

3-A[®] Sanitary Standards for Pressure Reducing and Back Pressure Regulating Valves for Milk and Milk Products, Number 64-00

Formulated by
International Association of Food Industry Suppliers (IAFIS)
International Association for Food Protection (IAFP)
United States Public Health Service (USPHS)
The Dairy Industry Committee (DIC)

It is the purpose of the IAFIS, IAFP, USPHS, and DIC in connection with the development of the 3-A Sanitary Standards program to allow and encourage full freedom for inventive genius or new developments. Pressure reducing and back pressure regulating valves specifications heretofore or hereafter developed which so differ in design, material, and fabrication, or otherwise as not to conform with the following standards but which, in the manufacturer's or fabricators opinion are equivalent or better may be submitted for the joint consideration of IAFIS, IAFP, USPHS, and DIC at any time. The 3-A Sanitary Standards and 3-A Accepted Practices provide hygienic criteria applicable to equipment and systems used to produce, process, and package milk, milk products, and other perishable foods or comestible products. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

A SCOPE

A1 These standards cover the sanitary aspects of pressure reducing and back pressure regulating valves used on processing equipment and on equipment and lines which hold or convey milk or milk products.

A2 In order to conform to these 3-A Sanitary Standards, pressure reducing and back pressure regulating valves shall comply with the following design, material and fabrication criteria.¹

B DEFINITIONS

B1 *Product*: Shall mean milk and milk production.

B2 *Back Pressure Regulating Valve*: Shall mean a device which controls product inlet pressure by responding to changes of the inlet pressure by means of a self-acting actuator.

B3 *Pressure Reducing Regulating Valve*: Shall mean a device which controls product outlet pressure by

responding to outlet pressure changes by means of a self-acting actuator.

B4 *Self-Acting Actuator*: Shall mean the device that reciprocates the plug and stem assembly on and off the valve seat within the valve body by means of product, cleaning or sterilization fluid forces within the valve body acting against a diaphragm or series of diaphragms separating the internal and external pneumatic or mechanical forces.

B5 *Diaphragm Neutral Position*: Shall mean the position and shape the diaphragm assumes with relationship to the valve body and the valve stem when there are no forces being exerted on either side of the diaphragm.

B6 *Bonnet*: Shall mean the chamber on the exterior side of the diaphragm.

B7 Surfaces

B7.1 *Product Contact Surfaces*: Shall mean all surfaces which are exposed to the product and surfaces from which liquids may drain, drop or be drawn into the product.

B7.2 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.

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

B8 *Mechanical Cleaning or Mechanically Cleaned:* Shall denote cleaning, solely by circulation and/or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned, by mechanical means.

C MATERIALS

C1 Metals

C1.1 All product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series² or corresponding Alloy Cast Institute (ACI) types³ (See Appendix, Section E.) or metal which under conditions of intended use is equally corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent, except that:

C2 Nonmetals

C2.1 Rubber and rubber-like materials may be used for gaskets, O-rings, seals, valve seats, valve plugs, diaphragms and parts having the same functional purposes.

C2.2 Rubber and rubber-like materials when used for the above specified applications shall comply with the applicable provisions of the current 3-A Sanitary Standards for Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment, Number 18-.

C2.3 Plastic materials may be used for gaskets, O-rings, seals, valve seats, valve plugs, diaphragms and parts having the same functional purposes.

C2.4 Plastic materials when used for the above-specified applications shall comply with the applicable provisions of the current 3-A Sanitary Standards for Multiple- Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-.

C2.5 Rubber and rubber-like materials and plastic

materials having product contact surfaces that are a bonded coating or a covering shall be of such a composition as to retain their surface and conformation characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.

C2.7 The final bond and residual adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials shall be nontoxic.⁴

C2.8 Diaphragms, O-rings and valve seats may also be made of hard rubber (a vulcanized rubber having a ratio of combined sulfur to rubber hydrocarbon in excess of 15 % and a Shore A Durometer value in excess of 90) that is nontoxic and relatively resistant to abrasion, will maintain its original characteristics such as form, shape and dimensions and will not affect the product and when subjected to the test regimen set forth in the current 3-A Standards for Plastic Materials Used as Product Contact Surfaces for Dairy Equipment, Number 20-, shall (a) comply with the criteria in Section I (1) and Section 1(3), (b) have maximum weight gains as set forth in Section 1(2) of 0.30 in the Cleanability Response, 0.30 in Product Treatment with Solution I and 0.30 in Product Treatment with Solution J.

C2.9 In a processing system to be sterilized by heat and operated at a temperature of 250° F (121° C) or higher, all materials having a product contact surface(s) used in the construction of pressure reducing and back pressure regulating valves and nonmetallic component parts shall be such that they can be (1) sterilized 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.

C3 Nonproduct Contact Surfaces

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

²The data for this series are contained in the *AISI Steel Products Manual, Stainless & Heat Resisting Steels*, November 1990, Table 2-1, pp. 17-20. Available from the American Iron and Steel Society, 186 Thorn Hill Road, Warrendale, PA 15086 (724) 776-1535.

³Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016 (708) 299-9160.

⁴Adhesives 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, DC 20402 (202)512-1800.

shall be relatively nonabsorbent durable and cleanable. Parts removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted

D **FABRICATION**

D1 **Surface Texture**

- D1.1 All product contact surfaces shall have a finish at least as smooth as a No. 4 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. Welded areas on product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets, and be free of imperfections such as pits, folds, and crevices.

D3 **Cleaning and Inspectability**

- D3.1 Appurtenances having product contact surfaces shall be removable for cleaning using simple hand tools used by operating or cleaning personnel, or they shall be cleanable in place and accessible for inspection employing simple hand tools used by operating or cleaning personnel.
- D3.2 Pressure reducing and back pressure regulating valves that are to be mechanically cleaned shall be designed so that the product contact surfaces of the internal valve body, diaphragm and plug, and all nonremovable components thereto can be mechanically cleaned and are easily accessible for inspection.
- D3.3 Product contact surfaces not designed to be mechanically cleaned shall be accessible for cleaning and inspection when in an assembled position or when removed. Removable parts shall be demountable using simple hand tools used by operating or cleaning personnel.
- D3.4 Pressure reducing or back pressure regulating valves to be used in a processing system to be sterilized or those to be mechanically cleaned shall comply with the following:

- D3.4.1 Due to the inherent tendency to close or to regulate and restrict flow under certain pressure conditions, pressure reducing and back pressure regulating valves to be used in such a system must be designed so that they can be easily maintained fully open either by a mechanical device or by pneumatic forces without removal from the processing system.

- D3.4.2 Where heat sterilization is used, the construction shall be such that all product contact surfaces 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) operate at the temperature required for processing.

- D3.4.3 Where steam or other sterilizing medium is used, the connection(s) on the inlet and outlet shall be such that the steam lines or other sterilizing medium lines can be securely fastened to the pressure reducing and back pressure regulating valves.

D4 **Draining**

- D4.1 All product contact surfaces shall be self-draining when the regulating valve is properly installed and the valve is in the open position.

D5 **Sanitary Fittings and Connections**

- D5.1 All sanitary fittings and connections shall conform with the applicable provisions of the current 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products, Number 63-.

D6 **Gaskets**

- D6.1 Gaskets having a product contact surface shall be removable or bonded.
- D6.2 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, and the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded.