

3-A Sanitary Standard for General Requirements

American National Standard



ANSI/3-A 00-01-2018

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)

3-A SSI Effective Date: June 5, 2017
ANSI Approval Date: February 1, 2018

American National Standard

Approval of an American National Standard requires verification by ANSI that the requirements for due process, consensus, and other criteria for approval have been met by the standards developer. Consensus is established when, in the judgment of the ANSI Board of Standards Review, substantial agreement has been reached by directly and materially affected interests. Substantial agreement means much more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that a concerted effort be made toward their resolution. The use of American National Standards is completely voluntary; their existence does not in any respect preclude anyone, whether he has approved the standards or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standards. The American National Standards Institute does not develop standards and will in no circumstances give an interpretation of any American National Standard. Moreover, no person shall have the right or authority to issue an interpretation of an American National Standard in the name of the American National Standards Institute. Requests for interpretations should be addressed to the secretariat or sponsor whose name appears on the title page of this standard.

CAUTION NOTICE: This American National Standard may be revised or withdrawn at any time. The procedures of the American National Standards Institute require that action be taken periodically to reaffirm, revise, or withdraw this standard. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.

TABLE OF CONTENTS

TITLE	1
TABLE OF CONTENTS	3
DISCLAIMERS	6
FOREWORD	6
 A SCOPE	 7
 B NORMATIVE REFERENCES	 9
 C DEFINITIONS	 13
C1 Bond	13
C1.1 Metallurgical Bond	13
C1.2 Bonded Joints.....	13
C2 Burr	13
C3 Cleaning	13
C3.1 Clean-in-Place (CIP) Cleaning	13
C3.2 Clean-Out-of-Place (COP) Cleaning	13
C3.3 Manual Cleaning	12
C3.4 Dry Cleaning	13
C4 Cleanable or Cleanability	13
C4.1 CIPable.....	13
C5 Close Coupled	13
C6 Corrosion Resistant	14
C7 Dead End	14
C8 Essential Functional Reason	14
C9 Fittings	14
C9.1 CIP Fittings	14
C9.2 Manually Cleaned Fittings.....	14
C10 Gasketed Joint	14
C11 Impervious	14
C12 Inspectable	14
C13 Interference Fit	14
C14 Mechanical Force Seal	14
C15 Nonabsorbent	14
C16 Nontoxic Materials	15
C17 Normative	15
C18 Opening	15
C19 Permanent Joint	15
C20 Processing Area	15
C21 Product	15
C22 Readily Accessible	15
C23 Readily Removable	15
C24 Regulatory Agency	15
C25 Roughness Average (R_a)	15

C26	Sanitizing or Sanitization.....	15
C27	Sealed.....	15
C28	Simple Hand Tools	15
C29	Soil	15
C30	Soldering and Brazing	16
	C30.1 Soldering.....	16
	C30.2 Solder	16
	C30.3 Brazing.....	16
	C30.4 Brazing Filler Metal.....	16
C31	Solution	16
C32	Steam or Sterilizing Media Chambers	16
C33	Sterilization	16
C34	Substantially Flush.....	16
C35	Surface Modification	16
	C35.1 Surface Treatments	16
	C35.2 Coatings, Overlays and Encapsulations	16
C36	Hot Isostatic Pressing (HIP).....	16
C37	Surfaces	17
	C37.1 Product Contact Surfaces.....	17
	C37.2 Solution Contact Surfaces.....	17
	C37.3 Nonproduct Contact Surfaces	17
C38	Validate	17
D	MATERIALS	17
D1	Product Contact Surfaces	17
	D1.1 Metals.....	17
	D1.2 Nonmetals	18
D2	Nonproduct Contact Surfaces	20
E	FABRICATION OF PRODUCT AND SOLUTION CONTACT SURFACES	
E1	Surface Texture	21
E2	Joints	22
	E2.1 Permanent Joints	22
	E2.2 Non-Permanent Joints	24
E3	Coatings	25
E4	Cleaning and Inspectability	25
E5	Draining	26
E6	Dead Ends	26
E7	Gaskets, Gasket Retaining Grooves, O-rings and Seals	27
E8	Radii	28
E9	Threads	31
	E9.1.1 Exposed Threads.....	31
	E9.2 Enclosed Threads.....	33
E10	Perforated Surfaces	34
E11	Coil Springs	34
E12	Shafts	35

E13	Bearings	35
E14	Openings and Covers (Other Than Personnel Access Ports) ...	35
E15	Temperature-Sensing Device Connections	36
F	FABRICATION OF NONPRODUCT CONTACT SURFACES	37
F1	Surfaces	37
F2	Joints	37
F3	Coatings	38
F4	Cleaning and Inspectability	38
F5	Draining	38
F6	Threads	38
F7	Service Piping and Lines	38
F8	Panels, Doors, or Access Ports	39
F9	Guards and Other Safety Devices	39
F10	Supports	39
F11	Name and/or Information Plates (Nameplates)	39
F12	Sterilizing Chambers	40
F13	Bearings	40

APPENDIX

1	STAINLESS STEEL AND EQUIVALENT MATERIALS	41
2	PRODUCT CONTACT SURFACE FINISH	48
3	AIR VENTING	49
4	CIP CLEANING	49
5	ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE ...	50
5.1	Purpose	50
5.2	Scope	50
5.3	Responsibilities	50
5.4	Applicability	50
5.5	References	51
5.6	EDTCF	51
5.7	Confidentiality	52
5.8	File Location	52
5.9	File Retention	52
6	INSTRUCTION HANDBOOK FOR INSTALLATION, MAINTENANCE AND CLEANING	53
6.1	Installation of the Equipment and Associated Equipment	53
6.2	Instructions for Use	53
6.3	Maintenance	53
6.4	Cleaning	53
7	HARMONIZATION	53

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.

3-A Sanitary Standards Inc. (SSI), its employees and its volunteer committees/working groups shall not incur any obligation or liability for damages, including consequential damages, arising from or in connection with the development, use, interpretation, or reliance upon this 3-A Sanitary Standard.

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. Illustrations are not intended to show all variations of the equipment or system nor are they exclusive of alternate approved methods. Illustrations are non-normative.

Metric conversions are provided for convenience and are not intended to be mandatory.

The Appendix is an advisory or informative section unless specifically cited in the Materials or Fabrication Section as requiring conformance.

Foreword

This 3-A Sanitary Standard establishes minimum sanitary (hygienic) requirements for design, materials, fabrication, and/or installation of equipment and/or system(s).

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, and regulatory agencies, and by other SDOs to assure that adequate public health protections exist for the equipment or systems and covered products. 3-A SSI uses this document as its primary source of sanitary criteria for 3-A Symbol authorization and certification.

This 3-A Sanitary Standard was developed jointly by 3-A SSI, the United States Public Health Service (USPHS) / United States Food and Drug Administration (USFDA), the United States Department of Agriculture (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: 3-A SSI, 6888 Elm Street, Suite 2D, McLean, VA 22101-3829, USA or by fax: (703)-761-6284, or by e-mail to: 3-ainfo@3-a.org.

A SCOPE

- A1 This 3-A Sanitary Standard defines the general requirements for sanitary (hygienic) equipment intended for processing milk, milk products, foods, food ingredients, beverages, or other edible materials.
- A2 To conform to this 3-A Sanitary Standard, equipment shall meet the following criteria for design, material of construction, fabrication techniques, and installation, as applicable. In addition, equipment shall meet the criteria defined in the corresponding 3-A Sanitary Standard for the specific equipment type.
- A3 Specific additional requirements and exceptions to the general requirements contained herein are defined in the individual 3-A Sanitary Standards and 3-A Accepted Practices, listed in Sections A3.1 and A3.2.

A3.1 3-A Sanitary Standards

Note: New 3-A Sanitary Standards shall be considered to be included in this section 45 days after they have been accepted by the Consensus Body without revision of this General Standard.

Doc. No. Title (3-A Sanitary Standard for:)

- 01- Insulated Tanks
- 02- Centrifugal and Positive Rotary Pumps
- 04- Homogenizers and Reciprocating Pumps
- 05- Stainless Steel Automotive Transportation Tanks for Bulk Delivery and Farm Pick-up Service
- 10- Filters Using Single Service Filter Media
- 11- Plate Type Heat Exchangers
- 12- Tubular Heat Exchangers
- 13- Farm Milk Cooling and Holding Tanks
- 16- Product Evaporators and Vacuum Pans
- 17- Formers, Fillers, and Sealers of Containers for Fluid Products
- 18- Multiple-Use Rubber and Rubber-Like Materials
- 19- Batch and Continuous Freezers for Ice Cream, Ices, and Similarly Frozen Foods
- 20- Multiple-Use Plastic Materials
- 21- Centrifugal Separators and Clarifiers
- 22- Silo-Type Storage Tanks
- 23- Equipment for Packaging Viscous Products
- 24- Non-Coil Type Batch Pasteurizers
- 25- Non-Coil Type Batch Processors
- 26- Sifters for Dry Products
- 27- Equipment for Packaging Dry Products
- 28- Flow Meters
- 29- Air Eliminators

- 30- Farm Milk Storage Tanks
- 31- Scraped Surface Heat Exchangers
- 32- Uninsulated Tanks
- 33- Metal Tubing
- 34- Portable Bins for Dry Products
- 35- Blending Equipment
- 36- Inline Rotor-Stator Mixers
- 38- Cottage Cheese Vats
- 39- Pneumatic Conveyors for Dry Products
- 40- Bag Collectors
- 41- Mechanical Conveyors for Dry Products
- 42- In-Line Strainers
- 44- Diaphragm Pumps
- 45- Crossflow Membrane Modules
- 46- Refractometers and Energy-Absorbing Optical Sensors
- 49- Air-Driven Sonic Horns for Dry Products
- 50- Level Sensing Devices for Dry Products
- 51- Plug-Type Valves
- 52- Plastic Plug-Type Valves
- 53- Compression-Type Valves
- 54- Diaphragm-Type Valves
- 55- Boot Seal-Type Valves
- 56- Inlet and Outlet Leak-Protector Plug-Type Valves
- 57- Disc-Type Valves
- 58- Vacuum Breakers and Check Valves
- 59- Automatic Positive Displacement Samplers for Fluid Products
- 60- Rupture Disc Assemblies
- 61- Steam Injection Heaters
- 62- Hose Assemblies
- 63- Sanitary Fittings
- 64- Pressure Reducing and Back Pressure Regulating Valves
- 65- Sight and/or Light Windows and Sight Indicators in Contact With Product
- 68- Ball-Type Valves
- 70- Italian-Type Pasta Filata Style Cheese Cookers
- 71- Italian-Type Pasta Filata Style Cheese Moulders
- 72- Italian-Type Pasta Filata Style Moulded Cheese Chillers
- 73- Shear Mixers, Mixers, and Agitators
- 74- Sensors and Sensor Fittings and Connections
- 75- Belt-Type Feeders
- 78- Spray Cleaning Devices Intended to Remain in Place
- 81- Auger-Type Feeders
- 82- Pulsation Dampening Devices
- 83- Enclosed Cheese Vats and Tables
- 84- Personnel Access Ports for Wet Applications

- 85- Double-Seat Mixproof Valves
- 87- Mechanical Strainers
- 88- Machine Leveling Feet and Supports
- 95- Transportation Tank Vents
- 101- Pipeline Product Recovery Equipment Using Projectiles
- 103- Robot-based Automation Systems

A3.2 3-A Accepted Practices

Note: New 3-A Accepted Practices shall be considered to be included in this section 45 days after they have been accepted by the Consensus Body without revision of this General Standard.

Doc. No. Title (3-A Accepted Practice for:)

- 603- Sanitary Construction, Installation, Testing, and Operation of High-Temperature Short-Time and Higher-Heat Shorter-Time Pasteurizer Systems
- 604- Supplying Air Under Pressure in Contact with Product and Product Contact Surfaces
- 605- Permanently Installed Product and Solution Pipelines and Cleaning Systems
- 606- Design, Fabrication, and Installation of Milking and Milk Handling Equipment
- 607- Spray Drying Systems
- 608- Instantizing Systems
- 609- A Method of Producing Culinary Steam
- 610- Sanitary Construction, Installation, and Cleaning of Crossflow Membrane Processing Systems
- 611- Farm Milk Cooling and Storage Systems
- 612- Plant Environmental Air Quality

B NORMATIVE REFERENCES

- B1 The above listed 3-A Sanitary Standards and 3-A Accepted Practices, and the following documents listed in this section shall be considered as Normative References (their use is mandatory when they apply), and the provisions of the referenced documents shall apply to this 3-A Sanitary Standard without further reference in this document, unless necessary to describe special considerations.

For the purpose of this 3-A Sanitary Standard, the most current approved version of the following referenced standards and other documents shall apply, unless otherwise noted.

Ref. No. Title

1. Grade “A” Pasteurized Milk Ordinance (latest revision), available at:
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007966.htm>
or at:
<http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM291757.pdf>

2. American Society of Mechanical Engineers (ASME) B46.1 - *Surface Texture Waviness and Lay*. Available from the American Society of Mechanical Engineers, Three Park Ave., New York, NY 10016-5990, Phone: (800) 843-2763 or at: <http://www.asme.org>
3. National Primary Drinking Water Regulation of the Environmental Protection Agency (EPA), The Code of Federal Regulations (CFR), Title 40, Parts 141, 142, and 143. Available at: <http://water.epa.gov/drink/contaminants/index.cfm>
4. Sanitizing or Sanitization related normative references:
 - a. 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 regulations);
 - b. The Code of Federal Regulations (CFR), Title 40, Part 152.500, Pesticide registration and classification procedures, requirements for devices;
 - c. The Code of Federal Regulations (CFR), Title 40, Part 161.640, Data requirements for registration, product performance data; and
 - d. 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).

The above items are for sale by the Superintendent of Documents, U.S. Government Printing Office, 732 North Capitol Street, Washington, DC 20401, Phone: (202) 512-1800 or at: <http://www.gpoaccess.gov/cfr/index.html>

5. AWS D18.1 – *Specification for Welding of Austenitic Stainless Steel Tube and Pipe Systems in Sanitary (Hygienic) Applications*;

AWS D18.2 – *Guide to Weld Discoloration Levels on Inside of Austenitic Stainless Steel Tube*;

AWS D18.3 – *Specification for Welding of Tanks, Vessels, and Other Equipment in Sanitary (Hygienic) Applications*; and

Published by the American Welding Society, 8669 Doral Boulevard, Suite 130, Doral, FL 33166, Phone: (800) 443-9353, <http://pubs.aws.org/>

6. *Advanced Materials and Processes*, Volume 137(1), “Coatings and Coating Practices” by H. Herman, “Surface Modification” by F. A. Smidt. ASM International, 9639 Kinsman Road, Materials Park, OH 44073, Phone: (440) 338-5151 or at: <http://asminternational.org>
7. AMS 2430, *Shot Peening, Automatic*. SAE International, 400 Commonwealth Dr., Warrendale, PA 15096-0001 or at: <http://www.sae.org>
8. AMS 2406 / AMSQQC320, *Plating Chromium, Hard Deposit*. SAE International, 400 Commonwealth Dr., Warrendale, PA 15096-0001, Phone: (877)-606-7323 or at: <http://www.sae.org>
AMS 2403 / AMS QQN290, *Nickel Plating (Electrodeposited)*. SAE International, 400 Commonwealth Dr., Warrendale, PA 15096-0001, Phone: 877-606-7323 or at: <http://www.sae.org>
9. ASTM A959, *Standard Guide for Specifying Harmonized Standard Grade Compositions for Wrought Stainless Steels*. ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832 9555 or at: www.astm.org
10. *Stainless Steels: A Steel Products Manual*, Association for Iron & Steel Technology, 186 Thorn Hill Road, Warrendale, PA 15086, Phone: (724) 814 3000 or at: www.aist.org
11. *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 or at: www.sfsa.org
12. The Code of Federal Regulations (CFR), Title 21, Part 170-199 – Indirect Food Additives. The above item is for sale by the Superintendent of Documents, U.S. Government Printing Office, 732 North Capitol Street, Washington, DC 20401, Phone: (202) 512-1800 or at: <http://www.gpoaccess.gov/cfr/index.html>
13. EHEDG Guideline 35, *Hygienic Welding of Stainless Steel Tubing in the Food Processing Industry*. European Hygienic Engineering & Design Group. Published by EHEDG www.ehedg.org
14. *Machinery's Handbook*, published by Industrial Press Inc., 989 Avenue of the Americas, 19th Floor, New York, NY 10018, Phone: (888) 528-7852, Available at: <http://new.industrialpress.com>
15. EHEDG Guideline 2, *A Method for Assessing the In-Place Cleanability of Food Processing Equipment*. European Hygienic Engineering & Design Group. Published by EHEDG, Available at: www.ehedg.org
16. Aerospace Standard (AS) 568C, *Aerospace Size Standard for O-Rings*, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086-0001, Phone: (877)-606-7323, Available at: <http://www.sae.org>

17. ISO 3601-1, *Fluid Power Systems – O-Rings – Part 1: Inside diameters, cross-sections, tolerances and design codes*, 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, Available at: www.iso.org
18. ASTM A351 *Standard Specification for Castings, Austenitic, for Pressure-Containing Parts*;

ASTM A743 *Standard Specification for Castings, Iron-Chromium, Iron-Chromium-Nickel, Corrosion Resistant, for General Application*;

ASTM A744 *Standard Specification for Castings, Iron-Chromium-Nickel, Corrosion Resistant, for Severe Service*;

Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9555 or at: <http://www.astm.org>
19. ASTM A988/988M *Standard Specification for Hot Isostatically-Pressed Stainless Steel Flanges, Fittings, Valves, and Parts for High Temperature Service*. Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9555 or at: <http://www.astm.org>
20. ASTM E1417 *Standard Practice For Liquid Penetrant Testing*. Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9555 or at: <http://www.astm.org>
21. ASTM E165 *Standard Practice For Liquid Penetrant Examination For General Industry*. Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9555 or at: <http://www.astm.org>
22. ASTM E433 *Reference Photographs for Liquid Penetrant Inspection*. Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9555 or at: <http://www.astm.org>
23. ASTM C1147 *Standard Practice For Determining the Short Term Tensile Weld Strength of Chemical Resistant Thermoplastics*. Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9555 or at: <http://www.astm.org>
24. GRAS status; available at:
<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/default.htm>
25. Threshold of Regulation Exemption; available at:
<http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/ThresholdRegulationExemptions/ucm093685.htm>
26. Inventory of Effective Food Contact Substance (FCS) Notifications; available at:
<http://www.accessdata.fda.gov/scripts/fdcc/?set=FCN>

C DEFINITIONS

- C1 *Bond*: The adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.
- C1.1 *Metallurgical Bond*: A bond created between a metal alloy substrate and metal alloy coating where an interchange of molecules occurs at the interface between the substrate and the coating.
- C1.2 *Bonded Joints*: A permanent fastening of two different components utilizing the adhesive or cohesive forces of the materials being joined. (Refer to C1 Bond.)
- C2 *Burr*: A thin ridge or sharp area remaining after cutting, drilling, shearing, or punching a material.
- C3 **Cleaning**
- C3.1 *Clean-in-Place (CIP) Cleaning*: 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. (Note: Components of the equipment, which are not designed to be cleaned-in-place, are removed from the equipment to be cleaned-out-of-place (COP) or manually cleaned.)
- C3.2 *Clean-Out-of-Place (COP) Cleaning*: 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 a circulating pump(s).
- C3.3 *Manual Cleaning*: Removal of soil when the equipment is partially or totally disassembled. Soil removal is effected by 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.
- C3.4 *Dry Cleaning*: Cleaning with a vacuum cleaner and/or dry brushes and other tools manipulated by hand.
- C4 *Cleanable or Cleanability*: The suitability of materials of construction, design and fabrication required to assure that the equipment can be freed of soil.
- C4.1 *CIPable*: The design and fabrication of equipment which allows the equipment surfaces to be cleaned by CIP methods for a prescribed time and at a prescribed solution concentration, flow rate, pressure, and temperature demonstrated to be effective.
- C5 *Close Coupled*: Mounting or connecting of components so that the intervening product contact area separating the components is as short as possible.

- C6 *Corrosion Resistant:* A surface or material which has the property to retain its original surface characteristics for its predicted service period under normal use and when exposed to the conditions encountered in the environment of its intended use, including cleaning, sanitizing treatment, and/or sterilization.
- C7 *Dead End:* 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.
- C8 *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.
- C9 **Fittings**
- C9.1 *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.
- C9.2 *Manually Cleaned Fittings:* Removable joint fittings of which the design requires dismantling for manual cleaning.
- C10 *Gasketed Joint:* The static seal established using a flexible rubber, rubber-like, or plastic material, compressed between equipment components to create a seal at the interface of the materials joined. (Refer to C27 Sealed.)
- C11 *Impervious:* Not permitting passage or penetration of a liquid. (Note: This definition applies to metals only.)
- C12 *Inspectable:* Designed, fabricated and installed to make product contact surfaces available for close visual observation.
- C13 *Interference Fit:* A fit having limits of size, so specified that an interference always results when mating parts are assembled and which is free of crevices capable of harboring microorganisms.
- C14 *Mechanical Force Seal:* The seal established between a flexible rubber, rubber-like, or plastic material when pressed into a special groove in a component using a combination of compression, pressure, and the unique geometrical shapes of the joined materials to create a seal at the interfaces of the joined materials. A mechanical force seal is not intended for routine disassembly for cleaning.
- C15 *Nonabsorbent:* A material, which under normal use and when exposed to the conditions encountered in the environment of its intended use, including cleaning, sanitizing treatment, and/or sterilization, will not permit the infiltration or retention of liquids and/or materials which will support the growth of microorganisms.

- C16 *Nontoxic Materials:* Substances, which under normal use and when exposed to the conditions encountered in the environment of its/their intended use, including cleaning, sanitizing treatment, and/or sterilization, are in compliance with applicable requirements of the USFDA.
- C17 *Normative:* Terms, references, or statements which are mandatory.
- C18 *Opening:* A hole through the product contact surface of equipment that is unsealed and is connected to external piping or is open to the atmosphere.
- C19 *Permanent Joint:* A joint between two components which is unable to be disassembled.
- C20 *Processing Area:* A room or area suitable for the manufacturing and packaging of products.
- C21 *Product:* Milk, milk products, foods, food ingredients, beverages, or other edible materials.
- C22 *Readily Accessible:* A location that can be safely reached by personnel from the floor, other permanent work area, or stable platform (permanent or moveable).
- C23 *Readily Removable:* Designed, fabricated and installed to be quickly separated from the equipment, with or without the use of simple hand tools.
- C24 *Regulatory Agency:* The agency or body with jurisdictional authority for the monitoring and the regulation of activities related to food safety and public health protection.
- C25 *Roughness Average (R_a):* An arithmetical mean of the absolute values of the surface profile departure within a sampling length. (Refer to B1, Reference 2.)
- C26 *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 B1, Reference 4.)
- C27 *Sealed:* Closed to the penetration of fluids by the application of one or more continuous welds, soldering, brazing, coatings, overlays, encapsulations, adhesives, rubber, rubber-like or plastic gaskets under compression, mechanical force seals, or press-fits or shrink-fits.
- C28 *Simple Hand Tools:* A screwdriver, wrench, mallet, or readily available dedicated tool(s) normally used by operating and cleaning personnel.
- C29 *Soil:* Unwanted organic residue or inorganic matter.

C30 Soldering and Brazing

- C30.1 *Soldering*: A joining process that produces coalescence of materials by heating them to the soldering temperature and using a filler metal having a liquidus not exceeding 840°F (450°C) and below the solidus of the base metals. The filler metal is distributed between closely fitted faying surfaces of the joint by capillary action or by wetting the surfaces of the work pieces.
- C30.2 *Solder*: The metal or alloy used as a filler metal in soldering, which has a liquidus not exceeding 840°F (450°C) and below the solidus of the base metal.
- C30.3 *Brazing*: A joining process that produces coalescence of materials by heating them to the brazing temperature in the presence of filler metal having a liquidus above 840°F (450°C) and below the solidus of the base metal. The filler metal is distributed between the closely fitted faying surfaces of the joint by capillary action.
- C30.4 *Brazing Filler Metal*: The metal or alloy used as a filler metal in brazing, which has a liquidus above 840°F (450°C) and below the solidus of the base metal.
- C31 *Solution*: Water or any mixture of cleaning agents, sanitizers and water used for flushing, cleaning, rinsing, or sanitizing.
- C32 *Steam or Sterilizing Media Chambers*: The space(s) that defines the separation between the sterile area and the non-sterile area. Steam or other sterilizing media is introduced into these chambers.
- C33 *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.
- C34 *Substantially Flush*: Mating surfaces or other juxtaposed surfaces that are not more than 1/32 in. (0.794 mm) off-set from each other, except for pipeline and tubular piping welds which must meet AWS/ANSI D18.1. (Refer to B1, Reference 5.)
- C35 **Surface Modification** (Refer to B1, Reference 6)
- C35.1 *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.
- C35.2 *Coatings, Overlays and Encapsulations*: A process where a different material is deposited to create a product contact surface. There is a buildup of new material. The coating, overlay, or encapsulation material does not alter the physical properties of the substrate.
- C36 *Hot Isostatic Pressing (HIP)*: A solid state process which applies heat and pressure in an inert gas to a casting or injection molding of near net shapes of objects and parts to reduce internal voids in the final form.