

3-A Sanitary Standards, Inc.

Manual for Third Party Verification (TPV) for



3-A Symbol Authorization

3-A Process Certification (PC)

&



**3-A Replacement Parts and
System Component Qualification
Certificate (RPSCQC) Programs**

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 (PC) for some 3-A Accepted Practices. The 3-A PC is available to owners of systems who desire to show proof of an independent inspection/verification of a processing system.

In 2015, 3-A SSI approved a new voluntary Replacement Parts and System Component Qualification Certification Program (RPSCQCP). This program is for manufacturers of replacement parts or systems components who desire to show proof that such replacement parts or system components are compatible with the design criteria found in the relevant 3-A Sanitary Standard(s)/ Accepted Practice(s).

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, 3-A Process Certification and Replacement Parts & System Component Qualification 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 to the TPV program should be submitted in writing to:

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A INTRODUCTION

A1 TPV Program Requirements and Limitations

- A1.1 The authorized appearance of a 3-A Symbol on equipment covered by a 3-A Sanitary Standard, a 3-A Process Certificate (PC) for a processing system covered by a 3-A Accepted Practice, or a 3-A Replacement Parts & System Component Qualification Certificate (RPSCQC) for replacement parts or system components covered by multiple 3-A Standards and Accepted Practices indicates verification by a third party that the parts, system components, equipment, or processing system conforms to the applicable 3-A Sanitary Standard or 3-A Accepted Practice. Appearance of the 3-A Symbol, 3-A PC, or 3-A RPSCQC 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.
- A1.2 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.
- A1.3 By issuing the 3-A Symbol, 3-A PC, or 3-A RPSCQC 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, 3-A PC AND RPSCQC

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, Processors to verify conformance to 3-A Accepted Practices and to obtain and maintain use of the 3-A PC and equipment manufacturers of replacement parts and system components to verify conformance to 3-A Sanitary Standard(s) and Accepted Practice(s) and to obtain and maintain the use of the 3-A RPSCQC. 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 3-A Accepted Practices (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 PC upon a successful TPV evaluation of the process. (Refer to Section D for details and guidance for TPV PC procedures and guidance.) Manufacturers of replacement parts and/or system components are not eligible for 3-A Symbol Authorization, but are authorized to display a 3-A RPSCQC upon a successful TPV evaluation of equipment. (Refer to Section E for details and guidance for TPV RPSCQC procedures and guidance.)
- B2.2 3-A SSI is responsible for the policies and the general administration of the TPV, 3-A Symbol Authorization, 3-A PC and 3-A RPSCQC 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 <http://www.3-a.org/3-A-Symbol/Manage-3-A-Symbol-Authorizations-Apply-Renew-Amend>. Information is also available upon request from the 3-A SSI office.

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

B3.1 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, 3-A PC, or 3-A RPSCQC signifies conformance to 3-A Sanitary Standards or 3-A Accepted Practices.

B3.2 3-A Sanitary Standards

B3.2.1 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.

B3.3 3-A Accepted Practices

B3.3.1 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 Authorization

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.
- B4.4 The companies so authorized, also known as 3-A Symbol licensees, agree to observe all provisions of the License Agreement for Use of the 3-A Symbol (Appendix 2, Exhibit 1) and all Provisions for the Use and Display of the 3-A Symbol (Appendix 2, Exhibit 2). 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 (PC)

- B5.1 Use of the 3-A PC program is strictly voluntary. Having a 3-A PC will provide 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.
- B5.1.1 A food processor may apply for a PC for a process, which is covered by a 3-A Accepted Practice, installed in their facility. The PC is for a single site and process.
- B5.1.2 A system design and installation firm or distributor/installer of such systems may apply for a PC for a process design and installation, which is covered by a 3-A Accepted Practice. The PC is for a single process, but is not site-specific.
- 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 Replacement Parts & System Component Qualification Certificate (RPSCQC)

B6.1 Participation in the 3-A SSI RPSCQC Program is voluntary and open to manufacturers of replacements parts or system components. The RPSCQC is beneficial to 3-A Symbol, PC Holders and customers because it affirms that such parts or system components are compatible with the design criteria found in the relevant 3-A Sanitary Standard(s). The RPSCQC is often used use in sales or marketing information.

B6.2 Applicants for a RPSCQC must submit all application materials on-line to 3-A SSI, including all required supporting information and payment. A company executive is required to verify the application, the Certificate of Quality Control, Certification of Conformance, and the 3-A RPSCQC Program Agreement. The applicant shall satisfy the following conditions:

B6.2.1 The applicant shall apply to 3-A SSI and pay a one-time application fee for participation in the program and the annual Certificate fee.

B6.2.2 The applicant shall obtain and submit a full Third Party Verification (TPV) inspection, including a site visit, for the replacement part(s) or system component(s) to be covered by the Certificate.

B6.2.3 The applicant is responsible for obtaining the TPV inspection. The TPV inspection must be conducted by an independent inspection professional credentialed by 3-A SSI, a Certified Conformance Evaluator (CCE).

B6.3 Original Equipment Manufacturers (OEMs) which hold a 3-A Symbol authorization or complete systems manufacturing/installation firms need not participate in this program. OEMs which have been granted a 3-A Symbol Authorization are considered as having met the requirements of this program for all associated replacement parts.

B6.4 Replacement parts include any items intended for use in equipment built in accordance to a 3-A Sanitary Standard, or a processing system covered by a 3-A Accepted Practice. A replacement part covered by its own 3-A Sanitary Standard cannot be eligible for participation in the program; for example, rupture vents are not eligible.

System components are any components that can be supplied that conform to a 3-A Accepted Practice after the components are installed in a processing system.

B6.5 The TPV shall be based on a specific declared base Standard(s) or Accepted Practice(s) (i.e., pumps, fillers, compression valves, Instantizing systems). In the case of a replacement part or system component that can cover multiple Standards or Accepted Practices, all Standards and Accepted Practices must be declared and the replacement part or system component shall meet the most restrictive criteria applicable from the base standard(s).

The 3-A SSI RPSCQC holder must obtain a renewal TPV inspection every five (5) years, similar to the renewal TPV inspection requirement for 3-A Symbol authorization.

B6.6 The Certificate holder shall be eligible to mark the replacement part or system component with the RPSCQC Mark to indicate participation in this program. The RPSCQC Mark is a registered mark owned and administered by 3-A SSI. Use of the RPSCQC Mark is subject to terms and conditions of 3-A SSI. The RPSCQC certificate will bear a complete listing of replacement part or system component types, the models/names, and serial numbers (if appropriate) which have been inspected and the specific 3-A Sanitary Standard(s) or Accepted Practice(s) that were used in the TPV inspection. 3-A SSI will make copies of complete Certificates available on-line for public inspection to help maintain the veracity of Certificates that have been issued.

Use of the Certificate is subject to provisions of the 3-A SSI Agreement which accompanies the application.

B6.7 Applicants shall observe requirements for the accepted commercial use of the 3-A Replacement Parts Symbol in 'Provisions for the Use and Display of the 3-A RPSCQC 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 Replacement Parts & System Component Qualification Certificate.

B6.8 To protect the interests of authorized 3-A RPSCQC licensees and to promote proper display of the RPSCQC Mark, 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 1).

B6.9 While not necessary, an OEM or systems design/installation firm which already possesses a 3-A Symbol Authorization or PC (and has obtained the required TPV inspection), may obtain a 3-A SSI RPSCQC if they desire to satisfy a customer request. The OEM or systems design/installation firm does not need obtain another TPV inspection for the RPSCQC. These companies have already participated in a TPV to verify that all of their component parts or systems, which may be used as replacement parts or system subcomponents, conform to the appropriate 3-A Standard(s) or Accepted Practice(s). Neither is the Certificate of Quality Control necessary to be filed by such applicants. However, the OEM or systems design/installation firm must complete an online application with a complete list of the items to be shown on the Certificate and the required fees. The applicant must also declare acknowledgment and attest to the provisions of the 3-A SSI RPSCQC Program Agreement.

An OEM may utilize the RPSCQC Program as an added quality assurance control step when purchasing component parts from outside suppliers. This arrangement is between the OEM and the supplier and not a requirement of 3-A SSI.

An organization holding a 3-A SSI RPSCQC may state this in its sales or marketing literature. The organization may state that items listed on the Certificate meet the requirements of the applicable provisions of 3 A Sanitary Standard(s) or Accepted Practice(s). 3-A SSI recommends the following declaration:

(Part Names/Models/Numbers, or System Component Names/Models/Numbers) holds a 3-A SSI Replacement Parts and System Component Qualification Certificate and conforms to applicable provisions of (3-A Sanitary Standard # or 3-A Accepted Practice #).

B6.10 Neither 3-A SSI nor its employees “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. Unauthorized use of the 3-A SSI RPSCQC, or improper statements regarding its scope or purpose is not allowed and may result in the discontinuance or revocation of the Certificate and/or other actions determined suitable by 3-A SSI.

Upon revision of the applicable 3-A Sanitary Standard or Accepted Practice, new Certificates, or renewals of Certificates, based upon the 3-A Sanitary Standard or Accepted Practice in effect prior to the revision shall not be valid for replacement parts or system components manufactured after the effective date of the revised 3-A Sanitary Standard or Accepted Practice. Holders of Certificates for replacement parts or system components manufactured after the effective date of the revised 3-A Sanitary Standard or Accepted Practice shall submit the documentation required.

When a holder of a Certificate wishes to modify the design, fabrication, or materials of construction of covered equipment or machinery or system components; or add one or more models conforming to the applicable 3-A Sanitary Standard or Accepted Practice upon which the new or renewal Certificate was predicated, the Certificate may be amended upon online application and approval by the CCE with supported documentation.

Certificates shall expire on the date shown. Each holder of a Certificate shall be notified by 3-A SSI and provided renewal information approximately 90 days prior to the expiration date. The application for renewal of a Certificate shall conform to provisions of the TPV Manual.

A Certificate may be relinquished by the holder.

All completed applications and all other required materials and payment shall be submitted on-line to 3-A SSI.

B7 3-A Symbol Authorization, 3-A PC and RPSCQC Lists

B7.1 The lists of holders of 3-A Symbol Authorizations, 3-A PC and RPSCQC 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 are actively updated through a secure online database.

B8 Policies of the TPV Program

B8.1 3-A Symbol Authorizations

B8.1.1 General information concerning the operation and requirements of the TPV Program is maintained by 3-A SSI on the organization web site at www.3-a.org. This general information includes the application instructions and license agreement for a new symbol or for the renewal or amendment of a current 3-A Symbol Authorization (Appendix 2, Exhibit 1).

B8.1.2 New 3-A Symbol Authorizations

- B8.1.2.1 Application for a new 3-A Symbol Authorization may be made at any time.
- B8.1.2.2 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 1). 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.
- B8.1.2.3 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 1).
- B8.1.2.4 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.
 - B8.1.2.4.1 3-A SSI reserves the right to reject a TPV inspection report. The reason for the rejection may be because of a change in the accreditation or status of the Certified Conformance Evaluator (CCE) who completed the inspection and inspection report, the length of time between the TPV inspection date shown on the report and the date of submission to 3-A SSI, or other reasons that would give 3-A SSI cause for concern about the validity of the inspection report at the time of submission to 3-A SSI for 3-A Symbol authorization.
- B8.1.3 3-A Symbol Authorization or 3-A Process Certification Renewals
 - B8.1.3.1 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 or system included in the 3-A Process Certification (PC), and the date of the most recent TPV inspection report in accordance with Section C of this Manual, TPV Inspection Requirements for 3-A Symbol Authorization and Section D of this Manual, TPV Inspection Requirements for TPV for 3-A PC. 3-A Symbol licensees must obtain a conforming TPV inspection report for all models of equipment included in the 3-A Symbol Authorization or system included in the 3-A Process Certification, at a minimum of once every five (5) years as provided in B8.2. 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.
 - B8.1.3.2 For those Symbol or Process Certification holders that must supply a conforming TPV inspection report for Symbol renewal, the report must be sent to 3-A SSI with their renewal paperwork. If the TPV site visit inspection was performed by the CCE, but if the CCE was unable to issue a conforming report due to issue(s) other than non-conformance (for example, an inability to locate/verify material certifications), the 3-A Symbol Authorization or 3-A Process Certification will be placed in the 'Probationary' category in the 3-A SSI Symbol or 3-A Process Certification Holder's List maintained on the 3-A SSI web site. In this case, the CCE shall notify the 3-A SSI staff of the condition(s) that caused the delay in completing the TPV report. This probationary status will commence on the 3-A Symbol model(s) or Process Certification expiration date and remain in effect until the Symbol or Process Certification holder submits a

conforming TPV report for the models or system covered by the 3-A Symbol Authorization or for a maximum of 90 days. The 3-A Symbol or 3-A Process Certification will be rescinded in situations where a conforming TPV report is not submitted within 90 days after the 3-A Symbol or 3-A Process Certification expiration date.

B8.1.3.3 The CCE is encouraged to review with the applicant ahead of time what items will be required for the completion of the TPV report. The CCE should receive these items ahead of time whenever possible to allow for the timely completion of the TPV report on the inspection date.

B8.1.4 3-A Symbol Authorization Amendments

All 3-A Symbol Authorization holders are required to keep their Certificate 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 non-administrative, simple or minor technical changes. Maintaining a relationship with a CCE can facilitate this process.

B8.1.4.1 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 contact a CCE to arrange for amendment. The CCE may submit 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*.

B8.1.4.2 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 full TPV inspection report may not be required. However, a CCE will need to submit online a TPV cover page and additional pages as necessary to assure that the modification results in continued conformance to the 3-A Sanitary Standard. The 3-A Symbol holder shall submit their application for amendment online.

B8.1.4.3 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.

B8.1.4.4 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 B8.1.3.1.

B8.2 5-year TPV Renewals

B8.2.1 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, or system included in the 3-A Process Certification, except as exempted in B8.2.1.2 for fabricators of large or custom equipment, and only when the large or custom equipment is not present for inspection.

B8.2.1.1 The most recently dated complete TPV inspection report may be from a new Authorization or Process Certification application, an Authorization or Process Certification renewal application, an Authorization or Process Certification amendment application, or a Report of Alleged Nonconformance (RAN) resolution, which affirms the conformance of all equipment or system covered by the Authorization or Process Certification. The TPV report must include an on-site visit and be signed and dated by an authorized CCE. **NOTE:** 3-A Symbol licensees or 3-A Process Certification holders are strongly encouraged to use the available Authorization or Process Certification amendment procedures to keep Authorizations or Process Certification as current as possible.

B8.2.1.2 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 issue a conditional TPV report without performing an on-site inspection or viewing the actual equipment. Before issuing a conditional TPV report, the CCE must perform a thorough review of drawings, materials certifications, and quality control programs to ensure 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. The conditional TPV report must be 'conforming' to allow continued use of the 3-A Symbol Authorization. The 'next TPV inspection due' date will be five years from the date of the conditional TPV report.

B8.2.1.3 When the manufacturer produces the first equipment under the conditional TPV report, a CCE must be contacted for a physical inspection. A final TPV report shall be issued following physical inspection of the manufacturing facility and the first equipment fabricated under the conditional TPV. If only the site visit and physical equipment review are conducted, the final TPV report does not reset the 'next TPV inspection due' date. However, if at the request of the applicant, the CCE performs a full TPV inspection during the site visit, including physical inspection of all models listed on the 3-A Symbol Authorization, review of the EDTCF, the quality control program, and any other items required for a full TPV, a complete TPV inspection report may be issued. In this case, the 'next TPV inspection due' date will be five years from the date of the complete TPV inspection report.

B8.3 3-A PC

B8.3.1 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.

- B8.3.2 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 instructions for a new certification or the renewal or amendment of a current 3-A PC and 3-A PC Program Agreement (Appendix 2, Exhibit 1).
- B8.3.3 New 3-A PC
- B8.3.3.1 Application for a new 3-A PC may be made at any time. Applications are made online through our secured database management platform and via website address: <http://www.3-a.org/3-A-Symbol/Manage-3-A-Symbol-Authorizations-Apply-Renew-Amend>
- After the applicant registers for their online account, they will be required to acknowledge their acceptance of program provisions and make payment. Payment can only be made after the CCE has uploaded all necessary documentation including TPV Report, Supplemental Data Sheet and annotated copy of 3-A Accepted Practice.
- B8.3.4 3-A PC Renewals
- B8.3.4.1 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. **NOTE:** The CCE is encouraged to review with the applicant ahead of time what items will be required for the completion of the TPV report. The CCE should receive these items ahead of time whenever possible to allow for the timely completion of the TPV report on the inspection date. Applicants shall submit the renewal package prior to the anniversary date of their certificate(s).
- B8.3.4.1.1 The annual renewal of the 3-A PC for a food processor requires the submission of the signed affidavit that a change(s) has not been made to the system. The food processor shall keep a log of all changes to the system for review as appropriate by the CCE.
- B8.3.4.2 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.

B8.3.4.3 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.

B8.3.4.4 The application form and materials may be transmitted electronically or hard copy.

B8.3.5 3-A PC Amendments

B8.3.5.1 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 online through our secured database management platform and via website address: <http://www.3-a.org/3-A-Symbol/Manage-3-A-Symbol-Authorizations-Apply-Renew-Amend>

There is no fee for amendments however, the CCE must upload all necessary documentation including TPV Report, Supplemental Data Sheet and annotated copy of 3-A Accepted Practice.

B8.3.5.2 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 E1.3, 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.

B8.4 Used, Repaired and Remanufactured Equipment

B8.4.1 These policies establish procedures for monitoring the continued conformance of used, repaired and remanufactured equipment and machines bearing the 3-A Symbol.

B8.4.2 As new or revised 3-A Sanitary Standards become effective, in-service equipment may continue to display the 3-A Symbol with the applicable 3-A Sanitary Standard version number 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 modification or repair (including replacement of parts) affecting the sanitary aspects of the equipment will require that it meet the current applicable 3-A Sanitary Standard(s). Substantial modifications do not include routine repair and maintenance.

B8.4.3 Used equipment that has been refurbished or repaired and with ownership retained by the original owner shall have the 3-A Symbol Authorization rescinded, unless it is refurbished to conform to the current applicable 3-A Sanitary Standard(s) and has been verified by a TPV inspection prior to being placed back into service. All modifications made are considered to be the responsibility of the user and not the OEM. The TPV report shall serve as documentation that the refurbished equipment remains in conformance.

- B8.4.4 Remanufacturers that specialize in repair and refurbishing of equipment may apply for 3-A Symbol Authorization covered under a specific 3-A Sanitary Standard for such equipment. These firms may purchase used equipment, make modifications and/or repairs and resell it under their own brand or the original OEM brand, or they may take used equipment under contract, make modifications and return it to the original owner.
- B8.4.4.1 Firms which purchase used equipment, make modifications, and/or repairs, and resell it under their own brand or the original OEM brand shall be responsible to assure that the equipment conforms in all aspects to the current applicable 3-A Sanitary Standard. These firms shall meet all of the applicable requirements of the TPV program, including but not limited to, the maintenance of an EDTCF.
- B8.4.4.1.1 If the firm resells the equipment under its own brand, their 3-A Symbol Authorization shall show specific and unique model numbers.
- B8.4.4.1.2 If the firm resells the equipment under the OEM brand, the firm shall indicate the original OEM name and model number, the firm's name, and the letter "R"; for example, "(OEM name)-(OEM model number)-(refurbisher name)-R".
- B8.4.4.1.3 If the firm provides repair or modification of the equipment under contract, follow the guidance under B8.4.3.
- B8.4.5 The 3-A Symbol Authorization shall be deemed void upon any modification to the equipment bearing a 3-A Symbol which renders the equipment noncompliant, or may cause it item to no longer meet the criteria of the most current and applicable 3-A Sanitary Standard(s).
- B8.4.6 All parties engaged in the purchase of used equipment, replacement parts or systems components are encouraged to determine if the equipment or parts intended for purchase conforms to the criteria of the current and appropriate 3-A Sanitary Standard(s) or Accepted Practice(s) (in the case of systems components). One indication of conformance of replacement parts or systems components is participation by the supplier of those parts in the 3-A SSI Replacement Parts and Systems Components Qualification Certificate Program. When discrepancies are observed with a 3-A Sanitary Standard's criteria, a RAN may be completed and sent to 3-A SSI for further investigation.
- B8.4.7 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 F4.

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 a 3-A PC, refer to Section D. For information on TPV inspections related to a 3-A RPSCQC, refer to Section E.

C1 Notice to Applicants

C1.1 3-A SSI shall send notice to 3-A Symbol licensees when a TPV renewal is required as provided in B8.1.3.1.

C2 Format of TPV Report for 3-A Symbol Authorization

C2.1 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.

C2.2 Report Language

C2.2.1 TPV reports shall be prepared using Standard English and typed.

C2.3 Cover Page

C2.3.1 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.

C2.3.2 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."

C2.3.2.1 Applicant: Record the applicant's complete name and mailing address.

C2.3.2.2 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."

C2.3.2.3 TPV Report Completion Date: The TPV Report Completion Date is the date that the CCE completes the site visit, at which time all of the TPV inspection requirements must be satisfied. Review of the equipment drawings, material certifications, quality control programs, etc. can either occur before this date or on this date. The CCE is to enter this date in the designated area in the upper right of the TPV report cover page. 3-A SSI must receive the TPV report within 15 working days of this date.

C2.3.2.4 3-A Sanitary Standard: Record the number and effective date of the covering 3-A Sanitary Standard used for the verification.

- C2.3.2.5 3-A 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.
- C2.3.2.6 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.
- C2.3.2.7 Type of Verification: Place an "X" in the appropriate box.
- C2.3.2.8 Check the appropriate box for the declared method of cleaning and include the equipment model numbers. Only one of the three options below may be checked.
- C2.3.2.8.1 Clean-in-Place Model Number(s): Check this box only if all the model(s) evaluated have been declared by the fabricator to have been designed for CIP cleaning. This applies even if small appurtenances or jumper connections are manually cleaned or utilized. List the model numbers in the space provided. Use additional page(s), if needed. Include the page(s) after the cover page.
- C2.3.2.8.2 Clean-Out-of-Place/Manual Cleaning Model Number(s): Check this box only if all the model(s) evaluated have been declared by the fabricator to have been designed for COP/Manual cleaning. List the model numbers in the space provided. Use additional page(s), if needed. Include the page(s) after the cover page.
- C2.3.2.8.3 Both CIP and COP Model Number(s): Check this box if the models evaluated have a mix of CIP and COP declared cleaning methods. List the model numbers in the space provided. Use additional page(s), if needed. Include the page(s) after the cover page.
- C2.3.3 Observations and Findings: List any information that is germane to the inspection that you feel necessary to convey. You may attach additional page(s), if needed.
- C2.3.4 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.
- C2.3.4.1 To mark the "In Conformance" box, there shall be no "X" marks on the 3-A Sanitary Standard used as the checklist, or in the "No" column of the Supplemental Information Sheet(s). When an "X" mark is made on either the 3-A Sanitary Standard used as the checklist, or in the "No" column of the Supplemental Information Sheet(s), the "Non-conformance" box shall be marked.
- C2.3.4.2 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.

C2.3.5 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.

C2.3.6 CCE Signature: The CCE must sign the report in order for it to be considered official.

C2.3.7 When 3-A SSI receives the typed report, the following information shall be added to the form.

C2.4 Supplemental Information Sheet(s)

C2.4.1 The CCE shall include the supplemental information sheet(s) for Symbol Authorization following the cover page, or if additional page(s) are included after the cover page to list model numbers or observations and/or findings, after those page(s).

C2.4.1.1 The supplemental information sheet(s) for Symbol Authorization shall be completed at least to include the following items:

- a. 3-A Standard No. displayed within Symbol: (XX-XX);
- b. Manual(s);
- c. Engineering Design and Technical Construction File (EDTCF);
- d. Copy of current 3-A Sanitary Standard(s) kept on file;
- e. Quality control program verified;
- f. Rubber certificates reviewed for all rubber parts; and
- g. Plastic certificates reviewed for all plastic parts.

C2.4.1.2 The supplemental information sheet(s) for Symbol Authorization must also include an explanatory comment for each applicable item listed in Section C3.6.

C2.4.1.3 The supplemental information sheet for Symbol Authorization may include other information deemed by the CCE to be appropriate.

C2.5 Verification Checklist Pages

C2.5.1 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.

C2.5.2 Each criteria paragraph in the Scope, 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

C2.5.2.1 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

C2.5.2.2 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

C2.5.3 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.
- C2.5.4 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 product inlet and outlet heat exchange surfaces shall be considered to meet these inspection requirements.

FTS
*

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 amendments or for the issuance of a 'conditional' TPV inspection report per Section B8.2.1.2. 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 3-A Standard's items require an explanatory comment on a "Supplemental Information Sheet" (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 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 Required EDTCF documentation:

- a. Table of Contents (listing all documents within the EDTCF or the locations where the items may be found);
- b. A copy of the 3-A Sanitary Standard to be applied to the subject equipment;
- c. An overall drawing or general arrangement drawing of the subject equipment;
- d. Full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment to the 3-A Sanitary Standard;
- e. If essential, any technical report or certificate obtained from a competent testing body or laboratory;
- f. Instructions for cleaning of the subject equipment or item referenced by the Standard (including a listing, as may be applicable, for all manually cleaned components or appurtenances and the procedures for cleaning of these items. (Example: silo tank door gasket);
- g. Material certifications for all materials of construction included in the equipment;
- h. For serial manufacturing, the internal measures that will be implemented to insure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Sanitary Standard;
- i. Change records; and
- j. Copy of the 3-A Symbol authorization, if applicable.

D TPV FOR 3-A PC

D1 Eligible Applicants

D1.1 This program is intended for use by applicants that utilize a process in conformance with the design, installation, or use criteria of a 3-A Accepted Practice. Applicants are limited to processors of food products and to complete system design and installation firms or distributor/installer for such complete system utilizing the applicable 3-A Accepted Practice.

D1.2 Systems covered by the *3-A Accepted Practice for the Sanitary Construction, Installation, Testing, and Operation of High-Temperature Short-Time and Higher-Heat Shorter-Time Pasteurizer Systems, Number 603-* are not eligible for this program.

D1.3 Fabricators of components of the eligible 3-A Accepted Practice systems may apply for a RPSCQC Mark under the 3-A Sanitary Standards, Inc. Replacement Parts and Systems Component Qualification Certificate Program. They are **not eligible** under the 3-A PC Program, as they do not fabricate complete systems.

D2 Notice to Applicants

D2.1 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.

D3 Format of TPV Report for 3-A PC

D3.1 TPV inspection 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 and associated 3-A Accepted Practice, type of verification, declaration of findings, and the CCE's signature; supplemental pages to document the verification (Appendix 3, Exhibit 2); and the initialed 3-A Accepted Practice used as the checklist. Additional pages are to be included for recording observations as necessary.

D3.2 Report Language

D3.2.1 TPV reports shall be prepared using Standard English and typed.

D3.3 Cover Page

D3.3.1 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.

D3.3.2 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."

D3.3.2.1 Applicant: Record the applicant's (Processor's) complete name and mailing address.

D3.3.2.2 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."

D3.3.2.3 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.

D3.3.2.4 TPV Report Completion Date: The TPV Report Completion Date is the date that the CCE completes the site visit, at which time all of the TPV inspection requirements must be satisfied. Review of the equipment drawings, material certifications, quality control programs, etc. can either occur before this date or on this date. The CCE is to enter this date in the designated area in the upper right of the TPV report cover page. 3-A SSI must receive the TPV report within 15 working days of this date.

D3.3.2.5 CCE: The CCE shall record his/her name.

D3.3.2.6 Process: Record a generic description of the equipment/process verified such as, "Culinary Steam System" or "Filtermat Drier System."

D3.3.2.7 3-A Accepted Practice: Record the number and effective date of the covering 3-A Accepted Practice used for the verification.

- D3.3.2.8 3-A PC 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.
- D3.3.2.9 Type of Verification: Place an "X" in the appropriate box.
- D3.3.2.10 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.
- D3.3.2.10.1 To mark the "In Conformance" box, there shall be no "X" marks on the 3-A Accepted Practice used as the checklist, or in the "No" column of the Supplemental Information Sheet(s). When an "X" mark is made on either the 3-A Accepted Practice used as the checklist, or in the "No" column of the Supplemental Information Sheet(s), the "Non-conformance" box shall be marked.
- D3.3.2.10.2 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.
- D3.3.2.11 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:
- D3.3.2.11.1 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.
- D3.3.2.12 CCE Signature: The CCE must sign the report in order for it to be official.
- D3.3.2.13 When 3-A SSI receives the typed report, the following information shall be added to the form.
- D3.3.2.13.1 Date Received: Record the date received by 3-A SSI.
- D3.3.2.13.2 Received By: Record the name of the individual who received the TPV Report at 3-A SSI.

D3.4 Supplemental Information Sheet(s)

- D3.4.1 The CCE shall include the supplemental information sheet(s) for PC immediately following the cover page, or if additional page(s) are included after the cover page to list observations and/or findings, after those page(s).
- D3.4.1.1 The supplemental information sheet(s) for PC shall be completed at least to include the following items:
- a. Manual(s);
 - b. Engineering Design and Technical Construction File (EDTCF);
 - c. Copy of current 3-A Accepted Practice kept on file;
 - e. Quality control program verified;
 - f. Rubber certificates reviewed for all rubber parts; and
 - g. Plastic certificates reviewed for all plastic parts.
- D3.4.1.2 The supplemental information sheet(s) for PC must also include an explanatory comment for each applicable item listed in Section D4.8.
- D3.4.1.3 The supplemental information sheet for PC may include additional information deemed by the CCE to be appropriate.

D3.5 Verification Checklist Pages

- D3.5.1 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.
- D3.5.2 Each criteria paragraph in the Scope, Materials, Fabrication, Installation (when present), 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

D3.5.2.1 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

D3.5.2.2 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.

N/A

D3.5.3 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.

D3.5.4 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
✱

D4 TPV Procedures for 3-A PC

- D4.1 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.
- D4.2 The TPV conformance inspection for a 3-A PC is to be conducted on the basis of an on-site detailed physical evaluation of an operating system in a processing facility or by reviewing the EDTCF and inspecting available components at a system design and installation firm, utilizing 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 at a processor 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. Items to be evaluated at a system design and installation firm could include, but are not limited to: the EDTCF, materials certifications, design drawings, available components, specifications for purchased components, evaluation of conformance of purchased components, employee training records, employee interviews, fabrication conformance records and quality control records. Also see section D4.8.5.10.
- D4.3 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.
- D4.4 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.

- D4.4.1 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.
- D4.5 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.
- D4.6 The TPV process inspection for a processor is site- and process-specific and applicable to only that location as provided in B7.3.1. The TPV process inspection for a system design and installation firm is process-specific and applicable to only that designated system's design configuration.
- D4.7 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).
- D4.8 The following checklist items require an explanatory comment on the Supplemental Information Sheet for PC (Appendix 3, Exhibit 2) when the criteria are applicable. As necessary, additional pages are to be added in order to clearly describe the observations.
 - D4.8.1 Scope
 - D4.8.1.1 Clearly describe the process under evaluation and verify that all of the associated equipment is included in the scope.
 - D4.8.1.2 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.
 - D4.8.1.3 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.
 - D4.8.2 Metals
 - D4.8.2.1 Cast CF-16F, CF-8 or CF-8m. If used, record the component and the cast grade.
 - D4.8.2.2 Aluminum alloys. If used, record the component and grade.
 - D4.8.2.3 Other recognized 3-A alloy. If used, record the component and the alloy.

- D4.8.2.4 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.
- D4.8.2.5 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.
- D4.8.3 Nonmetals
- D4.8.3.1 Rubber 3-A 18- compliant. If rubber or rubber-like materials are used, record the materials used, and that the certification documentation is available.
- D4.8.3.2 Plastic 3-A 20- compliant. If plastics are used, record the plastics used and that the certification documentation is available.
- D4.8.3.3 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.
- D4.8.3.4 Record the location of rubber or plastic used for special applications.
- D4.8.3.5 Cotton, wool, linen, silk, synthetic fibers, laminates, etc. If used, record the type of material and where the material is used.
- D4.8.3.6 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.
- D4.8.3.7 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.
- D4.8.4 Fabrication
- D4.8.4.1 Lap joints: If used, record where the technique is used, and the use is within the limitations of the 3-A Accepted Practice.
- D4.8.4.2 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.
- D4.8.4.3 Adhesives meets 21 CFR 175. If an adhesive is used, add the statement "Refer to Line 18."
- D4.8.4.4 Coatings. If used, record where the technique is used, and the use is within the limitations of the 3-A Accepted Practice.
- D4.8.4.5 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.

- D4.8.4.6 Record which parts of the process are self-draining or drainable and if they conform to the limitations of the 3-A Accepted Practice.
- D4.8.4.7 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.
- D4.8.4.8 Perforations/screens. If used, record where the materials are used, and the use is within the limitations of the 3-A Accepted Practice.
- D4.8.4.9 Record the type(s) of support(s) provided, e.g., legs, slab mounted, wall mounted, hanging mount, etc.
- D4.8.4.10 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 process, 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:
- D4.8.4.10.1 Required EDTCF documentation:
- a. Table of Contents (listing all documents within the EDTCF or the locations where the items may be found);
 - b. A copy of the 3-A Accepted Practice to be applied to the subject process;
 - c. An overall drawing or general arrangement drawing of the subject process;
 - d. Full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the process to the 3-A Accepted Practice;
 - e. If essential, any technical report or certificate obtained from a competent testing body or laboratory;
 - f. Instructions for cleaning of the subject process equipment or item referenced by the Accepted Practice (including a listing, as may be applicable, for all manually cleaned components or appurtenances and the procedures for cleaning of these items). (Example: silo tank door gasket);
 - g. Material certifications for all materials of construction included in the equipment;
 - h. For serial manufacturing, the internal measures that will be implemented to insure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Accepted Practices;
 - i. Change records; and
 - j. Copy of the 3-A PC, if applicable.

E TPV FOR 3-A RPSCQC

Note: This Section applies only to TPV inspections for 3-A RPSCQC.

For information on TPV inspections related to a 3-A Symbol Authorizations, refer to Section C. For information on TPV inspections related to a 3-A PC, refer to Section D.

E1 Eligible Applicants

Participation in the 3-A SSI Replacement Parts and System Component Qualification Certificate (RPSCQC) Program is open to manufacturers of replacements parts or system components. The RPSCQC is beneficial to certificate holders and customers because it affirms that such parts or system components are compatible with the design criteria found in the relevant 3-A Sanitary Standard(s) or 3-A Accepted Practice(s).

Applicants for a RPSCQC must submit all application materials on-line to 3-A SSI, including all required supporting information and payment. A company executive is required to verify the application, the Certificate of Quality Control, Certification of Conformance, and the 3-A RPSCQC Program Agreement.

Original Equipment Manufacturers (OEMs) which hold a 3-A Symbol authorization or complete systems manufacturing/installation firms need not participate in this program. OEMs which have been granted a 3-A Symbol Authorization are considered as having met the requirements of this program for all associated replacement parts. Complete systems manufacturing/installation firms should not participate in the 3-A process Certificate Program. While not necessary, an OEM or systems design/installation firm which already possess a 3-A Symbol Authorization or Process Certification (and has obtained the required TPV inspection), may obtain a 3-A SSI Replacement Part and System Component Qualification Certificate if they desire to satisfy a customer request. The OEM or systems design/installation firm does not need obtain another TPV inspection for the RPSCQC. These companies have already participated in a TPV to verify that all of their component parts or systems, which may be used as replacement parts or system subcomponents, conform to the appropriate 3-A Standard(s) or Accepted Practice(s). Neither is the Certificate of Quality Control necessary to be filed by such applicants. However, the OEM or systems design/installation firm must complete and return the application form with a complete list of the items to be shown on the Certificate and the required fees. The applicant must also sign and return the 3-A SSI RPSCQC Program Agreement.

The replacement part or system component manufacturer will obtain and submit a full Third Party Verification (TPV) inspection, including a site visit, for the replacement part(s) or system component(s) to be covered by the Certificate. The applicant is responsible for obtaining the TPV inspection. The TPV inspection must be conducted by an independent inspection professional credentialed by 3-A SSI, a Certified Conformance Evaluator (CCE). Replacement parts include any items intended for use in equipment built in accordance to a 3-A Sanitary Standard or a processing system covered by a 3-A Accepted Practice. A replacement part cannot be covered by its own 3-A Sanitary Standard to be eligible for participation in the program; for example, rupture vents are not eligible. System components are any components that can be

supplied that conform to a 3-A Accepted Practice after the components are installed in a processing system.

The TPV shall be based on a specific declared base standard or Accepted Practice (i.e., pumps, fillers, compression valves, instantizing systems). In the case of a replacement part or system component that can cover multiple standards or accepted practices, all standards and accepted practices must be declared and the replacement part or system component shall meet the most restrictive criteria applicable from the base standard(s).

Upon revision of the applicable 3-A Sanitary Standard or Accepted Practice, new Certificates, or renewals of Certificates, based upon the 3-A Sanitary Standard or Accepted Practice in effect prior to the revision shall not be valid for replacement parts or system components manufactured after the effective date of the revised 3-A Sanitary Standard or Accepted Practice. RPSCQC Holders for replacement parts or system components manufactured after the effective date of the revised 3-A Sanitary Standard or accepted practice shall submit the documentation required.

When a Certificate Holder wishes to modify the design, fabrication, or materials of construction of covered equipment or machinery or system components; or add one or more models conforming to the applicable 3-A Sanitary Standard or Accepted Practice upon which the new or renewal Certificate was predicated, the Certificate may be amended upon the filing of an application (or applications by the non-manufacturer and manufacturer(s), supported by pertinent data required).

Certificates shall expire on the date shown. Each holder of a Certificate shall be notified by 3-A SSI and provided renewal information approximately 90 days prior to the expiration date. The application forms for renewal of a Certificate shall conform to provisions of the TPV Manual.

A Certificate may be relinquished by the holder. If such relinquishment is announced by all of the manufacturers of replacement parts or system components for a non-manufacturer, the Certificate non-manufacturer automatically expires.

All completed applications and all other required materials and payment shall be submitted on-line to 3-A SSI.

E2 Notice to Applicants

- E2.1 3-A SSI shall send notice to 3-A RPSCQC Holders when a TPV renewal is required as provided in B8.1.3.1.

E3 Format of TPV Report for 3-A RPSCQC

E3.1 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(s) or Accepted Practice(s) used as the checklist, and supplemental pages to document the verification (Appendix 3, Exhibit 3). Additional pages may be included to record other observations as appropriate.

E3.2 Report Language

E3.2.1 TPV reports shall be prepared using Standard English and typed.

E3.3 Cover Page

The 3-A SSI RPSCQC holder must obtain a renewal TPV inspection every five (5) years, similar to the renewal TPV inspection requirement for 3-A Symbol authorization.

E.3.3.1 Each cover page and supporting page(s) shall refer to only one (1) evaluation. If a TPV inspection encompasses multiple replacement parts or system components which are maintained under different 3-A Sanitary Standards, these parts and components should be so identified to the conforming Standard(s) and or Accepted Practice(s).

E3.3.2 The CCE shall complete all of the information blocks on the TPV report cover page.

E3.3.2.1 Applicant: Record the applicant's complete name and mailing address.

E3.3.2.2 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."

E3.3.2.3 TPV Report Completion Date: The TPV Report Completion Date is the date that the CCE completes the site visit, at which time all of the TPV inspection requirements must be satisfied. Review of the equipment drawings, material certifications, quality control programs, etc. can either occur before this date or on this date. The CCE is to enter this date in the designated area in the upper right of the TPV report cover page. 3-A SSI must receive the TPV report within 15 working days of this date.

E3.3.2.4 3-A Sanitary Standard(s): Record the number and effective date of the covering 3-A Sanitary Standard(s) used for the verification.

E3.3.2.5 3-A Accepted Practice(s): Record the number and effective date of the covering 3-A Accepted Practice(s) used for the verification.

- E3.3.2.6 3-A Certificate Number: Record the 3-A Certificate number from the applicant's current 3-A Certificate. For a new 3-A Certificate, a number will be assigned by 3-A SSI.
- E3.3.2.7 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.
- E3.3.2.8 Type of Verification: Place an "X" in the appropriate box.
- E3.3.2.9 Observations and Findings: List any information that is germane to the inspection that you feel necessary to convey. You may attach additional page(s), if needed.
- E3.3.2.10 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.
- E3.3.2.11 To mark the "In Conformance" box, there shall be no "X" marks on the 3-A Sanitary Standard used as the checklist, or in the "No" column of the Supplemental Information Sheet(s). When an "X" mark is made on either the 3-A Sanitary Standard used as the checklist, or in the "No" column of the Supplemental Information Sheet(s), the "Non-conformance" box shall be marked.
- E3.3.2.12 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.
- E3.3.2.13 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.
- E3.3.2.14 CCE Signature: The CCE must sign the report in order for it to be considered official.
- E3.3.2.15 When 3-A SSI receives the typed report, the following information shall be added to the form.

E3.4 Supplemental Information Sheet(s)

- E3.4.1 The CCE shall include the supplemental information sheet(s) for the RPSCQC following the cover page, or if additional page(s) are included after the cover page to list model numbers or observations and/or findings, after those page(s).
- E3.4.1.1 The supplemental information sheet(s) for the RPSCQC shall be completed at least to include the following items:
- a. Manual(s);
 - b. Engineering Design and Technical Construction File (EDTCF);
 - c. Copy of current 3-A Sanitary Standard(s)/Accepted Practice(s) kept on file;
 - d. Quality control program verified;

- e. Rubber certificates reviewed for all rubber parts; and
 - f. Plastic certificates reviewed for all plastic parts.
- E3.4.1.2 The supplemental information sheet(s) for RPSCQC must also include an explanatory comment for each applicable item listed in Section C3.6.
- E3.4.1.3 The supplemental information sheet for Symbol Authorization may include other information deemed by the CCE to be appropriate.

E3.5 Verification Checklist Pages

- E3.5.1 The CCE shall use a full copy of the 3-A Sanitary Standard(s)/Accepted Practice(s) identified on the cover page as the base standard for the inspection. A copy of the marked up Standard(s)/Accepted Practice(s) 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(s)/Accepted Practice(s) except as described in this section.
- E3.5.2 Each criteria paragraph in the Scope, 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.
- E3.5.2.1 If the evaluation indicates the equipment is in nonconformance with the criteria, the paragraph shall be initialed and indicated by an “**X**”.
- E3.5.2.2 If the evaluation indicates the paragraph is not applicable; it shall be initialed and indicated by an “**N/A**.”
- E3.5.3 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(s)/Accepted Practice(s) to which the comment refers and clearly documents 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.
- E3.5.4 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*.

E4 TPV Procedures for 3-A RPSCQC

- E4.1 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.
- E4.2 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)/Accepted Practice(s). The CCE shall conduct the verification at a pace to assure all components are carefully evaluated against the 3-A Sanitary Standard(s)/Accepted Practice(s) criteria. 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.
- E4.3 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.
- E4.4 The CCE is to verify that the applicant has a written quality control procedure with documentation to assure conformance to the 3-A Sanitary Standard(s)/Accepted Practice(s).
- E4.5 The CCE shall perform an on-site evaluation at the applicant's manufacturing/fabrication or assembly location where the complete, assembled item identified for 3-A RPSCQC is available.
- E4.6 The following items require an explanatory comment on a "Supplemental Information Sheet" (Appendix 3, Exhibit 3) when the criteria are applicable. As necessary, additional pages are to be added in order to clearly describe the observations.
- E4.6.1 Scope
- E4.6.2 Metals
- E4.6.2.1 Cast CF-16F, CF-8 or CF-8m. If used, record the component and the cast grade.
- E4.6.2.2 Other recognized alloy. If used, record the component and the alloy.
- E4.6.2.3 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.
- E4.6.2.4 Gold or silver solder. If used, record the type of solder, and that the certification of conformance (silver solder only) is available.
- E4.6.3 Nonmetals

- E4.6.3.1 Rubber 3-A 18- compliant. If rubber or rubber-like materials are used, record the materials used, and that the certification documentation is available.
- E4.6.3.2 Plastic 3-A 20- compliant. If plastics are used, record the plastics used and that the certification documentation is available.
- E4.6.3.3 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.
- E4.6.4 Fabrication
 - E4.6.4.1 Adhesives meets 21 CFR 175. If an adhesive is used, add the statement “Refer to Materials paragraph ____.”
 - E4.6.4.2 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:
 - E4.6.4.3 Required EDTCF documentation:
 - a. Table of Contents (listing all documents within the EDTCF or the locations where the items may be found);
 - b. A copy of the 3-A Sanitary Standard(s)/Accepted Practice(s) to be applied to the subject equipment;
 - c. An overall drawing or general arrangement drawing of the subject equipment;
 - d. Full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment to the 3-A Sanitary Standard(s)/Accepted Practice(s);
 - e. If essential, any technical report or certificate obtained from a competent testing body or laboratory;
 - f. Instructions for cleaning of the subject equipment or item referenced by the Standard(s)/Accepted Practice(s).
 - g. Material certifications for all materials of construction included in the equipment;
 - h. For serial manufacturing, the internal measures that will be implemented to insure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Sanitary Standard(s)/Accepted Practice(s);
 - i. Change records; and
 - j. Copy of the RPSCQC certificate, if applicable.

F TPV REPORT SUBMISSION AND DISPUTE RESOLUTION

F1 TPV Report Submission

F1.1 Upon completion of the TPV inspection, the CCE shall provide the applicant with one signed original final report. Within 15 working days the CCE is to send a copy of the TPV report to 3-A SSI using the online CCE Portal. The CCE is encouraged to retain one copy and any notes taken during the evaluation.

F1.2 TPV Report of Conformance

F1.2.1 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 and the CCE shall submit the final TPV inspection report to 3-A SSI using the online CCE Portal within 15 working days.

F1.3 TPV Report of Non-Conformance

F1.3.1 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.

F1.3.1.1 New Authorization Applications

F1.3.1.1.1 If the applicant chooses to correct the non-conforming element(s), they may contract with the CCE to conduct a follow-up inspection 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, following the procedures described above. Within 15 working days the CCE is to send a copy of the conforming TPV inspection report to 3-A SSI via online CCE Portal.

F1.3.1.1.2 If the applicant chooses not to correct the non-conforming element(s), a copy of the report is provided to the applicant. Additionally, within 15 working days a copy is sent by the CCE to 3-A SSI for information purposes only.

F1.3.1.1.3 The flowchart showing TPV Inspection Procedures for New Applicants is shown in Chart 1.

F1.3.1.2 Renewal Applications

F1.3.1.2.1 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.

F1.3.1.2.2 Renewal applicants found to be in non-conformance will immediately have their Symbol revoked. If within six months the CCE and applicant submits a conforming TPV inspection report and the applicant submits the required renewal fee, the Symbol will be reinstated. If more than six months have elapsed since the receipt of the non-conforming TPV inspection report, an application for a new 3-A Symbol with the

appropriate fee and a new and conforming TPV inspection report must be submitted to 3-A SSI if the applicant desires a 3-A Symbol.

F1.3.1.2.3 The flowchart showing TPV Inspection Procedures for Renewal Applications is shown in Chart 2.

**Chart 1
TPV Inspection and Application Procedures
For New Applicants**

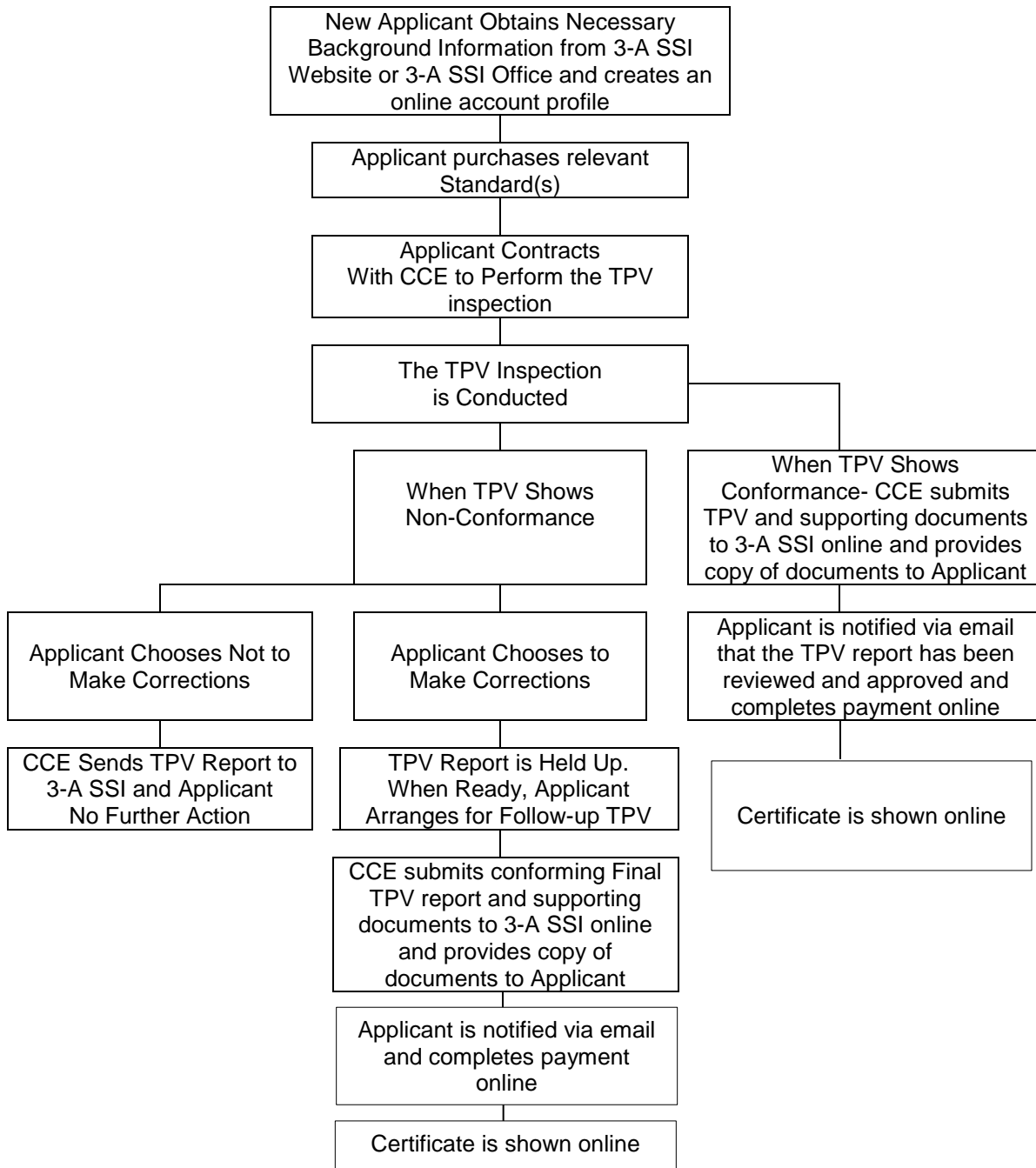
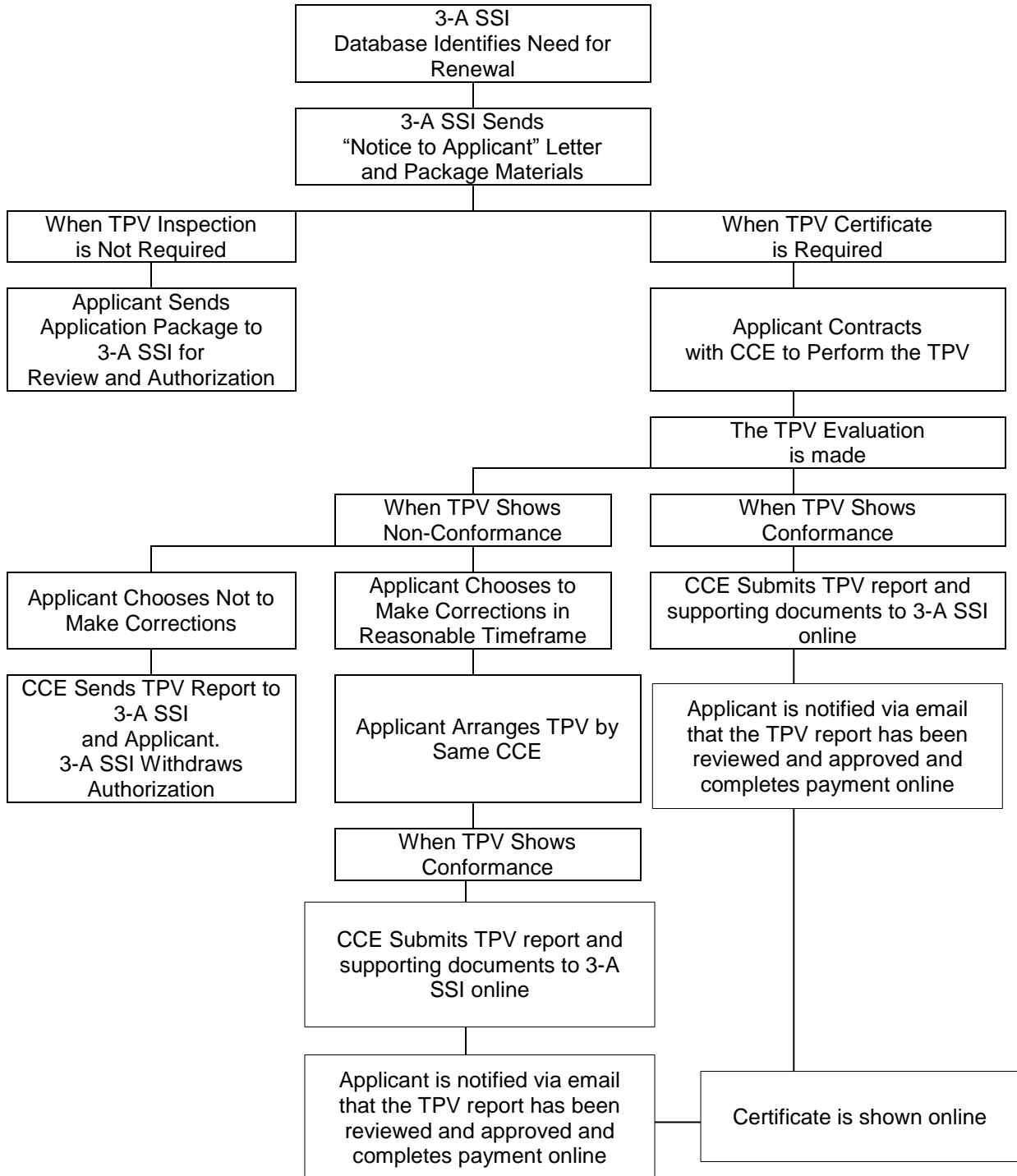


Chart 2

TPV Inspection and Application Procedures For End-of-year Renewal Applications



F1.4 TPV Report Associated with a RAN

F1.4.1 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;
- Within 15 working days of report issuance, send 3-A SSI a copy of the final follow-up report; and
- Retain a copy of the final follow-up report.

F2 Dispute Resolution

F2.1 The flowchart showing the TPV Dispute Review Procedures is shown in Chart 3.

F2.1.1 Interpretation Group (IG)

F2.1.1.1 Refer to *3-A SSI Procedures for the Development of 3-A Sanitary Standards and Accepted Practices*

F3 Dispute of a TPV Inspection Report

F3.1 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.

F3.1.1 Applicant's Rights and Procedures

F3.1.1.1 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.

F3.1.2 TPV Dispute Resolution

F3.1.2.1 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.

F3.1.2.2 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.

F3.1.2.3 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.

F3.1.2.3.1 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.

F3.1.2.3.2 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.

F3.1.3 3-A SSI Response to a TPV Report Dispute Resolution

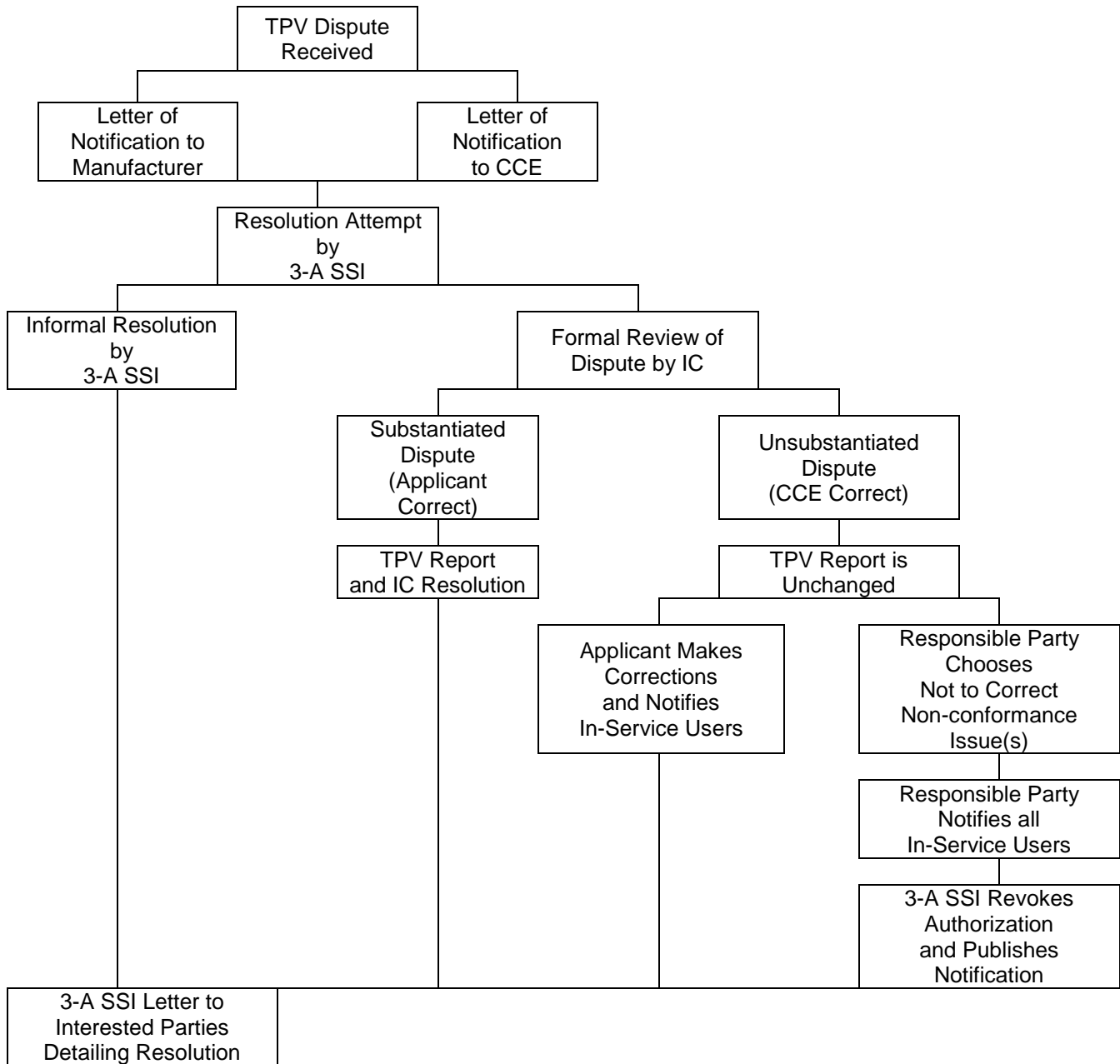
F3.1.3.1 Upon completion of the TPV Report Dispute Resolution Process, if a RAN is upheld, 3-A SSI and the TPV Coordinating Committee will be required to evaluate whether the RAN was the result of the CCE's failure to administer their responsibilities properly under the TPV program. If the evaluation 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



F4 Reports of Alleged Non-Conformance (RANs)

- F4.1 RANs may be submitted only on equipment which bears a valid 3-A Symbol authorization, a process covered by a valid 3-A PC, or equipment covered by a valid 3-A RPSCQC and an interested party believes there is a non-conformance issue with the equipment or the process.
- F4.1.1 The equipment of concern shall display the 3-A Symbol, as stated above, and the manufacturer of the equipment shall be current in their authorization status. The equipment shall be in actual commercial use, in a commercial channel of sale or distribution, or be presented by the fabricator as all of individual parts representing a complete unit.
- F4.1.2 The process of concern shall be installed in a processing facility and be in use or staged for commissioning.
- F4.2 The flowchart showing the Procedure for Reporting of Alleged Non-conformance is shown in Chart 4.
- F4.3 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, a process certified to a 3-A PC, or equipment certified to a 3-A RPSCQC 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 4 and 5, as applicable.
- F4.3.1 The RAN report will be considered by 3-A SSI upon receipt of the RAN, provided it contains all the information listed below:
1. Type of the equipment, machinery, or processor;
 2. Model Number or designation, or certified process (required);
 3. Serial Number (if available);
 4. Title of applicable 3-A Standard(s) or 3-A Accepted Practice;
 5. Authorization Number or PC Number;
 6. Address of the physical location where the observations were made (phone and fax numbers when available), except as described in section F4.3.2;
 7. Name, address, phone and fax numbers, and email address of contact individuals at the processing facility or the equipment manufacturer or process installer.
 8. Date of the observations;
 9. Specify if the equipment is new or has been modified;
 10. Specify the manufacturers intended method of cleaning;
 11. Specific criteria and wording from the applicable Standards or Accepted Practice for which conformance is not met. Detailed description of the observations, with supporting quantitative measurements (whenever possible), and the reason or rationale used to determine nonconformance; and
 12. Any other information the RAN submitter deems pertinent to the RAN.

- F4.3.2 When the submitter of a RAN is working for a client and has a Non-disclosure Agreement (NDA) in place, the submitter shall inform their client that an issue of nonconformance has been observed and that a RAN report must be filed. The submitter and the client shall mutually agree how to present the appropriate information required by F4.3.1 in the RAN report within the parameters of the NDA.
- F4.4 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 of the allegation(s). The manufacturer (including the installer(s) if appropriate) and/or user are to respond within ten (10) days to the 3-A SSI inquiry. Following the response from the manufacturer and/or user, 3-A SSI will investigate the validity of the allegation(s) and determine the responsible parties. 3-A SSI will seek the guidance and concurrence of the Chair of the 3-A Steering Committee and the Chair of the TPV Coordinating Committee on any aspect of the investigation of the allegations or the informal resolution.
- F4.5 3-A SSI will prepare an Informal RAN Resolution Proposal to seek resolution of observations which are not the result of differences of interpretation of the standard's or accepted practices' criteria. The Informal RAN Resolution Proposal acknowledgement shall be returned to 3-A SSI within 20 working days.
- F4.5.1 In the case of a multiple criteria RAN, the RAN submitter and the equipment manufacturer or installer (if they are the symbol holder), processor, or responsible party are obligated to accept or reject each individual proposal of the resolution.
- F4.5.2 Each refused proposal will require a specific, objective justification as to why it is inappropriate. No additional nonconformance issues, that were not part of the original RAN, can be added as part of the justification comments. (Any new nonconformance issue may be submitted as a new RAN.)
- F4.6 RAN observations which are not resolved by the informal resolution process and which are clear differences of interpretation of the standard or accepted practice as written will be forwarded to the 3-A SSI interpretations Group (IG) for resolution. The decisions of the IG are final and not subject to appeal.
- F4.7 Resolution of the RAN must be completed as timely as possible upon its receipt by 3-A SSI dependent upon the availability of the parties involved and the time necessary for 3-A SSI to properly investigate the allegations.
- F4.7.1 If the equipment manufacturer is determined to be the responsible party, they shall notify all purchasers of record of the in-service equipment sold. The notification shall include all units of equipment sold since the date of the last TPV inspection report documenting conformance. In addition, the equipment manufacturer shall keep 3-A SSI informed.
- F4.7.1.1 The manufacturer, when the subject of an upheld RAN, must be able "demonstrate" that they did notify customers of record (since the last TPV inspection) about the nonconformance, and if the manufacturer cannot prove that the customers of record were notified (or if 3-A SSI discovers that the customers were not notified), 3-A SSI may take "additional action" against the Symbol holder.

- F4.7.2 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, Process or RPSCQC Certificate.
- F4.8 Failure to provide complete information as requested by 3-A SSI within 20 working days by the RAN submitter will result in the RAN submission being cancelled due to lack of participation by the nonresponsive participant.
- F4.9 Failure to provide complete information requested by 3-A SSI within 20 working days by the responsible party identified for the equipment or process will result in the 3-A Symbol Authorization, 3-A PC or 3-A RPSCQC being rescinded.
- F4.9.1 The revocation of a 3-A Symbol Authorization, 3-A Process or RPSCQC Certificate, or non-renewal of either, will require a TPV Report of Conformance to be submitted with any future application for the equipment or process.
- F4.10 Any resolution shall include a documented plan of corrective action, mutually-agreed-upon by 3-A SSI and the responsible party of the confirmed nonconformance. The corrective action plan shall include scheduling of the corrective action(s) and be communicated to the interested parties.
- F4.10.1 If the equipment manufacturer is determined to be the responsible party;
- The 3-A Symbol Authorization, Process or RPSCQC Certification will immediately be placed in the category 'Probationary' in the 3-A SSI Symbol Holders' List maintained on the 3-A SSI web site. The 3-A Symbol or Certificate holder will remain in the category 'Probationary' until the plan for corrective action is completed.
 - The corrective action plan shall include scheduling of any necessary confirming TPV evaluation,
 - A plan to notify purchasers of record (since the last TPV inspection) of the non-conformance and what actions they need to take. This plan can be demonstrated by submitting a copy of any notification letter or email and a listing of the recipients to 3A SSI.
 - It is acknowledged that the full resolution of the nonconformance may require the production and installation of replacement parts, and the time-frame to accommodate the completion of all necessary actions shall be scheduled within the agreed upon corrective action plan.
 - If a corrective action plan or notification of purchasers of record is not implemented, the Symbol Authorization, Process or RPSCQC Certificate will be withdrawn.
- F4.10.2 If the processor is determined to be the responsible party;
- The corrective action plan shall include scheduling of any necessary evaluation confirming the equipment has been returned to full conformance. This inspection may be conducted and documented in writing by a 3-A SSI CCE, or state or Federal inspection agency.

- The time-frame to accommodate the completion of all necessary actions shall be scheduled within the agreed upon corrective action plan.
- If a corrective action plan or documented inspection is not implemented, the Symbol Authorization, Process or RPSCQC Certificate for that specific piece of equipment will be withdrawn and the appropriate regulatory inspection agencies will be notified.

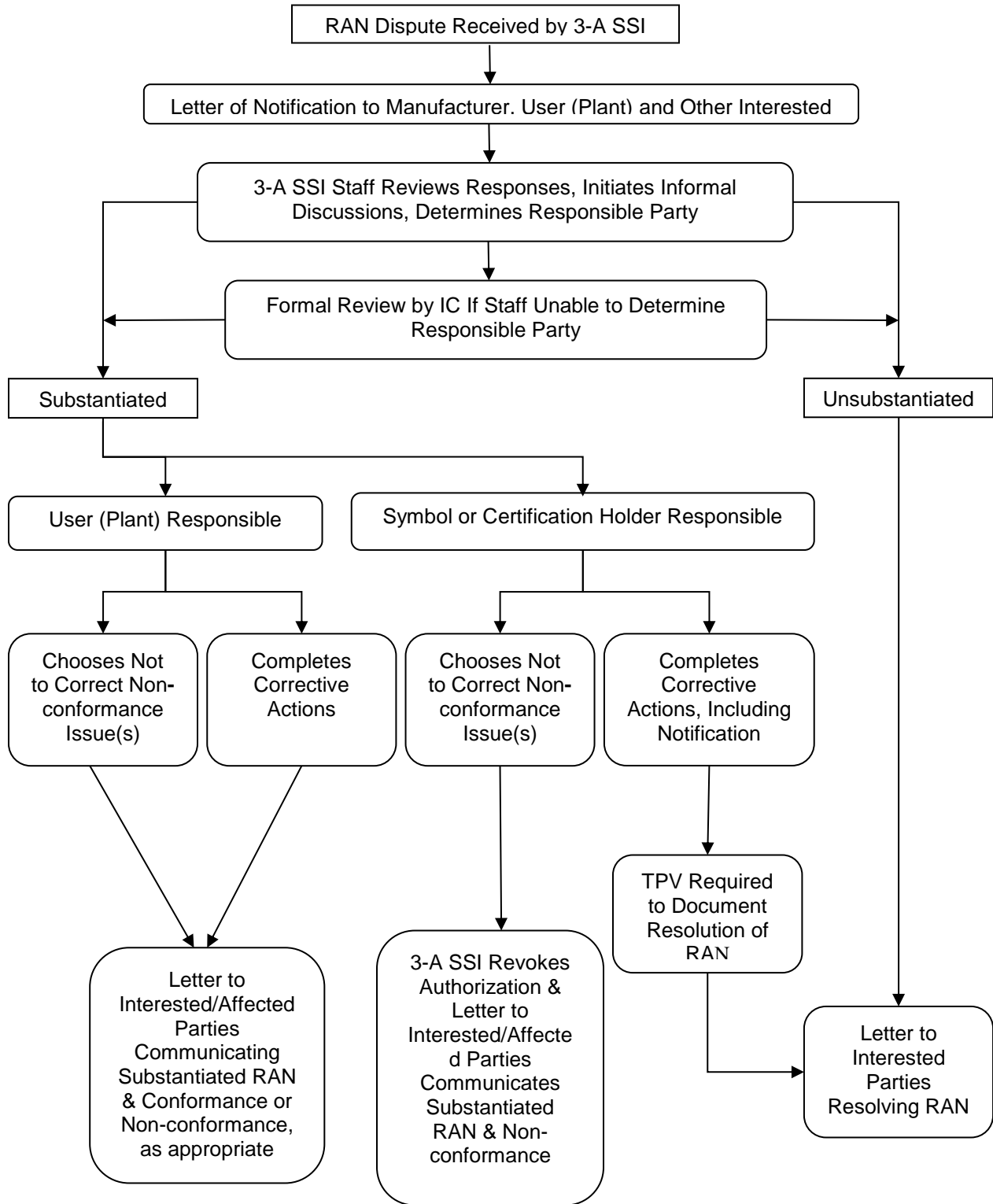
F4.11 3-A SSI reserves the right to place special conditions on the TPV inspection requirements for the holder of a 3-A Symbol Authorization, Process or RPSCQC Certificate which has been the subject of a RAN and corrective actions. These special conditions include, but are not limited to, the requirement 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, Process or RPSCQC Certificate.

F4.12 If the responsible party, either the equipment manufacturer or processor, 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, Process or RPSCQC Certificate on that piece of equipment is no longer sanctioned.

F4.13 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. A TPV evaluation is required to substantiate that non-conformance issues have been corrected. The new TPV establishes a new TPV cycle date.
4. When a non-conformance is substantiated and the responsible party chooses not to resolve the issue(s), 3-A SSI will revoke the 3-A Symbol Authorization, 3-A PC or RPSCQC.
5. Publish, when appropriate, non-renewed authorizations/ certifications on the 3-A SSI web site.
6. If the revocation of a 3-A Symbol, 3-A PC or RPSCQC use is for nonconforming design, process installation and implementation, or serial manufacture quality control reason, publish as in item 5.
7. When a substantiated RAN is due to 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 Authorization, PC or RPSCQC is revoked, the applicant will be required to send 3-A SSI a letter confirming that the use of the 3-A Symbol, 3-A PC or RPSCQC has been discontinued.
10. When a RAN is upheld, 3-A SSI will investigate to determine if the error was attributable to the original CCE's oversight or lack of knowledge. If this is found to be the case, the procedures identified in Section F3.1.3 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. The 3-A Symbol Council is no longer active and has disbanded.
- H3 **Administrative Officer (AO):** The person(s) that is/are 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) inspections for conformance of equipment, machinery and processes to 3-A Sanitary Standards and Accepted Practices 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 at 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, or process is in conformance to applicable 3-A Sanitary Standard or Accepted Practice. 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 Processing Suppliers Association (FPSA):** A trade association whose members are capital equipment and ingredient suppliers. FPSA is a Founding Member of 3-A SSI and represents the capital equipment stakeholders. Formerly known as the International Association of Food Industry Suppliers (IAFIS).
- H15 **Food Protection Trends (FPT):** A food safety related journal published by the International Association for Food Protection (IAFP).

- H16 **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)
- H17 **Inspection:** The process of measuring, examining, testing, gauging or otherwise comparing the unit with the applicable requirements. (ASQC)
- H18 **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.
- 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 Group (IG):** 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 **Report of Alleged Nonconformance (RAN):** This is a provision for reporting perceived non-conformance items. (Refer to Section F4.)
- H28 **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)
- H29 **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)
- H30 **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).
- H31 **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.
- H32 **Verification:** The process of determining whether implementation is in conformance to some specific Standard(s) and/or specification(s). (IEEE)
- H33 **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, 3-A PC AND 3-A RPSCQC APPLICATION AND RELATED DOCUMENTS*

*All TPV forms contained in this manual are examples only and may not represent the most current version.

Instructions for New, Renewals or Amendments to 3-A Symbol Authorizations, RPSCQC and Process Certificates

3-A SSI has implemented a new management database platform, which requires all new applicants to register an account through our 3-A website. This database provides 3-A SSI, CCE and applicant real-time usability and functionality. Information is stored securely and is made available to both the applicant and appropriate CCE to ensure accuracy and real-time updates.

Instructions for New Applicants:

To sign in or register your new company account:

1. Navigate to the 3-A website at <http://www.3-a.org/>
2. Click on **Sign In** in the upper right corner
3. Enter your Username and Password
4. Click **Sign In**

If you are not registered, click on **Register Now!** Follow the steps, and you will be sent an email with instructions for setting your username and password. If you forget your username or password, click on **Can't access your account?**, enter your username or email address and click on **Reset Password**. You will receive an email with instructions for resetting your credentials.

Sign In

Sign in below if you have a website account.

 Remember me next time

[Can't access your account?](#)

Not Registered?
Don't have an account for 3A website? Create one in just a few simple steps. [Register Now!](#)

► Sign into the 3-A website. The **Sign In** link will be replaced with **My Account**. Click on the link and choose **Manage My Account**. The information you provided when registering will be displayed.

1. Click on **Create/Affiliate with Company**
2. Enter your company name into the Search Wizard and click on **Find Company**. If your company does not yet exist in the 3-A database, click on **Create New Company** and enter your company's information. Click **Create Company**

When your Certified Conformance Evaluator (CCE) has completed his Third Party Verification (TPV) report, he will search for your company and will upload the report and accompanying documents. You will be sent notice of approval by 3-A.

- Upon notice of your TPV's approval, sign into your account on the 3-A website
1. Click on the **3-A Symbol Tab** and choose **Manage 3-A Symbol Authorizations**
 2. Click on the blue magnifying glass next to your Certificate order and confirm that the information in the Address, Contact and Total fees is correct. You will be required to check the box affirming that you have read the terms and conditions related to your new Certificate, and that no changes have been made to your equipment
 3. **Click on Submit & Pay!** Your Certificate fees will be transferred to the shopping cart
 4. Click on the **Cart** link in the upper right corner of the homepage. Confirm that the items in your cart and your name and address and email are correct
 5. Choose **Payment Method** and fill in your credit card information and purchase order number (P.O.) if applicable
 6. Click **Submit Payment**

You will be emailed a receipt and your Certificate will now be live and valid through December 31st of the current year. Please also note your next TPV date and plan to schedule and inspection with a 3-A CCE prior to its expiration in five years.

Sign into the 3-A website. The **Sign In** link will be replaced with **My Account**. Click on the link and choose **Manage My Account**. The information you provided when registering will be displayed.

3. Click on **Create/Affiliate with Company**
4. Enter your company name into the Search Wizard and click on **Find Company**. If your company does not yet exist in the 3-A database, click on **Create New Company** and enter your company's information
5. Click **Create Company**

When your Certified Conformance Evaluator (CCE) has completed his Third Party Verification (TPV) report, he will search for your company and will upload the report and accompanying documents. You will be sent notice of approval by 3-A.

- ▶ Upon notice of your TPV's approval, sign into your account on the 3-A website
 7. Click on the **3-A Symbol Tab** and choose **Manage 3-A Symbol Authorizations**
 8. Click on the blue magnifying glass next to your Certificate order and confirm that the information in the Address, Contact and Total fees is correct. You will be required to check the box affirming that you have read the terms and conditions related to your new Certificate, and that no changes have been made to your equipment
 9. **Click on Submit & Pay!** Your Certificate fees will be transferred to the shopping cart
 10. Click on the **Cart** link in the upper right corner of the homepage. Confirm that the items in your cart and your name and address and email are correct
 11. Choose **Payment Method** and fill in your credit card information and purchase order number (P.O.) if applicable
 12. Click **Submit Payment**

You will be emailed a receipt and your Certificate will now be live and valid through December 31st of the current year. Please also note your next TPV date and plan to schedule and inspection with a 3-A CCE prior to its expiration in five years.

To apply for an amendment to a current Symbol Authorization

Contact your company's-authorized 3-A SSI CCE.

Note: Applicants will be asked to acknowledge they have read and agree to the Declaration of Applicant (and License Agreement and Provisions For Use Of The 3-A Symbol if a 3-A Symbol Authorization Application) as follows:

DECLARATION OF APPLICANT

The Applicant hereby declares and attests that: (1) the equipment listed herein conforms in all respects to provisions of the applicable, currently effective, 3-A Sanitary Standard(s)/ 3-A Sanitary Standard(s); (2) all information and assertions in the application, as well as the Certification of Quality Control and the Certification of Conformance, are true, accurate, and complete; (3) the Applicant agrees to the provisions of the License Agreement for Use of the 3-A Symbol and Provisions for Use and Display of the 3-A Symbol; and (4) the person submitting this Declaration is authorized to act for, and legally bind, the Applicant. 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 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:

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 *Provisions for Use and Display of the 3-A Symbol* and other 3-A SSI rules and procedures, as amended from time to time, including the timely payment of licensing fees, any late fees or similar charges that may be assessed, and provisions of the Third Party Verification program for 3-A Symbol authorization.
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 at the end of the calendar year or at the end of the month in which a required TPV report is due. 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 SSI 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

1. General Requirements

The 3-A Symbol is authorized for use on equipment and in conjunction with the marketing of such equipment and machinery that meets the requirements of published 3-A Sanitary Standards, subject to the 3-A SSI License Agreement and these Provisions for the Use and Display of the 3-A Symbol.

- 1.1. Special Provisions for Use and Display of the 3-A Symbol for Authorizations under Standards 18- and 20-.

This special provision applies to licensees holding 3-A Symbol authorization(s) under 3-A Sanitary Standards 18-, *Multiple-use Rubber and Rubber-like Materials* and 20-, *Multiple-use Plastic Materials*.

A licensee under Standards 18- and 20- must restrict symbol use to printed materials accompanying the product or other acceptable written uses, such as a web site. Items (parts) made from the compliant rubber or plastic must not bear the 3-A Symbol. This is because Standards 18- and 20- are 3-A sanitary materials, i.e. compositional standards, and not standards for the design of a finished type of equipment or component. Including the 3-A Symbol on plastic or rubber items made with compliant material is not allowed because it implies the finished item is covered by an equipment standard, which is not the case.

2. Elective Use and Display of the 3-A Symbol

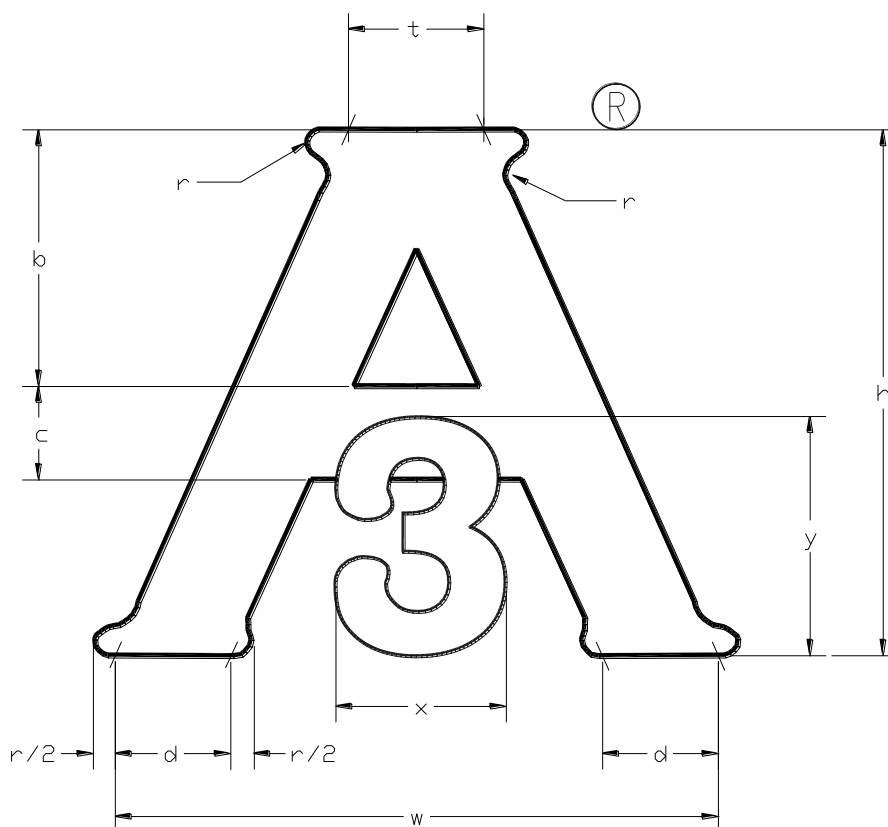
Use and display of the 3-A Symbol on equipment is non-mandatory for licensees. A licensee may elect to not display the 3-A symbol on authorized equipment due to design, materials, or fabrication modifications or a customer request.

- 2.1. If a licensee chooses to not display the 3-A Symbol and the hyphenated standard number and revision number (XX-XX) on units of specific model(s) of equipment for which it holds authorization, the following shall apply:
 - 2.1.1. The licensee shall make no use or display of the 3-A Symbol in any manner in the promotion or sale of any unit which does not bear the 3-A Symbol.
 - 2.1.2. The licensee shall make no representation, express or implied, in any manner to assert that such equipment which does not bear the 3-A Symbol conforms to 3-A Sanitary Standards or provisions for 3-A Symbol authorization.
 - 2.1.3. The 3-A Symbol Authorization certificate shall not be considered proof of conformance for equipment which does not display the 3-A Symbol.
 - 2.1.4. Any piece of equipment that does not display the 3-A Symbol is to be considered as not covered by any aspect of the 3-A Symbol authorization program.

3. Use and Display of the 3-A Symbol on Equipment

- 3.1. A licensee may mark and/or affix the 3-A Symbol only to specific models/names of equipment for which 3-A Symbol authorization has been granted. The licensee shall assure that any such display on equipment is compatible with all applicable hygienic design criteria.

- 3.2. A licensee shall provide sufficient information on the equipment to allow for third party traceability of the symbol. This may be accomplished by the Symbol Holder's nameplate, the company name if no nameplate is provided, a company logo, or Authorization number at the discretion of the Symbol Holder.
- 3.3. Where possible, the 3-A Symbol 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 and revision 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, or the nameplate in a clear, concise, permanent manner. Where the nature or size of the equipment makes the above impractical, the 3-A Symbol and hyphenated standard number and revision number shall be stamped, etched, or embossed on the equipment or affixed in any other permanent manner.
- 3.4. A licensee may display the 3-A Symbol on authorized equipment using one of the following electronic formats provided by 3-A SSI: 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 the licensee upon request. If the licensee wishes to reproduce the 3-A Symbol, the following specifications shall be used:



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.

4. Non-equipment Use and Display of the 3-A Symbol

Licensees may wish to show the 3-A Symbol or otherwise promote the fact of 3-A Symbol authorization for equipment in other ways beyond the actual display on authorized equipment, such as in advertisements, brochures, fliers, catalogs, news releases, web sites, or other promotional communication. These guidelines apply to all such non-equipment use and display of the 3-A Symbol to help licensees accurately and properly promote 3-A Symbol authorization.

- 4.1. References to '3-A', '3-A Standards', or similar references in promotional materials are not substitutes for 3-A Symbol authorization display on equipment. Advertising references are informational and not proof of 3-A Symbol authorization. The licensee is solely responsible for assuring the completeness and the veracity of all non-equipment references.
- 4.2. 3-A SSI does not "approve," "certify," "rate," or "endorse" the design, construction, or use of the equipment and the licensee should not make such references. In non-equipment references, a licensee may state that the items for which 3-A Symbol authorization has been granted meet the requirements of the respective 3-A Sanitary Standard, hold 3-A Symbol authorization, or similar.
- 4.3. For non-equipment use and display, the 3-A Symbol must be reproduced in accordance with one of the formats specified by 3-A SSI for equipment display, except that, for non-equipment use and display, licensees are encouraged, but not required, to show the full 3-A Sanitary Standard hyphenated standard number and revision number immediately below the 3-A Symbol as required on equipment.
- 4.4. The 3-A Symbol should never appear more prominently in any advertising or packaging than the name of the licensee holding the authorization.
- 4.5. Do not use the 3-A Symbol or reference 3-A Symbol authorization on company stationery, business cards or signs, or within Internet domain names or company names. Use of these references on such materials could incorrectly imply more than a third-party authorization or relationship between the licensee and 3-A SSI, or incorrectly imply that all products you manufacture have been authorized by 3-A SSI.
- 4.6. If you use a 3-A Symbol on your web site, you must ensure that visitors to your web site are able to clearly identify which of your products have been authorized by 3-A SSI to use and display the 3-A Symbol and which have not.
- 4.7. References to 3-A Symbol authorization can be made only when you are authorized by 3-A SSI to use the 3-A Symbol on your equipment.
- 4.8. If 3-A Symbol authorization is expired or withdrawn for any reason, all material that refers to your authorization must be immediately removed from distribution, and further use of the 3-A Symbol must be discontinued.

- 4.9. If some products appearing in a web site, brochure, ad or catalog are authorized to use and display the 3-A Symbol but others are not, the licensee must ensure the wording and placement of 3-A Symbol references make it clear which products are in fact authorized by 3-A SSI and which are not. Do not use the 3-A Symbol in general advertising or promotional material to suggest that non-authorized products have, in fact, been authorized.
- 4.10. Do not state a link between 3-A Symbol authorization and any other organization. For example, statements such as 'Meets USDA/3-A Criteria', or 'Conforms to FDA/USDA/3-A Standards Criteria' or similar descriptions are inappropriate.

**3-A SANITARY STANDARDS, INC.
LICENSE AGREEMENT FOR USE OF THE 3-A REPLACEMENT PARTS AND SYSTEM
COMPONENT QUALIFICATION MARK**

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:

1. 3-A SSI grants to the RPSCQC Holder a nonexclusive license to use the RPSCQC Mark as specified in the attached Certificate.
2. The RPSCQC Holder agrees to comply with *Provisions for Use and Display of the RPSCQC Mark* and other 3-A SSI rules and procedures, as amended from time to time, including the timely payment of licensing fees, any late fees or similar charges that may be assessed, and provisions of the Third Party Verification program for 3-A RPSCQC.
3. The RPSCQC Holder agrees that, as between RPSCQC Holder and 3-A SSI, 3-A SSI is the owner of the RPSCQC Mark, and the RPSCQC Holder 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. The RPSCQC Holder's certificate and Mark usage will terminate at the end of the calendar year, or at the end of the month in which a required TPV report is due. However, the RPSCQC Holder 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 the RPSCQC Holder 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 the RPSCQC Holder in any manner except with 3-A SSI's prior written consent, nor shall the RPSCQC Holder have the right to grant sublicenses.
7. The RPSCQC Holder agrees that it will use the RPSCQC Mark only on replacement parts or system components that meet applicable requirements within 3-A SSI Standards or Accepted Practices, including as amended or interpreted in the future.
8. If it is determined by 3-A SSI that any replacement parts or system components referenced in the Certificate does not conform at any time to the applicable 3-A SSI Standard or Accepted Practice, including as amended or interpreted in the future; or if the RPSCQC Holder is determined by 3-A SSI to have made any materially false statement in any application or affidavit; or if the RPSCQC Holder 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 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, the RPSCQC Holder shall immediately discontinue the use of the RPSCQC Mark.
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. The RPSCQC Holder 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 replacement parts or system components of the RPSCQC Holder.
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 RPSCQC MARK**

1. General Requirements

The RPSCQC Mark is authorized for use on replacement parts or system components and in conjunction with the marketing of such replacement parts or system components that meet the requirements of published 3-A Sanitary Standards or 3-A Accepted Practices, subject to the RPSCQC License Agreement and these Provisions for the Use and Display of the RPSCQC Mark.

2. Use and Display of the RPSCQC Mark

- 2.1 The RPSCQC Holder shall mark and/or affix the RPSCQC mark only to specific models/names of replacement parts or system components for which the RPSQC has been granted. The RPSCQC Holder shall assure that any such display on replacement parts or system components is compatible with all applicable hygienic design criteria.
- 2.2 The RPSCQC Holder shall provide sufficient information on the replacement parts or system components to allow for third party traceability. This shall be accomplished by including the RPSCQC Holder's certificate number and may include the RPSCQC Holder's company name, company logo, or similar identification.
- 2.3 The RPSCQC Holder shall display the RPSCQC Mark on replacement parts or system components using one of the electronic formats provided by 3-A SSI. 3-A SSI will provide a copy of the RPSCQC Mark in the desired electronic format(s) to the RPSCQC Holder upon request. If the RPSCQC Holder wishes to reproduce the RPSCQC Mark, the following specifications shall be used:



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

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 TM shall be proportionally displayed as part of the RPSCQC Mark.

3. Non-equipment Use and Display of the RPSCQC Mark

RPSCQC Holders may wish to show the RPSCQC Mark or otherwise promote the fact of RPSCQC Certificate for replacement parts or system components in other ways beyond the actual display on replacement parts or system components, such as in advertisements, brochures, fliers, catalogs, news releases, web sites, or other promotional communication. These guidelines apply to all such non-equipment use and display of the RPSCQC Mark to help RPSCQC Holders accurately and properly promote RPSCQC Certificate.

- 3.1. References to RPSCQC, or similar references in promotional materials are not substitutes for the RPSCQC Mark display on replacement parts or system components. Advertising references are informational and not proof of RPSCQC Certificate. The RPSCQC Holder is solely responsible for assuring the completeness and the veracity of all non-equipment references.
- 3.2. 3-A SSI does not “approve,” “certify,” “rate,” or “endorse” the design, construction, or use of the replacement parts or system components and the RPSCQC Holder should not make such references. In non-equipment references, a RPSCQC Holder may state that the items for which the RPSCQC has been granted meet the requirements of the respective 3-A Sanitary Standard or Accepted Practice, hold the RPSCQC Mark, or similar.
- 3.3. For non-equipment use and display, the RPSCQC Holder Mark must be reproduced in accordance with one of the formats specified by 3-A SSI for equipment display, except that, for non-equipment use and display, RPSCQC Holders are encouraged, but not required, to show the Certificate number immediately below the RPSCQC Mark as required on replacement parts or system components.
- 3.4. The RPSCQC Mark should never appear more prominently in any advertising or packaging than the name of the RPSCQC Holder.
- 3.5. Do not use the RPSCQC Mark or reference RPSCQC on company stationery, business cards or signs, or within Internet domain names or company names. Use of these references on such materials could incorrectly imply more than a third-party verification or relationship between the RPSCQC Holder and 3-A SSI, or incorrectly imply that all products manufactured have a certificate.

- 3.6. If you use a RPSCQC Mark on your web site, you must ensure that visitors to your web site are able to clearly identify which of your products are listed on the RPSCQC and are allowed to be associated with, use and display the RPSCQC Mark and which have not.
- 3.7. References to RPSCQC certificate can be made only when you are granted by 3-A SSI to use the RPSCQC Mark on your replacement parts or system components.
- 3.8. If the RPSCQC Certificate is expired or withdrawn for any reason, all material that refers to your authorization must be immediately removed from distribution, and further use of the RPSCQC Mark must be discontinued.
- 3.9. If some replacement parts or system components appearing in a web site, brochure, ad or catalog are granted to use and display the RPSCQC Mark, but others are not, the RPSCQC Holder must ensure the wording and placement of RPSCQC Mark references make it clear which replacement parts or system components products are in fact granted to use the RPSCQC Mark and which are not. Do not use the RPSCQC Mark in general advertising or promotional material to suggest that other replacement parts or system components are granted use of the RPSCQC Mark.
- 3.10. Do not state a link between a RPSCQC Certificate and any other organization. For example, statements such as 'Meets USDA/3-A Criteria', or 'Conforms to FDA/USDA/3-A Standards Criteria' or similar descriptions are inappropriate.

APPENDIX 3

TPV FORMS AND RELATED DOCUMENTS

THIRD PARTY VERIFICATION REPORT FOR 3-A SYMBOL AUTHORIZATION	
Applicant:	TPV Inspection Completion Date:
Verification Location:	CCE:
	Equipment Type:
	3-A Sanitary Standard:
3-A Authorization Number:	
Applicant/Verification Contact (name, phone no., email address):	
Type of Verification: <input type="checkbox"/> New Authorization <input type="checkbox"/> Conditional <input type="checkbox"/> Renewal Authorization <input type="checkbox"/> Final <input type="checkbox"/> Amendment <input type="checkbox"/> Follow-up	
<input type="checkbox"/> Clean-in-Place Model Number(s) (use serial # if no model #) (use separate page, if needed):	
<input type="checkbox"/> Clean-Out-of-Place/Manual Cleaning Model Number(s) (use serial # if no model #) (use separate page, if needed):	
<input type="checkbox"/> Both CIP and COP. List Model Number(s) (use serial # if no model #) (use separate page, if needed):	
Observations and Findings:	
Declaration of Findings: <input type="checkbox"/> Nonconformance (<i>Note: If any "No" items are checked, the "Nonconformance" box shall be marked.</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.) <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.	
CCE Signature:	

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 Report Completion Date:
	CCE:
	Process:
Verification Location:	3-A Accepted Practice:
Applicant/Verification Contact (name, phone no., email address):	3-A Process Certification Number:
Type of Verification <input type="checkbox"/> New Authorization <input type="checkbox"/> Conditional <input type="checkbox"/> Renewal Authorization <input type="checkbox"/> Final <input type="checkbox"/> Amendment <input type="checkbox"/> Follow-up	
<input type="checkbox"/> Clean-in-Place Model Number(s) (use serial # if no model #) (use separate page, if needed):	
<input type="checkbox"/> Clean-Out-of-Place/Manual Cleaning Model Number(s) (use serial # if no model #) (use separate page, if needed):	
<input type="checkbox"/> Both CIP and COP. List Model Number(s) (use serial # if no model #) (use separate page, if needed):	
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 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:	

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					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					

THIRD PARTY VERIFICATION REPORT FOR 3-A REPLACEMENT PARTS & SYSTEM COMPONENT QUALIFICATION CERTIFICATION	
Applicant:	TPV Report Completion Date:
	CCE:
Verification Location:	Replacement Part(s)/System Components(s):
	3-A Sanitary Standard(s)/Accepted Practice(s):
Applicant/Verification Contact (name, phone no., email address):	3-A RPSCQC Number:
Type of Verification: <input type="checkbox"/> New Authorization <input type="checkbox"/> Conditional <input type="checkbox"/> Renewal Authorization <input type="checkbox"/> Final <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:	

SUPPLEMENTAL INFORMATION SHEET FOR REPLACEMENT PARTS & SYSTEM COMPONENT QUALIFICATION 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					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					



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/3-A-Symbol/Search-Database-of-Current-Certificates>

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 or replacement parts or system components with a Replacement Parts & System Component Qualification Certificate (RPSCQC), or a system with a Process Certificate (PC). If you believe equipment in use in the dairy and food industry that displays a 3-A Symbol, or a RPSCQC Mark, or PC and does not conform to a 3-A Sanitary Standard or Accepted Practice, 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 F4 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, RPSCQC Mark, or PC even if the manufacturer's literature states "3-A compliance" or "conformance" or otherwise suggests the equipment is eligible to display a 3-A Symbol, RPSCQC Mark, or PC. If you encounter use of the 3-A Symbol, 3-A RPSCQC Mark, PC, or statements asserting conformance to 3-A criteria by a company that is not an authorized 3-A Symbol, RPSCQC or PC 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/Accepted Practice: List the most current version of the standard or Accepted Practice or the version of the standard/accepted practice identified on the Symbol/ PC/ RPSCQC Mark 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: The equipment must be in commercial use or in a commercial channel of sale or distribution. Provide the specific details.
 - 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:

Eric Schweitzer
Director of Standards and Certification Programs
3-A Sanitary Standards, Inc.
6888 Elm Street, Suite 2D
McLean, Virginia, USA 22101-3829
E-mail: erics@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 PC; visit www.3-a.org or look under: <http://www.3-a.org/Parts-Process-Certificates/3-A-Process-Certificate-Program>

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 equipment that displays a current 3-A Symbol Authorization or replacement parts or system components with a Replacement Parts & System Component Qualification Certificate (RPSCQC), or a system with a Process Certificate (PC). If you believe equipment in use in the dairy and food industry that displays a 3-A Symbol, a RPSCQC Mark, or PC and does not conform to a 3-A Sanitary Standard or Accepted Practice, 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 F4 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, RPSCQC Mark, or PC even if the manufacturer's literature states "3-A compliance" or "conformance" or otherwise suggests the equipment is eligible to display a 3-A Symbol, RPSCQC Mark, or PC. If you encounter use of the 3-A Symbol, 3-A RPSCQC Mark, PC, or statements asserting conformance to 3-A criteria by a company that is not an authorized 3-A Symbol, RPSCQC or PC 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 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:

Eric Schweitzer
Director of Standards and Certification Programs
3-A Sanitary Standards, Inc.
6888 Elm Street, Suite 2D
McLean, Virginia, USA 22101-3829
E-mail: erics@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.

APPENDIX 4

ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE EXAMPLE



**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 *Format and Style Manual*, Version 4, Appendix 8, is to be maintained by the fabricator as evidence of complying with 3-A Sanitary Standards, or for a processor complying with an Accepted Practice. The file may contain more or less information as applicable to the equipment or system.

1.1 Purpose

1.1.1 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 subassemblies supplied by the manufacturer thereof to be in conformance to the sanitary criteria found in 3-A Sanitary Standards or 3-A Accepted Practices.

1.2 Scope

1.2.1 This EDTCF applies to _____ specified by:

1.2.1.1 3-A Sanitary Standards for {full title}, Number {document number}.

1.2.1.2 3-A Accepted Practices for {full title}, Number {document number}.

1.2.1.3 List all applicable 3-A Sanitary Standards and 3-A Accepted Practices.

1.3 Responsibilities

1.3.1 The EDTCF is maintained by {name and title of responsible official} who is responsible for maintaining, publishing, and distributing the EDTCF.

1.3.2 Implementation: All divisions, specifically development engineering, standards engineering, sales engineering, and product departments are responsible for implementing the EDTCF.

1.4 Applicability

1.4.1 The 3-A Sanitary Standards and 3-A Accepted Practices are voluntarily applied as suitable sanitary criteria for dairy and food processing equipment. 3-A Sanitary Standards are referenced in the Grade A PMO, which provides that equipment manufactured in conformity to 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance. The 3-A Sanitary Standards and Accepted Practices are also referenced in 7 CFR 58 Subpart B-- General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service. This subpart requires all new, replacement or modified equipment and all processing systems, cleaning systems, utensils, or replacement parts to comply with the most current, appropriate 3-A Sanitary Standards or 3-A Accepted Practices.

1.5 References

1.5.1 List any additional regulations that apply to the equipment or system covered by this EDTCF.

1.5.2 Also show the date of conformity or 3-A Symbol Authorization and certificate number, if authorized.

1.6 EDTCF

1.6.1 The Engineering Design and Technical Construction File shall contain the following items:

- a. Table of Contents (listing all documents within the EDTCF or the locations where the items may be found);
- b. A copy of the 3-A Sanitary Standard to be applied to the subject equipment;
- c. An overall drawing or general arrangement drawing of the subject equipment;
- d. Full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment to the 3-A Sanitary Standard or 3-A Accepted Practice;
- e. If essential, any technical report or certificate obtained from a competent testing body or laboratory;
- f. Instructions for cleaning of the subject equipment or item referenced by the standard (including a listing, as may be applicable, for all manually cleaned components or appurtenances and the procedures for cleaning of these items. (Example: silo tank door gasket);
- g. Material certifications for all materials of construction included in the equipment;
- h. For serial manufacturing, the internal measures that will be implemented to insure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Sanitary Standards or 3-A Accepted Practices;
- i. Change records; and
- j. Copy of the 3-A Symbol authorization, if applicable.

1.6.2 The Engineering Design and Technical Construction File may further optionally contain the following:

- a. A list of the essential requirements of the standards or practices;
- b. Other technical specifications which were used when the equipment was designed;
- c. A copy of the instructions for the product (instruction manuals/instruction books);
- d. A description of methods adopted;
- e. Any technical report giving the results of tests carried out internally by Engineering or others;

- f. 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);
- g. A determination of the foreseeable lifetime of the product (optional);
- h. Engineering reports;
- i. Laboratory reports;
- j. Bills of material;
- k. Wiring diagrams, if applicable;
- l. Purchase order engineering files;
- m. Hazard evaluation committee reports, if executed;
- n. Customer specifications; and
- o. Any notified body technical reports and certification tests.

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

1.6.4 The documentation referred to in 1.6.1, above, need not permanently exist in a material manner in the EDTCF, but it must be possible to assemble the documentation and make it available within a period of time commensurate with its importance (one week is considered reasonable time). At a minimum, each product EDTCF must physically contain an index of the applicable documents of 1.6.1, above.

1.6.5 The EDTCF may be in hard copy or digital format.

1.7 Confidentiality

1.7.1 The EDTCF is the property of the manufacturer and may be shown at its discretion, except that all or part of this file will be available to the 3-A Sanitary Standards Inc. or a regulatory agency for cause and upon request.

1.8 File Location

1.8.1 The EDTCF is maintained at {location}.

1.9 File Retention

1.9.1 The EDTCF (including all documentation referred to in 1.6.1) shall be retained and kept available for 12 years following the date of placing the equipment in use or from the last unit produced in the case of series manufacture.

APPENDIX 5

3-A SSI Fee Schedule

<http://www.3-a.org/3-A-Symbol/Schedule-of-Fees>

For New Applications, Renewals and Amendments:

<http://www.3-a.org/3-A-Symbol/Manage-3-A-Symbol-Authorizations-Apply-Renew-Amend>

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 D4.2.4 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 D4.	September 21, 2009

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.	September 21, 2009
B7.1.4 revised to clarify when the 3-A Symbol holder must submit a TPV inspection in the case of making an amendment.	September 21, 2009
B7.2 revised to clarify that the TPV anniversary date of record maintained for the licensee is the date of the most recent <u>complete</u> TPV inspection for <u>all</u> equipment included in the Authorization.	September 21, 2009
Section C3.5.1 revised to allow no site visit for an amendment that is not of 'sanitary significance'.	September 21, 2009
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.	September 21, 2009
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.	September 21, 2009
Appendix 2, Exhibit 3, 'Use and Display of the 3-A Symbol' retitled 'Promotion Tips for Use and Display of the 3-A Symbol'.	September 21, 2009
B7.1.3, second paragraph, was modified to note lapsed Authorizations will be removed from the Symbol Holders List if not renewed in 30 days. Added new text stating, "If renewal is not completed within the first six months of the year, a new 3-A Symbol application, including a new TPV inspection report, is required."	March 22, 2011
In Appendix 3, Exhibit 3, for the RAN form to 3-A Standard, Instructions Item "f" was reworded to include "The equipment must be in commercial use or in a commercial channel of sale or distribution. Provide the specific details."	March 22, 2011
Added a new section in Section D (as D1) to describe "eligible applicants". Under the Process Certification Program, all references to the Replacement Part Qualification Certificate Program (RPQCP) were changed to the Replacement Parts and System Component Qualification Certificate Program (RPSCQCP). Made several other changes in D2 - D4 as well.	April 4, 2011
Revised the Symbol application to fix a few typos and to make it consistent with the current application displayed on the 3-A web site.	September 1, 2011

In section C2.3.2, replaced the word “Reference” with “Scope” to indicate that the CCE does not have to initialize the reference section and does have to initial the scope of the standard when performing a TPV inspection.	September 27, 2011
In B7.3.4.1 amplified that for yearly Process Certification renewals, a current TPV inspection report must be submitted and the PC application in the Appendix was updated to include “a current TPV inspection report” in the items that must be returned to 3-A SSI.	October 4, 2011
B7.2.1.2 revised to state the CCE may issue a “conditional” TPV report when a large/custom piece of equipment is not available for inspection and that the CCE shall issue a final TPV report after the first piece of equipment is manufactured under the conditional report.	October 19, 2011
Added B7.1.3.2 to state that Symbol holders who must supply a conforming TPV inspection report for renewals, but do not, will be replaced under “probationary” status and information is included as to duration of this status and Symbol rescission.	October 19, 2011
Added B7.1.3.3 stating the CCE is encouraged to ask client for items ahead of time to help with timely TPV report issuance.	October 19, 2011
In B7.3.4.1 added clarification that for Process Certification renewals, a new conforming TPV inspection report must be submitted.	October 19, 2011
Complete rewrite of C2.2.4 to stipulate that the TPV report now only has the “TPV Report Completion Date” (the TPV inspection date was removed) and defines this date. The same change was made in D3.2.4 for the Process Certification TPV report. Both the Symbol and Process Certification TPV report cover pages appearing in the Appendix were revised to reflect this change.	October 19, 2011
E1.1.1 and E1.2.1.1 revised to add the requirement that the CCE shall submit the TPV report to 3-A SSI within 15 working days of completion.	October 19, 2011
E1.2.1.2 revised to state that renewal applicants found to be in non-conformance.	October 19, 2011
will immediately have their Symbol revoked and if the applicant then submits a conforming TPV report and required fees within six months, the Symbol will be reinstated. Conforming reports received after six months will require a new application.	October 19, 2011
E1.3.1 revised to add the requirement that the CCE shall submit the TPV report to 3-A SSI within 15 working days of completion.	October 19, 2011

For the PC program, revised B5, B7, and D1 to differentiate food processors and system design and installation firms. Both may have PCs, but the requirements are different. This revision spells out those differences. November 16, 2011

Revised Section E4 to include Sub-Sections E4.5.1 and E4.5.1.1 to add the requirement of customer notification of non-compliant equipment (E4.5.1). This section was mistakenly omitted in the previous revision of the *Manual*. April 2, 2012

Revised TPV report cover page in Appendix to indicate method of cleaning. June 27, 2012

Revised the instructions in Section 2.2 for completing the TPV Report cover page to include conveying the equipment method of cleaning. July 20, 2012

Revised the TPV Report cover page in Appendix 3, Exhibit 1 to include “Conditional” and “Final” TPV report types. Revised Section B7.4 (Used, Repaired and Remanufactured Equipment) to include “repaired” equipment and to stipulate that a conforming TPV inspection report is required whenever an OEM wishes to retain a Symbol after the used equipment is refurbished. In addition, verbiage added to allow equipment remanufacturers and refurbishers to apply for 3-A Symbol Authorization after they take ownership of used equipment. The document was completely reviewed and editorial changes made, including numbering of all sections, which caused many section’s numbers to change. Revised B7.2 to clarify the requirements of the ‘conditional TPV report’ issued by a CCE for manufacturers of large/custom equipment and details when the CCE must visit the manufacturing facility to inspect the equipment produced under the ‘conditional TPV report’ and defines the ‘next TPV inspection due’ date for large/custom equipment manufacturers. December 14, 2012

Indicated in C2.3.11.1 and D3.3.2.10.1 that any “X” marks in the “No” column of the Supplemental Information Sheet must result in a “nonconforming” TPV report. In C3.6.4.5.1 updated the EDTCF list of required items the 3-A Symbol holder/applicant must have, to reflect the current EDTCF as it appears in the *Format & Style Manual*, Version 4. Did likewise in D4.8.4.10.1 for the Process Certification. Updated Appendix 4 (EDTCF Example) to reflect the current requirements, as conveyed in *Format & Style Manual*, Version 4. January 16, 2013

Added B7.1.2.4.1 to stipulate 3-A SSI may place limits on TPV report acceptance from a CCE due to various reasons. March 8, 2013

Added E4.1 to clarifies that 3-A SSI can pursue license violations, such as non-conformance, only if the equipment maintains a current license. October 17, 2013

Added E4.1.1 to clarify that the licensed equipment be in use or in commerce. The intent is to avoid RANs submitted on equipment that has been rejected, retired, decommissioned, etc. and the source must be must identified. Equipment in a disassembled state may be subject to a RAN, October 17, 2013

but not work-in-progress at a fabricator or assembly operation.

Added E4.1.2 as per E4.1.1 clarification	October 17, 2013
Added E.4.2 to identify location of flowchart that shows the Procedure for Reporting of Alleged Non-conformance is shown in Chart 4.	October 17, 2013
Added E4.3 which moves details of information to be shown on the RAN to new section.	October 17, 2013
Added E4.3.1 so as to identify information that is required to be provided by the RAN submitter in order for 3-A SSI to properly investigate the RAN.	October 17, 2013
Added E4.3.2 which serves to provide an additional new advisory to the RAN submitter.	October 17, 2013
Added E4.4 for further clarification of current provision. Removes requirement for referring 'validity' of allegation to the Interpretations Committee.	October 17, 2013
Added E4.5 to guide 3-A SSI in seeking resolution of the non-conformance if there is no issue of interpretation. Establishes Informal RAN Resolution 'sign off' to accept or reject the Informal Resolution in its entirety or individual items. The 'sign off' must be agreed by all parties, including the RAN submitter.	October 17, 2013
Added E4.5.1 and E4.5.2 to provide "agreement" requirements	October 17, 2013
Added E4.6 to clarify only issues that involve the interpretation of wording will be conveyed to the IC.	October 17, 2013
Added E4.7 to provides flexibility for investigation and resolution of RAN.	October 17, 2013
Moved E4.7, E4.7.1.1 and E4.7.2 requirements to new sections.	October 17, 2013
Revised E4.8 to place responsibility upon parties from whom 3-A SSI seeks 'sign off' to reply in a timely manner.	October 17, 2013
Revised E4.9 to place responsibility upon parties from whom 3-A SSI seeks 'sign off' to reply in a timely manner.	October 17, 2013
Added E4.9.1 which was no change from requirement in last rev. under E4.10.	October 17, 2013
Added E4.10.1 which was no change from requirement in last rev. under E4.8.	October 17, 2013
Added E4.10.2 which was no change from requirement in last rev. under E4.9.	October 17, 2013

Added E4.11 which was no change from requirement in last rev. under E7.2	October 17, 2013
Added E4.12 which had no change from requirement in last rev. requirement is now shown in E4.10.	October 17, 2013
Added E4.13 and minor revision to requirements now shown under E4.10.	October 17, 2013
Revised License Agreement and Provisions for Use and Display of the 3-A Symbol, mainly to clarify equipment and non-equipment display of 3-A Symbol.	February 12, 2014
Revised B7.1.4 for non-administrative amendments	April 27, 2015
Revised Appendix 3 Exhibit 1 and 2 TPV Report Forms and added Exhibit 3 RPSCQC TPV Report Form	July 16, 2015
Added payment forms to Appendix 5	October 8, 2015
Added RPSCQC info to Intro/title, Forward, Table of Contents, new Section E and RAN instructions In Appendix 3	April 14, 2016
Revised all sections to agree with new online database management and Instructions for new, renewal and amendment applications	April 14, 2016
Revised interpretation policy	April 18, 2016
Amended application forms and instructions; Charts 1 and 2 in F1.3	April 19, 2016
Amended B8.1.3, B8.2 and B8.3-B8.3.4.4 to incorporate Process Certification and renewal requirements	January 3, 2017
Added additional requirement for Provisions For The Use And Display Of The 3-A Symbol Appendix 2, Exhibit 1, 3.2	June 8, 2017
Updated Process Certificate TPV Cover Page with cleaning methods columns; removed cleaning methods requirements in E3.3.2.9-E3.3.2.12 for RPSCQC	June 21, 2018
Added RPSCQC program, use and display provisions and license agreement requirements in B6.6 and Appendix 2, Ex. 2	April 18, 2019