require all volunteers to read and sign this volunteer disclosure of interest and copyright assignment agreement. Information disclosed will be maintained by the ATCC SDO Office of the Director and included in the relevant records with respect to applicable standards.

Please indicate your volunteer activities with the ATCC® SDO by checking the appropriate box:

- I am participating in ATCC SDO standards development activity in my personal capacity.
- I am participating in ATCC SDO standards development activity in my capacity as an employee of _____ (employer), with the consent of my employer.
- I am participating in ATCC SDO standards development activity in my capacity as a U.S. Federal government employee.

All contributions made by any member or volunteer to the ATCC SDO while participating in ATCC SDO standards development activity shall be and become the sole property of ATCC and therefore any and all copyright and other intellectual property rights therein are owned solely and exclusively by the ATCC SDO. Contributions made to any ATCC SDO committee or workgroup must be original to the undersigned. The undersigned must provide documentary information regarding the origin of material contributed to the standards development process which is not original. Contributions must not infringe on the copyright of others. By intent, the standards development process is designed to be open, transparent and subject to review and comment by the community of interest. Volunteers participating in ATCC SDO standards development activity understand that information shared during this process cannot be kept confidential and agree not to disclose confidential and proprietary information during their participation.

Disclosure of Interest

Procedures used by the ATCC SDO meet ANSI requirements for openness, balance, consensus and due process. In accordance with ANSI requirements, ATCC SDO is sensitive to conflicts of interest that may affect the participation of ATCC SDO volunteers, and believes it important that any potential conflicts be disclosed in the standards development process. To that end, each SDO volunteer must describe below,

and update as appropriate, any potential conflicts of interest, and acknowledges that such description will be disclosed as part of the standards development process.

The following are professional and personal organizations and activities in which I am engaged, and financial or other interests of mine that may relate to or impact my standards development activity (you may attach a *curriculum vitae* and supplement with description below).

1. I certify that I have read this ATCC SDO Volunteer Disclosure of Interest and Copyright Assignment Agreement and agree to abide by its principles and requirements.
2. I acknowledge that I am not an equity holder or partner of ATCC and that I am not entitled to any benefits that would be received in such capacities, that I will receive no cash or equity compensation for my ATCC SDO Volunteer activities, and that I have no workers' compensation rights with respect to such activities. I agree to avoid any conflicts of interest with respect to my participation as an ATCC SDO volunteer.
3. I confirm that any intellectual property that exists by virtue of my activities as an ATCC SDO Volunteer is and shall be owned by ATCC.
4. For U.S. Federal government employees, I agree that my signature represents that I participated in the development of an ATCC SDO consensus document as part of my official duties and cannot claim or assign copyright.

In witness whereof, the parties have executed this Agreement as of the date last written below.

ATCC® SDO VOLUNTEER

Volunteer/member signature

Date

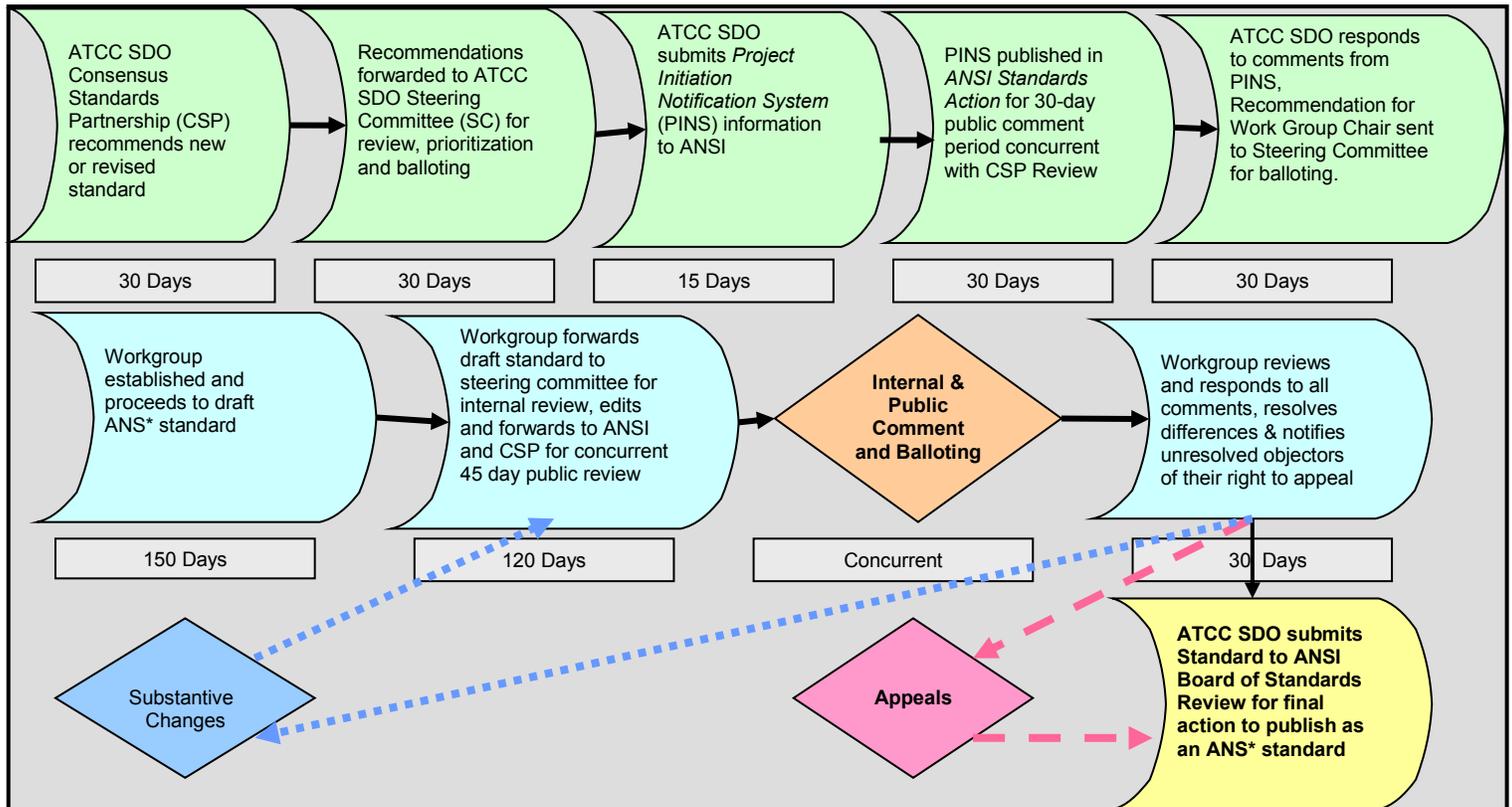
ATCC® SDO OFFICE OF THE DIRECTOR

Director

Date

Appendix 26.2

ATCC SDO Standards Development Process Flowchart



NOTE: Numbered days under each activity is tentative and is intended only as a guide.