



3-A Sanitary Standards, Inc.

**Procedures for the Development and
Maintenance of 3-A SSI Standards
and 3-A Accepted Practices**

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FOREWORD

3-A Sanitary Standards, Inc. (3-A SSI) is a not-for-profit 501(c)(3) organization whose mission is to enhance product safety for consumers of food, beverages, pharmaceutical products, and other comestibles through the development and use of standards and accepted practices, known collectively as 3-A SSI Standards and 3-A Accepted Practices. The standards and accepted practices developed for food, beverage, and dairy processing equipment are known as 3-A Sanitary Standards and 3-A Accepted Practices. The standards for pharmaceutical manufacturing equipment are known as P3-A Standards.

Background

The history of 3-A Sanitary Standards and 3-A Accepted Practices extends back to the 1920s when the entities representing equipment fabricators, users/processors and sanitarians formulated the first uniform standards for fittings used on milk pipelines. The standards became known as the 3-A Sanitary Standards in recognition of the three stakeholder groups.

3-A SSI was officially incorporated in August 2002 by the organizations now representing these stakeholder groups, also known as the Founding Member Organizations. These Founding Member Organizations include the 3-A Sanitary Standards Symbol Administrative Council (Council); American Dairy Products Institute (ADPI); International Association for Food Protection (IAFP); Food Processors Suppliers Association (FPSA); and the International Dairy Foods Association (IDFA). Two representatives of each Founding Member Organization serve as voting members on the 3-A SSI Board of Directors. The 3-A SSI Board of Directors includes three non-voting Directors consisting of one member of the 3-A Steering Committee and one representative each of the Food and Drug Administration/Public Health Service (FDA/PHS) and the U.S. Department of Agriculture (USDA).

With the formation of 3-A SSI, the three interest groups became organized in a single, independent entity. The structure of 3-A SSI was designed to balance the three interest groups in the leadership and in the day-to-day management of standards development. A new 3-A Steering Committee, balanced by interest group, was designated to manage the 3-A Sanitary Standards development program.

These procedures are designed to comply with the American National Standards Institute *ANSI Essential Requirements: Due Process Requirements for American National Standards*. The purpose of the document is twofold: 1) provide a concise overview of the role and the function of the 3-A Steering Committee as they operate within the ANSI voluntary consensus system; and 2) provide the 3-A Steering Committee with a procedure manual for developing American National Standards, according to rules that 3-A SSI must observe in order to operate as an ANSI-accredited Standards Developing Organization.

PART 1 - GENERAL

1.1 Purpose

3-A Sanitary Standards (for equipment) or 3-A Accepted Practices (for systems) establish criteria for equipment, materials, hygienic design, and fabrication to assure the cleanability of equipment used for dairy, food, pharmaceutical, or other comestible processing, packaging and handling. 3-A Accepted Practices may include installation, control and regulatory criteria. Equipment performance and operator safety are not included.

The procedures shall govern the activities of 3-A SSI related to the development, approval, revision, reaffirmation or withdrawal of 3-A Sanitary Standards and 3-A Accepted Practices for the sanitary design, fabrication and installation of equipment and machinery for dairy, food or other comestibles. When submitting standards for ANSI approval, 3-A SSI will submit all required ANSI forms (or their equivalent) and comply with all required ANSI administrative practices in accordance with the *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

A Glossary of Key Terms used in these Procedures is shown in Appendix C.

1.2 Management, Authority, and Responsibility for 3-A SSI Standards and 3-A Accepted Practices Activities

Overall management of 3-A SSI is vested in the Board of Directors. The 3-A Steering Committee shall report and be responsible to the Board of Directors of 3-A SSI. Management, authority, and responsibility for the 3-A Sanitary Standards and 3-A Accepted Practices activities rests with the 3-A Steering Committee and its appointed Work Groups (WGs).

PART 2 – PROCEDURES FOR THE DEVELOPMENT OF 3-A SANITARY STANDARDS AND 3-A ACCEPTED PRACTICES

2.1 3-A Sanitary Standards and 3-A Accepted Practices Interest Groups

The 3-A Sanitary Standards and 3-A Accepted Practices development activity encompasses three cooperating interest groups.

- a) Equipment Fabricators - The Equipment Fabricators Group represents those persons, companies or trade associations and their consultants who are original equipment manufacturers (OEMs), fabricators, distributors or installers of equipment covered by 3-A Sanitary Standards and/or 3-A Accepted Practices.
- b) Processors/Users - The Processors/Users Group represents those persons, companies or trade associations and their consultants who are users of dairy, and/or food processing equipment or systems covered by 3-A Sanitary Standards and/or 3-A Accepted Practices.
- c) Public Interest – The Public Interest Group represents state and local milk regulatory officials (Sanitarians), representative(s) from academia, the USDA Dairy Programs, the FDA and other sanitarians, consumers and others.

All interest group members should possess a general knowledge of sanitary principles, and knowledge of equipment and systems used to process, package, and handle dairy products and other comestibles.

2.2 Secretariat

3-A SSI (herein designated as “Secretariat”) shall be responsible for maintaining the duties of the Secretariat for all WGs and ad hoc groups established in accordance with these procedures:

- a) Organize the WGs and ad hoc groups in consultation with the 3-A Steering Committee.
- b) Oversee compliance with these procedures.
- c) Maintain rosters of all committees, WGs, and ad hoc groups and a list of standards or other documents for which it is responsible.
- d) Provide administrative support for the 3-A Steering Committee, WGs and ad hoc groups, including secretarial services; arrange meetings; prepare and distribute meeting agendas, minutes, ballots and draft standards; and maintain adequate records.
- e) Submit proposed standards and revisions thereto approved by the WG or 3-A Steering Committee for public review, ANSI review, and approval.
- f) Publish approved 3-A Sanitary Standards or 3-A Accepted Practices and approved revisions and addenda.
- g) Perform other administrative functions as required by these procedures, including oversight of compliance with these procedures, the administration of appeals and interpretations.

2.3 3-A Steering Committee

In accordance with the Bylaws of 3-A SSI, the Board of Directors of 3-A SSI shall designate the voting membership of the 3-A Steering Committee.

The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance in accordance with the historical criteria for balance, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.

The standards development process shall not be dominated by any single interest category, individual or organization. Dominance means a position or exercise of dominant authority,

leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.

The Committee may appoint non-voting members at its discretion. Non-voting members shall include: 1) representatives of regional, national, or international organizations materially affected by 3-A Sanitary Standards and/or 3-A Accepted Practices, 2) interested parties willing to share information or to harmonize standards, or 3) individuals who can perform a function deemed important to the completion of the 3-A Steering Committee's goals.

2.3.1 3-A Steering Committee Chair

The Board of Directors of 3-A SSI shall appoint a Chair of the Committee, either from among the committee members or as an additional voting member.

The Chair shall:

- a) Assure that meeting agendas have been prepared by the Secretariat with adequate input from committee members, and other interested parties.
- b) Oversee the distribution of agendas by the Secretariat in a timely fashion that will permit proper consideration of issues by committee members.
- c) Attend and preside at 3-A Steering Committee meetings.
- d) Conduct meetings in accordance with all due process requirements. On questions of parliamentary procedures not covered in these procedures, *Robert's Rules of Order* (latest edition) should be followed to expedite due process.
- e) Present policy issues to the 3-A SSI Board of Directors for consideration and action.
- f) Recommend to the 3-A SSI Board of Directors the replacement of nonparticipating voting members.
- g) Evaluate requests for new 3-A Sanitary Standards or 3-A Accepted Practices activity for relevance to the mission and goals of 3-A SSI and assign the task to the appropriate WG in conjunction with the appropriate Work Group Chair Officers.

The voting members shall elect a Vice Chair from the voting members to assist the Chair and to assume the duties of the Chair in the absence of the Chair. The term for the Vice Chair shall correspond to the term of office for the 3-A Steering Committee chair.

2.3.2 3-A Steering Committee Responsibilities

The 3-A Steering Committee shall:

- a) Determine policies and procedures for the committee and WGs consistent with the general requirements of these Procedures.
- b) Administer these policies and procedures for the committee and WGs.
- c) Oversee the current inventory of 3-A Sanitary Standards and 3-A Accepted Practices and recommend actions to assure that documents are presented for revision, reaffirmation or withdrawal every five (5) years.
- d) Evaluate requests for new 3-A Sanitary Standards or 3-A Accepted Practices activity for relevance to the mission and goals of 3-A SSI and assign the task to the appropriate WG.
- e) Assign priorities for proposed new 3-A Sanitary Standards or 3-A Accepted Practices activity and, if necessary, to those in progress.
- f) Maintain liaison with other national and international standards development organizations and other bodies as necessary on matters of relevance to 3-A Sanitary Standards and 3-A Accepted Practices.

Voting members of the Steering Committee shall:

- a) Advise and provide the Chair and the Secretariat with appropriate information pertaining to the general application of 3-A Sanitary Standards and 3-A Accepted Practices in relation to industry and regulatory requirements.
- b) Participate on a regular basis in committee meetings. If a member is unable to attend these meetings, a written explanation to the Chair may be required.
- c) Respond to all correspondence requiring a reply by the closing date.
- d) Submit ballots by the identified closing date.

2.3.3 Criteria for the Consideration of 3-A Sanitary Standards and 3-A Accepted Practices

The 3-A Steering Committee shall employ the following criteria when evaluating the need for new, revised or amended 3-A Sanitary Standards or 3-A Accepted Practices.

- a) 3-A SSI, through its consensus document development activities, supports the compatibility of provisions of 3-A Sanitary Standards and 3-A Accepted Practices with federal, state and local regulations.
- b) Only equipment, materials, and fabrications processes that are available on the commercial market are eligible for consideration for new, revised or amended 3-A Sanitary Standards or 3-A Accepted Practices.
- c) Demonstrated need (by Applicant) for the requested standard amendment or revision.
- d) Scheduled 5-year up-dates.

2.3.4 Actions Requiring Approval by a Majority of the 3-A Steering Committee

The following actions require approval by a majority of the voting membership of the Committee whether at a meeting, letter, or e-mail ballot:

- a) Adoption of committee operating procedures, interest category, or revisions thereof.
- b) Approval of minutes.
- c) Approval to initiate work on a new, or revisions to an existing 3-A Sanitary Standard or 3-A Accepted Practice, or withdrawal of an existing 3-A Sanitary Standard or 3-A Accepted Practice.
- d) Formation (and later disbandment) of WGs.

Following approval by the 3-A Steering Committee, actions shall follow the Protocol for Document Development shown in Appendix A.

2.4 3-A Work Groups

The 3-A Steering Committee may designate WGs to expedite work of the Steering Committee. The formation (and later disbandment) of a WG requires approval by a majority vote of the 3-A Steering Committee. A list of current WGs is maintained on the 3-A SSI web site. The scope and duties delegated to the WG shall be approved at the time it is formed, and subsequent changes in scope or duties shall also require approval by the 3-A Steering Committee. The charge to the WG shall clearly state whether the WG is responsible for developing the definitive content of one or more standards and for responding to views and objections thereon.

WG members are designated by the 3-A Steering Committee from the three 3-A SSI interest categories. The 3-A Steering Committee shall maintain membership of at least two representatives from each interest category in each WG. The WG must notify the 3-A Steering Committee and the Secretariat of any changes in membership.

The WG Chair makes nominations for appointments and discharges to the WG with recommendation of the Secretariat and approval by the 3-A Steering Committee. In addition to interest category affiliation, the 3-A Steering Committee may apply specific criteria in the designation of members of a WG, such as whether a candidate is knowledgeable of the specific equipment, systems or materials covered by the 3-A document(s) assigned to the WG. They may be, but are not limited to, original equipment manufacturers (OEMs), suppliers to OEMs, consultants of record to OEMs or consumers.

The number of members of a specified WG is not limited. Each member is considered as a voting member. There shall be only one (1) voting member per entity (i.e., company or company division, federal or state agency, or university) on a WG. The determination of a company or company division for the purpose of participation on a WG shall be made by the WG Chair and based upon the type of equipment manufactured, used, or inspected. For example, a company that manufactures plate heat exchangers, tubular heat exchangers, and ice cream freezers may have a voting member from each entity on the respective WG provided the equipment is manufactured by separate company divisions; similarly, a processing company that produces fluid milk and dry milk at separate operations may have a voting member from each entity.

The 3-A Steering Committee Chair shall review the scope, duties, and membership of all WGs annually. The 3-A Secretariat shall maintain for each WG a membership roster that includes the following information:

- a) Title of the WG and its designation;
- b) Scope of the WG;
- c) Chair and Vice Chair;
- d) Name of members, addresses, and business affiliations, e-mail, phone, fax, etc.;
- e) Interest category (i.e., Fabricator, User, Sanitarian);

2.4.1 3-A Work Group Chair

The WG shall elect a Chair and Vice Chair from their members. There is no fixed term for either of these positions. A vote for a Chair or Vice Chair will be called by the Secretariat whenever either position resigns or a request for a vote has been received from at least three (3) group members.

The WG Chair is responsible for:

- a) Preparing agendas and planning for meetings necessary to carry out the function of the WG.
- b) Directing the formulation and development of the documents assigned to the WG.
- c) In consultation with the Secretariat, preparing draft documents of the WG for balloting.
- d) Maintaining appropriate administrative records relating to the actions of the WG.
- e) Regular participation in WG meetings and other 3-A SSI meetings/functions as is deemed necessary to conduct the business of the WG.
- f) Reviewing and resolution of comments and negative ballots pertaining to WG documents.
- g) Selection of a WG member to act as the Liaison and Technical Advisor for Interpretations Group (IG) deliberations, when needed.

2.4.2 3-A Work Group Responsibilities

As assigned by the 3-A Steering Committee, the WG is responsible for drafting:

- a) All or a portion of a 3-A Sanitary Standard or 3-A Accepted Practice,
- b) Responses to comments,
- c) Comments on international standards, or
- d) Other ballot functions as directed by the 3-A Steering Committee.

The WG is also responsible for providing a liaison and technical advisor to the Interpretations Group (IG) for matters of 3-A Sanitary Standard or 3-A Accepted Practice interpretation, when requested.

WG members shall:

- a) Participate on a regular basis in WG meetings.
- b) Actively participate in the routine functions of the WG, such as soliciting comments and seeking reconciliation of viewpoints on any tentative document.
- c) Answer all correspondence requiring a reply and ballots by the closing date.

A WG member may be removed from the WG for:

- a) Two successive unexcused absences from WG meetings,
- b) Failure to respond to two consecutive WG ballots, or
- c) Failure to respond to correspondence from the Chair of the WG.

Written notice to the committee member of this action will be provided by the Secretariat.

2.4.3 3-A Work Group Majority Requirements

A ballot of the members of the WG shall be taken in accordance with Sections 2.5.4.2 and 2.5.4.3 for the approval of a draft 3-A Sanitary Standard or 3-A Accepted Practice or any substantive change in the content of a 3-A Sanitary Standard or 3-A Accepted Practice to be presented to the Steering Committee for final approval. For a WG ballot to be “official” and valid, a return by at least 50% of available votes is required in each Interest category. Should any interest category have more than 50% of their submitted ballots voting “Negative (with reasons)”, the document shall not advance to the Steering Committee until the outstanding issues are resolved.

2.4.4 3-A Work Group Observers

Anyone interested in participating in the activities of any WG will be, at a minimum, assigned observer membership. Observer members are invited to actively participate in all WG activities and are encouraged to comment on all documents. Observer members shall not have a vote but the WG must consider their comments.

2.5 Consensus and Due Process Policies

“Consensus” means directly and materially affected interest categories 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.

2.5.1 Steering Committee

The Steering Committee shall consist of the voting members of the 3-A Steering Committee and other interested parties approved by the 3-A SSI Board of Directors, and must also be in one of the interest categories defined in Section 2.1 of these procedures. The Steering Committee shall be sufficiently diverse to ensure reasonable balance without dominance by a single interest category in accordance with *ANSI Essential Requirements: Due Process Requirements for American National Standards*. If the Steering Committee lacks balance in accordance with ANSI’s historical criteria for balance, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.

The affiliation and interest category of each member of the Steering Committee shall be made available to interested parties upon request. Affiliation refers to the interest category that the Steering Committee member represents. If the Steering Committee member is serving in an

individual capacity, then the name of the individual, that person's employer and interest category should be available. In such case, employer contact information is not required.

Voting by the Steering Committee occurs after the document has been developed by the assigned WG and has been subject to appropriate public notice(s) with resolution of any comments or concerns raised through the public notice(s).

The Steering Committee shall be responsible for:

- a) Voting on approval of proposed 3-A Sanitary Standards and 3-A Accepted Practices within the scope of the 3-A Steering Committee;
- b) Maintaining the standards developed by 3-A SSI designated as American National Standards in accordance with *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

Steering Committee members who do not return two consecutive ballots shall be contacted to confirm their continuing interest. A non-response to this contact after (30) days will be considered a lack of interest and the non-responsive member will be removed from the Steering Committee. A removed Steering Committee member may reapply for participation on the Steering Committee.

2.5.2 Coordination and Harmonization

Good faith efforts shall be made to resolve potential conflicts between and among existing American National Standards and candidate American National Standards.

2.5.2.1 Definition of Conflict

Conflict within the ANS process refers to a situation where, viewed from the perspective of a future implementer, the terms of one standard are inconsistent or incompatible with the terms of the other standard such that implementation of one standard under terms allowable under that standard would preclude proper implementation of the other standard in accordance with its terms.

2.5.2.2 Coordination/Harmonization

3-A SSI will make a good-faith effort to resolve potential conflicts and to coordinate standardization activities intended to result in harmonized American National Standards. A "good faith" effort will require substantial, thorough and comprehensive efforts to harmonize a candidate ANS and existing ANSs. Such efforts will include, at minimum, compliance with all relevant sections of these procedures. 3-A SSI will retain evidence of such efforts in order to demonstrate compliance with this requirement to the satisfaction of the appropriate ANSI body.

2.5.3 Notification of Standards Development or Activity

2.5.3.1 3-A Sanitary Standards and Accepted Practices

Proposals for new 3-A Sanitary Standards or 3-A Accepted Practices or reaffirmation, revision or withdrawal of existing 3-A Sanitary Standards or 3-A Accepted Practices shall be announced to the Founding Member Organizations of 3-A SSI (ADPI, IAFP, FPSA, and IDFA), FDA Milk Safety Branch, USDA Dairy Programs, industry trade press, and other interested parties to give the opportunity for participation by all directly and materially affected persons.

2.5.3.2 American National Standards

In addition to the aforementioned requirements for industry notification, at the initiation of a project to develop or revise a candidate 3-A Sanitary Standard or 3-A Accepted Practice as an American

National Standard notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for listing in *Standards Action*.

A PINS form may be submitted, but is not required, at the initiation of a project to reaffirm or withdraw an American National Standard.

When 3-A SSI is required to submit a PINS form, a statement will be submitted and published as part of the PINS announcement. The statement will include:

- a) an explanation of the need for the project, and
- b) identification of the stakeholders (e.g., equipment fabricators, processors/users, public interest, etc.) likely 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.

Comments received in connection with a PINS announcement shall be handled in accordance with these procedures. If the Secretariat 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 Secretariat and the commenter and shall be concluded before the Secretariat may submit a draft standard for public review. If the deliberation does not take place within the 90-day period and the Secretariat can demonstrate that it has made a good faith effort to schedule and otherwise organize it, then the Secretariat 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.

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 Secretariat to the commenter and to ANSI. Upon submission of the Deliberation Report, the Secretariat may continue with the submission of the draft standard for public review. If additional deliberations take place, they should not delay the submission of the draft 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 Secretariat shall include all of the Deliberation Report(s) with the BSR-9 submittal to the ANSI Board of Standards Review (BSR) for consideration should 3-A SSI 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 addition, proposals for new 3-A Sanitary Standards or 3-A Accepted Practices to be developed as American National Standards, or reaffirmation, revision or withdrawal of existing 3-A Sanitary Standards or 3-A Accepted Practices that are 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. The comment period shall be one of the following:

- A minimum of (30) days if the full text of the revision(s) can be published in *Standards Action*;
- A minimum of (45) 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 (60) days, if neither of the aforementioned options is applicable.

2.5.4 Voting Procedures and Policies

2.5.4.1 Ballots

New 3-A Sanitary Standards or 3-A Accepted Practices, reaffirmation and revision of existing 3-A Sanitary Standards or 3-A Accepted Practices, and the withdrawal of 3-A Sanitary Standards or 3-A Accepted Practices shall be approved by electronic ballot of the Steering Committee. This includes e-mail and facsimile.

Administrative and editorial changes to 3-A Sanitary Standards and 3-A Accepted Practices that are non-substantive may be decided by a majority of the members present at a regularly scheduled meeting of the 3-A Steering Committee.

2.5.4.2 Voting

The ballot notification shall include:

- a) The purpose and intended application of the 3-A Sanitary Standard or 3-A Accepted Practice;
- b) A brief history and explanation of how the document was developed;
- c) A copy of the complete proposed 3-A Sanitary Standard or 3-A Accepted Practice or the relevant portion under consideration when the Steering Committee member has previously received the complete standard;
- d) Official ballot(s) to all voting body members.

Each member of the voting body shall vote one (1) of the following positions:

- Affirm;
- Affirm, with comment;
- Negative, with reasons; or
- Abstain, with reasons (for example, "no interest").

A negative ballot, to be accepted, shall be accompanied by explanation of the public health or hygienic design issue with appropriate citations of regulation, if applicable, for the negative ballot and shall include specific wording or actions that would resolve the objection.

The member submitting the ballot and the date of ballot submission shall be verified. A typed name on an electronic ballot shall be considered as a signature. Voting by alternates or proxies is not permitted. A sample ballot is shown in Appendix B.

2.5.4.3 Voting Period

The voting period for ballots shall end no less than (30) days from the date of issue or as soon as all ballots are returned, whichever comes earlier. An extension may be granted at the Secretariat's option, when warranted.

A follow-up notification requesting immediate return of the ballot shall be sent to members whose votes have not been received within (10) calendar days before the ballot closes.

Within thirty (30) days after the close of an electronic ballot, the Secretariat shall report the results, including all comments, to the Chair and Document Leader(s). All ballots with reasons shall be resolved in accordance with Section 2.5.4.6.

2.5.4.4 Majority Requirements for Actions by the Steering Committee

The following actions require a ballot with a total return by at least 80% of the Steering Committee. Approval requires an affirmative vote by a minimum of 70% of the entire Steering Committee.

Approval of a new 3-A Sanitary Standard or 3-A Accepted Practice, withdrawal of an existing 3-A Sanitary Standard or 3-A Accepted Practice, or reaffirmation of an existing document.

Approval of revision or addendum to part or all of a 3-A Sanitary Standard or 3-A Accepted Practice.

Approval of a negative vote being found persuasive.

Approval for submission to ANSI of a change in scope.

2.5.4.5 Reporting Votes

The results of each vote on all 3-A Sanitary Standard or 3-A Accepted Practice 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.

Listing of comments submitted.

2.5.4.6 Resolution of Comments

When the balloting or Public Notice comment period has been closed, the Secretariat shall forward the ballot tally and all comments to the Document Leader(s), Chair of the 3-A Steering Committee and the Chair of the WG. Prompt consideration shall be given to the written views and objections of all voters, including written comments from public review. An effort to resolve all written objections shall be made, and each objector shall be advised in writing of the disposition of the objection and the reasons thereof.

Objections that are not accompanied by reasons shall be recorded as “negative without reasons” and no further resolution shall be required. Objections given with reasons shall be referred by the Secretariat to the Chair of the WG and Document Leader(s) responsible for the document in question. The WG Chair and Document Leader(s) shall classify each ballot or Public Notice comment as substantive or non-substantive and seek consensus through a resolution of comments. If it is determined that substantive changes are required, specific language for the revision shall be prepared and approved by the WG. Only the revised provision(s) shall be re-balloted by the Steering Committee and submitted for public review if a candidate ANS document. If an item has had prior discussion, i.e. substantially the same comment(s) is repeated that was previously made on the same issue within the same revision cycle of a particular document, it shall not be necessary to reconsider it unless new information has been introduced.

Negative votes, with proposed technical changes, may be found persuasive only by a re-ballot of the issue. Resolution of the unresolved issue shall be in accordance with Section 2.5.4.4. If after the re-ballot, the author’s original negative ballot is still unresolved, he or she shall be informed in writing of his or her right to appeal substantive procedural action or inaction and that an appeals process exists within the procedures used by 3-A SSI. The appeals process is outlined in Section 2.12.

The WG Chair and Document Leader(s) shall prepare a statement giving the rationale for their resolution on each comment with the names of individuals and organizations involved in the determination.

Unresolved objections, attempts at resolution and any substantive change made in a proposed 3-A Sanitary Standard or 3-A Accepted Practice shall be reported to the Steering Committee in order to afford all members of the Steering Committee an opportunity to respond, reaffirm, or change their vote.

2.6 Substantive Changes

All substantive change(s) made to a draft candidate ANS 3-A Sanitary Standard or 3-A Accepted Practice 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. The comment period shall be one of the following:

- A minimum of (30) days if the full text of the revision(s) can be published in *Standards Action*;
- A minimum of (45) 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 (60) days, if neither of the aforementioned options is applicable.

The proposed substantive change(s) will also require an additional 30-day ballot for the Steering Committee. Only the substantive changes, not the entire draft, are subject to these follow-up requirements. A substantive change in a proposed 3-A Sanitary Standard or 3-A Accepted Practice is one that directly and materially affects the use of the 3-A Sanitary Standard or 3-A Accepted Practice. Examples of substantive changes are below:

- a) "Shall" to "should" or "should" to "shall";
- b) Addition, deletion or revision of requirements, regardless of the number of changes;
- c) Addition of mandatory compliance with referenced standards.

2.7 Report of Final Result

The Secretariat shall report the final result of the voting, by interest categories, to the Steering Committee, the 3-A SSI Board of Directors, the 3-A Steering Committee, WG and other entities as determined by the 3-A SSI Board of Directors.

2.8 Submittal of Standard

If the 3-A Sanitary Standard or 3-A Accepted Practice is a candidate American National Standard, upon completion of the procedures for voting, resolution of comments, and appeals, the proposed 3-A Sanitary Standard or 3-A Accepted Practice shall be submitted to ANSI by the Secretariat for ANSI final approval.

The information supplied to ANSI by the Secretariat shall include the following material required by ANSI as outlined in the *ANSI Essential Requirements: Due Process Requirements for American National Standards*:

- a) Title and designation of the proposed American National Standard;
- b) Indication of the type of action requested;
- c) A declaration that applicable procedures were followed;
- d) A declaration that the proposed standard is within the scope of the previously registered standards activity;

- e) A declaration that conflicts with another American National Standard have been addressed in accordance with these procedures;
- f) A roster of the Steering Committee that indicates: the vote of each member including abstentions and unreturned ballots, if applicable; the interest category of each member; and a summary thereof;
- g) A declaration that all appeal actions related to the approval of the proposed standard have been completed;
- h) A declaration that the criteria contained in the ANSI patent policy have been met, if applicable; and
- i) Identification of all unresolved negative views and objections, with names of the objector(s), and a report of attempts toward resolution.

2.9 Publication of 3-A American National Standards

3-A SSI will publish and make available its new and revised 3-A American National Standards as soon as possible, but no later than six months after approval as an American National Standard. If a 3-A American National Standard is not published within six months following its approval, 3-A SSI will request an extension of this deadline from the ExSC or its designee. Such a request will be in writing, will supply the reason for the delay, and will indicate a firm final date for publication.

2.10 Effective Date of Standards

The effective date for 3-A Sanitary Standards and 3-A Accepted Practices shall be (45) days following approval by the Steering Committee.

2.11 Meetings

Meetings of the 3-A Steering Committee or a WG shall be held at the request of the respective Chairs or Secretariat or by petition of one-third or more of Committee members. Where used in this document, meeting refers to in-person, on-line or phone conference.

2.11.1 Open Meetings

Meetings of the WG shall be open to all members and others having an interest. At least (15) days notice of meetings shall be given by the Secretariat. Meetings that require travel shall require at least (60) days notice. An agenda shall be prepared and distributed with the meeting notice.

Observers shall not have the right to vote. Observers shall be entitled to receive copies of meeting reports if requested in writing.

2.12 Appeals

Persons who have directly and materially affected interests and who have been or may be adversely affected by a procedural action or inaction of the Steering Committee or the Secretariat have the right to appeal. Informal appeals to 3-A SSI staff are available and should be attempted first by contacting staff and requesting as such. Staff will discuss the matter among the parties and attempt to reach a mutually agreeable resolution. If the informal appeal is unsuccessful, the formal appeals process that follows may be pursued.

2.12.1 Notice of Appeal

Notice of intention to appeal a procedural issue must be filed by certified mail with the Secretariat within (30) days after the date of notification of right to appeal or at any time with respect to inaction. The complaint shall state the nature of the objection(s) including any adverse effects, the section(s) of these Procedures or the specific actions or inactions that are at issue, and the specific remedial action(s) that would satisfy the appellant's concerns. Previous efforts to resolve the objection(s) and the outcome of each shall be noted.

2.12.2 Response to an Appeal

Within (30) days after the receipt of the complaint, the Secretariat shall respond in writing to the appellant, specifically addressing each allegation in the complaint to the extent possible. The Secretariat shall attempt to resolve the complaint informally.

If the appellant and the Secretariat are unable to resolve the written complaint informally in a manner consistent with these Procedures, the Secretariat shall schedule a hearing with the appropriate appeals panel on a date agreeable to all participants, and providing at least (10) calendar days notice.

2.12.3 Appeals Panel and the Hearing

The 3-A Steering Committee shall appoint a three-person appeals panel. The appeals panel shall consist of three individuals who have not been directly involved in the dispute and who will not be materially affected by any decision made in the dispute. The panel will consist of one representative of each interest category selected from members of the 3-A SSI Board of Directors. Two of the appointees must be acceptable to the appellant. Two of the appointees must be acceptable to the 3-A Steering Committee. The appeals panel will act only on questions of conformance to Procedures.

2.12.4 Conduct of the Hearing

Within (15) days of the inability to resolve the matter informally, the Appeals Panel shall meet with the appellant and Secretariat. The appellant has the responsibility of demonstrating improper actions or inaction, the adverse effects there from and the efficacy of the requested remedial action. The Secretariat has the responsibility of demonstrating that the Steering Committee and the Secretariat took all actions in question in compliance with these Procedures and that the requested remedial action would be ineffective or detrimental.

2.12.5 Decision

The appeals panel shall render its decision in writing within (30) days, stating its findings of fact and conclusions, with reasons therefore and citing the evidence. The Secretariat shall notify the appellant and the 3-A Steering Committee of the decision of the appeals panel, which shall be binding and final on all concerned.

2.13 Interpretations Policy

2.13.1 Submission of Requests

Requests for interpretations of 3-A Sanitary Standards or 3-A Accepted Practices shall be submitted in writing to the Secretariat using the Request for the Interpretation of 3-A Sanitary Standards and 3-A Accepted Practices Criteria Form. The request form is available on line at <http://www.3-a.org/Standards-Committees/Interpretations-and-Public-Review-Drafts> or upon request from the Secretariat.

The Secretariat shall encourage requesters to avoid open-ended questions and pose their interpretation question in a form such that it can be answered with a "yes" or "no" response (for example: "Does the standard allow for ..." as opposed to "Explain the meaning of ...").

The Secretariat shall promptly acknowledge receipt of the request to the requester with written information on the actions that will be taken.

The Secretariat may directly respond to a request for interpretation only if the question posed can be answered by making a direct citation to the 3-A Sanitary Standard or 3-A Accepted Practice. The Chair of the 3-A Steering Committee must concur in the response of the Secretariat.

2.13.2 Appointment of Interpretations Group

Requests that cannot be resolved by the Secretariat in accordance to 2.13.1 shall be forwarded by the Secretariat to a review body called the Interpretations Group (IG). Formation of the IG shall be coordinated by the Secretariat and shall consist of five voting members appointed in the following manner.

The USDA representative to the 3-A SSI Board of Directors shall designate one voting member.

The FDA representative to the 3-A SSI Board of Directors shall designate one voting member.

The voting members of the Board of Directors from the three interest groups (Equipment Fabricators, Processors/Users, and Public Interest) shall designate one voting representative of each 3-A SSI Interest Group from the membership of the Work Group which is responsible for oversight of the document for which the interpretation has been requested, or other subject matter expert.

The Chair of the 3-A Steering Committee may designate other subject matter experts to join the IG as non-voting participants in the review of a request for interpretation,

The Chair of the 3-A Steering Committee shall act as Chair of the IG. The Chair shall convene the IG, including non-voting members and the Secretariat, to conduct a review of the request for interpretation within 30 days from the date of receipt of the request by the Secretariat.

2.13.3 Review and Voting

An interpretation by the IG shall be limited to providing clarification and explanation of the existing Standard or Practice. Interpretations should not give rise to lengthy explanations that may inadvertently modify or amend the Standard or Practice. If an interpretation is due to faulty or unclearly written criteria, the IG shall recommend to the 3-A Steering Committee that conflicting issues should be resolved by amendment or revision to the 3-A Sanitary Standard(s) or 3-A Accepted Practice(s). The IG may also recommend how such issues should be handled until the 3-A Sanitary Standard(s) or 3-A Accepted Practices(s) is amended or revised.

A 2/3 affirmative vote of IG voting members via conference call, meeting, or electronic letter ballot is required for passage of an official interpretation.

If a final decision cannot be concluded within a period of 30 days, the Secretariat shall notify the requester that the request is being processed, the reason(s) for the delay; and an estimate of when a decision will be issued.

A summary of each IG decision, including the citation of any regulations or references that supported the decision, shall be published on the 3-A SSI web site to foster uniform interpretation of the criteria. The Secretariat shall make notification of the decision to all 3-A SSI stakeholder groups, including the 3-A SSI Board of Directors.

2.14 Commercial Terms and Conditions

3-A SSI will comply with the most current version of ANSI's Commercial Terms and Conditions Policy. This policy states that guarantees, warranties, and other commercial terms and conditions will not be included in an American National Standard. The appearance that a 3-A Standard endorses any particular products, services or companies will be avoided. If a sole source exists for essential equipment, materials or services necessary to comply with or to determine compliance

with a 3-A Standard, a footnote or informative annex will be included that provides the name and address of the source, and will also state that “equivalent” equipment, materials or services may be used.

2.15 Metric Policy

3-A Sanitary Standards and 3-A Accepted Practices shall be written in dual Metric and U.S. customary units as follows. All consensus documents will be published in dual units in a single document. All values will be rounded to acceptable values in both U.S. and Metric units, and not necessarily mathematical equivalents. All U.S. and Metric values are to be agreed by the appropriate WG.

2.16 Patent Policy

A proposed 3-A SSI American National Standard may include the use of an essential patented claim (one whose use would be a requirement for compliance with that standard), if it is considered that technical reasons justify this approach. If 3-A SSI receives a notice that a proposed or approved 3-A American National Standard may require the use of such a patent claim, the procedures in this clause shall be followed.

3-A SSI shall receive from the patent holder or party authorized to make assurances on its behalf, in written or electronic form, either:

- a) assurance in the form of a general disclaimer to the effect that such party does not hold and does not currently intend holding any essential patent claim(s); or
- b) assurance that a license to such essential patent claim(s) will be made available to applicants desiring to utilize the license for the purpose of implementing the standard either:
 - i) under reasonable terms and conditions that are demonstrably free of any unfair discrimination; or
 - ii) without compensation and under reasonable terms and conditions that are demonstrably free of any unfair discrimination.

A record of the patent holder’s statement shall be retained in both the 3-A SSI files and with ANSI.

When 3-A SSI receives from a patent holder the assurance set forth in b) above, the 3-A Sanitary Standard or 3-A Accepted Practice shall include a note substantially as follows:

NOTE – The user’s attention is called to the possibility that compliance with this standard may require use of an invention covered by patent rights.

By publication of this 3-A Sanitary Standard or 3-A Accepted Practice, no position is taken with respect to the validity of any such claim(s) or of any patent rights in connection therewith. If the patent holder has filed a statement of willingness to grant a license under these rights on reasonable and nondiscriminatory terms and conditions to applicants desiring to obtain such a license, then the details may be obtained from 3-A SSI.

Neither 3-A SSI or ANSI is responsible for identifying all patents for which a license may be required by an American National Standard or for conducting inquiries into the legal validity or scope of those patents that are brought to their attention.

2.17 Records Retention Policy

The Secretariat shall retain the necessary documents and records pertaining to the development of new and maintenance of existing 3-A standards to demonstrate compliance with all aspects of these accredited procedures. This may include, but is not limited to, ballots, public comments,

correspondence, meeting notices, and minutes of meetings pertaining to the development of a 3-A Sanitary Standards or 3-A Accepted Practices, for a period of five years or until the 3-A Sanitary Standard or 3-A Accepted Practice is confirmed, revised or withdrawn, whichever is longer.

Records concerning the withdrawal of a 3-A Sanitary Standard or 3-A Accepted Practice shall be retained for at least five years from the date of withdrawal or for a duration consistent with the audit schedule, whichever is longer.

Records may be kept in an electronic format. Provisions shall be made for a back-up set(s) of records if the original records are kept in an electronic format. At least one set of back-up records shall be maintained at an off-site location.

Provisions shall be made to retain returned ballots in an unalterable format.

2.18 Revisions of Rules, Policies, and Procedures

Revisions of any of the rules, policies, and procedures included in these Procedures require approval of the 3-A SSI Board of Directors.

2.19 Maintenance of 3-A Standards

3-A SSI develops and revises its standards using the Periodic Maintenance method.

2.20 Withdrawal of an American National Standard

2.20.1 Administrative withdrawal

In the event that a PINS or BSR-8 has not been submitted for a 3-A American National Standard within five years after its approval, 3-A SSI may request an extension of time to reaffirm or revise the standard, or shall withdraw the standard. A 3-A American National Standard that has not been reaffirmed or revised within the five-year period, and that has been recommended for withdrawal by the ExSC or its designee, will be withdrawn at the close of a 30-day public review notice in ANSI's *Standards Action*. 3-A American National Standards that have not been revised or reaffirmed within ten years from the date of their approval as American National Standards will be withdrawn and such action shall be announced in *Standards Action*.

2.20.2 Withdrawal by 3-A SSI

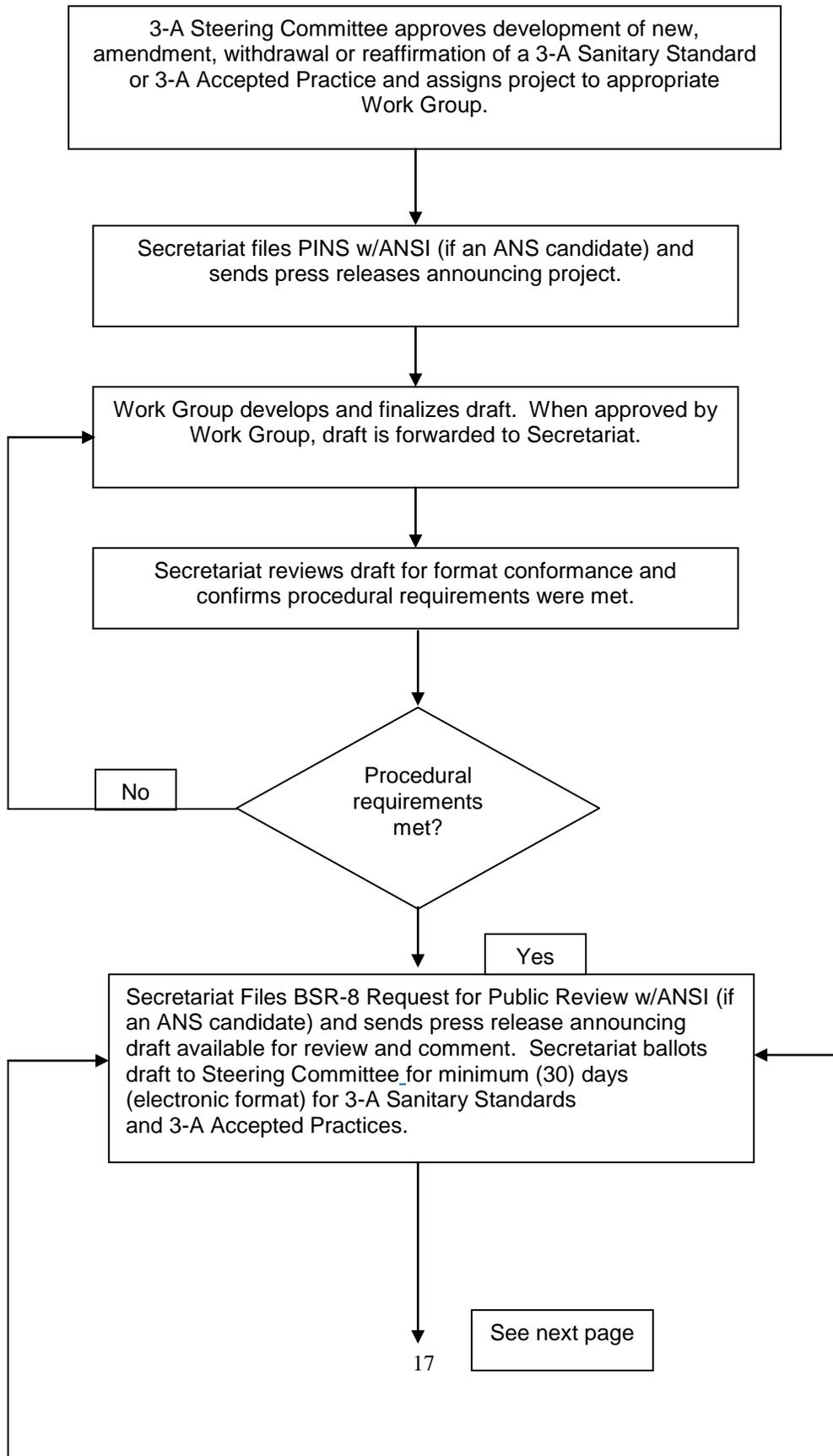
If 3-A SSI wishes to withdraw its approval of one or more of its 3-A American National Standards, it may do so without a Steering Committee vote. If 3-A SSI does withdraw one or more of its 3-A American National Standards, then 3-A SSI will notify ANSI immediately and the standard shall be withdrawn as an ANS and announced in *Standards Action*.

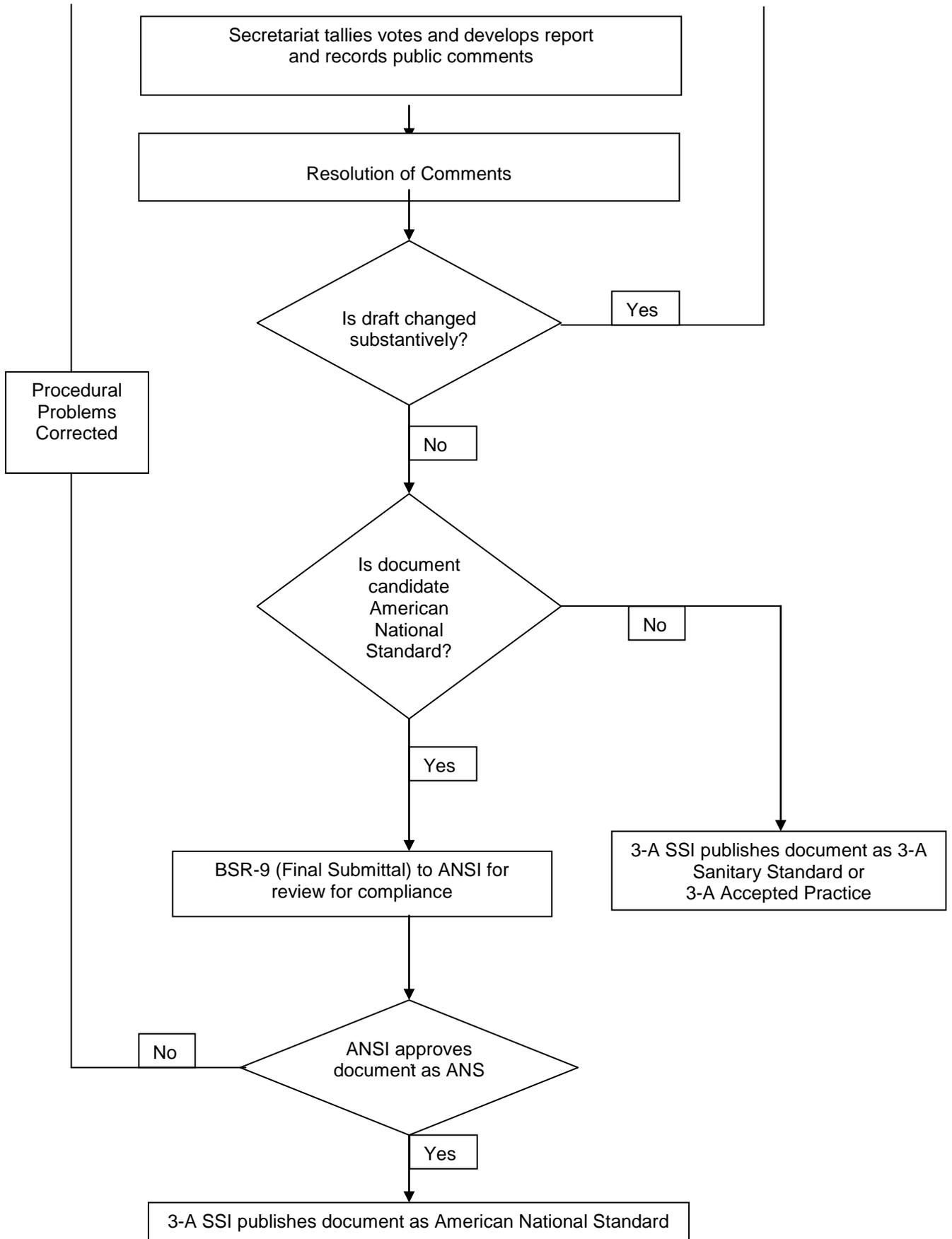
2.20.3 Discontinuance of a standards project

3-A SSI may abandon the processing of a proposed new or revised 3-A American National Standard or portion thereof if it has followed its accredited procedures. A written justification for such an action will be made available upon receipt of any written request received by the 3-A SSI within (60) days of the date of the final action.

Appeals of such actions will be made to the Executive Standards Council based on procedural noncompliance.

APPENDIX A Protocol for Document Development





APPENDIX B

Sample Electronic Ballot

3-A {Document Name and Number}
Number {Ballot #}, Ballot Date, mm-dd-yy
This ballot must be returned by {closing date}

3-A Sanitary Standards Ballot
3-A Sanitary Standards Inc.
6888 Elm Street, Suite 2D
McLean, VA 22101

For Steering Committee or Work Group Member Ballot

- _____ **AFFIRM**
- _____ **AFFIRM WITH COMMENT** (Comment required)
- _____ **NEGATIVE** (Comment required)
- _____ **ABSTAIN** (Comment required)

Name of Commenter	Clause/ Sec. #	Editorial ("E") Technical ("T")	Comment/ Proposed Change (Negative comments without proposed changes will not be considered) See Procedures 2.5.4.1	Document Leader/ WG Chair Classification S= "Substantive NS= non-substantive	Resolution of Comments

Information and Instructions

1. The return of this ballot is **REQUIRED** from all voting members. A voting member who fails to return two consecutive ballots may be removed from the voting body.
2. Affirmative votes with comment may be cast for minor or editorial changes to any text. Include specific changes when applicable.
3. Negative votes must be accompanied by an explanation and a suggested revision to overcome the negative. Negative votes on finding a negative from a previous ballot persuasive do not require comments to be submitted.
4. If you are not prepared or qualified to vote affirmatively or negatively on any item, please check **ABSTAIN** and provide the reason(s).

APPENDIX C

Glossary of Key Terms

3-A Steering Committee - The 3-A Steering Committee is responsible for the oversight of all 3-A Sanitary Standards and 3-A Accepted Practices. In accordance with the bylaws of 3-A SSI, the 3-A SSI Board of Directors designates the membership of the 3-A Steering Committee. The Committee is balanced by interest category.

American National Standard - The designation American National Standard is used to identify any standard that has received American National Standards Institute (ANSI) approval or been approved by an ANSI-accredited standards developer who has been granted authority to designate its standards as American National Standards. ANSI approval of these standards is intended to verify that the principles of openness and due process have been followed in the approval procedure and that a consensus of those directly and materially affected by the standards has been achieved.

BSR-8 Request for Public Review - This is a form submitted by ANSI-accredited standards developers to initiate a public review announcement in ANSI's *Standards Action*. This form is to be submitted for all standards actions and when a substantive change is made to a draft that has already had public review in *Standards Action*.

BSR-9 American National Standard (ANS) Formal Submittal - This document is used to transmit the final submittal of a candidate American National Standard to ANSI. A standard should only be submitted to ANSI for approval if all of the appropriate evidence of consensus accompanies it in accordance with the *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

Steering Committee - The consensus body responsible for voting on the approval of proposed American National Standards and other matters requiring Steering Committee action as provided in these Procedures. In accordance with the *ANSI Essential Requirements: Due Process Requirements for American National Standards*, the Steering Committee shall have a balance of interests as defined by the developer. For 3-A Sanitary Standards and 3-A Accepted Practices, the Steering Committee consists of all members and other interested parties appointed by the 3-A SSI Board of Directors.

Interest Categories - the Secretariat has defined specific interest categories or groups to help establish the criteria for balance.

For 3-A Sanitary Standards and 3-A Accepted Practices, interest categories are defined in these procedures appropriate for the activities of 3-A SSI. These categories are:

- a) **Equipment Fabricators** - The Equipment Fabricators Category shall represent those persons, companies or trade associations and their consultants who are original equipment manufacturers (OEMs), fabricators, distributors and installers of equipment covered by 3-A Sanitary Standards and/or 3-A Accepted Practices.
- b) **Processors/Users** - The Processors/Users Category shall represent those persons, companies and trade associations and their consultants who are users of dairy, and/or food processing equipment or systems covered by 3-A Sanitary Standards and/or 3-A Accepted Practices.
- c) **Public Interest** – The Public Interest Category represents state and local milk regulatory officials (Sanitarians), representative(s) from academia, the USDA Dairy Programs, the FDA and other sanitarians, consumers and others.

Interpretations Group – For 3-A Sanitary Standards and 3-A Accepted Practices, the Interpretations Group provides official 3-A SSI interpretation of words, phrases, and criteria within 3-A Sanitary Standards and, when needed, 3-A Accepted Practices. The IG consists of 5 members designated by the 3-A SSI Board of Directors in accordance with the 3-A SSI Policy Manual, Interpretation of 3-A Sanitary Standards and 3-A Accepted Practices.

PINS Form - The Project Initiation and Notification System (PINS) form is for the use of ANSI-accredited standards developers to submit information to ANSI for publishing in ANSI *Standards Action*. The PINS form is used to announce the initiation of a project to draft or to revise an American National Standard.

Secretariat - The secretariat is 3-A SSI, which is sanctioned by ANSI to serve as the primary administrative authority responsible for the general coordination of 3-A SSI activities associated with 3-A Sanitary Standards and 3-A Accepted Practices in accordance with these procedures and *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

Work Groups - the Secretariat has designated Work Groups, which are responsible for overseeing the maintenance and development of 3-A Sanitary Standards or 3-A Accepted Practices for groups of similar equipment or materials. Designation of a WG is the responsibility of the 3-A Steering Committee. A current list of WGs and rosters of WG representatives are maintained on the 3-A SSI web site. Each WG is composed of experts representing fabricators of related types of equipment, systems, and materials and representatives of the users and sanitarian interest categories. Suppliers to OEMs, consultants of record to OEMs or consumers, may also be designated. Their primary responsibility is to provide technical input during the development of initial proposals or revisions and amendments to existing 3-A SSI documents.

APPENDIX D TIMETABLES

3-A SSI Activity	Activity Needed	Minimum Timeframe
Public Notice of Activity	Notice contains only reference to action	30-day comment period
Announcement of Opportunity for Public Review/Comment	Notice contains information on obtaining the full text of action for review	30-day comment period if full text available in ANSI <i>Standards Action</i> 45-day comment period if available in electronic format 60-day comment period if available by other format
Ballot results	Report to Work Group, Steering Committee and 3-A SSI Board of Directors	Within (30) days of the end of the ballot period.
Notice of Intention to Appeal	To the 3-A Secretariat	Within (30) days of the notification of the action
Response to Notice of Intention to Appeal	Report to appellant	Within (30) days of receipt of the Notification of Intention to Appeal
Convening of Appeals Panel	Report to all interested parties	Within (15) days of inability to resolve the issue informally
Appeals panel decision	Report to all interested parties	Within (30) days of conclusion of the hearing