

3-A Sanitary Standards, Inc.

Manual for Third Party Verification (TPV)

for



3-A Symbol Authorization

and

3-A Process Certification

FOREWORD

The administration of the 3-A Symbol program and the general oversight of documents generally known for many decades as '3-A' Sanitary Standards and '3-A' Accepted Practices has undergone significant changes in recent years.

Since the introduction of the 3-A Symbol in 1956, the use of the 3-A Symbol was based on a system of self-certification by the applicant. The 3-A Symbol Administrative Council, Inc. was responsible for the general administration of the 3-A Symbol licensing program. The development and maintenance of all '3-A' consensus documents was accomplished through an informal collaboration of organizations representing the three primary interest groups – dairy equipment manufacturers, dairy equipment users and state and federal regulatory sanitarians.

During the late 1990s, the key stakeholders evaluated the need for a new structure to support the entire range of these activities. The interest groups included the Food Processing Suppliers Association (FPSA), the International Association for Food Protection (IAFP), the International Dairy Foods Association (IDFA), the American Dairy Products Institute (ADPI), and the 3-A Symbol Administrative Council. Representatives of the U.S. Department of Agriculture and the U.S. Food and Drug Administration also participated in the discussions of a new organizational structure between 1999 and 2002.

3-A Sanitary Standards, Inc. (3-A SSI) officially began operations in January 2003. Representatives of the three interest groups became vested in the leadership of a new, independent nonprofit organization with a full time professional staff. 3-A SSI is responsible for administration of the 3-A Symbol program, coordination of all consensus documents, education on sanitary design, and other activities.

With the creation of 3-A SSI, a new Third Party Verification (TPV) inspection requirement was implemented as a condition for holding authorization to use the 3-A Symbol. The TPV requirement applies to all equipment built to 3-A Sanitary Standards that is licensed to display the 3-A Symbol. A licensee must engage an inspection/verification professional accredited by 3-A SSI, a Certified Conformance Evaluator (CCE), to conduct an on-site evaluation of finished equipment and other product attributes to affirm the equipment conforms to the provisions of the applicable 3-A Sanitary Standard. Any deficiencies discovered in an inspection/verification must be corrected before the equipment can be authorized to display the 3-A Symbol. Equipment manufacturers that do not comply with the TPV inspection requirement will lose their right to display the 3-A Symbol on their products.

Beginning in 2003, designated groups of equipment became subject to the new inspection requirement each calendar year, based on the number of the specific 3-A Sanitary Standard. As of the end of 2006, the integration was virtually completed. The requirement for a TPV inspection now applies to all types of equipment built to a 3-A Sanitary Standard.

In 2007, 3-A SSI approved a new voluntary 3-A Process Certification for some 3-A Accepted Practices. The 3-A Process Certification is available to owners of systems who desire to show proof of an independent inspection/verification of a processing system.

The TPV program is designed to enhance the integrity of the 3-A SSI programs by affirming that equipment fabricated in accordance to 3-A Sanitary Standards or processing systems are manufactured and installed in accordance to 3-A Accepted Practices. The independent inspection programs of 3-A SSI provide assurance of hygienic equipment design and thereby benefits regulatory sanitarians, equipment fabricators, processors, and consumers.

3-A SSI has established a TPV Coordinating Committee to review and recommend changes in the TPV program. This edition of the 3-A SSI “Manual for Third Party Verification (TPV) for 3-A Symbol Authorization and 3-A Process Certification” has been reviewed by the TPV Coordinating Committee to ensure it is consistent with the mutual objectives of all the stakeholders in 3-A SSI and the shared goal of hygienic equipment design.

Suggestions for improvements to this document and the TPV program should be submitted in writing to:

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TABLE OF CONTENTS

FOREWORD	i
TABLE OF CONTENTS	iii
A INTRODUCTION	v
A1 TPV Program Requirements and Limitations	v
B MANUAL FOR THIRD PARTY VERIFICATION (TPV) FOR 3-A SYMBOL AUTHORIZATION AND 3-A PROCESS CERTIFICATION	1
B1 How to Use This Manual.....	1
B2 3-A Sanitary Standards, Inc.	1
B3 3-A Sanitary Standards and 3-A Accepted Practices	2
B3.1 3-A Sanitary Standards	2
B3.2 3-A Accepted Practices.....	2
B4 3-A Symbol	2
B5 3-A Process Certification	3
B6 3-A Symbol Authorization and 3-A Process Certification Lists	3
B7 Policies of the TPV Program.....	3
B7.1 3-A Symbol Authorizations.....	3
B7.2 Re-certification of TPV Evaluations	5
B7.3 3-A Process Certification	5
B7.4 Used and Remanufactured Equipment.....	7
C TPV INSPECTION REQUIREMENTS FOR 3-A SYMBOL AUTHORIZATION	9
C1 Notice to Applicants.....	9
C2 Format of TPV Report for 3-A Symbol Authorization.....	9
C3 TPV Procedures for 3-A Symbol Authorization.....	13
D TPV FOR 3-A PROCESS CERTIFICATION	16
D1 Notice to Applicants.....	16
D2 Format of TPV Report for 3-A Process Certification.....	16
D2.1 Report Language	16
D2.2 Cover Page	16
D2.3 Verification Checklist Pages	18
D3 TPV Procedures for 3-A Process Certification	20
E TPV REPORT SUBMISSION AND DISPUTE RESOLUTION	24
E1 TPV Report Submission	24
E1.1 TPV Report of Conformance.....	24
E1.2 TPV Report of Nonconformance	24
E1.3 TPV Report Associated with a RAN.....	27
Chart 1: TPV Certification Procedures Flowchart for New Applicants	25
Chart 2: TPV Certification Procedures Flowchart for Renewal Applicants	26
E2 Dispute Resolution	27
E2.1 Interpretation Committee.....	27
E3 Dispute of a TPV Inspection Report	27
E3.1 Applicant's Rights and Procedures	28
E3.2 TPV Dispute Resolution	28
E3.3 3-A SSI Response to a TPV Report Dispute Resolution.....	28
Chart 3: TPV Dispute Review Procedures Flowchart.....	29

E4 Reports of Alleged Nonconformance (RANs)	30
Chart 4: Procedure for Reporting of Alleged Non-conformance.....	33
APPENDIX 1: GLOSSARY OF TERMS.....	34
APPENDIX 2: 3-A SYMBOL AUTHORIZATION AND 3-A PROCESS CERTIFICATION	
APPLICATION FORMS AND RELATED DOCUMENTS.....	38
Exhibit 1, Application and License Agreement for 3-A Sanitary Standards Symbol	39
Exhibit 2, Provisions for the Use and Display of the 3-A Symbol.....	42
Exhibit 3, Promotion Tips for Use and Display of the 3-A Symbol	46
Exhibit 4, Sample Letter: Notice of Renewal for 3-A Symbol Authorization	48
Exhibit 5, Application and Agreement for 3-A Process Certification	50
APPENDIX 3: TPV FORMS AND RELATED DOCUMENTS.....	54
Exhibit 1, Third Party Verification Report for 3-A Symbol Authorization	55
Exhibit 2, Third Party Verification Report for 3-A Process Certification	57
Exhibit 3, Report of Alleged Nonconformance to 3-A Sanitary Standard.....	59
Exhibit 4, Report of Alleged Nonconformance to 3-A Accepted Practice.....	63
APPENDIX 4: ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE	67
APPENDIX 5: 3-A SSI FEE SCHEDULE AND PAYMENT FORM	71
DOCUMENT TRACKING	73

A INTRODUCTION

A1 TPV Program Requirements and Limitations

The authorized appearance of a 3-A Symbol on equipment covered by a 3-A Sanitary Standard or a 3-A Process Certification on a processing system covered by a 3-A Accepted Practice indicates verification by a third party that the equipment or processing system conforms to the applicable 3-A Sanitary Standard or 3-A Accepted Practice. Appearance of the 3-A Symbol or 3-A Process Certification does not represent an endorsement of the equipment or process by 3-A SSI as to its quality, sanitation, or safety. 3-A SSI disclaims all warranties, expressed or implied, with respect to such equipment or process, including warranties of marketability and fitness for use. 3-A SSI also disclaims any and all liability for injury to persons or property, or other damages of any nature, including special, indirect, consequential, compensatory, and punitive damages, directly or indirectly resulting from the performance operation, or the failure to operate, of any equipment or process.

Certified Conformance Evaluator (CCE) status is achieved by satisfying a combination of defined education, experience, and examination requirements. Certification is not an assurance of competence or ability. 3-A SSI disclaims liability for any injury to persons or to property, or other damages of any nature whatsoever, including special, indirect, consequential, compensatory, and punitive damages, directly or indirectly resulting from negligent conduct or other acts or omissions of any individual certified as a CCE.

By issuing the 3-A Symbol or 3-A Process Certification, and by providing for certification of individuals as CCEs, 3-A SSI is not undertaking to render professional or other services for or, on behalf of, any person or entity. 3-A SSI does not undertake to perform any duty owed by any person or entity to someone else. 3-A Sanitary Standards and 3-A Accepted Practices are developed through a consensus development process that brings together individuals representing varied viewpoints and interests to achieve consensus. While 3-A SSI administers the process and establishes rules to promote fairness in the development of consensus, it does not independently test, evaluate, or verify the accuracy of any information or the soundness of any judgments contained in the 3-A Sanitary Standards or 3-A Accepted Practices.

B MANUAL FOR THIRD PARTY VERIFICATION (TPV) FOR 3-A SYMBOL AUTHORIZATION AND 3-A PROCESS CERTIFICATION

B1 How to Use This Manual

- B1.1 All timeframes, limits, response times, etc., referenced in days are to be interpreted as working days and as target times designed for the timely completion of the various aspects of the TPV program.
- B1.2 Any reference to the singular form may be assumed applicable to the plural form. Any reference to the masculine form shall be assumed applicable to the feminine form.
- B1.3 Any reference to a responsible organization, person, or position shall be assumed applicable to any other organization, person, or position to which authority has been duly delegated.
- B1.4 This manual establishes the policies and procedures for equipment suppliers to verify conformance to 3-A Sanitary Standards and to obtain and maintain authorization to use the 3-A Symbol, and for processors to verify conformance to 3-A Accepted Practices and to obtain and maintain use of the 3-A Process Certification (3-A PC). These procedures include requirements for initial and periodic inspections to determine conformance. The manual also contains procedures for submitting nonconformance reports, how they are resolved, and the de-listing method for verified nonconformance reports. Reinstatement procedures are included. These policies and procedures apply to new as well as used and remanufactured equipment.

B2 3-A Sanitary Standards, Inc.

- B2.1 3-A Sanitary Standards, Inc. (3-A SSI) is a not-for-profit 501(c)(3) organization dedicated to protecting public health. 3-A SSI executes its mission by: (a) developing 3-A Sanitary Standards and 3-A Accepted Practices for sanitary equipment design, fabrication and materials of construction; and (b) by providing a TPV program to monitor equipment conformance to individual 3-A Sanitary Standards and E-3-A Sanitary Standards (collectively 3-A Sanitary Standards). 3-A Accepted Practices are not eligible for 3-A Symbol authorization but are authorized to display a 3-A Process Certificate upon a successful TPV evaluation of the process. (Refer to Section D for details and guidance for TPV Process Certification procedures and guidance.)
- B2.2 3-A SSI is responsible for the policies and the general administration of the TPV, 3-A Symbol authorization and 3-A PC programs. The Board of Directors of 3-A SSI may revise at any time the policies and procedures contained in this manual. The Board of Directors also determines the fee structure deemed necessary to support the administration of these programs (Appendix 5). The fee structure is subject to periodic change. Current application forms and fees are maintained on the 3-A SSI web site at www.3-a.org under 'The 3-A Symbol and Third Party Verification', see 'Forms'. Information is also available upon request from the 3-A SSI office.

B3 3-A Sanitary Standards and 3-A Accepted Practices

The acceptance by local, state and federal regulators of 3-A Sanitary Standards and 3-A Accepted Practices which are created through the participation of regulatory control officials, processors (users) and suppliers of equipment and machinery is an advantage to all of the stakeholders. The display of a 3-A Symbol or 3-A PC signifies conformance to 3-A Sanitary Standards or 3-A Accepted Practices.

B3.1 3-A Sanitary Standards

B3.1.1 3-A Sanitary Standards provide sanitary (hygienic) criteria for materials, design, fabrication, cleanability and, if necessary, installation of identified equipment and machinery. 3-A SSI develops documents with the active participation of three stakeholder groups representing regulatory control officials, processors (users) and suppliers of equipment and machinery. Numerous committees representing the three stakeholder groups participate in a voluntary consensus process to develop and maintain 3-A Sanitary Standards. Proposed standards are reviewed by, and must be approved by, the three stakeholder groups.

B3.2 3-A Accepted Practices

B3.2.1 3-A Accepted Practices provide sanitary (hygienic) criteria for materials, design, fabrication, cleanability and installation of identified equipment and machinery to create a defined process. 3-A SSI develops documents with the active participation of the three stakeholder groups representing regulatory control officials, processors (users) and suppliers of equipment and machinery. Numerous committees representing the three stakeholder groups participate in a voluntary consensus process to develop and maintain 3-A Accepted Practices. Proposed 3-A Accepted Practices are reviewed by, and must be approved by, the three stakeholder groups.

B4 3-A Symbol

B4.1 The 3-A Symbol is a registered mark owned and administered by 3-A SSI. Use of the 3-A Symbol is subject to terms and conditions of 3-A SSI.

B4.2 The authorized use (display) of the 3-A Symbol is beneficial to all stakeholder groups. The TPV inspection, required for 3-A Symbol authorization, documents the manufacturer's commitment to conformance to the applicable 3-A Sanitary Standard(s). Use of the 3-A Symbol indicates to regulators and processors that a credible, objective, third party has verified that the equipment conforms to applicable 3-A Standard(s) and will meet applicable regulatory requirements.

B4.3 Equipment and machinery inspected in accordance to requirements of the TPV program and determined to conform to the applicable 3-A Sanitary Standard(s) will be authorized to use the 3-A Symbol.

The companies so authorized, also known as 3-A Symbol licensees, agree to observe all Provisions for the Use and Display of the 3-A Symbol (Appendix 2, Exhibit 2) and all provisions of the License Agreement for Use of the 3-A Symbol

(Appendix 2, Exhibit 1). Rubber and plastic materials meeting 3-A Sanitary Standards 18- or 20- must restrict symbol use to printed materials accompanying the product or other acceptable written uses such as a web site.

B5 3-A Process Certification

- B5.1 Use of the 3-A PC is strictly voluntary. The 3-A PC provides assurance to regulators and buyers that a credible, objective, third party has verified that the processing system conforms to the applicable 3-A Accepted Practice(s). Obtaining a TPV inspection for a 3-A PC documents and reinforces the processor's commitment to conformance to the applicable 3-A Accepted Practice(s). The 3-A PC is beneficial to all 3-A SSI stakeholder groups but particularly to the processors holding the 3-A PC as they will be able to promote their food products as manufactured in a certified process. However, the use (display) of the 3-A PC is site and process-specific and is only available to processors who have installed processes covered by a 3-A Accepted Practice.
- B5.2 The cost assessed for a TPV inspection, required to qualify for a 3-A PC, is based upon a negotiated contract established between a CCE and the applicant for the 3-A PC TPV inspection. 3-A SSI has no role in this contract.
- B5.3 *The 3-A Accepted Practices for the Sanitary Construction, Installation, Testing, and Operation of High-Temperature Short-Time and Higher-Heat Shorter Time Pasteurizer Systems, Number 603-*, is not eligible for TPV inspection and a 3-A PC.
- B5.4 Equipment, machinery, and processes evaluated using the TPV inspection program and determined to conform to the applicable 3-A Accepted Practice(s) will be granted the 3-A PC as evidence of conformance. Equipment and machinery must be authorized to use the 3-A Symbol if a 3-A Sanitary Standard exists for that equipment and machinery. Equipment and machinery which conforms to a 3-A Sanitary Standard but is not authorized to use the 3-A Symbol shall not be eligible for a 3-A PC. Companies, known as certificate holders, will sign a declaration agreeing that the 3-A PC will be used only for processes fully complying with the relevant 3-A Accepted Practice(s) and that the company will observe all other applicable requirements in the display of a 3-A PC (Appendix 2, Exhibit 5).

B6 3-A Symbol Authorization and 3-A Process Certification Lists

- B6.1 The lists of holders of 3-A Symbol authorizations and 3-A PC will be available only on the 3-A SSI web site. The lists can be accessed at no charge from www.3-a.org. The lists will be updated monthly.

B7 Policies of the TPV Program

- B7.1 3-A Symbol Authorizations
 - B7.1.1 General information concerning the operation and requirements of the TPV Program is maintained by 3-A SSI on the organization web site as noted in B2.2.

This general information includes:

- The application form and license agreement used for a new symbol or the renewal or amendment of a current 3-A Symbol authorization (Appendix 2, Exhibit 1).

B7.1.2 New 3-A Symbol Authorizations

B7.1.2.1 Application for a new 3-A Symbol authorization may be made at any time.

B7.1.2.2 Applicants shall observe requirements for the accepted commercial use of the 3-A Symbol in 'Provisions for the Use and Display of the 3-A Symbol' (Appendix 2, Exhibit 2). This also lists the specific documents that must be submitted to 3-A SSI in the application package for a new 3-A Symbol authorization.

To protect the interests of authorized 3-A Symbol licensees and to promote proper display of the 3-A Symbol, 3-A SSI may issue periodic updates on the proper reproduction and commercial use of the 3-A Symbol, such as Use and Display of the 3-A Symbol (Appendix 2, Exhibit 3).

B7.1.2.3 A TPV inspection report is required with the submission of the application for all new 3-A Symbol Authorizations, unless notified otherwise in writing by 3-A SSI.

Upon approval of an application to use the 3-A Symbol, 3-A SSI will issue a numbered certificate of 3-A Symbol Authorization to the applicant. 3-A SSI will also list the name of the licensee on the list of current 3-A Symbol holders.

B7.1.3 3-A Symbol Authorization Renewals

All 3-A Symbol Authorizations are renewable on a calendar year basis (January 1 through December 31). Renewal notices are sent not less than 90 days prior to the start of the license year (Appendix 2, Exhibit 4). The notification packet will contain materials and information necessary to complete the renewal.

Licensees will receive a grace period of fifteen (15) days beyond the renewal due date specified by 3-A SSI. The licensee may request in writing up to fifteen (15) additional days. A late fee will be assessed by 3-A SSI for renewals completed more than fifteen (15) days after the start of the license year. The 3-A Symbol Authorization shall be rescinded if the renewal is not completed within thirty (30) days after the start of the license year.

B7.1.3.1 3-A SSI maintains a record for each licensee showing key contact information, date of original application, a complete list of all equipment included in the 3-A Symbol authorization, and the date of completion of the most recent TPV inspection in accordance with Section C of this Manual, *TPV Inspection Requirements for 3-A Symbol Authorization*. 3-A Symbol licensees must obtain a TPV re-inspection of all equipment included in the 3-A Symbol authorization at a minimum of once every five (5) years as provided in B7.2. 3-A SSI will so notify a licensee when a TPV inspection report is required to assure uninterrupted authorization to use the 3-A Symbol (Appendix 2, Exhibit 4).

B7.1.4 3-A Symbol Authorization Amendments

All 3-A Symbol authorization holders are required to keep their authorization current by submitting an application for amendment when there is a change of sanitary significance in equipment listed in a 3-A Symbol authorization, the addition of new equipment, or for administrative, simple or minor technical changes. Maintaining a relationship with a CCE can facilitate this process.

B7.1.4.1 Changes of sanitary significance are defined as changes in design, fabrication, or materials of construction that affect the hygienic or operational characteristics of the equipment or require independent evaluation to ensure continued conformance to applicable 3-A Sanitary Standards. To make an amendment to a 3-A Symbol authorization due to a change of sanitary significance, submit the application for amendment and amendment fee to 3-A SSI, along with a TPV inspection report to verify the modifications meet the current 3-A Sanitary Standard's criteria. The TPV inspection report shall be at least a signed TPV Report cover page, with additional pages as necessary or a complete TPV inspection in accordance with Section C of this Manual, *TPV Inspection Requirements for 3-A Symbol Authorization*.

B7.1.4.2 When an amendment is for the addition of a size variation (serial design) of a previously authorized design or other change which is not of sanitary significance, an accompanying TPV inspection report is not required. However, a CCE should be requested to review the changes to assure that the modification results in continued conformance to the 3-A Sanitary Standard. The 3-A Symbol holder shall submit the application for amendment and amendment fee to 3-A SSI. Submission of the TPV inspection report is optional.

B7.1.4.3 If an amendment of a 3-A Symbol authorization has not been submitted and a non-conformance is determined by a subsequent TPV inspection or a substantiated Report of Alleged Nonconformance (RAN), the applicant shall be required to notify all purchasers of record of the equipment since the last recorded documentation of conformance of the non-conformance issue(s) and arrange for repairs or upgrades to bring the equipment into conformance.

B7.1.4.4 A TPV inspection report submitted in support of a 3-A Symbol authorization amendment may be limited in nature as described in Section C3.5.1 and specific to the equipment described in the application or product information shown on a current 3-A symbol authorization. If so, the TPV inspection report submitted in support of an amendment shall not re-set the 3-A Symbol holder's official date of completion of the most recent TPV inspection as defined in Section B7.1.3.1.

B7.2 Re-certification of TPV Evaluations

B7.2.1 An on-site TPV re-inspection shall be performed at least every five (5) years from the date of the previous on-site inspection that encompasses all equipment included in the 3-A Symbol authorization.

B7.2.1.1 The most recently dated complete TPV inspection report may be from a new authorization application, an authorization renewal application, an authorization amendment application, or a Report of Alleged Nonconformance (RAN) resolution, which affirms the conformance of all equipment covered by the authorization. The TPV report must include an on-site visit and be signed and dated by an authorized CCE. **NOTE:** 3-A Symbol licensees are strongly encouraged to use the available authorization amendment procedures to keep their authorizations as current as possible.

B7.2.1.2 A fabricator of large or custom made equipment may not have a finished item of equipment available at the time of the five-year re-certification. In such case, the CCE may complete the TPV without viewing the actual equipment through a thorough review of drawings, materials certifications, and quality control programs to assure that a system is in place to continue making equipment in conformance with the corresponding standard(s). For equipment that may support multiple options or appurtenances, all of these options or appurtenances shall be evaluated to be included as part of the re-certification. These requirements shall be verified by a site visit.

B7.3 3-A Process Certification

B7.3.1 The 3-A PC shall apply to a single processing system which is covered by a 3-A Accepted Practice and eligible for 3-A PC at a specific site.

B7.3.2 General information concerning the operation and requirements of the 3-A PC Program is maintained by 3-A SSI on the organization web site as noted in B2.2.

This general information includes:

- The application form used for a new certification or the renewal or amendment of a current 3-A PC and 3-A PC Program Agreement (Appendix 2, Exhibit 5).

B7.3.3 New 3-A Process Certification

B7.3.3.1 Application for a new 3-A PC may be made at any time. The application package shall include the following:

- A copy of the completed application form and signed Agreement,
- The Table of Contents of the Engineering Design and Technical Construction File (EDTCF), including reference to (Appendix 4); List of Engineering Drawing Numbers; Materials Certifications (Plastics, Rubbers, Adhesives, Undocumented Metal Alloys, etc.),
- A copy of the TPV inspection report, and
- Payment to 3-A SSI.

B7.3.4 3-A Process Certification Renewals

B7.3.4.1 All 3-A PC certificates are renewable on an anniversary basis. Renewal notices are sent not less than 90 days prior to the start of the license year. The notification will contain materials and information necessary to obtain the renewal. The renewal of a

3-A PC requires the submission of all items listed in the application package as shown in B7.3.3.1. Applicants shall submit the renewal package prior to the anniversary date of their certificate(s).

B7.3.4.2 If the 3-A PC holder's renewal application is not received by 3-A SSI within at least ten (10) days of the anniversary date, it is the holder's responsibility to determine the status of the materials. A grace period of fifteen (15) days will be automatically granted. The licensee may request in writing up to fifteen (15) additional days. A late fee will be assessed by 3-A SSI for renewals completed more than fifteen (15) days after the start of the certificate. The 3-A PC shall be rescinded if the renewal is not completed within thirty (30) days after the start of the certificate year.

B7.3.4.3 For all certificates, 3-A SSI shall respond within ten (10) days. If the certificate is denied, thirty (30) days are granted to resolve any non-conformance issues. If non-conformance issues are unresolved, the 3-A PC will be rescinded.

B7.3.4.4 The application form and materials may be transmitted electronically or hard copy.

B7.3.5 3-A Process Certification Amendments

B7.3.5.1 All 3-A PC holders are encouraged to keep their certification current by submitting amendments for changes in design, fabrication, materials of construction, or steps in the process. Amendments to a 3-A PC may be made by submitting the application for amendment and amendment fee to 3-A SSI. The 3-A PC holder may choose to submit a TPV inspection report to verify that modifications meet the current 3-A Accepted Practices criteria.

B7.3.5.2 If an amendment on a 3-A PC has not been submitted and a non-conformance is determined by a TPV inspection as provided in Section E1.2, the applicant shall immediately discontinue promoting, in any manner, that their process is certified by 3-A SSI and make reasonable attempts to contact all customers regarding the loss of 3-A PC. To qualify for reinstatement of their 3-A PC, the applicant shall immediately arrange to make the necessary corrections to achieve conformance to the covering 3-A Sanitary Standards and 3-A Accepted Practices.

B7.4 Used and Remanufactured Equipment

B7.4.1 These policies establish procedures for monitoring the continued conformance of used or remanufactured equipment and machines bearing the 3-A Symbol.

B7.4.2 As new or revised 3-A Sanitary Standards become effective, in-service equipment may continue to display the 3-A Symbol as authorized using the 3-A Sanitary Standards in effect at the time of the original authorization and installation, provided that the equipment is not in violation of any policy of the authorized inspection or regulatory agency having jurisdiction. Any substantial modifications to the equipment will require that it meet the most current and applicable 3-A Sanitary Standard(s). Substantial modifications do not include routine repair and maintenance.

B7.4.3 3-A Symbol Authorization is initially granted to original equipment manufacturers.

Remanufacturers may apply for 3-A Symbol Authorization covered under a specific 3-A Sanitary Standard for such equipment prior to sale.

- B7.4.3.1 Used equipment and machinery remanufacturers may submit to 3-A SSI a proposal to be granted the authority to display a 3-A Symbol Authorization on specific models and types of equipment. The authority will include all requirements specified for the TPV program including periodic evaluations by CCEs.
- B7.4.4 The 3-A Symbol Authorization shall be deemed void upon any modification to the equipment bearing a 3-A Symbol, which renders or may cause the item to no longer meet the criteria of the most current and applicable 3-A Sanitary Standard(s).
- B7.4.5 All parties engaged in the purchase of used equipment or replacement parts are encouraged to determine if the equipment or parts intended for purchase conforms to the criteria of the current, appropriate 3-A Sanitary Standard(s). One indication of conformance of replacement parts is participation by the supplier of those parts in the *3-A SSI Replacement Part Qualification Certificate Program*. When discrepancies are observed with the 3-A Sanitary Standard's criteria, a RAN may be completed and sent to 3-A SSI for further investigation.
- B7.4.6 When 3-A SSI receives a RAN for a piece of used, remanufactured, or transferred equipment or machinery, 3-A SSI shall follow the procedures cited in Section E4.

C TPV INSPECTION REQUIREMENTS FOR 3-A SYMBOL AUTHORIZATION

Note: This Section applies only to TPV inspections for 3-A Symbol authorization. For information on TPV inspections related to 3-A PC, refer to Section D.

C1 Notice to Applicants

- C1.1 3-A SSI shall send notice to 3-A Symbol licensees when TPV certification is required as provided in B7.1.2.

C2 Format of TPV Report for 3-A Symbol Authorization

TPV reports shall follow a standard format to assure uniformity and provide for ease of monitoring. The report shall consist of the cover page identifying the applicant, equipment evaluated, type of verification, declaration of findings, and the CCE's signature, and the initialed 3-A Sanitary Standard used as the checklist, and supplemental pages to document the verification (Appendix 3, Exhibit 1). Additional pages may be included to record other observations as appropriate.

C2.1 Report Language

- C2.1.1 TPV reports shall be prepared using Standard English and typed.

C2.2 Cover Page

Each cover page and supporting page(s) shall refer to only one (1) evaluation. If a TPV inspection encompasses multiple equipment or machinery type(s) which are maintained under different 3-A Sanitary Standards, a separate TPV report shall be prepared for each separate authorization.

- C2.2.1 The CCE shall complete all of the information blocks on the TPV report cover page. If information is not available, such as the applicant has not assigned a serial number to the equipment, please use the phrase "Not Applicable."
- C2.2.2 Applicant: Record the applicant's complete name and mailing address.
- C2.2.3 Verification Location: Record the location address where the verification was conducted. If the verification is conducted at the same location as the applicant's address, please use the phrase "Same as Applicant."
- C2.2.4 Date: The TPV Cover Page has spaces for two dates. The "TPV Inspection Date" is the date(s) during which the physical or drawings review and the site visit were conducted. The "Report Completion Date" is the date upon which all final information has been evaluated and the CCE considers the evaluation completed. Record these date(s) in the appropriate spaces. When the final TPV report is filed with 3-A SSI, the "Date of Report Completion" becomes the anniversary date used to determine future TPV re-certification.
- C2.2.5 CCE: The CCE shall record his/her name.

- C2.2.6 Equipment or Machinery Type: Record a generic description of the equipment verified such as “Compression Valve” or “Fluid Milk Filler.”
- C2.2.7 Model Number: Record the model number(s) of the equipment verified.
- C2.2.8 Serial Number: Record the serial number(s), if applicable, of the equipment verified.
- C2.2.9 3-A Sanitary Standard: Record the number and effective date of the covering 3-A Sanitary Standard used for the verification.
- C2.2.10 Applicant/Verification Contact: Record the name and telephone number of the applicant contact who can respond to inquiries pertaining to the verification or who should be provided a copy of the final completed report. A fax number or e-mail address may also be included.
- C2.2.11 3-A Symbol Authorization Number: Record the 3-A Symbol Authorization number from the applicant’s current 3-A Symbol Authorization certificate. For a new 3-A Symbol Authorization, a number will be assigned by 3-A SSI.
- C2.2.12 Type of Verification: Place an “X” in the appropriate box.
- C2.2.13 Declaration of Findings: Upon completion of the verification, indicate whether the equipment verified was in conformance or non-conformance by placing an “X” in the appropriate box.
 - C2.2.13.1 To mark the “In Conformance” box, there shall not be any “X” marks on the 3-A Sanitary Standard used as the checklist as provided in C2.3.2.1. If any provisions of the 3-A Sanitary Standard used for the TPV inspection are checked with an “X,” the “Non-conformance” box shall be marked.
 - C2.2.13.2 When the “Non-conformance” box is marked, additional statements specifically describing which criteria from the 3-A Sanitary Standard were not in conformance shall be included in the “Observations and Findings” column or on an attached page.
- C2.2.14 Observations and Findings: This section is to provide a summary of the non-conformance items observed. The following are examples of objective statements of non-conformance.

Examples of statements used in a TPV inspection conducted under *3-A Sanitary Standard #53-03, Compression-Type Valves for Milk and Milk Products*:

D2.1 The valve body could not be readily disassembled; it was held in place by 6 bolts.

D4.1 There was no radius at the juncture of the valve stem to the gasket plate; 1/16 in. is required.

D7.7 The power actuator was bolted flush with the valve body and did not provide any clearance.

D7.8 The power actuator could not be removed from the valve stem.

- C2.2.15 CCE Signature: The CCE must sign the report in order for it to be considered official.
- C2.2.16 When 3-A SSI receives the typed report, the following information shall be added to the form.
 - C2.2.16.1 Date Received: Record the date received by 3-A SSI.
 - C2.2.16.2 Received By: Record the name of the individual who received the TPV Report.
 - C2.2.16.3 Verification Number: 3-A SSI shall assign a unique verification number to facilitate tracking and filing of all verification reports.

C2.3 Verification Checklist Pages

- C2.3.1 The CCE shall use a full copy of the 3-A Sanitary Standard identified on the cover page as the base standard for the inspection. A copy of the marked up standard used by the CCE as the inspection checklist may be provided to the prospective licensee as part of the TPV inspection report. Due to copyright restrictions, neither the CCE nor the prospective licensee shall copy or further distribute any 3-A Sanitary Standard except as described in this section.
- C2.3.2 Each criteria paragraph in the Reference, Materials, Fabrication, and referenced required Appendix sections shall be initialed by the CCE to indicate that the criteria has been evaluated and is in conformance.

Example of section initialed by the CCE to indicate conformance:

D7 Sanitary Metal Tubing

D7.1 Metal tubing with a continuous circular cross-section shall conform to the 3-A Sanitary Standards for Polished Metal Tubing, Number 33-, except that: *FTS*

- C2.3.2.1 If the evaluation indicates the equipment is in nonconformance with the criteria, the paragraph shall be initialed and indicated by an "X".

Example of section initialed by the CCE to indicate nonconformance:

D7 Sanitary Metal Tubing

D7.1 Metal tubing with a continuous circular cross-section shall conform to the 3-A Sanitary Standards for Polished Metal Tubing, Number 33-, except that: *FTS*
X

C2.3.2.2 If the evaluation indicates the paragraph is not applicable; it shall be initialed and indicated by an "N/A."

Example of section initialed by the CCE to indicate not applicable:

D4.3 Product contact surface not designed to be mechanically cleaned shall be easily accessible for manual cleaning and inspection either when in an installed position or when removed. Demountable parts shall be readily removable.

FTS
N/A

C2.3.3 As appropriate, any comments or explanatory notes shall be made on a "Supplemental Information Page." The comments or notes shall reference the specific provision (Section and paragraph number) of the 3-A Sanitary Standard to which the comment refers and clearly document the observed non-conformance. When a paragraph presents more than one criteria, the CCE shall assure that all of the criteria are evaluated and appropriate comments recorded.

Examples of comments entered as Supplemental Information in a TPV inspection conducted under *3-A Sanitary Standard #53-03, Compression-Type Valves for Milk and Milk Products*:

C2.2 The certification of the rubber gasket material could not be documented.

D2.1 The valve body could not be readily disassembled.

D4.1 There was no radius at the juncture of the valve stem to the gasket plate.

D7.7 The power actuator was bolted flush with the valve body and did not provide any clearance.

D7.8 The power actuator could not be removed from the valve stem.

C2.3.4 The CCE shall determine prior to beginning the TPV inspection whether the prospective licensee has designed the equipment to clean by CIP or manual methods. On the copy of the 3-A Sanitary Standard used as the base standard for the inspection, the appropriate cleanability paragraph is to be indicated by a large asterisk*.

Example of large asterisk * used to indicate method of cleaning.

D4.2.1 A tubular heat exchanger that is one or more continuous coiled tubes without profile modifications, and that is to be CIP cleaned, shall have representative product contact surfaces easily accessible for inspection. Access to the

FTS
*

product inlet and outlet heat exchange surfaces shall be considered to meet these inspection requirements.

D4.3 Product contact surfaces not designed to be mechanically cleaned shall be easily accessible for manual cleaning and inspection either when in an installed position or when removed. Demountable parts shall be readily removable.

C3 TPV Procedures for 3-A Symbol Authorization

- C3.1 The TPV inspection is performed under an agreement between the CCE and the applicant. All fees and expenses for the TPV inspection are to be established between the two parties.
- C3.2 The CCE shall use his/her knowledge and experience to conduct a detailed physical evaluation of the equipment, engineering drawings, and documentation associated with the equipment to be verified for conformance to the 3-A Sanitary Standard(s). This may include general assembly drawings and drawings of individual equipment components and sub-assemblies. The CCE shall conduct the verification at a pace to assure all components are carefully evaluated against the 3-A Sanitary Standard's criteria. If the equipment offered for evaluation can be configured using multiple optional components or accessories, all of the optional features must be presented for evaluation. The CCE shall be diligent in asking sufficient questions to determine such items as the identification of all materials of construction, options, or add-on features offered with the equipment, methods of fabrication, etc. are in conformance to the 3-A Sanitary Standard. The CCE shall request and review all certifications for components fabricated from rubber or rubber-like materials, plastic materials, adhesives, or metal alloys not identified by the applicable 3-A Sanitary Standard(s). Throughout the evaluation, the CCE shall exercise critical observation/critical analysis (as in careful judgment and scholarly recommendations) at all times.
- C3.3 When the inspection is to evaluate a series of equipment, which is of an identical design except for scaling up or down in size, only one set of drawings representative of the basic design needs to be evaluated.
- C3.4 The CCE is to verify that the applicant has a written quality control procedure with documentation to assure conformance to the 3-A Sanitary Standards.
- C3.5 The CCE shall perform an on-site evaluation at the 3-A Symbol applicant's manufacturing/fabrication or assembly location where the complete, assembled item identified for 3-A Symbol Authorization is available, except that;
- C3.5.1 A site visit may not be required for Symbol Authorization amendment or renewal applications. Administrative, simple or minor technical changes can be documented without a site visit by sending the CCE copies of the appropriate materials certifications, change drawings and samples of the modified unit or component for

review. A site visit will be appropriate when the change(s) are greater and more complex.

C3.5.2 When deemed necessary by the CCE conducting a TPV inspection, an additional on-site evaluation shall be performed at the equipment installation location of the applicant's choice to evaluate a fully assembled equipment installation for items being evaluated for conformance to the following 3-A Sanitary Standards:

- 16- Evaporators
- 22- Silo Tanks
- 39- Pneumatic Conveyors
- 40- Bag Collectors

C3.6 The following standards items require an explanatory comment on a "Supplemental Information Page" (Refer to Appendix 3, Exhibit 1) when the criteria are applicable. As necessary, additional pages are to be added in order to clearly describe the observations.

C3.6.1 A. Scope

C3.6.2 Metals

C3.6.2.1 Cast CF-16F, CF-8 or CF-8m. If used, record the component and the cast grade.

C3.6.2.2 Other recognized 3-A Alloy. If used, record the component and the alloy.

C3.6.2.3 Alloy equivalent to above. If a non-listed alloy is used, record the alloy used, the component(s) fabricated from the alloy, and the certification of equivalency documentation.

C3.6.2.4 Gold or Silver Solder. If used, record the type of solder, and that the certification of conformance (silver solder only) is available.

C3.6.3 Nonmetals

C3.6.3.1 Rubber 3-A 18- compliant. If rubber or rubber-like materials are used, record the materials used, and that the certification documentation is available.

C3.6.3.2 Plastic 3-A 20- compliant. If plastics are used, record the plastics used and that the certification documentation is available.

C3.6.3.3 Adhesives meets 21 CFR 175. If adhesives are used, record the adhesive(s) used, and that the documentation of 21 CFR 175 conformance is available.

C3.6.4 Fabrication

C3.6.4.1 Adhesives meets 21 CFR 175. If an adhesive is used, add the statement "Refer to Materials paragraph ____."

C3.6.4.2 Agitators (meets criteria). Record the type of agitator(s) provided, e.g., top mounted, side mounted, bottom mounted, etc.

- C3.6.4.3 Record the type(s) of support(s) provided, e.g., legs, slab mounted, wall mounted, hanging mount, etc. "Refer to line 88."
- C3.6.4.4 Appurtenances meet referenced 3-A Sanitary Standards. Record each non-conforming appurtenance on a separate line. Identify the specific appurtenance and the corresponding covering 3-A Sanitary Standard. If there are any non-conforming observations, they are to be clearly documented that the appurtenances do not conform to 3-A Sanitary Standards.
- C3.6.4.5 Engineering Design and Technical Construction File (EDTCF) (Appendix 4). This information, which may be assembled from multiple sources, is to be used by the CCE as a primary source of verification details. Since each EDTCF is unique to the equipment type manufactured, the amount and types of information present will vary widely. The CCE shall review the EDTCF carefully, and utilizing his/her expertise, determines if the file is complete. In order to mark this item with an "X" in the "Yes" column at least the following sections, as listed in the 3-A Sanitary Standards Format and Style Manual document, shall be present in the EDTCF:
- C3.6.4.5.1 Other documentation:
- a. An overall drawing of the subject equipment;
 - b. Full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment to the 3-A Standards or 3-A Accepted Practices;
 - c. If essential, any technical report or certificate obtained from a competent testing body or laboratory. (The following examples are not intended to be an all-inclusive list: plastic certification, rubber certification, adhesive certification, air filter certification, etc.);
 - d. A copy of the instructions for the product (Instruction Manuals/Instruction Books);
 - e. For serial manufacturing, the internal measures that will be implemented to ensure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Sanitary Standards;
 - f. Bills of material;
 - g. Purchase order engineering files documenting modifications to the design; and
 - h. Change records.

D TPV FOR 3-A PROCESS CERTIFICATION

D1 Notice to Applicants

D1.1 3-A SSI shall notify authorized 3-A PC holders prior to their certificate renewal dates with appropriate notification materials. Notification letters will be sent at least ninety (90) days prior to the anniversary renewal date. The notification packet will contain materials and information necessary to obtain the renewal.

D2 Format of TPV Report for 3-A Process Certification

TPV reports shall follow a standard format to assure uniformity and provide for ease of monitoring. The report shall consist of a cover page identifying the applicant, process evaluated, type of verification, declaration of findings, the CCE's signature, and the initialed 3-A Accepted Practice used as the checklist, and supplemental pages to document the verification (Appendix 3, Exhibit 2). Additional pages are to be included for recording observations as necessary.

D2.1 Report Language

D2.1.1 TPV reports shall be prepared using Standard English and typed.

D2.2 Cover Page

Each cover page and support page(s) shall refer to one identified specific evaluation. If a TPV inspection is for multiple processes encompassed under different 3-A Accepted Practices, a separate TPV inspection report shall be prepared for each separate process.

D2.2.1 The CCE shall complete all of the information blocks on the TPV Report cover page. If information is not available, such as the applicant has not assigned a serial number to the equipment, please use the phrase "Not Applicable."

D2.2.2 Applicant: Record the applicant's (Processor's) complete name and mailing address.

D2.2.3 Verification Location: Record the location address where the verification was performed. If the verification is performed at the same location as the applicant's address, use the phrase "Same as Applicant."

D2.2.4 Date: The TPV Cover Page has space for two dates. The "TPV Inspection Date" is the date(s) during which the physical or drawings review and the site visit were conducted. The "Report Completion Date" is the date upon which all final information has been evaluated and the CCE considers the evaluation completed. Record these date(s) in the appropriate spaces. When the final TPV report is filed with 3-A SSI, the "Date of Report Completion" becomes the anniversary date used to determine future TPV re-certification.

D2.2.5 CCE: The CCE shall record his/her name.

- D2.2.6 Process Evaluated: Record a generic description of the equipment/process verified such as, “Culinary Steam System” or “Filtermat Drier System.”
- D2.2.7 3-A Accepted Practice: Record the number and effective date of the covering 3-A Accepted Practice used for the verification.
- D2.2.8 Applicant/Verification Contact: Record the name and telephone number of the applicant contact who can respond to inquiries pertaining to the verification or who should be provided a copy of the final completed report. A fax number or e-mail address may also be included.
- D2.2.9 3-A Process Certification Number: Record the 3-A PC number from the applicant’s current certificate. For a new 3-A PC, a certificate number will be assigned by 3-A SSI.
- D2.2.10 Type of Verification: Place an “X” in the appropriate box.
- D2.2.11 Declaration of Findings: Upon completion of the inspection, indicate whether the equipment was in conformance or non-conformance by placing an “X” in the appropriate box.
- D2.2.11.1 To mark the “In Conformance” box, there shall not be any “X” marks on the 3-A Accepted Practice used as the checklist. If any items are checked, the “Non-conformance” box shall be marked.
- D2.2.11.2 When the “Non-conformance” box is marked, additional statements specifically describing which criteria from the base 3-A Accepted Practice were not in conformance must be included in the “Observations and Findings” column or on an attached page.
- D2.2.12 Observations and Findings: This section is to provide a summary of specific non-conformance items observed. The following are examples of statements of non-conformance:
- Examples of specific statements of non-conformance using the base document 3-A Accepted Practice Number 607-05, *Spray Drying Systems for Milk and Milk Products*:
- C1.3.1 The certification of the rubber gasket material could not be documented.
- D4.2 The lap weld was not properly installed downward, which created a ledge that can retain product residues.
- D7.1 There was a shadow area in the primary collector cyclone which was not being cleaned.
- E5.4 A self-closing exhaust stack cover was not present.
- D2.2.13 CCE Signature: The CCE must sign the report in order for it to be official.

D2.2.14 When 3-A SSI receives the typed report, the following information shall be added to the form.

D2.2.14.1 Date Received: Record the date received by 3-A SSI.

D2.2.14.2 Received By: Record the name of the individual who received the TPV Report at 3-A SSI.

D2.2.14.3 Verification Number: 3-A SSI shall assign a unique verification number to facilitate the tracking and filing of all verification reports.

D2.3 Verification Checklist Pages

D2.3.1 The CCE shall use a full copy of the 3-A Accepted Practice identified on the cover page as the base document for the inspection. A copy of the marked up 3-A Accepted Practice used by the CCE as the inspection checklist may be provided to the prospective licensee as part of the TPV inspection report. Due to copyright restrictions, neither the CCE nor the prospective licensee shall copy or further distribute any 3-A Accepted Practice except as described in this section.

D2.3.2 Each criteria paragraph in the Reference, Materials, Fabrication, Installation, and referenced required Appendix sections shall be initialed by the CCE to indicate that the criteria has been evaluated and is in conformance.

Example of section initialed by the CCE to indicate conformance:

D2 Surface Texture

D2.1 Product contact surfaces and processing air contact surfaces (for air not to be heated) shall have a finish at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form (see Appendix Section G.), except that:

FTS

D2.3.2.1 If the evaluation indicates the equipment is in nonconformance with the criteria, the paragraph shall be initialed and indicated by an "X."

Example of section initialed by the CCE to indicate nonconformance:

D2 Surface Texture

D2.1 Product contact surfaces and processing air contact surfaces (for air not to be heated) shall have a finish at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form (see Appendix Section G.), except that:

FTS
X

- D2.3.2.2 If the evaluation indicates the paragraph is not applicable; it shall be initialed and indicated by an “**N/A.**”

Example of section initialed by the CCE to indicate not applicable:

D8.2.1.1 A pressure-sensing device shall be provided to detect rupture or air leakage from hollow tubular gaskets used as inflatable seals. FTS
N/A

- D2.3.3 As appropriate, any comments or explanatory notes shall be made on a “Supplemental Information Page”. The comments or notes shall be identified as to which criteria paragraph number the comment refers and clearly document the observed non-conformance. When a paragraph presents more than one criteria, the CCE shall assure that all of the criteria are evaluated and appropriate comments recorded.

Examples of comments entered as Supplemental Information in a TPV inspection conducted under the base document *3-A Sanitary Standard #53-03, Compression-Type Valves for Milk and Milk Products*:

D2.2 The certification of the rubber gasket material could not be documented.

D2.1 The valve body could not be readily disassembled.

D4.1 There was no radius at the juncture of the valve stem to the gasket plate.

D7.7 The power actuator was bolted flush with the valve body and did not provide any clearance.

D7.8 The power actuator could not be removed from the valve stem.

- D2.3.4 The CCE shall determine prior to beginning the TPV inspection whether the Fabricator has designed the equipment to clean by CIP or manual methods. On the copy of the 3-A Accepted Practice used as the verification pages, the appropriate cleanability paragraph is to be indicated by a large asterisk *.

Example of large asterisk * used to indicate method of cleaning:

D7.1 Spray dryer components that are to be mechanically cleaned shall be designed so that the product contact surfaces of the components and all nonremoved appurtenances thereto can be mechanically cleaned and are readily accessible and inspectable, except that: FTS
*

D3 TPV Procedures for 3-A Process Certification

- D3.1 The TPV 3-A PC is performed under an agreement between the CCE and the applicant. All fees and expenses for the verification are to be established between these two parties.
- D3.2 The TPV conformance inspection using a 3-A Accepted Practice for a 3-A PC is to be conducted on the basis of a detailed physical evaluation of the operation of a processing facility operating under the particular 3-A Accepted Practice(s) for which the applicant has requested a 3-A PC. The TPV inspection shall confirm that all details of the 3-A Accepted Practice are in conformance. Items to be evaluated could include, but are not limited to: company policy manuals, plant operation manuals, processing records, equipment and facility cleaning records, employee training records, employee interviews, regulatory inspection records, and third party auditing records.
- D3.3 The CCE shall conduct the verification at a pace to assure all components and processing options utilized by the applicant are carefully evaluated against the appropriate criteria of the 3-A Accepted Practice. If the process offered for evaluation can be configured using multiple optional components or accessories, all of the optional features must be presented for evaluation. The CCE shall be diligent in asking pertinent questions to determine such items as the identification of all materials of construction, options, or add-on features that are a part of the process, methods of manufacturing, maintenance, etc. are in conformance to the 3-A Accepted Practice(s). Throughout the evaluation, the CCE shall exercise critical observational/critical analysis techniques (using careful judgment and scholarly recommendations) at all times.
- D3.4 The CCE shall use his/her knowledge and experience to conduct a detailed physical evaluation of the process equipment and a review of all processing documents, engineering drawings and documentation associated with the process to be verified. This may include: make sheets, daily production logs, testing results, and other pertinent production records, general equipment assembly drawings, piping and ducting, drawings of individual equipment components, and other pertinent documents and information.
- D3.4.1 All processing equipment included in the 3-A PC that is addressed in a 3-A Sanitary Standard(s) shall be covered by a 3-A Symbol authorization.
- D3.5 The CCE shall request and review all certifications for components fabricated from rubber or rubber-like materials, plastic materials, adhesives, or metal alloys not identified by the applicable 3-A Standard and/or 3-A Accepted Practice.
- D3.6 The TPV process inspection is site- and process-specific and applicable to only that location as provided in B7.3.1.1. The CCE shall perform the evaluation on-site at the applicant's manufacturing location where the complete, assembled process for the 3-A PC is available.
- D3.7 The CCE shall verify that the processing plant location has an appropriately written and implemented quality control and process control procedure with adequate

documentation to assure conformance to the 3-A Sanitary Standard(s) and/or 3-A Accepted Practice(s).

D3.8 The following checklist items, identified in this Section, also require an explanatory comment when the line item is applicable. As necessary, additional pages are to be added in order to clearly describe the observations.

D3.8.1 Scope

D3.8.1.1 Clearly describe the process under evaluation and verify that all of the associated equipment is included in the scope.

D3.8.1.2 List all associated equipment that is covered by a 3-A Sanitary Standard(s) and displays the 3-A Symbol. Any further TPV evaluation is not required on these components unless a significant non-conformance issue is observed. In such case, a RAN report shall be issued for the non-conforming equipment.

D3.8.1.3 List all associated equipment that is not covered by a 3-A Sanitary Standard(s). These components shall require a full evaluation according to the criteria and hygienic principles addressed in the 3-A Sanitary Standard(s) or, if there are not 3-A Sanitary Standard(s) applicable, according to the criteria within the covering 3-A Accepted Practice.

D3.8.2 The 3-A Accepted Practice copy shall be used as the checklist is to evaluate the process as well as equipment and machinery that is not covered by a 3-A Sanitary Standard and the installation criteria for the entire process. The following criteria paragraphs may require additional comment or explanation when applicable.

D3.8.3 Metals

D3.8.3.1 Cast CF-16F, CF-8 or CF-8m. If used, record the component and the cast grade.

D3.8.3.2 Aluminum Alloys. If used, record the component and grade.

D3.8.3.3 Other recognized 3-A Alloy. If used, record the component and the alloy.

D3.8.3.4 Alloy equivalent to above. If a non-listed alloy is used, record the alloy used, the component(s) fabricated from the alloy, and the certification of equivalency documentation.

D3.8.3.5 Gold or Silver Solder. If used, record the type of solder, where the solder is used, and that the certification of conformance (silver solder only) is available.

D3.8.4 Nonmetals

D3.8.4.1 Rubber 3-A 18- compliant. If rubber or rubber-like materials are used, record the materials used, and that the certification documentation is available.

D3.8.4.2 Plastic 3-A 20- compliant. If plastics are used, record the plastics used and that the certification documentation is available.

- D3.8.4.3 Adhesives meets 21 CFR 175. If adhesives are used, record the adhesive(s) used, and that the documentation of 21 CFR 175 conformance is available.
- D3.8.4.4 Record the location of rubber or plastic used for special applications.
- D3.8.4.5 Cotton, wool, linen, silk, synthetic fibers, laminates, etc. If used, record the type of material and where the material is used.
- D3.8.4.6 Filter materials: If used, record the type of material, where the material is used, and that the certification of conformance to filter efficiency criteria is available and conforms to the 3-A Accepted Practice requirements.
- D3.8.4.7 Glass: If used, record the type of glass, where the glass is used, and that the certification of conformance (heat resistance) is available; and the uses are within the 3-A Accepted Practice limitations.
- D3.8.5 Fabrication
 - D3.8.5.1 Lap joints: If used, record where the technique is used, and the use is within the limitations of the 3-A Accepted Practice.
 - D3.8.5.2 Press or shrink fits: If used, record where the technique is used, and the use is within the limitations of the 3-A Accepted Practice.
 - D3.8.5.3 Adhesives meets 21 CFR 175. If an adhesive is used, add the statement "Refer to Line 18."
 - D3.8.5.4 Coatings. If used, record where the technique is used, and the use is within the limitations of the 3-A Accepted Practice.
 - D3.8.5.5 Cleaning and inspectability. Processes may include multiple components that are subjected to a variety of cleaning methods. Evaluate and record which components are Clean-in Place (CIP) cleaned, manually cleaned, or dry cleaned.
 - D3.8.5.6 Record which parts of the process are self-draining or drainable and if they conform to the limitations of the 3-A Accepted Practice.
 - D3.8.5.7 Foam or hollow gaskets: If used, record where the gasket types are used, and the uses are within the limitations of the 3-A Accepted Practice.
 - D3.8.5.8 Perforations/Screens. If used, record where the materials are used, and the use is within the limitations of the 3-A Accepted Practice.
 - D3.8.5.9 Record the type(s) of support(s) provided, e.g., legs, slab mounted, wall mounted, hanging mount, etc.

D3.8.5.10 Engineering Design and Technical Construction File (EDTCF) (Appendix 4). This information, which may be assembled from multiple sources, is to be used by the CCE as a primary source of verification details. Since each EDTCF is unique to the equipment type manufactured, the amount and types of information present will vary widely. The CCE shall review the EDTCF carefully, and utilizing his/her expertise, determines if the file is complete. In order to mark this item as in conformance at least the following sections, as listed in the 3-A Sanitary Standards Format and Style Manual, shall be present in the EDTCF:

D3.8.5.11 Other documentation:

- a. An overall drawing of the subject process;
- b. Detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment to the 3-A Standards or 3-A Accepted Practices;
- c. Any technical report or certificate obtained from a competent testing body or laboratory. (The following examples are not intended to be an all-inclusive list: plastic certification, rubber certification, adhesive certification, air filter certification, etc.);
- d. A copy of the instructions for the product (Instruction Manuals/Instruction Books);
- e. Bills of material;
- f. Purchase order engineering files documenting modifications to the design; and
- g. Change records.

E TPV REPORT SUBMISSION AND DISPUTE RESOLUTION

E1 TPV Report Submission

Upon completion of the TPV inspection, the CCE shall provide both the applicant and 3-A SSI with one signed original final report. The copy sent to 3-A SSI is to be accompanied with a cover letter or e-mail explaining the nature of the submission. The CCE is encouraged to retain one copy and any notes taken during the evaluation.

E1.1 TPV Report of Conformance

E1.1.1 When the final TPV inspection report indicates there are no non-conformance issues, a copy of the final TPV report is provided to the applicant for submission to 3-A SSI. Additionally, the CCE shall send an information copy to 3-A SSI.

E1.2 TPV Report of Non-Conformance

E1.2.1 When a final TPV inspection report reveals non-conformance issues, the applicant may choose to either correct or not correct the non-conforming element(s) of the equipment.

E1.2.1.1 New Authorization Applications

If the applicant chooses to correct the non-conforming element(s), they may contract with the CCE to conduct a follow-up verification to verify that the corrections have been completed and conform to the applicable 3-A Sanitary Standard or 3-A Accepted Practice. In such case, the interim non-conformance verification report is to be considered a draft document and should not be submitted to 3-A SSI as a final report. Upon completion of necessary corrections and the follow-up verification, the CCE will issue a final "Conformance" report and follow the procedures described above.

If the applicant chooses not to correct the non-conforming element(s), a copy of the report is to be provided to the applicant. Additionally, a copy is to be sent by the CCE to 3-A SSI for information purposes only.

The flowchart showing TPV Certification Procedures for New Applicants is shown in Chart 1.

E1.2.1.2 Renewal Applications

The CCE shall complete a TPV inspection report documenting the non-conformance issues. The applicant and 3-A SSI shall receive a copy promptly upon the completion of the final report.

Renewal applicants found to be in non-conformance shall follow the procedures specified in Section E1.2.1.1, except that the necessary corrections and follow-up verification shall be accomplished in thirty (30) days.

The flowchart showing TPV Certification Procedures for Renewal Applications is shown in Chart 2.

**Chart 1
TPV Certification Procedures
For New Applicants**

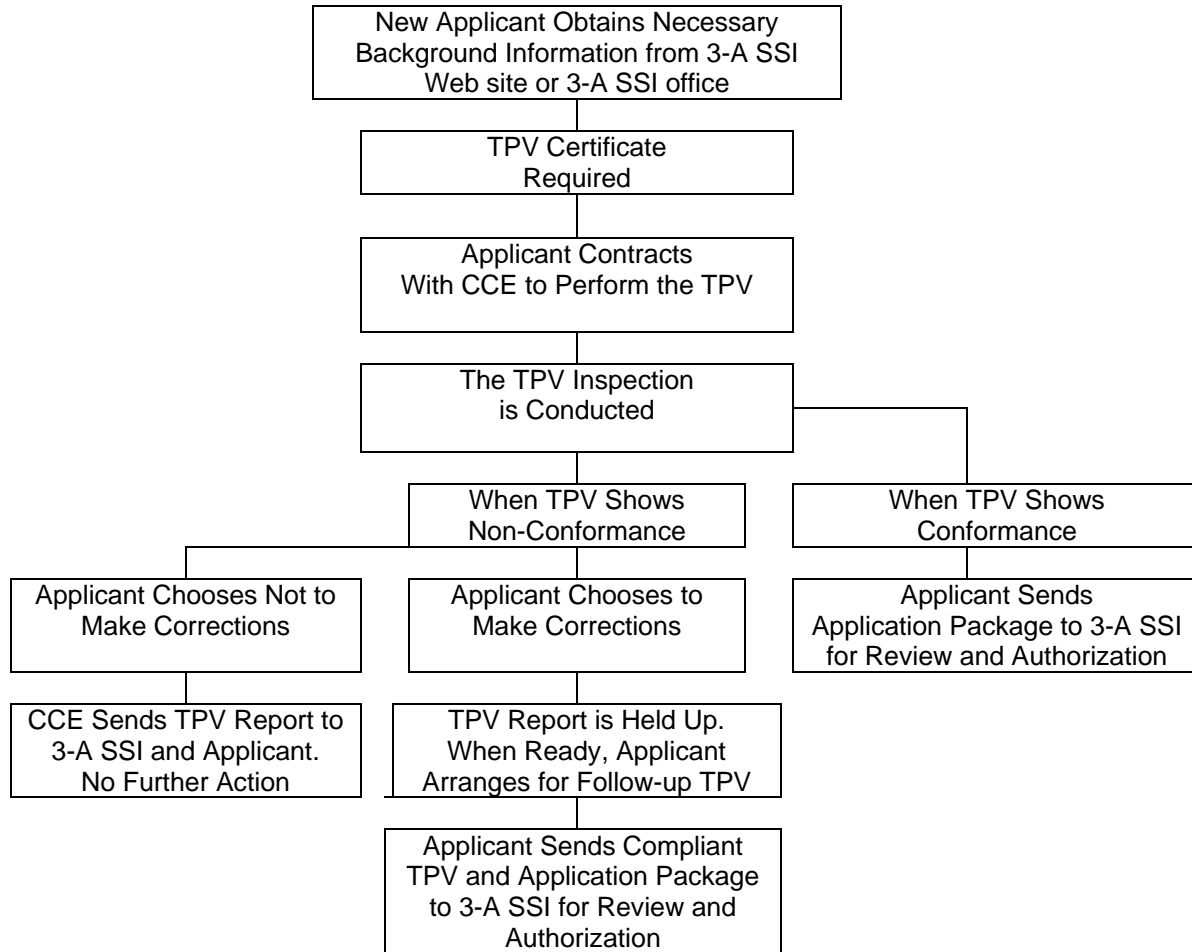
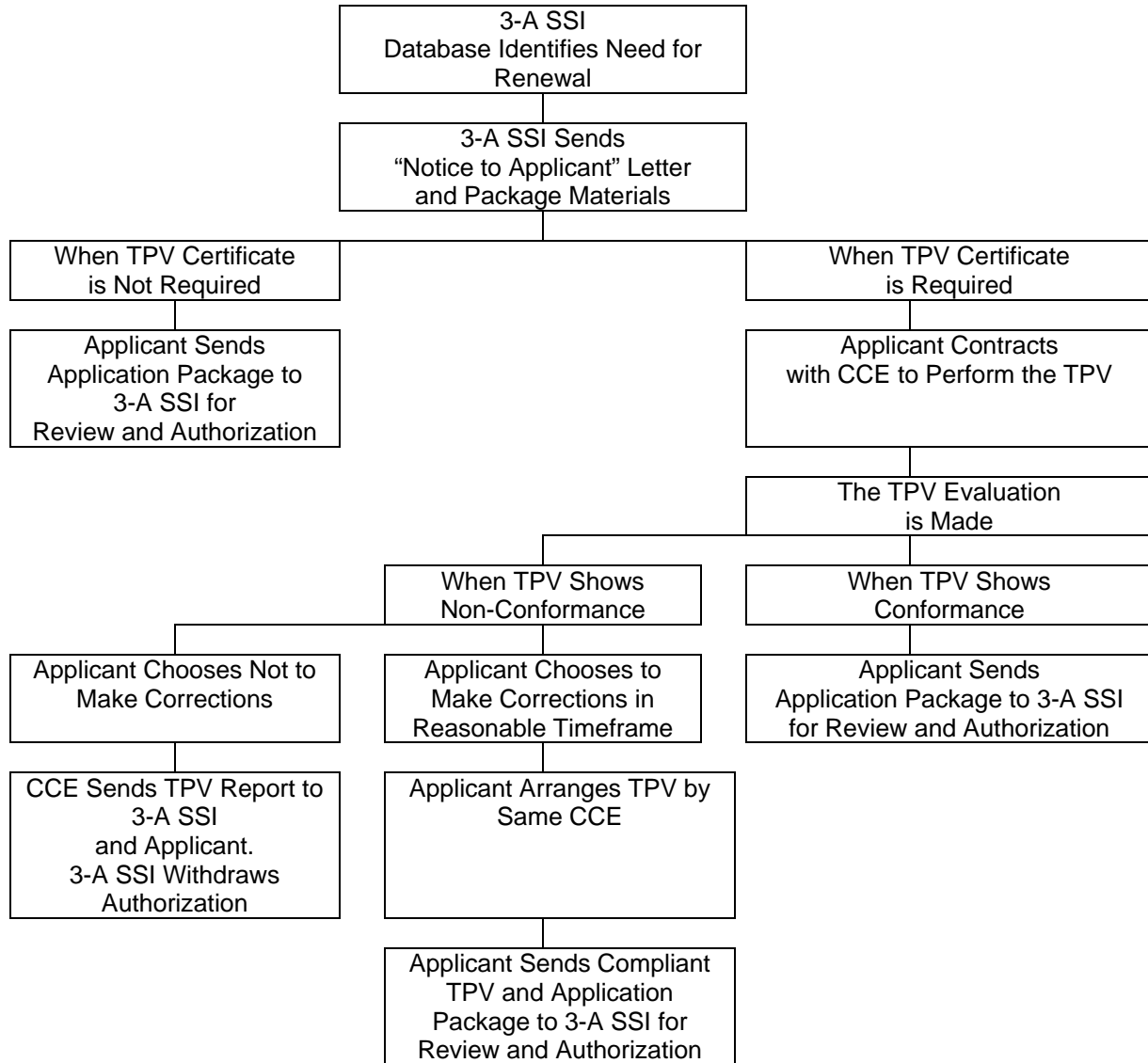


Chart 2

**TPV Certification Procedures
For Renewal Applications**



E1.3 TPV Report Associated with a RAN

E1.3.1 If a CCE is officially involved in the resolution of a RAN, the CCE conducting any follow-up activities shall provide the:

- Applicant the signed, original, final follow-up report;
- 3-A SSI a copy of the final follow-up report; and
- The CCE shall retain a copy of the final follow-up report.

E2 Dispute Resolution

The flowchart showing the TPV Dispute Review Procedures is shown in Chart 3.

E2.1 Interpretation Committee (IC)

E2.1.1 3-A SSI shall establish a 3-A IC comprised of eight (8) members. The members selected shall equally represent the three 3-A stakeholder groups: Fabricators, Users, and Sanitarians. In addition, the USDA shall appoint one representative and the FDA shall appoint one representative. The chair is selected from and by the members of the IC for a one (1)-year term. The committee members shall be knowledgeable in a broad range of 3-A Sanitary Standards, 3-A Accepted Practices and sanitary principles. In the event of an unavoidable tie vote, the issue shall be resolved by the 3-A SSI Board of Directors (BOD).

E2.1.2 Any IC member who is a party to any RAN or TPV dispute shall recuse him/herself from all IC deliberations and decisions related to the dispute.

E2.1.3 The IC shall use the most cost-effective means to render decisions. Reviews and hearings shall be conducted electronically (e-mail, fax, conference calls, etc.) unless an in-person meeting is specifically requested by one of the parties to the dispute. In such case, the requesting party shall assume all cost for the assembly of the IC and other affected parties.

E2.1.4 The IC will also provide, on request, a binding interpretation of the 3-A Sanitary Standards and 3-A Accepted Practices criteria, which are not associated with a RAN investigation or a TPV evaluation, except that, issues concerning legal pasteurization will only be issued with the concurrence of the FDA.

E2.1.5 When appropriate, the IC may also recommend that conflicting issues be resolved by amendment or revision to the 3-A Sanitary Standard(s) or 3-A Accepted Practice(s). The IC may also recommend how such issues should be handled until the 3-A Sanitary Standard(s) or 3-A Accepted Practice(s) is amended or revised.

E3 Dispute of a TPV Inspection Report

This type of dispute occurs between a CCE and an Applicant during the conduct of a TPV inspection before the granting or withdrawal of a 3-A Symbol authorization or 3-A PC and does not involve the submission of a RAN.

E3.1 Applicant's Rights and Procedures

E3.1.1 An applicant may challenge the results of a final TPV inspection report. Any such challenge shall be dated within fifteen (15) days of the completion of the TPV inspection conducted by the CCE and submitted in writing to 3-A SSI. The challenge shall be specific to the particular criteria in the 3-A Sanitary Standard or 3-A Accepted Practice that is alleged to be improperly applied. The applicant shall also provide a concise description of the materials, design, and fabrication utilized to support the challenge.

E3.2 TPV Dispute Resolution

E3.2.1 Upon receipt of the challenge, 3-A SSI will review the submitted documentation and provide written notification of the dispute to both the applicant and the CCE.

E3.2.2 3-A SSI will contact the CCE and the applicant to attempt to resolve the dispute through an informal "meeting of the minds" of the affected parties. If all the parties agree with the submitted documentation and proposed resolution of the dispute as applicable, 3-A SSI will notify all parties in writing of the resolution of the dispute and attach the resolution to the TPV report.

E3.2.3 If 3-A SSI and the parties cannot agree during the informal discussions to resolve the dispute, 3-A SSI will submit the dispute documentation to the IC for review. All decisions of the IC are final and are not subject to further appeal.

E3.2.3.1 If the IC determines the dispute is in favor of the applicant' position; i.e., the applicant is correct and the equipment is manufactured in conformance with the standard criteria, 3-A SSI will notify all the parties of the resolution of the dispute in favor of the applicant in writing and attach the IC determination to the TPV report in order to document the resolution.

E3.2.3.2 If the IC determines that the dispute is in favor of the CCE's position, i.e. the applicant is incorrect and the 3-A Standard was not followed correctly, 3-A SSI will notify all the parties of the resolution of the dispute in writing.

E3.3 3-A SSI Response to a TPV Report Dispute Resolution

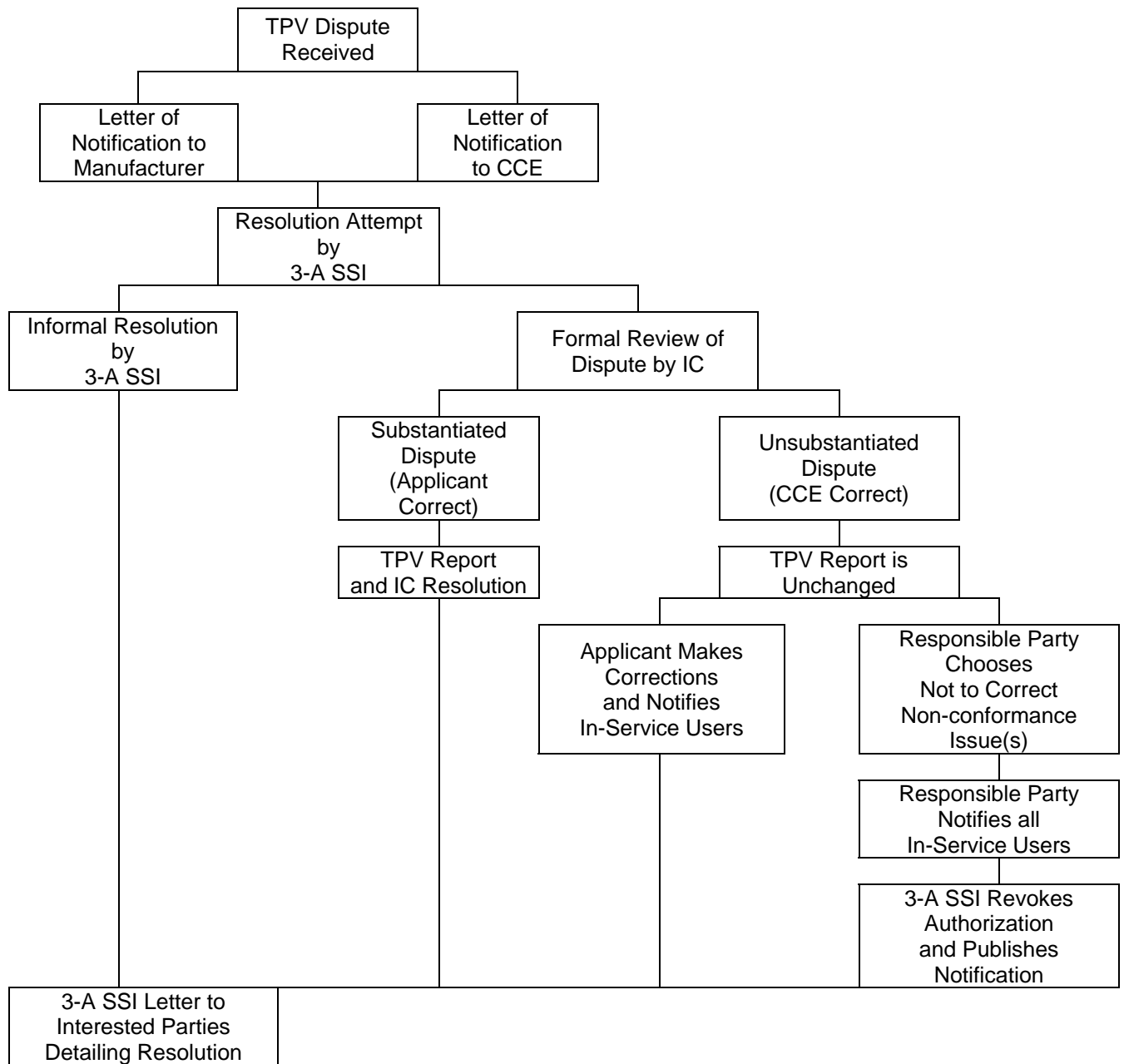
E3.3.1 Upon completion of the TPV Report Dispute Resolution Process, if a RAN is upheld, 3-A SSI and the TPV Coordinating Committee will be required to evaluate whether the RAN was the result of the CCE's failure to administer their responsibilities properly under the TPV program. If the evaluation conducted results in evidence supporting a CCE performance issue, 3-A SSI shall:

- Conduct an evaluation of recent TPV reports submitted by the CCE to evaluate whether the CCE performance area(s) of concern was limited to the RAN or are more extensive.
- Identify specific CCE performance deficiencies and:
 1. Establish a retraining program to address specific CCE performance deficiencies, or

2. Notify the CCE that their certification has been suspended for cause either for a specified time or permanently revoked for cause. If suspended for a specified time, 3-A SSI will be responsible for establishing criteria that will allow the CCE to be re-certified at a future date.

Chart 3

TPV DISPUTE REVIEW PROCEDURES FLOWCHART



E4 Reports of Alleged Non-Conformance (RANs)

RANs are submitted after an applicant has been granted a 3-A Symbol authorization or a 3-A PC and an interested party believes there is a non-conformance issue with the equipment or the process.

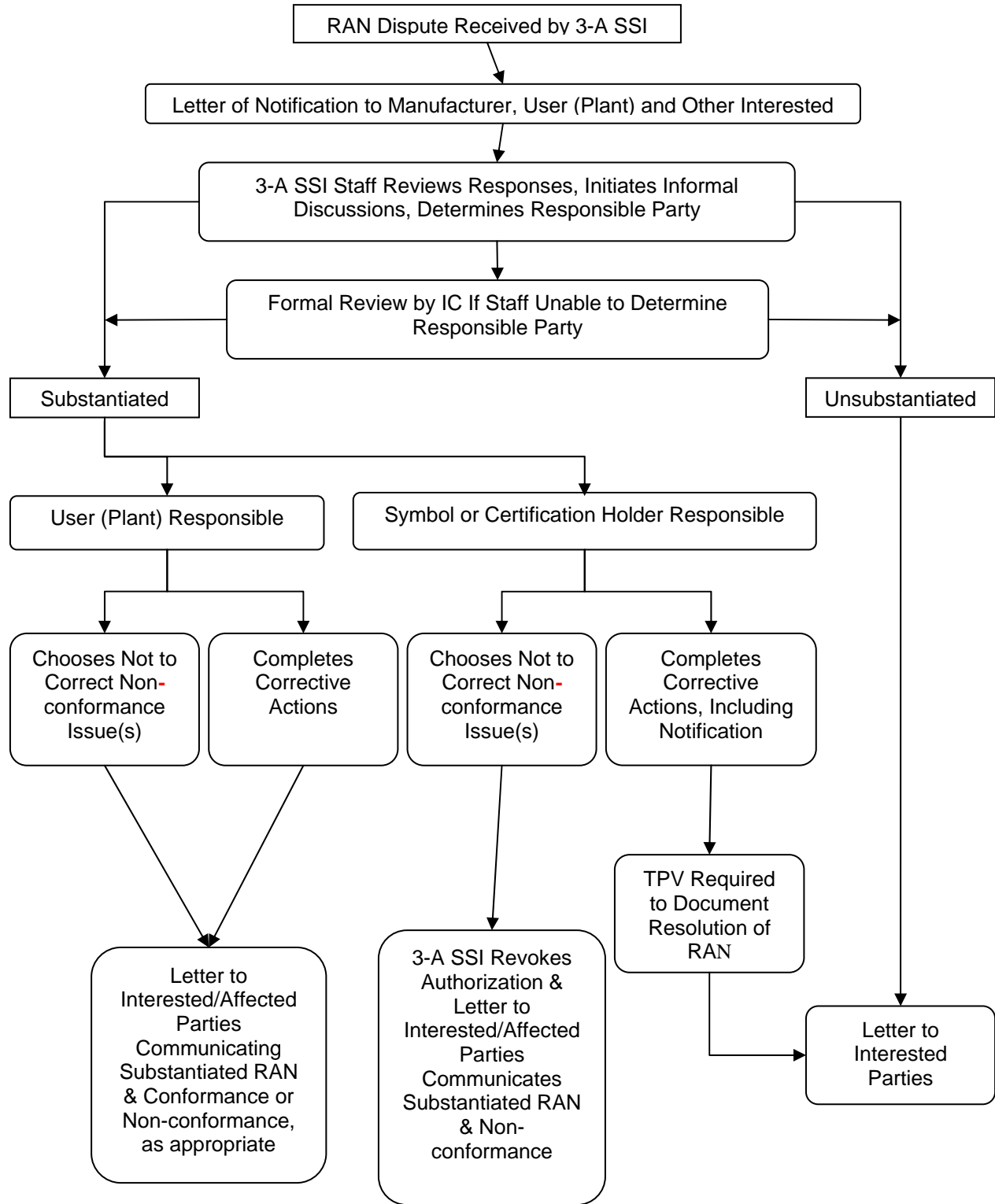
The flowchart showing the Procedure for Reporting of Alleged Non-conformance is shown in Chart 4.

- E4.1 All users of 3-A Sanitary Standards and 3-A Accepted Practices (regulators, industry users, and fabricators) are encouraged to submit a RAN whenever non-conformance to a 3-A Sanitary Standard or a 3-A Accepted Practice is suspected. Alleged non-conformance of 3-A Symbol bearing equipment or a 3-A PC, may be submitted to 3-A SSI at any time. A current form for reporting non-conformance is available from www.3-a.org or in Appendix 3, Exhibits 3 and 4. The report shall contain all the necessary information for 3-A SSI to support the allegation including but not limited to:
1. Name of the equipment, machinery, or processor;
 2. Model or certified process;
 3. Serial Number (if available);
 4. Physical location (address, phone and fax numbers);
 5. Title of applicable 3-A Standard(s) or 3-A Accepted Practice;
 6. All criteria for which conformance is not met and the reasons, including quantitative measurements, if appropriate; and
 7. Any other appropriate documentation.
- E4.2 Within ten (10) days of receipt, 3-A SSI shall notify the alleged non-conforming party(s) of the allegation, the 3-A Sanitary Standard or 3-A Accepted Practice criteria in question, and procedures to be followed to obtain resolution to the allegation(s). The manufacturer (including the installer(s) if appropriate) and user are to respond within ten (10) days to the 3-A SSI inquiry. Following the response from the manufacturer and the user, 3-A SSI will evaluate the validity of the allegation within ten (10) days, with advice from the 3-A SSI Interpretations Committee (IC) as appropriate (Refer to Section E3). All interested parties are encouraged to maintain appropriate files.
- E4.3 Resolution of the RAN must be completed within ninety (90) days of its receipt by 3-A SSI or the 3-A Symbol Authorization or 3-A PC will be rescinded. The revocation of the 3-A Symbol Authorization or 3-A PC use or a non-renewal of an application will require a TPV report of conformance to be submitted with any future application for the equipment or process.
- E4.4 Resolution shall include a documented, mutually-agreed-upon plan for corrective action, scheduling of the corrective actions, and scheduling of the appropriate TPV evaluation. To accommodate the completion of all necessary actions, the actual performance of some activities may exceed the ninety (90) days provided they have been scheduled within an agreed upon timeframe.

- E4.5 If the equipment manufacturer is determined to be the responsible party, the 3-A Symbol Authorization will immediately be placed in the category 'Probationary' in the 3-A SSI Symbol Holder's List maintained on the 3-A SSI web site. The 3-A Symbol will remain in the category 'Probationary' until the plan for corrective action is completed.
- E4.5.1 3-A SSI reserves the right to place special conditions on the TPV inspection requirements for the holder of a 3-A Symbol Authorization which has been the subject of a RAN and corrective actions. These special conditions include, but are not limited to, the requirement for a TPV inspection at a more frequent interval than specified in B7.2.1 or random inspection of samples of finished equipment. The special conditions will be stated in writing to the holder of the 3-A Symbol Authorization.
- E4.6 If the processor is determined to be the responsible party, they shall immediately implement corrective actions to bring the equipment or process into conformance to applicable 3-A Standard(s) and/or 3-A Accepted Practice(s). In the case of a PC, the processor shall make reasonable attempts to contact all customers regarding the loss of their 3-A PC. In addition, the processor shall keep 3-A SSI informed of their corrective action progress.
- E4.6.1 If the responsible party is either the equipment manufacturer or processor and if either one of them chooses not to make the corrections, 3-A SSI will issue a notification, such as through issuance of a press release and/or through the 3-A SSI website, that the 3-A Symbol on that piece of equipment or the 3-A PC for the process is no longer sanctioned.
- E4.7 Throughout the evaluation and processing of the RAN, 3-A SSI's responsibilities and actions include:
1. A thorough review of all applications, non-conformance reports and appeals with advice from the 3-A SSI IC, when needed.
 2. Communication of decisions to all materially affected parties and organizations.
 3. If non-conformance is substantiated, a TPV evaluation is required to resolve the non-conformance issue(s). When resolved, a new TPV date is established.
 4. If a non-conformance is substantiated and the applicant chooses not to resolve the issue(s), actions shall be taken to revoke the 3-A Symbol Authorization or 3-A Process Certification.
 5. Publish, when appropriate, non-renewed Authorizations on the 3-A SSI web site.
 6. If the revocation of a 3-A Symbol or 3-A Process Certification use is for non-conforming design, process installation and implementation, or serial manufacture quality control reason, publish as in item 5.
 7. If a substantiated RAN is due to in-plant (user) modification, only the appropriate Regulatory Agency authorities will be notified.
 8. Communicate issues of public health significance to Regulatory Agencies and encourage them to report non-conformance issues.
 9. When a 3-A Symbol or 3-A Process Certification Authorization is revoked, the applicant will be required to return the 3-A Symbol Authorization or 3-A Process Certification certificate, and a letter confirming that the use of the 3-A Symbol or 3-A Process Certification has been discontinued.

10. If the RAN is upheld, 3-A SSI will be required to evaluate whether the RAN is the result of a CCE's oversight. If this is found to be the case, the procedures identified in Section E.3.4. will be followed.
11. Engage legal counsel whenever necessary.

Chart 4
PROCEDURE FOR REPORTING OF
ALLEGED NON-CONFORMANCE



APPENDIX 1

GLOSSARY OF TERMS

The following terms and definitions are commonly used in reference to the evaluation and certification industries. Not all of the terms are used in this document. They are presented here to provide a common understanding of terms that may be used in association with the work conducted under the 3-A SSI TPV and 3-A Symbol Authorization Program. Organization acronyms may be found in Standards Management.¹

- H1 **3-A Steering Committee:** Implements the policies and procedures for developing 3-A Sanitary Standards and 3-A Accepted Practices. The committee reviews requests for new Standards activity as to their relevance to the industry, and for conformance to federal and state regulations.
- H2 **3-A Symbol Administrative Council:** Is a founding member of 3-A SSI and has granted 3-A SSI the right to authorize the use of the 3-A Symbol under the TPV program.
- H3 **Administrative Officer (AO):** The person(s) that is responsible for accomplishing the functions of 3-A Symbol Authorization, renewals, non-conformance, record keeping and any other described in the TPV Manual.
- H4 **American Dairy Products Institute (ADPI):** A trade association representing dairy processor stakeholders and which is a Founding Member of 3-A SSI.
- H5 **Certification Body:** An impartial body possessing the necessary competence and other qualifications to sponsor and operate a certification program. A certification body is an organization under whose authority a certification program is developed, promulgated, operated, and financed, and with whose name the certification program is identified. (ANSI). 3-A SSI is the Certification Body for 3-A Sanitary Standards and 3-A Accepted Practices.
- H6 **Certification System:** The organizational and procedural process or the institutional mechanism for accomplishing product certification. (EIPSC).
- H7 **Certification:** The act of issuing a warranty, certificate, or mark or other appropriate evidence that attests that a product or service conforms to specific standards or specifications. (ILAC).

Quality assurance programs are used to assure that the product(s) continue to comply with the specified requirements. Satisfactory tests, inspections, and quality assurance are the basis for certification. Evidence of certification may be by labeling of the product. (ASTM E699)

¹ Source for most is Standards Management – a handbook for profits; edited by Robert B. Toth. ANSI, 1430 Broadway, New York, NY 10018.

- H8 **Certified Conformance Evaluator (CCE):** Person(s) meeting the requirements of 3-A SSI to perform third party verification (TPV) for conformance of equipment and machinery to 3-A Sanitary Standards criteria. The CCE must have a current recognition (certification) document.
- H9 **Conformance:** The state of having satisfied the requirements of some specific standard(s) and/or specification(s). (IEEE)
NOTE: “Conformance” is used with respect to voluntary Standards and specifications, whereas “compliance” is used with respect to mandatory Standards and regulations. (OSCI)
- H10 **Consensus Procedures:** The rules and regulations of a recognized or duly appointed authority that pertain to the development of Standards: (1) requiring that all known interested and affected parties be given due notice of the initiation and development of a Standard; (2) providing interested and affected parties the opportunity to participate in the development of each Standard; (3) providing for the considerations of all significant objections to the Standard; and (4) reaching substantial agreement in support of the Standard with no unresolved objections, as judged by a panel of Standards professionals. (OSCI)
- H11 **Consensus:** General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. (ISO)
NOTE: Consensus need not imply unanimity. (ISO)
- H12 **Engineering Design and Technical Construction File (EDTCF):** This file consists of the recorded information necessary to demonstrate that a machine and/or equipment is in conformance to applicable 3-A Sanitary Standards. The information is collected from multiple sources and is the primary source for verification details. An example of an EDTCF is found on pages 87 through 90 of this manual. Examples are also found in 3-A Sanitary Standards.
- H13 **Food and Drug Administration (FDA):** The U.S. federal agency responsible for protecting domestic and imported food, drugs, devices and the cosmetics supply from adulteration or misbranding.
- H14 **Food Protection Trends (FPT):** A food safety related journal published by the International Association for Food Protection (IAFP).
- H15 **Harmonization:** The process whereby two or more nations (or Standards bodies) agree on the content and application of a Standard. Harmonization is accomplished by modification of a national Standard (or agreement on a common document by two or more Standards bodies) so that it is consistent with the harmonized Standard or by countries agreeing to accept products and services that are in conformance to the harmonized Standard even if they do not conform to the requirements of their national Standard. Furthermore, a Standard may be said to be harmonized if its text is technically equivalent to another Standard (e.g., a national Standard which is technically equivalent to an international Standard.) (EIPSC)

- H16 **Inspection:** The process of measuring, examining, testing, gauging or otherwise comparing the unit with the applicable requirements. (ASQC)
- H17 **International Association for Food Protection (IAFP):** A professional society whose interest is protecting public health and food protection. IAFP is a Founding Member of 3-A SSI and represents the regulatory stakeholders.
- H18 **International Association of Food Industry Suppliers (IAFIS):** A trade association whose members are capital equipment and ingredient suppliers. IAFIS is a Founding Member of 3-A SSI and represents the capital equipment stakeholders.
- H19 **International Dairy Food Association (IDFA):** A trade association representing dairy processor stakeholders and is a Founding Member of 3-A SSI.
- H20 **International Standard:** A Standard that is adopted by an international Standardizing/Standards organization and made available to the public. (ISO)
- H21 **Interpretations Committee (IC):** The committee is the arbitrator on disputed actions in 3-A Symbol authorizations and RANs. The committee will also resolve questions on variant application of 3-A criteria.
- H22 **Mark of Conformity:** The sign or symbol owned or controlled by the certification body that is used exclusively by the third party certification program to identify products or services as being certified and is registered as a certification mark with the U.S. Patent Office under the Trade Mark Act of 1946. (ANSI)
- H23 **Qualified Product:** A product that has been inspected, evaluated, tested, or otherwise determined to be in conformance to applicable or specified provisions of reference Standards, codes, or other requirements and approved for listing in a qualified products list (QPL). (EIPSC)
- H24 **Qualified Products List (QPL):** A list of products which have met the qualification requirements stated in the applicable specification, including appropriate product identification and test or qualification reference with the name and plant address of the manufacturer or distributor, as applicable. QPL is the accepted abbreviation for the term Qualified Products List. Department of Defense (DOD)
- NOTE:** The above definition as used here applies to the 3-A Symbol Holders List.
- H25 **Quality Assurance:** A planned system of activities whose purpose is to provide assurance that the overall quality control program is in fact being effectively implemented (Refer to "Quality Control"). This system involves a continuing evaluation of the adequacy and effectiveness of the overall quality control program with a view to having corrective action initiated where necessary. For a specific material, product, service, etc., this involves verification, audits, and evaluations of the quality factors that affect the specification, production, inspection, and use of the material product, service, system, or environment. (ASTM E699)

- H26 **Quality Control:** A planned system of activities whose purpose is to provide a level of quality that meets the needs of users; also, the use of such a system. The objective of quality control is to provide an overall system integrating the quality factors of several steps, including: the proper specification for what is wanted; production to meet the full intent of the specification; inspection to determine whether the resulting material, product, service, etc., is in accord with the specification; and review of usage to determine necessary revisions of the specification. (ASTM E699)
- H27 **Recognition Arrangement:** A written agreement or document between the 3-A SSI and the CCE to accept data for the determination of product conformance to 3-A Sanitary Standards.
- H28 **Report of Alleged Nonconformance (RAN):** This is a provision for reporting perceived non-conformance items. (Refer to Section B7.4.)
- H29 **Self-Certification:** A form of certification by a producer, on its own authority and not under the procedures of a third party certification program, that a product or service is in conformance to the designated Standards or specifications. (ANSI)
- H30 **Standard:** A prescribed set of rules, conditions, or requirements concerned with the definition of terms; classification of components; delineation of procedures; specification of dimensions, materials, performance, design, or operations; measurement of quality and quantity in describing materials, products, systems, services, or practices; or descriptions of fit and measurement of size. (OMB)
- H31 **Third Party Verification (TPV):** A form of certification in which the producer's claim of conformity is verified (reviewed and verified) as part of the certification program, by a technically and competent body or person other than one controlled by the producer or the buyer. (Adapted from ANSI).
- H32 **United States Department of Agriculture (USDA):** The federal department responsible for ensuring a safe, affordable, nutritious, and accessible U. S. food supply through inspection and regulation of meat, poultry and egg products, and providing grading and standardization programs for selected agricultural commodities.
- H33 **Verification:** The process of determining whether implementation is in conformance to some specific Standard(s) and/or specification(s). (IEEE)
- H34 **Voluntary Standard:** A Standard that is usually developed by a consensus process for voluntary use and with which there is no obligation to comply. However, a voluntary Standard may become quasi-mandatory or mandatory as a result of its use, reference, or adoption by a regulatory authority. (EIPSC)

APPENDIX 2

3-A SYMBOL AUTHORIZATION AND 3-A PROCESS CERTIFICATION APPLICATION FORMS AND RELATED DOCUMENTS*

*All TPV forms contained in this manual are examples only and may not represent the most current version. Forms maintained on the 3-A SSI web site are the most current and supersede all other versions. Forms are available at www.3-a.org under 'The 3-A Symbol & Third Party Verification', 'Forms', or follow the link to www.3-a.org/symbol/forms.htm.



**APPLICATION
FOR
3-A SANITARY STANDARDS SYMBOL**

Check one:

New Application

Renewal

Amendment

Authorization #: _____

Authorization #: _____

The application shall apply to only one type of equipment to which 3-A Sanitary Standards pertain.

Company Name: _____ Web site: _____

Address: _____

(City)

(State)

(Zip)

(Country)

(Phone)

(Fax)

(Primary Contact E-mail)

TYPE OF EQUIPMENT: _____

MODEL DESIGNATIONS:

(For Renewals and Amendments, list changes or modifications on a separate page and attach to this application.)

(Attach separate sheet if necessary)

DECLARATION OF THE APPLICANT

It is hereby declared and affirmed that the equipment herein listed comply in all respects with the applicable provisions of currently effective 3-A Sanitary Standards for:

(3-A Sanitary Standard Title)

(3-A Sanitary Standard Number)

(Effective Date)

Upon issuance of this new authorization or renewal, Applicant agrees to abide by the terms of the attached 3-A Sanitary Standards, Inc. License Agreement for Use of the 3-A Symbol.

CERTIFICATION OF QUALITY CONTROL BY APPLICANT

The Applicant herein is committed to the maintenance of consistently high levels of quality in the design, materials, and fabrication of products bearing the 3-A Symbol. We maintain a documented program to monitor conformance to the criteria of 3-A Sanitary Standard listed herein, including the following:

- All materials of construction including all plastics, rubbers, adhesives, and metal alloys not listed in the standards are verified as in conformance.
- All drawings accurately depict fabrication criteria.
- All machinists, welders, grinders, polishers, and other fabrication and installation employees are monitored to assure conformance on all units produced.
- All changes and modifications to the design, materials, or fabrication techniques meet or exceed specified criteria and are properly documented.
- We acknowledge that 3-A SSI may share any information of confirmed nonconformance to materially affected parties, including regulatory agencies and individuals in accordance with provisions of the TPV manual.
- If applicable, describe here any quality control or quality management program to which the company is certified.

CERTIFICATION OF CONFORMANCE BY APPLICANT

New Applicant:

- The design, materials, and fabrication used for the equipment referenced above have been reviewed.

Renewal or Amendment Applicant:

- The design, materials, and fabrication used for the equipment referenced above have not been changed or modified since the prior authorization.
- The design, materials, or fabrication of the equipment referenced above have been changed or modified* since the prior authorization, as described below. Attached is a copy of the current TPV certificate and report covering the changes. List changes or modifications (add additional pages as necessary):

** Refer to B7.1.4.1 of the TPV Manual for more information.*

We, the undersigned, do hereby certify and attest that these statements and information provided with this form are true, complete, and accurate. We acknowledge that any failure to provide true, complete, and accurate information will result in the immediate forfeiture of all 3-A Symbol authorizations and fees.

3-A Symbol Authorization Number: _____
(insert number)

Date:	Date:
President/CEO Name (print):	Director of Engineering or Head of Manufacturing Name (print):
Signature:	Signature:

Please return to 3-A SSI:

- The completed Application and**
- Payment or the attached payment information sheet.**

**3-A SANITARY STANDARDS, INC.
LICENSE AGREEMENT FOR USE OF THE 3-A SYMBOL**

This License Agreement is entered into by and between 3-A Sanitary Standards, Inc. (hereinafter "3-A SSI"), and Applicant listed above (hereinafter "Licensee").

The parties agree as follows:

The parties agree as follows:

1. 3-A SSI grants to Licensee a nonexclusive license to use the 3-A Symbol as specified in the attached Certificate.
2. Licensee agrees to comply with all 3-A SSI rules and procedures, as amended from time-to-time, including Provisions for Use and Display of the 3-A Symbol, the timely payment of licensing fees and any late fees or similar charges that may be assessed, and all provisions of the Third Party Verification program.
3. Licensee agrees that, as between Licensee and 3-A SSI, 3-A SSI is the owner of the 3-A Symbol, and Licensee shall not take any actions which are inconsistent with 3-A SSI's ownership rights including, but not limited to, challenging 3-A SSI's rights.
4. Licensee's authorization to use the 3-A Symbol will terminate each year on the anniversary date of the Certificate. However, this License will be automatically renewed each successive year for an additional twelve-month period under the same terms and conditions, except as modified by 3-A SSI, provided that Licensee has fully complied with all rules and procedures for such renewal.
5. No association, agency, apparent agency, employer/employee relationship, partnership, or joint venture of any kind is created by this Agreement.
6. This Agreement shall not be assignable or transferable by Licensee in any manner except with 3-A SSI's prior written consent, nor shall Licensee have the right to grant sublicenses.
7. The Licensee agrees that it will use the 3-A Symbol only on equipment that meets applicable 3-A SSI standards and specifications, including as amended or interpreted in the future.
8. If it is determined by 3-A SSI that any equipment referenced in the Certificate does not conform at any time to the applicable 3-A SSI standard or specification, including as amended or interpreted in the future; or if Licensee is determined by 3-A SSI to have made any materially false statement in any application or affidavit; or if Licensee otherwise defaults in any of its obligations under this Agreement, then 3-A may immediately terminate this Agreement, without prejudice to any other rights which 3-A SSI may have.
9. Upon termination or expiration of this License, 3-A SSI may in its discretion so notify governmental authorities and others, including via the 3-A SSI web site. In addition, Licensee shall immediately discontinue the use of the 3-A Symbol.
10. This Agreement shall not grant any right or remedy to any person or entity that is not a party to this agreement.
11. This Agreement shall be interpreted and governed by the laws of the Commonwealth of Virginia. Exclusive jurisdiction for any claim or dispute between the parties resides in federal or State court in Northern Virginia, and the parties agree and expressly consent to the exercise of personal jurisdiction in the Commonwealth of Virginia.
12. This License contains the entire agreement between the parties as to the subject matter referenced herein. No agreement, statements, or representations not herein contained shall have any force and effect.
13. Licensee shall indemnify and hold 3-A SSI harmless for any costs, including judgments, settlements, and attorney's fees, incurred by 3-A SSI in defense of any legal proceeding alleging, in whole or in part, injury caused by any equipment of Licensee.
14. Paragraphs 3, 9, 11, 13 and this paragraph 14 survive termination of this Agreement.



3-A SANITARY STANDARDS, INC. PROVISIONS FOR THE USE AND DISPLAY OF THE 3-A SYMBOL

Use and Display of the 3-A Symbol is Non-mandatory

Use and display of the 3-A Symbol on equipment is voluntary. If a licensee elects to not display the 3-A Symbol on a specific model(s) of equipment for which it holds authorization, the following shall apply:

- The licensee shall make no use or display of the 3-A Symbol in any manner in the promotion or sale of such equipment.
- The licensee shall make no representation, express or implied, in any manner to assert that such equipment conforms to 3-A Sanitary Standards or provisions for 3-A Symbol authorization.
- The 3-A Symbol Authorization certificate shall not be considered proof of conformance for equipment which does not display the 3-A Symbol.

Elective Use and Display of the 3-A Symbol

If a licensee chooses to use and display the 3-A Symbol on a specific model(s) of equipment for which it holds authorization, the licensee shall observe the provisions shown below.

The 3-A Symbol is authorized for use on and in conjunction with the marketing of equipment and machinery that meets the requirements of published 3-A Sanitary Standards, subject to specific requirements of 3-A SSI for reproducing or displaying the mark and provisions of the 3-A SSI License Agreement for Use of the 3-A Symbol.

A licensed 3-A Symbol holder (licensee) may mark and/or affix the 3-A Symbol only to specific models/names of equipment encompassed within a 3-A Symbol authorization. An organization holding authorization to use the 3-A Symbol for such equipment may also state this fact in its advertising literature.

The 3-A Symbol shall be reproduced as specified in the enclosed Requirements for 3-A Symbol Reproduction.

The 3-A Symbol, where possible, shall be made of stainless steel, and shall be affixed upon the equipment in juxtaposition to the nameplate or shall be part of the nameplate. The hyphenated standard number of the 3-A Sanitary Standard with which the equipment complies shall appear immediately in conjunction with the 3-A Symbol and be affixed to the equipment or machinery, the 3-A Symbol, or the name-plate in a clear, concise, permanent manner. Where the nature or size of the equipment is such as to make the above impracticable, the 3-A Symbol and hyphenated standard number shall be stamped, etched, or embossed on the equipment; or affixed in any other permanent manner.

Completed applications and other required documents shall be submitted to 3-A Sanitary Standards, Inc., 6888 Elm Street, Suite 2D, McLean, VA 22101-3829. A duplicate copy shall be maintained by the applicant.

Each application for a new 3-A Symbol authorization shall be accompanied by:

1. A copy of the TPV Report issued by a Certified Conformance Evaluator (CCE) and a properly completed Application for 3-A Symbol Authorization.

2. A specimen of the nameplate to be used or a drawing showing the nameplate with exact dimensions and full text (not including data for specific models).
3. A specimen of the 3-A Symbol and the full 3-A Sanitary Standard hyphenated standard number to be employed, or a drawing showing its height; and, if not made of stainless steel, a sample and description of the material to be used, and the manner of its attachment. (See attached)
4. Descriptive literature and photographs or drawings depicting specific features. Detailed drawings of specified parts or areas are to be furnished upon request of 3-A SSI.
5. The appropriate application fee made payable to 3-A SSI.

Each authorization shall remain in effect for one (1) calendar year, or portion thereof, and may be extended by renewal for periods of one (1) year, subject to the requirements of 3-A SSI.

Upon revisions of 3-A Sanitary Standards, authorizations predicated upon the 3-A Sanitary Standards in effect prior to the revision shall not be valid for equipment manufactured after the effective date of the revised 3-A Sanitary Standards. Holders of authorizations for equipment manufactured after the effective date of the revised 3-A Sanitary Standards shall submit the documentation required.

When a holder of an authorization wishes to modify the design, fabrication, or materials of construction of covered equipment or machinery; or, add one or more models of equipment or machinery conforming to the 3-A Sanitary Standards upon which authorization in effect was predicated, the authorization may be amended upon the filing of an application and other required information.

Each holder of an authorization shall be notified before an authorization expires and shall be furnished a form for renewal of the authorization, or shall be notified that the authorization cannot be renewed, as the case may be.

The application forms for renewal of an authorization, to be furnished by 3-A SSI, shall conform, with appropriate modification, to the provisions of the TPV Manual.

Authorizations may be relinquished by the holders. If such relinquishment is announced by all of the manufacturers of equipment or machinery for a non-manufacturer, the authorization of the non-manufacturer automatically expires.

Any authorization for which application for renewal is not made shall become invalid on the day following the date of expiration. If all of the manufacturers for a non-manufacturer fail to renew their authorizations, the authorization of the non-manufacturer automatically expires.

If a 3-A Symbol authorization is lapsed for a period of more than six months from the date of expiration, the licensee will be required to submit a new TPV Report issued by a Certified Conformance Evaluator (CCE) and a properly completed Application for 3-A Symbol Authorization.

The right of the holder of an authorization to use the 3-A Symbol on the equipment and machinery covered by the authorization shall cease upon the cancellation or termination of the said authorization by 3-A SSI with cause.

Information regarding relinquished, canceled, or revoked authorizations is published on the 3-A Sanitary Standards Inc. web site.



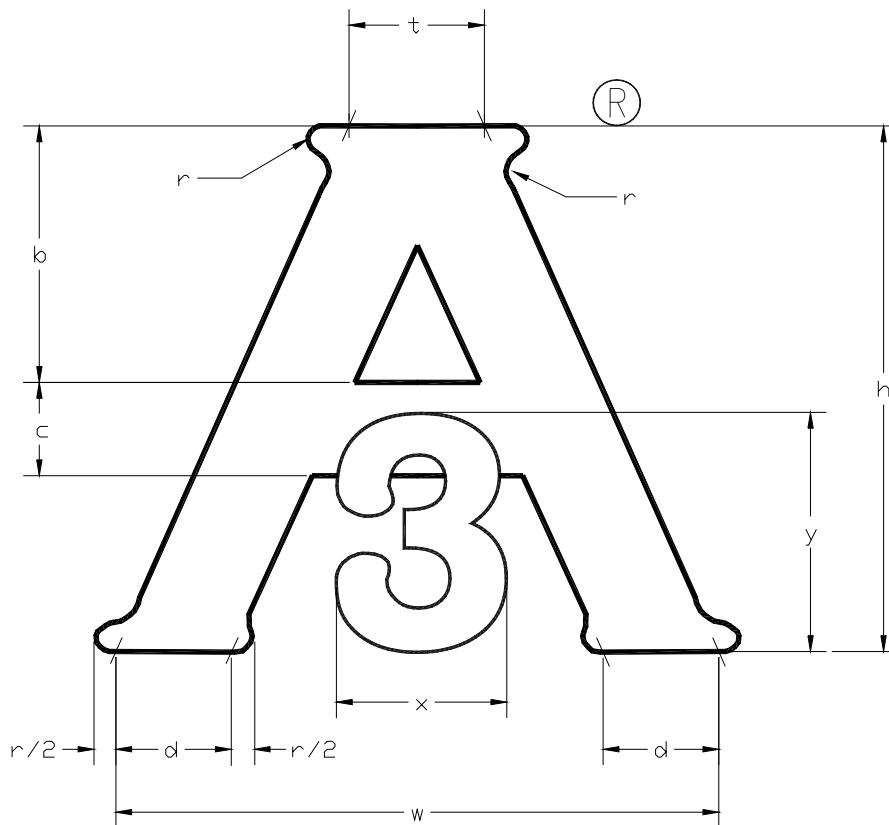
Standard Number ## - ##

**3-A SANITARY STANDARDS, INC.
REQUIREMENTS FOR 3-A SYMBOL REPRODUCTION**

3-A SSI recommends that licensees reproduce the 3-A Symbol using one of the following electronic formats: DWG, DXF, TIFF, Illustrator and EPS. 3-A SSI will provide a copy of the 3-A Symbol in the desired electronic format(s) to licensees upon request.

See the following page for specific design criteria.

These specifications shall apply to all methods of 3-A Symbol display.



Standard Number ## -

Capital Gothic A outline with serifs, on which is superimposed the antique numeral 3.

- Ratio of width, w to $h = 1.08:1$
- Ratio of width at top, t to $h = .26:1$
- Ratio of distance from top to top of cross bar, b to $h = .49:1$
- Ratio of width of cross bar, c to $h = .175:1$
- Ratio of width of side bars, d to $h = .21:1$
- Ratio of height of figure 3, y to $h = .45:1$
- Ratio of width of figure 3, x to $h = .333:1$ (maximum)
- Radius of serif, r to $h = .0625:1$

On reproductions with $h=1/2$ or less, the serifs may be omitted.

The registered designation ® shall be proportionally displayed as part of the 3-A Symbol.

The full 3-A Sanitary Standard hyphenated standard number and version shall appear immediately below the 3-A Symbol.



Promotion Tips for Use and Display of the 3-A Symbol

3-A SSI does not “approve,” “certify,” “rate,” or “endorse” the design, construction, or use of the equipment and there shall be no statements or implications, which might so indicate. A licensee may state in advertising literature that items for which they have been issued 3-A Symbol authorization meet the requirements of the 3-A Sanitary Standards. Unauthorized use of the 3-A Symbol, or statements to that effect and statements about 3-A Sanitary Standards conformance is not permitted.

3-A SSI encourages authorized 3-A Symbol holders to use the 3-A Symbol in equipment publicity and promotion, consistent with application and licensing requirements. Here are some important “Do’s” and “Don’ts” concerning the display and use of the 3-A Symbol.

DO

- Reproduce the 3-A Symbol to the dimensional requirements specified in the Application and License Agreement for Authorization to Apply the 3-A Sanitary Standards Symbol to Equipment.
- Reproduce the 3-A Symbol on stainless steel, where possible. If the nature or size of the equipment requires, reduce the size of the 3-A Symbol.
- Show the hyphenated 3-A Sanitary Standard Number immediately below the 3-A Symbol. The format must be complete with the standard number and version: # # - # #.
- Affix the 3-A Symbol to the equipment in juxtaposition to the nameplate or as part of the nameplate. The 3-A Symbol may be stamped, etched, embossed or welded on the equipment. If welded, continuously weld the nameplate or 3-A Symbol to the equipment. Alternatively, self-adhesive, durable stickers may be used.
- Be sure the display of the 3-A Symbol is compatible with all criteria for hygienic design:
 - Exposed surfaces must be relatively smooth, relatively free of pockets and crevices, and be cleanable.
 - Joints must be continuously welded.
 - If welding is not possible, recessed socket head bolts or rivets must not be used.
- Be sure the surface facilitates cleaning and inspection. The surface must be relatively free of areas where liquids or product residues can accumulate and not be cleaned out.
- Use the 3-A Symbol in advertising or promotional information only in conjunction with equipment/machinery for which the 3-A Symbol authorization has been granted. For example, if 3-A Symbol authorization has been granted for Centrifugal and Positive Rotary Pumps (3-A Sanitary Standard No. 02-10), the holder shall not show the 3-A Symbol or otherwise infer 3-A Symbol authorization for other types of equipment for which it does not hold 3-A Symbol authorization.

DON'T

- Misrepresent equipment not authorized to display a 3-A Symbol in an advertisement of equipment, which is authorized to display the 3-A Symbol.
- State the company or organization holds 3-A Symbol authorization; the 3-A Symbol pertains specifically to authorized equipment.
- State or suggest that the equipment is 'approved,' 'certified,' 'authorized,' 'rated,' or 'endorsed', by 3-A SSI, or some equivalent claim. 3-A Symbol authorization is granted based on meeting specific license requirements, including a Third Party Verification (TPV) inspection. The TPV program verifies that equipment is designed and manufactured to the appropriate 3-A Sanitary Standards.
- Make reference to the 3-A Symbol or 3-A Symbol authorization unless your organization maintains a current 3-A Symbol authorization for a given type of equipment/machinery.
- Use rivets or socket head screws to attach nameplates or 3-A Symbols to equipment.
- State a link between 3-A Symbol authorization and any other organization. For example, "Meets USDA/3-A criteria" or "Conforms to FDA/USDA/3-A Standards Criteria" are inappropriate.

If you have a specific question concerning the use or display of the 3-A Symbol, contact 3-A SSI.

###



3-A Sanitary Standards Inc.
6888 Elm Street, Suite 2D
McLean, Virginia, 22101-3829
PH: 703-790-0295 FAX: 703-761-6284
www.3-a.org

(Sample Renewal Letter)

{Date}

«Sir_Name» «ContactFirstName» «ContactLastName»
«Company_Name»
«Address_1»
«Address_2»
«City» «StateOrProvince» «Zip_Code»
«Country»

NOTICE OF RENEWAL FOR 3-A SYMBOL AUTHORIZATION

Dear «Sir_Name» «ContactLastName»:

We are sending this notice and invoice for renewal of the 3-A Symbol authorization(s) maintained by your company as enclosed. All licenses are maintained on a calendar year period.

Enclosed you will find a renewal form(s) to renew your authorization(s). The invoice amount reflects the renewal of the authorization(s) for **calendar 200_**.

TPV Re-inspection

In accordance to requirements of the 3-A SSI Third Party Verification (TPV) Program for 3-A Symbol Authorization, 3-A Symbol licensees must obtain a TPV re-inspection at a minimum of once every five years. Our records show the TPV re-inspection of equipment under this 3-A Symbol authorization must be submitted to 3-A SSI before:

TPV Re-inspection Date: Month/Year

Your 3-A Symbol authorization will automatically expire after this date if 3-A SSI does not receive your TPV Report.

Renewal Checklist

Be sure to verify the following for your renewal submission to 3-A SSI:

1. Please verify the **contact information** shown on your renewal application for accuracy and completeness; please show the current email and update your mailing address as needed.
2. If there are no changes in the **scope of equipment** covered by your authorization, please submit your renewal form showing the same model designations as before. Your renewal will cover only model designations currently listed on your certificate.
If you wish to make changes in the scope of equipment covered by your authorization, such as adding additional model designations, mark your changes clearly on the form and we will show these changes on your new certificate.

**If you make changes in the equipment listing any time after the issuance of this renewal certificate, you must submit a completed Application for Amendment of 3-A Symbol Authorization and submit with payment to 3-A SSI.*

3. Be sure to **sign and date** the renewal application.
4. Please include the **annual renewal fee** of \$_____ per authorization with your renewal form.
5. Return the **completed renewal application and payment in a single package to 3-A SSI by December 1, 200** . You can expect delays in the processing of your renewal if we must match applications and payments that are sent separately.

We will be sending your renewal certificate(s) for your 3-A Symbol authorization(s) in early 200_.

Thanks for your continuing investment your support for a new era of integrity for the 3-A Symbol program.

Sincerely,

Timothy R. Rugh

Timothy R. Rugh, CAE
Executive Director

enclosures

3-A Sanitary Standards, Inc.

APPLICATION FOR 3-A PROCESS CERTIFICATION

Check one:

New Application

Renewal

Amendment

Certificate # _____

Certificate # _____

The application shall apply to a processing system which is covered by a 3-A Accepted Practice and eligible for 3-A Process Certification. This application pertains only to the specific site and processing system shown below.

Company Name: _____ Web site: _____

Address: _____

(City)

(State)

(Zip)

(Country)

(Phone)

(Fax)

(Primary Contact E-mail)

Hereby applies to the 3-A Sanitary Standards, Inc. for a 3-A Process Certification for the following:

(3-A Accepted Practice Number)

(3-A Accepted Practice Title)

Effective Date of 3-A Accepted Practice)

(For Renewals and Amendments, list changes or modifications below or continue on a separate page and attach to this application.)

DECLARATION OF THE APPLICANT

It is hereby declared and affirmed that the processing system herein listed complies in all respects with the applicable provisions of currently effective 3-A Accepted Practice named above.

It also is hereby declared that the signer of this application has understands and will observe all provisions of the 3-A SSI Process Certification Program as provided in the attached Agreement and in the equipment inspection requirements set forth in the 3-A Sanitary Standards, Inc. Manual for Third Party Verification (TPV) for 3-A Symbol Authorization and 3-A Process Certification (TPV Manual).

CERTIFICATION OF QUALITY CONTROL BY APPLICANT

The Applicant herein is committed to the maintenance of consistently high levels of quality in the design, materials, and fabrication of the processing system identified in the 3-A Process Certification. We maintain a documented program to monitor conformance to the criteria of 3-A Accepted Practice (_____), including the following:

Practice Name and Number

- All materials of construction including all plastics, rubbers, adhesives, and metal alloys not listed in the standards are verified as in conformance.
- All drawings accurately depict fabrication criteria.
- All machinists, welders, grinders, polishers, and other fabrication and installation employees are monitored to assure conformance on all units produced.
- All changes and modifications to the design, materials, or fabrication techniques meet or exceed specified criteria and are properly documented.
- We acknowledge that 3-A SSI may share any information of confirmed nonconformance to materially affected parties, including regulatory agencies and individuals in accordance with provisions of the TPV manual.
- If applicable, describe here any quality control or quality management program to which the company is certified.

CERTIFICATION OF CONFORMANCE BY APPLICANT

New Applicant:

- The design, materials, and fabrication used for the equipment referenced above have been reviewed and meet all of the appropriate criteria of the 3-A Accepted Practice.

Renewal Applicant:

- The design, materials, and fabrication used for the process referenced in this application have not been changed or modified since the prior authorization dated (_____).
- The design, materials, or fabrication of the equipment referenced above have been changed or modified* since the prior authorization as described below. List changes or modifications (add additional pages as necessary):

**Refer to B7.3.5.1 of the TPV Manual for more information.*

- Attached is a copy of the current TPV certificate and report covering the changes.

Date:	Date:
President/CEO Name (print):	Director of Engineering or Head of Manufacturing Name (print):
Signature:	Signature:

Please return to 3-A SSI:

- The completed Application and**
- Payment or the attached payment information sheet.**

3-A Sanitary Standards, Inc.

3-A Process Certification Program

AGREEMENT

This Agreement dated _____ is entered into by and between 3-A Sanitary Standards, Inc. (hereinafter "3-A SSI"), and _____ (hereinafter "Applicant").

WHEREAS, 3-A SSI has established the *3-A Process Certification Program* (hereinafter "Program") through which processors may apply for a 3-A Process Certificate (hereinafter, "Certificate") indicating conformance of specified processing systems to a 3-A Accepted Practice; and

WHEREAS, Applicant has applied to 3-A SSI for a Certificate for the specified processing system identified in Applicant's application.

THEREFORE, the parties agree as follows:

1. Applicant shall comply with all 3-A SSI rules and procedures associated with the Program, as amended from time-to-time. This includes timely payment of fees, Third Party Verification, and public communications, including advertising, of Applicant that refer to the Certificate or the Program.
2. Should Applicant successfully complete the Third Party Verification process with respect to any processing system, Applicant shall be permitted to display, copy, and distribute, without alteration, a Certificate prepared and issued by 3-A SSI acknowledging conformance of such processing system to the named 3-A Accepted Practice.
3. This Agreement does not transfer to, or bestow any rights upon, Applicant with respect to the 3-A Symbol, nor may Applicant utilize the 3-A Symbol. Without limiting the foregoing, Applicant shall not in any manner attach or affix the 3-A Symbol to any processing system or include any other markings or words on any processing system intended to indicate conformance with 3-A Sanitary Standards or 3-A Accepted Practices or participation in the Program.
4. 3-A SSI is the owner of the 3-A Symbol and the Program, and Applicant shall not take any actions which are inconsistent with 3-A SSI's ownership rights including, but not limited to, challenging 3-A SSI's rights.
5. Applicant's authorization to use the Certificate as authorized by this Agreement will terminate each year on the expiration date of the Certificate. However, this Agreement will be automatically renewed each successive year for an additional twelve-month period

under the same terms and conditions, except as modified by 3-A SSI, provided that Applicant has fully complied with all rules and procedures for such renewal.

6. No association, agency, apparent agency, employer/employee relationship, partnership, or joint venture of any kind is created by this Agreement.
7. This Agreement is not assignable or transferable by Applicant in any manner.
8. If it is determined by 3-A SSI that the processing system referenced in the Certificate does not conform at any time to the applicable 3-A Accepted Practice, including as amended or interpreted in the future; or if Applicant is determined by 3-A SSI to have made any materially false statement in any application or affidavit; or if Applicant otherwise defaults in any of its obligations under this Agreement, then 3-A SSI may immediately terminate this Agreement, without prejudice to any other rights which 3-A SSI may have.
9. Upon termination of this Agreement for any reason, Applicant shall immediately discontinue the use of the Certificate and shall return the same to 3-A SSI. In addition, 3-A SSI may in its discretion communicate such termination to governmental authorities and others, including via the 3-A SSI web site, and the reasons therefor.
10. This Agreement shall not grant any right or remedy to any person or entity that is not a party to this Agreement.
11. This Agreement shall be interpreted and governed by the laws of the Commonwealth of Virginia. Exclusive jurisdiction for any claim or dispute between the parties resides in federal or State court in Northern Virginia, and the parties agree and expressly consent to the exercise of personal jurisdiction in the Commonwealth of Virginia.
12. This Agreement contains the entire agreement between the parties as to the subject matter referenced herein. No agreement, statements, or representations not herein contained shall have any force and effect.
13. Applicant shall indemnify and hold 3-A SSI harmless for any costs, including judgments, settlements, and attorney's fees, incurred by 3-A SSI in defense of any legal proceeding alleging, in whole or in part, injury caused by any equipment of Applicant.
14. Paragraphs 3, 9, 11, 13 and this paragraph 14 survive termination of this Agreement.

Dated: _____ By: _____
Name of Company

Signature of Authorized Representative

3-A SANITARY STANDARDS, INC.

Dated: _____ By: _____

APPENDIX 3

TPV FORMS AND RELATED DOCUMENTS

THIRD PARTY VERIFICATION REPORT FOR 3-A SYMBOL AUTHORIZATION	
Applicant:	TPV Inspection Date:
	CCE:
	Equipment Type:
Verification Location:	Model Number:
	Serial Number:
	3-A Sanitary Standard:
Applicant/Verification Contact (name and phone number):	3-A Authorization Number:
Type of Verification: <input type="checkbox"/> New Authorization <input type="checkbox"/> Report of Alleged Nonconformance (RAN) <input type="checkbox"/> Renewal Authorization <input type="checkbox"/> Appeal <input type="checkbox"/> Amendment <input type="checkbox"/> Follow-up	
Declaration of Findings: <input type="checkbox"/> Nonconformance (<i>Note: If any "No" items are checked, the "Nonconformance" box shall be marked.</i>) <i>When the "Nonconformance" box is marked, additional statements specifically describing which criteria from the base 3-A Sanitary Standards were not in conformance must be included in the "Observations and Findings" column or on an attached page.</i> <input type="checkbox"/> Conformance I, the undersigned CCE, do hereby certify that the equipment covered by this report has been thoroughly evaluated and complies with all the appropriate criteria of the covering 3-A Sanitary Standards.	
Observations and Findings:	
CCE Signature:	Report Completion Date:
To be completed by 3-A Symbol Administrative Officer:	
Date Received:	Verification Number:
Received By:	
AO office use only File Number:	

SUPPLEMENTAL INFORMATION SHEET FOR SYMBOL AUTHORIZATION

		Yes	No	NA	Observations and Findings
1	3-A Standard No. displayed within Symbol: (XX-XX)				
2	Manual(s)				
	Engineering Design and Technical Construction File (EDTCF)				
3	Copy of current 3-A Sanitary Standard(s) kept on file				
4	Quality control program verified				
5	Rubber certificates reviewed for all rubber parts				
6	Plastic certificates reviewed for all plastic parts				
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					

THIRD PARTY VERIFICATION REPORT FOR 3-A PROCESS CERTIFICATION	
Applicant:	TPV Inspection Date:
Verification Location:	CCE:
	Process:
Applicant/Verification Contact (name and phone number):	3-A Accepted Practice:
	3-A Process Certification Number:
Type of Verification: <input type="checkbox"/> New Certification <input type="checkbox"/> Report of Alleged Nonconformance (RAN) <input type="checkbox"/> Renewal Certification <input type="checkbox"/> Appeal <input type="checkbox"/> Amendment <input type="checkbox"/> Follow-up	
Declaration of Findings: <input type="checkbox"/> Nonconformance: <i>(Note: If any "No" items are checked, the "Nonconformance" box shall be marked.) When the "Nonconformance" box is marked, additional statements specifically describing which criteria from the base 3-A Accepted Practice were not in conformance must be included in the "Observations and Findings" column or on an attached page.)</i> <input type="checkbox"/> Conformance: I, the undersigned CCE, do hereby certify that the equipment covered by this report has been thoroughly evaluated and complies with all the appropriate criteria of the covering 3-A Accepted Practice.	
Observations and Findings:	
CCE Signature:	Report Completion Date:
To be completed by 3-A Process Certification Administrative Officer:	
Date Received:	Verification Number:
Received By:	
AO office use only File Number:	

SUPPLEMENTAL INFORMATION SHEET FOR PROCESS CERTIFICATION

		Yes	No	NA	Observations and Findings
1	Manual(s)				
2	Engineering Design and Technical Construction File (EDTCF)				
	Copy of current 3-A Accepted Practice kept on file				
3	Quality control program verified				
4	Rubber certificates reviewed for all rubber parts				
5	Plastic certificates reviewed for all plastic parts				
6					
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3-A Sanitary Standards, Inc.
6888 Elm Street, Suite 2D
McLean, VA 22101-3829
Phone: (703) 790-0295

REPORT OF ALLEGED NONCONFORMANCE TO A 3-A SANITARY STANDARD

Before you complete this Report:

- ⇒ Be sure to read and follow the instructions attached to this Report Form.
- ⇒ Verify that the equipment maintains a current 3-A Symbol authorization; visit www.3-a.org or look under: <http://www.3-a.org/symbol/holders.htm>.

Type of equipment _____

Applicable 3-A Sanitary Standard _____

Does the equipment display a 3-A Symbol? (Yes/No) _____

Name of Equipment Manufacturer _____

Model and serial no. (If available) _____

The equipment is: NEW _____ MODIFIED _____

Manufacturer's intended cleaning method: Manual _____ COP _____ CIP _____

Other (explain) _____

Date of observation: _____

Location of equipment _____

Business Name

Street

City

State

Zip

AO office use only

File Number:

OBSERVATIONS:

In the space below give specific description of the item(s) of nonconformance. Give the appropriate 3-A Sanitary Standard criteria paragraph, which relates to the non-conformance item(s) in question (All paragraphs in the 3-A Sanitary Standards are clearly numbered). Use additional pages as necessary.

3-A Sanitary Standard Section and Paragraph(s)	Reason for Nonconformance

Person making this report _____ Title _____

Company name _____

Street address _____ City _____ State _____ Zip _____

E-mail address _____ Phone number _____

Date _____ Signature _____

INSTRUCTIONS

The Report of Alleged Nonconformance (RAN) pertains only to equipment that displays a current 3-A Symbol authorization. If you believe equipment in use in the dairy and food industry that displays the 3-A Symbol does not conform to a 3-A Sanitary Standard, report such equipment to 3-A Sanitary Standards, Inc. (3-A SSI). The report must be submitted in writing using this form.

For a detailed description of the RAN program, see Section B6.6 of the *Manual for Third Party Verification (TPV) and 3-A Symbol Authorization* posted on the 3-A SSI web site at www.3-a.org.

Do not submit a RAN for equipment that does not display a 3-A Symbol, even if the manufacturer's literature states "3-A compliance" or "conformance" or otherwise suggests the equipment is eligible to display a Symbol. If you encounter use of the 3-A Symbol or statements asserting conformance to 3-A criteria by a company that is not an authorized 3-A Symbol holder, please inform 3-A SSI and provide samples or other evidence of the potential misuse. 3-A SSI will take appropriate action in all cases of unauthorized 3-A Symbol use or questionable claims.

1. Complete the RAN form.
 - a. Type of equipment: List the type of equipment and confirm that it is covered by the scope of the standard in question.
 - b. 3-A Sanitary Standard: List the most current version of the standard or the version of the standard identified in the Symbol on the equipment.
 - c. Model and Serial Number: If available, list these numbers as it helps to identify if the equipment is covered by the Symbol Authorization.
 - d. Indicate whether the equipment is new or modified: This information helps 3-A SSI determine the responsible party.
 - e. Manufacturer's method of cleaning: This information is necessary to determine which paragraphs of the standard apply.
 - f. Date, Location, Equipment Fabricator: Self-explanatory.
 - g. Display of symbol: Record if the symbol is displayed and if the 3-A Standard number and version is included in the symbol.
 - h. Reference paragraph and observed nonconformance: Complete as many sections as necessary to identify your concerns. Provide the complete description of the exact nature of the alleged non-conformance in the "Observations" section. Be sure to ask the correct question to which you are seeking an interpretation. For example, if you are concerned that a feature of the design does not lend itself to CIP cleaning, the

nonconformance occurs in the paragraph that deals with CIP cleaning not necessarily a more specific paragraph that allows for both CIP and manual cleaning of an individual component. Your comment may be “Does not conform to CIP cleaning as (component) create a non-cleanable crevice when fully assembled.”

NOTE: Do not consider a feature to be in non-conformance if the standard is silent on the issue unless the feature is associated with a “such as” statement. RANs are only appropriate for nonconformance to stated provisions in a specific standard.

2. Send the completed RAN form, with supporting documentation to:

Nate Wall
Director of Standards and Certification Programs
3-A Sanitary Standards, Inc.
6888 Elm Street, Suite 2D
McLean, Virginia, USA 22101-3829
E-mail: nwall@3-a.org
Fax: 703-761-6284

We will acknowledge the receipt of your completed RAN form and investigate your allegation. If we need additional information, or have questions, we will contact you.

Thank you.



3-A Sanitary Standards, Inc.
6888 Elm Street, Suite 2D
McLean, VA 22101-3829
Phone: (703) 790-0295

REPORT OF ALLEGED NONCONFORMANCE TO A 3-A ACCEPTED PRACTICE

Before you complete this Report:

- ⇒ Be sure to read and follow the instructions attached to this Report Form.
- ⇒ Verify that the equipment maintains a current 3-A Symbol authorization; visit www.3-a.org or look under: <http://www.3-a.org/symbol/holders.htm>.

Type of process _____

Applicable 3-A Accepted Practice _____

Does the applicant claim a 3-A Process Certification? (Yes/No) ___

Name of Processor _____

Address of Processor _____

The process is: NEW _____ MODIFIED _____

Manufacturer's intended cleaning method: Manual _____ COP _____ CIP _____

Other (explain) _____

Date of observation: _____

Location of the process _____
Business Name

Street _____ City _____ State _____ Zip _____

AO office use only
File Number: _____

OBSERVATIONS:

In the space below give specific description of the item(s) of nonconformance. Give the appropriate 3-A Accepted Practice criteria paragraph, which relates to the non-conformance item(s) in question (All paragraphs in the 3-A Accepted Practice are clearly numbered). Use additional pages as necessary.

3-A Accepted Practice Section and Paragraph(s)	Reason for Nonconformance

Person making this report _____ Title _____

Company name _____

Street address _____ City _____ State _____ Zip _____

E-mail address _____ Phone number _____

Date _____ Signature _____

INSTRUCTIONS

The Report of Alleged Nonconformance (RAN) pertains only to process that has been granted a 3-A Process Certification. If you believe the process in use in the dairy and food industry that has a 3-A Process Certification does not conform to the applicable 3-A Accepted practice, report such process to 3-A Sanitary Standards, Inc. (3-A SSI). The report must be submitted in writing using this form.

For a detailed description of the RAN program, see Section E of the *Manual for Third Party Verification (TPV) and 3-A Symbol Authorization* posted on the 3-A SSI web site at www.3-a.org.

Do not submit a RAN for a process that has not been granted a 3-A Process Certification, even if the manufacturer's literature states "3-A compliance" or "conformance" or otherwise suggests the equipment is eligible to display a Process Certification. If you encounter use of the 3-A Process Certification or statements asserting conformance to 3-A criteria by a company that is not an authorized 3-A Process Certificate holder, please inform 3-A SSI and provide samples or other evidence of the potential misuse. 3-A SSI will take appropriate action in all cases of unauthorized 3-A Process Certification use or questionable claims.

1. Complete the RAN form.
 - a. Type of equipment: List the type of process and confirm that it is covered by the scope of the accepted practice in question.
 - b. 3-A Accepted Practice: List the most current version of the accepted practice or the version of the accepted practice identified on the Process Certification.
 - c. Indicate whether the process is new or modified: This information helps 3-A SSI determine the responsible party.
 - e. Manufacturer's method of cleaning: This information is necessary to determine which paragraphs of the accepted practice apply.
 - f. Date, Location, Processor: Self-explanatory.
 - g. Granted a 3-A Process certification: Self-explanatory.
 - h. Reference paragraph and observed nonconformance: Complete as many sections as necessary to identify your concerns. Provide the complete description of the exact nature of the alleged non-conformance in the "Observations" section. Be sure to ask the correct question to which you are seeking an interpretation. For example, if you are concerned that a feature of the design does not lend itself to CIP cleaning, the nonconformance occurs in the paragraph that deals with CIP cleaning not necessarily a more specific paragraph that allows for both CIP and manual cleaning of an individual component. Your comment may be "Does not conform to CIP cleaning as (component) create a non-cleanable crevice when fully assembled."

NOTE: Do not consider a feature to be in non-conformance if the accepted practices is silent on the issue unless the feature is associated with a “such as” statement. RANs are only appropriate for nonconformance to stated provisions in a specific standard.

2. Send the completed RAN form, with supporting documentation to:

Nate Wall
Director of Standards and Certification Programs
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We will acknowledge the receipt of your completed RAN form and investigate your allegation. If we need additional information, or have questions, we will contact you.

Thank you.

APPENDIX 4

ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE EXAMPLE



AO office use only File Number:

**3-A SANITARY STANDARDS, INC.
GUIDANCE FOR THE ESTABLISHMENT OF AN
ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE**

The **Engineering Design and Technical Construction File (EDTCF)** is information, which may be assembled from multiple sources, and will be used by the Certified Conformance Evaluator (CCE) as a primary source of verification details during a Third Party Evaluation (TPV). Since each EDTCF is unique to the equipment types manufactured, the amount and types of information present will vary widely.

The following example of an EDTCF, as listed in the 3-A Sanitary Standards Form and Style Manual, Appendix O, (October 2007), is to be maintained by the fabricator as evidence of complying with 3-A Sanitary Standards. The file may contain more or less information as applicable to the equipment or system.

1 Purpose

- 1.1 To establish and document the material, fabrication, and installation (where appropriate) requirements for the engineering design and technical construction files for all products, assemblies, and sub-assemblies supplied by the manufacturer thereof to be in conformance to the sanitary criteria found in 3-A Sanitary Standards. It is recommended that the engineering and construction file be submitted with applications for 3-A Symbol use authorization.

2 Scope

- 2.1 This EDTCF applies to equipment specified by:
 - 2.1.1 3-A Sanitary Standards for {full title}, Number {document number}
 - 2.1.2 List all other applicable 3-A Sanitary Standards
 - 2.1.3 Other referenced documents. List by full title and document number.

3 **Responsibilities**

- 3.1 This EDTCF is maintained by: The Engineering Manager (or other company official) {name and title of responsible official} is responsible for maintaining, publishing, and distributing this EDTCF.
- 3.2 Implementation: All divisions, specifically development engineering, standards engineering, sales engineering, and product departments are responsible for implementing this EDTCF.

4 **Applicability**

- 4.1 The 3-A Sanitary Standards and are voluntarily applied as suitable sanitary criteria for dairy and food processing equipment. 3-A Sanitary Standards are referenced in the Grade A Pasteurized Milk Ordinance: “Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance. They are also required in plants accepted for USDA grading.

5 **References**

- 5.1 List any additional regulations that apply to the equipment or system covered by this EDTCF.
- 5.2 Date of conformity or 3-A Symbol authorization and certificate number, if authorized.

6 **Design and Technical Construction File**

- 6.1 The Engineering Design and Technical Construction File may consist of the following:
 - a. an overall drawing of the subject equipment;
 - b. full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment with the 3-A Standards or 3-A Practices;
 - c. a list of:
 - (1) the essential requirements of the standards or practices;
 - (2) other technical specifications, which were used when the equipment was designed;
 - d. a description of methods adopted;
 - e. if essential, any technical report or certificate obtained from a competent testing body or laboratory;
 - f. any technical report giving the results of tests carried out internally by engineering or others;
 - g. documentation and test reports on any research or tests on components, assemblies and/or the complete product to determine and demonstrate that by its design and construction the product is capable of being installed, put into service, and operated in a sanitary manner (optional);
 - h. a determination of the foreseeable lifetime of the product (optional);
 - i. a copy of the instructions for the product (instruction manuals/instruction books);
 - j. for serial manufacturing, the internal measures that will be implemented to insure that the equipment will continue to be manufactured in conformity with the provisions of the 3-A Sanitary Standards;
 - k. engineering reports;
 - l. laboratory reports;

- m. bills of material;
- n. wiring diagrams, if applicable;
- o. sales order engineering files;
- p. hazard evaluation committee reports, if executed;
- q. change records;
- r. customer specifications;
- s. any notified body technical reports and certification tests;
- t. copy of the 3-A Symbol authorization, if applicable.

6.2 The file does not have to include detailed plans or any other specific information regarding the sub-assemblies, tooling, or fixtures used for the manufacture of the product unless knowledge of them is essential for verification of conformity with the basic sanitary requirements found in 3-A documents.

6.3 The documentation referred to in 6.1 above need not permanently exist in a material manner in the EDTCF, but it must be possible to assemble them and make them available with a period of time commensurate with its importance (one week is considered reasonable time). As a minimum, each product EDTCF must physically contain an index of the applicable document of 6.1 above.

6.4 The EDTCF may be in hard copy or software form.

7 **Confidentiality**

7.1 The EDTCF is the property of the manufacturer and is shown at their discretion, except that all or part of this file will be available to the 3-A Symbol Administrative Officer or a regulatory agency for cause and upon request.

8 **File Location**

8.1 The EDTCF shall be maintained at {location}.

9 **File Retention**

9.1 The EDTCF (including all documentation referred to in 6.1) shall be retained and kept available for twelve (12) years following the date of completion of the TPV inspection and placing the product in use or from the last unit produced in the case of series manufacture.

APPENDIX 5

3-A SSI Fee Schedule and Payment Form



**3-A Sanitary Standards, Inc.
Fee Schedule and Payment Form**

The list of fees and a payment form is available on-line. Payment may be made by credit card or by check in U.S. dollars to 3-A SSI. Payment must accompany the application package to assure prompt processing of the application.

To download the current fees and payment form, use this electronic link [Schedule of Fees and Payment Form](#) or go to www.3-a.org/symbol/fees_payment_form.pdf.

DOCUMENT TRACKING

<u>Action:</u>	<u>Date:</u>
Initial Issuance	January 2003
Incorporation of CCE Recommendations	November 2006
Separation of CCE Certification Criteria and Revision of TPV Checklist	August 1, 2007
Consolidation of separate certifications into Application forms for 3-A Symbol authorization And 3-A Process Certification	December 7, 2007
Modified TPV Report and Supplemental Information pages for 3-A Symbol and 3-A Process Certification. Provisions on Use and Display of 3-A Symbol clarified to specify display of complete 3-A Sanitary Standard and current version in conjunction with the 3-A Symbol. Announces 3-A Symbol in electronic format for licensees.	January 22, 2009
Sections B7.1.4.1 and B7.1.4.2 were revised to stipulate that the CCE must review and authorize all changes and send staff at least a TPV report cover page to authorize Symbol amendments. Added a new section (B7.2.1.2) to provide guidance for fabricator and CCE for TPV inspection of "large/custom" equipment items for when the items are not available for CCE inspection. In Section C2.2.4 clarified that there are now two date blocks on the TPV Report cover page. One is the "TPV Inspection Date" and the other is the "Report Completion Date" both dates must be recorded in the appropriate spaces. Section D2.2.4 was changed accordingly to reflect the two dates now used. A new section (C3.5.1) was added noting that a site visit may not be required for Symbol Authorization amendments or renewals in which the existing authorization does not include equipment changes of sanitary significance. Appendix 2, Exhibit 1 was changed accordingly. Section E1 was revised to require that the TPV report copy sent to 3-A SSI must be accompanied with a cover letter or e-mail explaining the nature of the submission.	April 6, 2009
Section B5.4 was revised to require that equipment must be authorized to use the 3-A Symbol if a 3-A Sanitary Standard exists for that equipment and machinery.	August 9, 2009
Numerous minor editorial revisions made in Section D3.	

B7.1.3.1 revised to clarify that the complete listing of equipment shown in a 3-A Symbol authorization is the equipment that must be re-inspected at least once every five years.

B7.1.4 revised to clarify when the 3-A Symbol holder must submit a TPV inspection in the case of making an amendment.

B7.2 revised to clarify that the TPV anniversary date of record maintained for the licensee is the date of the most recent complete TPV inspection for all equipment included in the authorization.

Section C3.5.1 revised to allow no site visit for an amendment that is not of 'sanitary significance'.

Section E4.5 revised to create new 'Probationary' category in Symbol Holder's list to identify companies subject to an upheld RAN.

September 21, 2009

New Section E4.5.1 added to allow for special conditions on TPV inspection for companies subject to a RAN and corrective actions.

Appendix 2, Exhibit 2, Provisions for the Use and Display of the 3-A Symbol modified to provide non-mandatory display of 3-A Symbol and conditions licensee must observe. Some provisions of previous Appendix 2, Exhibit 3 'Use and Display of the 3-A Symbol' incorporated.

Appendix 2, Exhibit 3, 'Use and Display of the 3-A Symbol' retitled 'Promotion Tips for Use and Display of the 3-A Symbol'.