

3-A Sanitary Standards, Inc. 2011 Annual Report



Moving Ahead in Our Mission





Our Mission

It is the mission of 3-A Sanitary Standards, Inc. to enhance product safety for consumers of food, beverages, and pharmaceutical products through the development and use of 3-A Sanitary Standards and 3-A Accepted Practices.

3-A SSI — Promoting Sanitary Design Expertise

3-A Sanitary Standards, Inc. (3-A SSI) stepped up this year to support the education of many key audiences on the importance of sanitary design, the value of 3-A Sanitary Standards and 3-A Accepted Practices, and the 3-A Symbol. 3-A SSI has fostered a new and important knowledge base of sanitary design expertise through its Work Groups of subject matter experts, independent equipment inspection professionals, and a more robust resource center on all aspects of sanitary design.

The high level of outreach by 3-A SSI reflects a multi-year commitment to expanding recognition and demand for the '3-A brand'. 3-A SSI participated as a trusted and dedicated training partner this year to bring comprehensive education about 3-A Sanitary Standards and the 3-A Symbol to audiences across the U.S. and to guests from around the world. The expanded Knowledge Center and comprehensive new video resources kindled new recognition and demand for '3-A' equipment and other resources. In the coming year, 3-A SSI will expand and improve its resources on hygienic design, 3-A Sanitary Standards and 3-A Accepted Practices, the 3-A Symbol program and related licensing requirements.

3-A SSI increased its outreach to key audiences of processors, regulatory professionals, fabricators and others this year through participation in training seminars, conferences and trade shows. More opportunities will be available in the coming year as recognition grows of 3-A SSI as a valued information and education resource.

The passage of important new safety legislation this year will focus the attention of the public, regulatory professionals, processors and equipment fabricators on the entire food safety chain and new ways to protect public health. In particular, the role of voluntary third party certification programs based on proven standards and practices will receive wider consideration and demand to meet regulatory objectives in the coming years.

3-A SSI reflects a strong partnership of public and private cooperation with a shared commitment to protecting the public health. We hope to strengthen this relationship in the coming period, enhance the integrity of the 3-A SSI standards we develop, and broaden recognition of the voluntary 3-A Symbol program.

The mission objectives of 3-A SSI include:

- ▶ Develop, maintain and publish uniform standards and practices for the sanitary (hygienic) design, fabrication, installation and operation of equipment and machinery.
- ▶ Use state-of-the-art, science-based expertise for the development of sanitary standards and accepted practices.
- ▶ Harmonize with global standards and guidelines as appropriate.
- ▶ Promote the use of 3-A Sanitary Standards, 3-A Accepted Practices, and the 3-A Symbol.
- ▶ Authorize use and maintain the integrity of the 3-A Symbol.
- ▶ Maintain a uniform system to regulate and enforce proper use of the 3-A Symbol to best enhance consumer product safety.
- ▶ Provide education concerning sanitary design principles, application of 3-A Sanitary Standards and 3-A Accepted Practices, and use of the 3-A Symbol.

Officers

Ronald Schmidt, Chair
University of Florida

Dan Meyer, Vice Chair
American Dairy Products Institute

Carl Buell, Secretary
Leprino Foods Company

Lou Beaudette, Treasurer
Admix, Inc.

Directors

Kenneth Anderson
Harold Wainess & Associates

Warren S. Clark, Jr.
3-A Sanitary Standards Symbol Administrative Council, Inc.

Ray Dyke
Agri-Mark, Inc.

Jon Gardner
International Dairy Foods Association

Larry Hanson
Johnsonville Sausage, LLC

Robert F. Hennes
Chief, FDA/CFSAN-Milk Safety Branch

David Jamison
USDA/AMS, Dairy Grading

F. Tracy Schonrock
3-A Steering Committee.

David Seckman
Food Processing Suppliers Association

Counsel

Hugh Webster
Webster, Chamberlain & Bean

Committee Leadership

Communications & Education Committee
Larry Hanson, Johnsonville Sausage, LLC

Finance Committee
Lou Beaudette, Admix, Inc.

Third Party Verification Coordinating Committee
F. Tracy Schonrock

Interpretations Committee
Randy Elsberry, FDA Regional Dairy Specialist
Office of Regulatory Affairs, Pacific Region

3-A Steering Committee
F. Tracy Schonrock

P3-A Steering Committee
Paul Hoblitzell, Eli Lilly Co.

3-A SSI Staff

Timothy R. Rugh, CAE, *Executive Director*
Nate Wall, *Director, Standards and Certification*
Philomena Short, *Technical Assistant*

Renewal Inspections Strengthen 3-A Symbol Program

3-A SSI completed inspections for a substantial number of current 3-A Symbol authorizations due for a periodic verification of conformance to 3-A Sanitary Standards. 3-A SSI requires all authorized 3-A Symbol holders to obtain a complete Third Party Verification (TPV) re-inspection of licensed equipment at least once every five years, or whenever there is a significant change in materials or production processes.

The TPV inspection requirement was initiated in 2003 as a requirement for a fabricator or marketer to obtain 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 a credentialed inspection professional, a Certified Conformance Evaluator (CCE), to conduct an on-site evaluation of finished equipment and other product attributes to affirm the equipment conforms to provisions of the applicable 3-A Sanitary Standard. Any deficiencies discovered in an inspection 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 risk losing the authorization to use the 3-A Symbol.

Since the TPV program was implemented, nearly 1,000 TPV inspections have been completed at fabrication facilities in the U.S. and 24 other countries around the world to verify the equipment conforms to 3-A Sanitary Standards. Inspections have been completed for equipment fabricated in the U.S. and other countries including Argentina, Austria, Belgium, Brazil, Canada, China, Denmark, England, Finland, France, Germany, Israel, Italy, Japan, Korea, Mexico, Netherlands, New Zealand, Poland, Spain, Sweden, Switzerland, Taiwan, and Thailand.

3-A SSI introduced a new on-line, searchable database of 3-A Symbol licensees this year to increase recognition of all currently licensed 3-A Symbol holders. The public information provides detailed information on models/equipment covered under a company's license to assist regulatory sanitarians, processors, equipment fabricators, and other interested parties. The information is searchable by the unique authorization number, equipment type/standard or company name. A copy of the actual authorization certificate may also be printed from the database. The list includes all of the current fabricators that conform to 3-A Sanitary Standards for dairy and food processing equipment and meet provisions of the 3-A Symbol authorization program.

The TPV requirement has enhanced the level of integrity and recognition of the 3-A Symbol for everyone concerned with the safety of consumers of food, beverages and pharmaceutical products, fulfilling one of the primary mission objectives of 3-A SSI.

Introduced in 1956, the 3-A Symbol is a registered mark used to identify equipment that meets 3-A Sanitary Standards for design and fabrication. Voluntary use of the 3-A Symbol on dairy and food equipment conveys assurance that equipment meets sanitary standards, provides accepted criteria to equipment manufacturers for sanitary design, and establishes guidelines for uniform evaluation and compliance by sanitarians.



3-A SSI Strengthens International Protection of 3-A Symbol

In an era of expanding international commerce in processing equipment and wider industry use of equipment built to 3-A sanitary standards, 3-A SSI took important steps this year to maintain the integrity of the 3-A Symbol.

3-A SSI applied for official trademark registration of the 3-A Symbol in China to help raise general awareness of the mark and 3-A SSI's property rights. Under international trademark registration rules, registered protection of the mark in China will become final around mid-2012, unless a provisional refusal is made by the Chinese Trademark Office. The official registration of the mark in China will enhance the ability of 3-A SSI to enforce its property rights in China and obtain relief from infringing parties in a legal proceeding. 3-A SSI may seek registration of the mark in other countries at a later date.

3-A SSI also registered the 3-A Symbol trademark with the U.S. Customs and Border Protection (CBP), Intellectual Rights Branch. Registration in the CBP database will allow inspection officers to verify imported goods at all ports of entry and seize any infringing goods. Effective now, the CBP registration provides a valuable new safeguard for 3-A SSI if information becomes available about shipments of goods with unauthorized display of the 3-A Symbol headed to the U.S.

3-A SSI licenses use of the 3-A Symbol to fabricators to identify equipment that meets 3-A Sanitary Standards for design and fabrication. Voluntary use of the 3-A Symbol by dairy and food equipment fabricators assures processors that equipment meets sanitary standards, provides accepted criteria to equipment manufacturers for sanitary design, and establishes guidelines for uniform evaluation and compliance by sanitarians in the U.S. 3-A SSI currently licenses use of the 3-A Symbol to fabricators in the U.S. and 24 other countries around the world, including China. "Registration of the 3-A Symbol in China will help 3-A SSI convey the need for proper licensing when we encounter any unauthorized use of the mark

or potentially misleading claims," according to 3-A SSI Executive Director Tim Rugh.

A casual on-line search today will yield literally hundreds of manufacturers or marketers of food processing equipment. Many of these entities state claims such as 'meets 3-A', 'conforms to 3-A standards', or the equipment may include '3-A' in a model name or designation. Such references attempt to capitalize on the broad, positive recognition of the 3-A Symbol by suggesting the equipment meets the criteria for 3-A Symbol authorization. Unless the supplier has verified conformance through the voluntary 3-A Symbol licensing program, the buyer is solely responsible for verifying whether the equipment meets the desired (and expected) sanitary design and fabrication criteria.

In the past year, 3-A SSI introduced a new 'buyer beware' resource on the 3-A SSI web site to help processors, consumers, equipment specifiers and others identify equipment sellers that make false or misleading claims of conforming to the sanitary design or fabrication criteria of 3-A Symbol authorization. The new resource lists companies and marketing web sites that feature misleading or false information about the sanitary design of products used widely in dairy and other food processing applications. Several updates were made to the information during the year.

3-A SSI also announced postings during the year to the Probationary List of currently authorized 3-A Symbol licensees. The new information is intended to assist regulatory sanitarians, processors, equipment fabricators, and other interested parties. The Probationary List was added to disclose information on any licensee that is responsible for a finding of non-conformance, including the company name and the specific type and model of equipment. The listing helps inform all concerned parties that the licensee is addressing specific issues it has acknowledged require correction. The licensee remains in this status until a plan for corrective action is completed and verified by third party inspection.

New Resources Added to Knowledge Center

A number of new resource papers on topics in sanitary design were added to the Knowledge Center following extensive changes and additions introduced last year to the on-line technical resources. The Knowledge Center offers a broad and comprehensive array of resources on hygienic design, 3-A Sanitary Standards and 3-A Accepted Practices, the 3-A Symbol program and related licensing requirements. All of the resources are available without restriction and free of charge.

A new video gallery introduced last year continues to attract significant user activity. Five videos are available for viewing on-line or downloading at no charge:

- ▶ **More Than Just a Symbol: The 3-A Story (10:38)**—This is a great introduction to the organization 3-A Sanitary Standards, Inc. and the 3-A Symbol licensing program.
- ▶ **Essentials of Sanitary Design: The 3-A Format and Style Manual (2:12:50)**—For those seeking an in-depth understanding of sanitary design criteria, this is a comprehensive review of the elements common to 3-A Sanitary Standards and 3-A Accepted Practices.
- ▶ **The Certified Conformance Evaluator and the TPV Inspection Overview (9:10)**—This short video offers a good primer to the requirements for the credential ‘Certified Conformance Evaluator’ required for an independent professional to conduct a Third Party Verification (TPV) inspection. A general overview of the TPV inspection required for 3-A Symbol authorization is also presented.
- ▶ **Trust But Verify: The TPV Inspection for 3-A Symbol Authorization (53:44)**—This presentation takes you from start to finish in the Third Party Verification (TPV) inspection. While this demonstration covers a sample centrifugal pump, the inspection process is similar for other types of equipment covered by a 3-A Sanitary Standard.
- ▶ **Maintaining 3-A Symbol Integrity: Reporting Alleged Non-conformance (10:37)**—This is a short but important review of how issues of alleged non-conformance of 3-A Symbol authorization should be handled. While the oversight for conformance rests with the licensee, other parties can and should help watch for products in possible non-conformance to protect the integrity of the 3-A Symbol.

3-A SSI continues to promote the expanded Knowledge Center in outreach to various organizations and for general inquiries.



3-A SSI Recognizes Volunteer Service

3-A SSI recognizes the extraordinary dedication and commitment of individuals who contribute to the development of voluntary standards and the mission of 3-A SSI. The annual Volunteer Service Awards program was introduced in 2008 to recognize the outstanding service of these individuals. Nominations for the awards are made by fellow volunteers among the three stakeholder groups in 3-A SSI.

The following award recipients were announced this year:

Winners of the 3-A SSI Volunteer Service Awards for 2010 announced at the meeting included:

- ▶ Helen Piotter (Dean Foods) received the Leadership Service Award for outstanding service to 3-A SSI voluntary standards development and significant contributions to the mission of 3-A SSI.
- ▶ Chuck Meek (Tetra Pak) received the Advancement Award for outstanding accomplishments on behalf of 3-A SSI.

3-A SSI Expands Education Role

3-A SSI furthered its reputation as a valued education resource this year with expanded training programs on Pharmaceutical (P3-A) Standards and education on leading topics on sanitary design at the 3-A SSI Annual Meeting in Milwaukee.

The P3-A education program attracted professionals interested in the development or application of equipment standards for the production of Active Pharmaceutical Ingredients (APIs). This year's program attracted representatives from across the industry around the world, including equipment fabricators, pharmaceutical manufacturers, and others. A half-day Pharmaceutical 3-A (P3-A) Education and Training Program explored topics including The Mission of P3-A Standards, P3-A Standards in the Marketplace, The P3-A Symbol, and New Standards Development.

A second, full-day education program, ‘3-A and Global Hygienic Design’, opened with the perspectives of U.S. stakeholders – processors, fabricators and regulatory sanitarians – on the emerging food safety legislative/regulatory environment and the implications for 3-A SSI. Topics and speakers for the program included:

- ▶ 3-A and EHEDG: Partnering in Hygienic Design - Knuth Lorenzen (GEA Tuchenhausen), President, European Hygienic Engineering & Design Group (EHEDG) and F. Tracy Schonrock, Chair, 3-A Steering Committee.
- ▶ Sanitary Couplings: EHEDG and 3-A - Andrew Timperley, Timperley Consulting.
- ▶ Rubber and Plastics Formulations for Food Contact – Mike Zumbrum, ALLPure Technologies Inc.
- ▶ Evaluating Stainless Steels - Jim Fritz, TMR Stainless
- ▶ Stainless Casting: Innovations and Improvements - Raymond Monroe, Steel Founders Society of America
- ▶ Foreign Matter Testing - John Yacoub and Robert Scott, Safeline Mettler Toledo.

3-A SSI Enhances Professionalism of Inspection Program

3-A SSI continued to advance the knowledge and skills of its accredited Certified Conformance Evaluators (CCEs) during a year of high demand for new and renewal Third Party Verification (TPV) inspections. CCEs are independent equipment inspection professionals accredited by 3-A SSI to verify the conformance of equipment to 3-A Sanitary Standards in the TPV inspection program. In the past year alone, the CCEs performed more than 150 equipment TPV inspections for the five-year renewal of new 3-A Symbol applications.

The TPV Coordinating Committee, consisting of regulatory sanitarians, fabricator and processor representatives, supervised a special training seminar for CCEs. Seminar participation is required for maintenance of CCE accreditation. The Committee coordinated a series of phone conferences throughout the year to establish and revise TPV Program procedures and exchange information on the application of 3-A Sanitary Standards and other hygienic design issues relating to the performance of TPV inspections. The Committee also published several bulletins to provide guidance on consistent and uniform CCE inspection services. The new bulletins are available on the 3-A SSI web site.

3-A SSI Consensus Development

3-A SSI relies on a community of dedicated subject matter experts from all interest groups to participate in the consensus process for developing and maintaining the large inventory of essential 3-A Sanitary Standards and 3-A Accepted Practices. At the direction of the 3-A Steering Committee, 14 Working Groups (WGs) coordinate the drafting of new or revised documents within particular groups of related equipment. All 14 WGs mobilized this year to revise current documents and create new standards. Collectively, the WGs devoted countless hours of discussion via phone conferences and online meetings using WebEx for document review.

Among the key accomplishments this year:

- ▶ Completing the major revision of the Format & Style Manual (Version 4), used as a guide to 3-A Sanitary Standards development and revision. Update of the Manual follows the same consensus process utilized in developing all of the 3-A Sanitary Standards. This revision is currently undergoing Consensus Body ballot now.
- ▶ Revisions were approved to the following 3-A Sanitary Standards and 3-A Accepted Practices: 11-09 (Plate Type Heat Exchangers), 24-03 (Non-Coil Type Batch Pasteurizers), 31-06 (Scraped Surface Heat Exchangers), 55-02 (Boot-Seal Type Valves), and 62-02 (Hose Assemblies), 58-01 (3-A Sanitary Standard for Vacuum Breakers and Check Valves), and 85-02 (3-A Sanitary Standard for Double-Seat Mixproof Valves).
- ▶ Quarterly standards developers conference calls were continued to support the effectiveness and efficiency of leaders and participants in the consensus development process.
- ▶ Over 190 conference calls were held to develop and revise the content of the 3-A Standards and Accepted Practices within the Work Group document subgroups.
- ▶ Approximately 26 letter ballots were completed.
- ▶ There currently are 76 active standards development and revision proposals.

This year 3-A SSI revised its standards development procedures to continue to be in compliance with the American National Standards Institute's (ANSI) Essential Requirements for openness, balance, consensus and due process (the ANSI procedures). 3-A SSI, an ANSI Accredited Standards Developer, may submit new standards developed in accordance with ANSI requirements as American National Standards.



3-A SSI Outreach to New Audiences

3-A SSI conducted some of the most extensive and important outreach programs in its history this year. The slate of events included a series of training seminars oriented to the work of professional regulatory sanitarians as well as participation in several major dairy industry trade shows.

March 10-13, 2010	FPSA Annual Conference	Cancun, MX
April 8-11, 2010	Tri-State Dairy Processors Convention (mid South)	Hot Springs, VA
May 12, 2010	PA Milk, Food, & Environmental Sanitarians	State College, PA
July 18-20, 2010	Process Expo	Chicago, IL
July 21, 2010	FDA Training Workshop	Windsor, CT
August 1-4, 2010	IAFP Annual Convention	Anaheim, CA
August 11, 2010	FDA Training Workshop	Boise, ID
September 13-15	International Dairy Show	Dallas, TX
September 15, 2010	FDA Training Workshop	Oklahoma City, OK
October 5, 2010	PAMFES Approved Inspector Training	Gibsonia, PA
October 7, 2010	PAMFES Approved Inspector Training	Harrisburg, PA

The training resources of 3-A SSI from years of coordinating the TPV inspection program were showcased to support technical training programs for state regulatory professionals in Pennsylvania and for FDA professionals in three regional workshops.

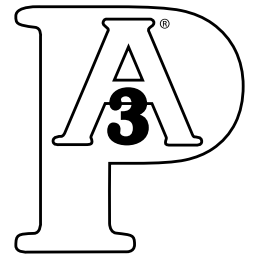
Each FDA workshop included a one-day presentation dedicated to 3-A Sanitary Standards and 3-A Accepted Practices, the 3-A Symbol program, the TPV inspection, and a hands-on demonstration of sample equipment (valves). The training program helped increase knowledge of the application of 3-A Sanitary Standards for equipment and the requirements for the 3-A symbol program.

Volunteer CCEs supported the FDA training workshops including Gabe Miller, Mel Jolly, and Robert Elbich. 3-A Steering Committee Chair F. Tracy Schonrock provided professional support for the Pennsylvania training sessions.

Pharmaceutical (P3-A) Standards

A series of revisions to the current ANSI P3-A pump standard were circulated for a public review and ballot. A number of changes were offered and further balloting and review will be required.

The Pharmaceutical 3-A (P3-A) Council continues to work on four other new standards projects, including Agitated Filter Dryers, Vessels and Agitators, Mills and Classification Equipment, and Process Heat Exchangers.





3-A Sanitary Standards Inc.

6888 Elm Street, Suite 2D

McLean, Virginia 22101-3829

PH: 703-790-0295 FAX: 703-761-6284

www.3-a.org