

# 3-A<sup>®</sup> Sanitary Standard for Sensors and Sensor Fittings and Connections, Number 74-06

*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)*

**Effective: August 15, 2013**

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

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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 Standard.

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 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 Sensors and Sensor Fittings and Connections. 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), 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](mailto:3-ainfo@3-a.org).

**A SCOPE**

- A1 This 3-A Sanitary Standard applies to the sanitary aspects of sensors and sensor fittings and connections for equipment which contains or processes milk and milk products and on pipelines which convey milk and milk products and to sensors and sensor fittings and connections within recirculation cleaning systems.
- A2 To conform to this 3-A Sanitary Standard, sensors and sensor fittings and connections shall conform to the following criteria for design, materials of construction, fabrication techniques and the current revisions or editions of all referenced documents cited herein and, in the case of field-installed adaptors or spuds and their associated sensors, installation criteria.

**B NORMATIVE REFERENCES**

- B1 The following listed 3-A Sanitary Standards and other documents shall be considered as Normative References and the provisions of the referenced documents shall apply to this Standard without further reference in this document unless necessary to describe special considerations.

**B2 3-A Sanitary Standards**

| <u>Doc. No.</u> | <u>Title (3-A Sanitary Standard for:)</u>     |
|-----------------|-----------------------------------------------|
| 18-             | Multiple-Use Rubber and Rubber-Like Materials |
| 20-             | Multiple-Use Plastic Materials                |
| 33-             | Metal Tubing                                  |
| 63-             | Sanitary Fittings                             |

**B3 Other References and Standards**

| <u>Ref. No.</u> | <u>Title</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.              | <p>The Code of Federal Regulations (CFR), Title 21, Part 110.3 (o) Current good manufacturing practice in manufacturing, packaging, or holding human food, definitions. (FDA's definition of sanitize from the GMP regs).</p> <p>The Code of Federal Regulations (CFR), Title 40, Part 152.500 Pesticide registration and classification procedures, requirements for devices.</p> <p>The Code of Federal Regulations (CFR), Title 40, Part 161.640 Data requirements for registration, product performance data.</p> <p>The Code of Federal Regulations (CFR), Title 40, Part 180.940 Tolerances and exemptions from tolerances for pesticide chemicals in food, tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions).</p> <p>For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Phone: (202) 512-1800 or at <a href="http://www.gpoaccess.gov/cfr/index.html">http://www.gpoaccess.gov/cfr/index.html</a>.</p> |
| 2.              | <p><i>Advanced Materials and Processes</i>, Volume 137(1), "Coatings and Coating Practices" by H. Herman, "Surface Modification" by F. A. Smidt. ASM International, Materials Park, OH 44073, Phone: (216) 338-5151, Internet <a href="http://asminternational.org">http://asminternational.org</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.              | <p>SAE AMS 2406, Chromium Plating (Electrodeposited). SAE-AMS QQ-N-290A, Nickel Plating (Electrodeposited). SAE International, 400 Commonwealth Dr., Warrendale, PA 15096-0001, Internet: <a href="http://www.sae.org">http://www.sae.org</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

4. *AIST Stainless Steels: A Steel Products Manual*, Association for Iron & Steel Technology, 186 Thorn Hill Road, Warrendale, PA 15086, Phone: (724) 814 3000, Internet: [www.aist.org](http://www.aist.org)
5. *Steel Casting Handbook, Supplement 2*, Steel Founders Society of America, 780 McArdle Dr., Unit G, Crystal Lake, IL 60014, Phone: (815) 455-8240, Fax: (815) 455-8241, Internet: [www.sfsa.org](http://www.sfsa.org)
6. The Code of Federal Regulations (CFR), Title 21, Parts 175 – Indirect Food Additives: Adhesives and Components of Coatings. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, Phone: (202) 512-1800, Internet: <http://www.gpoaccess.gov/cfr/index.html>
7. *Machinery's Handbook*, published by Industrial Press Inc., 200 Madison Avenue, New York, NY 10157, Phone: (888) 528-7852, Internet: <http://new.industrialpress.com>
8. EHEDG Guideline 2, *A Method for Assessing the In-Place Cleanability of Food Processing Equipment*. European Hygienic Engineering & Design Group. Published by EHEDG, [www.ehedg.org](http://www.ehedg.org)
9. Aerospace Standard (AS) 568, *Aerospace Size Standards for O-rings*, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086, Phone: (724)-776-4841, Internet: <http://www.sae.org>
10. ISO 3601-1:2002: *Fluid Power Systems, Sealing Devices – O-Rings – Part 1: Inside diameters, cross-sections, tolerances and size identification code*, The International Organization for Standardization (ISO), 1 ch. de la Voie-Creuse, Postale 56, CH -1211, Geneva 20, Switzerland, Phone: +41-22-749-01-11, Internet: [www.iso.org](http://www.iso.org)
11. ASTM Specifications for Cast Grades A351/A351M, A743/A743M and A744/A744M. Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9500 or at <http://www.astm.org>
12. ASTM A959, *Specifying Harmonized Standard Grade Compositions for Wrought Stainless Steels, Standard Guide for*, Available from ASTM 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832 9500, Internet: [www.astm.org](http://www.astm.org)

## C DEFINITIONS

- C1 *Product*: Milk, milk products, or other related products.
- C2 *Solutions*: Water or any mixture of cleaning agents, sanitizers and water used for flushing, cleaning, rinsing, or sanitizing.
- C3 **Surfaces**
- C3.1 *Product Contact Surfaces*: All surfaces which are exposed to the product and surfaces from which splashed product, liquids or material may drain, drop, diffuse, or be drawn into the product or onto product contact surfaces.
- C3.2 *Nonproduct Contact Surfaces*: All exposed surfaces from which splashed product, liquids, or other materials cannot drain, drop, diffuse or be drawn into or onto the product or product contact surfaces.
- C4 *Substantially Flush*: Mating Surfaces or other juxtaposed surfaces that are not more than 1/32" (0.80 mm) off-set from each other (examples: gasketed joints employing recessed O-rings or seals which are intended for CIP; and circular flat or wavy diaphragms with uniform crests and troughs that are welded to a sensor face).

- C5 *Sensor Fittings and Connections* (hereinafter referred to as “fittings”): Fittings and/or connections for instruments or their sensing elements that will be installed in product equipment and in sanitary pipelines for the measurement of fluid parameters and/or properties. These may include temperature, pressure, liquid level, pH, oxidation-reduction potential (ORP), viscosity, density, conductivity, or composition.
- C5.1 *CIP Fittings*: Fittings designed to be cleaned while fully assembled. If such a fitting has a removable joint, the joint is self-centering, employs a gasket, and the resulting gasketed joint forms a substantially flush interior surface.
- C5.2 *Manually Cleaned Fittings*: Removable joint fittings of which the design requires dismantling for manual cleaning.
- C6 *Essential Functional Reason*: A condition or feature of design or fabrication that cannot be modified and is required for the proper operation of the equipment.
- C7 **Sensors**
- C7.1 *pH Sensor*: A device which is sensitive to hydrogen ion activity requiring a hydrogen ion-sensitive electrode and a reference electrode providing electrolytic contact with the product or solution.
- C7.2 *Oxidation-Reduction Potential (ORP) Electrode*: A noble metal electrode sensitive to electrochemical potential of the product or solution and a reference electrode providing electrolytic contact with the product or solution.
- C7.3 *Conductivity Sensor*: A device sensitive to resistance changes in the product or solution as a function of ionic concentration.
- C7.4 *Pressure Sensor*: A device sensitive to changes in force per unit area as exerted by the product or solution.
- C7.5 *Temperature Sensor*: A device sensitive to the degree of hotness or coldness of a product or solution.
- C7.6 *Viscosity Sensor*: A device sensitive to the flow resistance of product or solution.
- C7.7 *Liquid Level Sensor*: A device capable of measuring liquid product or solution height either directly or indirectly, or as a function of pressure.
- C7.7.1 *Ultrasonic Level Sensor*: A device capable of measuring liquid product or solution height using high frequency sound energy.
- C7.7.2 *Microwave Level Sensor*: A sensor that uses microwave energy to detect the presence or absence of liquid or a sensor that uses microwave energy for continuous level measuring of liquid product.
- C7.8 *Composition Sensor*: A device capable of measuring the chemical constituents of the product or solution.
- C7.9 *Vibrating Element Sensor*: A device capable of measuring product or solution properties using the change in resistance to movement of a vibrating element.
- C7.10 *Density Sensor*: A sensor designed to measure the relative mass per unit volume (also referred to as “specific gravity”) of a liquid as compared to that of water.
- C8 *Noble Metal(s)*: Metals, such as gold, silver, platinum, and iridium which have a relatively positive electrode potential, and which do not enter readily into chemical combination with nonmetals. These materials have a high resistance to corrosive attack by acids and corrosive agents and resist atmospheric oxidation.
- C9 *Bond*: The adhesive or cohesive forces holding materials together. This definition excludes interference fits.

**C10 Cleaning**

- C10.1 *Clean-in-Place (CIP) Cleaning:* (CIP): The removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned. Components of the equipment, which are not designed to be cleaned in place, are removed from the equipment to be COP or manually cleaned. Product contact surfaces to be CIP cleaned are inspectable, except as specified in E1.4.2.1.
- C10.2 *Manual Cleaning:* Removal of soil 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, and high or low pressure hoses, with cleaning aids manipulated by hand.
- C10.3 *Clean Out of Place (COP): Clean-Out-of-Place (COP):* Removal of soil when the equipment is partially or totally disassembled. Soil removal is effected by circulating chemical solutions and water rinses in a wash tank, which may be fitted with circulating pump(s).
- C11 *Sanitizing or Sanitization:* A process to adequately treat a clean product contact surface that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer. Any process used must be acceptable to the regulatory agency. (Refer to B3, Reference No. 1.)
- C12 *Sterilization:* A process effected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria and inactivates relevant bacterial spores of public health concern.
- C13 *Simple Hand Tools:* A screwdriver, wrench, mallet, or readily available dedicated tool(s) normally used by operating and cleaning personnel.
- C14 **Surface Modification** (Refer to B3, Reference No. 2)
- C14.1 *Surface Treatments:* Processes where chemical composition or mechanical properties of the existing surface are altered. There is no appreciable build up of new material or removal of existing material.
- C14.1.1 Surface treatments include:
1. Mechanical (grinding, polishing)
  2. Thermal (surface hardening laser, electron beam)
  3. Chemical (etching, oxidation, passivation)
  4. Electropolishing
- C14.2 *Coatings, Overlays and Encapsulations:* A process where a different material is deposited to create a product contact surface. There is a build up of new material. The coating, overlay, or encapsulation material does not alter the physical properties of the substrate.
- C14.2.1 Coating processes include:
1. Chemical (conversion coatings except anodizing)
  2. Engineering Plating (e.g., Electrodeposition {Refer to B3, Reference. No. 3}, gold plating)
  3. Thermal Spraying (e.g., flame, plasma, arc spray)
  4. Physical Vapor Deposition
  5. Chemical Vapor Deposition
- C15 *Readily or Easily Removable:* Designed, fabricated, and installed to be quickly separated from the equipment with or without the use of simple hand tools.

- C16 *Nontoxic Materials:* Substances, which under the conditions of their use are in compliance with applicable requirements of the FDA.
- C17 *Corrosion Resistant:* A surface or material which has the property to retain its original surface characteristics for its predicted service period, when exposed to the conditions encountered in the environment of intended use, including contact with product, cleaning and sanitizing chemicals, steam, or sterilization compounds or solutions.
- C18 *Inspectable:* Designed, fabricated and installed to make product contact surfaces available for close visual observation.
- C19 *Interference Fit:* A force or shrink fit of mating parts which, when assembled, results in an interference under all conditions of intended use that permits no clearance for the migration of liquids.

## D MATERIALS

### D1 Product Contact Surfaces

All 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 including cleaning and sanitization treatment or sterilization.

#### D1.1 Metals

- D1.1.1 Product contact surfaces shall be of stainless steel of the American Iron and Steel-Technology (AIST) 300 Series, excluding 301, 302, and 303 (Refer to B3, Reference No. 4) or corresponding Alloy Cast Institute (ACI) types (Refer to B3, Reference No. 5) or metal which under conditions of intended use is at least as corrosion resistant as 304 stainless steel, and is nontoxic and nonabsorbent. (Refer to Appendix, Section G.) Alloys containing lead, leachable copper, or other toxic materials shall not be used. Where welding is involved, the carbon content of the stainless steel shall not exceed 0.08%, except that:
- D1.1.2 Solder, when used, shall be gold- or silver-containing solder and shall be corrosion resistant, free of cadmium, lead and antimony, nonabsorbent, and shall not impart any toxic substance to the product when exposed to the conditions encountered in the environment of intended use, including cleaning and sanitization treatment or sterilization.
- D1.1.3 Noble metals or their oxides may be used for pH or ORP electrodes and parts having the same functional purposes and shall be nontoxic.

#### D1.2 Nonmetals

- D1.2.1 Glass may be used in pH or ORP electrodes and, when used, shall be heat and chemical resistant and nontoxic. (See Section F2.)
- D1.2.2 Internal fluids, when used, shall be non-toxic and shall meet the requirements of the Federal Food, Drug and Cosmetic Act, as amended.
- D1.2.3 Carbon and ceramic materials (including tungsten carbide) may be used for ion-permeable materials on pH electrodes or reference junctions in pH or ORP sensors, level sensors, or pressure sensors. Carbon and ceramic materials shall be inert, nontoxic, insoluble, and resistant to scratching, scoring, and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and sanitizing treatment or sterilization. The carbon and ceramic materials shall be nonpermeable to microorganisms and shall have an average pore size less than 0.20 µm.

- D1.2.4 Rubber and rubber-like materials may be used for sensor insulators, sensor holders, gaskets, diaphragms, bonded coatings and coverings, and parts having the same functional purposes, and when used for the specified application(s), shall conform to the applicable provisions of 3-A Sanitary Standard, Number 18-.
- D1.2.5 Plastic materials may be used for sensors, sensor insulators, sensor holders, gaskets, diaphragms, bonded coatings and coverings, and parts having the same functional purposes and when used for the above-specified application(s), shall conform to the applicable provisions of 3-A Sanitary Standard, Number 20-.
- D1.2.6 Ion-permeable plastic materials may be used on pH electrodes or reference junctions in pH or ORP sensors. Plastic materials shall be nonpermeable to microorganisms and shall have an average pore size less than 0.20 µm.
- D1.2.6.1 Plastic materials, when used for the above-specified applications, shall meet the requirements of the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces in Dairy Equipment, Number 20-, except for Section H2 (weight gain).
- D1.2.7 Adhesives used for bonding rubber and rubber like materials, bonding plastic materials, and bonding of carbon or ceramic components shall be nontoxic. Adhesives shall comply with 21 CFR 175 - Indirect Food Additives: Adhesives and Components of Coatings (Refer to B3, Reference No. 6).

## D2 Nonproduct Contact Surfaces

- D2.1 All nonproduct contact surfaces shall be of corrosion resistant material or material that is rendered corrosion resistant. If the surfaces are coated, including painted surfaces, the coating 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.

## E FABRICATION

### E1 Product Contact Surfaces

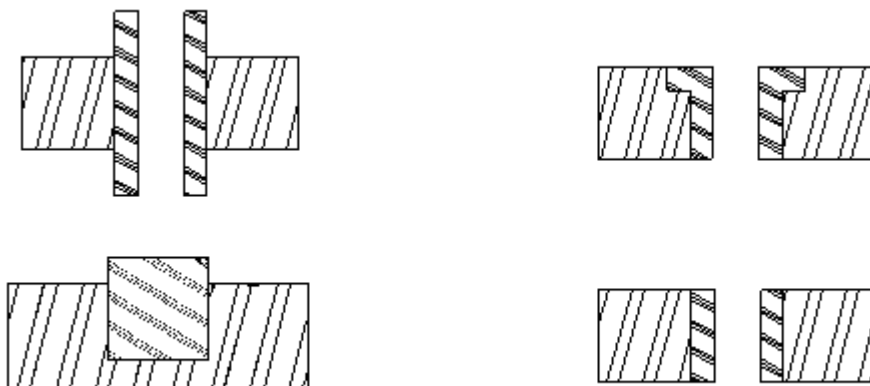
#### E1.1 Surface Texture

- E1.1.1 Surfaces, including fabricated, welded and soldered joints, shall be at least as smooth as a 32 µin. (0.8 µm) R<sub>a</sub> finish and shall be free of pits, folds, crevices, cracks, and misalignments in the final fabricated form. (Refer to Appendix, Section H.)

#### E1.2 Permanent Joints

- E1.2.1 All permanent joints in metallic surfaces shall be continuously welded, except that:

- E1.2.1.1 Where neither welding nor soldering is practical, interference fits may be used to produce crevice-free permanent joints. Joints of this type may only be used to assemble metal-to-plastic parts having circular cross sections, free of shoulders or relieved areas. Interference fits may be used only for level sensors. (Refer to B3, Reference No. 7.) If interference fit procedures are to be used, supporting documentation shall be available to demonstrate the joints suitability. The tightness of the interference fit shall be validated to demonstrate that there is no migration past the joint under the conditions of intended use. This shall be accomplished by using EHEDG Guideline 2, A Method for Assessing the In-place Cleanability of Food Processing Equipment (refer to B3, Reference No. 8) or other validated applicable test method. (See the following illustrations of acceptable interference fits.)



E1.2.1.2 Gold- or silver-bearing solder may be used for attaching fiber optic sensors into fittings.

### E1.3 **Bonded Materials**

E1.3.1 Rubber and rubber-like materials, and plastic materials, and carbon or ceramic seal component materials may be bonded. The bond shall be continuous and mechanically sound. The rubber and rubber-like material, the plastic material, and carbon or ceramic seal component materials shall not separate from the base material to which it is bonded when exposed to the conditions encountered in the environment of intended use, including cleaning and sanitizing treatment or sterilization.

### E1.4 **Cleaning and Inspectibility**

E1.4.1 Sensors intended for COP or manual cleaning shall be designed and fabricated so all product contact surfaces are inspectable, either when in an installed position or when removed. Junctures between components may or may not be gasketed or sealed. All demountable appurtenances that require removal for cleaning shall be readily removable.

E1.4.2 Sensors intended for CIP cleaning shall be designed and fabricated so all product contact surfaces, including all non-removed appurtenances, can be CIP cleaned. Junctures between components shall be sealed or designed for manual or COP cleaning.

E1.4.2.1 All CIP cleaned surfaces, including all non-removed appurtenances, shall be inspectable, except that:

E1.4.2.1.1 Surfaces that are a continuous tube of the same size shall have representative surfaces available for inspection.

E1.4.2.2 All demountable appurtenances that require removal for cleaning and/or inspection shall be readily removable.

### E1.5 **Gaskets, Gasket Retaining Grooves, and O-rings and Seals**

E1.5.1 Gaskets shall be removable or bonded.

E1.5.2 Grooves in gaskets shall be no deeper than their width.

E1.5.3 Gasket retaining grooves for removable gaskets shall not exceed 1/4 in. (6.35 mm) in depth or be less than 1/4 in. (6.35 mm) wide, except those for O-rings with cross-section dimensions 1/4 in. (6.35 mm) or smaller, and those provided for in the 3-A Sanitary Standards referenced in Section B, Normative References.