

3-A[®] Sanitary Standards for Centrifugal Separators and Clarifiers, Number 21-01

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

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.

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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 Centrifugal Separators and Clarifiers.

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), 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 the 3-A Secretary, 1451 Dolley Madison Boulevard, Suite 150; McLean, VA 22101-3850, USA or by fax: 703-761-6284, or by e-mail to: 3-ainfo@3-a.org.

A SCOPE

- A1 These Standards cover the sanitary aspects of centrifugal separators or clarifiers used to separate fractions of milk or milk products or other liquid food products or to centrifugally remove dense phase material from products. This machine starts at the product inlet(s) and terminates at the product outlet(s) and the nonproduct discharge(s), if included.

These Standards do not cover cyclonic types of separators, decanters, basket centrifuges and other types of devices and the spacers (caulks) for separator or clarifier discs and their attachment to the discs. (See Appendix M.)

- A2 In order to conform to these 3-A Sanitary Standards, centrifugal separators or clarifiers shall comply with the following design, material, and fabrication criteria and the applicable documents referenced herein.¹

B DEFINITIONS

- B1 *Product*: Shall mean milk and milk products or other liquid 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 *Centrifugal Separators (Separators) and Centrifugal Clarifiers (Clarifiers)*: Shall mean machines in which products are separated into their components or fractions using centrifugal force generated by a rotating chamber.

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.

- B5.1.1 *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 and is limited to centripetal pumps.

- 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 Surface Modification²

- B6.1 *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.

- B6.1.1 Surface treatments include:

1. Mechanical (shot peening³, polishing)
2. Thermal (surface hardening laser, electron beam)
3. Electropolishing

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 (216) 338-5151.

³ AMS-S-13165, *Shot Peening of Metal Parts*. Society of Automotive Engineers (AWS), 400 Commonwealth Dr., Warrendale, PA 15096-0001.

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

- B6.2 *Coatings*: Shall mean the results of a process where a different material is deposited to create a new surface. There is appreciable, typically more than 1 µm, build-up of new material. The coating material does not alter the physical properties of the substrate.
- B6.2.1 Coating processes include:
1. Chemical (conversion coatings)
 2. Engineering Plating (e.g., Electrodeposition⁴, gold)
- B7 *Safe Water*: Shall mean water from a supply properly located, protected, and operated, and shall be of a safe, sanitary quality. The water shall meet the standards prescribed in the National Primary Drinking Water Regulation of the Environmental Protection Agency (EPA) as referenced in The Code of Federal Regulations⁵ (CFR), Title 40, Parts 141, 142, and 143. (Information also available from the environmental protection agency [EPA] Drinking Water Hot Line: 800-426-4791.)
- B8 *Soil*: Shall mean the presence of unwanted organic residue or inorganic matter, with or without microorganisms, including food residue, in or on the equipment.
- B9 *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.
- B10 *Easily or Readily Removable*: Shall mean quickly separated from the equipment with the use of simple hand tools, and, if necessary, with the use of lifting equipment.
- B11 *Easily or Readily Accessible*: Shall mean a location which can be safely reached by personnel from a floor, platform, or other permanent work area.
- B12 *Inspectable*: Shall mean all product contact surfaces can be made available for close visual observation.
- B13 *Simple Hand Tools*: Shall mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench, mallet or dedicated tools supplied.
- B14 *Nontoxic Materials*: Shall mean those substances which under the conditions of their use are in compliance with applicable requirements of the Food, Drug, and Cosmetic Act of 1938, as amended.
- B15 *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.
- B16 *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.
- B17 *Bond*: Shall mean the adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.
- B18 *Substantially Flush*: Shall mean mating surfaces or other juxtaposed surfaces shall be within 1/32 in. (0.794 mm).
- B19 *Snug Interference Fit*: Shall mean a condition of fit between two parts that requires pressure to force parts together without apparent tightness or looseness. The parts must be pounded or forced or driven together. This is also referred to as a "force fit."

⁴ Federal Specification #QQ-C-320B for Chromium Plating (Electrodeposited) with Amendment 4. Federal Specification #QQ-N-290A for Nickel Plating (Electrodeposited). Available from the General Services Administration, Federal Supply Services Bureau, Specification Section, 470 East L'Enfant Plaza, Suite 8100, Washington, DC 20407 (202) 755-0325.

⁵ For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (202) 512-1800.

C MATERIALS**C1 Metals**

C1.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AISI) 300, (except 301 and 302) Series⁶ or corresponding Alloy Cast Institute (ACI) types⁷ (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, except that:

C1.1.1 Optional metal alloy may be used for separator or clarifier bowls, shafts, retaining rings, and nuts. (See Appendix, Section E for composition of acceptable optional metal alloys.)

C1.2 Bowl components and centripetal pump assemblies and wear surfaces on shafts made of the materials provided for in C1.1 may have their product contact surfaces modified by surface treatment or coating(s).

C1.3 Separator and clarifier shafts and bowls may also be made of stainless steel of the AISI 400 Series that is made as corrosion resistant as AISI 300 (except 301 and 302) Series by surface treatment or coating(s), or made of nontoxic, nonabsorbent metal that is as corrosion resistant, under the conditions of intended use, as stainless steel of the AISI 300 Series (except 301 and 302).

C2 Nonmetals

C2.1 Rubber and rubber-like materials may be used for O-rings, seals, gaskets, 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 Used as Product Contact Surfaces in Dairy Equipment, Number 18-.

C2.2 Plastic materials may be used for O-rings, gaskets, seals, bearings, sight and light lenses 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 Used as Product Contact Surfaces for Dairy Equipment, Number 20-.

C2.2.2 Plastic used for sight and/or light openings shall be of a clear, heat-resistant type.

C2.3 Rubber and rubber-like and 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.

C2.4 The adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials shall be nontoxic.⁸

C2.5 Where materials having certain inherent functional purposes are required for specific applications, such as rotary seals, bowl discharge nozzles, wear surfaces and coatings for wear surfaces, carbon, and/or ceramic materials, including tungsten carbide 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.

C2.6 Glass may be used in sight openings, and when used, shall be of a clear, heat-resistant type.

⁶ 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, 410 Commonwealth Drive, Warrendale, PA 15086 (412) 776-1535.

⁷ Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 60016 (708) 299-9160.

⁸ 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 (202) 512-1800.

C3 Nonproduct Contact Surfaces

- C3.1 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.

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, except that:
- D2.1.1 In such cases where welding is impractical, press or shrink-fitting may be employed where necessary for essential functional reasons for sleeves on shafts or locating pins on bowl components, (See Appendix, Section H.)
- D2.1.2 Components of centrifugal and centripetal pumps may be joined by metal-to metal bonding. The resulting joints between the mating parts shall be tight without any cracks, spaces or gaps.
- D2.1.3 Product contact surfaces produced by welding⁹, metal-to-metal bonding, and press-fitting or shrink-fitting shall be at least as smooth as a No. 4 ground finish on stainless steel sheets and which are

free of imperfections such as pits, folds, and crevices. Crevices may be eliminated by coating (See Section D4). See Appendix, Section H for press-fitting and shrink-fitting restrictions and limitations.

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, the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded.

- D3.2 Bonded metal-to-metal 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, the materials shall not separate.

D4 Coatings

- D4.1 Coatings, if used, shall be free from surface delamination, pitting, flaking, spalling, blistering, and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment.
- D4.2 The minimum thickness of electrodeposited coatings shall not be less than 0.0002 in. (0.005 mm) for all product contact surfaces.
- D4.3 Thermospray materials used as coatings shall be at least 0.003 in. (0.08 mm) thick.

⁹ Criteria for hygienic welds may be found in AWS/ANSI D18.1 – *Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems in Sanitary (Hygienic) Applications*. Available from the American Welding Society, 550 N.W. LeJeune Rd., Miami, FL 33126, phone: (305) 443-9353, fax: (305) 443-7559, e-mail: info@amweld.org; and EHEDG Doc. 9 – *Welding Stainless Steel to Meet Hygienic Requirements*. Available from the European Hygienic Equipment Design Group, Ellen Moens, Avenue Grand Champ 148, 1150 Brussels, Belgium.