



**Operating Procedures
for the
Development of American National Standards
by
3-A Sanitary Standards, Inc.**

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1. Introduction

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. These procedures constitute 3-A SSI's method of developing evidence of consensus for the approval, reaffirmation, revision, or withdrawal of American National Standards in accordance to the *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

2. Standards Activities Organization

The 3-A Steering Committee of 3-A SSI shall have the authority to initiate a project to develop, reaffirm, revise, or withdraw a standard.

The 3-A Steering Committee shall designate the Secretariat. Duties of the Secretariat will include:

- a) Overseeing the consensus body's compliance with ANSI procedure;
- b) Maintaining a roster of the consensus body and a list of standards for which the consensus body is responsible;
- c) Providing administrative work, including secretarial services, preparation and distribution of ballots, draft standards and maintenance of adequate records;
- d) Submitting candidate standards approved by the consensus body, with supporting documentation, for ANSI review and approval as American National Standards;
- e) Performing other administrative functions as required by these procedures.

3. Notification of Standard Development and Coordination

Notification of standards activity shall be announced in suitable media as appropriate to demonstrate an opportunity for participation by all directly and materially affected persons. The Secretariat shall develop and maintain a list of stakeholders consisting of organizations, companies, government agencies, standards developers, and individuals known to be or who have indicated that they are directly and materially affected by the standard.

Prior to the notification of standards development, the Secretariat shall survey its list of stakeholders in writing via electronic means about the process for ensuring evidence of consensus in the development of its standards and shall include the title, designation, scope, description, purpose and intended use of the standard. Notification of standards activity shall also be announced in suitable media as appropriate to demonstrate provision of opportunity to participate by all who are directly or materially affected. Electronic communication is the preferred method of communication.

The Secretariat shall ensure the consensus body is aware of and considers each addition or revision to the standard. Revisions to the standard shall be made in compliance with the *ANSI Essential Requirements*.

The information supplied to ANSI by the Secretariat shall include all relevant material required by ANSI as outlined in the *ANSI Essential Requirements*. If the Secretariat does not submit the PINS to ANSI within a reasonable period of time, any member(s) of the consensus body may

make the submittal.

- 3.1 Notification of standards activity shall be made by the Secretariat to ANSI via the Project Initiation Notification System (PINS) in accordance with section 2.5 *ANSI Essential Requirements*.
- 3.2 A 30 day period for resolution shall be given to the written views and objections and comments that proposed standard duplicates or conflicts with an existing American National Standard (ANS) or previously announced candidate ANS.
- 3.3 A 30 day period shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or formal public review of 3-A SSI's standards in ANSI's *Standards Action*.
- 3.4 Notification of standards development, including response to comments received in response to the filing of PINS and BSR-8 forms with ANSI, and coordination shall comply with the requirements contained in clause 2.5 of the *ANSI Essential Requirements*.

4. Organization of the Consensus Body

The Secretariat, with approval of the 3-A SSI Board of Directors, shall select a consensus body upon the close of the application period. 3-A SSI will strive for balance so that no single interest category constitutes more than one-third of the membership of a consensus body. By adhering to ANSI's due process of openness, balance and consensus, 3-A SSI's standards will serve and protect the public.

In selection of members to the consensus body, consideration shall be given to the need for balance, prevention of potential dominance of a single interest group, the need for active and engaged participation by members of each interest category, the members' qualifications and their ability to participate.

The consensus body shall be sufficiently diverse to ensure reasonable balance in accordance with the *ANSI Essential Requirements*. If the 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 consensus body shall be created from persons who express interest in serving 3-A SSI's activity and shall be required to fill out an application.

- 4.1 Responsibilities of the Consensus Body
 - a) Review proposal of new standards or revisions to current standards.
 - b) Vote on approval of the American National Standards.
 - c) Act on other matters requiring action as provided in these procedures.

The consensus body shall serve on an ad hoc basis when required to review a standard, and shall have no continuing existence beyond the completion of the subject activity.

5. Consensus Body Membership

Members of the consensus body shall consist of organizations, companies, government agencies, individuals, etc., having a direct and material interest in the activities of 3-A SSI and food processing related equipment. Membership in the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted based on technical qualifications or other such requirements.

- 5.1 Application
A request for membership on the consensus body shall be addressed to the

Secretariat and shall indicate the applicant's direct and material interest in 3-A SSI and its supporting organizations, qualifications and willingness to participate actively. In addition, if the applicant is an organization, company, or government agency, it shall identify a representative (and an alternate, if desired). The application period shall be not less than 30 days from the date of announcement by 3-A SSI.

In recommending applications for consensus body membership, the Secretariat shall consider the following:

- a) Need for active participation by each interest category;
- b) Potential for achieving or maintaining balance;
- c) Extent of interest expressed by the applicant and the applicant's willingness to participate actively;
- d) Representative identified by the applicant organization, company, or government agency.

5.2 Interest categories

All appropriate interests that are directly and materially affected by the standards activity of 3-A SSI shall have the opportunity for fair and equitable participation. Each member shall propose its own interest category as appropriate and in accordance with the consensus body's established categories.

Categories include:

- a) Equipment Fabricators - Persons, companies or trade associations and their consultants who are original equipment manufacturers (OEMs), fabricators, distributors, installers of equipment, or fabrication design consultants covered by 3-A Sanitary Standards and/or 3-A Accepted Practices.
- b) Processors/Users - 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 – Federal, State and local Regulatory officials (Sanitarians) and representative(s) from academia, or consumers.

5.3 Membership roster

The Secretariat shall maintain a current and accurate consensus body roster and shall distribute it to the consensus body representatives and otherwise on request. The roster shall include the following:

- a) Title of the standard(s)
- b) Scope of the standard(s);
- c) Secretariat: name of organization, name of secretary, and address(es);
- d) Members: name of person, organization or agency, its representative and alternate (as applicable), addresses, and business affiliations; or name, address, and business affiliation of individual member(s);
- e) Interest category of each member;
- f) Tally of interest categories: total of voting members and subtotals for each interest category.

Members of the consensus body shall participate in meeting or discussion interactions as necessary. A simple majority of the members of the consensus body shall constitute a quorum. If a quorum is not present, actions may be taken subject to confirmation by letter ballot. Failure to participate in meeting or in voting by mail ballot may result in dismissal from the group.

6. Voting

A letter ballot form shall be used by 3-A SSI for voting. The ballot form shall provide opportunity for the consensus body member to vote one of the following positions:

- a) Affirmative;
- b) Affirmative, with comment;
- c) Negative, with reasons (the reasons for a negative vote shall be given and if possible should include specific wording or actions that would resolve the objection);
- d) Abstain.

3-A SSI shall indicate conspicuously on the ballot form that negative votes unaccompanied by comments related to the proposal will be recorded as “negative without comments” without further notice to the voter. Comments not related to the proposal submitted with a negative vote shall be documented and considered in the same manner as submittal of a new proposal. If clear instruction is provided on the ballot, and a negative vote without comments related to the proposal is received, the vote may be counted as a “negative without comment” for the purposes of establishing a quorum and reporting to ANSI.

A follow-up notice shall be sent to consensus body members not responding within 10 days prior to the close of the ballot. The consensus body ballot may be closed at the end of 30 days or sooner if all consensus body members have responded. An extension of up to 60 days shall be granted upon request from any consensus body member giving a legitimate reason.

Those not on the consensus body list who have a direct and material interest in the standard have an opportunity to participate in the review of the standard during the public review process, announced in *Standards Action*.

Approval of a new standard, revision or reaffirmation of an existing standard, or an addendum to part or all of an existing standard shall require that at least 80% of the consensus body cast a vote (counting abstentions) and a minimum of 70% of those voting approve (not counting abstentions).

Views and objections resulting from the consensus body shall be dealt with in accordance with clause 7.

7. Disposition of Views and Objections

Prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in *ANSI Standards Action*.

In connection with an objection articulated during a public comment period, or submitted with a vote, an effort to resolve all expressed objections accompanied by comments related to the proposal under consideration shall be made, and each such objector shall be advised in writing (including electronic communications) of the disposition of the objection and the reasons. If resolution is not achieved, each such objector shall be informed in writing that an appeals process exists within procedures used by 3-A SSI. In addition, each objection resulting from public review or submitted by a member of the consensus body, and which is not resolved must be reported to the ANSI BSR.

When this process is completed in accordance with these written procedures, 3-A SSI may consider any comments received subsequent to the closing of the public review and comment period, or shall consider them in the same manner as a new proposal. Timely comments that are not related to the proposal under consideration shall be documented and considered in the same

manner as submittal of a new proposal. The submitter of the comments shall be so notified.

Unresolved objections, attempts at resolution and any substantive change made in a proposed American National Standard shall be reported to the consensus body in order to afford all members of the consensus body an opportunity to respond and reaffirm or change their vote.

Substantive changes to a standard revision will undergo a public review in accordance with ANSI procedural requirements. A substantive change in a proposed American National Standard is one that directly and materially affects the use of the standard.

8. Submittal of Standard

Upon completion of the final actions of the consensus body, for disposition of views and objections, and for appeals, the proposed standard and BSR-9 form shall be submitted to ANSI for approval.

The information to be supplied to ANSI shall include:

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

3-A SSI shall take action to revise or reaffirm a standard within five years of the last approval date of the standard.

9. Appeals

9.1 Complaint

Persons who have directly and materially affected interests and who believe they have been or will be adversely affected by a standard within the committee's jurisdiction, or by the lack thereof, shall have the right to appeal procedural actions or inactions of the committee or sponsor.

The appellant shall submit a complaint in writing via mail or electronic means

with the sponsor within 15 days after the date of notification of action or at any time with respect to inaction. The complaint shall state the nature of the objection(s) including any adverse effects, the section(s) of these procedures or the standard that are at issue, 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.

9.2 Response

3-A SSI will forward any complaints to the 3-A SSI ANSI Consensus Body for discussion and response. Within 30 days after receipt of the complaint, 3-A SSI shall respond in writing via mail or electronic means to the appellant, specifically addressing each allegation of fact in the complaint to the extent of the respondent's knowledge.

9.3 Hearing

If the appellant and 3-A SSI are unable to resolve the written complaint informally in a manner consistent with these procedures, 3-A SSI shall schedule a hearing with an appeals panel on a date agreeable to all participants, giving a least 10 working days' notice.

9.4 Appeals Panel

The appeals panel shall consist of three individuals knowledgeable as to the policy and other concerns related to the appeal who do not have demonstrably real or apparent conflicts of interest with the subject of the appeal or the person filing the appeal. The 3-A SSI and the appellant will select the members of the appeals panel. If the appellant and 3-A SSI cannot agree on the composition of the panel within three weeks from the start of the selection process, the 3-A SSI may appoint the panel.

9.5 Conduct of the Hearing

The appellant has the burden of demonstrating adverse effects, improper actions or inaction, and the efficacy of the requested remedial action. 3-A SSI has the burden of demonstrating that the committee or sponsor took all actions in compliance with these procedures and that the requested remedial action would be ineffective or detrimental. Each party may adduce other pertinent arguments, and members of the appeals panel may address questions to individuals.

Robert's Rules of Order (latest edition) shall apply to questions of parliamentary procedure for the hearing not covered herein.

The aforementioned hearing may be conducted via meeting or teleconference.

9.6 Decision

The appeals panel shall render its decision in writing via mail or electronic means within 30 days, stating findings of fact and conclusions, with reasons therefore, based on a preponderance of the evidence. The Secretariat shall notify the appellant in writing of the decision of the appeals panel.

The panel may dispose of the case in any of the following manners:

- a) Finding for the appellant remanding the action to the committee or the sponsor with a specific statement of the issues and facts in regard to which fair and equitable action was not taken.
- b) Finding for the respondent, with a specific statement of the facts that demonstrate fair and equitable treatment of the appellant and the appellant's objections.

- c) Finding that new, substantive evidence has been introduced, and remanding the entire action to the committee or the sponsor for appropriate reconsideration.

10. Records Retention

Records concerning new, revised or reaffirmed ANSI standards will be retained for one complete development cycle or until the standard is revised. This may include, but is not limited to, ballots, public comments, correspondence, meeting notices, and minutes of meetings pertaining to the development of 3-A Sanitary Standard, for a period of five years or until the 3-A Sanitary Standard is reaffirmed or revised, whichever is longer. Records concerning withdrawn standards will be retained until five years from date of withdrawal.

11. Interpretations Policy

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.

- 11.1 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.

- 11.2 Appointment of Interpretations Group
Requests that cannot be resolved by the Secretariat in accordance to 11.1 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 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. The Secretariat shall notify the requester in writing of the final decision of the IG.

12. 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.

13. 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. Participants in the 3-A SSI standards development process are encouraged to bring patents with claims believed to be essential to the attention of 3-A SSI. If 3-A SSI receives a notice that a proposed or approved 3-A SSI American National Standard may require the use of such a patent claim that is not already covered by an existing assurance, the procedures in this clause shall be followed.

Such assurance shall indicate that the patent holder (or third party authorized to make assurance on its behalf) will include in any documents transferring ownership of patents subject to the assurance, provisions sufficient to ensure that the commitments in the assurance are binding on the transferee, and that the transferee will similarly include appropriate provisions in the event of future transfers with the goal of binding each successor-in-interest. The assurance shall also indicate that it is intended to be binding on successors-in-interest regardless of whether such provisions are included in the relevant transfer documents.

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 the files of 3-A SSI and shall be made publicly available (at 3-A SSI's election, either on the 3-A SSI website or ANSI's LOA repository).

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 SSI Standard, 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 nor 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.

14. Commercial Terms and Conditions

For the purpose of development, approval and maintenance of American National Standards, 3-A SSI shall comply with the American National Standards Institute (ANSI) *Essential Requirements* policies related to commercial terms and conditions and such standards will not include guarantees, warranties or other commercial terms and conditions.

15. Antitrust Policy

American National Standards shall be developed in accordance with applicable antitrust and competition laws and meetings amongst competitors to develop American National Standards are to be conducted in accordance with these laws.

16. Criteria for Withdrawal of a Standard

- 16.1 Withdrawal of a standard process
3-A SSI as an ANSI-accredited Standards Developer may withdraw one or more of its approved American National Standards without a vote of the relevant consensus body. If 3-A SSI does withdraw an approved standard, the 3-A SSI will notify ANSI immediately and the standard shall be withdrawn as an ANS and announced in ANSI's *Standards Action*.
- 16.2 Discontinuance of a standards process
3-A SSI may 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 relevant consensus body. 3-A SSI as an ANSI-accredited Standards Developer, 3-A SSI will notify ANSI immediately of such actions which will be announced in ANSI *Standards Action*.
- 16.3 Withdrawal for cause
3-A SSI shall comply with the American National Standards Institute (ANSI) *Essential Requirements* policies pertaining to requests for withdrawal of an ANS for cause.