

3-A[®] Sanitary Standard for Boot Seal Type Valves, Number 55-02

Standards Developing Organizations

3-A Sanitary Standards, Inc. (3-A SSI)

In collaboration with

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United States Food and Drug Administration (USFDA)

United States Department of Agriculture (USDA)

European Hygienic Engineering & Design Group (EHEDG)

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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 Boot Seal Type Valves.

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 was 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 3-A Sanitary Standard covers the sanitary aspects of boot seal type valves used as components on processing equipment and pipelines that hold or convey milk, milk products, and other food products. The valve assembly includes an actuator moving a piston rod, a boot seal attached to the piston rod and supported by it, and a valve housing or body enclosing the boot seal and providing entry and exit points for the product. Product enters the boot seal type valve at the inlet connection and exits at the outlet connection.
- A2 In order to conform to this 3-A Sanitary Standard, Boot Seal Type Valves 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**Doc. No. Title (3-A Sanitary Standards for:)**

18-	Multiple-Use Rubber and Rubber-Like Materials
20-	Multiple-Use Plastic Materials
33-	Metal Tubing
63-	Sanitary Fittings

B3 Other References and Standards

1. AIST Steel Products Manual, Stainless & Heat Resisting Steels, Table 2-1. Association for Iron & Steel Technology (AIST), 410 Commonwealth Drive, Warrendale, PA 15086, Phone: (412) 776-1535.
2. Steel Casting Handbook, Supplement 2, 1999, available from 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 and A744/A744M. Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9500.
4. ASTM specifications for Wrought Grades A-276, A-582, and A-666. Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9500.
5. (ANSI)/American Society of Mechanical Engineers (ASME) B46.1 - Surface Texture Waviness and Lay. Available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017-2392, Phone: (212) 705-7722.
6. Aerospace Standard (AS) 568, Aerospace Size Standards for O-rings, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086, Phone: (724) 776-4841.
7. ISO 3601-1:2002 Fluid Power Systems, Sealing Devices – O-Rings – Part I: Inside diameters, cross-sections, tolerances, and size identification code., The International

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

8. AWS/ANSI D18.1 – Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems in Sanitary (Hygienic) Applications and AWS D18.2 – Guide to Weld Discoloration Levels on Inside of Austenitic Stainless Steel Tube (ANSI Approved) Published by American Welding Society, 550 N.W. LeJeune Rd., Miami FL, Phone: (800) 443-3953, www.aws.org
9. EHEDG Doc. 9 – Welding Stainless Steel to Meet Hygienic Requirements. European Hygienic Engineering & Design Group. Published by EHEDG, www.ehedg.org
10. EHEDG Doc. 35 – Welding of Stainless Steel Tubing in the Food Industry, European Hygienic Engineering & Design Group. Published by EHEDG, www.ehedg.org
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 or at <http://www.gpoaccess.gov/cfr/index.html>.
12. The Code of Federal Regulations (CFR), Title 29, Part 1910.147 - The Control of Hazardous Energy. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Phone: (202) 512-1800 or at <http://www.gpoaccess.gov/cfr/index.html>.
13. The Code of Federal Regulations (CFR), Title 21, Part 177 Indirect Food Additives: Polymers. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Phone: (202) 512-1800 or at <http://www.gpoaccess.gov/cfr/index.html>.
14. GAR C-9 Cast Microfinish Comparator. Available from Gar Electroforming Division, Electroformers Inc., 11 Augusta Drive, Commerce Park, PO Box 340, Danbury, CT 06813-0340, Phone: (203) 744-4300.
15. EHEDG Doc. 2 – A Method for Assessing the In-Place Cleanability of Food Processing Equipment, European Hygienic Engineering & Design Group. Published by EHEDG, www.ehedg.org
16. 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>.

C DEFINITIONS

- C1 *Bond*: The adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.
- C2 **Cleaning**
- C2.1 *Clean-in-Place (CIP) Cleaning*. (CIP—previously referred to as mechanical 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.
- C2.2 *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).

- C2.3 *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.
- C2.4 *Soil:* Unwanted organic or inorganic matter.
- C2.5 *Sanitization:* A process to adequately treat product contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
- C2.6 *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.
- C3 *Cleanable or Cleanability:* The suitability of materials of construction, design and fabrication required to assure that the equipment can be freed from soil.
- C3.1 *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.
- C4 *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.
- C5 **Fittings**
- C5.1 *CIP Fittings:* Fittings, conforming to 3-A Standard 63- for Sanitary 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.
- C5.2 *Manually Cleaned Fittings:* Removable joint fittings, conforming to 3-A Standard 63- for Sanitary Fittings, of which the design requires dismantling for manual cleaning.
- C6 *Inlet:* An opening that allows product, solutions, steam, or air to enter the equipment.
- C7 *Outlet/Product Outlet:* An opening that allows product or solutions to exit the equipment.
- C8 *Product:* Milk, milk products and other food products.
- C9 *Readily Removable:* Designed, fabricated, and installed to be quickly separated from the equipment with or without the use of simple hand tools.
- C10 *Roughness Average (R_a):* An arithmetical mean of the absolute values of the surface profile departure within a sampling length. (Refer to B3, Reference No. 5.)

C11 Surfaces

C11.1 *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.

C11.2 *Nonproduct Contact Surfaces:* All other exposed surfaces that are not product contact surfaces.

C12 Surface Modification

C12.1 *Surface Treatments:* Processes where chemical composition or mechanical properties of the existing surface are altered. There is no appreciable build-up of new material or removal of existing material.

C12.1.1 Surface treatments include:

1. Mechanical (grinding, polishing)
2. Chemical (etching, oxidation, passivation)
3. Electropolishing

C12.2 *Coatings:* A process where a different material is deposited to create a product contact surface. There is a build-up of new material. The coating material does not alter the physical properties of the substrate.

C13 *Boot Seal:* The boot seal includes multiple functional aspects in one part. The boot seal has a stiff rubber or rubber-like or plastic outer membrane that seals an entry or exit point, a resilient and movable middle section that can flex to accommodate the stroke length of the stem, an internal support to attach the seal to the actuator stem and an external feature which seats in the valve housing and seals it to prevent product entering the chamber around the valve piston rod and actuator assembly.

C14 *Inspectable:* Designed, fabricated and installed to make product contact surfaces available for close visual observation.

D MATERIALS**D1 Product and Solution Contact Surfaces****D1.1 Metals**

D1.1.1 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 B3, Reference No. 1) or corresponding Alloy Cast Institute (ACI) types (Refer to B3, 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 H.) Where welding is involved, the carbon content of the stainless steel shall not exceed 0.08%.

D1.1.2 The valve stem and inner boot seal support may be made of stainless steel of AISI 300 or 400 series or nontoxic, nonabsorbent metal which is as corrosion resistant, under the conditions of intended use, as 304 stainless steel.