

3-A® Sanitary Standard for Non-Coil Type Batch Pasteurizers, Number 24-03

*Standards Developing Organizations
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in collaboration with
United States Public Health Service (USPHS)/
United States Food and Drug Administration (USFDA)
United States Department of Agriculture (USDA)
European Hygienic Engineering & Design Group (EHEDG)*

Effective: July 16, 2010

Note: The highlighted text denotes changes to the previous document.

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Disclaimers

3-A Sanitary Standards and 3-A Accepted Practices are developed through the efforts of experts, working on a volunteer basis, using science-based information and their professional experiences to reach consensus decisions on the sanitary (hygienic) criteria in these 3-A documents.

3-A SSI, its employees and its volunteer committees/working groups shall not incur any obligation or liability for damages, including consequential damages, arising from or in connection with the development, use, interpretation, or reliance upon this 3-A Sanitary Standard.

3-A Sanitary Standards and 3-A Accepted Practices do not include provisions for mechanical, electrical, or personnel safety. Such safety criteria are established by government regulations and other standards development organizations (SDOs). Other SDO standards may be referenced.

Drawings and illustrations contained herein are examples to assist in understanding the criteria in this 3-A Sanitary Standard. Appendix drawings and illustrations are not intended to show all variations of the equipment or system nor are they exclusive of alternate approved methods. Appendix drawings and illustrations are non-normative.

Foreword

This 3-A Sanitary Standard establishes minimum sanitary (hygienic) requirements for design, materials, fabrication, and/or installation of Non-Coil Type Batch Pasteurizers.

This 3-A Sanitary Standard is for use on a voluntary basis by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by other SDOs to assure adequate public health protections exist for the equipment or systems and covered products. 3-A SSI uses these documents as its source of sanitary criteria for 3-A Symbol authorization.

This 3-A Sanitary Standard is developed jointly by 3-A SSI, the United States Public Health Service (USPHS)/United States Food and Drug Administration (USFDA), the United States Department of Agriculture – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our intent to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome at any time for consideration by 3-A SSI. Please forward comments to 3-A SSI, 6888 Elm Street, Suite 2D; McLean, VA 22101-3829, USA or by fax: 703-761-6284, or by e-mail to: 3-ainfo@3-a.org.

A SCOPE

- A1 This standard covers the sanitary aspect of non-coil type batch pasteurizers used to pasteurize milk, fluid milk products, or other fluid food products and includes those appurtenances necessary to meet pasteurization requirements.

This Standard shall be deemed inclusive of the points where the product enters and exits the non-coil type batch pasteurizer.

- A2 In order to conform to this 3-A Sanitary Standard, non-coil type batch pasteurizers shall conform to the following criteria for design, materials of construction, fabrication techniques and installation, as appropriate, and the current revisions or editions of all referenced documents cited herein.

B NORMATIVE REFERENCES

- B1 The following listed 3-A Sanitary Standards, 3-A Accepted Practices and other documents shall be considered as Normative References and the provisions of the referenced documents shall apply to this Standard without further reference in this document, unless necessary to describe special considerations.

B2 3-A Sanitary Standards

<u>Doc. No.</u>	<u>Title (3-A Sanitary Standards for:)</u>
18-	Multiple-Use Rubber and Rubber-Like Materials
20-	Multiple-Use Plastic Materials
33-	Polished Metal Tubing
56-	Inlet and Outlet Leak-Protector Plug-Type Valves
63-	Sanitary Fittings
65-	Sight and/or Light Windows and Sight Indicators
73-	Shear Mixers, Mixers and Agitators
74-	Sensors and Sensor Fittings and Connections Used on Equipment
78-	Spray Devices to Remain in Place
84-	Personnel Access Port for Wet Applications
88-	Machine Leveling Feet and Supports

B3 3-A Accepted Practices

Doc. No.	Title (3-A Accepted Practice for:)
604-	Supplying Air Under Pressure in Contact with Product, and Product Contact Surfaces
609-	Accepted Practice for Culinary Steam

B4 Other References and Standards

Ref. No.	Title
1.	<i>AIST Steel Products Manual, Stainless & Heat Resisting Steels</i> , Table 2-1. Association for Iron & Steel Technology (AIST), 410 Commonwealth Drive, Warrendale, PA 15086, Phone: (412) 776-1535. www.AIST.org
2.	Steel Founders Society of America, 780 McArdle Dr., Unit G, Crystal Lake, IL 60014, Phone: (815) 455-8240, Fax: (815) 455-8241, Internet: www.sfsa.org
3.	ASTM specifications for Cast Grades A351/A351M, A743/A743M and A744/A744M. Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9500.
4.	AWS/ANSI D18.1 – Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems in Sanitary (Hygienic) Applications. AWS D18.2 – Guide to Weld Discoloration Levels on Inside of Austenitic Stainless Steel Tube (ANSI Approved) AWS D18.3/D18.3M - Specification for Welding of Tanks, Vessels, and Other Equipment in Sanitary (Hygienic) Applications (ANSI Approved) Published by American Welding Society, 550 N.W. LeJeune Rd., Miami FL, Phone: (800) 443-3953, www.aws.org .
5.	EHEDG Doc. 9 – Welding Stainless Steel to Meet Hygienic Requirements. European Hygienic Engineering & Design Group. Published by EHEDG, www.ehedg.org
6.	Grade “A” Pasteurized Milk Ordinance, http://www.cfsan.fda.gov/~ear/pmo03toc.html .
7.	The Code of Federal Regulations (CFR), Title 21, Parts 175 – Indirect Food Additives: Adhesives and Components of Coatings. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, Phone: (202) 512-1800 or at http://www.gpoaccess.gov/cfr/index.html .
8.	Aerospace Standard (AS) 568, Aerospace Size Standards for O-rings, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086, Phone: (724)-776-4841.

- 9 ISO 3601-1: The International Organization for Standardization (ISO), 1 Rue de Varembe, Case Postale 58, CH 1 1211, Geneva, Switzerland, Phone: +41-22-734-1240.

C DEFINITIONS

C1 *Product:* Milk, fluid milk products, and other fluid food products.

C2 Surfaces

C2.1 *Product Contact Surfaces:* All surfaces which are exposed to the product and surfaces from which splashed product, liquids or material may drain, drop, or be drawn into the product or onto product contact surfaces.

C2.2 *Nonproduct Contact Surfaces:* All exposed surfaces from which splashed product, liquids, or other materials cannot drain, drop, or be drawn into the product or onto the product contact surfaces.

C3 *Lining:* All surfaces used to contain the product, including the ends, sides, bottom, and top.

C4 *Shell:* The material covering the exterior of the insulation and/or heat exchange jacket.

C5 *Breast:* That portion of the metal used to join the lining to the shell.

C6 *Bridge:* A cover on an open top type tank which is open on both sides and is permanently attached to the lining on opposite sides of the tank. It may be used to support a removable or nonremovable main cover(s) and accessories.

C7 *Readily Accessible:* A location that can be safely reached by personnel from the floor, other permanent work area or stable platform (permanent or moveable).

C8 Cleaning

C8.1 *Clean-in-Place (CIP) Cleaning:* The removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned. Components of the equipment, which are not designed to be cleaned in place, are removed from the equipment to be COP or manually cleaned.

C8.2 *Clean-Out-of-Place (COP):* Removal of soil when the equipment is partially or totally disassembled. Soil removal is effected by circulating chemical solutions and water rinses in a wash tank, which may be fitted with circulating pump(s).

C8.3 *Manual Cleaning:* Removal of soil when the equipment is partially or totally disassembled. Soil removal is effected with chemical solutions and water rinses with the assistance of one or a combination of brushes, nonmetallic scouring pads and scrapers, and high or low pressure hoses,

with cleaning aids manipulated by hand.

C9 *Cleanable or Cleanability:* The suitability of materials of construction, design and fabrication required to assure that the equipment can be freed from soil.

C10 *Inspectable:* Designed, fabricated and installed to make product contact surfaces available for close visual observation.

C11 *Readily Removable:* Designed, fabricated, and installed to be quickly separated from the equipment with or without the use of simple hand tools.

C12 *Simple Hand Tools:* A screwdriver, wrench, mallet, or readily available dedicated tool(s) normally used by operating and cleaning personnel.

D MATERIALS

D1 Product Contact Surfaces

D1.1 Metals

Product contact surfaces shall be of stainless steel of the American Iron and Steel Technology (AIST) 300 Series, excluding 301, 302, and 303 (Refer to B4, Reference No. 1.) or corresponding Alloy Cast Institute (ACI) types (Refer to B4, Reference No. 2.) or metal which under conditions of intended use is at least as corrosion resistant as 304 stainless steel and is nontoxic and nonabsorbent. (Refer to Appendix, Section F.) Where welding is involved, the carbon content of the stainless steel shall not exceed 0.08%. Alloys containing lead, leachable copper or other toxic metals shall not be used.

D1.2 Nonmetals

D1.2.1 Rubber and rubber-like materials may be used for measuring devices (except measuring sticks), slingers or drip shields, agitator seals, agitator guides, protective caps for openings (other than personnel access ports) and/or sanitary fittings, scraper blades, and bonded or removable gaskets and when used for the above-specified application(s), shall conform to the applicable provisions of 3-A Sanitary Standard, Number 18-.

D1.2.2 Plastic materials may be used for bearings, measuring devices (except measuring sticks), slingers or drip shields, agitator seals, agitator guides, protective caps for openings (other than personnel access ports) and/or sanitary fittings, sight and light ports, scraper blades, bonded or removable gaskets, seals and when used for the above-specified application(s), shall conform to the applicable provisions of 3-A Sanitary Standard, Number 20-.

D1.2.3 Rubber and rubber-like materials or plastic materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use, including cleaning and sanitizing.

D1.2.4 Adhesives used for bonding rubber, rubber-like, plastic, carbon, and ceramic materials shall be nontoxic and comply with 21 CFR 175 — *Indirect Food Additives: Adhesives and Components of Coatings* (Refer to B4, Reference No.7).

D1.2.5 Carbon and ceramic materials (including tungsten carbide) may be used for bearing surfaces and rotary seals, and when used, shall be inert, nonporous, nontoxic, nonabsorbent, insoluble, and resistant to scratching, scoring, and distortion when exposed to the conditions encountered in the environment of intended use, including cleaning and sanitizing.

D2 Nonproduct Contact Surfaces

D2.1 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 removable for cleaning having both product and nonproduct contact surfaces shall not be painted.

E FABRICATION

E1 Product Contact Surfaces

E1.1 Surface Texture (Refer to Appendix, Section G)

E1.1.1 Surfaces, including fabricated, welded joints, and soldered joints, shall be at least as smooth as a 32 $\mu\text{in.}$ (0.8 μm) R_a finish and shall be free of pits, folds, crevices and cracks, in the final fabricated form. (Refer to Appendix, Section G.)

E1.2 Permanent Joints

E1.2.1 All permanent joints in metal surfaces shall be continuously welded.

E1.2.2 Permanent joints in sanitary tubing shall be welded in accordance with either AWS/ANSI D18.1 (Refer to B4, Reference No. 4) or EHEDG Doc. 9 (Refer to B4, Reference No. 5).

E1.3 Bonded Materials

E1.3.1 When rubber, rubber-like, plastic, carbon, and ceramic materials are bonded, the bond shall be continuous, be mechanically sound, and not separate when exposed to the conditions encountered in the environment of intended use, including cleaning and sanitizing.