Review paper
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THE VALUE OF 3-A SANITARY STANDARDS FOR PROCESSING EQUIPMENT

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Abstract

3-A Sanitary Standards and 3-A Accepted Practices are internationally recognized as criteria for the fabrication of hygienically designed food processing equipment. Hygienic design of processing equipment is vital for the production of safe, wholesome and high quality food products.

This paper presents a brief history of 3-A Sanitary Standards, Inc. (3-A SSI), how the corporation is structured, and the process for development of the 3-A documents. 3-A SSI is a not-for-profit corporation that administers the development and maintenance of 3-A Sanitary Standards and 3-A Accepted Practices. The objectives of 3-A SSI are:

- To produce uniform standards and practices.
- To use state-of-the-art, science-based expertise for document development.
- To harmonize with global standards and guidelines.
- To promote the use of 3-A Standards and the 3-A Symbol.
- To educate on the value of hygienic design and fabrication of processing equipment.

This paper also discusses the types and number of 3-A documents available, how the documents are developed, the structure of the documents, the value and use of the 3-A Symbol, and how to obtain additional information about 3-A SSI and its documents.

In conclusion the use of 3-A Sanitary Standards and 3-A Accepted Practices can improve food safety and be of benefit to food processors, equipment fabricators and regulatory officials.

Key words: *3-A, hygienic design, processing equipment, standards, food safety, sanitation*.

1. Introduction

3-A Sanitary Standards and 3-A Accepted Practices [1] are internationally recognized as criteria for the fabrication of hygienically designed food processing equipment. Hygienic design of processing equipment is vital for the production of safe, wholesome and high quality food products.

The 3-A Sanitary Standards and 3-A Accepted Practices are a basis for regulatory requirements for the inspection and approval of dairy and food processing equipment in the United States and for the fabricators of that equipment throughout the world. 3-A Sanitary Standards, Inc. (3-A SSI) and the European Hygienic Engineering and Design Group (EHEDG [2]) work together to be the worldwide recognized experts in the field of hygienic design.

2. History of 3-A SSI

3-A Sanitary Standards, Inc. is a relatively new administrative entity. However, 3-A Standards have been used for almost 100 years. The first 3-A Standard was published in 1920 and established criteria for milk pipeline fittings. At that time, the United States was becoming a more urbanized country. Products from farms and food production facilities had to be transported long distances from rural farming areas to the urban markets. Each State and most of the very large metropolitan areas, such as, New York City, Chicago, and Los Angeles had Public Health departments responsible for protecting the health of their citizens. The largest of the public health departments wielded tremendous influence over the products, factories, and processes that they would allow into their jurisdictions. Unfortunately, this influence was not joined with consistency. Each of these jurisdictions could, and often did impose conflicting requirements of acceptability.

The cooperative efforts grew among the primary stakeholders and in 1944 the U. S. Public Health Service [3] joined 3-A to assure that the standards developed would conform to regulatory requirements. This added input from the regulatory sanitarians added significant prestige to the entire acceptance of the 3-A Standards

as they were developed and introduced. Fabricators and users of equipment could now be assured that the equipment or processes they installed would be acceptable to the regulatory bodies during plant inspections.

The popularity and use of the 3-A standards continued to increase. Equipment fabricators eventually wanted a method to advertize and proclaim their conformance. Users of the equipment also wanted an easy method to identify which of the many pieces of equipment available were in conformance. The 3-A Symbol (Fig. 1) was created in 1954 to meet this demand.

Figure 1. 1954 3-A Symbol

The latest improvement to the program came with the establishment of 3-A SSI in 2002 as the sole administrative body to administer all 3-A activities (Figure 2). Prior to this time, the administration was divided between three different groups with only loose coordination between them. The writing of the standards was the function of the equipment fabricators trade association, Food Products Supply Association (FPSA) [5]. The publication of the completed documents was the function of the International Association for Food Protection (IAFP) [6]. The authorizing and administration of the 3-A Symbol Program was held by the 3-A Symbol Council (which is no longer in existence). Each of these organizations relinquished control of their segment to create 3-A SSI.

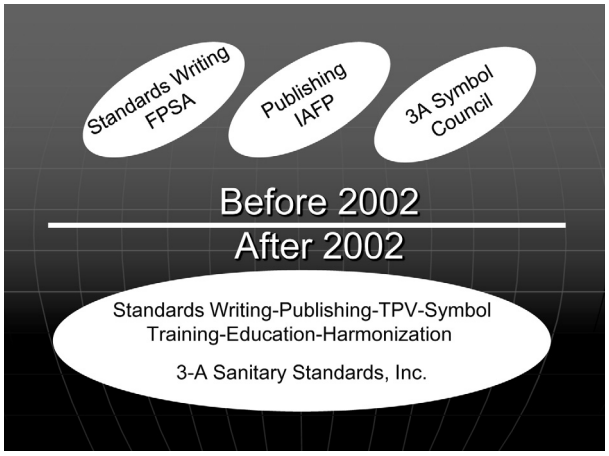

Figure 2. 3-A program activities before and after 2002

3-A SSI is incorporated under the United States Tax Code as an independent, not-for-profit corporation. The organization is administrated by an independent staff under the direction of a Board of Directors. The Board of Directors is selected from each of the three stakeholder groups:

- Food Processors or users
- Equipment Fabricators
- Regulatory Sanitarians

The regulatory sanitarian group consists of representatives of the Food and Drug Administration (FDA [4]), the United States Department of Agriculture (USDA [7]), and individual State sanitarians.

2.1 Objectives of 3-A SSI

The priority goals of 3-A SSI are:

- Develop and maintain uniform standards and practices.
- Utilize state-of-the-art, science-based expertise for the development of standards and practices.
- Harmonize with other global standards and guidelines and standards writing organizations.
- Promote the use of the 3-A Sanitary Standards
- Promote, authorize the use of, and maintain the integrity of the 3-A Symbol.
- Provide education for sanitary design principles, application of 3-A Sanitary Standards and 3-A Accepted Practices, and the use of the 3-A Symbol

2.2 3-A Documents

Currently, there are 70 3-A Sanitary Standards, eight 3-A Accepted Practices, two E3-A Sanitary Standards, and two P3-A Sanitary Standards [1]. The E3-A Sanitary Standards are for unique egg processing equipment types (egg breakers and egg pasteurizers). The P3-A Sanitary Standards are unique to Active Pharmaceutical Ingredients processing equipment. The remaining standards are used extensively in the dairy and food processing industry.

3-A SSI develops two types of documents. They are 3-A Sanitary Standards and 3-A Accepted Practices. A 3-A Sanitary Standard is specific to a type of equipment; e.g. pumps, storage vessels, compression-type valves, sensor fittings, etc. A 3-A Accepted Practice is for specific systems that may or may not include equipment covered by a 3-A Standard. 3-A Accepted Practices cover systems, such as, High-Temperature Short-Time Pasteurizer Systems, Spray Drying Systems, systems for the production of Culinary Steam, etc.

Each of the documents is structured with the same format, which include the following sections:

- Title Page: The title is concise enough to identify the equipment or system being covered by the document.
- Effective Date: The date that the 3-A Sanitary Standards or 3-A Accepted Practices goes into effect.
- Table of Contents
- Scope (Section A): The scope should amplify the Title. For equipment, it should state the function and limits of the equipment and should be distinguishable from those found in other standards. For Accepted Practices, it should identify the nature of the system, the subject or application, and should be distinguishable from those found in other Accepted Practices. In both cases, the scope should be concise, but complete enough to define the boundaries of the equipment or system.
- Normative References (Section B): The Normative References is subdivided into Sections for 3-A Sanitary Standards, 3-A Accepted Practices, and Other References. These references are effectively part of the standard or accepted practice.
- Definition of Terms (Section C): Terminology and definitions are limited to those used in the 3-A document.
- Materials (Section D): This Section considers the self-limiting characteristics of the materials that comprise the equipment. Sanitary specifications dictate allowed materials, with the ultimate criteria being based on the environment of its intended use.
- Fabrication (Section E): All equipment is to be designed to be 100% cleanable and to preclude the contamination of the product or the processing environment. Sanitary criteria always include surface finish requirements (generally equivalent to or smoother than a 32 µin. (0.8 µm R_a) that is free from imperfections such as pits, folds, and crevices, limitations of radii, draining requirements, accessibility for cleaning and inspection, and design requirements for the proposed method of cleaning.
- Installation: Installation criteria, when provided, may include but is not limited to regulatory requirements; proper juxtaposition of equipment, floor, wall or ceiling clearance; and interconnections and hard wiring for required regulatory controls.
- Appendix: The Appendix is an advisory or informative section of 3-A Sanitary Standards or 3-A Accepted Practices unless specifically cited in the Fabrication Section as requiring conformance.

All 3-A documents are developed using the consensus process to assure that all interested parties (stakeholders) have the opportunity to participate and comment on the details of the document. 3-A SSI procedures follow the requirements of the American National Standards Institute (ANSI) [8], *Essential Requirements: Due Process Requirements for American National Standards*.

As a general rule, 3-A documents establish criteria to accommodate multiple methods of cleaning of the equipment from complete disassembly and manual cleaning to clean-in-place (CIP). Therefore, conformance to 3-A criteria does not automatically imply compatibility with CIP cleaning. CIP cleaning does not preclude regular breakdown of equipment for inspection.

2.3 3-A Symbol

Consistent with other Standards Writing Organizations (SDO), such as, the EHEDG, Underwriters Laboratories (UL [9]), and NSF [10], 3-A SSI also has a certification and symbol display program.

Display of the 3-A Symbol is a voluntary program available to equipment manufacturers to allow them to publicly declare that their equipment conforms to the criteria of a specific 3-A Sanitary Standard by placing a 3-A Symbol onto their equipment. This, in turn, allows the buyers and users of the equipment to have the assurance that the equipment is of hygienic design and will meet the regulatory requirements upon inspection.

3-A SSI has administration control over the authorization process and is the owner of the copyrighted symbol. An applicant wishing to display the symbol must enter into a licensing agreement with 3-A SSI. Authorization is based on a Third Party Verification (TPV) of the equipment against the criteria of the covering standard. The TPV is conducted by a 3-A SSI accredited Certified Conformance Evaluator (CCE) at the site of manufacturing or final assembly.

2.4 The Value of Participation of the Regulatory Sanitarians

One pillar of the success and acceptance of 3-A Sanitary Standards and 3-A Accepted Practices in the United States is the long-term participation of the regulatory sanitarian community. The FDA, USDA, and State regulatory agencies have been active participants in the document development process since the mid 1940's. This long and intimate association, during which their concerns are heard and dealt with, has provided the regulators with the confidence that the

documents are in compliance with the regulations. They are assured that as the regulations evolve and change over time, the 3-A Sanitary Standards and 3-A Accepted Practices will reflect those changes. In many cases, the 3-A Sanitary Standards are cited in Federal and State regulations. The dairy and food processing plants benefit as they also have the assurance that equipment meeting the standards, if properly cleaned and maintained, will be accepted during routine regulatory inspections.

2.5 3-A SSI and EHEDG

3-A SSI and EHEDG have a long history of cooperation. The documents of the two organizations support the same basic principles of hygienic design. The documents are not interchangeable but complement and support each other. Efforts by the organizations to harmonize hygienic principles, terminology and the use of their documents are an on-going process.

3. Conclusions

- The 3-A Sanitary Standards and 3-A Accepted Practices are a valuable resource and tool for the design, fabrication and use of hygienic food processing equipment. The documents are developed utilizing state-of-the-art, science based expertise from multiple interested stakeholders. The development process includes regulatory agencies to assure the widest possible acceptance of the standards and accepted practices.
- Hygienic design of processing equipment leads to safe food and greater sales while lowering cleaning and maintenance cost.

4. References

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