

3-A[®] Sanitary Standards for Double-Seat Mixproof Valves, Number 85-03

*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)*

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

Foreword

This 3-A Sanitary Standard is to establish minimum sanitary (hygienic) requirements for Double-Seat Mixproof Valves. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

This 3-A Sanitary Standard is for voluntary use by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by 3-A SSI 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 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.

A SCOPE

- A1 These standards cover the sanitary aspects of double-seat mixproof valves used on processing equipment and on equipment and lines which hold or convey milk, milk products, and other comestibles.
- A2 These valves cannot be used to separate raw milk and milk products from pasteurized milk, milk products, and other comestibles.
- A3 In order to conform to these 3-A Sanitary Standards, double-seat mixproof valves shall conform to the following in design, material and fabrication criteria and the applicable documents referenced herein.¹

B DEFINITIONS

- B1 *Product*: Shall mean milk, milk products, and other comestibles.
- B2 *Solutions*: Shall mean water and/or those homogeneous mixtures of cleaning agents and/or sanitizers and water used for flushing, cleaning, rinsing, and sanitizing.
- B3 *Double-Seat Mixproof Valves*: Shall mean valves which have two independent valve seats separated by a self-draining opening to atmosphere (vent) between the valve seats. Double-Seat Mixproof Valves are also known as Single-Bodied Double-Seat Valves. Double-Seat Mixproof Valves may either weld or clamp their upper and lower valve bodies.
- B4 **Surfaces**
- B4.1 *Product Contact Surfaces*: Shall mean all surfaces which are exposed to the product and surfaces from which liquid may drain, drop, diffuse, or be drawn into the product.
- B4.2 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.
- B5 *Mechanical Cleaning or Mechanically Cleaned*: Shall mean soil removal by impingement, circulation, or flowing cleaning agent solutions and water rinses onto and over the surfaces to be cleaned by mechanical means in equipment or systems specifically designed for this purpose.
- B6 *Bond*: Shall mean the adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.
- B7 *Corrosion Resistant*: Shall mean the surface has the property to maintain its original surface characteristics for its predicted service period when exposed to the conditions encountered in the environment of intended use, including expected contact with product and cleaning, sanitizing, or sterilization compounds or solutions.
- B8 *Easily or Readily Accessible*: Shall mean a location which can be safely reached by personnel from a floor, other permanent work area or stable platform (permanent or moveable).
- B9 *Easily or Readily Removable*: Shall mean separated from the equipment with the use of simple hand tools.
- B10 *Inspectable*: Shall mean all product contact surfaces can be made available for close visual observation.
- B11 *Nontoxic Materials*: Shall mean those substances which under the conditions of their use are in compliance with applicable requirements of the Food and Drug Administration.
- B12 *Sanitizing or Sanitization*: Shall mean a process applied to a cleaned surface which is capable of reducing the numbers of the most resistant human pathogens by at least 5 log₁₀ reductions (99.999%) to 7 log₁₀ reductions (99.99999%) by applying accumulated 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.

¹ Use current revisions or editions of all referenced documents cited herein.

B13 *Simple Hand Tools*: Shall mean implements such as a screwdriver, wrench, or mallet normally used by operating and cleaning personnel.

B14 *Sterilization*: Shall mean a process effected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria and inactivates relevant bacterial spores.

C MATERIALS

C1 Metals

C1.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Technology (AIST) 300 Series² (excluding 301 and 302) or corresponding Alloy Cast Institute (ACI) types³ (See Appendix, Section E.), or metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent.

C2 Nonmetals

C2.1 Rubber and rubber-like materials may be used for gaskets, O-rings, seat seals, body seals, stem seals and stem bearings and parts having the same functional purposes.

C2.1.1 Rubber and rubber-like materials, when used for the above-specified application(s), shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials, Number 18-.

C2.2 Plastic materials may be used for gaskets, O-rings, seat seals, body seals, stem seals, stem bearings and cleaning nozzles and parts having the same functional purposes.

C2.2.1 Plastic materials, when used for the above-specified application(s), shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials, Number 20-.

C2.3 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 and in cleaning and bactericidal treatment or sterilization.

C2.4 The adhesive, if used, for bonding rubber and rubber-like materials and bonding plastic materials shall be nontoxic.⁴

C3 Sterilizability

C3.1 In a processing system to be sterilized by heat and operated at a temperature of 250°F (121°C) or higher, all materials having product contact surface(s) used in the construction of fittings, valves, tubing, gaskets and nonmetallic component parts shall be such that they can be (1) sterilized by saturated steam or water under pressure (at least 15.3 psig or 106 kPa) at a temperature of at least 250°F (121°C) and (2) operated at the temperature required for processing.

C4 Nonproduct Contact Surfaces

C4.1 All nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used shall adhere. All nonproduct contact surfaces shall be relatively nonabsorbent, durable, and cleanable. Parts removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted.

² 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. www.AIST.org

³ Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016.

⁴ Adhesives shall comply with 21 CFR 175 - Indirect Food Additives: Adhesives and Components of Coatings. Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

D FABRICATION**D1 Surface Texture**

- D1.1 All product contact surfaces shall have a finish at least as smooth as a 32 $\mu\text{in.}$ (0.8 μm) ground finish on stainless steel sheets and be free of imperfections such as pits, folds, and crevices in the final fabricated form. (See Appendix, Section F.)

D2 Permanent Joints

- D2.1 All permanent joints in metallic product contact surfaces shall be continuously welded.

D3 Bonded Materials

- D3.1 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be bonded in a manner that the bond is continuous and mechanically sound, so that, when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization, the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded.

D4 Cleaning and Inspectability

- D4.1 Double-seat mixproof valves shall be designed to be mechanically cleaned so that the product contact surfaces and the self-draining opening to the atmosphere between the valve seats and all nonremoved appurtenances thereto can be mechanically cleaned and are readily removable, and inspectable.

D5 Draining

- D5.1 When installed, all product and solution contact surfaces shall be self-draining except for normal adherence, provided further that the following criteria shall apply:

- D5.1.1 Valves with stem seals and guide bushing recesses which are not self-draining shall be constructed so that they can be readily disassembled and are inspectable with or without the use of simple hand tools.

- D5.1.2 Where a valve stem penetrates the valve body, the space outboard of the stem seal is considered to be a product contact surface that is normally dry and self draining only when disassembled. The valve design shall provide a leakage path for visual leak detection for the space outboard of the stem seal. See the following non-normative illustration for an example of this concept.

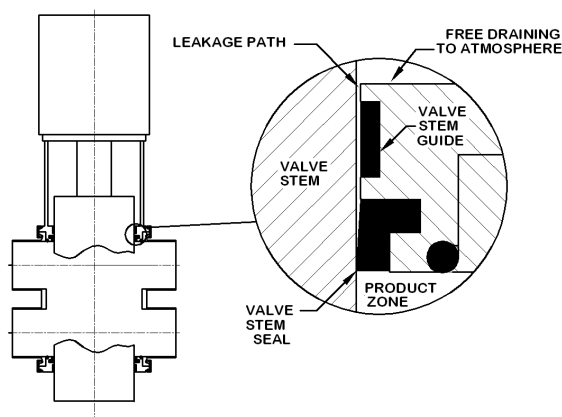


ILLUSTRATION OF LEAK DETECTION PATH CONCEPT (Illustration is Non-normative)

- D5.1.3 Valve stem guides or bearings may be used and if used shall be placed outboard of the seal.
- D5.1.4 Stem guides or bearings that are split to allow insertion are deemed to be in compliance with the leak path requirements of D5.1.2 providing there is at least a 1/32 inch gap in the split of the bearing in the installed position.

D6 Sterilization Systems

- D6.1 In a processing system to be sterilized by heat and operated at a temperature of 250°F (121°C) or higher, fittings, valves, gaskets (if used) and nonmetallic component parts shall conform to the applicable provisions of this standard and the following:
- D6.2 The construction shall be such that they can be (1) sterilized by saturated steam or water under pressure at a temperature of 250°F (121°C) and (2) operated at the temperature required for processing.
- D6.3 The fittings and valves, used in such a system not designed so that it automatically is shut down if the product pressure in the system becomes negative and cannot be started until the system is resterilized, shall have a chamber for steam or other sterilizing medium surrounding the portion of a pipeline fitting, joint, valve, etc., adjacent to the product. The fittings and valves shall be constructed so that the steam or other sterilizing medium chamber may be exposed for inspection.
- D6.4 Where steam or other sterilizing medium is used, the connection(s) on the fitting shall be such that the steam or other sterilizing medium lines can be securely fastened to the fitting.

D7 Fittings

- D7.1 All sanitary fittings and connections shall conform to the applicable provisions of the 3-A Sanitary Standards for Sanitary Fittings, Number 63-, except that:
- D7.1.1 Compression-type fittings may be used for cleaning solutions supplied to the atmospheric vent and directed to waste.

D8 Sanitary Tubing

- D8.1 Metal tubing shall conform to the applicable provisions of 3-A Sanitary Standards for Polished Metal Tubing, Number 33-.

D9 Gaskets

- D9.1 Gaskets having a product contact surface shall be removable or bonded.
- D9.2 Gaskets maintained in grooves by cohesive force bonding shall be installed in such a manner that the bond is continuous and mechanically sound, so that, when exposed to the conditions encountered in the environment of intended use in cleaning and sanitizing treatment the gasket does not separate from the base material to which it is bonded.

D10 Radii

- D10.1 All internal angles of less than 135° on product contact surfaces shall have radii of not less than 1/16 in. (1.6 mm) except that:
- D10.1.1 The seat seal gasket grooves for cohesively bonded gaskets may have radii of less than 1/16 in. (1.6 mm). Sharp corners shall be avoided.
- D10.1.2 Those radii provided for in D7.1 may have a radii less than 1/16 in (1.6mm).
- D10.2 Radii in standard O-ring grooves shall be as specified in Appendix, Section H.
- D10.3 Radii in nonstandard O-ring grooves shall be those radii closest to a standard O-ring as specified in Appendix, Section H.

D11 Threads

- D11.1 There shall be no threads on product contact surfaces.

D12 Shaft Seals

- D12.1 Shafts of double-seat mixproof valves shall have a shaft seal that is of a packless type and is sanitary in design, and shall be readily removable and inspectable.

D13 Additional Fabrication Requirements

A double-seat mixproof valve consists of a valve housing with two chambers. Each chamber has at least one port connected with a pipeline in the piping system. Between the two chambers the valve seat area is arranged with two seats, usually one atop the other with a separation cavity in between. The seats consist of an upper and lower closure device, typically a disc, which are connected to independent upper and lower shafts for opening, closing and individual seat lifting. The self-draining opening between the two seats is open to atmosphere.

- D13.1 Double-seat mixproof valves shall have a self-draining opening to atmosphere between the valve seats. The opening to atmosphere between the two seats shall be cleanable and designed in such a manner that a leak cannot result in the build up of pressure.
- D13.2 Both valve seats shall automatically assume the fully blocked position upon loss of air or power (fail safe).
- D13.3 The valve shall be capable of providing an electrical signal when in the closed position.
- D13.4 Valves may have metal to metal or rubber or rubber-like material to metal valve seats. The rubber or rubber-like material, if used, shall be either removable or bonded and shall conform to the criteria in subsection C2.
- D13.5 Valves may have metal-to-metal or plastic-to-metal valve seats. The plastic material, if used, shall be either removable or bonded and shall conform to the criteria in subsection C2.
- D13.6 Valves with powered actuators shall have an open space of at least 1.0 in. (25 mm), clear for inspection, between the actuator and the valve body.
- D13.7 Powered actuators shall be readily removable from valve body and stem.

D14 Additional Requirements to Separate Milk and Milk Products from Cleaning and Sanitizing Solutions.

- D14.1 The two blocking valves seats shall be position detectable (capable of interrupting an electrical signal when either seat is out of position by more than 1/16in.) (1.59mm) or the exception in D14.2.1.2 is applied.

D14.1.1 Valve seat position detection shall require the valve manufacturer to supply the devices necessary to detect the valve seat positions and movements within the criteria of Section D14.1, provided further that the devices shall be capable of providing electrical feedback to external automation to indicate each valve seat position.

- D14.2 The drainable opening (vent) to the atmosphere between the valve seats shall be at least equal to the largest pipeline size connected to the mixproof valve or one of the exceptions in D14.2.1 is applied.

- D14.2.1 The minimal cross-sectional area for the vent opening shall be equal to that of the largest pipe diameter for double-seat mixproof valve for separation of cleaning and processing circuits, except that one of the following criteria may be applied:

D14.2.1.1 If the cross-sectional area of the vent opening is less than that of the largest pipe diameter for the double seat valve, data shall be submitted to show that the maximum pressure in the space between the two valve seats for the double seat valve is equivalent to or less than the maximum pressure in the space between the two blocking seats of two automatically controlled compression type valves (three-way valve to the drain and a two-way valve separating product lines from cleaning and sanitizing solution lines). (See Appendix I2.)

D14.2.1.2 In low pressure, gravity drain applications (for example, cheese curd transfer lines from cheese process vats) where the product line is the same size or larger than the cleaning or sanitizing solution line, the vent may be the size of the solution line and the valves or valve seats need not be position detectable. In order to accept this variation, the valve(s) must fail to the blocked position upon loss of air or power, and there shall be no pumps capable of pushing milk or milk product, cleaning solutions, or sanitizing solutions into this valve arrangement.