

3-A[®] Sanitary Standards for Personnel Access Ports for Wet Applications, Number 84-02

*Standards Developing Organizations
3-A Sanitary Standards, Inc. (3-A SSI)
in collaboration with
United States Public Health Service (USPHS)
United States Department of Agriculture (USDA)
European Hygienic Engineering & Design Group (EHEDG)*

Effective: June 1, 2007

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

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 Standards.

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 (it) 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 Personnel Access Ports for Wet Applications. 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), 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 the 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 atmospheric or pressure-type personnel access ports and associated covers for wet applications. They may include the mounting flanges, hinges, covers, dust covers and may be of the inside swing, outside swing, sliding, or removable types. These standards do not include installation criteria.

A2 In order to conform to these 3-A Sanitary Standards personnel access ports shall conform to the following in design, material and fabrication criteria.¹

A3 Normative references**Doc. No. Title (3-A Sanitary Standard for:)**

- 18- Multiple-Use Rubber and Rubber-Like Materials
- 20- Multiple-Use Plastic Materials
- 33- Polished Metal Tubing
- 55- Boot Seal-Type Valves
- 59- Automatic Positive Displacement Samplers for Fluid Products
- 63- Sanitary Fittings
- 65- Sight and/or Light Windows and Sight Indicators in Contact with Product
- 74- Sensors and Sensor Fittings and Connections
- 78- Spray Devices to Remain in Place
- 605- Permanently Installed Product and Solution Pipelines and Cleaning Systems

B DEFINITIONS

B1 *Product*: Shall mean milk and 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 *Personnel Access Ports (PAP)*: Shall mean assemblies that allow personnel entry into equipment.

B4 Surfaces

B4.1 *Product Contact Surfaces*: Shall mean all surfaces which are exposed to the product and surfaces from which liquids may drain, drop, diffuse or be drawn

into the product.

B4.2 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.

B5 Cleaning

B5.1 *Mechanical Cleaning or Mechanically Cleaned*: Shall mean soil removal by impingement, circulation or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned by mechanical means in equipment or systems specifically designed for this purpose.

B5.2 *Manual (COP) Cleaning*: Shall mean soil removal 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, high or low pressure hoses and tank(s) which may be fitted with recirculating pump(s), and with all cleaning aids manipulated by hand.

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 *Dust Cover*: Shall mean the exterior cover of the personnel access port that encloses the inner cover and sanitary vent, which seals against the deck plate. Dust cover when closed should prevent tampering with the inner cover and vent. Hinge pin must not be removable when the dust cover is in the closed position.

B9 *Easily or Readily Accessible*: Shall mean a location which can be safely reached by personnel from a floor, other permanent work area, stable platform, (permanent or moveable).

B10 *Easily or Readily Removable*: Shall mean separated from the equipment with the use of simple hand tools if necessary.

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

- B11 *Inspectable*: Shall mean all product contact surfaces can be made available for close visual observation.
- B12 *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.
- B13 *PAP Covers*: Shall mean the moveable component(s) that closes and/or seals the PAP. Covers may include doors and/or dust covers.
- B14 *Roughness Average (Ra)*: Is the logarithm to the base 10 of the arithmetic mean of the surface profile usually expressed in microinches (μin.) or micrometers (μm) related to surface roughness (ASME-BPE).²
- B15 *Simple Hand Tools*: Shall mean implements such as a screwdriver, wrench, or mallet normally used by operating and cleaning personnel.
- B16 *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.

C MATERIALS

C1 Metals

- C1.1 All product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series³ (except 301 and 302) or corresponding Alloy Cast Institute (ACI)⁴ types (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.

² Available from American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017-2392.

³ *AISI Steel Products Manual, Stainless & Heat Resisting Steels*, Table 2-1. Available from the American Iron and Steel Society, 186 Thorn Hill Road, Warrendale, PA 15086.

⁴ Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016.

C2 Nonmetals

- C2.1 Rubber and rubber-like materials may be used for gaskets, O-rings, seals, sample-port diaphragms, vent components, covers, coverings, 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 Standard, Number 18-.
- C2.2 Plastic materials may be used for gaskets, O-rings, seals, sample-port diaphragms, vent components, covers, coverings, 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 Standard, Number 20-.
- C2.3 The adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials shall be nontoxic.⁵

C3 High Temperature Materials

- C3.1 In a processing system to be operated at a temperature of 250°F (121°C) or higher, all materials having product contact surface(s) used in the construction of PAPs 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.

⁵ 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.