

3-A Sanitary Standards, Inc.



**Dairy Practices Council
48th Annual Conference
11/08/2017**



Task Force V, Milking Systems & Procedures

**Tentative 3-A Sanitary Standard for Unitized
Equipment for Automated Milking Installations,
B-102-00-A**

3-A Sanitary Standards, Inc.

Agenda

- 3-A SSI History/Mission/3-A SSI Structure
- Standards & Accepted Practices
- 3-A Sanitary Standards for General Requirements, ANSI/3-A 00-00-2014
- Draft 3-A Sanitary Standard for Unitized Equipment for Automated Milking Installations, B-102-00-A

What is 3-A SSI?

3-A Sanitary Standards, Inc. (3-A SSI) is a not-for-profit 501(c)(3) Accredited Standards Developing (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 Structure

3-A SSI Steering Committee

Food Processing Suppliers Association (FPSA)

International Association for Food Protection (IAFP)

International Dairy Foods Association (IDFA)

American Dairy Products Institute (ADPI)

U.S. Department of Agriculture (USDA)

U.S. Food and Drug Administration (FDA)

European Hygienic Equipment Design Group (EHEDG)

- **Regulatory Sanitarians**
- **Food and Beverage Processors**
- **Equipment Fabricators**

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.



3-A SSI Mission

-Promoting Food Safety Through Hygienic Design Values:

<http://www.3-a.org/Whats-Going-On-at-3-A/Events>

May 14-18, 2018 Hilton Minneapolis, Bloomington, MN

-Maintain and advance a credible Third Party Verification Program

<http://www.3-a.org/TPV-Resources/Third-Party-Verification-Programs-and-Resources>

-Promote worldwide recognition and adoption of 3-A Sanitary Standards and 3-A Accepted Practices: <http://www.techstreet.com/3a>

-Administer an efficient consensus process for standards development:

<http://www.3-a.org/Standards-Committees/Working-Groups>

-Serve as an authoritative resource on sanitary equipment design, addressing the education and training needs of all stakeholders:

<http://www.3-a.org/Knowledge-Center/About-the-Knowledge-Center>

3-A SSI Mission

Knowledge Center

<http://www.3-a.org/Knowledge-Center/About-the-Knowledge-Center>

<http://www.3-a.org/Knowledge-Center/Resource-Papers>

<http://www.3-a.org/Knowledge-Center/Resource-Links>

<http://www.3-a.org/Knowledge-Center/Video-Resources>

3-A SSI Mission

Knowledge Center

NEW:

E-Learning Modules:

<http://www.3-a.org/http://www.3-a.org/Knowledge-Center/E-learning-Modules>

- 1.0. Overview of Principles of Hygienic Design & Foundation Elements
- 2.0. Basics of Hygienic Equipment Design
- 3.0. Basics of Hygienic Facility Design & Environmental Controls

3-A SSI Mission

Knowledge Center

NEW:

Quick Guides:

<http://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?'](#)

3-A SSI Standards & Practices

3-A SSI was accredited by the American National Standards Institute (ANSI) 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 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
- Materials and Materials Testing
- General Requirements

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 9/08/2014

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 SSI General Requirements for Sanitary Standards

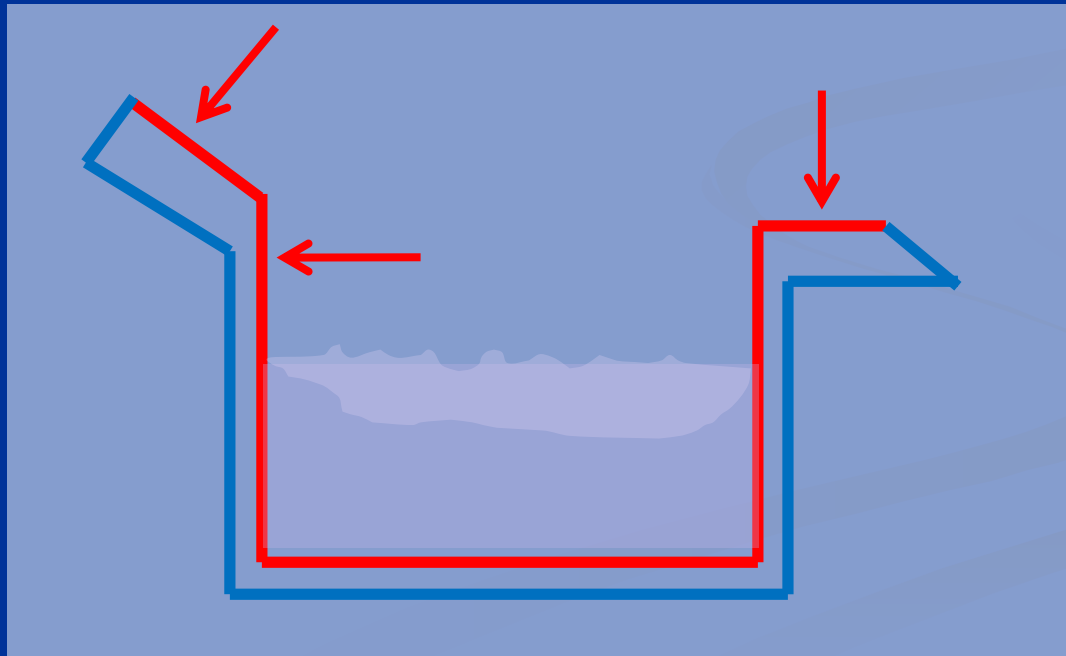
Scope:

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.

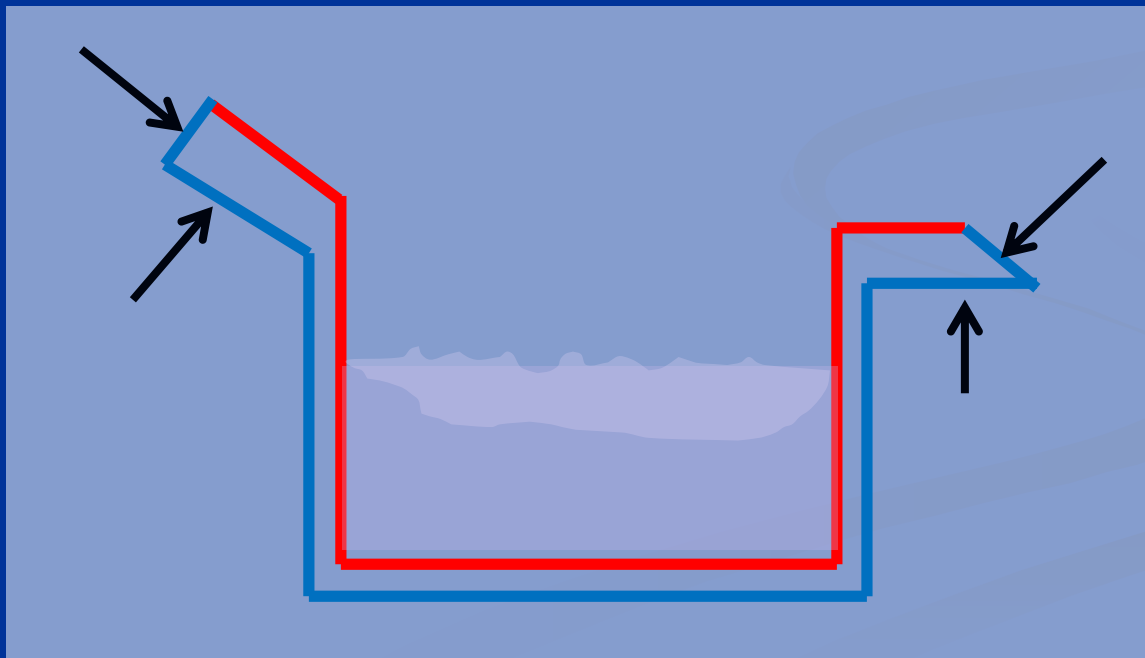
Structure of General Requirements

- 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.



Key Sections of GR

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

Key Sections of GR

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).

Key Sections of GR

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.

Key Sections of GR

Surface Texture of Product/Solution Contact Surfaces

- Surfaces, including fabricated, welded, soldered, and brazed joints, shall be at least as smooth as a 32 $\mu\text{in. } R_a$ (0.8 $\mu\text{m } R_a$) finish and shall be free of pits, folds, crevices, and cracks in the final fabricated form

Key Sections of GR

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/Projects

- *3-A Sanitary Standard for Robot-based Automation Systems, Number 103-00*

Manufacturers, Processors and Sanitarians came to 3-A SSI to develop consensus sanitary design requirements for automated robotic systems due to the growing demand and increase in such systems in the food and dairy plants.

New Standards/Projects

- *Proposed 3-A Sanitary Standard for Automated Milking Installations*

Manufacturers, Processors and Sanitarians came to 3-A SSI to develop consensus sanitary design requirements for new installations requiring block and bleed valve configurations to allow the sanitization of milking equipment.

New Standards/Projects

- *Harmonization with PMO*

Appendix Q of the USFDA Pasteurized Milk Ordinance:

OPERATION OF AUTOMATIC MILKING INSTALLATIONS FOR THE PRODUCTION OF GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRAPASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING OR RETORT PROCESSED AFTER PACKAGING

Appendix Q of PMO

- This Appendix is intended to clarify how AMIs are to be constructed, installed, perform, monitored, maintained, etc. to be considered in compliance with this Ordinance.
- **GENERAL REQUIREMENTS FOR AMI COMPUTER SYSTEMS** AMIs have computer systems that are programmed for monitoring and/or controlling various sensors, instrumentation and the operational state of various devices such as pumps and valves; have data collection, storage and reporting systems; and have communication network capabilities for multiple uses and locations.
- The dairy farm shall have an identified representative(s) that has been trained by the AMI manufacturer or AMI manufacturer's designated representative to make program changes to the AMI system.

Appendix Q of PMO

- ITEM 1r. ABNORMAL MILK AMIs shall have the capability to identify and discard milk from animals that are producing milk with abnormalities.
- ITEM 2r. MILKING BARN, STABLE OR PARLOR – CONSTRUCTION
- ITEM 3r. MILKING BARN, STABLE OR PARLOR– CLEANLINESS ITEM 9r. UTENSILS AND EQUIPMENT– CONSTRUCTION AMIs are the same as any other milking system from a sanitary construction and installation standpoint and shall meet the same standards as a conventional milking system in respect to construction, installation, inspectability, the fit and finish of the milk product-contact surfaces, etc.

Appendix Q of PMO

■ 9r. UTENSILS AND EQUIPMENT– CONSTRUCTION

AMIs are the same as any other milking system from a sanitary construction and installation standpoint and shall meet the same standards as a conventional milking system in respect to construction, installation, inspectability, the fit and finish of the milk product-contact surfaces, etc.

■ ITEM 10r. UTENSILS AND EQUIPMENT– CLEANING

AMIs are a continuous milking system and shall be shut down to clean at an interval sufficient to prevent the milking system from building up with soils. It is recommended that this interval not to exceed eight (8) hours.

Appendix Q of PMO

- ITEM 11r. UTENSILS AND EQUIPMENT – SANITIZATION AMIs shall be sanitized after each cleaning and/or before each use, as is the case with any other milking system.
- ITEM 12r. UTENSILS AND EQUIPMENT – STORAGE AMIs shall have positive air ventilation systems in operation whenever the milking system is being cleaned and/or sanitized.
- ITEM 13r. MILKING – FLANKS, UDDERS AND TEATS AMI manufacturers shall submit data to FDA to show that the teat prepping system employed in their milking system is equivalent to Item 13r.

Appendix Q of PMO

- ITEM 14r. PROTECTION FROM CONTAMINATION The teat cups (inflations) of the milking cluster shall be adequately shielded, or variations may be individually evaluated and found to also be acceptable by FDA and the Regulatory Agency
- AMIs are designed to automatically shift from milking to cleaning/sanitizing positions; therefore, **adequate separation of milk and CIP solution shall be provided to minimize the risk of cross contamination of milk with cleaning and/or sanitizing solutions. A fail-safe valve system providing protection equivalent to an inter-wired block-and-bleed valve arrangement, as referenced in Item 14r of this Ordinance, shall be located as needed to prevent cross contamination.**

Appendix Q of PMO

- ITEM 18r. RAW MILK COOLING For AMIs the raw milk for pasteurization, ultra-pasteurization, aseptic processing and packaging or retort processed after packaging shall be cooled to 10°C (50°F) within four (4) hours or less after starting the milking operation and the milk shall be cooled within two (2) more hours to 7°C (45°F). The milk in the farm bulk milk tank/silo shall not exceed 7°C (45°F) after that time.

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

B-102-00-A Scope

A1 This 3-A Sanitary Standard applies to the sanitary aspects of the unitized equipment for an automated milking installation (AMI) inclusive of the equipment applied to a hooved animal 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. The unitized equipment shall begin with the teat preparation and ends at the outlet of the valve assembly used to separate the milking system lines for normal milk, abnormal milk, and cleaning and sanitizing solutions from the downstream milk line(s), and shall perform automated controls and data recording of each lactating animal inclusive of abnormal milk, CIP cleaning, and one or more of the following functions:

Teat washing components of teat preparation, Teat sanitizing components of teat preparation, Teat cup handling components, Sensing instruments, Product routing and transportation components, Product transfer equipment for acceptable product, Separation of abnormal milk, contaminated milk, undesirable milk, and cleaning/sanitizing solution(s).

B-102-00-A

A2 The equipment components of the AMI may be robotically operated and may consist of:

Teat cup attacher, Teat cup remover, Teat cup liner, Pulsation system, Dip supply valve, Manifold

Milk hoses, Collection cup, Pre-milk collection chambers, Milk flow sensors milk meter shut-off valves, Milk quality sensors, Receiver unit, Disc-type valves, Decision valves, Dump receiver, Flapper valves, Milk pump, Check valves, Air purge valves, Block and bleed valves, Divert valves, Piping, Mixproof valves

B-102-00-A

A3 This standard does not include milking barn, house, stable or parlor criteria of construction as required for Grade “A” Milk per the PMO. These include but are not limited to:

rails, gates to retain the animal in the milking position, feed containers for the animal, animal waste removal from stall area.

B-102-00-A

Normative References:

- 00- General Requirements
- 01- Insulated Tanks
- 02- Centrifugal and Positive Rotary Pumps
- 29- Air Eliminators
- 32- Uninsulated Tanks
- 33- Metal Tubing
- 42- In-line Strainers
- 44- Diaphragm Pumps
- 46- Refractometers
- 53- Compression-Type Valves
- 54- Diaphragm-Type Valves
- 55- Boot Seal Valves
- 57- Disc-Type Valves
- 58- Vacuum Breakers and Check Valves
- 59- Automatic Positive Displacement Samplers
- 62- Hose Assemblies
- 63- Sanitary Fittings
- 64- Pressure Reducing/ Back Pressure Regulating Valves
- 65- Sight and/or Light Windows and Sight Indicators
- 74- Sensors and Sensor Fittings and Connections
- 78- Spray Cleaning Devices Intended to Remain in Place
- 85- Double-Seat Mixproof Valves
- 88- Machine Leveling Feet and Supports
- 604- Supplying Air Under Pressure
- 606- Design, Fabrication, and Installation of Milking and Milk Handling Equipment

Questions?

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

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