



3-A Sanitary Standards, Inc. 2010 Annual Report

Moving Ahead in Our Mission



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3-A SSI – The Trusted Resource on Sanitary Design

3-A Sanitary Standards, Inc. (3-A SSI) achieved major progress this year in educating audiences on the importance of sanitary design, the value of 3-A Sanitary Standards and 3-A Accepted Practices, and the 3-A Symbol. The groundwork was set for an even greater role in outreach and education in the coming year.

Drawing from research conducted earlier on the ‘3-A brand’, 3-A SSI introduced the most significant expansion of education resources in its history with a revamped Knowledge Center and comprehensive new video resources, all available on-line at no charge. The new resources offer broad and comprehensive education on hygienic design, 3-A Sanitary Standards and 3-A Accepted Practices, the 3-A Symbol program and related licensing requirements for audiences across the U.S. and around the world.

3-A SSI stepped up 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.

As concern about food safety grows among the public, regulatory professionals, processors and equipment fabricators, increased attention will be focused 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.

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.

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.

New Inspection Cycle for 3-A Symbol Program

3-A SSI began re-inspections this year for the largest volume 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 program was initiated in 2003 as a requirement for maintaining 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, more than 720 TPV inspections have been completed at fabrication facilities in the U.S. and 22 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 Austria, Belgium, Brazil, Canada, China, Denmark, England, Finland, France, Germany, Israel, Italy, Japan, Korea, Mexico, Netherlands, New Zealand, Spain, Sweden, Switzerland, Taiwan, and Thailand.

3-A SSI maintains a public list on its web site to increase recognition of all currently licensed 3-A Symbol holders. The public information assists regulatory sanitarians, processors, equipment fabricators, and other interested parties. The public list is organized by equipment type to show the names of fabricators that conform to 3-A Sanitary Standards for dairy and food processing equipment and meet provisions of the 3-A Symbol authorization program.

Along with the list of current 3-A Symbol licensees, 3-A SSI maintains a separate list of discontinued 3-A Symbol holders. This information shows the reason for discontinuation, such as the equipment is no longer in production, the equipment was consolidated in another 3-A Symbol authorization resulting from a change in company ownership, or the failure of the holder to maintain the authorization in accordance with the terms and conditions for use of the 3-A Symbol.

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 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.



New Public Information Adds Awareness for 3-A Symbol Program

3-A SSI introduced two significant additions to its web site information to help maintain public confidence in equipment manufactured in accordance with 3-A Sanitary Standards and displaying the 3-A Symbol.

A new ‘buyer beware’ resource was introduced 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.

Today literally hundreds of sellers market food processing equipment on-line or through B2B web sites, and many state claims such as ‘meets 3A’, ‘conforms to 3A standards’, or the equipment may include ‘3A’ 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 is an authorized 3-A Symbol holder, the buyer is solely responsible for verifying whether the equipment meets the desired (and expected) sanitary design and fabrication criteria.

3-A SSI identified found a number of such unsupported statements of conformance to 3-A Sanitary Standards, 3-A Certification, or authorization to use the 3-A Symbol, including descriptions for ‘sanitary butterfly valves’, for which no 3-A Sanitary Standard exists. To assist processors, buyers or specifiers, 3-A SSI publishes a list of the entities it has contacted to request the removal of the 3-A Symbol or correction of false or misleading claims. The new resource is available on the 3-A SSI web site under ‘The 3-A Symbol’. 3-A SSI updates the listings on a periodic basis. 3-A SSI encourages those searching for food processing equipment that meets stringent criteria for sanitary design and fabrication to verify the equipment maintains authorization to display the 3-A Symbol.

3-A SSI also added a new Probationary List to web site information on 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.

Expanded Knowledge Center Features New Video Resources

3-A SSI announced a major expansion of its on-line technical resources with the opening of a revamped Knowledge Center and new video resources. The new 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.

The new video gallery includes five titles which are available for viewing on-line or downloading at no charge. The new video titles and approximate run times include:

- ▶ **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.

The video resources include links to other relevant resources on the 3-A SSI website and outlines of the presentation material contained in the video, all free of charge. The new video resources were designed as high-value, user-friendly tools to introduce all interested parties to the ‘value of 3-A’, from understanding the fundamentals of hygienic design to the details of a typical TPV inspection, which is required for authorization to use and display the 3-A Symbol.

Announcement of the new video resources contributed to an increase in unique visitors and a 26% increase in the number visits to the 3-A SSI web site in the first month alone. 3-A SSI continues to promote the expanded Knowledge Center in outreach to various organizations and for general inquiries.

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. The half-day program covered a series of topics including from the mission and scope of new P3-A standards, new P3-A standards in the marketplace, the P3-A symbol, and new standards projects.

The 2009 general industry education program, *The Science of Cleaning*, featured expert presentations from leading authorities on a range of key topics in today's sanitary design environment. Representatives from across the U.S. and Europe participated, including equipment fabricators, regulatory sanitarians and processors.

The program featured expert presentations on key topics in hygienic equipment design, including:

- ▶ **EHEDG Perspective on Equipment Design and Guidelines**—Knuth Lorenzen (GEA Tuchenhausen) President, EHEDG and Dr. Mark Morgan (Purdue University)

- ▶ **Perspectives on U.S. Design and Inspection Criteria**—Steve Sims (Milk Safety Branch, FDA), Philip Wolff (USDA/AMS, Dairy Grading Branch), and Richard K. Smith (Consultant)
- ▶ **Defining Cleaning and Sanitizing**—Dr. Valente Alvarez (Department of Food Science and Technology, The Ohio State University)
- ▶ **Cost and Environmental-saving CIP: Mechanical Force**—Bo Boye Busk Jensen (Alfa Laval Tank Equipment)
- ▶ **Reducing the Environmental Impact of CIP**—Gabe Miller (Sani-Matic, Inc.)
- ▶ **What's New in Cleaners and Sanitizers?**—Dr. Ron Schmidt (University of Florida)
- ▶ **Evaluation of Over-the-Road Food-Grade Bulk Tanker Sanitation**—Paul Winniczuk, Ph.D. (University of Florida)
- ▶ **Mechanical Force Seals**—Andrew Timperley (Timperley Consulting)
- ▶ **Welding and Surface Finishing**—Dick Avery (Nickel Institute)
- ▶ **Dairy Metals**—Sam Sahu (Waukesha Foundry)



Volunteer Service Awards Announced

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:

- ▶ Mr. Don Wilding (Illinois Dept. of Public Health, Div. of Food, Drugs and Dairies) received the Leadership Service Award for a record of significant contribution to 3-A SSI voluntary standards development and outstanding service in enabling 3-A SSI to attain its objectives.
- ▶ Mr. J. Mel Jolly (Consultant) received the Advancement Award for outstanding accomplishments on behalf of 3-A SSI.
- ▶ Mr. Stuart Salvador (Paul Mueller Co.) received the Next Generation Award. This award honors an individual who has been engaged in 3-A SSI standards development activities for less than five years and has demonstrated leadership, dedication and significant contributions to the development of 3-A Sanitary Standards or 3-A Accepted Practices.

3-A SSI Enhances Professionalism of Inspection Program

3-A SSI maintained its commitment to building knowledge and expertise among its accredited Certified Conformance Evaluators (CCEs) throughout a very active year. 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. This past year alone, the CCEs performed over 150 equipment Third Party Verification inspections for the 3-A Symbol program.

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 a 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, create new standards, or in some cases, withdraw a document. Collectively, the WGs devoted hundreds of hours of discussion via phone conferences and meetings.

Among the key accomplishments this year:

- ▶ The establishment of a new Working Group, the Format & Style Manual WG, chartered with developing and revising the *Manual*, used as a guide to 3-A Standards development and revision. Development and revision of the *Manual* follows the same consensus process utilized in developing all of the 3-A Sanitary Standards.
- ▶ The following 3-A Sanitary Standards and 3-A Accepted Practice revisions were published: 27-06 (Equipment for Packaging Dry Products), 33-02 (Metal Tubing), 85-01 (Double-Seat Mixproof Valves), and 610-02 (Sanitary Construction, Installation, and Cleaning of Crossflow Membrane Processing Systems).
- ▶ 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 Sanitary Standards and 3-A Accepted Practices within the Work Group document subgroups.
- ▶ Approximately 23 letter ballots were completed.
- ▶ There currently are 70 active standards development and revision proposals.

This year 3-A SSI attained re-accreditation by the American National Standards Institute (ANSI) as a Standards Developer Organization. ANSI accreditation signifies the new procedures meet the Institute's Essential Requirements for openness, balance, consensus and due process. Formal accreditation provides the opportunity for 3-A SSI to submit new standards developed in accordance with ANSI requirements as American National Standards.



3-A SSI Outreach to New Audiences

3-A SSI expanded its outreach programs to many diverse audiences this year, including current 3-A Symbol holders and many potential new 'customers'.

3-A SSI continued its liaison with dairy representatives from emerging markets around the world as part of the U.S. Department of Commerce Special American Business Internship Training Program (SABIT). In September, 3-A SSI met with a group of dairy industry professionals from Central Asia, Western Eurasia and the Caucasus. 3-A SSI briefed the delegates on 3-A Sanitary Standards, 3-A Accepted Practices and the 3-A Symbol. SABIT's Dairy Processing and Packaging program aims to give participants a comprehensive understanding of the dairy industry in the U.S., with an emphasis on processing technologies, processing and packaging equipment, production automation, industry standards, safety regulations, strategic planning, marketing techniques, and other important industry topics.



3-A SSI reached out to many other audiences in the U.S. this year, including current 3-A Symbol holders and many potential new 'customers'.

April 28-29, 2009	CIP Cleaning and Sanitation Workshop	Columbus, OH
July 12-15, 2009	IAFP Annual Convention	Grapevine, TX
August 26, 2009	FDA Training Seminar	Black Mountain, NC
September 20, 2009	Food Industry Suppliers Association	Lake Tahoe, CA
October 5-7, 2009	Process Expo	Las Vegas, NV
October 28-31, 2009	Worldwide Food Expo, McCormick Place	Chicago, IL

Pharmaceutical (P3-A) Standards

The Pharmaceutical 3-A (P3-A) Council of 3-A SSI initiated a revision of one current standard and launched work on four new standards activities.

A series of technical revisions were proposed for the current P3-A standard for centrifugal pumps. The standard was introduced in 2008.

New standards are in development for Agitated Filter Dryers, Vessels and Agitators, Mills and Classification Equipment, and Process Heat Exchangers.

Upon approval of the new equipment standards, 3-A SSI will introduce commercial use of the new P3-A Symbol for use in conjunction with the marketing of equipment and machinery that meets the requirements of published P3-A Standards. The new registered mark combines the established and respected 3-A Symbol with the stylized 'P' to indicate conformance to a P3-A Standard.

The P3-A Symbol was designed for voluntary display on equipment or machinery that conforms to a P3-A Standard. Use of the P3-A Symbol is subject to the general licensing provisions of 3 A SSI, including the inspection of sample equipment by a Certified Conformance Evaluator (CCE). A prospective licensee must submit a report of conformance for specific names/models of equipment to obtain authorization to display the mark. The third party verification inspection requirement for use of the P3-A Symbol enhances the recognition and the value of the P3-A Symbol for equipment fabricators, regulatory professionals and processors alike.

The commercial display of the P3-A Symbol is intended to benefit equipment fabricators and customers:

- ▶ Equipment fabricators gain broad acceptance of their products because the P3-A Symbol conveys the equipment conforms to materials, design and fabrication criteria critical to acceptance by customers and regulatory authorities. P3-A Standards criteria help reduce the cost of dies, tools and intended delivery time that would result without uniform criteria.
- ▶ Users and specifiers of equipment used for the production of Active Pharmaceutical Ingredients (APIs) gain confidence in the compatibility of equipment because experts on equipment design, pharmaceutical production and other authorities helped develop each P3-A Standard. They know the equipment meets basic criteria for the intended application.





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