#### 3-A Sanitary Standards, Inc.







3-A Standards & Acceptance in US Markets

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### Agenda

- 3-A SSI History/Mission/3-A SSI Structure
- Evolution of Technology/Standards/APs and Acceptance in US
- 3-A Sanitary Standards for General Requirements, ANSI/3-A 00-01-2018
- Third Party Verification Program
- Work Group Projects (Harmonization, Format & Style Revisions, Active Projects)
- 3-A SSI Resources
- Questions & Answers

#### 3-A SSI Mission Statement

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.



#### What is 3-A SSI?

3-A Sanitary Standards, Inc. (3-A SSI) is a not-for-profit 501(c)(3) Accredited Standards Developer (ASD) organization dedicated to protecting public health.

#### 3-A SSI executes its mission by:

- Developing 3-A Sanitary Standards and 3-A Accepted Practices for sanitary equipment design, fabrication and materials of construction
- Providing a TPV program to monitor equipment conformance to individual 3-A Sanitary Standards.

### History of 3-A SSI

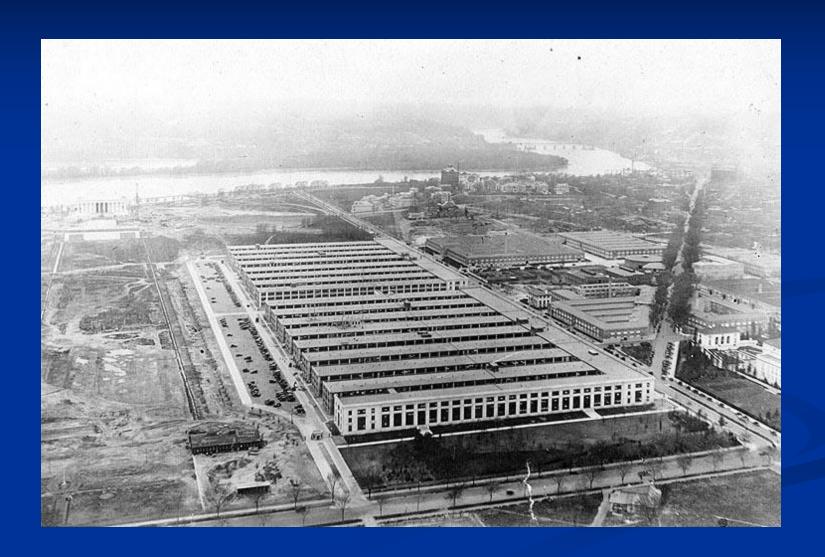
1920 First Standard

1944 USPH Participation

1956 First Symbol

2002 3A-SSI 2003 TPV

Today



### 3-A SSI Standards & Practices

3-A SSI was accredited by the American National Standards Institute (ANSI) as an American Standards Developer in 2004. Consensus development process is audited and in accordance with ANSI Essential Requirements

- Hygienic design criteria for equipment designed and manufactured for use in milk and food products.
- Equipment is designed for cleanability and inspectability.

#### 3-A SSI Structure

Steering Committee
Third-Party Verification Coordinating Committee
Food Processing Suppliers Association (FPSA)
International Association for Food Protection (IAFP)
International Dairy Foods Association (IDFA)
U.S. Department of Agriculture (USDA/AMS)
U.S. Food and Drug Administration (FDA/CFSAN)
European Hygienic Equipment Design Group (EHEDG)

- Public Interest/Regulatory Sanitarians
- User/Processors
- Equipment Fabricators

### 3-A Sanitary Standards WGs

- Vessels
- Fillers
- Valves and Fittings
- Pumps and Mixers
- Heat Exchangers
- Conveyors and Feeders
- Instruments
- Concentrating Equipment

- Farm/Raw Milk
- Cheese and Butter Equipment
- Process & Cleaning Systems
- Plant Support Systems
- Materials and Materials Testing
- General Requirements

### Organizational Stakeholders

The United States Public Health Service (USPHS or PHS) <u>USPHS</u> is a collection of agencies of the Department of Health and Human Services concerned with public health, containing nine out of the department's twelve operating divisions. PHS had its origins in the system of marine hospitals that originated in 1798. In 1871 these were consolidated into the Marine Hospital Service, and shortly afterwards the position of Surgeon General and the PHSCC were established. As the system's scope grew to include quarantine authority and research, it was renamed the Public Health Service in 1912.

Pasteurization was invented during a time when millions of people became sick and died of tuberculosis, scarlet fever, typhoid fever, and other diseases that were transmitted through raw milk. Pasteurization has prevented millions of people from becoming ill. Routine pasteurization of milk began in the United States in the 1920s and became widespread by 1950 as a means to reduce contamination and reduce human illnesses. It led to dramatic reductions in the number of people getting sick. Most public health professionals and health care providers consider pasteurization one of public health's most effective food safety interventions ever!

#### A brief history of raw milk and the law

Pasteurization — the process of briefly heating a substance to high temperatures in order to kill bacteria — was first widely applied to milk in the US during the 1920s.

At the time, the country was rapidly urbanizing, so milk had to travel a greater distance before reaching most customers. In an era before widespread refrigeration and knowledge of proper sanitary practices, this gave bacteria inside milk more time to grow, leading to outbreaks of tuberculosis and other diseases. In response, the FDA and other health officials began encouraging pasteurization. By the 1950s, the treatment was essentially universal for commercially sold milk. Since 1987, the FDA has banned all sales of unpasteurized milk for human consumption that has crossed state lines. Different states, though, have different rules regarding raw milk sold within their borders.







Originally, milking and processing took place on the dairy farm itself. Later, cream was separated from the milk by machine on the farm, and transported to a factory to be made into butter. The skim milk was fed to pigs. This allowed for the high cost of transport (taking the smallest volume high-value product), primitive trucks and the poor quality of roads. Only farms close to factories could afford to take whole milk, which was essential for cheesemaking in industrial quantities, to them.

- Originally milk was distributed in 'pails', a lidded bucket with a handle. These proved impractical for transport by road or rail, and so the milk churn was introduced, based on the tall conical shape of the butter churn. Later large railway containers were introduced, enabling the transport of larger quantities of milk, and over longer distances.
- The development of refrigeration and better road transport, in the late 1950s, has meant that most farmers milk their cows and only temporarily store the milk in large refrigerated bulk tanks, from where it is later transported by truck to central processing facilities.

In the United States, a dairy cow produced about 5,300 pounds (2,400 kg) of milk per year in 1950, while the average Holstein cow in 2019 produces more than 23,000 pounds (10,000 kg) of milk per year. [16]

A. C. BALDWIN. Cow-Milker. No. 212,423. Patented Feb. 18, 1879. Fig.1 Fig.

Baldwin's Hygienic Gove-Milker 1879

This machine consisted of a hand pump connected to a container with a rubber cup that fitted all four teats and pumped them simultaneously. These were both continuous milkers, which proved to be painful to the cows causing them to kick over buckets and contaminate the milk. They did, however, pave the way for future generations of milking machines.

Specification forming part of Letters Patent No. 212,423, dated February 18, 1879; application filed December 21, 1878.

To all whom it may concern:

Be it known that I, Mrs. Anna Corey Baldwin, of Newark, in the county of Essex and State of New Jersey, have invented a new and useful Improvement in Cow-Milkers, known as a "Hygienic Glove-Milker," of which the following is a specification:

In the drawings, Figure 1 is a side elevation.

Fig. 2 is a plan.

My invention relates to appliances for milking cows, wherein a sack or case of elastic rubber is placed over the udder, having at the top a contracting band, made to press closely against the udder, to prevent the air from entering into the case. This sack terminates below in four tubes for the teats, with a pressure-band to close about the upper end of the teat, and the lower ends of the tubes widen out into one tube or sack, the four tubes uniting in one, which extends and connects with a suction-pump, the operation of which on the case and on the pressure-bands draws the milk. This becomes a glove-milker, like an inverted glove-the upper part as the hand on the udder, and the tubes and bands as the thumb and fingers on the teats.

The operation of milking is similar to handmilking, in which the tube extending to the pump compares to an arm, and the tubes and bands for the teats to fingers pressing them, the pressure coming from the suction of the

pump.

A is an elastic rubber sack or case, and B is an elastic compress-band at the upper end, the whole to close over the udder and keep out the air. C C are tubes in the lower end of the case, which are a division of the case

into four tubes for the insertion of the teats; and on these tubes are placed elastic rings D, to be pushed up to the upper end of the tubes, when the teats are in them, to prevent any air that might possibly have passed into the case above from passing into the tubes.

The lower ends of the tubes C run together and form one tube, E, which extends out laterally to form a connection with a suctionpump, F. The pump and milking apparatus may be stationary, and the cow be driven into a certain position relative to it, or may be

portable.

The action of the pump exhausts the air from all the case and tubes, and then draws the milk by the reciprocating pressure, which flows out to fill the vacuum in the tube E, and by the pump is discharged into the pail G.

This simple and harmless method of milking will do the work many times faster than the old hand process, and at a great saving of

tax on the hands of the milker.

A rubber band attached to each side of the case, and extending over the back of the cow, may be used, if needed, to assist in holding the case in position on the udder.

What I claim as my invention, and desire

to secure by Letters Patent, is—

The case A, with the band B to fit on the udder, and the connecting-tubes C C and bands D to fit on the teats, in combination with the tube E and pump F, substantially as and for the purposes specified.

MRS. ANNA COREY BALDWIN.

Witnesses:

HORACE HARRIS, GEO. B. ADAMS.

- Hand milking a cow is an age-old art, basically with a pail, a stool, and two well-conditioned hands you're on your way to becoming a dairy farmer.
- Hand milking was the way of the world until the late 1800's when the first handheld pump milker was invented in 1860 by Lee Colvin in New York. Anna Baldwen, a New Jersey farmer, invented and patented the first milking machine in the United States, known as the "Hygienic Glove Milker" 1879, which was also one of the first American patents listed.
- This machine consisted of a hand pump connected to a container with a rubber cup that fitted all four teats and pumped them simultaneously. These were both continuous milkers, which proved to be painful to the cows causing them to kick over buckets and contaminate the milk. They did, however, pave the way for future generations of milking machines.

#### ■ The First Parts Upgrade

- The pulsator, a part that ensures intermittent flow instead of constant milking, was invented in 1895 and was first put in the Thistle Vacuum Milker; it worked great, but had a few sanitation issues. The pulsator proved to be a better alternative than continuous suction and during the next 20 years several variations of these machines would be used on dairy farms around the world.
- Surge Bucket Milker.

Invented by Herbert McCornack in the early 1920s, this machine surged and moved back and forth, mimicking a calf's natural milking movements. This machine consisted of four short rubber tubes, which made for better sanitation, cleaning, and was more efficient as the vacuum pump was mounted inside the bucket.

- Not much changed during the next thirty years, but when changes happened, they were significant. In the 1950's and 1960's pipeline systems entered the chat. Installed above the milking stalls, pipelines fed into a centralized vat allowing for milking several cows at the same time.
- Introducing Automatic Milking Systems
- Although this would take more than a decade from concept to installation, the first automated commercial milking parlour (or AMS short for automatic milking systems), which was set up in the Netherlands in 1992, revolutionized the dairy industry as a whole.
- Milking robot includes a robotic arm that sterilizes each teat then attaches milking cups guided by lasers.
- Growth of Automatic Milking Systems

#### Technology Evolution/Standardization

- Growth of Automatic Milking Systems
- In 2000, there were approximately 800 AMS farms worldwide; in 2010, there were approximately 10,000 AMS farms worldwide; and today there are more than <u>35,000 Robotic Dairy System</u> (RDS) units worldwide.
- From the first automation on a dairy farm to today, there have been multiple enhancements to the process. The impact? Greater efficiency, better animal welfare, *and* better farmer welfare.

better for the land, the herd, the consumer, the farmer.

#### Technology Evolution/Standardization

- Innovation Milking one cow at a time to rotatory milking parlors.
- Radio Frequency Identification (RFID) tag is read when each cow walks into their milking stall.
- Cow is provided tailored nutrients based on their milking data, health, and body conditioning.
- Individual milk can be tested and then their milk either proceeds to the central vat or be routed to the dump bucket alerting farm staff to any issues that particular cow might have.
- The cow exits the parlor and returns to their barn/stall

#### Technology Evolution/Standardization

- With these systems, cows spend less time being milked, which leaves more time for comfortably resting.
- An average person can milk, by hand, four cows per hour.
- AMIs with a 40 unit rotary parlor can milk up to 220 cows per hour.

- History Of AMS Timeline
- Catheter milking machine 1819 Catheter milking machine first appeared. It was machine tubes made of wood or featuring quills, which could be inserted into the teats, forcing the sphincter muscle to open and allowing milk to flow out of the mammary gland.

- 1851 Hodges and Brockenden developed the earliest vacuum machine that used a large guttapercha cup connected with a hand pump, and was operated by fitting over the entire udder. In the same year, Anna Baldwin developed a similar milker, using a pitcher pump and bucket.
- **1860** L.O./Colvin invented the first successful hand-operated vacuum milker.

- The earliest vacuum milking machine 1889 The first vacuum machines Murchland milking machine named after its inventor William Murchland, commercially entered the British market.
- 1889 In Scotland, William Murchland invented a very successful vacuum milker, which hung suspended under the cow.
- 1898 The USDA finally tested and gave its approval to a pulsator milking machine.

- 1898 The famous Thistle machine was the first to incorporate such a pulsator into the design, which combined a steam-driven pump to effect both suction and squeezing movements.
- 1917 New Zealand dairy farmer Norman Daysh invented the first mechanized milking system for dairy cows. It was finetuned by DeLaval and commercially launched.

- 1922 Herbert McCornack invented the surge milker. This new machine incorporated a tug and pulling motion to the pulsating vacuum of previous milking machines.
- 1952 The herringbone milk parlor was invented in New Zealand.
- 1971 The first automatic milking system was patented in former East Germany.

■ 1980 – NEDAP Co in the Netherlands developed an electronic individual identification system and used it for automatic concentrate feeders in free-stall barns. The Federal Research Institute for Agriculture at Kiel in Germany completed some fundamental aspects of an automatic milking system using ultrasonic sensors, a CCD camera, and a laser to locate the teats.

- 1983 IMAG-DLO at Wageningen in The Netherlands organized the second symposium, entitled "Automation in Dairying."
- 1985 The first milking cup is attached to a cow using a robotic arm under an experimental setting.
- 1986 Hokkaido Konsen Agricultural
   Experiment Station and Hokkaido Industry
   Research Institute started together developing a milking robot.

- 1987 The third symposium on "Automation in Dairying" was held in The Netherlands. Of 47 presentations, seven concerned the automation of milking, including three from the UK, two from West Germany, one from France, and one from Denmark.
- 1988 The research council and the UK Ministry of Agriculture set up a robotic milking project.

- 1990 A automatic milking system developed by CEMAGREF in France was tested for a short period.
- 1992 The first commercial AMS installed on a farm in The Netherlands. It represented one of the most significant technological advances in the dairy industry due to its capability to reduce negative human influences, such as procedural error and microbiological contamination on the resulting milk quality.

- 1992 A Review and Design of Robotic Milking Systems, Mottram, listed the challenges to overcome during milking.
- 1993 A report issued by the Silsoe Research Institute outlined the technology used by one prototype milking robot to tackle the attachment problem.

■ 1996 – The milking robot developed by Duvelsdorf in West Germany used a computer database of the positions of the teats, and an ultrasonic sensor and light barrier established the exact position. This system was taken over by Westfalia in Germany in 1996 and named Leonardo.

## **Equipment Evolution**

- 1997— Alfa Laval in Sweden commercialized the first Voluntary Milking System (VMS). The Advancing Livestock Technology started the project "Promotion of a practical automatic milking system." A committee of the IDF reported field experience Automatic Milking Review IDF2000.
- 1999 Japanese milking robot "Dairy Dream" hit the market.

## **Equipment Evolution**

- 2000 Approximately 800 farms worldwide started using AMS. In Japan, the milking robots were testing at four public agricultural experimental stations and were in use at over 20 private dairy farms.
- **2001** Under Greenfield Project, Hamilton, the first cow milked in New Zealand using an AMS.
- **2007** Approximately 8000 AMS units became operational on farms in 22 countries worldwide.
- 2008 First commercial AMS farms were established in New Zealand.

## **Equipment Evolution**

- **2009** AMS was estimated to be deployed on more than 8000 dairy farms in over 25 countries worldwide.
- **2010** The number of AMS rose to 10000. The first automatic rotary milking parlor was released.
- **2020** 3-A SSI Publishes 1<sup>st</sup> Edition of 3-A Sanitary Standard for Unitized Equipment for Automated Milking Installations, Number 102-00

## Technology Evolution/Standardization

### AMS/AMI

- GEA Farm Technologies
- Lely (Netherlands), Lely Astronaut
   AMS
- DeLaval (Sweden), DeLaval VMS
- Fullwood (UK), Merlin AMS
- Milkomax (Canada), Tie-StallAMS
- BoumaticRobotics (NL), MR-S1, MR-D1
- ADF Milking (UK),
   Manufacturer of the Automatic
   Dipping and Flushing system.

- SAC (Denmark), purchased the Dutch manufacturer of the *Galaxy Robot AMS* in 2005, sell under the brands *SAC RDS Futureline MARK II, Insentec Galaxy Starline*, BouMatic's ProFlex
- Softech (Ahmedabad, India) Manufacturer of Automatic Milk Collection System.
- JSC Mototecha Lithuania, manufacturer of mobile milking parlour systems.

# Voluntary Standards

Incorporated By Reference

3-A Sanitary Standards & Accepted Practices are provided free and available at U.S. Library of Congress

Incorporation by reference is a drafting tool that enables federal agencies to give legal effect to materials that are already published elsewhere. This is allowed under a provision of the Freedom of Information Act, 5 U.S.C. § 552(a)(1). Section 552(a) requires agencies to publish regulations in the Federal Register in order to enforce them. Section 552(a)(1) provides that if material published elsewhere is "reasonably available to the class of persons affected" and the Director of the Federal Register approves its incorporation by reference, that material will be "deemed published" in the Federal Register.

# Voluntary Standards

It is most controversially used to incorporate privately authored voluntary consensus standards into health and safety regulations without infringing the standards developers' copyright. Federal law and policy, embodied in the National Technology Transfer and Advancement Act of 1995 and Office of Management and Budget (OMB) Circular A-119, requires federal agencies to use these standards instead of creating "government-unique" technical standards purely to serve regulatory purposes.[2] In some countries, a specification of a patent application may incorporate by reference the content of a previous patent, patent application, or non-patent publication. The information incorporated by reference is treated as part of the text of the application as filed.[3]

# 3-A Sanitary Standards

 USDA – General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service

All new, replacement or modified equipment and all processing systems, cleaning systems, utensils, or replacement parts shall comply with the most current, appropriate 3-A Sanitary Standards or 3-A Accepted Practices.

# 3-A Sanitary Standards

USPHS/FDA Pasteurized Milk Ordinance (PMO)

Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance.

# 3-A SSI General Requirements for Sanitary Standards

ANSI approved 2/01/2018

The GR is a normative baseline document ("A Level"), which stands on its own by establishing the common fabrication criteria of hygienic design principles and definitions found throughout all 3-A SSI Standards & Accepted Practices.

With all the common elements in one base Standard, all individual equipment Standards and Accepted Practices will reference the General Requirements Standard as a normative reference. Only specific fabrication criteria with necessary exceptions or additions to the GR will be found in the "B Level" Standards/Accepted Practices.

### 3-A Sanitary Standard for Portable Bins for Dry Milk and Dry Milk Products, Number 34-02

Formulated by International Association of Food Industry Suppliers (IAFIS) International Association for Food Protection (IAFP) United States Public Health Service (USPHS)

It is the purpose of the IAFIS, IAFP, USPHS, and DIC in connection with the development of the 3-A Sanitary Standards Program to allow and encourage full freedom for inventive genius or new developments. Portable dry milk bin specifications heretofore or hereafter developed which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for program to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for program to allow and or the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for program to allow and encourage full freedom for inventive genius or new developments. Portable dry milk bin specifications heretofore or hereafter developed which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for program to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for program to the following standards and 3-A Acceptable program to the fabricator's opinion, are equivalent or better, may be submitted for program to the fabricator's opinion, are equivalent or better, may be submitted for program to the fabricator's opinion, are equivalent or better, may be submitted for program to the fabricator's opinion, are equivalent or better, may be submitted for program to the fabricator's opinion, are equivalent or better, may be submitted for program to the fabricator's opinion, are equivalent or better, may be submitted for program to the fabricator's opinion, are equivalent or better, and the fabricator's opinion are equivalent or bett

#### A SCOPE

- A1 This 3-A Sanitary Standard covers the sanitary aspects of portable bins for storage, transportation and handling of dry milk and dry milk products in bulk. They do not pertain to (1) stationary bins, (2) bins (tanks) installed on automotive highway equipment, or (3) piping and appurtenances that are not attached to the bin.
- A2 In order to conform to this 3-A Sanitary Standard, dry milk bins shall comply with the following design, material, and fabrication criteria, and the applicable documents referenced herein. 1

#### B **DEFINITIONS**

B1 *Product:* Shall mean the dry milk or dry milk product which is stored and/or transported in this equipment.

- B2 Dry Milk Bins: (Referred to hereinafter as "bins"). Shall mean portable bins in which products are stored and/or transported.
- B3 Product Contact Surfaces: Shall mean all surfaces that are exposed to the product or from which liquids and/or solids may drain, drop or be drawn into the product.
- B4 Nonproduct Contact Surfaces: Shall mean all other exposed surfaces.
- B5 Mechanical Cleaning or Mechanically Cleaning: Shall denote cleaning, solely by circulation and/or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned, by mechanical means.

#### C MATERIALS

C1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series<sup>2</sup> or corresponding Alloy Cast Institute<sup>3</sup>

<sup>1</sup>Use current revision or editions of all referenced documents cited herein.

<sup>2</sup>The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steels*, November 1990, Table 2-1, pp. 17-20. Available from the American Iron and

Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086 (412) 776-1535.

<sup>3</sup>Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016 (708)

# 3-A SSI Format & Style '03-

3-A Sanitary Standard for Pneumatic Conveyors for Dry Milk and Dry Milk Products, Number 39-01

Standards Developing Organizations 3-A Sanitary Standards, Inc. (3-A SSI) in collaboration with United States Public Health Service (USPHS)

United States Department of Agriculture (USDA)

European Hygienic Engineering & Design Group (EHEDG)

Adopted November 16, 2003

# 3-A SSI Format & Style '03-

#### A SCOPE

aspects of equipment used in systems solely for the pneumatic conveying of dry milk, dry milk products, or other dry comestibles utilizing air flow which is caused by either a pressure or vacuum differential. These standards are not intended to cover pneumatic conveying equipment or systems that are an integral part of a spray drying or instantizing system unless specifically referenced for that purpose in the applicable 3-A Sanitary Standard or 3-A Accepted Practice. The equipment begins at the point at which product enters the conveyor and ends at the point(s) where product is discharged from the conveyor. With respect to air, the equipment begins at the point at the point at the point where conveying air leaves the final filter and ends at the entrance of the air/product separator equipment. These standards also include any required product accumulation, conditioning and metering equipment which are located before product introduction into the conveying air pipeline and which are provided by the equipment manufacturer.

This 3-A Sanitary Standard does not cover the use of:

- Air slide type conveyors which convey product using air flow through a permeable membrane type media or perforated plate.
- 2. Wand type pneumatic conveying equipment from open containers or bags where ambient air can be introduced to convey product.
- 3. Product storage bins, hoppers, silos that are part of the air/product separation equipment.
- 4. Bag collectors, when used as air/product separators, which are covered by 3-A Sanitary Standards for Bag Collectors, No. 40-.
- A2 In order to conform to this 3-A Sanitary Standard, pneumatic dry milk conveyors shall conform to the following design, material and fabrication criteria.

#### A3 Normative references

- A3.1 Doc. No. Title (3-A Sanitary Standard for:)

  18- Multiple-Use Rubber and Rubber-Like Materials

  20- Multiple-Use Plastic Materials

  50- Level Sensing Devices for Dry Products

  53- Compression-Type Valves

  62- Hose Assemblies
- <sup>1</sup> Use current revisions or editions of all referenced documents cited herein.

- Indicators in Contact with Product
- 66- Caged-Ball Valves
- 74- Sensors and Sensor Fittings and
- Connections Used on Equipment
- 78- Spray Devices to Remain in Place
- A3.2 **Doc. No.** Title (3-A Accepted Practice for:)
  604- Supplying Air Under Pressure in
  Contact with Product, and Product
  - 605- Permanently Installed Product and Solution Pipelines and Cleaning Systems

#### DEFINITIONS

- B1 Product: Shall mean the dry milk, dry milk products or other dry comestibles which are conveyed pneumatically in this equipment.
- B2 Dry Milk Conveyors (Referred hereinafter as "conveyors"): Shall mean equipment in which product is conveved pneumatically.
- B3 Conveying Air: Shall mean air in contact with and used to convey product.
- B3.1 Air Under Positive Pressure: Shall mean air, the pressure of which has been increased by mechanical means to exceed atmospheric pressure by one of the following methods:
- B3.1.1 *Compressors*: Shall mean equipment such as rotary screw and reciprocating piston type which compresses air to a maximum of 150 psig.
- B3.1.2 Fans and Blowers: Shall mean equipment such as centrifugal fans, regenerative vane and positive displacement type blowers which increases air pressure to a maximum of 15 psig.
- B3.2 Air Under Negative Pressure: Shall mean air, the pressure of which has been decreased by mechanical means to below atmospheric pressure by one of the following methods:
- B3.2.1 Vacuum Pumps: Shall mean equipment such as; rotary screw, air operated ejector and vane type which decreases air pressure to a maximum vacuum of 29 in.-Hg (737 mm-Hg).

# 3-A SSI General Requirements for Sanitary Standards

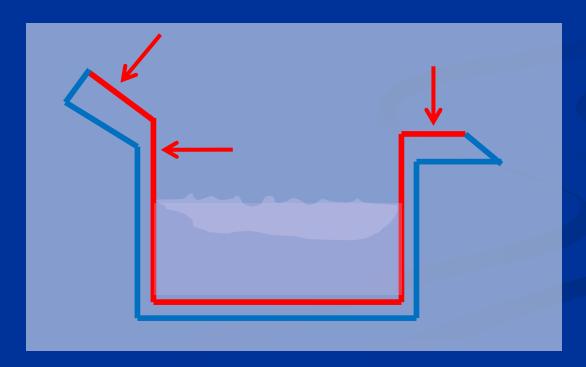
## Scope:

This 3-A Sanitary Standard defines the general requirements for sanitary (hygienic) equipment intended for processing milk, milk products, foods, food ingredients, beverages, or other edible materials.

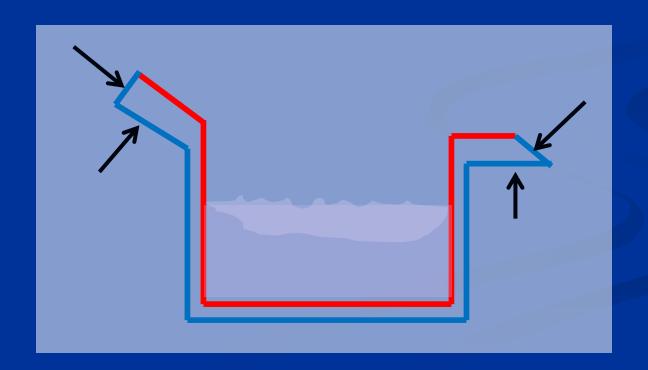
# Structure of General Requirements

- Product Contact
- Non Product Contact

Product Contact Surfaces: All surfaces which are exposed to the product and from which splashed product, liquids, or soil may drain, drop, diffuse or be drawn into the product or onto surfaces that come into contact with product contact surfaces of packaging materials.



Nonproduct Contact Surfaces: All exposed surfaces from which splashed product, liquids, or other soil cannot drain, drop, diffuse or be drawn into or onto the product, product contact surfaces, open packages, or the product contact surfaces of package components.



- PRODUCT & NONPRODUCT CONTACT SURFACES
- Material of Construction
- Surface Texture
- Permanent Joints/Non-Permanent Joints
- Cleaning and Inspectability
- Draining
- Gaskets, Gasket Retaining Grooves, O-rings and Seals
- Radii
- Threads (exposed/ enclosed)
- Coil Springs
- Shafts and bearings
- Openings and Covers

### **Materials for Product Contact Surfaces:**

### Metals/Non-metals

- All materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics under normal use and when exposed to the conditions encountered in the environment of their intended use, including cleaning, sanitizing treatment, and/or sterilization.
- Product contact surfaces shall not impart any toxic substance into the product under normal use and when exposed to the conditions encountered in the environment of their intended use, including cleaning, sanitizing treatment, and/or sterilization. (Note: Reference applicable Federal law and regulation).

Materials for Non-Product Contact Surfaces: Metals/Non-metals

• All nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If the surfaces are coated, including painted surfaces, the coating shall adhere. All nonproduct contact surfaces shall be relatively nonabsorbent, durable, and cleanable. Parts that are removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted.

Surface Texture of Product/Solution Contact Surfaces

Surfaces, including fabricated, welded, soldered, and brazed joints, shall be at least as smooth as a 32 μin. R<sub>a</sub> (0.8 μm R<sub>a</sub>) finish and shall be free of pits, folds, crevices, and cracks in the final fabricated form

Surface Texture of Non-Product Contact Surfaces

Exposed surfaces shall have relatively smooth finishes and be relatively free of pockets and crevices where soil or liquid can collect.

# Applying the GR to New Tech

- New food processing equipment technologies or those without current hygienic design standards can utilize the sanitary construction requirements in the *General Requirements* Standard
- Mature technologies that request
  Standardization for specific hygienic design
  requirements can utilize the *General Requirements*as a normative reference and add only specific
  requirements or exclusions to the *General*Requirements.

## **New Standards in Automation**

- 3-A Sanitary Standard for Robot-based Automation Systems, Number 103-00 — Effective 10/13/2016
- This 3-A Sanitary Standard applies to the sanitary use of industrial robot systems integral with food processing, preparation, or other applications or industries where process equipment cleaning and sanitization is required. This standard addresses the robot and ancillary robotic system equipment, including the robot base, end of arm tooling (EOAT), tool changers, and robot dressing.
- This standard does not apply to robots associated with milking systems on dairy farms.

## **New Standards in Automation**

- 3-A Sanitary Standard for 3-A Sanitary Standard for Unitized Equipment for Automated Milking Installations, Number 102-00 - Effective 3/12/2020
- Applies to the sanitary aspects of the unitized equipment for an automated milking installation (AMI) inclusive of the equipment applied to a hooved mammal to extract milk and continues to all components as used in the automated milking installation exclusive of the container or tank or vessel in which the milk is cooled and stored and from which the milk is removed from the dairy farm.

# ITEM 9r. UTENSILS AND EQUIPMENT - CONSTRUCTION

- "AMIs shall comply with all applicable Grade "A" PMO requirements and/or 3-A Standards.
- 3-A Sanitary Standards and Accepted Practices for dairy equipment are developed by 3- A Sanitary Standards, Inc. (3-A SSI). 3-A SSI is comprised of equipment fabricators, processors, and regulatory sanitarians, which include: State milk regulatory officials, USDA Agricultural Marketing Service Dairy Programs, the USPHS/FDA Center for Food Safety and Applied Nutrition (CFSAN) Milk Safety Team (MST), academic representatives and others. Equipment manufactured in conformity with 3-A Sanitary Standards and Accepted Practices complies with the sanitary design and construction standards of this Ordinance

# Active Standards Development Projects

- WG12- **B-604-05-A** Air Under Pressure for Product
- WG3- B-68-00-A Ball Valves
- WG1- **B-22-08-A** Silo Tank considerations for AMIs
- WG9- **B-13-11-A** Farm Milk Cooling/Holding Tank considerations for AMIs
- WG12- **T-00-01-A** 12<sup>th</sup> meeting ANSI draft designee- 5 year review- projected publication end of 2023

# Get Involved/Industry Support

- 3-A SSI Working Groups
- Working Groups are free to attend/meet 1x/mo.
- Serve as a Voting Member or Observer (Nonvoting Member)
- We greatly appreciate our volunteer Working
   Group Members and greater industry support
- Public Interest/Regulatory Professionals
- User/Processors
- Equipment Fabricators

- Established in 2003
- TPV Coordinating Committee
- Certified Conformance Evaluator
- 3-A Symbol Authorization
- 3-A Process Certificate
- 3-A RPSCQC (Replacement Parts & System Components Qualification Certificate)

- TPV Manual <u>TPV Manual</u>
- Criteria for CCEs: Criteria for CCEs Manual
- CCE Exam- Open Applications due March 2023

- EDTCF (Engineering Design Technical Construction File)
- Material Certificates
- Bill of Materials
- Engineering Change Orders
- TPV Inspection by CCE (Individual Equipment Standard and General Requirements Standard)
- Visual inspection

- 5 year TPV inspection cycle
- Yearly renewal and affidavit required for 3-A Symbol, 3-A RP Mark, 3-A Process Cert.
- Updated Standards require Amendment Report from CCE

RP Mark

3-A Symbol

RPSCQC

No.

## B Level Published Standards

00-01-2018 ANSI/3-A General Requirements		6/2017
01-09	Insulated Tanks	11/2013
02-12	Centrifugal and Positive Rotary Pumps	10/2020
04-06	Homogenizers and Reciprocating Pumps	6/2021
05-16	Transportation Tanks for Bulk Delivery and Farm Pick-up Service	10/2016
11-10	Plate Type Heat Exchangers	2/2020
12-08	Tubular Heat Exchangers	6/2021
17-13	Formers, Fillers, and Sealers of Containers for Fluid and Viscous Products	5/2020
21-02	Centrifugal Separators and Clarifiers	6/2022
26-06	Sifters for Dry Products	12/2019
27-08	Equipment for Packaging Non-fluid Products	12/2021
28-06	Flow Meters	2/2019
30-02	Farm Raw Milk Storage Tanks	7/2018
31-07	Scraped Surface Heat Exchangers	1/2018
32-04	Uninsulated Tanks	2/2020
33-03	Metal Tubing	4/2016
38-01	Open Cheese Vats and Tables	3/2018
42-02	In-Line Strainers	1/2017
44-03	Diaphragm Pumps	11/2001
45-03	Crossflow Membrane Modules	12/2016

## B Level Published Standards

46-04	Refractometers and Energy-Absorbing Optical Sensors	11/2019
50-02	Level Sensing Devices for Dry Products	10/2020
53-07	Compression-Type Valves	7/2021
58-02	Vacuum Breakers and Check Valves	3/2018
61-02	Steam Injection Heaters	11/2018
63-04	Sanitary Fittings	9/2019
70-03	Italian-Type Pasta Filata Style Cheese Cookers	11/2019
74-07	Sensors and Sensor Fittings and Connections	3/2019
78-03	Spray Cleaning Devices Intended to Remain in Place	4/2019
81-01	Auger-Type Feeders	8/2018
83-01	Enclosed Cheese Vats and Tables	11/2019
88-01	Machine Leveling Feet and Supports	10/2019
102-00	Unitized Equipment For Automated Milking Installations	3/2020
103-00	Robot-based Automation Systems	10/2016
605-05	Installation and CIP of Processing Equipment and Hygienic Pipelines	7/2021
610-03	Sanitary Construction, Installation, and Cleaning of Membrane Processing Systems	3/2018

## **3-A SSI Resources**

3-A SSI Annual Meeting
May 8-11, 2023 Hilton Minneapolis, Bloomington, MN

- -Maintain and advance a credible Third Party Verification Program: TPV Manual
- -Promote worldwide recognition and adoption of 3-A Sanitary Standards and 3-A Accepted Practices: <a href="http://www.techstreet.com/3a">http://www.techstreet.com/3a</a>;
- -Administer an efficient consensus process for standards development: <a href="https://www.3-a.org/Standards-Committees/Working-Groups">https://www.3-a.org/Standards-Committees/Working-Groups</a>
- -Serve as an authoritative resource on sanitary equipment design, addressing the education and training needs of all stakeholders: <a href="https://www.3-a.org/Knowledge-Center/About-the-Knowledge-Center">https://www.3-a.org/Knowledge-Center/About-the-Knowledge-Center</a>

## 3-A SSI Knowledge Center

**E-Leaning Modules:** 

https://www.3-a.org/Knowledge-Center/E-learning-Modules

**Overview of Principles of Hygienic Design** 

**Hygienic Equipment Design** 

**Hygienic Facility Design and Environmental Controls** 

**Cleaning and Sanitizing** 

## 3-A SSI Knowledge Center

### **Quick Guides:**

https://www.3-a.org/Knowledge-Center/Quick-Guides

3-A Symbol Overview

Third Party Verification (TPV)

Proper Use/Display of the 3-A Symbol

Buyer Beware: Is It Really '3-A?'

## **Questions?**

More info available at 3-A SSI: www.3-a.org

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