

# 3-A® Sanitary Standard for Homogenizers and Reciprocating Pumps, Number 04-05

*Standards Developing Organizations  
3-A Sanitary Standards, Inc. (3-A SSI)  
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: June 15, 2012**

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

## TABLE OF CONTENTS

|                                            |   |
|--------------------------------------------|---|
| <b>TITLE</b> .....                         | i |
| <b>DISCLAIMERS</b> .....                   | v |
| <b>FOREWORD</b> .....                      | v |
| <b>A SCOPE</b> .....                       | 1 |
| <b>B NORMATIVE REFERENCES</b> .....        | 1 |
| <b>C DEFINITIONS</b> .....                 | 3 |
| C1 Bond .....                              | 3 |
| C2 Burr .....                              | 3 |
| C3 Cleaning .....                          | 3 |
| C3.1 Clean-in-Place (CIP) Cleaning .....   | 3 |
| C3.2 Clean-Out-of-Place .....              | 3 |
| C3.3 Manual Cleaning .....                 | 3 |
| C4 Cleanable or Cleanability .....         | 3 |
| C4.1 CIPable .....                         | 3 |
| C5 Corrosion Resistant .....               | 3 |
| C6 Dead End .....                          | 3 |
| C7 Fittings.....                           | 3 |
| C7.1 CIP Fittings .....                    | 3 |
| C7.2 Manually Cleaned Fittings.....        | 3 |
| C8 Hot Isostatic Pressing (HIP) .....      | 3 |
| C9 High Velocity Oxyfuel Spray (HVOF)..... | 3 |
| C10 Inlet .....                            | 4 |
| C11 Inspectable.....                       | 4 |
| C12 Nontoxic Materials .....               | 4 |
| C13 Outlet/Product Outlet.....             | 4 |
| C14 Processing Area .....                  | 4 |
| C15 Product .....                          | 4 |
| C16 Pumps.....                             | 4 |
| C16.1 Reciprocating Pump .....             | 4 |
| C16.2 Homogenizer .....                    | 4 |
| C17 Readily Accessible .....               | 4 |
| C18 Readily Removable .....                | 4 |
| C19 Roughness Average ( $R_a$ ).....       | 4 |
| C20 Safe Water .....                       | 4 |
| C21 Sanitizing or Sanitization.....        | 4 |
| C22 Simple Hand Tools .....                | 4 |
| C23 Soil .....                             | 4 |
| C24 Solution .....                         | 4 |
| C25 Sterilization .....                    | 4 |
| C26 Substantially Flush .....              | 4 |
| C27 Surfaces .....                         | 5 |
| C27.1 Product Contact Surfaces .....       | 5 |
| C27.2 Nonproduct Contact Surfaces.....     | 5 |
| C27.3 Splash Contact Surfaces .....        | 5 |

|                 |                                                                |           |
|-----------------|----------------------------------------------------------------|-----------|
| C28             | Surface Modification .....                                     | 5         |
| C28.1           | Surface Treatments .....                                       | 5         |
| C28.2           | Coatings, Overlays and Encapsulations .....                    | 5         |
| <b>D</b>        | <b>MATERIALS .....</b>                                         | <b>5</b>  |
| D1              | Product Contact Surfaces.....                                  | 5         |
| D1.1            | Metals .....                                                   | 5         |
| D1.2            | Nonmetals.....                                                 | 6         |
| D1.3            | Lubrication Media .....                                        | 7         |
| D2              | Nonproduct Contact Surfaces .....                              | 7         |
| <b>E</b>        | <b>FABRICATION .....</b>                                       | <b>7</b>  |
| E1              | Product Contact Surfaces.....                                  | 7         |
| E1.1            | Surface Texture .....                                          | 7         |
| E1.2            | Permanent Joints.....                                          | 7         |
| E1.4            | Coatings.....                                                  | 8         |
| E1.5            | Cleaning and Inspectability .....                              | 8         |
| E1.6            | Draining.....                                                  | 8         |
| E1.7            | Gaskets, Gasket Retaining Grooves, O-rings and Seals.....      | 8         |
| E1.8            | Radii .....                                                    | 9         |
| E1.9            | Threads.....                                                   | 10        |
| E1.10           | Coil Springs.....                                              | 10        |
| E1.11           | High-Temperature Systems .....                                 | 10        |
| E1.12           | Pistons or Plungers .....                                      | 11        |
| E1.13           | Bearings or Bushings.....                                      | 11        |
| E1.14           | Homogenizing Valves .....                                      | 11        |
| E1.15           | Safety Relief Valves .....                                     | 11        |
| E2              | Nonproduct Contact Surfaces .....                              | 11        |
| E2.1            | Surfaces .....                                                 | 11        |
| E2.2            | Joints .....                                                   | 11        |
| E2.3            | Name and Information Plates .....                              | 12        |
| E2.4            | Coatings.....                                                  | 12        |
| E2.5            | Cleaning and Inspectability .....                              | 12        |
| E2.6            | Draining.....                                                  | 12        |
| E2.7            | Threads.....                                                   | 12        |
| E2.8            | Service Piping and Lines .....                                 | 13        |
| E2.9            | Panels, Doors, or Access Ports .....                           | 13        |
| E2.10           | Guards and Other Safety Devices .....                          | 13        |
| E2.11           | Supports.....                                                  | 14        |
| E2.12           | Special Considerations .....                                   | 14        |
| <b>APPENDIX</b> |                                                                |           |
| <b>F</b>        | <b>STAINLESS STEEL AND EQUIVALENT MATERIALS .....</b>          | <b>15</b> |
| <b>G</b>        | <b>PRODUCT CONTACT SURFACE FINISH .....</b>                    | <b>20</b> |
| <b>H</b>        | <b>ELECTROLESS NICKEL ALLOY .....</b>                          | <b>20</b> |
| <b>I</b>        | <b>STERILIZING TIME/TEMPERATURE.....</b>                       | <b>20</b> |
| <b>J</b>        | <b>ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE ....</b> | <b>20</b> |
| <b>K</b>        | <b>INSTRUCTION HANDBOOK, MAINTENANCE, AND CLEANING .....</b>   | <b>22</b> |

## Disclaimers

3-A Sanitary Standards, Inc. (3-A SSI) and collaborating organizations do not assume or undertake to discharge all or any responsibilities of manufacturers or any other user of 3-A Sanitary Standards or 3-A Accepted Practices. 3-A SSI is not responsible to any individual, organization or entity for the use of 3-A Standards and 3-A Accepted Practices. It is the science-based opinions, professional findings of volunteer experts and consensus that provides the sanitary (hygienic) criteria included in 3-A documents.

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

3-A Sanitary Standards, Inc., its employees and its volunteer committees shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the development, use, interpretation of, and reliance upon this 3-A Standard.

Drawings and illustrations contained herein are to assist in understanding the criteria in this 3-A Standard. Drawings and illustrations are not intended to show all variations of the equipment or system nor are they to exclude alternate methods meeting this standard. Drawings and illustrations are non-normative.

## Foreword

This 3-A Standard is to establish minimum sanitary (hygienic) requirements for Homogenizers and Reciprocating Pumps. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

This 3-A Standard is for voluntary use by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by 3-A Sanitary Standards, Inc. to assure adequate public health protection exist for the devices and covered products. 3-A Sanitary Standards, Inc. use these documents as the source for sanitary criteria as part of 3-A Symbol authorization.

This 3-A Standard was developed jointly by 3-A Sanitary Standards, Inc. (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 purpose to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome any time for consideration by the 3-A Sanitary Standards Committees. Please forward comments to 3-A SSI, 6888 Elm Street, Suite 2D, McLean, VA 22101-3829 USA. By fax: 703-761-6284. By e-mail to: [3-ainfo@3-a.org](mailto:3-ainfo@3-a.org).

**A SCOPE**

A1 This 3-A Sanitary Standard covers the sanitary aspects of homogenizers and reciprocating pumps, and their integral ancillary components, for milk, milk products and other liquid food products. Product enters the homogenizer or reciprocating pump at the product inlet and exits at the product outlet.

A2 This 3-A Sanitary Standard does not include drum-type pumps.

A3 In order to conform to this 3-A Sanitary Standard, homogenizers and reciprocating pumps 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-             | Metal Tubing                                                  |
| 42-             | In-Line Strainers                                             |
| 53-             | Compression-Type Valves                                       |
| 63-             | Sanitary Fittings                                             |
| 74-             | Sensors and Sensor Fittings and Connections Used on Equipment |
| 82-             | Pulsation Dampening Devices                                   |
| 88-             | Machine Leveling Feet and Supports                            |

B3 3-A Accepted Practices

| <u>Doc. No.</u> | <u>Title (3-A Accepted Practice for:)</u>                                                                                                   |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| 603-            | Sanitary Construction, Installation, Testing, and Operation of High-Temperature Short-Time and Higher-Heat Shorter-Time Pasteurizer Systems |
| 604-            | Supplying Air Under Pressure in Contact with Product or Product Contact Surfaces                                                            |
| 609-            | Method of Producing Steam of Culinary Quality                                                                                               |

B4 Other References and Standards

| <u>Ref. No.</u> | <u>Title</u>                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.              | American Society of Mechanical Engineers (ASME) B46.1 - <i>Surface Texture Waviness and Lay</i> . Available from the American Society of Mechanical Engineers, Three Park Ave., New York, NY 10016-5990, Phone: (212) 705-7722 or at <a href="http://www.asme.org">http://www.asme.org</a>                                                                                                                                               |
| 2.              | National Primary Drinking Water Regulation of the Environmental Protection Agency (EPA), The Code of Federal Regulations (CFR), Title 40, Parts 141, 142, and 143. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, Phone: (202) 512-1800 or the EPA web site at: <a href="http://water.epa.gov/drink/contaminants/index.cfm">http://water.epa.gov/drink/contaminants/index.cfm</a> |

3. Grade "A" Pasteurized Milk Ordinance, available from:  
[www.fda.gov/food/foodsafety/product-specificinformation/milksafety/default.htm](http://www.fda.gov/food/foodsafety/product-specificinformation/milksafety/default.htm)
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](http://www.aws.org)
5. *Advanced Materials and Processes*, Volume 137(1), "Coatings and Coating Practices" by H. Herman, "Surface Modification" by F. A. Smidt. ASM International, Materials Park, OH 44073, Phone: (216) 338-5151, Internet <http://asminternational.org>
6. AMS-S-13165, *Shot Peening of Metal Parts*. SAE International, 400 Commonwealth Dr., Warrendale, PA 15096-0001, Internet: <http://www.sae.org>
7. SAE AMS 2406, Chromium Plating (Electrodeposited). SAE-AMS QQ-N-290A, Nickel Plating (Electrodeposited). SAE International, 400 Commonwealth Dr., Warrendale, PA 15096-0001, Internet: <http://www.sae.org>
8. AIST *Stainless Steels: A Steel Products Manual*, Association for Iron & Steel Technology, 186 Thorn Hill Road, Warrendale, PA 15086, Phone: (724) 814 3000, Internet: [www.aist.org](http://www.aist.org)
9. Steel Casting Handbook, Supplement 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](http://www.sfsa.org)
10. MIL-C-26074E. *Military Specification: Coatings, Electroless Nickel Requirements For*. Standardization, Document Automation & Production Service (Department of Navy), 700 Robbins Avenue, Building 4, Section D, Philadelphia, PA 19111-5094, Phone: (215) 697-2179, Fax: (215) 697-1462.
11. 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, Internet: <http://www.gpoaccess.gov/cfr/index.html>
12. *Machinery's Handbook*, published by Industrial Press Inc., 200 Madison Avenue, New York, NY 10157, Phone: (888) 528-7852, Internet: <http://new.industrialpress.com>
13. Aerospace Standard (AS) 568, Aerospace Size Standards for O-rings, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086, Phone: (724)-776-4841, Internet: <http://www.sae.org>
14. ISO 3601-1:2002: *Fluid Power Systems, Sealing Devices – O-Rings – Part 1: Inside diameters, cross-sections, tolerances and size identification code*, The International Organization for Standardization (ISO), 1 ch. de la Voie-Creuse, Postale 56, CH -1211, Geneva 20, Switzerland, Phone: +41-22-749-01-11, Internet: [www.iso.org](http://www.iso.org)

15. 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. [www.astm.org/standard/index.shtml](http://www.astm.org/standard/index.shtml)

## C DEFINITIONS

C1 *Bond*: The adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.

C2 *Burr*: A thin ridge or sharp area remaining after cutting, drilling, or punching a material.

### C3 Cleaning

C3.1 *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.

C3.2 *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).

C3.3 *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.

C4 *Cleanable or Cleanability*: The suitability of materials of construction, design and fabrication required to assure that the equipment can be freed from soil.

C4.1 *CIPable*: The design and fabrication of equipment which allows the equipment surfaces to be cleaned by CIP methods for a prescribed time and at a prescribed concentration, flow rate, pressure, and temperature demonstrated to be effective.

C5 *Corrosion Resistant*: A surface or material which has the property to retain its original surface characteristics for its predicted service period, when exposed to the conditions encountered in the environment of intended use, including contact with product, cleaning and sanitizing chemicals, steam, or sterilization compounds or solutions.

C6 *Dead End*: An area or space wherein a product, ingredient, cleaning or sanitizing agent, or other extraneous matter may be trapped, retained, or not completely displaced during operational or cleaning procedures.

### C7 Fittings

C7.1 *CIP Fittings*: Fittings designed to be cleaned while fully assembled. If such a fitting has a removable joint, the joint is self-centering, employs a gasket, and the resulting gasketed joint forms a substantially flush interior surface.

C7.2 *Manually Cleaned Fittings*: Removable joint fittings of which the design requires dismantling for manual cleaning.

C8 *Hot Isostatic Pressing (HIP)*: The application of high pressure and temperatures through the medium of a pressuring gas (usually argon or nitrogen), during the precision casting of near net shapes of solid parts and the layering of coatings on substrates, to remove internal porosity and voids, via diffusion bonding, both at the surface and within the casting and coating.

C9 *High Velocity Oxyfuel Spray (HVOF)*: A thermal spray dry process that produces a dense non-porous metal coating from metal powder (usually of a composition inclusive of nickel, nichrome, inconel, chrome oxide and ceramics-tungsten carbide) using a fuel (usually propylene, hydrogen, propane, kerosene/oxygen) which heats the powder to a molten state during the high-velocity delivery at the part to be coated using a propellant gas.

C10 *Inlet*: An opening that allows product, solutions, steam, or air to enter the equipment.

- C11 *Inspectable*: Designed, fabricated and installed to make product contact surfaces available for close visual observation.
- C12 *Nontoxic Materials*: Substances, which under the conditions of their use, are in compliance with applicable requirements of the FDA.
- C13 *Outlet/Product Outlet*: An opening that allows product or solutions to exit the equipment.
- C14 *Processing Area*: A room or area suitable for the manufacturing and packaging of products.
- C15 *Product*: Milk, milk products or other liquid food products.
- C16 **Pumps:**
- C16.1 *Reciprocating Pump*: A positive displacement pump that moves product by reciprocating motion of a plunger(s) or a piston(s) operating in a cylinder(s).
- C16.2 *Homogenizer*: A reciprocating pump which employs a specially designed homogenizing valve(s) for the purpose of reducing particle size and creating an even dispersion and uniform product emulsion. The homogenizing valve(s) may be installed at the homogenizer and/or at a downstream location by means of a suitable high-pressure resistant connection.
- C17 *Readily Accessible*: A location that can be safely reached by personnel from the floor, other permanent work area or stable platform (permanent or moveable).
- C18 *Readily Removable*: Designed, fabricated, and installed to be quickly separated from the equipment with or without the use of simple hand tools.
- C19 *Roughness Average ( $R_a$ )*: An arithmetical mean of the absolute values of the surface profile departure within a sampling length. (Refer to B4, Reference No. 1.)
- C20 *Safe Water*: Water from a supply properly located, protected, and operated, and shall be of a safe, sanitary quality. The water shall meet the standards as described in the National Primary Drinking Water Regulation of the Environmental Protection Agency (EPA) (Refer to B4, Reference No. 2) or Category I Reclaimed Process Water as described in Appendix D of the PMO. (Refer to B4, Reference No. 3.)
- C21 *Sanitizing or Sanitization*: A process applied to a clean surface which is capable of reducing the numbers of the most resistant human pathogens by at least 5  $\log_{10}$  reductions (99.999%) to 7  $\log_{10}$  reductions (99.99999%) by applying hot water, hot air, or steam, or by applying an EPA-registered sanitizer according to label directions. Sanitizing may be effected by mechanical or manual methods.
- C22 *Simple Hand Tools*: A screwdriver, wrench, mallet, or readily available dedicated tool(s) normally used by operating and cleaning personnel.
- C23 *Soil*: Unwanted organic residue or inorganic matter.
- C24 *Solution*: Water or any mixture of cleaning agents, sanitizers and water used for flushing, cleaning, rinsing, or sanitizing.
- C25 *Sterilization*: A process effected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria and inactivates relevant bacterial spores of public health concern.
- C26 *Substantially Flush*: Mating surfaces or other juxtaposed surfaces that are not more than 1/32 in. (0.80 mm) off-set from each other, except for pipeline and tubular piping welds which must meet AWS/ANSI D18.1. (Refer to B4, Reference No. 4.)