

3-A[®] Sanitary Standards for Spray Cleaning Devices Intended to Remain in Place, Number 78-01

*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)*

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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 Spray Cleaning Devices Intended to Remain in Place. 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, 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, USA. By fax: 703-761-4334. By e-mail to: trugh@3-a.org.

A SCOPE

A1 These standards cover the sanitary aspects of spray cleaning devices attached to stainless steel solution supply tubes intended to remain in place during processing operations and used on storage and processing equipment and machinery for milk, milk products, or other comestibles. These standards do not cover spray cleaning devices which are removed prior to processing operations.

A2 In order to conform to these 3-A Sanitary Standards, spray cleaning devices shall conform to the following 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 Surfaces

B3.1 *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.

B3.2 *Solution Contact Surfaces*: Shall mean the interior surfaces of the equipment or system which are used exclusively for supply and recirculation of cleaning and/or sanitizing solutions, except those used to supply concentrated cleaning and/or sanitizing materials to the point of use.

B3.3 *Nonproduct Contact Surfaces*: Shall mean all other exposed surfaces.

B4 Cleaning

B4.1 *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.

B4.1.1 *Cleaned In Place (CIP)*: Shall mean mechanical cleaning of equipment, the cleanability of which has been sufficiently established such that all product or solution contact surfaces do not have to be readily accessible for inspection (for example, silo-type tanks or welded pipelines).

B5 Surface Modification²

B5.1 *Surface Treatments*: Shall mean a process whereby chemical compositions or mechanical properties of the existing surface are altered. There is no appreciable, typically less than 1 µm build-up of new material, or removal of existing material.

B5.1.1 Surface treatments include:

1. Mechanical (shot peening³, polishing)
2. Thermal (surface hardening, laser, electron beam)
3. Diffusion (carburizing, nitriding)
4. Chemical (etching, oxidation)
5. Electropolishing

B6 *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 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.

² Additional information on surface modification is contained in *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.

³ AMS-S-13165, *Shot Peening of Metal Parts*. Available from Society of Automotive Engineers, Inc. (SAE), 400 Commonwealth Drive, Warrendale, PA 15096-0001.

- B7 *Sterilization:* Shall mean a process effected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria and inactivates relevant bacterial spores.
- B8 *Readily or Easily Removable:* Shall mean quickly separated from the equipment with the use of simple hand tools if necessary.
- B9 *Simple Hand Tools:* Shall mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench, or mallet.
- B10 *Easily or Readily Accessible:* Shall mean a location which can be safely reached by an employee from the floor, platform, or other permanent work area.
- B11 *Inspectable:* Shall mean all product contact surfaces can be made available for close visual observation.
- B12 *Dead End:* Shall mean 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.
- B13 *Substantially Flush:* Shall mean mating surfaces or other juxtaposed surfaces shall be within 1/32 in. (0.794 mm).
- B14 *Close Coupled:* Shall mean mating surfaces or other juxtaposed surfaces that are less than twice the nominal diameter or cross section of the mating surfaces or a maximum of 5 in. (127 mm).

C MATERIALS

C1 Metals

- C1.1 Product and solution contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300 Series⁴ or corresponding Alloy Cast Institute (ACI) types⁵ (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.

⁴ The data for this series are contained in the *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.

⁵ Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016.

C2 Nonmetals

- C2.1 Plastic materials may be used for all spray cleaning devices, seals, O-rings, gaskets, and parts having the same functional purposes.
- C2.1.1 Plastic materials, when used for the above-specified applications(s), shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials, Number 20-.
- C2.2 Rubber and rubber-like materials may be used for coatings, seals, O-rings, gaskets, and parts having the same functional purposes.
- C2.2.1 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-.
- C2.3 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 final bond and residual adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials shall be nontoxic.⁶
- C2.5 Where materials having certain inherent functional purposes are required for specific applications, such as seals and/or bearing components, carbon and/or ceramic materials may be used. Carbon and/or ceramic materials shall be inert, nonporous, nontoxic, nonabsorbent, insoluble, resistant to scratching, scoring, and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.

⁶ 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.