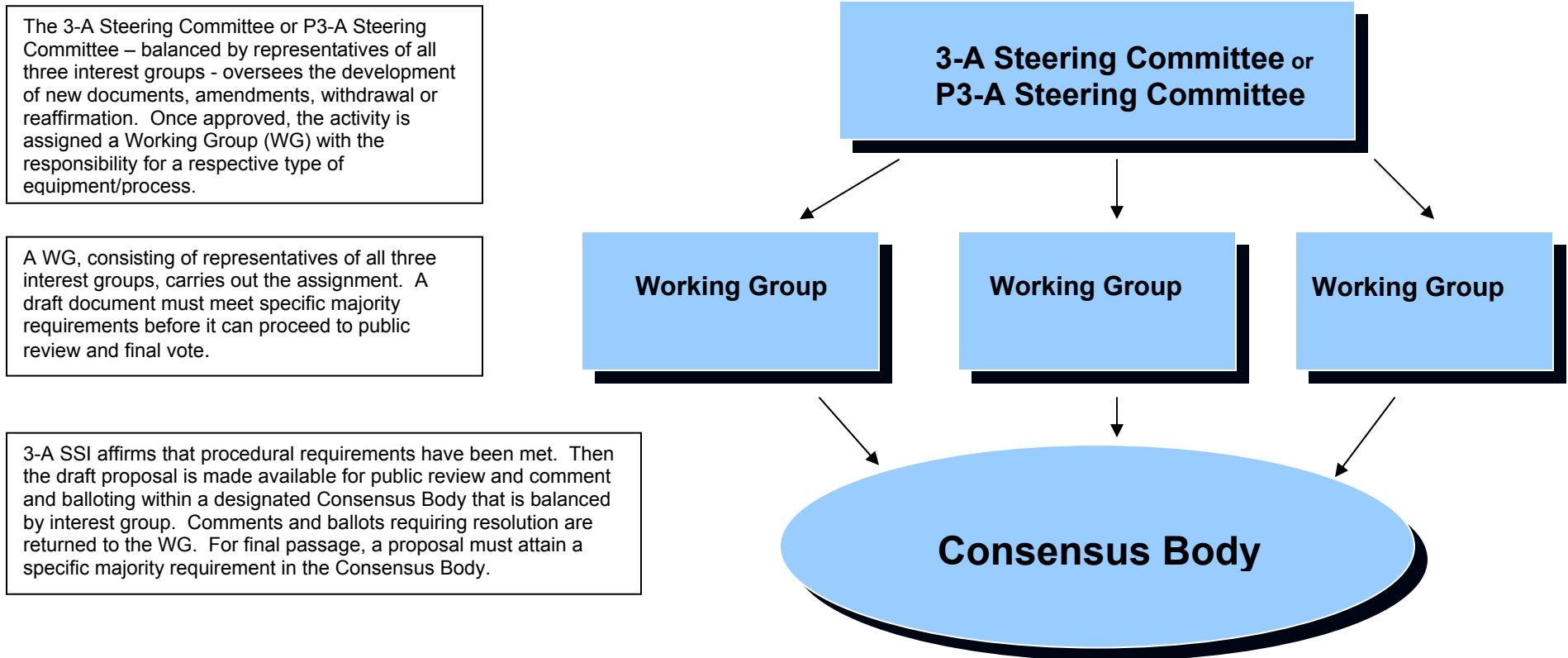




New Procedures for the Development and Maintenance of 3-A SSI Standards and 3-A Accepted Practices

The formation of 3-A Sanitary Standards, Inc. (3-A SSI) organized three stakeholder groups that share a long history of cooperation in 'the 3-A process' – regulatory sanitarians, fabricators, and processors - 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. In 2005, the 3-A SSI Board of Directors approved the formation of a separate P3-A Steering Committee to manage the development of standards for equipment used in manufacturing active pharmaceutical ingredients (APIs).

These new *3-A SSI Procedures* are designed to conform to the American National Standards Institute (ANSI) *Essential Requirements: Due Process Requirements for American National Standards*. The new 3-A SSI procedures provide: 1) a concise overview of the role and the function of the respective Steering Committees as each operates within 3-A SSI and the ANSI voluntary consensus system; and 2) a procedure manual for the 3-A SSI to develop American National Standards, consistent with the requirements for 3-A SSI as an ANSI-accredited Standards Developing Organization.





3-A Sanitary Standards, Inc.

**A User's Guide
To
3-A SSI Ballot Procedures and Rules for
Developing 3-A Sanitary Standards and
Accepted Practices**

Latest Revision Date: August 27, 2008

NOTE: Approved by the 3-A SSI Board of Directors, this revision rewords Work Group ballot passage requirements. Passage of a proposal now expressed as less than 50% negative votes. See sections 9.a.i, 9.b.ii and Table 1 of the User's Guide.

Likewise, Section 2.4.3 of the Standards Development Procedures was revised to reflect the same Board of Directors decision.

This document outlines the balloting process for proposed new, or revisions to existing 3-A Sanitary Standards and 3-A Accepted Practices. This Guide is intended to supplement the *3-A SSI Procedures for the Development and Maintenance of 3-A Sanitary Standards and 3-A Accepted Practices*. The complete *Procedures* follow this short Guide.

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A User's Guide to 3-A SSI Ballot Procedures and Rules for Developing 3-A Sanitary Standards and 3-A Accepted Practices

Anyone with a vested interest in 3-A Sanitary Standards or 3-A Accepted Practices (AP) may propose to revise an existing document or to develop a new document.

GETTING STARTED

1. Proposal must be approved for development by the 3-A Steering Committee

A proposal to revise an existing, or to propose a new 3-A Sanitary Standard or 3-A Accepted Practice must first be approved by the 3-A Steering Committee (SC). The initial proposal should be completed and sent to 3-A SSI staff using the 3-A Sanitary Standards & 3-A Accepted Practices Project Proposal Form, available on the 3-A SSI web site: <http://www.3-a.org/standards/index.htm>. Staff will forward the proposal to the SC. The SC will take approximately 45 days (via their ballot process) to either approve the proposal to be developed in the appropriate WG or deny further development of the proposal.

Once approved, the activity is conveyed to the appropriate Work Group (WG); at the discretion of the WG, the actual drafting may be further assigned to a smaller Document Subgroup (DS) of subject matter experts in accordance with the 3-A SSI, *Procedures for the Development and Maintenance of 3-A Sanitary Standards and 3-A Accepted Practices*. The drafters must incorporate reference information from the most recent revision of the 3-A Format and Style Manual, Number 00-XX. A copy of the document is available at the Technical Resource Center of the 3-A SSI web site at: [Format Style Manual for 3-A Sanitary Standards and 3-A Accepted Practices \(PDF\)](#)

2. 5-year up-dates to existing 3-A Sanitary Standards and 3-A Accepted Practices

The 5-year updates are exempt from the SC approval process, as they are required by 3-A SSI policy. Staff will notify the WG Chairs one year prior to the 5-year anniversary date of the document to begin the process of review and affirmation or modification of the document.

WORK GROUPS

3. Revision of proposal within the Work Group

If the SC approves development of the proposal or if staff assigns a 5-year review, staff sends the proposal to the appropriate WG for development. Usually, the person who submitted the proposal to 3-A SSI becomes the Document Leader for the proposal and manages its technical revision. This person may, with the consent of the WG Chair, recruit other interested subject matter experts to assist in the proposal's development. The individual(s) responsible for the development of the proposal is called the "Document Subgroup (DS)".

The drafters must develop the document in the proper format, according to the most recent revision of the 3-A Format and Style Manual, Number 00-XX. A copy of the document is available at the Technical Resource Center of the 3-A SSI web site at: [Format Style Manual for 3-A Sanitary Standards and 3-A Accepted Practices \(PDF\)](#). The DS develops the draft with informal WG review and comment prior to an official WG ballot. Staff will coordinate the informal review and comment e-mails.

4. Preparation of Original (First) Work Group Ballot

When the document meets the satisfaction of the DS, the Document Leader consults with the WG Chair and conveys the draft to staff. Staff reviews the draft for proper formatting, then prepares a ballot which is distributed to the entire WG. If the proposal is one page or less it is included on the ballot form. If the proposal is greater than one page in length, it is included as a separate document attached to the ballot. Any other supporting material will also be included as attachments to the ballot. The attachments are listed in the cover letter. The ballot and attachments are conveyed via e-mail to the WG for voting (45 days). In the case of a revision, the current standard (or Accepted Practice) is sent as a reference.

5. Voting on Ballots

The following rules pertain to the ballot, and appear on the ballot:

- a. Only the proposal presented in the ballot form is open for voting and comment. The proposal is indicated by the following text edits: [Blue Underlined Text Indicates Additions](#). ~~Red Strike Through Text Indicates Deletions~~ from the original copy. Voters may not vote or comment on any other part of the 3-A Standard or Accepted Practice. This includes unedited sentences appearing in the same clause, paragraph, or section of the 3-A Standard or Accepted Practice, whether or not they appear in the ballot.

If comments are received on other than blue underlined or red strike through text, they will not be recorded and the vote will not be valid. Staff will send an e-mail to the voter stating this, and if time allows, another opportunity to vote on the proposal will be allowed, within the confines of the rules.

b. Voting for Original WG ballots is limited to the following choices:

Choices as shown on Ballot	Explanation of choice
"Affirm"	Your ballot agrees with the entire document as presented.
"Affirm, with comment"	Your ballot agrees with the intent of the document as presented but you wish to offer suggested changes that are technical or editorial in nature, not substantive.*
"Negative, with reasons"	Your ballot does not agree with some aspect of the document and you feel it should not progress until your substantive comments are resolved. See paragraph 5c.
"Abstain, with reasons"	You do not feel competent to ballot on the document. See paragraph 5d.
"Remove my name from the WG Roster"	Self-explanatory.

* A substantive change 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.

- c. A negative ballot shall be accompanied by an explanation of the public health or hygienic design issue, with applicable citations of regulation, and shall include specific wording or actions that would resolve the objection. *Negative votes without reasons and recommended wording to resolve the issue will not be accepted or counted.*
- d. Abstentions should be reserved for only those situations where a conflict of interest may arise if you vote. The situation in which a member's company does not manufacture the specific type of equipment covered by the ballot is **not** considered as a justification to "Abstain". WG members are advised to vote based on knowledge and experience with established sanitary design principles as they relate to the 3-A Standards and Accepted Practices. Excessive abstentions will prevent a ballot from passing.
- e. Only one vote per company is permitted. Those WG members having the same company affiliation should coordinate the vote among company members. In cases where staff receives multiple ballots of the same choice (vote) from the same company, staff will record only one vote and all comments submitted. If a company reports both "Affirm" and "Negative" ballots, they will be invalidated until staff receives a unified vote. Staff will send the company an e-mail informing them of the status of their ballot.
- f. The Work group ballot period is 45 days. Approximately ten days before the ballot closes, staff will send a reminder e-mail to the WG stating who has not voted and the due date of the ballot. The reminder will contain the original letter ballot and proposal for ease of voting.
- g. Staff may remove members from the WG for not voting on two consecutive ballots.

6. Closing the Ballot and Determination of a Valid Quorum

For the WG ballot to be official, 50% or greater ballot returns must be received from each of the three interest groups (fabricators, users, and sanitarians).

7. Review of WG Ballot Comments

After the ballot closes and staff issues the interim ballot report, all comments are reviewed and classified by the Document Leader and the WG Chair, with help from the other DS members as necessary.

a. Classification of comments.

- i. Classification of substantive comments will be made based on the criteria contained in *3-A SSI Procedures for the Development and Maintenance of 3-A SSI Standards and 3-A Accepted Practices, section 2.6.* When

the classification of a comment is in doubt, it should be considered as substantive in order to receive full consideration.

- ii. All other comments that do not meet the criteria for ‘substantive’ are considered editorial in nature, or were submitted with an “Affirm with comment” ballot, shall be considered as non-substantive editorial comments.

b. Resolution of Comments

i. Non-substantive Editorial Comments

Comments that do not meet the classification for substantive comments, are editorial in nature, or were submitted with an “Affirm with comments” ballot may be accepted or rejected at the discretion of the DS Leader. These changes do not require any further balloting.

ii. Substantive Comments

Comments classified as “substantive” (non-editorial) shall be resolved in the following manner:

First, the DS Leader or a representative shall contact the commenter to discuss the comments. If after the discussion and additional explanation of the intent of the proposal and the comment, the commenter agrees to withdraw the comment, he or she will be requested to inform staff by e-mail that the comment is withdrawn. One option is to withdraw the comment with the understanding that the desired change will be held for consideration during a future revision.

Second, if the comment(s) are not withdrawn the proposed substantive change(s) will require a WG Recirculation “A” ballot to determine whether the proposed change is persuasive (the change should be made) or non-persuasive (the original proposal should be retained). All substantive comments from all authors are included as separate items on the Work Group Recirculation “A” ballot.

- iii. “Negative with reasons” ballots, which are **NOT** accompanied by the required explanation of the public health or hygienic design issue, with appropriate citations of regulation, and including specific wording (text) or actions that will resolve the objection will not require any further resolution. Such ballots that lack any rationale, as required, cannot be evaluated.

8. Work Group “A” Recirculation Ballot

- a. The Work Group “A” Recirculation Ballot is a second WG ballot. Its purpose is to determine if the proposed substantive comment, which was not withdrawn, is persuasive (the change should be made) or whether it is non-persuasive (the original proposal should be retained). All substantive comments from all commenters are included as separate ballot items. Staff develops the WG “A” Recirculation Ballot. There may be multiple items on the ballot.

Recirculation ballots are designed to allow voting on each separate issue (change) proposed from the original ballot draft. There may be multiple changes to vote on. Staff sends the recirculation ballot to the WG via e-mail. The recirculation ballot closes in thirty (30) days. Ten days before ballot close, staff sends a reminder to the WG for the return of ballots from those who have not voted.

- b. Voting on each item presented on the Work Group Recirculation ballots (“A” and “B”) is limited to the following choices:

Choices as shown on Ballot	Explanation of choice
“Yes, I accept the proposed (new) wording” (persuasive)	Your ballot agrees with the proposed substantive change as presented in the re-circulation ballot.
“Yes, I accept the proposed (new) wording, with comment” (persuasive)	Your ballot agrees with the intent of the proposed substantive change as presented but you wish to offer suggested changes that are editorial in nature for consideration, not substantive changes.
“No, I want to retain the original (ballot) wording” (non-persuasive)	Your ballot does not agree with some aspect of the proposed substantive change and you want to retain the original wording from the original draft WG Ballot. <u>See paragraph 8c for options if you do not like the original AND re-circulation ballot wording choices.</u>
“Abstain, with reasons”	You do not feel competent to ballot on the document. See paragraph 5d.

- c. There may be situations on a recirculation ballot when through the supplemental documentation the balloter does not favor either the proposed substantive change or the original wording. At this stage of the balloting process there are few options. The balloter can “Abstain, with reason”. The ballot will count as a ballot returned. A “Negative” (non-persuasive) ballot will count as accepting the original wording even though the voter does not agree. This is because the ballot is not sufficient to reject both options. If, however, the voter’s position is matched by 50%, or more, of his/her stakeholder group, the proposal will not proceed to the Consensus Body and the voter will have the opportunity to discuss the issue in more detail within the WG. If, on the other-hand, the voter’s position is not matched by at least 50% of his/her stakeholder group, the voter’s only option is to request that the issue become a new WG project (for future revision) by petitioning the Steering Committee as per Section 1.

9. Requirements for the WG project to proceed to the Consensus Body

For the proposal to move to the next (and final) level of voting, the following applies:

- a. For the Original Working Group Ballot:
 - i. There must be less than fifty percent (50%) of “Negative with reasons” votes. (This equates to fifty percent (50%), or greater, of all eligible voters in each stakeholder group voting “Affirm” or “Affirm, with comment”).
 - ii. All “Negative with reason” votes received during the ballot must be resolved during the informal resolution of comments (see section 7.b.ii., first) without substantive changes to the draft.
 - iii. “Negatives without comment” and “Abstain” ballots are not counted.
- b. For the Work Group “A” Re-Circulation Ballot:
 - i. All sections of the proposal, which do not have a request for a substantive change, are considered as accepted by the WG.
 - ii. Substantive changes, which are subjected to a Work Group “A” Recirculation Ballot, require less than fifty percent (50%) of “No, I want to retain the original (ballot) wording” votes. (This equates to fifty percent (50%), or greater, of all eligible voters in each stakeholder group voting “Yes, I accept the proposed (new) wording” or “Yes, I accept the proposed (new) wording, with comment”).
- c. When a ballot satisfies the requirements of a. or a. followed by b., the DS, with the aid of staff, prepares the final draft proposal, based on the original proposal and the re-circulation ballot results for delivery to the Consensus Body.
- d. When a ballot does not satisfy the requirements of a. or a. followed by b., the proposal is returned to the DS for additional discussion and development. At this point, the entire ballot process begins over.

10. Reports to WG (See Appendix 1)

- a. Interim ballot report — Following an original WG Ballot in which substantive comments were received and not resolved by the informal discussion, an interim ballot report will be issued. This interim ballot report clearly indicates that the issue has not yet passed, the tally of all votes, by interest category, a tally of the number and percentage of ballots received from each of the interest categories, and a listing of all comments with of name and company affiliation of those who commented. The comments are segregated by “Negative with reasons”, “Affirmative with comments” comments, and “Abstentions with reasons”. Staff will identify any “Negative without reasons” ballots. Staff will also identify any comments that are not related to the ballot at hand (the open sections of the standard). No further resolution of these ballots is required. Staff sends the ballot report to the WG and to the SC Chair.
- b. Final ballot report — Following an original WG Ballot in which no substantive comments were received or a successful recirculation ballot, staff issues the final ballot report.
 - i. When the final ballot report is issued after the original ballot, follow the guidance of paragraph a. above.
 - ii. When the final ballot report is issued after a recirculation ballot, the report shall list, for each item on the ballot, a vote tally indicating the vote and lists all comments, by those who voted. By the nature of the re-circulation ballot choices, the ballot will either indicate that each item balloted will be included in the proposal, or not be included in the proposal. The re-circulation ballot report is sent to the WG and SC Chair.

11. Work Group “B” Recirculation Ballot

- a. Any Consensus Body ballot or public comments, which is classified as substantive (requesting technical change) and not withdrawn by the commenter, must be sent back to the WG to determine if they are persuasive. A Work Group “B” Recirculation ballot shall follow the same procedures outlined in Section 8, Work Group “A” Recirculation Ballot.

- b. After the 30-day Work Group “B” Recirculation ballot closes, staff issues an interim ballot report. Those technical changes proposed that are found persuasive (pass the vote) and any editorial comments are written into the draft proposal by the DS. Staff reviews the revised draft proposals to ensure no additional changes are made that are outside the scope of the ballot and comments returned.
- c. The draft proposal resulting from the Work Group “B” Recirculation ballot is returned to the Consensus Body for a final Consensus Body recirculation ballot (see Section 15).

CONSENSUS BODY

12. Consensus Body Ballot and Public Comment

The Consensus Body is the final level of approval as defined by the 3-A SSI, *Procedures for the Development and Maintenance of 3-A Sanitary Standards and 3-A Accepted Practices*. The Consensus Body is balanced in number by the three stakeholder groups — manufacturers, processors and sanitarians. Balloting in this manner, along with the opportunity for the public to provide comments, ensures standards are developed within the guidelines of ANSI for openness to all interested parties. *These standards are consensus based.*

When preparing the Consensus Body ballot, staff first ensures that the WG proposal includes all balloted changes (from the initial ballot, and recirculation “A” ballot, if applicable) and that no new, un-balloted substantive changes were introduced. The ballot includes a cover letter that outlines the issues and gives a brief history of the proposal’s development and balloting by the WG. As in the WG ballot, if the proposal is over one page in length, it is attached to the ballot transmittal e-mail as a separate document. If the proposal is one page or less it is contained as a page of the ballot. Staff also ensures that the proposal is in the final editorial format, including the double column layout.

If the proposal contains any new or altered *Format and Style Manual* criteria, the DS is strongly encouraged to provide supporting documentation as to why they have proposed the criteria and how it conforms to basic sanitary design and protection of public health.

The prepared ballot is emailed to the Consensus Body with its cover letter and all supporting documentation including all WG ballot reports.

When the Consensus Body Ballot is sent, a notice is posted on the 3-A SSI web site that states the proposal is open for comments from the public, describes the proposal, and states how to obtain the proposal and provide comments on it.

The following rules apply to Consensus Body ballots:

- a. Only the proposed change(s) is/are open for voting and comment. Blue Underlined Text Indicating Additions. ~~Red Strike Through Text Indicating Deletions~~. No other parts of the 3-A Standard or Accepted Practice are open for voting or comment.
- b. Consensus Body members must vote one of the following:

Choices as shown on Ballot	Explanation of choice
“Affirm”	Your ballot agrees with the entire document as presented.
“Affirm, with comment”	Your ballot agrees with the intent of the document as presented but you wish to offer suggested non-substantive editorial changes for consideration.
“Negative, with reasons”	Your ballot does not agree with some aspect of the document and you feel it should not progress until your substantive comments are resolved. See paragraph 12c.

- c. A negative ballot must 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. Negative votes without reasons and recommended wording to resolve the issue will not be counted.
- d. Only votes submitted electronically (via e-mail) will be accepted.
- e. All 3-A Consensus Body members must vote.

- f. The ballot must be received by the due date. The Consensus Body ballot period is 45 days. Approximately ten days before the ballot closes, staff will send an e-mail to the Consensus Body stating who has not voted and the due date of the ballot. The reminder will contain the original letter ballot and proposal for ease of voting.

13. Closing the Ballot and Determination of a valid quorum.

The quorum requirements are 80% of eligible Consensus Body members (16 out of a total of 19 returns).

- a. If the quorum requirements are not met, Staff may extend the ballot period in an attempt to get enough ballot returns to close the ballot.
- b. If the quorum requirements are satisfied, staff issues an interim ballot report within 30 days.

14. Review of Consensus Body Ballot Comments

Consensus Body ballot comments and any public comments received are reviewed as in Section 7, (Review of WG Comments). The commenters are contacted and the comments discussed with them. **All substantive comments not withdrawn are sent back to the Work Group for resolution**, following the procedures Section 11, Work Group “B” (second) Recirculation Ballot.

If there are no “**Negative with reason votes**” (or invalid ones), the ballot will have been deemed to pass. If no public comments asking for substantive changes were received, the proposal will have passed and will be promptly published as a revised or new 3-A Standard or Accepted Practice.

If public comments are received suggesting substantive change, they must be balloted to the Work Group as a Work Group “B” Recirculation ballot.

15. Consensus Body Recirculation Ballot

- a. Following the completion of the WG evaluation of Consensus Body and public substantive comments (see section 12) a final proposal draft of the outstanding issues are returned to the Consensus Body for a final recirculation ballot. The Consensus Body Recirculation ballot is to determine if the technical changes made as the result of the Work Group “B” recirculation ballot are acceptable to the Consensus Body. Only the substantive issues raised in the original Consensus Body ballot will appear on the Consensus Body Recirculation ballot. Nothing else is open for ballot or comment.
- b. Voting for the Consensus Body Recirculation ballot is limited to the following choices:

Choices as shown on Ballot	Explanation of choice
“Yes, I accept the proposed (new) wording” (persuasive)	Your ballot agrees with the proposed substantive change as presented.
“Yes, I accept the proposed (new) wording, with comment” (persuasive)	Your ballot agrees with the intent of the proposed substantive change as presented but you wish to offer suggested non-substantive editorial changes for consideration.
“No, I want to retain the original (balloted) wording” (non-persuasive)	Your ballot does not agree with some aspect of the proposed substantive change and you want to retain the original wording from the original draft Ballot. See paragraph 8c for options when you don’t like either choice.

- c. The recirculation ballots are designed to allow voting on each separate substantive issue (change) proposed from the original Consensus Body ballot draft. There may be multiple issues to vote on. Staff sends the Consensus Body Recirculation ballot via e-mail. The recirculation ballot closes in thirty (30) days. Ten days before ballot close, staff sends a reminder to those who have not voted.

16. Requirements for passage of a 3-A Sanitary Standard or 3-A Accepted Practice

In accordance with the *Procedures for the Development and Maintenance of 3-A Sanitary Standards and 3-A Accepted Practices*, a document is passed when the following requirements are met for either an Original Consensus Body ballot or a Consensus Body Recirculation ballot for substantive issues:

- i. A minimum of 80% of all eligible Consensus Body voters returns a ballot.
- ii. A minimum of 70% of all eligible Consensus Body voters must vote “Affirm” or “Affirm with comment”.
- iii. No unresolved substantive comments were submitted by Consensus Body voters or from public comment.

17. Consensus Body Reports

Interim and final ballot reports will follow the same procedures as for WG ballot reports. See section 10.

EMERGENCY REVISION PROCEDURES

18. Rapid Response Balloting Procedures

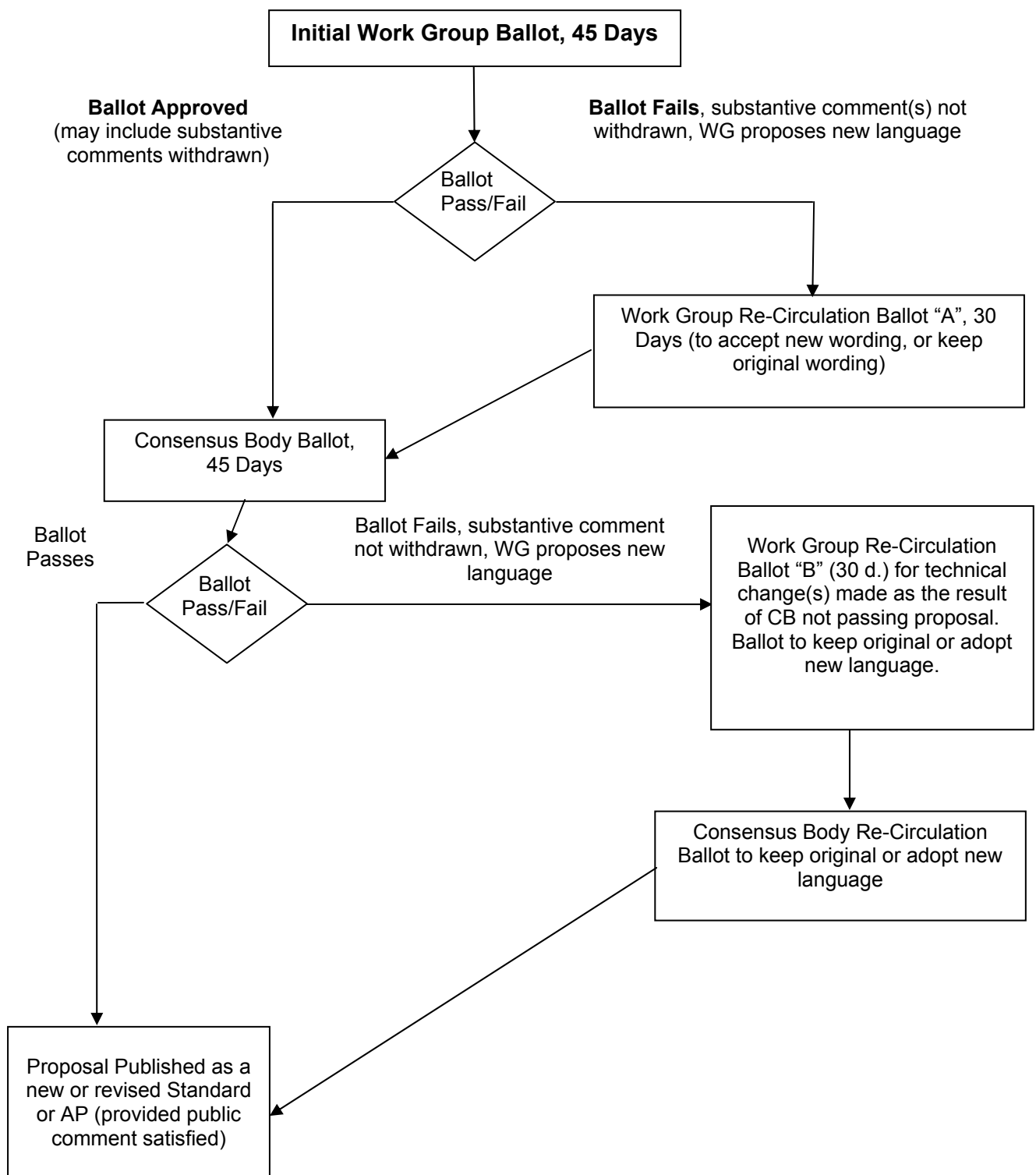
Occasionally, there are situations that require 3-A SSI to amend 3-A Sanitary Standards or 3-A Accepted Practices as expediently as possible (within 30 days whenever possible). In such cases, provided that certain parameters concerning the request for amendment can be satisfied, the Steering Committee, which represents all of the interested stakeholder groups, will assume the responsibilities of the Working Group.

a. Identification of a Rapid Response Issue

Any interested stakeholder, Certified Conformance Evaluator (CCE), or 3-A SSI staff member can make a request for consideration for a rapid response to the Steering Committee. The Steering Committee, with technical advice from the appropriate Working Group Chair, will determine if the request is a valid issue. If *the issue is valid*, all voting members of the Steering Committee must unanimously agree that the issue is non-controversial.

b. Steering Committee/Consensus Body Action

The Steering Committee and the appropriate Working Group Chair will establish the exact wording and changes to be made to the document. These changes will be balloted to the Consensus Body on an abbreviated ballot schedule.





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BALLOT REPORT

Motion: (Identify the purpose of the ballot)						
Balloting Body: <input type="checkbox"/> Work Group (Insert number and name)				<input type="checkbox"/> Consensus Body		
Ballot Type: <input type="checkbox"/> Original <input type="checkbox"/> Recirculation "A" <input type="checkbox"/> Recirculation "B"				<input type="checkbox"/> Original <input type="checkbox"/> Recirculation		
Vote Tally:	Fabricator	Processor	Sanitarian		Actual	Min Required
Total Seats (filled)				Ballots returned		16*
Ballots "Affirm"				Ballots "Affirm"		14**
Ballots "Negative"				Ballots "Negative"		
Ballots "Abstain"				No Reply		
No Reply				* 80% of available votes returned		
Ballots "Negative without comment"				** 70% of available votes must Affirm		
% "Negative" *	%	%	%			
* Less than 50% "Negative" required per interest group.						
Action: <input type="checkbox"/> Approved for passage to Consensus Body <input type="checkbox"/> Substantive comments received requiring WG Recirculation "A" ballot (if comments not withdrawn)				<input type="checkbox"/> Document Approved <input type="checkbox"/> Substantive comments received requiring WG recirculation "B" ballot (if comments not withdrawn)		

(The above table may be repeated as often as necessary to accommodate multiple issue recirculation ballots)

Voting Record:

Member (WG – Company CB - Name)	Interest Group	Affirm	Neg	Abstain	No Reply	No Reply Previous Ballot
	Insert Fab, Proc, or San					
(Add lines as necessary for the group)						

Ballot Comment Summary:

Negative with reason:

(List or state "None")

Affirmative with comment:

(List or state "None")

Comments not relative to the ballot issue(s)

(List or state "None")



3-A Sanitary Standards, Inc.

**Procedures for the Development and
Maintenance of 3-A SSI Standards
and 3-A Accepted Practices and
P3-A Standards**

Latest Revision Date: October 2, 2009

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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); International Association of Food Industry Suppliers (IAFIS); 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.

Subsequent to the formation of 3-A SSI, in July 2003, a number of representatives of active pharmaceutical ingredient (API) manufacturers approached 3-A SSI regarding the development of standards for cleanable equipment for use in manufacturing APIs. The API manufacturers and several equipment manufacturers formed a P3-A Steering Committee to develop the concept, organization and standard development procedures within 3-A SSI. In February 2005, the 3-A SSI Board of Directors approved the formal establishment of the P3-A Steering Committee within the structure of 3-A SSI. The P3-A Steering Committee, balanced by interest group, was designated to manage the P3-A standards development.

These new 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 and the P3-A Steering Committee as they operate within the ANSI voluntary consensus system; and 2) provide the 3-A Steering Committee and the P3-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 and P3-A 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 and P3-A Standards for the design, fabrication and installation of cleanable equipment for manufacturing pharmaceutical ingredients and drug products. 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 Working Groups (WGs).

The P3-A Steering Committee shall report and be responsible to the Board of Directors of 3-A SSI. Management, authority, and responsibility for the P3-A Standards activities rests with the P3-A Steering Committee and its appointed Working 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, consumers and others.
- 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, consumers and others.
- c) Sanitarians Group – The Sanitarians Group shall represent state or local milk regulatory officials (Sanitarians), and 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 membership of the 3-A Steering Committee shall be sufficiently diverse to ensure reasonable balance without dominance by any single interest group.

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.

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 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 groups, 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 Working Groups

The 3-A Steering Committee may designate WGs to expedite the work of the Consensus Body. 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 groups. The 3-A Steering Committee shall maintain membership of at least two representatives from each interest group 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 group 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 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 group (i.e., Fabricator, User, Sanitarian);
- f) Tally of classifications: total of voting members and subtotals for each interest group.

2.4.1 3-A Working 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 Committee (IC) deliberations, when needed.

2.4.2 3-A Working 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 Committee (IC) 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 Working 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 Consensus Body for final approval. Should any interest group have more than 50% of their submitted ballots voting “Negative (with reasons)”, the document shall not advance to the Consensus Body until the outstanding issues are resolved.

2.4.4 3-A Working 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 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 Consensus Body

The Consensus Body 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. The Consensus Body shall be sufficiently diverse to ensure reasonable balance without dominance by a single interest group in accordance with *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

The affiliation and interest group of each member of the Consensus Body shall be made available to interested parties upon request. Affiliation refers to the interest group that the Consensus Body member represents. If the Consensus Body member is serving in an individual capacity, then the name of the individual, that person’s employer and interest group should be available. In such case, employer contact information is not required.

Voting by the Consensus Body 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 Consensus Body 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*.

Consensus Body 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 Consensus Body. A removed Consensus Body member may reapply for participation on the Consensus Body.

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

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 (Council, ADPI, IAFP, IAFIS, and IDFA), FDA Milk Safety Branch, USDA Dairy Programs, industry trade press, and other interested parties to announce the opportunity for participation by all directly and materially affected persons. At the initiation of a project to develop or revise a candidate 3-A Sanitary Standard or 3-A Accepted Practice, notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for listing in *Standards Action*.

In addition, proposals for new 3-A Sanitary Standards or 3-A Accepted Practices and proposals to revise, reaffirm, or withdraw approval of existing 3-A Sanitary Standards or 3-A Accepted Practices 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 thirty (30) days if the full text of the revision(s) can be published in *Standards Action*;
- A minimum of forty-five (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 sixty (60) days, if neither of the aforementioned options is applicable.

Such listing may be requested at any stage in the development of the proposal and may be concurrent with final balloting. However, any substantive change subsequently made in a proposed 3-A Sanitary Standard or 3-A Accepted Practice requires listing of the change in *Standards Action*.

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 Consensus Body. 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 Consensus Body 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 forty-five (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 ten (10) business 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. All ballots with reasons shall be resolved in accordance with Section 3.3.6.

2.5.4.4 Majority Requirements for Actions by the Consensus Body

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

- 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 Consideration of Views and Objections

When the balloting or Public Notice comment period has been closed, the Secretariat shall forward the ballot tally to the 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 responsible for the document in question. The WG shall consider each ballot or Public Notice comment and seek consensus on how it should be addressed. If in the process, the WG determines 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 Consensus Body and submitted for public review. 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 shall prepare a statement giving the rationale for its action on each comment. The statement should also include the names of individuals and organizations involved in the WG 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 Consensus Body in order to afford all members of the Consensus Body an opportunity to respond, reaffirm, or change their vote. The Consensus Body shall have twenty-one (21) days to respond to the disposition of comments and revised draft.

2.6 Substantive Changes

Substantive change(s) made to a draft 3-A Sanitary Standard or 3-A Accepted Practice by the Work Group in order to resolve comments or objections 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 thirty days if the full text of the revision(s) can be published in *Standards Action*;
- A minimum of forty-five days if the document is available in an electronic format, deliverable

within one day of a request, and the source (e.g., URL or an E-mail address) from which it can be obtained by the public is provided to ANSI for announcement in *Standards Action*; or

- A minimum of sixty days, if neither of the aforementioned options is applicable.

The proposed substantive change(s) will also require an additional 30-day ballot for the Consensus Body. 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:

- d) "Shall" to "should" or "should" to "shall";
- e) Addition, deletion or revision of requirements, regardless of the number of changes;
- f) 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 groups, to the Consensus Body, 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, disposition of views and objections, and appeals, the proposed 3-A Sanitary Standard or 3-A Accepted Practice shall be submitted to ANSI by the Secretariat. The information supplied to ANSI by the Secretariat shall include all relevant material required by ANSI as outlined in the *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

The information supplied to the 3-A SSI Board of Directors and ANSI shall include:

- a) Title and designation of the proposed 3-A Sanitary Standard or 3-A Accepted Practice.
- b) Indication of the type of action requested.
- c) A declaration that the established Procedures were followed.
- d) A declaration regarding the disposition of objections to the approval of the proposed 3-A Sanitary Standard or 3-A Accepted Practice.
- e) A summary of the voting and unreturned ballots.
- f) A roster of the Consensus Body and applicable WG at the time of the Consensus Body ballot.

If the 3-A Sanitary Standard or 3-A Accepted Practice is not to be submitted as a candidate American National Standard, the same procedures shall be followed, except for the submission of ANSI documents.

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 forty-five (45) days following approval by the Consensus Body.

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 fifteen (15) days notice of meetings shall be given by the Secretariat. Meetings that require travel shall require at least sixty (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 Consensus Body 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 thirty (30) days after the date of notification of approval 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 thirty (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 ten (10) business 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 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.

2.12.4 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 Consensus Body 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 thirty (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

Requests for interpretations of 3-A Sanitary Standards or 3-A Accepted Practices shall be submitted in writing to the Secretariat. Requests that cannot be resolved informally by the

Secretariat shall be forwarded by the Secretariat to the 3-A SSI Interpretations Committee (IC). The IC provides official 3-A SSI interpretation of words, phrases, and criteria within 3-A Sanitary Standards and, when needed, 3-A Accepted Practices.

The IC will respond within thirty (30) calendar days to all inquiries upon receipt of the inquiry by the IC Chair. If a final decision cannot be concluded within a period of thirty (30) days, the inquirer shall be notified that the request is being processed, the reason(s) for the delay; and an estimate of when a decision will be issued.

All IC decisions shall be issued to the inquirer and Secretariat in writing. The interpretation shall include specific explanations of how the decision was reached including citation of any regulations or references that supported the decision.

A summary of each IC decision shall be published on the 3-A SSI web site to foster uniform interpretation of the criteria as well as distributed to the WG Chair, 3-A Steering Committee members, Certified Conformance Evaluators, and 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 Periodic Maintenance

3-A Sanitary Standards or 3-A Accepted Practices shall be reviewed and action taken to revise, reaffirm or withdraw the standard on a schedule not to exceed five years from the date of its approval as a 3-A Sanitary Standard or 3-A Accepted Practice.

No more than four years after approval of a 3-A Sanitary Standard or 3-A Accepted Practice, the 3-A Steering Committee shall initiate action to review the 3-A Sanitary Standard or 3-A Accepted Practice.

2.20 Withdrawal of 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 Consensus Body 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.

PART 3 – PROCEDURES FOR THE DEVELOPMENT OF P3-A STANDARDS

3.1 Procedures

P3-A standards shall be developed by a canvass procedure that conforms to the *ANSI Essential Requirements: Due Process for American National Standards*.

3.2 Property

P3-A Standards will be the property of 3-A Sanitary Standards, Inc. (3-A SSI).

3.3 Secretariat

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

- a) Organize the WGs and ad hoc groups in consultation with the P3-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 P3-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 P3-A Steering Committee for public review, ANSI review, and approval.
- f) Publish approved P3-A standards 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.

3.4 P3-A Steering Committee

The standards development procedures shall be managed by the P3-A Steering Committee.

The P3-A Steering Committee shall have no more than 11 voting members. The committee will include at least five pharmaceutical manufacturers, at least two pharmaceutical equipment suppliers, and three other interested parties, one of which may be from the U.S. Food and Drug Administration.

The officers of the P3-A Steering Committee shall be a chair and a vice-chair. The committee may add nonvoting members such as representatives of other standards organizations, academia, or other interested parties to provide relevant industry input and feedback.

3.5 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.

3.5.1 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.

3.5.2 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.

3.6 Notification of Standards Development and Coordination

Notification of standards activity shall be announced in suitable media as appropriate to demonstrate the opportunity for participation by all directly and materially affected persons. At the initiation of a project to develop or revise an American National Standard, notification shall be transmitted to ANSI using the Project Initiation Notification System (PINS) form, or its equivalent, for announcement in *Standards Action*.

If written comments are received within 30 days from the publication date of a PINS announcement in *Standards Action*, and such 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 in *Standards Action*, a deliberation of representatives from the P3-A Steering Committee and the relevant stakeholder groups shall be held within 90 days from the comment deadline. The purpose of the deliberation is to develop a consensus on whether and how the standards development project should proceed. The deliberation shall be organized by the Secretariat and the commenter and shall be concluded before 3-A SSI submits a draft standard for public review. If the deliberation does not take place within the 90-day period, 3-A SSI must demonstrate that it has made a good faith effort to schedule and otherwise organize it. The outcome of a deliberation shall be conveyed in writing by the Secretariat and, if possible, jointly with the commenter, to the ANSI Board of Standards Review (BSR) for consideration should 3-A SSI ultimately submit the candidate standard to ANSI for approval.

In addition, proposals for new American National Standards and proposals to revise, reaffirm, or withdraw approval of existing American National Standards shall be transmitted to ANSI using the BSR-8 form, or its equivalent, for listing in *Standards Action* in order to provide an opportunity for public comment. The comment period shall be one of the following:

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

Such listing may be requested at any stage in the development of the proposal, at the option of the standards developer, and may be concurrent with final balloting. However, any substantive change subsequently made in a proposed American National Standard requires listing of the change in *Standards Action*.

3.7 Consensus Body

The P3-A Steering Committee shall establish a Consensus Body, or Bodies, to vote on whether the draft standard(s) should be approved as a national standard(s).

3.7.1 Balance of Interests

The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. Historically the criteria

for balance are that a) no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety-related standards or b) no single interest category constitutes a majority of the membership of a consensus body dealing with other than safety-related standards.

3.7.2 Interest Groups

The interest groups shall include the following:

- a) Producer – A member who represents an organization that produces or sells materials, products, systems, or services covered in the scope of the proposed document shall be classified as a producer.
- b) User – A member who represents an organization that in the context of his/her profession purchases or uses materials, products, systems, or services covered in the scope of the proposed document shall be classified as a user provided that the member could not also be classified as a producer.
- c) General Interest – A member who does not fit into any of the preceding groups, for example: Government agency representatives; A&E firms; representatives of consumer groups; academia/research experts; or experts who, through career change or retirement, are no longer ‘active’ producers or users of materials, products, systems, or services within the scope of the proposed document.

The P3-A Steering Committee shall develop a list of potential canvasees consisting of those organizations, companies, government agencies, standards developers, individuals, etc., known to be, or who have indicated that they are, directly and materially affected by the standard.

The P3-A Steering Committee shall conduct a pre-canvass interest survey informing the potential canvasees in writing about the use of the canvass method for developing evidence of consensus, and, if the potential canvasees are interested in participating, the canvasee shall indicate an appropriate interest category classification.

The pre-canvass interest survey letter shall contain the title, designation, scope, and description of the standard along with the history of its development, purpose and intended application of the standard.

The time for response to the pre-canvass survey shall be 30 days.

The Steering Committee shall provide notice(s) of the intent to develop a standard to appropriate trade and other organizations and publications to solicit additional canvasees.

The affiliation and interest category of each member of the consensus body shall be made available to interested parties upon request.

Note 1. Affiliation refers to the entity that the consensus body member represents (which may or may not be that person’s employer). If the consensus body member is serving in an individual capacity, then the name of the individual, that person’s employer and interest category should be available. Contact information is not required.

Consensus Body 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 dropped from the consensus body. A dropped consensus body member may reapply for participation on the consensus body.

3.8 P3-A Working Groups

The P3-A Steering Committee shall establish Working Groups (WGs), as necessary, to develop draft standards for consensus. The P3-A Steering Committee shall determine the scope of work for the WG and appoint the chair of the WG.

The WGs shall have open membership; however, WGs shall have at least two members representing equipment manufacturers and two members representing pharmaceutical

manufacturers. WGs shall be encouraged to develop drafts using electronic tools and conference calls, when necessary.

The WGs shall submit the draft standard to the P3-A Steering Committee for consideration prior to canvass. A majority vote of the P3-A Steering Committee shall be required to accept the draft standard for canvass. If the draft standard is not accepted it shall be returned to the WG with an explanation of the reason(s) for rejection.

3.9 Voting Procedures and Policies

The P3-A Steering Committee shall conduct the canvass of the draft standard. The period for canvasses to respond shall be sixty (60) days. The canvass shall be by electronic means. This includes e-mail and facsimile.

The canvass shall include:

- a) the purpose and intended application of the standard;
- b) a brief history and explanation of how the standard was developed;
- c) a copy of the consensus list, consisting of the name, affiliation, and category of interest of each canvasee;
- d) a copy of the complete proposed standard or the relevant portion under consideration when the canvasee has previously received the complete standard;
- e) official letter ballot(s) to all canvassees.

Canvasses shall vote one (1) of the following positions:

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

Upon request, the standards developer shall provide to the canvasee a reasonable number of copies of the document being considered, to allow for a speedy determination of position by the canvasee.

The P3-A Steering Committee or Secretariat shall issue a reminder to canvasses that have not returned their ballot. The reminder shall be sent to canvasses ten (10) days prior to the ballot due date.

The P3-A Steering Committee shall provide notice to appropriate trade and other organizations and publications that a draft standard has been submitted to canvass and that a copy of the draft standard is available for public review.

3.10 Consideration of Views and Objections

The P3-A Steering Committee or Secretariat shall send all ballots and public comments to the relevant WG(s) for review and disposition.

The WG(s) shall inform commentors of the opportunity to participate in the discussion of their comments. The WG shall make an effort to resolve all expressed objections.

The WG(s) shall submit a written report of the disposition of comments, with rationale, and a revised draft, if necessary, to the P3A Steering Committee.

The P3-A Steering Committee shall circulate the WG's written report of the disposition of comments and revised draft to the Consensus Body.

The Consensus Body shall have 30 days to respond to the disposition of comments and revised draft.

Canvasees shall vote to approve, abstain (with comment) or object (with reasons).

The P3-A Steering Committee or Secretariat shall issue a reminder to canvasees that have not returned their ballot ten (10) days prior to the due date.

The P3-A Steering Committee shall notify each commentor in writing (including electronic communications) of the disposition of the objection and the reasons therefore. If resolution is not achieved, the commentor shall be informed in writing that an appeals process exists. The appeals process appears in Section 3.14.

3.11 Substantive Changes

Substantive change(s) made to a draft P3-A standard by the Work Group in order to resolve comments or objections 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 thirty days if the full text of the revision(s) can be published in *Standards Action*;
- A minimum of forty-five days if the document is available in an electronic format, deliverable within one day of a request, and the source (e.g., URL or an E-mail address) from which it can be obtained by the public is provided to ANSI for announcement in *Standards Action*; or
- A minimum of sixty days, if neither of the aforementioned options is applicable.

The proposed substantive change(s) will also require an additional 30-day canvass.

Only the substantive changes, not the entire draft, are subject to this follow-up requirement. A substantive change in a proposed P3-A Standard is one that directly and materially affects the use of the P3-A Standard. 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.

3.12 Approval of Standard

A successful canvass must have at least 60% of the ballots returned, with a majority of each interest category and two-thirds of all canvasees responding in favor of approval excluding abstentions or non-returned ballots.

3.13 Publication of P3-A American National Standards

3-A SSI will publish and make available its new and revised P3-A American National Standards as soon as possible, but no later than six months after approval as an American National Standard. If a P3-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.

3.14 Appeals

Persons who have directly and materially affected interests, and who have been or will be adversely affected by a standard being canvassed or by the lack thereof, shall have the right to appeal any procedural actions or inactions during the development of the standard. 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.

For a formal appeal, the appeal must be filed in writing with the P3-A Steering Committee or Secretariat.

The P3-A Steering Committee shall provide or arrange for an impartial appeals panel composed of at least three individuals knowledgeable as to the policy or other concerns related to the appeal. Such individuals must not have demonstrably real or apparent conflicts of interest with the subject of the appeal or the person filing the appeal.

The appeals panel shall submit a written report to the P3-A Steering Committee containing the decision of the panel and its rationale. The report shall be filed within 30 days of the appeal hearing. The P3-A Steering Committee shall forward a copy of the appeals panel report to the appellant and to the Consensus Body.

3.15 Interpretations Policy

Written inquiries requesting interpretation of the standards shall be responded to by the P3-A Steering Committee. The P3-A Steering Committee may refer the inquiry to the appropriate WG for guidance in responding to the inquiry. P3-A will provide written responses to those seeking requests for interpretations. Revisions to the standard resulting from requests for interpretations shall be processed in accordance with these procedures.

3.16 Commercial Terms and Conditions

P3-A 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 P3-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 P3-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.

3.17 Periodic Maintenance

Standards shall be reviewed and action taken to revise, reaffirm or withdraw the standard on a schedule not to exceed five years from the date of its approval as a P3-A Standard. No more than four years after approval of a P3-A standard, the P3-A Steering Committee shall initiate action to review the standard.

3.18 Metric Policy

English units are the standard units for P3-A standards. English units shall be followed with the metric equivalent in parentheses.

3.19 Patent Policy

A proposed P3-A American National Standard may include the use of a 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 P3-A 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 placed and 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 standard 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 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 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.

3.20 Records Retention Policy

All necessary documents and records, which may include, but are not limited to, ballots, public comments, correspondence, meeting notices, and minutes of meetings pertaining to the development and maintenance of a P3-A standard shall be retained for five years, or until the standard is reaffirmed, revised or withdrawn, whichever is longer.

Records concerning the withdrawal of a P3-A standard shall be retained for a period of five years from the date of withdrawal or for 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 of records if the original records are kept in an electronic format.

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

3.21 Withdrawal of Standard

3.21.1 Administrative withdrawal

A P3-A American National Standard will be withdrawn five years following approval, if the standard has not been revised or reaffirmed, unless an extension has been granted by the (ANSI) ExSC or its designee. A P3-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*. P3-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*.

3.21.2 Withdrawal by 3-A SSI

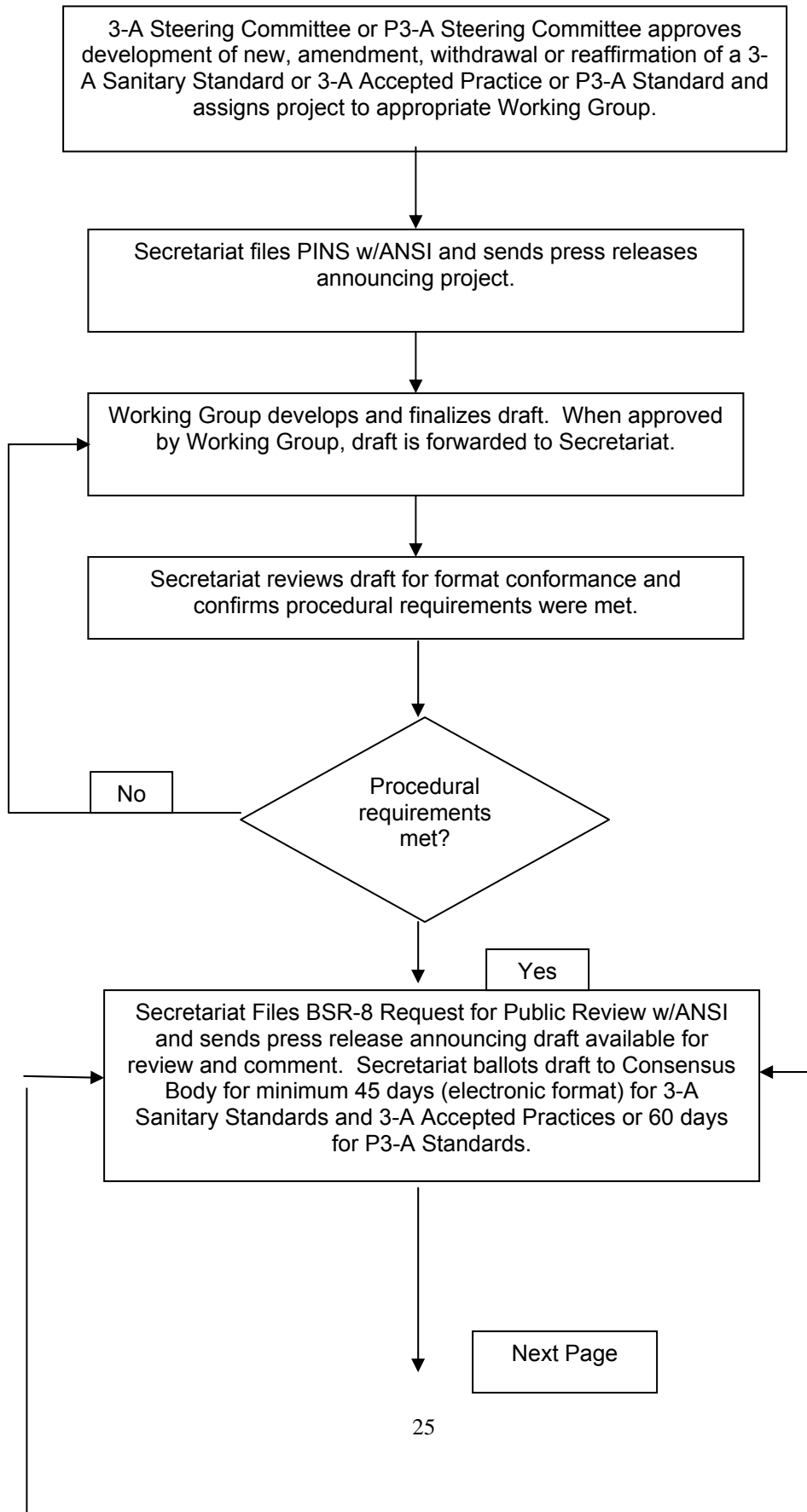
If 3-A SSI wishes to withdraw its approval of one or more of its P3-A American National Standards, it may do so without a canvass. If 3-A SSI does withdraw one or more of its P3-A American National Standards, then 3-A SSI will notify ANSI immediately and the standard shall be withdrawn as an ANS and announced in *Standards Action*.

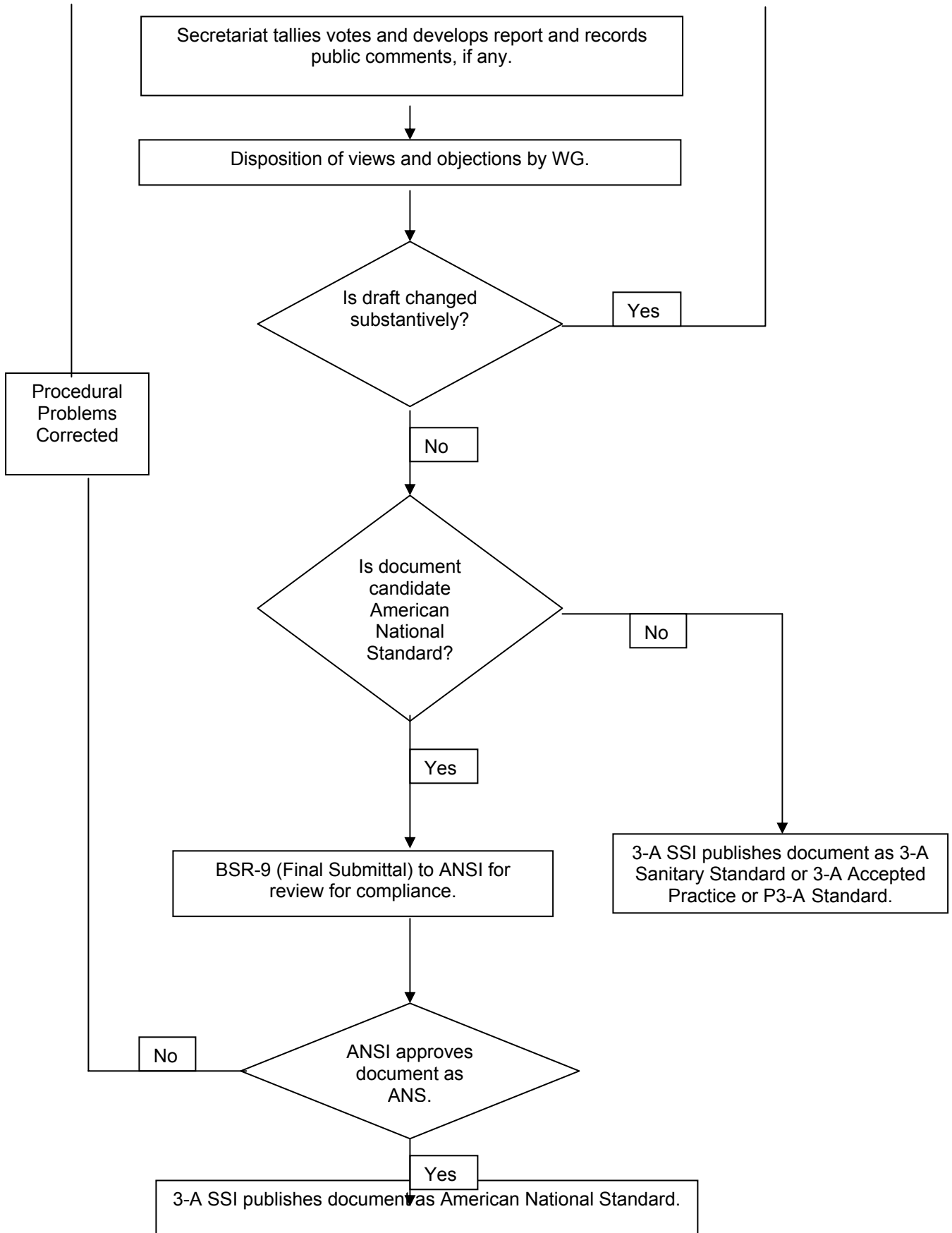
3.21.3 Discontinuance of a standards project

3-A SSI may abandon the processing of a proposed new or revised P3-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 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}

For Public Ballot

Name of Submitter:
Interest Group:

For Consensus Body or Working Group Member Ballot

User ID: (To be assigned)
Password: (To be assigned)

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

COMMENTS (where required):

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

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 group.

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*.

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

Interest Groups - 3-A SSI 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 groups are defined in these procedures appropriate for the activities of 3-A SSI. These groups are:

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

For P3-A Standards, interest groups are defined as follows:

- a) Producer – A member who represents an organization that produces or sells materials, products, systems, or services covered in the scope of the proposed document shall be classified as a producer.
- b) User – A member, or a member who represents an organization, that in the context of his/her profession purchases or uses materials, products, systems, or services covered in the scope of the proposed document shall be classified as a user provided that the member could not also be classified as a producer.
- c) General Interest – A member who does not fit into any of the preceding groups, for example: Government agency representatives; A&E firms; representatives of consumer groups; academia/research experts; or experts who, through career change or retirement, are no longer 'active' producers or users of materials, products, systems, or services within the scope of the proposed document.

Interpretations Committee – For 3-A Sanitary Standards and 3-A Accepted Practices, the Interpretations Committee provides official 3-A SSI interpretation of words, phrases, and criteria within 3-A Sanitary Standards and, when needed, 3-A Accepted Practices. The IC consists of eight 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 and P3-A Standards in accordance with these procedures and *ANSI Essential Requirements: Due Process Requirements for American National Standards*.

Working Groups - 3-A SSI has designated Working Groups, which are responsible for overseeing the maintenance and development of 3-A Sanitary Standards or 3-A Accepted Practices and P3-A Standards for groups of similar equipment or materials. Designation of a WG is the responsibility of the 3-A Steering Committee or P3-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 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.

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 Working Group, Consensus Body, 3-A SSI Board of Directors and 3-A Steering Committee or P3-A Steering Committee	Within 10 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