Promoting Food Safety Through Hygienic Design

Today it is truer than ever, hygienic design is everyone’s responsibility. And the foundation knowledge required for effective performance is far more extensive than ever before.

The entire ‘culture’ of a food processing operation must be invested in hygienic design, starting with the facility designers to everyone involved in the production, packaging and distribution of food products. In today’s world, the terms ‘sanitary design’ and ‘hygienic design’ are commonly used to describe the same requirements for food processing and facilities. Hygienic design is a process or a set of design principles to manage hazards and reduce food safety risks in food processing equipment, processes and facilities. Equipment design is a critical part of the hygienic design process, but it is only one of many inter-related elements. It is imperative for food processors to take a holistic approach to the design and also look at all of these segments: facility design, cleaning and sanitizing, operational design and GMPs, and the quality programs and regulations for the individual industries. Failure to address hygienic design in any of these segments will result in failure of the overall hygienic design process.

With implementation of the new Preventive Controls rules under the Food Safety Modernization Act (FSMA), all food and beverage manufacturers must prove that their operations are running with proper product safety prior to going to market, rather than merely becoming accountable after a safety violation. This means virtually all businesses must step up testing, documentation and auditing to meet ongoing compliance requirements.

All food industry professionals, whether specialists in engineering, quality assurance, product development, packaging, etc. must have comprehensive and multi-disciplinary knowledge that reflects all phases of the modern food processing operation. Regardless of the type of food, the systems, processes, and safety measures that help assure a safe product draw upon the same general principles of hygienic design. Professionals from across all food industries are reaching out to grow in the breadth and depth of knowledge that will enhance their career and the goal of food safety for the industry they serve. Career professionals must rely on a number of resources, including industry/professional associations, to help enhance their personal skills.

3-A SSI is recognized for a long record of accomplishment in developing criteria for the design of food processing equipment and systems. 3-A SSI continues to gain recognition for the baseline design criteria encompassed by the new 3-A SSI standard introduced in 2014, ANSI/3-A 00-00-2014, 3-A Sanitary Standards for General Requirements. This comprehensive document covers the sanitary design, materials of construction, and fabrication techniques for dairy and for other food and beverage equipment used to handle, process and package consumable products where a high degree of sanitation is required. Conformance to hygienic design and construction principles reflected in 3-A Sanitary Standards improves and facilitates cleaning and sanitation programs. It also facilitates validation. Without proper hygienic design and construction, validation of cleaning efficacy is difficult, if not impossible.

3-A SSI enters the new year with a high level of commitment, the expertise, and the new capability to support the growing needs of professionals from across the food industry. Where the safety of food matters, so does the integrity of hygienic design criteria.
3-A Symbol Authorization Program Continues Growth

The 3-A Symbol licensing program posted the eighth straight year of strong organic growth in 2015, with net growth just short of the record achieved in 2014. The licensing program reflects the increasing demand for 3-A Symbol authorization and the retention of licensees in this vital industry program.

A new Third Party Verification (TPV) inspection requirement for licensees reached final implementation in 2008 and the voluntary 3-A Symbol licensing program experienced positive net growth each year since then. The steady overall growth reflects the demand for food processing equipment meeting provable hygienic design criteria found in 3-A Sanitary Standards and the perceived value of the 3-A Symbol.

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.

The TPV inspection 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 inspection program began in 2003, nearly 2,000 equipment inspections have been completed at fabrication facilities in the U.S. and 29 other countries around the world to verify the equipment conforms to 3-A Sanitary Standards. Other countries include:

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The 3-A SSI website features on-line access to complete certificate information for all 3-A Symbol licensees. This public information offers 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 certificate search database is the most frequently visited area of the 3-A SSI web resources.

The TPV requirement, combined with easy access to licensee information, 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.
3-A SSI Reaches New Audiences

3-A SSI enhanced its role as a trusted resource on hygienic design this year by contributing articles to leading industry publications and providing customized workshops to key audiences. The outreach helped spread important knowledge about the critical role of hygienic equipment design and the many benefits of 3-A Sanitary Standards and 3-A Accepted Practices in a wide range of food processing applications.

3-A Sanitary Design Connections
Readership continued to grow for the quarterly e-newsletter 3-A Sanitary Design Connections, launched in 2013. Connections is designed to address a diverse and broad audience of readers from across the U.S. and around the world, including equipment fabricators, food processors, regulatory sanitarians, academic leaders and students. Representatives from these groups and many others follow Connections because of a common interest in the critical role of the hygienic design of equipment used in the processing of food or other products.

Each issue of Connections includes a lead or feature article on some prominent issue in hygienic equipment design or the role of 3-A Sanitary Standards, 'News of Interest' with relevant news about hygienic design from other sources, and 'What's New In 3-A SSI'. Lead stories in the past year included: "The Bridge to Hygienic Design," "Food Processing System Approvals and the Food Safety Modernization Act (FSMA)," "Focus on Training for Hygienic Equipment Design," and "The FSMA Preventive Controls Rules and Where 3-A Sanitary Standards Fit."

Connections has established a key role in building new awareness of hygienic equipment design and the benefits of 3-A SSI programs and resources. Each issue has achieved a very high open and click through rate. The number of Sponsored Link supporters for the education mission of 3-A SSI also reached a new record this year. The links are shown in each distribution of Connections.

Leading Industry Magazines

In addition, 3-A SSI contributed a special article, "Promoting Food Safety Through Hygienic Design," to Refrigerated & Frozen Foods magazine. The publication reaches 15,000 operation, packaging, production and supply chain executives in the North American market involved in the manufacturing and distribution of all the major categories of value-added, convenience products.

3-A SSI continued a series of three half-page display advertisements in Dairy Foods and Food Engineering (circulation 28,000+) magazines this year. The ads promote recognition of 3-A SSI's integral role in Promoting Food Safety Through Hygienic Design.

3-A SSI cooperated in the development of an extensive article, “3-A SSI & EHEDG Working to Synergize Hygienic Design Standards,” published in the October 2015 issue of Food Engineering. The article highlighted the ways 3-A SSI and the European Hygienic Engineering & Design Group (EHEDG) have cooperated over the past 20 years to create a synergistic set of hygienic design, testing and implementation standards for process equipment.

Trade Shows
3-A SSI maintained direct contact with key professionals across the food processing industry through participation in several key shows in 2015:

- Anuga FoodTec 2015, Cologne, Germany, March 24-27
- International Association for Food Protection – July 25-28, Portland, OR
- Process Expo – September 15-18, Chicago, IL

3-A SSI Hands-on Training
3-A SSI staff and volunteers provided customized on-site training on the elements of hygienic design and 3-A Sanitary Standards and 3-A Accepted Practices for key professional audiences this year. Eric Schweitzer of 3-A SSI and Lyle Clem (Electrol...
Specialties Co.) led a special training workshop for the Michigan Department of Agriculture & Rural Development, Food & Dairy Division-Dairy Section, on Oct. 14 in Grand Rapids, MI. The agenda for the day-long seminar included: 3-A SSI History/Mission, 3-A SSI Structure, TPV Program/TPV Manual, Standards/Accepted Practices, 3-A Sanitary Standards for General Requirements, ANSI/3-A 00-00-2014, 3-A Symbol, CCEs Certification and Continuing Education, Highlights and Overview of a TPV Inspection. Perhaps the most valuable feature of the workshop was a thorough ‘hands-on’ review of equipment design and application.

3-A SSI representatives Tim Rugh and Tracy Schonrock presented an update on 3-A SSI activities at the Plenary Meeting of EHEDG in Belgrade, Serbia on Oct. 15. The presentation included a report on the 3-A Symbol authorization program and a thorough review of the new General Requirements standard and the benefits it will provide to the management of 3-A SSI documents.

Other important outreach included a presentation on Oct. 22 to the PA Dept. of Ag., SE Approved Inspectors in Harrisburg, PA and a presentation on Nov. 12-13 for the Advanced CIP Cleaning and Sanitation Course at rOSU in Columbus, Ohio.

**New Data Management System Introduced**

3-A SSI introduced a new, integrated data management system this year to house and manage information for all 3-A SSI programs and activities. One of the most important functions of the new database is the on-line management of 3-A Symbol authorizations and other certificates.

One of the immediate benefits to licensees is having year-round access to certificate information in the new system. The Primary Contact can update company address and other information for the authorization at any time. This will allow for faster and easier updating of information. In addition, the system will expedite requests for amendments to a 3-A Symbol authorization. Any revision to models/names of equipment listed on a 3-A Symbol authorization certificate must be accompanied by a ‘check-off’ report from the CCE to support the request.

Some of the other benefits for staff and users of the system include:

- Integration of the system data with the 3-A SSI web site, eliminating multiple data bases and support functions.
- Integration with the accounting system and record-keeping functions of 3-A SSI.
- On-line meeting registration for 3 A SSI, eliminating the need for outside meeting registration services.

A brief tutorial ‘Introduction to the New 3-A SSI On-line System’ was posted on the 3-A SSI web site to help orient users to the new system. The tutorial appears in a section with several other Quick Guides on other important topics.

**Student Participation Reaches Record**

Interest in the 3-A SSI Student Travel Award program reached a new high this year in the number of applicants and the number of awards granted. The award is intended to help motivated, career-oriented students to participate in the annual education program of 3-A SSI and gain comprehensive knowledge about sanitary design for food processing equipment and systems.

Recipients of the 2015 awards included Diana Ayala, Texas Tech, Brenda Inestroza, Texas Tech, Zachary Metz, Univ. of Minnesota, Morrine Omolo, Univ. of Minnesota, Katelyn Ortega, Texas Tech, Martha Pena, Texas Tech, Alejandra Ramirez-Hernandez, Texas Tech, Celina To, Cal Poly San Luis Obispo, and Qing Wang, Univ. of Delaware.

The travel awards provided for the recipients to participate in the 3-A SSI education program, ‘The Bridge to Hygienic Design’, and related events on May 11-14, 2015 at the Clarion Hotel & Conference Center in Milwaukee, WI.
Candidates for the 2015 awards demonstrated interest and commitment to food safety and quality as a student enrolled full-time in a food technology, food science, dairy science or other closely related program (undergraduate or graduate level) at a college or university in the U.S. or Canada. Award recipients were selected by a 3-A SSI review committee on the basis of a personal essay, official transcripts and a letter of recommendation from a faculty member or department head.

3-A SSI Volunteer Recognition

The 3-A SSI Volunteer Service Awards recognize the extraordinary dedication and commitment of individuals who contribute to the development of voluntary standards and the mission of 3-A SSI. Nominations for the awards are made by fellow volunteers from the 3-A SSI stakeholder groups—regulatory sanitarians, fabricators, and processors—and others.

3-A SSI Chair Carl Buell (Leprino Foods Co.) announced the following award recipient for 2015:

Larry Hanson (CIP Concepts, LLC) received the 3-A SSI 'Richard K. Smith' Advancement Award for outstanding accomplishments on behalf of 3-A SSI.

3-A SSI Professional Education Program Grows

The education mission of 3-A SSI engaged a large and diverse group of participants this year in a full-day education program, 'The Bridge to Hygienic Design.' The education session was part of a full schedule of events on May 11–14, 2015 at the Clarion Hotel & Conference Center in Milwaukee, Wisconsin.

A special introductory program and networking session opened the program on Monday, May 11, '3-A SSI for Beginners and the Basics of Sanitary Design.' The introductory session was an informal, fast-moving introduction to 3-A SSI and an overview of the elements of hygienic equipment design that distinguish 3-A Sanitary Standards.

The one-day education program highlighted the importance of hygienic design from many perspectives, including product liability, allergen risk control, materials of equipment fabrication, improving upon 'legacy' equipment designs, and much more. Topics and speakers for the program included:

- **Where Hygienic Design and Food Safety Law Collide: How to Design Away Your Regulatory And Litigation Risk**—Shawn K. Stevens, Food Industry Counsel, LLC
- **Validation of Cleaning Systems: Allergens**—Melanie Downs, Ph.D. Food Allergy Research & Resource Program (FARRP), Univ. Of Neb./Lincoln
- **Advanced Chemistry and Microbiology of Food Processing Equipment**—David Blomquist, Ecolab
- **FSMA Update: The Role of 3-A in Your Preventive Controls Plan**—Ron Schmidt, Univ. Of Florida
- **The New 3-A Sanitary Standards General Requirements**—Lyle Clem (FSC), Chair, 3-A Steering Committee
- **Hygienic Design of Food Process Equipment in Asia**—Gary Coates, P.Eng., Nickel Institute, Coordinator—Americas
- **Pet Food Processing—New Attention to Hygienic Design—The Journey of Legacy Equipment to Hygienic Design**—Michele Evans, Executive Director, Food Safety & Quality, Diamond Petfoods
- **Expanding Knowledge of Hygienic Equipment Design**—Steve Stoner, Wisconsin Dept. Ag, Trade & Consumer Protection
- **Surface Finishes and Cleanability**—Paul Kennedy, Pragmatics, Inc.

The annual education program has evolved to serve a large and diverse group of professionals with a common interest in hygienic equipment design, including regulatory sanitarians, fabricators, and processors. Participants also benefit from networking with the leaders of 3-A SSI and other industry newcomers and first-time participants.

3-A SSI Certified Conformance Evaluators Build Inspection Expertise

3-A SSI strives for consistent and uniformly expert assessments of equipment by its accredited Certified Conformance Evaluators (CCEs). CCEs are independent equipment review professionals accredited by 3-A SSI to perform the Third Party Verification (TPV) inspection of equipment required for a 3-A Symbol authorization and other voluntary 3-A SSI certificate programs.
3-A SSI worked this year to support the knowledge and skills of the CCEs in their important inspection work through a period of substantial worldwide demand for new and renewal TPV inspections. The TPV Coordinating Committee, consisting of regulatory sanitarians, fabricator and processor representatives, coordinated a special training seminar for CCEs. In addition, the TPV Coordinating Committee conducted a series of phone conferences throughout the year to refine and improve TPV inspection program procedures and to 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 to all visitors on the 3-A SSI website.

Conversion of 3-A SSI Standards and Accepted Practices Underway

3-A SSI announced the release of ANSI/3-A 00-00-2014, 3-A Sanitary Standards for General Requirements. The new American National Standard (ANS) represents a comprehensive new foundation document for all 3-A SSI minimum sanitary (hygienic) requirements for design, materials, and fabrication/installation of equipment and systems.

Since the introduction of this major resource, 3-A SSI staff and volunteers have moved ahead with the conversion of all 3-A Sanitary Standards and 3-A Accepted Practices to reference the General Requirements. This work represents the largest undertaking in the history of 3-A SSI to update and refine its complete inventory of voluntary standards and practices.

Each of 3-A SSI’s 14 Work Groups started by choosing at least one pilot revision project to gain greater familiarity with the order of work and the structure of the General Requirements document. In brief, the conversion work will entail maintaining only the exclusionary or specific equipment criteria in the converted individual standards; all other relevant 'baseline' criteria from the General Requirements will be shown as a reference. Under the new tiered system of standards, the General Requirements will be easier to maintain and modify, as needed, to reflect the common criteria found throughout all 3-A Sanitary Standards and Accepted Practices. The equipment-specific criteria may include, but is not limited to, normative references, definitions, materials, fabrication criteria for product contact and non-product contact surfaces, installation, maintenance and cleaning recommendations.

The current list of active conversion projects by 3-A SSI Work Groups (WG) are as follows:

- **WG 1 (Vessels) amendment Project B-05-15-A for 3-A Sanitary Standard for Stainless Steel Automotive Transportation Tanks for Bulk Delivery and Farm Pick-Up Service, 05-15.**

- **WG 2 (Fillers) amendment Project B-17-11-A for 3-A Sanitary Standard for Fillers, Fillers, and Sealers of Containers for Fluid Milk and Fluid Milk Products, 17-11.**

- **WG 3 (Valves & Fittings) amendment Project B-42-01-A/B for 3-A Sanitary Standard for In-line Strainers, 42-01.**

- **WG 4 (Pumps & Mixers) amendment Project B-02-11-A for 3-A Sanitary Standards for Centrifugal and Positive Rotary Pumps, 02-11.**

- **WG 5 (Heat Exchangers) amendment Project B-31-06-A for 3-A Sanitary Standard for Scraped Surface Heat Exchangers, 31-06.**

- **WG 6 (Conveyors & Feeders) amendment Project B-81-00-A for 3-A Sanitary Standard for Auger-type Feeders, 81-00.**

- **WG 8 (Concentrating Equipment) amendment Project B-45-02-A for 3-A Sanitary Standard for Crossflow Membrane Modules, 45-02.**

- **WG 9 (Farm & Raw Milk) amendment Project B-13-11-A for 3-A Sanitary Standard for Farm Milk Cooling and Holding Tanks, 13-11.**

- **WG 10 (Cheese & Butter Equipment) amendment Project B-83-00-A for 3-A Sanitary Standard for Enclosed Cheese Vats and Tables, 83-00.**

The conversion of each individual document reflects a substantial contribution of volunteer attention and expertise through the stages drafting, reviewing, balloting and commenting and final editing each Standard from beginning to end. The strength of 3-A SSI rests upon the unwavering commitment of its volunteers to maintaining the most widely recognized and respected criteria for hygienic equipment design.
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