



3-A Sanitary Standards, Inc.

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

3-A SSI Board of Directors Approved: 10/09/2025

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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 ensure processing equipment and their equipment components can be easily cleaned and inspected through the consensus development and use of Standards and Accepted practices, known collectively as 3-A Sanitary Standards and 3-A Accepted Practices. These documents ensure the safety of consumers of all comestibles, end users of personal care products, and similar applications where a high degree of hygienic design is required.

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 Founding Member Organizations including 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). Today, three representatives from each Voting Member Organization serves as a voting members of the 3-A SSI Board of Directors. The 3-A SSI Board of Directors includes non-voting Directors consisting of the Chairperson of the 3-A Steering Committee, one representative each of the U.S. Food and Drug Administration/Public Health Service (FDA/PHS) and the U.S. Department of Agriculture (USDA), and others appointed by the Board of Directors.

The structure of 3-A SSI was designed to balance the three interest groups in leadership and 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 and 3-A Accepted Practices development program.

The purpose of this document is twofold: 1) provide a concise overview of the role and the function of the 3-A Steering Committee and 2) provide the 3-A Steering Committee with a procedure manual for developing 3-A Sanitary Standards and Accepted Practices and similar industry consensus documents intended for the development of non-American National Standards designated documents.

PART 1 - GENERAL

1.1 Purpose

3-A Sanitary Standards (for equipment) and 3-A Accepted Practices (for systems) establish the minimum criteria for ensuring the cleanability and inspectability of equipment used to handle, package and process all comestibles, personal care products and similar applications that require the highest degree of hygienic design. 3-A Accepted Practices may include installation, process cycles 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.

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 Ad Hoc Work Groups.

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) Fabricator – An organization representing primarily persons or firms (including companies, trade associations, employees, and/or consultants) engaged in the manufacture, fabrication, distribution, installation, or fabrication design of equipment or systems covered by 3-A Sanitary Standards and/or 3-A Accepted Practices.
- b) User - An organization representing primarily persons or firms (including companies, trade associations, employees, and/or consultants) engaged in the use of dairy, and/or food processing equipment or systems covered by 3-A Sanitary Standards and/or 3-A Accepted Practices.
- c) Regulatory Sanitarian – An organization representing primarily Federal, State or local Regulatory officials (Sanitarians) or representative(s) from academia

All interest group members should possess a general knowledge of hygienic design principles, and knowledge of equipment and systems used to process, package, and handle comestibles, personal care products and similar applications.

2.2 Secretariat

The Secretariat shall be responsible for maintaining 3-A Standards and 3-A Accepted Practices development activities in accordance with these procedures:

- a) Oversee compliance with these procedures.
- b) Organize Ad Hoc WGs in consultation with the 3-A Steering Committee.
- c) Maintain rosters of all Ad Hoc WGs and a list of standards or other documents for which it is responsible.
- d) Provide administrative support for the 3-A Steering Committee, Ad Hoc WGs, 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 to the 3-A Steering Committee for approval.
- f) Announce new projects and provide a public review opportunity for all draft 3-A Standards and 3-A Accepted Practices.
- g) Publish approved 3-A Sanitary Standards and 3-A Accepted Practices.
- h) 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 3-A Steering Committee shall have a balance of interests. Participants from diverse interest groups shall be sought with the objective of achieving balance. If the 3-A Steering Committee lacks balance in accordance with the historical criteria for balance, outreach to achieve balance shall be undertaken.

The standards development process shall not be dominated by any single interest group, 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 3-A Steering Committee may appoint non-voting members at its discretion. Non-voting members may 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.

There shall be a 3-A Steering Committee that shall establish standard operating procedures and shall oversee and prioritize 3-A Sanitary Standards and 3-A Accepted Practices development. Except as described below, the Committee shall have twelve (12) voting members: four (4) appointed by the Member Organizations in the User membership class; four (4) appointed by the Member Organizations in the Fabricator membership class; two (2) appointed by the Member Organizations in the Public Interest membership class; and one (1) each appointed by FDA/PHS, and USDA. The Committee may appoint non-voting members at its discretion. No voting member of the 3-A Committee may serve concurrently on the Corporation Board of Directors as a voting member. The 3-A Committee shall report and be responsible to the Board of Directors of the Corporation. The Board of Directors shall appoint a Chair of the Committee, either from among the Committee members or as a thirteenth, non-voting member. Other Committee officers may be elected by a majority vote of the voting members of the Committee. A simple majority of the voting members of the Committee shall constitute a quorum for the transaction of business, provided that at least one Committee member from each of the Member Classes is present.

2.3.1 3-A Steering Committee Chair

The 3-A SSI Board of Directors shall appoint a Chair of the 3-A Steering Committee.

The 3-A Steering Committee Chair shall:

- a) Assure that meeting agendas have been prepared by the Secretariat with adequate input from 3-A Steering 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 3-A Steering 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 and 3-A Accepted Practices activity for relevance to the mission and goals of 3-A SSI and assist in the organization of a balanced Ad Hoc WG.
- h) The Chair shall serve no more than two consecutive terms of three years.

The voting members of the Steering Committee shall elect a Vice Chair from amongst the voting members of the Steering Committee to assist the Steering Committee 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

While the outcome is not binding, unless binding provisions (patents, terms and conditions, etc.) are agreed to by the developer, participants are encouraged to develop a consensus on whether and how the standards development project should proceed.

The 3-A Steering Committee shall:

- a) Determine policies and procedures for the committee and Ad Hoc WGs consistent with the general requirements of these Procedures.
- b) Administer these policies and procedures for the committee and Ad Hoc 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 and 3-A Accepted Practices activity for relevance to the mission and goals of 3-A SSI and assemble a balanced Ad Hoc WG per project need.
- e) Assign priorities for proposed new 3-A Sanitary Standards and 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 3-A 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 3-A Steering 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.
- e) Voting members of the Steering Committee are required to sign and date a copy of the *Acknowledgement of Responsibilities*, annually.

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 and 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) Identification of at least more than one (1) manufacturer using equipment, materials, and fabrications processes that are available on the commercial market are eligible for consideration for new, revised and amended 3-A Sanitary Standards and 3-A Accepted Practices.
- c) Demonstrated need (by Applicant) for the requested standard amendment and revision to the 3-A Steering Committee. A presentation may be required after initial review.
- d) Scheduled 5-year updates.

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 3-A Steering Committee whether at a meeting, letter, or ballot:

Approval to initiate work on a new 3-A Sanitary Standard and 3-A Accepted Practice, and revisions to an existing 3-A Sanitary Standard and 3-A Accepted Practice, and withdrawal of an existing 3-A Sanitary Standard and 3-A Accepted Practice.

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

2.4 3-A Ad Hoc Work Group (WG)

The formation of an Ad Hoc WG will 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 3-A Standard and 3-A Accepted Practice.

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.

The Secretariat, in consultation with the 3-A Steering Committee Chair, may elect to disband any Ad Hoc WG that continues to lack meeting quorum and commitment to completing a referred project. Meeting quorum shall follow the requirements in Clause 2.4.3 Ad Hoc WG Majority Requirements.

Ad Hoc WG members are conferred by the Secretariat from the three 3-A SSI interest groups. The disbandment of the Ad Hoc WG shall follow the standards development project approval or disapproval by the Steering Committee.

The number of voting members of a Ad Hoc WG shall be no greater than (18) eighteen, with a maximum of (6) six voting Members in each interest group and minimum of (3) three voting Members in each interest group.

Observers (Non-Voting Members) may participate in any meeting of the Ad Hoc WG with prior notification to the Secretariat. There shall be only one (1) one voting member per entity (i.e., company or company division, federal or state agency, or university) on an Ad Hoc WG. The determination of a company or company division for the purpose of participation in an Ad Hoc WG shall be made by the Secretariat and based upon the type of equipment manufactured, used, or inspected.

2.4.1 3-A Ad Hoc Work Group Officers

The Ad Hoc WG shall elect an Ad Hoc WG Chair, Vice Chair, and Document Leader from the Ad Hoc WG.

The Ad Hoc WG Chair is responsible for:

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

2.4.2 3-A Ad Hoc Work Group

The Ad Hoc WG is responsible for:

- a) Conferring a Chair, Vice Chair, and Document Leader.
- b) Drafting all or a portion of a 3-A Sanitary Standard and 3-A Accepted Practice,
- c) Completing ballot functions as directed by the Secretariat.

The Ad Hoc WG may also be 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.

Ad Hoc WG members shall:

- a) Participate on a regular basis in Ad Hoc WG meetings.
- b) Actively participate in the routine functions of the Ad Hoc 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.

An Ad Hoc WG member may be removed from the Ad Hoc WG for:

- a) Failure to meet the Code of Ethics Requirements
- b) Failure to return a ballot

Written notice to the Ad Hoc WG member of this action will be provided by the Secretariat.

2.4.3 3-A Ad Hoc Work Group Majority Requirements

A ballot of the members of the Ad Hoc WG shall be taken in accordance with Sections 2.5.3 for the approval of a draft 3-A Sanitary Standard and 3-A Accepted Practice or any substantive change in the content of a 3-A Sanitary Standard and 3-A Accepted Practice to be presented to the 3-A Steering Committee for final approval. For an Ad Hoc WG ballot to be “official” and valid, a return by at least 50% of voting members is required in each interest group. Should any interest group have more than 50% of their submitted ballots voting “Negative (with reasons)”, the document shall not advance to the 3-A Steering Committee until the outstanding issues are resolved.

2.4.4 3-A Ad Hoc Work Group Observers

Observer members are invited to actively participate in all Ad Hoc WG activities and are encouraged to comment on all documents. Observer members shall not have a vote but the Ad Hoc WG shall respond to their comments.

2.5 Consensus and Due Process Policies

“Consensus” means directly and materially affected interest groups 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 3-A Steering Committee

The 3-A Steering Committee shall consist of voting members appointed by the 3-A SSI Board of Directors and other interested parties approved by the 3-A SSI Board of Directors. These interested parties must also be in one of the interest groups defined in Section 2.1 of these procedures. The voters shall be sufficiently diverse to ensure reasonable balance without dominance by a single interest group. If the voters lack balance outreach to achieve balance shall be undertaken.

The affiliation and interest group of each voter shall be made available to interested parties upon request. If the 3-A Steering Committee member is serving in an individual capacity, then the name of the individual, that person's employer and interest group shall be available. In such case, employer contact information is not required.

Voting by the 3-A Steering Committee may occur concurrently with an Ad Hoc WG ballot. All objections and submitted comments during the ballot and public review period shall be resolved and responded to.

3-A 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 3-A Steering Committee.

2.5.2 Notification of Standards Development or Activity

2.5.2.1 3-A Sanitary Standards and 3-A Accepted Practices

Proposals for new 3-A Sanitary Standards and 3-A Accepted Practices and reaffirmation, revision and withdrawal of existing 3-A Sanitary Standards and 3-A Accepted Practices shall be announced to give the opportunity for participation by all directly and materially affected persons.

2.5.2.2 American National Standards

For candidate American National Standards refer to the *Operating Procedures for the Development of American National Standards by 3-A Sanitary Standards, Inc. (3-A SSI)*.

2.5.3 Voting Procedures and Policies

2.5.3.1 Ballots

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

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.

2.5.3.2 Voting

The ballot notification shall include:

- a) The purpose and intended application of the 3-A Sanitary Standard and 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 and 3-A Accepted Practice or the relevant portion under consideration when the 3-A Steering Committee member has previously received the complete standard;

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 any comments that are related to the proposal under consideration and should 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.

2.5.3.3 Voting Period

The voting period for all ballots shall end no less than (45) 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 (15) calendar days before the ballot closes.

Within thirty (30) days after the close of an Ad Hoc WG or 3-A Steering Committee ballot, the Secretariat shall report the results and comments to the Ad Hoc WG and 3-A Steering Committee. Ballots with reasons shall be resolved in accordance with Section 2.5.4.6.

2.5.3.4 Majority Requirements for Actions by the 3-A Steering Committee

A simple majority of the voting members of the Steering Committee shall constitute a quorum for the following transactions of business, provided that at least one committee member from each of the Member Classes is present:

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

2.5.3.5 Reporting Votes

The results of each vote on all 3-A Sanitary Standard and 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 abstaining.
- Number of members not returning ballots.
- Listing of comments submitted.

2.5.3.6 Resolution of Comments

When the balloting and public review period has been closed, the Secretariat shall forward the ballot tally and all comments to the Chair of the Ad Hoc WG and Document Leader and the Chair of the 3-A Steering Committee. 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 appropriate proposed text per ballot instructions with reasons for a negative vote 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 Ad Hoc WG and Document Leader responsible for the document in question.

The Ad Hoc WG Chair and Document Leader shall classify each ballot and public review 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 Ad Hoc WG Chair and Document Leader. Only the revised provision(s) shall be re-balloted by the Ad Hoc WG and 3-A Steering Committee. 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.

All unresolved negative votes with comment from the 3-A Steering Committee and all unresolved objections from public review along with attempts at resolution shall be reported to the 3-A Steering Committee to ensure all members of the 3-A Steering Committee have an opportunity to respond, reaffirm, or change their vote. The recirculation of all unresolved objections shall be in accordance with Section 2.5.3.2. If after the recirculation ballot, any unresolved objectors remain unresolved, he or she shall be informed in writing of his or her right to appeal 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 2.10.

All unresolved objectors from public review shall be informed in writing of their right to appeal procedural action or inaction and that an appeals process exists within the procedures used by 3-A SSI.

The Ad Hoc WG Chair and Document Leader shall prepare a statement giving the rationale for their resolution on each comment with the names of individuals and organizations involved in the determination for a Final Ad Hoc WG Ballot or 3-A Steering Committee Ballot Report.

2.6 Substantive Changes

Proposed substantive change(s) require an additional 45-day ballot for the Ad Hoc Work Group and for the 3-A 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 and 3-A Accepted Practice is one that directly and materially affects the use of the 3-A Sanitary Standard and 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 results of each official ballot to the 3-A Steering Committee, Ad Hoc WG and other entities as determined by the 3-A SSI Board of Directors.

2.8 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 3-A Steering Committee.

2.9 Meetings

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

line or phone conference.

2.9.1 Open Meetings

Meetings of the Ad Hoc WG shall be open to all directly and materially affected persons. At least (15) days notice shall be provided by the Secretariat for any meetings. 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.

2.10 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 3-A 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.

2.10.1 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.

2.10.2 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.

2.10.3 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 group 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.

2.10.4 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 3-A 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.

2.10.5 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.

2.11 Interpretations Policy

2.11.1 Submission of Requests

Requests for interpretations of 3-A Sanitary Standards and 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 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~~ and 3-A Accepted Practice. The Chair of the 3-A Steering Committee must concur in the response of the Secretariat.

2.11.2 Appointment of Interpretations Group

Requests that cannot be resolved by the Secretariat in accordance with Clause 2.11.1 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 (Fabricator, User, and Regulatory Sanitarian) shall designate one voting representative of each 3-A SSI Interest Group from the membership of the Ad Hoc WG which was 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.

2.11.3 Review and Voting

An interpretation by the IG shall be limited to providing clarification and explanation of the existing 3-A Sanitary Standard or 3-A Accepted Practice. Interpretations should not give rise to lengthy

explanations that may inadvertently modify or amend the 3-A Sanitary Standard or 3-A Accepted 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 reached 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.

2.12 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 Ad Hoc WG.

2.13 Patent Policy

A proposed 3-A Sanitary Standard and 3-A Accepted Practice 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 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, revised, or approved 3-A Sanitary Standard or 3-A Accepted Practice 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 assurances 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.

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.

3-A SSI is not 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.

2.14 Records Retention Policy

The Secretariat shall retain all standards related records for one standards 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 a 3-A Sanitary Standard and 3-A Accepted Practice, for a period of five years or until the 3-A Sanitary Standard and 3-A Accepted Practice is reaffirmed, revised or whichever is longer.

Records concerning the withdrawal of a 3-A Sanitary Standard and 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.

2.15 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.

2.16 Maintenance of 3-A Standards

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

2.17 Procedures for the Development of a Provisional 3-A Sanitary Standard, Accepted Practice, or a Provisional Amendment to a 3-A Sanitary Standard, Accepted Practice, or ANS

Occasionally, there are situations that require 3-A SSI to issue a Provisional 3-A Sanitary Standard, Accepted Practice, or a Provisional Amendment to a 3-A Sanitary Standard, or 3-A Accepted Practice. In such cases, provided that certain conditions can be satisfied, a proposed amendment may be developed and submitted directly to the 3-A Steering Committee. The following situations include:

- a.) When implementation of the Provisional Amendment may result in an improvement to the safeguarding of life, and there is a well-established need for the prompt dissemination of information that addresses an emergency situation or other special circumstance;
- b.) When the use of the procedures of the standards developer would cause an undue delay in the issuance of a related standard; and
- c.) When a standards developer supports the development of a Provisional Amendment.
- d.) Request for Rapid Response Ballot

Any interested stakeholder can make a request for a Rapid Response ballot to 3-A SSI. The 3-A Steering Committee Chair, in consultation with the Secretariat and the Ad Hoc WG Chair, will review the request and determine whether a request for a Rapid Response ballot is justified. The following criteria will be used to determine whether the request is justified:

The proposed revision must be to update the 3-A Sanitary Standard or 3-A Accepted Practice.

For example, requesting the use of the Rapid Response ballot solely to allow a single company's product(s) to be in conformance to the standard would not constitute a valid reason to use this expedited ballot process.

e.) **3-A Steering Committee Action**

The Secretariat, in consultation with the 3-A Steering Committee Chair and the appropriate Ad Hoc Work Group Chair, will develop the exact wording and changes to be made to the document. These changes will be prepared in a ballot identified as a Rapid Response ballot and sent to the 3-A Steering Committee per Section 2.5.4.

2.17.1 Minimum consensus body ballot period

A standards developer using these procedures may utilize the minimum ballot period established by their accredited procedures or the consensus body may establish a ballot period that is not less than two weeks.

2.17.2 Comment resolution

All comments accompanying the provisional "rapid response" ballot shall be circulated to the 3-A Steering Committee in order to afford all members an opportunity to respond, reaffirm, or change their vote. For recirculation of comments, a minimum period of not less than one week is required. An attempt to resolve the comments received relative to the Provisional Amendment is not required.

2.17.3 Right to appeal

The right to appeal shall not be required in connection with the issuance of a Provisional Amendment. After the standard or revision has been issued, if a directly and materially affected party believes that the Provisional Amendment should be withdrawn, the clause for Withdrawals shall be followed.

2.17.4 Withdrawal

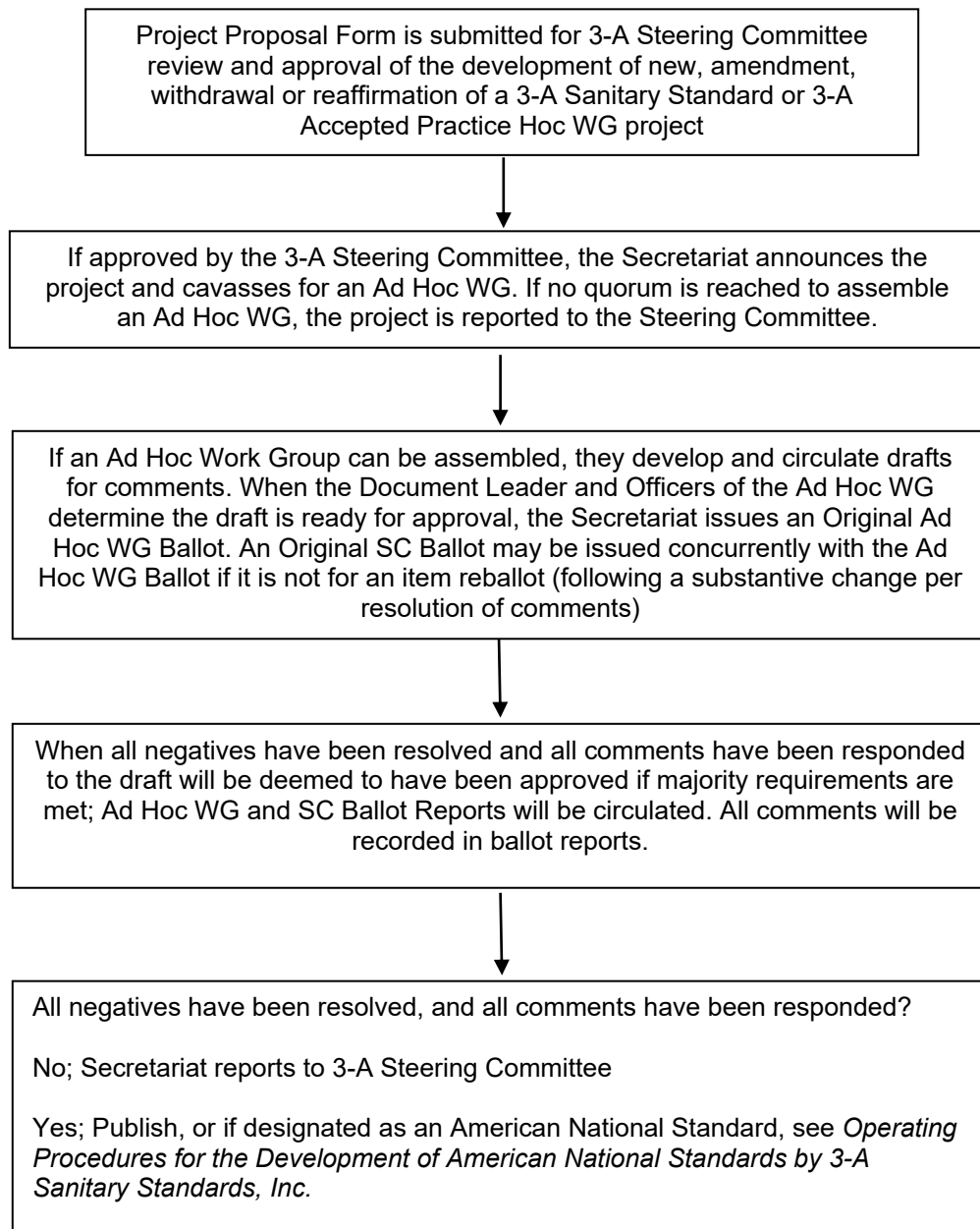
A Provisional Amendment shall exist for no longer than two years from the date on which it is approved by the standards developer. If consensus is achieved and the affected standard is published, the Provisional Amendment is superseded and shall be withdrawn. If consensus is not achieved, the Provisional Amendment shall be withdrawn at that time, but no later than two years from the date on which it was approved.

2.17.5 Identification of a Provisional Amendment

A 3-A Standard or an amendment to a 3-A Standard promulgated in accordance with these procedures shall be referred to as a Provisional Amendment, respectively, and identified clearly as such on the cover or title page.

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.

1250 H Street, N.W. Ste. 903-A

Washington, DC 20005

For 3-A Steering Committee or Ad Hoc WG Member Ballot

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

Name of Commenter	Clause/ Sec. #	Editorial ("E") Technical ("T") For classification by the Document Leader and WG Officers	Comment/ Proposed Change (Negative comments without proposed changes will not be considered)	Document Leader/ Ad Hoc 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

Ad Hoc Work Group (WG) - the Secretariat has designated Ad Hoc Work Groups, which are responsible for overseeing the maintenance and development of 3-A Sanitary Standards and 3-A Accepted Practices for groups. Designation of an Ad Hoc WG is the responsibility of the 3-A Steering Committee. A current list of Ad Hoc WGs and rosters of Ad Hoc WG representatives are maintained on the 3-A SSI web site. Each Ad Hoc WG is composed of experts representing fabricators of related types of equipment, systems, and materials and representatives of the users and sanitarian interest groups. 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.

Interpretations Group (IG) – 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 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.

Secretariat - The secretariat is 3-A SSI and serves as the primary administrative authority responsible for the general coordination of 3-A SSI activities associated with development and administration of 3-A Sanitary Standards and 3-A Accepted Practices in accordance with these procedures.

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 group. The 3-A Steering Committee is the consensus body responsible for voting on the approval of proposed 3-A Sanitary Standards or 3-A Accepted Practices and other matters requiring Steering Committee action as provided in these Procedures. The 3-A Steering Committee shall have a balance of interests as defined by the standards developer. For 3-A Sanitary Standards and 3-A Accepted Practices, the 3-A Steering Committee consists of all members and other interested parties appointed by the 3-A SSI Board of Directors.