



**Format and Style Manual
for
3-A Sanitary Standards and 3-A Accepted Practices
With Examples of Text for Criteria, Number 00-03**

June 1, 2009

Drafters Note:

Before starting a new or revised document, amendment, or reaffirmation of a document, refer to **Section I, How to Use This **Manual**, for guidance.**

When developing a new 3-A Sanitary Standard or 3-A Accepted Practice, insert, delete, or modify information as appropriate for the document being prepared.

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Section I

How to Use This Manual

Drafters Note: This section is for guidance during the preparation of 3-A documents and is not intended for inclusion in any drafts or final documents.

1. Introduction

Section II of this *Format and Style Manual* illustrates the format and verbiage that may be generally applied to develop a 3-A Sanitary Standard or 3-A Accepted Practice and to describe the sanitary concepts found in a standard or practice. 3-A Sanitary Standards or 3-A Accepted Practices do not cover machine safety, cost, efficiency, or any other nonsanitary considerations.

3-A Sanitary Standards are developed to detail the sanitary requirements for a specific type of equipment. Specifications include material selection, design, and fabrication applied to specific types of equipment. 3-A Accepted Practices are guidelines for systems and include the same level of sanitary criteria as 3-A Sanitary Standards, in addition to installation criteria where appropriate.

The material herein has been compiled from approved 3-A documents or concepts that have been adopted (or referenced) from other standards-writing bodies, (i.e., American Society for Testing and Materials (ASTM), American Society of Mechanical Engineers (ASME), American National Standards Institute (ANSI), European Hygienic Engineering & Design Group (EHEDG), American Welding Society (AWS), or NSF International). It is likely that revisions and/or additions will be necessary as technology and sanitary criteria are advanced.

The criteria found herein are to be used as a guide for preparing revisions or amendments to existing 3-A documents and writing new 3-A Sanitary Standards or 3-A Accepted Practices. Conformance to the suggested wording in this document will assist in the review and acceptance by the stakeholder groups. However, it is recognized that this general wording may not be suitable for all applications and the Work Groups (WG) may suggest other or modified wording. In such cases, they are encouraged to have adequate documentation available to provide the reason and justification for the variation.

This document is not intended as a substitute for approved 3-A documents or as general criteria if existing 3-A documents do not cover certain equipment or systems. 3-A SSI will consider proposals for new, revised, or amended 3-A Sanitary Standards or 3-A Accepted Practices at any time.

Upon application to and authorization by 3-A SSI, equipment meeting the requirements set forth in the specific 3-A Sanitary Standards may display the 3-A Symbol. Authorizations are not granted for systems (Process Certifications are granted). However, equipment used in these systems must meet the criteria in the appropriate 3-A Sanitary Standard. Application procedures for 3-A Symbol authorization are available on the 3-A SSI website, www.3-a.org.

The following is the recommended sequence for the text of 3-A documents. A brief explanation of the purpose and content of each section is also provided. The point system for numbering sequences in documents has been adopted by many national organization and government agencies. The point system found in 3-A documents uses alphabetic lettering (beginning with A) to denote major or primary sections and a combination of a letter and one or more numbers for secondary, tertiary, and quaternary sections.

The objective of the 3-A numbering system is to assign a unique designation to each division in the standards that will show the relationship of the specific section to all previous sections and give a comprehensive map to the location and relationship of each section to all others.

2 Document Format

2.1 Title Page--Required

The title is not intended to provide the scope. The title should be concise but complete enough to identify the equipment or system being covered by the document. Titles for analogous standards should be similar except for the distinctive feature(s) of the equipment or system. Both 3-A Sanitary Standards and 3-A Accepted Practices follow the same format.

Essential features common to all titles are the words “3-A Sanitary Standards for {**Name Of Equipment**}” or “3-A Accepted Practices for {**Name Of System**},” followed by the word “Number” and a four- or five-digit hyphenated document number; for example, 03-05 (for Standards) or 600-01 (for Accepted Practices). The document number includes the permanent serial number (two digits in standards, three digits in Accepted Practices), followed by a hyphen and a two-digit version number. The version number will increase by one with each revision or amendment. A document is defined as a revision when all Sections are open for discussion.

Amendments are changes only to selected parts of a standard or practice. The amendment will be identified with the name and document number of the standard or practice. Amendments will be incorporated into the body at a subsequent printing. The subsequent printing or publication on the website with incorporated amendments will be renumbered in the same manner as a revision.

Tentative 3-A documents will be identified by a “T-” preceding the document number; for example, T-03-05 or T-600-01. These tentative documents will list two

datelines: (1) the date the document was first drafted as a proposal and approved by the equipment Working Group(s) assigned to the project, listed as "Proposal... {Month & Year}," and (2) the date of the last revision, listed as "{Revision Number; For Example, 2nd, 3rd, or 4th} Revision... {Month & Year}." All tentative documents will have line numbers in the left hand margin for easy identification of discussion topics. The dates and line numbers are required on tentative documents only and are removed when the document is approved for signature. Tentative documents shall be so noted on each page.

During development and approval phases, T-documents are prepared in a single column per page format. Changes to the recommended *Format and Style Manual* wording shall be indicated by strikeouts and underlining.

The next few lines identifying 3-A SSI, USPHS/USFDA, USDA, and EHEDG, if appropriate, as the bodies formulating these documents are required. A statement by the three formulating organizations provides a basis for continual updating of 3-A documents.

2.1.1 **Effective Date--Required; No Letter Designation**

2.1.1.1 The effective date for 3-A Sanitary Standards and 3-A Accepted Practices shall be forty-five (45) days following approval by the Consensus Body.

2.2 **Table of Contents--Required**

2.2.1 A Table of Contents is to be created for each new or revised document. If an amendment creates a new criteria or an Appendix Section that is not included in the original document's Table of Contents the amendment shall include an updated Table of Contents as part of the amendment.

2.3 **Disclaimer--Required**

2.3.1 The Disclaimer, as presented in this *Format and Style Manual*, shall be included in all new, revised and amended documents that do not currently have this section.

2.4 **Foreword--Required**

2.4.1 The Foreword, as presented in this *Format and Style Manual* shall be included in all new, revised and amended documents that do not currently have this Section.

2.5 **Scope (Section A)--Required**

2.5.1 The scope should amplify the Title. For equipment, it should state the function and limits of the equipment and should be distinguishable from those found in other standards. For Accepted Practices, it should identify the nature of the system, the subject or application, and should be distinguishable from those found in other

Accepted Practices. In both cases, the scope should be concise, but complete enough to define the boundaries of the equipment or system. Remember, the scope is the statement of intent.

At times it is appropriate to include restrictions of the 3-A Sanitary Standards or Accepted Practices in the scope. However, the limits and functions of the equipment or system cannot be overemphasized, since the scope defines the criteria necessary for the rest of the document. Two approaches may be used to define these limits:

1. The preferred method for complex equipment and systems would identify common product inlet and outlet points for the equipment or system.
2. If the equipment design varies among manufacturers, making it impossible to identify common inlet and outlet points, then a sequential denotation of the unit operations performed may be used.

2.6 Normative References (Section B)--Required

2.6.1 A Normative References Section shall be included in all new and revised documents. The Normative References shall be subdivided into Sections for 3-A Sanitary Standards, 3-A Accepted Practices, and Other References. Only those documents that have specific application to the document being prepared are to be included. Once listed, the reference documents do not have to be further cited in the Fabrication Section, unless there are very specific qualifying criteria to be considered.

2.7 Definition of Terms (Section C)--Required

2.7.1 Terminology and definitions should be limited to those actually used in the 3-A document. It is customary to define the product contact and nonproduct contact surfaces and mechanical and manual cleaning in 3-A documents. Terms necessary to describe specific equipment or systems may be included, especially if the terms are not standard ones. Definitions are written in dictionary form with the defined terms italicized. Cyclical definitions are not permitted. For some standards and most Accepted Practices, this section should contain a sequential (with respect to process) listing of required components and, if necessary, optional components may be listed. (Note: For most Standards, this type of description would be placed in the scope as Section A2.)

2.8 Materials (Section D)--Required

2.8.1 This Section considers the self-limiting characteristics of the materials that comprise the equipment. Sanitary specifications dictate allowed materials, with the ultimate criteria being based on the environment of its intended use.

2.8.2 The benchmark for materials is the **AIST** 300, excluding 301, Series Stainless Steel or the Alloy Cast Institute (ACI) for cast equivalents. Metals that can be demonstrated

- to be at least as corrosion resistant as the AIST 300 Series Stainless Steel and are nontoxic and nonabsorbent are also acceptable. Exceptions to the AIST 300 Series Stainless Steel are usually permitted for specific materials reviewed by the 3-A Working Groups when the required function does not allow for the use of the AIST 300 Series Stainless Steel.
- 2.8.3 Rubber, rubber-like materials, and plastics are the most common material exceptions to stainless steel. Other permitted materials include the AIST 400 Series Stainless Steel, ceramic, carbon, and plating materials such as chromium or nickel, and other surface modifying materials and techniques. The exceptions to the AIST 300 Series Stainless Steels must specify certain parts or functions where required, and their use is then limited to those identified parts or functions.
- 2.8.4 The accepted materials must be suitable for sanitary application, durable, and nontoxic (as defined by the Food, Drug, and Cosmetic [FD&C] Act); they may also be a regulated indirect food additive or be demonstrated not to be a food additive or found on the FDA Premarket Notification List (Refer to www.fda.gov). Rubber, rubber-like, and plastic materials have their own 3-A Sanitary Standard and when these materials are used in product contact areas, they must conform to their respective Standard.
- 2.9 **Fabrication (Section E)--Required**
- 2.9.1 All equipment is to be designed to be 100% cleanable and to preclude the contamination of the product. Sanitary criteria always include surface finish requirements (generally equivalent to, or smoother than, a 32 $\mu\text{in.}$ (0.8 μm) R_a) that is free of imperfections such as pits, folds, and crevices, limitations of radii, draining requirements, accessibility for cleaning and inspection, and design requirements for the proposed method of cleaning (CIP, COP, manual, or dry brushing). The integrity of sealed product contact and nonproduct contact surfaces must not be compromised.
- 2.9.2 Conformance to 3-A criteria does not automatically imply compatibility with CIP cleaning, since most Standards provide for both manual cleaning and CIP cleaning. CIP cleaning does not preclude regular breakdown of equipment for inspection. Function is not included unless it is necessary for public health reasons such as ingredient addition, product removal; or in the case of aseptic equipment, automatic shutdown.
- 2.10 **Special Considerations (Section F)--Optional**
- 2.10.1 This Section is used where unique fabrication or installation requirements are necessary, such as where HTST pasteurization systems are integral with spray dryer systems or evaporators.
- 2.11 **Installation (Section G)--Optional for Standards but Required for Most Practices**

2.11.1 Installation criteria, when required, may include, but is not limited to, the Grade A PMO or other regulatory requirements; proper juxtaposition of equipment, floor, wall or ceiling clearance; and interconnections and hard wiring for required regulatory controls. In 3-A Accepted Practices this section is in the body; in 3-A Sanitary Standards, if used, it may be in either the body or the Appendix.

2.12 **Appendix--Optional**

2.12.1 The Appendix is an advisory or informative section of 3-A Sanitary Standards or 3-A Accepted Practices unless specifically cited in the Fabrication Section as requiring conformance. Although generally optional, this section is usually found in 3-A documents. The appendix usually includes references to stainless steel materials and provides methods for achieving and measuring the required product contact surface finish. It may also include other advisory information useful for proper construction, material specifications, installation, cleaning, and diagrams of the equipment or system covered by the 3-A Sanitary Standard or 3-A Accepted Practice.

2.12.2 Even when not considered as normative by reference, Regulatory Agencies under their procedures and authority may use the non-normative appendix information during inspections if no other guidance on appendix items is available from the fabricator or the processor. The appendix may also contain representative diagrams of equipment or systems and a suggested format for EDTCF (Refer to Section O).

3 **Abbreviations**

3.1 Certain universal abbreviations are commonly used without definition. These should be in accordance with existing industry and/or military usage. It is recommended that use of less common abbreviations be limited and that they be defined the first time they appear in the document by spelling out the word(s), followed by the abbreviation in parentheses. If the abbreviations are numerous, an abbreviation glossary may be compiled and placed in this Section of the document. Units of measure and their abbreviations should follow ASTM E 380 or ANSI Y10.19.

4 **Dual Dimensioning**

4.1 3-A documents are to use both in.-lb (IP) and the International System of Units (SI) units. The IP units are to be followed by SI units in parentheses. IP units are usually fractional while SI units are in decimal form. Metric conversion recommendations made by the 3-A Steering Committee are found in Section Q4.2.1. However, where measurements concern a legal requirement, such as pasteurization temperature, an exact metric conversion retaining proper significant figures should be done without compromising the IP legal requirements. For fractional units, three (3) significant figures is the norm. Decimal numbers are expressed as three (3) significant figures.

4.2 Inch-Pound (IP) to International System of Units (SI) Conversion

4.2.1 This Section gives guidance for application of SI and conversion of IP units to SI units. Information on the SI system is found in ASTM E380 *Standard Practice for Use of the International System of Units (SI) (the Modernized Metric System)*. The General Conference on Weights and Measures (CGPM) maintains the SI system. Guidance on IP to SI conversion values is further governed by recommendations made by the 3-A Steering Committee on May 18, 1992 (3-A Progress Report, 7 (2): July 1992) and those of a public health significance found in federal and state regulations. The recommendations on converted values herein will replace those adopted by the 3-A Steering Committee May 3, 1978. Pipe size in IP should be followed by SI size substitution equivalent in parentheses.

4.2.2 SI Units and Symbols Found or Potentially Used in 3-A Documents:

TABLE 5 - Base SI Units

Quantity	Unit	Symbol
Length	meter	m
Mass	kilogram	kg
Time	second	s
Electric current	ampere	A
Thermodynamic	kelvin	K
Amount of substance	mole	mol
Luminous intensity	candela	cd

TABLE 6- Derived SI Units

Quantity	Unit	Symbol	Formula
Frequency	hertz	Hz	1/s
Force	newton	N	Kg·m/s ²
Pressure	pascal	Pa	N/m ²
Energy	joule	J	N·m
Temperature	degree celsius	°C	K - 273.15

TABLE 7 - Supplementary SI Units

Quantity	Unit	Symbol
Plane angle	radian	rad
Solid angle	steradian	r

TABLE 8 - Units In Use With SI

Quantity	Unit	Symbol	Definition
Time	minute hour day week, month, etc.	min h d	1 min = 60 s 1 h = 60 min = 3600 s 1 d = 24 h = 86,400 s
Plane Angle	degree minute ^a second	° ' "	1° = (π/180) rad 1' = (1/60)° = (π/10,800) rad 1" = (1/60)' = (π/648,000) rad
Volume	liter ^b	L	1 L = 10 dL = 1000 mL
Pressure	Kilopascal Pounds per in ²	kPa psi	psi x 6.897 = kPa kPa x 0.145 = psi
Mass	metric ton	T	1 t = 1000 kg

^a Use discouraged.

^b Restrict use to volumetric capacity, dry measure, or measure of fluids. Prefix with only milli- or micro-.

^c 3-A use is m² or cm².

TABLE 9 - SI Prefixes

Multiplication Factor	Scientific Notation	Prefix	Symbol
1,000,000,000,000,000,000	1x10 ¹⁸	exa	E
1,000,000,000,000,000	1x10 ¹⁵	peta	P
1,000,000,000,000	1x10 ¹²	tera	T
1,000,000,000	1x10 ⁹	giga	G
1,000,000	1x10 ⁶	mega	M
1000	1x10 ³	kilo	k
100	1x10 ²	hecto ^a	h
10	1x10 ¹	deka ^a	da
0.1	1x10 ⁻¹	deci ^a	d
0.01	1x10 ⁻²	centi ^a	c
0.001	1x10 ⁻³	milli	m
0.000001	1x10 ⁻⁶	micro	μ
0.000000001	1x10 ⁻⁹	nano	n
0.000000000001	1x10 ⁻¹²	pico	p
0.000000000000001	1x10 ⁻¹⁵	femto	f
0.00000000000000001	1x10 ⁻¹⁸	atto	a

^a To be avoided where practical.

4.2.3 Rules for Conversion and Rounding

- 4.2.3.1 Conversion factors should be exact and based on those in ASTM E380. Conversion of IP to SI should consider the implied accuracy of the data being converted. The 3-A Steering Committee recommends (May 18, 1993 meeting) the IP to SI conversion be to exact SI units using normal rules of rounding and retention of significant figures. For most conversions, three or fewer decimal places are considered adequate for the implied or required accuracy of values used in 3-A documents, provided that accuracy for any value required by a State or Federal regulation is not compromised. (Fractional IP units shall be considered to have three (3) significant figures and SI units shall be rounded to three (3) significant figures.)
- 4.2.3.2 To round to fewer digits, if the first digit discarded is less than five (5), the last digit retained is not changed. When the first digit discarded is greater than five (5), or if it is five (5) followed by one or more nonzero digits, the last digit retained is increased by one. When the first digit discarded is exactly five (5), the last digit retained is rounded up if it is odd and remains the same if it is even. Provided that any value required by state or federal regulation be rounded during conversion so as not to compromise the original value.
- 4.2.3.3 Significant digits must be retained with consideration to the implied or required accuracy of an integral value. However, any digit that is necessary to define the specific value is significant. Zeros may be used either to indicate a specific value like any other digit and are significant, or they may indicate order of magnitude, in which case they may not be significant. The unequivocal identification of significant digits is only possible through knowledge of measurement circumstances. (Fractional IP units shall be considered to have three (3) significant figures and SI units shall be rounded to three (3) significant figures.)

4.2.4 Use of SI Prefixes

- 4.2.4.1 SI prefixes found in Section Q4.2.2, Table 9, are used to indicate orders of magnitude, thereby eliminating non-significant digits and leading zeros in decimal fractions. The selection of prefixes should be chosen so the numerical value lies between 0.1 and 1000, except that:
- 4.2.4.1.1 Area and volume values, by convention, may require the prefixes deka-, deci-, or centi-;
- 4.2.4.1.2 Tabular values used in the same context should be consistent in prefix use; and
- 4.2.4.1.3 For mechanical engineering drawings, the millimeter is used for all linear dimensions.
- 4.2.4.2 It is recommended that compound prefixes be avoided.

4.2.5 SI Conversion Values

The following Tables contain recommended IP to SI conversion values to be used in 3-A documents.

1. The values in this Table are not restrictive or inclusive, but are a guide to making IP to SI conversions.
2. Closing decimals used with single digit numbers and values ending in zero are used to establish significance. Three (3) significant figures are recommended.
3. The SI unit of volume is the cubic meter. The special name liter (L) is approved for the cubic decimeter but its use is restricted to volumetric capacity, dry measure, and measure of fluids. No prefix other than milli- or micro- should be used with liter.

TABLE 10 - Linear Conversion (in. to mm)

IP (in.) fraction	IP (in.) decimal	SI (mm)	IP (in.) fraction	IP (in.) decimal	SI (mm)	IP (in.) fraction	IP (in.) decimal	SI (mm)
1/32	0.03125	0.794	33/64	0.515625	13.1	1	1	25.4
3/64	0.04687	1.19	17/32	0.53125	13.5	1-1/4	1.25	31.8
1/16	0.0625	1.59	35/64	0.546875	13.9	1-1/2	1.50	38.1
5/64	0.07812	1.98	9/16	0.5625	14.3	1-3/4	1.75	44.4
3/32	0.09375	2.38	37/64	0.578125	14.7	2	2	50.8
7/64	0.10937	2.78	19/32	0.59375	15.1	2-1/4	2.25	57.2
1/8	0.125	3.18	39/64	0.609375	15.5	2-1/2	2.50	63.5
9/64	0.14062	3.57	5/8	0.625	15.9	2-3/4	2.75	69.8
5/32	0.15625	3.99	41/64	0.640625	16.3	3	3	76.2
11/64	0.17187	4.37	21/32	0.65625	16.7	3-1/4	3.25	82.6
3/16	0.1875	4.76	43/64	0.671875	17.1	3-1/2	3.50	88.9
13/64	0.20312	5.16	11/16	0.6875	17.5	3-3/4	3.75	95.2
7/32	0.21875	5.56	45/64	0.703125	17.9	4	4	102
15/64	0.23437	5.95	23/32	0.71875	18.3	4-1/2	4.50	114
1/4	0.25	6.35	47/64	0.734375	18.7	5	5	127
17/64	0.26562	6.75	3/4	0.75	19.0	5-1/2	5.50	140
9/32	0.28125	7.14	49/64	0.765625	19.4	6	6	152
19/64	0.29687	7.54	25/32	0.78125	19.8	7	7	178
5/16	0.3125	7.94	51/64	0.796875	20.2	8	8	203
21/64	0.32812	8.33	13/16	0.8125	20.6	9	9	229
11/32	0.34375	8.73	53/64	0.828125	21.0	10	10	254
23/64	0.35937	9.13	27/32	0.84375	21.4	12	12	305
3/8	0.375	9.52	55/64	0.859375	21.8	15	15	381
25/64	0.39062	9.92	7/8	0.875	22.2	18	18	457
13/32	0.40625	10.32	57/64	0.890625	22.6	20	20	508
27/64	0.42187	10.72	29/32	0.90625	23.0	24	24	610
7/16	0.4375	11.11	59/64	0.921875	23.4	25	25	635
29/64	0.45312	11.51	15/16	0.9375	23.8	30	30	762
15/32	0.46875	11.91	61/64	0.953125	24.2	35	35	889
31/64	0.48437	12.30	31/32	0.96875	24.1	36	36	914
1/2	0.500	12.70	63/64	0.984375	25.0	40	40	1020

TABLE 11 - Linear Conversion (in. to cm; ft to m)

IP (in.)	SI (cm)	IP (in.)	SI (cm)	IP (ft)	SI (m)	IP (ft)	SI (m)
45	114	75	190	10	3.05	35	10.7
48	122	80	203	12	3.66	36	11.0
50	127	84	213	15	4.57	40	12.2
55	140	85	216	18	5.49	50	15.2
60	152	90	229	20	6.10	60	18.3
65	165	95	241	24	7.32	70	21.3
70	178	96	244	25	7.62	80	24.4
72	183	100	254	30	9.14	90	27.4

**TABLE 12 - Fractional Linear Conversion
(in. to μm ; in. to mm)**

IP (in.)	SI (μm)	IP (in.)	SI (mm)
0.0002	5.	0.005	0.125
0.002	50.	0.008	0.200
0.003	80.	0.01	0.25
		0.04	1.00
		0.08	2.00

TABLE 13 - Volumetric Capacity Conversion (gal to L)

IP (gal)	SI (L)	IP (gal)	SI (L)	IP (gal)	SI (L)	IP (gal)	SI (L)
1	3.78	200	757.0	1,000	3,785	7,500	28,388
5	18.93	300	1,136	1,500	5,678	10,000	37,850
10	37.80	400	1,514	2,000	7,570	20,000	75,700
15	56.80	500	1,892	2,500	9,462	30,000	113,550
20	75.70	600	2,271	3,000	11,355	40,000	151,400
25	94.60	700	2,650	3,500	13,248	50,000	189,250
100	378.50	800	3,028	4,000	15,140	75,000	283,875
150	567.80	900	3,406	5,000	18,925	100,000	378,500
175	662.40						

TABLE 14 - Area Conversion (ft² to cm²; ft² to m²; in.² to cm²)

IP	1.0 ft ²	2.0 ft ²	2.5 in. ²	4.0 in. ²	6.0 in. ²	
SI	929 cm ²	0.19 m ²	16.13	25.81	38.71	45.2 ± 0.1 cm ²

TABLE 15 - Pressure Conversion (psig to kPa)

IP (psig)	1	2	15.3	250	300	30,000
SI (kPa)	6.89	13.72	105.5	1724	2068	206,843

TABLE 16 - Plane Angle Conversion (° to rad)

IP (°)	30	60	90	120	135	180	360
SI (rad)	0.52	1.05	1.57	2.09	2.36	3.14	6.28

TABLE 17 - Flow Rate Conversion (gpm to Lpm)

IP (gpm)	9.4	24.0	43.0	69.0	102.0	182.0	5 ft/s
SI (Lpm)	35.6	90.8	163.0	261.0	386.0	689.0	1.5 m/s

TABLE 18 - Other

Pitch: Calculate using linear dimensions.

Temperature: Calculate by using °C= (°F-32) x 5/9.

Normally temperatures expressed in a whole number of Fahrenheit degrees should be converted to the nearest 0.5 Celsius degrees. The number of significant figures retained depends on the implied accuracy of the original temperature, provided that when converting temperatures required by a regulation, they are never rounded to be less (for heating) or more (for cooling) than the original.

5 3-A Sanitary Standards, Inc.

- 5.1 3-A Sanitary Standards, Inc. is the sole authorized organization for the establishment and maintenance of 3-A Sanitary Standards and 3-A Accepted Practices, and granting authorizations to display the 3-A Symbol.

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6 The 3-A Sanitary Standards Working Groups

- 6.1 The 3-A Working Groups formulate 3-A Sanitary Standards, encompassing the sanitary design for specific equipment types or 3-A Accepted Practices relating to processing systems. All 3-A documents are developed through a uniform and detailed review of written proposals and must be fully acceptable to processors, equipment manufacturers, and sanitarians. Information on the 3-A Sanitary Standards Program, including single copies of standards and procedures for initiating new standards activity and committee appointments, may be directed to:

3-A Sanitary Standards, Inc.
6888 Elm Street, Suite 2D
McLean, VA 22101-3829
Telephone: (703) 790-0295
Fax: (703) 761-6284
E-mail 3-ainfo@3-a.org
URL: www.3-a.org

- 6.2 Upon formal acceptance of new, revised, or amended 3-A documents by 3-A SSI, a notice is published in *Food Protection Trends*, the primary IAFP journal. 3-A Sanitary Standards and 3-A Accepted Practices are available for purchase in English from www.3-a.org.

Section II

Preparation of a 3-A Document

**3-A[®] Sanitary Standard for {Insert Equipment Name
and Number}**
or
**3-A[®] Accepted Practice for {Insert Process Name and
Number}**

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)
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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 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 Accepted Practice**].

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 [**3-A Accepted Practice**]. 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 [**3-A Accepted Practice**] establishes minimum sanitary (hygienic) requirements for design, materials, fabrication, and/or installation of [Name equipment or system].

This 3-A Sanitary Standard [**3-A Accepted Practice**] 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 [**3-A Accepted Practice**] 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 – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG) [**Drafters Note:** Other SDOs may be added].

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 or Accepted Practice**} covers the sanitary aspects of {**name of equipment or system including, as appropriate, its function, boundaries, limits and unit operations in process or handling sequence,**}. Product enters the {**name of equipment or system**} at {**entry point**} and exits at {**point of exit**}.

And/or

The unit operations of the {**name of equipment or system**} include the following: {**unit operations in process or handling sequence**}.

Drafters Note: At times it may be desirable to add a sentence to indicate what is not included. If both entry-exit and unit operations are provided, they must each be complete, independent of each other and expressed in separate paragraphs.

- A2 In order to conform to this 3-A {**Sanitary Standard or Accepted Practice**}, {**name of equipment or system**} shall conform to the following criteria for design, materials of construction, fabrication techniques and installation, as appropriate, and the current revisions or editions of all referenced documents cited herein.

B NORMATIVE REFERENCES

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

Drafters Note: The following lists the current standards, accepted practices, and other references and standards routinely referenced in 3-A documents. When preparing a new or revised document, check with the 3-A SSI staff to be sure the listings include all new 3-A Sanitary Standards, 3-A Accepted Practices and other references and standards. DO NOT include this entire listing. Select for inclusion only those documents that are necessary and applicable to the document being prepared.

Care should be taken in choosing Normative references to ensure that there are no circular references as this can lead to difficulty in determining which standard takes precedence. (For example, Standard A references Standard B as normative, and Standard B references Standard A as normative.) If a circular reference is unavoidable, then additional notes need to be added to alert readers to the circular nature of the reference, and add any necessary clarifications to avoid any ambiguities or contradictions.

B2 **3-A Sanitary Standards****Doc. No. Title (3-A Sanitary Standards for:)**

- 01- Storage Tanks
- 02- Centrifugal and Positive Rotary Pumps
- 04- Homogenizers and Reciprocating Pumps
- 05- Stainless Steel Automotive Transportation Tanks
- 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 Other 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- Polished 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
- 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 Discs
- 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 Used on Equipment
- 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

B3 **3-A Accepted Practices**

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- Method of Producing Steam of Culinary Quality
- 610- Sanitary Construction, Installation, and Cleaning of Crossflow Membrane Processing Systems
- 611- Farm Milk Cooling and Storage Systems

B4 **Other References and Standards**

Drafters Note: When selecting references from the following list, care must be taken to assure that the cited references do not create conflicting requirements.

- | <u>Ref. No.</u> | <u>Title</u> |
|-----------------|---|
| 1. | <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. |
| 2. | AMS-S-13165, <i>Shot Peening of Metal Parts</i> . Society of Automotive Engineers (AWS), 400 Commonwealth Dr., Warrendale, PA 15096-0001. |
| 3. | SAE-AMS-QQ-C-320, Chromium Plating (Electrodeposited). SAE-AMS QQ-N-290A, Nickel Plating (Electrodeposited). Society of Automotive Engineers (AWS), 400 Commonwealth Dr., Warrendale, PA 15096-0001. |
| 4. | National Primary Drinking Water Regulation of the Environmental Protection Agency (EPA), The Code of Federal Regulations (CFR), Title 40, Parts 141, 142, and 143. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, Phone: (202) 512-1800 or the EPA web site at: http://www.epa.gov/OGWD/.) |
| 5. | <i>AIST Steel Products Manual, Stainless & Heat Resisting Steels</i> , Table 2-1. Association for Iron & Steel Technology (AIST), 410 Commonwealth Drive, Warrendale, PA 15086, Phone: (412) 776-1535. www.AIST.org |
| 6. | <i>Steel Casting Handbook, Supplement 2, 1999</i> , 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 |
| 7. | MIL-C-26074E. <i>Military Specification: Coatings, Electroless Nickel Requirements For</i> . Standardization, Document Automation & Production Service (Department of Navy), 700 Robbins Avenue, Building 4, Section D, Philadelphia, PA 19111-5094, Phone: (215) 697-2179, Fax: (215) 697-1462. |
| 8. | 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. www.astm.org/standard/index.shtml |
| 9. | ASTM specifications for Wrought Grades A-276, A-582, and A-666. Available from ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, Phone: (610) 832-9500. www.astm.org/standard/index.shtml |
| 10. | (ANSI)/American Society of Mechanical Engineers (ASME) B46.1 - <i>Surface Texture Waviness and Lay</i> . Available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017-2392, Phone: (212) 705-7722. www.ANSI_standard,his.com |
| 11. | Aerospace Standard (AS) 568, Aerospace Size Standards for O-rings, published by SAE, 400 Commonwealth Drive, Warrendale, PA 15086, Phone: (724)-776-4841. |

12. 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. www.iso.org
13. AWS/ANSI 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 (ANSI Approved)

AWS D18.3/D18.3M - Specification for Welding of Tanks, Vessels, and Other Equipment in Sanitary (Hygienic) Applications (ANSI Approved)

Published by American Welding Society, 550 N.W. LeJeune Rd., Miami FL, Phone: (800) 443-3953, www.aws.org.
14. EHEDG Doc. 9 – Welding Stainless Steel to Meet Hygienic Requirements. European Hygienic Engineering & Design Group. Published by EHEDG, www.ehedg.org
15. *Machinery's Handbook*, published by Industrial Press Inc., 200 Madison Avenue, New York, NY 10157, Phone: (888) 528-7852.
16. 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 or at <http://www.gpoaccess.gov/cfr/index.html>.
17. The Code of Federal Regulations (CFR), Title 29, Part 1910.147 - The Control of Hazardous Energy. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Phone: (202) 512-1800 or at <http://www.gpoaccess.gov/cfr/index.html>.
18. The Code of Federal Regulations (CFR), Title 21, Part 177 Indirect Food Additives: Polymers. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Phone: (202) 512-1800 or at <http://www.gpoaccess.gov/cfr/index.html>.
19. Grade “A” Pasteurized Milk Ordinance, <http://www.cfsan.fda.gov/~ear/pmo03toc.html>.
20. GAR C-9 Cast Microfinish Comparator. Available from Gar Electroforming Division, Electroformers Inc., 11 Augusta Drive, Commerce Park, PO Box 340, Danbury, CT 06813-0340, Phone: (203) 744-4300. <http://www.finishing.com/Shops/industrial/garelectroforming.shtml>
21. EHEDG Doc. 7 – A Method for the Assessment of Bacterial Tightness of Food Processing Equipment. European Hygienic Engineering & Design Group. Published by EHEDG, www.ehedg.org

22. The Code of Federal Regulations (CFR), Title 21, Part 108 Emergency permit control. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Phone: (202) 512-1800 or at <http://www.gpoaccess.gov/cfr/index.html>.
23. The Code of Federal Regulations (CFR), Title 21, Part 113 Thermally processed low-acid foods packaged in hermetically sealed containers. For sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, Phone: (202) 512-1800 or at <http://www.gpoaccess.gov/cfr/index.html>.

C DEFINITIONS

Drafters Note: Choose or propose only those definitions appropriate to the standard or practice being written.

C1 *Bond:* The adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.

Drafters Note: The definition term "cohesive force" shall be interpreted to apply only to the molecular forces in effect for platings and other coatings as defined by C31.2.1. The term "cohesive forces" does not apply to the fabrication process of using unique geometrical shapes of gasket and groove to retain a gasket as is done, for example, on several valve designs. When this definition is used, section E1.3 from this manual must also be included.

C1.1 *Mechanical Force Seal:* The seal established between a flexible rubber, rubber-like, or plastic material when pressed into a special groove in a metal or glass component using a combination of compression, pressure, and the unique geometrical shapes of the joined materials to create a tight seal at the interface of the materials joined during conditions of intended use including processing, cleaning, sanitizing, or sterilization. A mechanical force seal is not intended for routine disassembly for cleaning.

Drafters Note: This fabrication process is considered as a form of mechanical force seal, which is specifically excluded by the definition for bond. When this definition is used, section E1.2.1.4 from this manual must also be included

C2 *Burr:* A thin ridge or sharp area remaining after cutting, drilling, or punching a material.

C3 Cleaning

C3.1 *Clean-in-Place 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.

Drafters Note: Insert one of the following statements as the last sentence of C3.1.

Product contact surfaces to be CIP cleaned are inspectable.

(or)

Product contact surfaces to be CIP cleaned are inspectable except as specified in E1.5.2.2.

- C3.2 *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).
- C3.3 *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.
- C3.4 *Dry Cleaning*: Cleaning with a vacuum cleaner and/or dry brushes and other tools.
- C4 *Cleanable or Cleanability*: The suitability of materials of construction, design and fabrication required to assure that the equipment can be freed from 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 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.

Drafters Note: Refer to E.1.7.1 for inclusion of appropriate dimensions.

- C6 *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.
- 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.

Drafters Note: Specific dimensions or ratios should be included, as appropriate, in the fabrication section.

- 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 *Inlet:* An opening that allows product, solutions, steam, or air to enter the equipment.

C11 *Inspectable:* Designed, fabricated and installed to make product contact surfaces available for close visual observation.

Drafters Note: The addition of the following or similar phrasing, “with or without the use of visual aids (i.e. boroscope or mirror)” may be added when necessary.

C12 *Nontoxic Materials:* Substances, which under the conditions of their use, are in compliance with applicable requirements of the FDA.

C13 *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

C14 *Outlet/Product Outlet:* An opening that allows product or solutions to exit the equipment.

C15 *Perforated Screens:* Metal sheets, which have punched, cut, drilled or formed openings or holes.

C16 *Recovered Process Water:* Water recovered from operational processes that has been subsequently handled and treated in such a manner that it is considered a safe water supply by the appropriate Regulatory Agency as described in Appendix D of the PMO. (Refer to B4, Reference No. 19.)

C17 *Processing Area:* A room or area suitable for the manufacturing and packaging of products.

C18 *Product:* Milk, milk products or other **related** products. **{Dry Products or Other Specific Product Types may be Substituted.}**

C19 *Readily Accessible:* A location that can be safely reached by personnel from the floor, other permanent work area or stable platform (permanent or moveable).

- Drafters Note:** In view of the TPV program, this definition is inappropriate for standards of small equipment or components. Proper accessibility is to be addressed in the standards of the equipment on which the components are used.
- C20 *Readily Removable:* Designed, fabricated, and installed to be quickly separated from the equipment with or without the use of simple hand tools.
- C21 *Regulatory Agency:* The state or local agency having regulatory jurisdiction, or the validation for compliance (testing, timing and sealing) with legal pasteurization criteria as set forth in the PMO. (Refer to B4, Reference No. 19.)
- C22 *Roughness Average (R_a):* An arithmetical mean of the absolute values of the surface profile departure within a sampling length. (Refer to B4, Reference No. 10.)
- C23 *Safe Water:* Water from a supply properly located, protected, and operated, and shall be of a safe, sanitary quality. The water shall meet the standards as described in the National Primary Drinking Water Regulation of the Environmental Protection Agency (EPA) (Refer to B4, Reference No. 4) or Category I Reclaimed Process Water as described in Appendix D of the PMO. (Refer to B4, Reference No. 19.).
- C24 *Sanitizing or Sanitization:* A process applied to a clean surface which is capable of reducing the numbers of the most resistant human pathogens by at least 5 \log_{10} reductions (99.999%) to 7 \log_{10} reductions (99.99999%) by applying 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.
- C25 *Sealed:* Closed to the penetration of fluids by the application of one or more continuous welds, coatings, overlays, encapsulations, solders, adhesives, rubber, rubber-like or plastic gaskets under compression, mechanical force seals, or press-fits or shrink-fits.
- Drafters Note:** When this definition is used, sections E1.2.1.4.2 and E1.11.7 must be included in the document.
- C26 *Shadow Areas:* Obstructed areas on product contact surfaces where cleaning solutions will not flow or impinge directly across or on the surface.
- C27 *Simple Hand Tools:* A screwdriver, wrench, mallet, or readily available dedicated tool(s) normally used by operating and cleaning personnel.
- C28 *Soil:* Unwanted organic residue or inorganic matter.
- C29 *Solution:* Water, or any mixture of cleaning agents or sanitizers and water used for flushing, cleaning, rinsing, or sanitizing.

- C30 *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.
- C31 *Substantially Flush:* Mating surfaces or other juxtaposed surfaces that are not more than 1/32 in. (0.794 mm) offset from each other, except for pipeline and tubular piping welds which must meet AWS/ANSI D18.1. (Refer to B4, Reference No. 13.)
- C32 **Surfaces**
- C32.1 *Product Contact Surfaces:* All surfaces which are exposed to the product and surfaces from which splashed product, liquids or material may drain, drop, diffuse **{Where Applicable}**, or be drawn into the product or onto product contact surfaces. **{Surfaces That Come Into Contact With Product Contact Surfaces Of Packaging Materials May Be Included In This Definition For Some Equipment.}**
- C32.2 *Solution Contact Surfaces:* All interior surfaces of the equipment or system, including associated piping, that are used for supplying and recirculating cleaning and/or sanitizing solutions, except those used to supply concentrated cleaning and sanitizing chemicals from bulk storage to the point of chemical addition.
- C32.3 *Nonproduct Contact Surfaces:* All exposed surfaces from which splashed product, liquids, or other materials cannot drain, drop, diffuse **{Where Applicable}** or be drawn into or onto the product, product contact surfaces, open packages, or the product contact surfaces of package components.
- C32.4 *Processing Air Contact Surfaces:* Surfaces in contact with filtered air prior to coming in contact with the product, commencing at the filter frame of the final air filter and ending at the first downstream product contact surface.
- C32.5 *Exhaust Air Contact Surfaces:* Surfaces of air ducts, plenum chamber(s) (if provided), and appurtenances from the final product contact surface to the exhaust stack discharge.
- C33 **Surface Modification (Refer to B4, Reference No. 1)**
- C33.1 *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.

C33.1.1 Surface treatments include:

Drafters Note: Select only appropriate treatment(s).

1. Mechanical (grinding, polishing, shot peening) (Refer to B4, Reference No. 2)
2. Thermal (surface hardening laser, electron beam)
3. Diffusion (carburizing, nitriding)
4. Chemical (etching, oxidation, passivation)
5. Ion Implantation
6. Electropolishing

C33.2 *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.

C33.2.1 Coating processes include:

Drafters Note: Select only appropriate process(es).

1. Chemical (conversion coatings except anodizing)
2. Engineering Plating (e.g., Electrodeposition {Refer to B4, Reference. No. 3}, gold plating)
3. Thermal spraying (e.g., flame, plasma, arc spray)
4. Physical Vapor Deposition
5. Chemical Vapor Deposition

C34 *Unitized:* The connection, assembly, or attachment of functional sub-units to form a complete machine.

C35 **{Add Definitions as Needed}**

D MATERIALS**D1 Product Contact Surfaces**

Drafters Note: When appropriate for the document being prepared Splash Contact, Solution Contact or Air Contact surfaces may be added to the heading.

D1.1 Metals

D1.1.1 Product contact surfaces shall be of stainless steel of the **Association for Iron and Steel Technology (AIST)** 300 Series, excluding 301, 302, and 303, (Refer to B4, Reference No. 5) or corresponding Alloy Cast Institute (ACI) types (Refer to B4, Reference No. 6) 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 H.) Where welding is involved, the carbon content of the stainless steel shall not exceed 0.08%.

D1.1.2 **{List Applications}** may be covered by a coating of electroless nickel alloy. (Refer to B4, Reference Number 7 and Appendix, Section J.)

D1.1.3 **{List Applications}** made of the materials provided for in D1.1.1 may have their product contact surfaces modified by surface coating(s).

D1.1.4 **{List Applications}** may also be made of other nontoxic, structural metal(s) that have their product contact surfaces modified by coating(s).

D1.1.5 **{List Applications}** may be made of stainless steel of **AIST** 302, 303, 400 series, or nontoxic, nonabsorbent metal which is as corrosion resistant, under the conditions of intended use, as 304 stainless steel.

Drafters Note: 303 Stainless Steel is rapidly corroded in the presence of Nitric Acid. If allowed, the Cleaning and Inspectability Section of Section E should include cautionary criteria.

D1.1.6 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**). **{If Optional Parenthetical Words are Used, Also See D1.3 and E1.16.}**

D1.2 Nonmetals

D1.2.1 Rubber and rubber-like materials may be used for **{All Required Application(s) Including Coatings}** and when used for the specified application(s), shall conform to the applicable provisions of 3-A Sanitary Standard, Number 18-.

- D1.2.2 Plastic materials may be used for **{All Required Application(s) Including Coatings}** and when used for the above-specified application(s), shall conform to the applicable provisions of 3-A Sanitary Standard, Number 20-.
- D1.2.3 **{Rubber and Rubber-Like Materials or Plastic Materials; Choose one or Both as Appropriate}** 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 sanitizing treatment **(or sterilization)**. **{If the Optional Parenthetical Words are Used, Also Refer to D1.3 & E1.16.}**
- D1.2.4 Adhesives used for bonding rubber and rubber-like materials, bonding plastic materials, and bonding of carbon or ceramic seal components shall be nontoxic. Adhesives shall comply with 21 CFR 175 - Indirect Food Additives: Adhesives and Components of Coatings (Refer to B4, Reference No.16).
- D1.2.5 Carbon and ceramic materials (including tungsten carbide) may be used for **{List Applications}** and when used, 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, including cleaning and sanitizing treatment **(or sterilization)**. **{If the Optional Parenthetical Words are Used, Refer to D1.3 and E1.16.}**
- D1.3 **High-Temperature Materials**
- D1.3.1 In equipment or a processing system to be sterilized by heat at a temperature of 250°F (121°C) or higher, all materials having product contact surface(s) 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.
- D1.4 **{Additional Materials may be Listed as Needed}**
- 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

Note: The illustrations shown in this Fabrication Section are not to be interpreted as engineering drawings to be followed precisely. The illustrations are presented only to visually represent an example of the criterion described in the associated paragraph.

Drafters Note: The above “Note:” is to be included in any standard or accepted practice in which illustrations are included in the Fabrication section. Refer to all visual representations included as an “illustration(s)” to distinguish them from engineering drawings, which show precise dimensions, component placement, and tolerances. Illustrations should be included in the Fabrication Section when they are deemed appropriate to visually clarify an example of a criterion. When the illustration represents a concept for which more than one design will satisfy, precede the illustration(s) with the parenthetical statement “(See following illustrations of examples)”. When illustrations are more general in nature, such as exploded views, system configurations, generalized proprietary illustrations, etc., they should be placed in the appendix.

Select only the following criteria paragraphs that apply to the document being prepared. Additional criteria paragraphs should be added when needed for the specific 3-A Sanitary Standard or 3-A Accepted Practice under development or revision. Adjust the numbering sequences as necessary.

E1 Product Contact Surfaces

Drafters Note: When appropriate for the document being prepared Splash Contact, Solution Contact or Air Contact surfaces may be added to the heading.

E1.1 Surface Texture (Refer to Appendix, Section I.)

E1.1.1 Surfaces, including fabricated, welded and soldered joints, shall be at least as smooth as a 32 $\mu\text{in.}$ (0.8 μm) R_a finish and shall be free of pits, folds, crevices, and cracks in the final fabricated form. (Refer to Appendix, Section I.), except that;

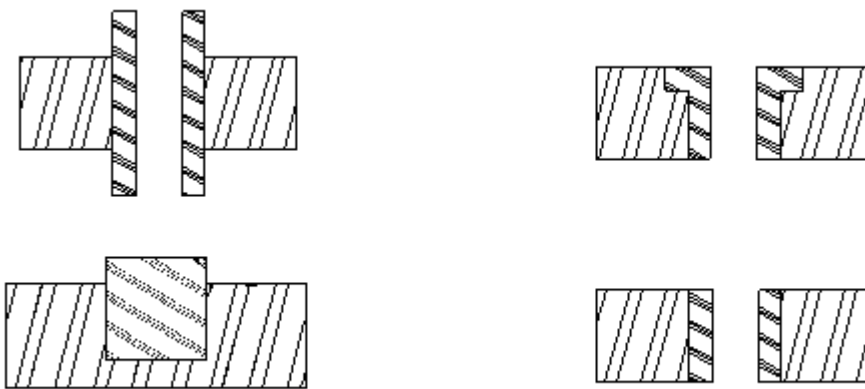
Drafters Note: If the document being prepared allows for rougher surfaces for specified applications, an “except that” statement and appropriate subsections must be added. These exceptions may be proposed for filter materials, membranes, product release surfaces, etc.

E1.1.1.1 Sanitary tubing joints, welded in accordance with E1.2.2, and free of pits, folds, crevices, and cracks, and misalignments, may have an as-welded **interior** surface finish.

E1.2 Permanent Joints

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

E1.2.1.1 Press-fits, **force-fits**, or shrink-fits may be used to produce crevice-free permanent joints only when neither welding nor soldering is practical. Joints of these types may only be used to assemble metallic parts having circular cross sections, free of shoulders or relieved areas. Press-fitting, **force-fitting**, or shrink-fitting may be used for **{List all Application(s)}**. (Refer to B4, Reference No.15.) (See the following illustrations of acceptable press-fits, force-fits, or shrink-fits.)



E1.2.1.2 If press-fit or shrink-fit procedures are to be used for metal-to-plastic or plastic-to-plastic joints, supporting documentation shall be available to demonstrate the joints suitability. The tightness of the press-fit or shrink-fit seal shall be validated to demonstrate that there is no migration past the seal under the conditions of intended use. This shall be accomplished using the EHEDG Document No. 7, Test for Bacterial Tightness or other equally effective test(s).

E1.2.1.3 Gold- or silver-bearing solder may be used for flushing joints or for attaching **{List all Application(s)}**.

E1.2.1.4 A mechanical force seal may be used for **{List all Application(s)}**. The tightness of the seal shall be validated to demonstrate that there is no migration past the seal. The interior of the gasket groove shall be designed so the groove is inspectable and cleanable when the gasket is removed.

E1.2.1.4.1 The manufacturer shall provide a field replacement procedure for the mechanical force seal that has been validated **to the original installation** tightness **to prevent liquid penetration past the seal**.

E1.2.1.4.2 The surfaces behind mechanical force seals shall be easily cleanable and inspectable or the impermeability of the seal shall be established by an appropriate test.

E1.2.2 Permanent joints in sanitary tubing shall be welded in accordance with either AWS/ANSI D18.1 (Refer to B4, Reference No. 13) or EHEDG Doc. 9 (Refer to B4, Reference No. 14).

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). **{If the Optional Parenthetical Words are Used, Refer to D1.3 and E1.16.}**

E1.4 Coatings

E1.4.1 Coatings, when used, shall be free of delamination, pitting, flaking, spalling, blistering, or distortion when exposed to the conditions encountered in the environment of intended use, including cleaning and sanitizing treatment (or sterilization). **{If the Optional Parenthetical Words are Used, Refer to D1.3 and E1.16.}**

E1.4.2 Electrodeposited coatings shall be at least 0.0002 in. (0.005 mm) thick.

E1.4.3 Thermospray material coatings shall be at least 0.003 in. (0.076 mm) thick.

E1.4.4 Plastic or rubber and rubber-like materials, when used as a coating, overlay, or encapsulation, shall be at least 0.001 in. (0.025 mm) thick.

E1.5 Cleaning and Inspectability

E1.5.1 Equipment intended for COP or manual cleaning shall be designed and fabricated so all product contact surfaces are readily accessible and inspectable either when in an installed position or when removed. Junctures between components may or may not be gasketed or sealed. All demountable appurtenances shall be readily removable.

E1.5.2 Equipment 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.

E1.5.2.1 All CIP cleaned surfaces, including all non-removed appurtenances, shall be readily accessible and inspectable. All demountable appurtenances shall be readily removable.

Drafters Note: Some equipment may have large appurtances that are designed for CIP cleaning and do not require frequent dismantling. These appurtances may be identified as being “removable” rather than “readily removable” if required.

E1.5.2.2 When cleanability by CIP **{List Applications}** has been documented and accepted by the regulatory agency, the design shall provide that representative surfaces are readily accessible, and inspectable.

Drafters Note: Include E1.5.2.2 only when the reference to this Section is included in C3.1 and the CIP cleanability of the equipment specified has been documented and accepted by the Regulatory Authority.

E1.5.3 Surfaces, including appurtenances, not designed to be CIP cleaned shall be readily accessible and inspectable when either in an installed position or when removed. All demountable appurtenances shall be readily removable.

E1.5.4 When parts having product contact surfaces are too large or heavy for manual handling, appropriate mechanical means for handling shall be provided by the fabricator or user.

E1.6 **Draining**

E1.6.1 Surfaces shall be self-draining except for typical clingage or adherence.

Drafters Note: Additional specifications, such as those for slope or pitch, or a qualifying phrase (for example, “when properly installed”) may be added. The preferred criterion is for equipment to be self-draining. However, it is recognized that some designs cannot meet this criteria and may be designed to be drainable or large equipment may have portions that are self-draining or drainable. Select the appropriate alternate paragraph for inclusion in the document. Do not include all criteria paragraphs in the same document.

Alternate Paragraph 1

Surfaces shall be drainable and provided with sufficient drain points so the equipment can be drained.

Alternate Paragraph 2

Surfaces shall be self-draining except for typical clingage or adherence and **{List all Application(s)}** may be made to be drainable with sufficient drain points so the equipment can be drained.

E1.7 Fittings and Valves

Drafters Note: This section should not be included unless there is a very specific reason necessary to clarify the application of the 3-A Sanitary Standards listed in Section B Normative References. An example would be to specify a leak detection outlet valve dimension for a vat pasteurizer, which are, “They shall be designed to be attached to a pasteurizer so that the combined length of the valve inlet passage in the valve body and of any passage of corresponding diameter in the pasteurizer does not exceed the diameter of the passage in the valve.” Other applications and dimensions may be used as appropriate.

E1.7.1 When components are close coupled, the intervening product contact surfaces shall be the lesser of:

1. Twice the nominal diameter or cross section of the mating surfaces, or
2. A maximum of 5.0 in. (127 mm) as measured from the **outer shell** of the vessel to the point at which product is stopped by a valve seat or fitting cap.

Drafters Note: Drawings, as appropriate, to demonstrate the close-coupled dimensions should be added.

E1.8 Temperature-Sensing Device Connections

E1.8.1 A product temperature-sensing device, if provided, shall be located so any heating or cooling jacket does not influence the device.

E1.8.2 If the fitting for a temperature-sensing device does not pierce the lining, either

1. The temperature-sensing element receptacle shall be securely attached to the exterior of the lining, or
2. Means to attach temperature-sensing elements securely to the exterior of the lining shall be provided.

E1.8.3 The fitting for a temperature-sensing device intended for sensing processing or holding temperature in a vessel shall be located no higher than the 20% capacity level of the vessel.

E1.9 Instruments

Drafters Note: This section should not be included unless there is a very specific reason necessary to clarify the application of the standards listed in Section B, Normative References.

E1.10 Sanitary Tubing

Drafters Note: This section should not be included unless there is a very specific reason necessary to clarify the application of the standards listed in Section B, Normative References.

E1.11 Gaskets, Gasket Retaining Grooves, O-rings and Seals

E1.11.1 Gaskets shall be removable or bonded.

E1.11.2 Grooves in gaskets shall be no deeper than their width unless the gasket is readily removable and reversible for cleaning.

E1.11.3 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 (except that:)

E1.11.3.1 **{Provide Additional Exceptions if Necessary.}**

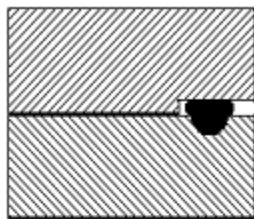
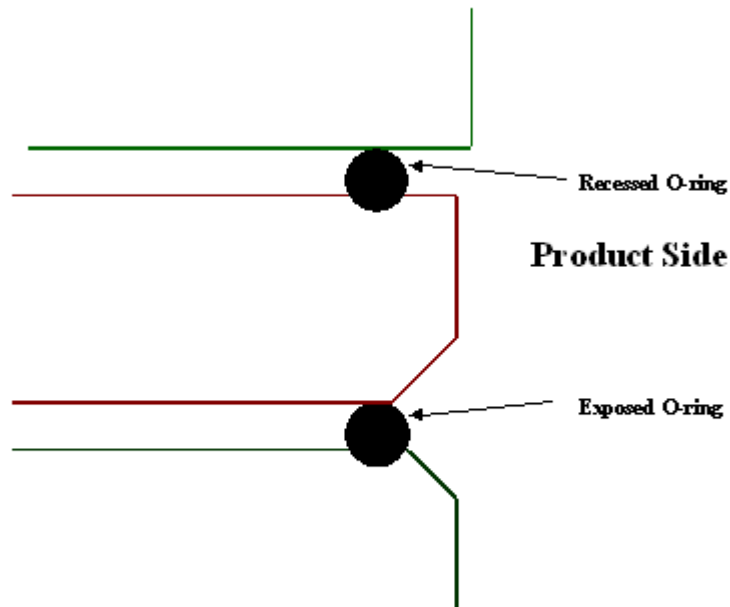
E1.11.4 Gaskets between flat sealing surfaces shall be substantially flush with the product contact surfaces. The juncture shall create a crevice-free joint, without any unsupported gasket material.

E1.11.5 Surfaces with two or more O-rings or seals in a row between product contact and nonproduct contact surfaces shall have a leak-detection port between them that is open to the atmosphere and visible to the operator, unless this area is designed for manual or COP cleaning. The leak-detection port shall be a minimum of 1/8 in. (3.18 mm) in diameter.

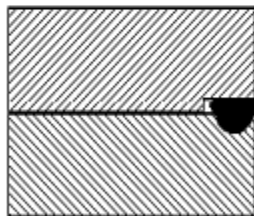
Drafters Note: In some standards, leak detection may be required between these two gaskets even when they are designed for manual cleaning.

E1.11.6 Gasketed joints employing recessed O-rings or seals which are intended for CIP shall be substantially flush so that some of the O-ring or seal surface will be partially exposed to cleaning solutions (See following illustrations of examples).

E1.11.7 The surfaces behind removable gaskets under compression shall be easily cleanable and inspectable.



HARD TO CLEAN RECESSED SEAL LOCATION
(NOT ACCEPTABLE FOR CIP CLEANING. MUST BE DISASSEMBLED FOR CLEANING)



EASY TO CLEAN BY C.I.P.
(SEAL LOCATED AND COMPRESSED TO FIT FLUSH OR WITH SLIGHT BULGE)

Drafters note: when E1. 11.6. is used, include the definition of “Substantially Flush” in the definitions section.

E1.12 Radii

- E1.12.1 The radii where the head(s) and the side wall(s) of a tank or vessel join shall be a minimum of 3/4 in. (19.0 mm).
- E1.12.2 All angles of less than 135° shall have radii of at least **{Provide suitable numbers, 1/4 in. (6.35 mm) or 1/8 in. (3.18 mm)}**, except that:

Drafters Note: The preferred base criterion is for radii to be a minimum of 1/4 in. However, it is recognized that some designs cannot meet this criteria and may need the smaller 1/8 in. radii criteria. Select the appropriate base radii criteria for inclusion in the document. Do not include both criteria in the same document.

- E1.12.2.1 Smaller radii may be used for **{List all Application(s)}**. Such radii shall be at least 1/32 in. (0.794 mm).
- E1.12.2.2 The radii in grooves in gaskets or in retaining grooves for removable gaskets shall be a minimum of **{1/8 in. (3.18 mm) or 1/16 in. (1.59 mm)}**, except for retaining grooves for O-rings with a cross section dimension 1/4 in. (6.35 mm) or smaller, and those provided for in the 3-A Sanitary Standards referenced in Section B, Normative References.

Drafters Note: The preferred criterion is for these radii to be a minimum of 1/8 in. (3.18 mm). However, it is recognized that some designs cannot meet this criteria and may need the smaller radii criteria. Select the appropriate base radii criteria for inclusion in the document. Do not include both criteria in the same document.

E1.12.2.3 Radii in retaining grooves for standard circular cross section O-rings shall be as specified in the Table below (Refer to B4, Reference No. 11 and B4, Reference No. 12).

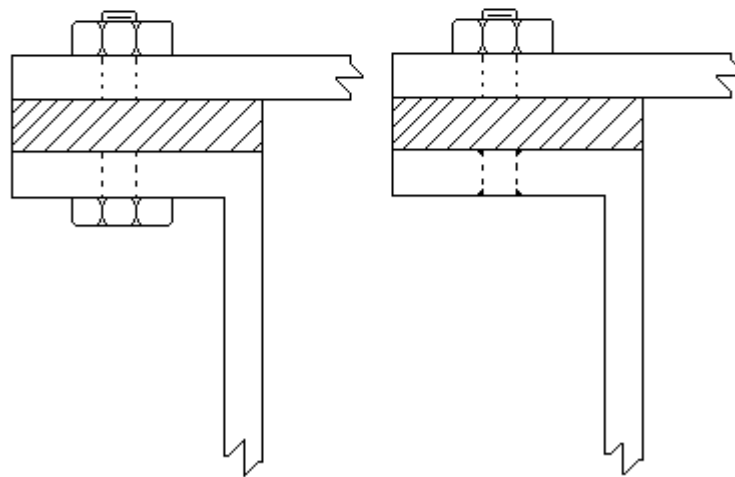
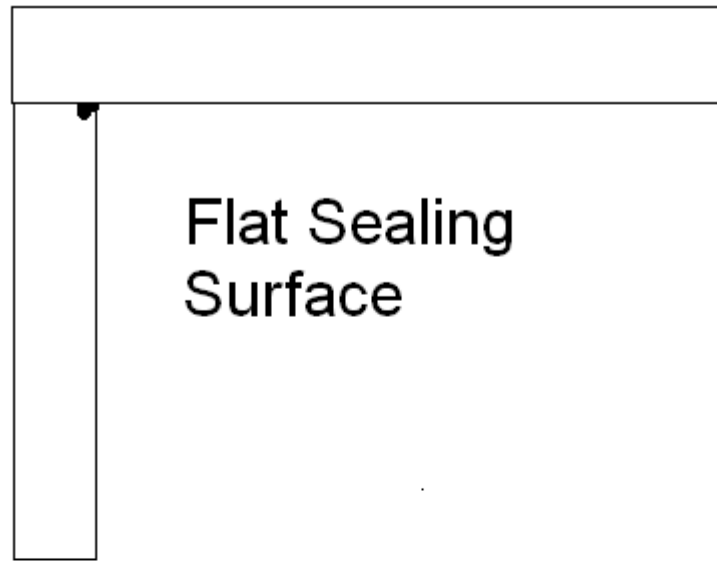
O-Ring Cross Section, Nominal (AS 568)	O-Ring Cross Section, Nominal (AS 568)	O-Ring Cross Section, Nominal (ISO 3601-1)	Minimum Groove Radius
1/16 in.	0.073 in.	1.85 mm	0.016 in. (0.406 mm)
3/32 in.	0.106 in.	2.69 mm	0.031 in. (0.787 mm)
1/8 in.	0.143 in.	3.63 mm	0.031 in. (0.787 mm)
3/16 in.	0.215 in.	5.46 mm	0.062 in. (1.575 mm)
1/4 in.	0.281 in.	7.14 mm	0.094 in. (2.39 mm)

E1.12.2.4 Radii in gasket retaining grooves and seats for seals with a nonstandard circular, square, rectangular, or other shaped cross section O-ring with the shorter dimension 1/4 in. (6.35 mm) and smaller shall be those radii closest to the standard circular cross section O-ring as specified in E1.12.2.3. To determine minimum radius in the retaining groove for a nonstandard O-ring, compare its cross-section dimension with those shown in column 2 of the Table above, determine which is closest, and use the applicable minimum groove radius. For a square O-ring, use the flat-to-flat side dimension for comparison. For a rectangular or other shaped O-ring, use the dimension that will fit into the retaining groove.

E1.12.2.5 There are no minimum radii requirements for soldered joints or for the product contact junctures of press- or shrink-fits.

Drafters Note: Use the above exception(s) only when the Standard specifically provides for soldered joints and/or press- or shrink-fits. (Refer to Section E1.2.1.1 or E1.2.1.3)

E1.12.2.6 There are no minimum radii requirements for the product contact junctures of flat sealing surfaces. (See following illustrations of examples.)



Drafters Note: No special fabrication provision is needed to allow use of flat sealing surfaces; therefore this exception is appropriate for any 3-A Sanitary Standard where flat-sealing surfaces might be utilized. Flat sealing surfaces shall be easily inspectable and readily removable for COP or manual cleaning.

E1.12.2.7 There are no minimum radii requirements for exposed sanitary threads except for the knuckle thread, DIN 405, provided for by Section E1.13.1.1.

Drafters Note: Use the above exception only when the 3-A Standard will provide for exposed threads under the special provisions of option 2 Section E1.13.1.

E1.12.2.8 Gasket retaining grooves for bonded gaskets are not subject to width, depth, or minimum radii requirements.

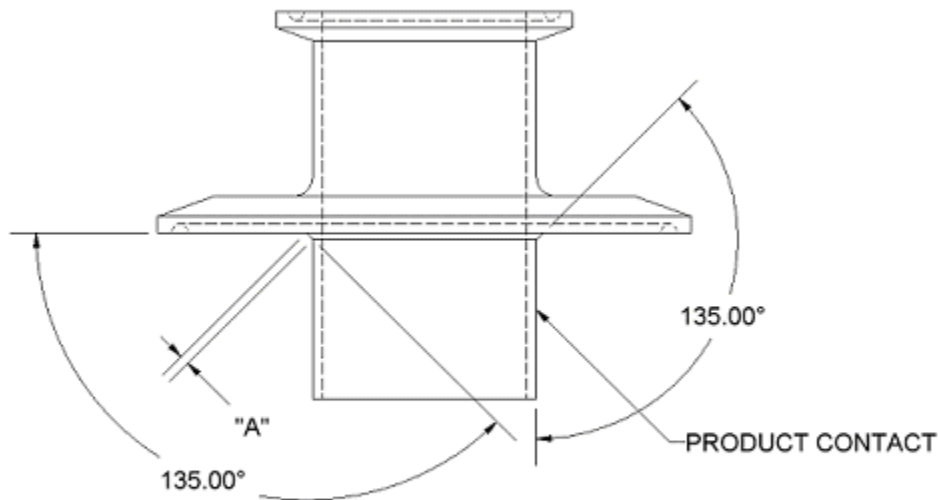
Drafters Note: When the above criterion is added to the standard, Sections C12, D1.2.4, and E1.3.1 must also be added.

E1.12.2.9 When the thickness, or in the case of round stock, the diameter of one or both parts joined is 3/16 in. (4.76 mm) or less, the minimum radii for fillets of welds shall be at least 1/8 in. (3.18 mm).

Drafters Note: This section should not be used unless E1.12.2 specifies the 1/4 in. base criterion.

E1.12.2.10 There are no minimum radius requirements for retaining grooves for mechanical force seals defined in C1.1, or for the juncture between product contact surfaces and the exposed part of an O-ring.

E1.12.3 In such case on a machined component when a radius in a 90° corner is replaced with a pair of 135° angles, the distance between the corners (the hypotenuse of the resulting isosceles right triangle) shall be no less than 1/32 in. (0.794 mm) inches for the dimension “A” in the **illustration** below.



MACHINED FROM ONE PIECE OF METAL

Drafters Note: The above option for replacing the radius with machined angles is not restricted to only fittings as in the illustration (provided the angle is inspectable), and should only be used when the required base radius of the standard cannot be properly inserted due to restrictions of available space, thickness of the material, interference with the proper fitting of a gasket, or on small or fractional size components.

E1.13 Threads

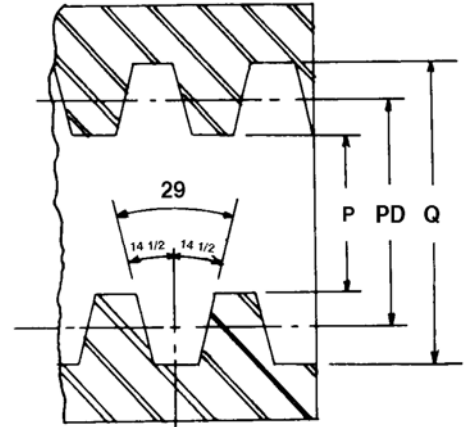
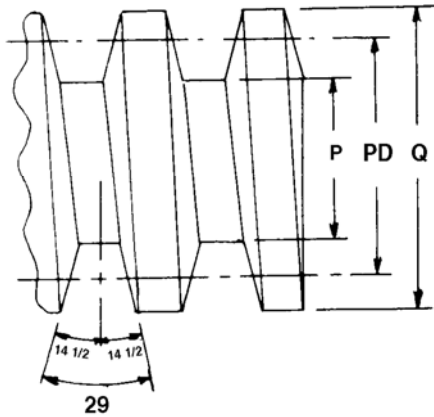
Option 1 E1.13.1 There shall be no exposed or enclosed threads on product contact surfaces.

Option 2 E1.13.1 Use of threads is not recommended and threads should not be used when other means of attachment is available. When no acceptable alternative is available and threads are required for essential functional reasons, the following criteria shall apply:

E1.13.1.1 Exposed Threads

E1.13.1.1.1 Where exposed threads are necessary for attaching **{List Applications}**, the threads shall be of sanitary design conforming to one of the following illustrations:

1. ACME Thread conforming to the following drawing:



EXTERNAL THREAD DIMENSIONS

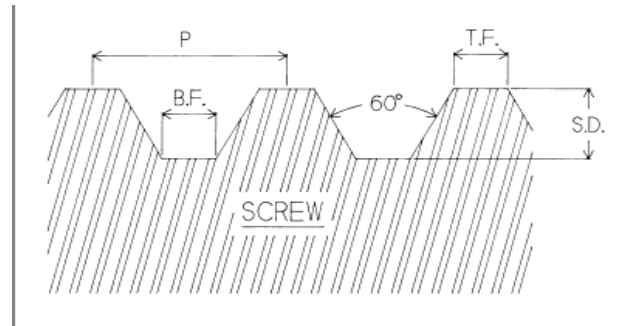
Size	Acme Threads per in.	P	Q	Pitch Dia.	Tolerance P,Q & P.D.
1	8	1.317	1.462	1.3995	+0.000 / -.018
1 1/2	8	1.849	1.994	1.9315	+0.000 / -.019
2	8	2.381	2.526	2.4635	+0.000 / -.020
2 1/2	8	2.913	3.058	2.9955	+0.000 / -.021
3	8	3.445	3.590	3.5275	+0.000 / -.022
4	6	4.509	4.695	4.6120	+0.000 / -.025

INTERNAL THREAD DIMENSIONS

Size	Acme Threads per in.	P	Q	Pitch Dia.	Tolerance P,Q & P.D.
1	8	1.352	1.497	1.4145	+0.018 / -.000
1 1/2	8	1.884	2.029	1.9465	+0.019 / -.000
2	8	2.416	2.561	2.4785	+0.020 / -.000
2 1/2	8	2.948	3.093	3.0105	+0.021 / -.000
3	8	3.480	3.625	3.5425	+0.022 / -.000
4	6	4.544	4.730	4.6270	+0.025 / -.000

2. The American Standard Stub Acme Thread conforming to the following drawing;

American Standard Stub Acme Thread

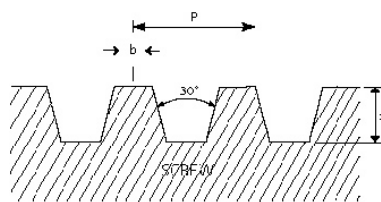


P = PITCH	$P = 1/T.P.I.$
S.D. = SINGLE DEPTH	$S.D = 0.433 \times P$
T.F. = TOP FLAT	$T.F. = 0.250 \times P$
B.F. = BOTTOM FLAT	$B.F. = 0.227 \times P$
T.P.I. = THREADS PER INCH	

The thread angles shall be not less than 60° and with not more than 8 threads to the inch (25.4 mm), nor less than 5/8 in. (15.9 mm) major basic diameter.

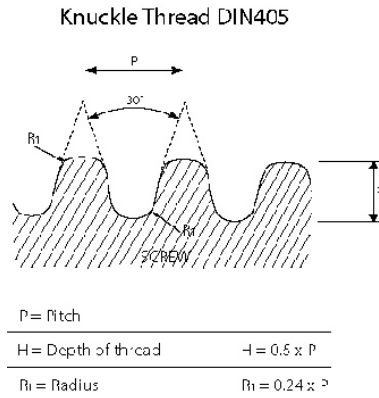
3.

Trapezoid Thread DIN103



P = Pitch	
H = Depth of thread	$H = 0.5 \times P$
b = Top / Bottom flat	$b = 0.37 \times P$

4.



- E1.13.1.1.2 The length of a nut, if used on any of the threads described in E1.13.1.1.1, shall not exceed 3/4 of the basic thread diameter. The nut shall be of the open type.
- E1.13.1.1.3 Equipment components with exposed threads as described above shall be designed for manual or COP cleaning.
- E1.13.1.2 **Enclosed Threads**
- E1.13.1.2.1 Where enclosed threads are necessary for attaching the **{List Applications}**, the enclosed threads shall conform to all of the following:
- E1.13.1.2.1.1 The enclosed thread assembly shall be designed for CIP cleaning.
- E1.13.1.2.1.2 The threads shall be sealed from the product by means of an O-ring, gasket or similar type seal.
- E1.13.1.2.1.2.1 The seal shall have a controlled compression by means of a positive stop.
- E1.13.1.2.1.2.2 The tightness of the seal shall be validated to demonstrate that there is no migration past the seal under the conditions of intended use. This shall be accomplished using the European Hygienic Equipment Design Group (EHEDG) test for bacterial tightness titled "Test # 7: A method for the assessment of bacteria tightness of food processing equipment" or other equally effective test(s).
- E1.13.1.2.1.2.3 The manufacturer shall provide seal replacement procedures and frequencies that will ensure bacterial tightness. (See Appendix P.)
- E1.13.1.2.1.3 Enclosed threads shall be cleanable and drainable.
- E1.13.1.2.1.4 The manufacturer shall provide validated cleaning procedures should the area behind the seal become soiled. (See Appendix P.)

E1.14 Perforated Surfaces

E1.14.1 Perforations in surfaces for **{List Applications}** may be round, square, rectangular or crescent-shaped.

E1.14.1.1 If round, the holes shall be at least 1/32 in. (0.794 mm) in diameter.

E1.14.1.2 If square or rectangular, the least dimension shall be at least 0.02 in. (0.51 mm) with corner radii of no less than 0.005 in. (0.13 mm).

E1.14.1.3 If crescent-shaped, the opening shall be at least 0.004 in. (0.102 mm) wide at the widest part and the perforations shall be at least 0.02 in. (0.508 mm) long. Internal angles of the perforations shall be well defined and free of crevices. One side of the perforated component may have machine mark indentations around the perforations. The other side may have projections around the perforations, together with shallow open grooves between the rows of perforations.

E1.14.2 All perforations shall be free of burrs.

E1.14.3 Surfaces with perforations smaller than 1/32 in. (0.794 mm) shall be readily accessible and be designed for CIP cleaning.

E1.15 Coil Springs

E1.15.1 Coil springs shall be made of round cross-section stock.

E1.15.2 Coil ends of springs intended for CIP shall not be modified to produce a flat mounting surface.

E1.15.3 When used, modified coil ends terminating with ears or tabs, shall not be modified to produce square or rectangular shaped ears or tabs.

E1.15.4 Coil springs under compression conditions of intended use shall not eliminate all spacing between the coils. There shall be a minimum of 1/32 in. space between each coil when under compression or the spring shall be designed for COP or manual cleaning.

E1.15.5 Coil springs shall have at least 3/32 in. (2.38 mm) spacing between coils, including end coils, when the spring is in the relaxed condition, except that:

E1.15.5.1 Springs less than 1 in. (25.4 mm) outside diameter may have openings between coils of less than 3/32 in. (2.38 mm) when the spring is in the relaxed condition and, when under compression, some spacing between the coils shall remain open. Such springs shall be **intended** for COP or manual cleaning.

- E1.15.6 A spring may have point contact at the end coils and at intermediate coils with retainer rings, inclusive of axial contact with rotating shafts, as required for torque transmission.
- E1.15.7 All applications and assemblies using coil springs shall be designed, fabricated, and installed to make product contact surfaces available for close visual observation when either in an installed position or when removed.

Drafters Note: If special requirements for spring design are necessary for proper force application or alignment, show criteria and/or a drawing in this location. Add wording requiring cleanability documentation for any spring design different from the shown preferred design.

E1.16 **High-Temperature Systems**

- E1.16.1 Equipment designed for use in a processing system to be sterilized by heat at a temperature of 250°F (121°C) or higher shall conform to the following:
- E1.16.2 The design and fabrication shall be such that all surfaces 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.
- E1.16.3 The steam or other sterilizing medium chamber(s) shall be constructed so the interior surfaces are inspectable.
- E1.16.4 Seal(s) of sanitary design shall be provided between the product contact surface(s) and the steam or other sterilizing medium chamber.

E1.17 **Shafts**

- E1.17.1 Shafts that pass through a product contact surface above the product level shall be designed to provide means to prevent the entrance of contaminants through the portion of the opening surrounding the shaft.
- E1.17.2 Shafts that pass through a product contact surface below the product level or designed to be located outside a processing area shall have a packless-type seal of sanitary design that is readily accessible and inspectable.

E1.18 **Bearings**

- E1.18.1 Bearings having a product contact surface shall be of a non-lubricated or product-lubricated type.

E1.18.2 Lubricated bearings, including permanently sealed types, when used, shall be located outside the product contact surface with at least 1 in. (25.4 mm) clearance between the bearing and the nearest product contact surface and such clearance shall be open for inspection.

E1.19 **Openings and Covers (Other Than Personnel Access Ports)**

Drafters Note: For Personnel Access Ports add a Normative Reference and referral to 3-A Sanitary Standard Number 84-.

E1.19.1 Openings through a product contact surface shall have permanently attached sanitary connections or shall be flanged outward at least 3/8 in. (9.52 mm).

E1.19.2 All non-permanently attached sanitary pipelines, agitators, and other appurtenances entering vertically through a product contact surface shall be fitted with a sanitary umbrella deflector that overlaps the edges of the outward flanged opening to prevent the entrance of contaminants.

E1.19.3 Other openings shall have removable covers, which shall be pitched to the outside, and be downwardly flanged to make close contact with the edges of the outwardly flanged openings in the product contact surface.

E1.20 **Agitators**

Drafters Note: This section should not be included unless there is a very specific reason necessary to clarify the application of the 3-A Sanitary Standards listed in Section B, Normative References.

E2 **Nonproduct Contact Surfaces**

E2.1 **Surfaces**

E2.1.1 Exposed surfaces shall have relatively smooth finishes, and be relatively free of pockets and crevices.

E2.1.2 Knurled surfaces shall not be used.

E2.1.3 Internal surfaces of motors are not considered exposed surfaces. Motors shall be located in a manner to prevent cooling fan airflow from blowing directly onto exposed products or product contact surfaces.

E2.2 **Joints**

E2.2.1 Permanent joints subject to product residue shall be continuously welded. Welded junctures do not require grinding or polishing. **{and if other nonproduct contact**

surface areas are required to be ground and polished, such as the breast to the shell of a vessel, list the exception here} except that:

E2.2.1.1 Where welding is not possible for functional or safety reasons, bolted joints may be used. When braces or frames are hollow, the integrity of the braces or frames shall not be compromised by drilling into the hollow interiors. If bolting is required, welded studs to the exterior or fully welded sleeves shall be employed.

E2.2.1.2 Recessed socket head bolts shall not be used, except that:

E2.2.1.2.1 Recessed socket head bolts may be used provided they are away from any product (or splash) contact surfaces, are shielded from any product residues and mounted so that the socket heads drain. Recessed socket head bolts may be used on rotating horizontal shafts.

E2.2.1.3 Rivets shall not be used, except on the nameplates of gear reducers, pneumatic cylinders, hydraulic cylinders, motors, electrical enclosures, and instrument transmitter housings.

E2.2.1.4 When external lap joints for sheathing over insulated areas are used, they shall be overlapped downward and overlapped joints shall be sealed between the mating surfaces with suitable sealants.

E2.3 Coatings

E2.3.1 If the framework and exterior panels of the equipment are not made of corrosion resistant metal they shall be painted or coated. When coatings are used, they shall be free from delamination, pitting, flaking, spalling, blistering, or distortion when exposed to the conditions encountered in the environment of intended use, including cleaning and sanitizing.

E2.4 Cleaning and Inspectability

E2.4.1 Surfaces shall be designed and fabricated to facilitate cleaning and inspectability, and shall be relatively free of areas where liquids or product residues can accumulate and not be cleaned out.

E2.5 Draining

E2.5.1 Surfaces shall be designed to minimize the pooling of liquids and to insure that liquids cannot drain into the product or onto product contact surfaces.

E2.6 Threads

E2.6.1 Exposed threads shall be minimized. The exposed threads shall not exceed one half (½) the nominal diameter of the thread, except that:

E2.6.1.1 Threads that are subject to routine product splash during processing and cleaning shall be covered by an enclosed nut.

E2.7 **Service Piping and Lines**

E2.7.1 Cables or hoses with exposed braided coverings shall not be used.

E2.7.2 Electrical and utility connections shall be as remote as practical from the product contact areas of the equipment.

E2.7.3 Exhaust air from pneumatic equipment shall be piped away from product contact surfaces.

E2.7.4 Components using machinery fluids (e.g. lubricating and hydraulic fluids, and signal transfer fluids) shall be installed to prevent fluid ingress into the product or onto product contact surfaces.

E2.7.5 Hose clamps of the worm gear type shall not be used.

E2.8 **Panels, Doors, or Access Ports**

E2.8.1 Panels, doors, or access ports shall be provided to allow access to the interior of the equipment.

E2.8.2 Panels, doors, or access ports shall be constructed in a manner that will prevent the entrance of contaminants.

E2.8.3 Panels and doors having both a product contact surface and a nonproduct contact surface shall meet the fabrication criteria of a product contact surface.

E2.8.4 The use of hinges, wing nuts, latches, and similar easy-opening fastening devices are recommended to allow easy access without special tools.

E2.8.5 Any hinges, wing nuts, latches, and similar easy-opening fastening devices used shall be attached so as to minimize the use of fasteners and the creation of cracks and crevices.

E2.8.6 Hinges shall be of a sanitary design that can be readily disassembled. Continuous or piano-type hinges shall not be used on the equipment or its control cabinets unless such hinges are located at least 18 in. (457 mm) from any product or splash contact surface.

E2.9 Guards and Other Safety Devices

E2.9.1 Guards required by personnel safety standards shall be removable for cleaning and inspection of the equipment. Guards shall be designed to minimize the accumulation of debris and liquids.

E2.9.2 **{Additional Devices May Be Listed.}**

E2.10 Supports

Drafters Note: Select the following section(s) that apply.

E2.10.1 Supports made of hollow stock shall be sealed.

E2.10.2 Leg ends or feet shall be smooth with rounded ends or, if flat, suitable for sealing to the floor.

E2.10.3 Casters, if provided, shall be of sufficient size to provide a clearance of at least 4 in. (102 mm) between the lowest part of the base of the equipment and the floor. Casters shall be easily cleanable, durable under conditions of intended use, including cleaning and sanitizing and of a size that will permit easy movement of the equipment.

Drafters Note: Greater clearance may be required for large equipment.

E2.10.4 If mounted on a slab or island, the base shall be designed for sealing to the slab or island surface. The slab or island shall be of sufficient height so that the bottoms of all product connections are at least 4 in. (102 mm) above the floor. The mounting surface of the slab or island shall be coated with a suitable layer of waterproof mastic material, which will harden without cracking. The junction of the equipment base and the slab or island shall be sealed.

E2.10.5 If mounted directly on a wall or column, the area of attachment of the equipment to its mounting surface shall be designed for sealing to the wall or column. If the design of the equipment is to be mounted offset from a wall or column it shall provide at least a 4 in. (102 mm) clearance between the outside of the equipment and the wall or column.

Drafters Note: Other suitable methods of support or mounting equipment may be necessary and should be considered.

E2.10.6 Supporting structures, braces, catwalks, stairs, and handrails are not considered as nonproduct contact surfaces of the equipment but are considered as part of the building structure.

E2.11 Name and Information Plates

E2.11.1 Name and information plates, when used, shall be continuously welded or effectively sealed to the equipment, **except on components listed in Section E2.2.1.3 where rivets are allowed.**

E2.11.2 Non-metallic, adhesive-backed name and information plates are also acceptable.

E2.11.3 An information plate, when necessary to convey special information, shall be attached in juxtaposition to the nameplate. Alternatively, the information may appear on the nameplate:

Drafters Note: As appropriate, one or more information plate statements may be required. The information plate statements may be dictated by the requirements in individual standards. Some examples appear below.

1. Maximum temperature and pressure at which the equipment can be operated.
2. A statement that, to prevent corrosion or damage, the recommendations of the manufacturer shall be followed with respect to time, temperature, and the concentration of specific cleaning solutions and chemical bactericide.

Drafters Note: This is of special importance when optional metals are used that are susceptible to acid cleaners.

3. "This equipment * designed for steam sterilization."
* Insert one of the following:
 - (a) "is"
 - (b) "is not"
4. "The insulation of this vessel conforms to the requirements for a storage tank to be installed * a building."
* Insert one of the following:
 - (a) "wholly within"
 - (b) "partially outside of"
5. "The agitator of this storage tank is designed so that the portion of agitator shaft outside of the storage tank * in a processing area."
* Insert one of the following:
 - (a) "does not have to be"
 - (b) "must be"

6. This vessel is designed for **{Everyday or Every Other Day}** pick-up. Maximum rate at which milk can enter this tank and meet the cooling requirements of the 3-A Sanitary Standard for Cooling and Holding Tanks, Number 13- is **{Number}** U.S. gal/hr (**{Number}** L/hr). When milk enters the tank at the maximum rate, the minimum condensing unit capacity is **{Number}** BTU/hr at **{Number}** °F (**{Number}** kJ/hr at **{Number}** °C) suction temperature. **{The Btu (kJ) Capacity Specified is to be at the Saturated Suction Temperature Designated by the Manufacturer.}**
7. This equipment requires manual cleaning in accordance with the manufacturer's recommendations.
8. This equipment * designed for CIP cleaning. Clean in accordance with the manufacturer's recommendation.
 - * Insert one of the following:
 - (a) "is"
 - (b) "is not"

E2.12 **{Additional Nonproduct Contact Surface Fabrication Criteria may be Added as Needed.}**

F SPECIAL CONSIDERATIONS

Drafters Note: As appropriate for the document being prepared, include criteria for a special nature.

G INSTALLATION

Drafters Note: As appropriate for the document being prepared, include criteria for installation. This section is most commonly used for 3-A Accepted Practices but may also be included in 3-A Sanitary Standards.

APPENDIX

H STAINLESS STEEL AND EQUIVALENT MATERIALS

H1 Stainless steel conforming to the applicable composition ranges established by AIST for wrought products, or by ACI for cast products, should be considered in conformance to the requirements of Section D1.1 herein. The first reference cited in D1.1.1 sets forth the chemical ranges and limits of acceptable stainless steel of the 300 Series. Cast grades of stainless steel corresponding to types 303, 304, and 316 are designated CF-16F, CF-8, and CF-8M, respectively. The chemical compositions of these cast grades are covered by ASTM specifications A351/A351M, A743/A743M and A744/A744M (Refer to B4, Reference Number 8).

Fabrication of stainless steel equipment and components, including cutting, grinding, and finishing, should be performed with materials and tools properly segregated for such purposes and not previously used on other metals. This is to prevent cross-contamination of the stainless steel with other metal contaminants.

H2 **TABLE 1** (Refer to B4, Reference No. 8 and B4, Reference No. 9.)

WROUGHT PRODUCTS TYPICALLY USED				
UNS # Grade Designation	ASTM Material Standard Pub. No.	AIST/SAE Grade Designation	Properties	ASTM Grade Designation
S30300	A582	303	Free-Machining S.S.; Austenitic	303
S30400	A276 A666	304	Austenitic S.S.	304
S30403	A276 A666	304L	Low Carbon Austenitic S.S.	304L
S31600	A276 A666	316	Austenitic S.S. plus Mo*	316
S31603	A276 A666	316L	Low Carbon Austenitic S.S. plus Mo*	316L

*Molybdenum

TABLE 2

CAST PRODUCTS			
UNS # Grade Designation	ASTM Material Standard Pub. No.	ACI Grade Designation	Common Names
J92500	A351 A743 A744	CF-3	Cast 304L
J92800	A351 A743 A744	CF-3M	Cast 316L
J92600	A351 A743 A744	CF-8	Cast 304
J92900	A351 A743 A744	CF-8M	Cast 316
J92180	A747	Nb7 Cu – 1	Cast 17-4 PH
J92110	A747	Nb7 Cu –2	Cast 15-5 PH
N26055	A494	CY5Sn BiM	Alloy 88
J92701	A743	CF-16F	Free Machining Austenitic S.S.

TABLE 3 - OPTIONAL METAL ALLOYS

Optional metal alloys having the following compositions are examples considered in compliance with Section D1.1.1 herein. (Percentages are maximums unless range is given.)

Com. Name	UNS N08367	UNS S21800	UNS S20161	UNS N26055	UNS N26455	UNS S17400	UNS S15500	UNS S32900	UNS R20500	UNS R50400
	ASTM A743	ASTM A743		ASTM A494	ASTM A494	ASTM A747	ASTM A747		ASTM A560	ASTM B67
	Mat'l Std	Mat'l Std		Mat'l Std	Mat'l Std	Mat'l Std	Mat'l Std		Mat'l Std	Mat'l Std
	CN-3MN	CF-10 SMnN		CY5SnBi M	CW-2M	Nb7Cu-1	Nb7Cu-2		50Cr-50Ni	C-2
	AL-6XN®	Nitronic-60	Gall-Tough	Alloy 88	Hastelloy-C®	17-4 PH	15-5 PH	329 Duplex	50/50	Titanium
C	0.03	0.10	0.15	0.05	0.02	0.07	0.07	0.08	0.10	0.10
Mn	2.00	7.00-9.00	4.00-6.00	1.50	1.00	0.70	0.70	1.00	0.30	
Si	1.00	3.50-4.50	3.00-4.00	0.50	0.80	1.00	1.00	0.75	1.00	
P	0.04	0.04	0.04	0.03	0.03	0.035	0.035	0.04	0.02	
S	0.01	0.03	0.04	0.03	0.03	0.03	0.03	0.03	0.02	
Cr	20.0-22.0	16.0-18.0	15.0-18.0	11.0-14.0	15.0-17.5	15.5-17.5	14.0-15.50	23.0-28.0	48.0-52.0	
Ni	23.5-25.5	8.00-9.00	4.00-6.00	Balance	Balance	3.60-4.60	3.50-5.50	2.50-5.00	Balance	
Mo	6.0-7.0			2.0-3.5	15.0-17.5			1.00-2.00		
Nb						0.15-0.35	0.15-0.35			
Cu	0.75					2.50-3.20	2.50-3.20			
N	0.18-0.26	0.08-0.18	0.08-0.20			0.05	0.05		0.30	0.03
Fe	Balance	Balance	Balance	2.00	2.00	Balance	Balance	Balance	1.00	0.30
Sn				3.0-5.0						
Bi				3.0-5.0						
W					1.0					
Ti									0.50	Balance
Al									0.25	
Other										H = 0.015 O = 0.25

H3 Metal alloys or metals other than the above may be as corrosion resistant as 300 Series Stainless Steel. This may be shown when metal alloys or metals are tested in accordance with ASTM G31 *Laboratory Immersion Corrosion Testing of Metals* and have a corrosion rate of less than 10.0 mil per year. The test parameters, including the type of chemical(s), their concentration(s), and temperature(s), should be representative of cleaning and sanitizing conditions used in the equipment. Alloys containing lead, leachable copper, or other toxic metals are not to be used.

H4 The minimum criteria for metals in section D1.1 are based on experience with the processing of milk and conventional dairy products. More corrosion-resistant metals may be appropriate when the equipment is used to process modified dairy products or

other non-dairy food products, especially those containing salts or having high acidity/low pH or both, and processed at high temperatures. The corrosive effect of galvanic currents should also be considered when choosing suitable materials, particularly when different metals are used in the same system.

Drafters Note: Include the above optional section H4 when appropriate for the equipment or item covered. Show equipment or item in blank space in third line. **Include the above optional section H4 when appropriate for the equipment or item covered. Show equipment or item in blank space in third line.**

I **PRODUCT CONTACT SURFACE FINISH**

I1 Surface finish, obtained by mechanical polishing with 150 grit or better silicon carbide (aluminum oxide or other standard approved abrasives) properly applied on stainless steel sheets, is considered in conformance to the requirements of Section E1.1.1 herein. Representative areas of the finished surfaces should be tested to verify that the final finish is at least as smooth as R_a 32 $\mu\text{in.}$ (0.8 $\mu\text{m.}$)

I2 Surface finish on sheets (less than 3/16 in. (4.76 mm) thickness) of 2B (cold rolled) stainless steel, inspected and selected to be free of pits, folds and crevices are generally found to be as smooth as, or smoother than, stainless steel sheets with an $R_a \leq 32 \mu\text{in.}$ ($\leq 0.8 \mu\text{m.}$) finish and are acceptable, if free of imperfections, for the fabrication of equipment.

J **ELECTROLESS NICKEL ALLOY**

An electroless nickel alloy coating having the following composition is deemed to be in compliance with D1.1.2 herein:

Nickel - 90% minimum,
Phosphorous - 6% minimum and 10% maximum as a supersaturated solution of nickel phosphide in nickel,
Trace amounts of carbon, oxygen, hydrogen, and nitrogen,
No other elements allowed.

K **AIR VENTING**

K1 To insure adequate venting of the {**Name Of Equipment**} which will protect it from internal pressure or vacuum damage during normal operation, the critical relationship between minimum vent size and maximum filling or emptying rates should be observed. The size of the free vent opening of a tank should be at least as large as those shown in the table below:

Minimum Free Vent Opening Size (Inches, I.D./mm, I.D)	Maximum Filling/Emptying Rate (Gallons per minute/liters per minute)
[SUPPLY APPROPRIATE NUMBERS TO COMPLETE TABLE]	
For example	
3'' vent w/2'' CIP line	400 gpm (1514 lpm)
4'' vent w/2'' CIP line	700 gpm (2650 lpm)
6'' vent w/2'' CIP line	1600 gpm (6057 lpm)

K2 The above sizes are based on normal operation and are sized to accommodate air only and not liquid. A perforated vent cover, if used, should have a free opening area equal to at least one and one-half (1 ½) times the area of the vent opening in the tank. The venting system covered in the preceding paragraphs is intended to provide venting during filling and emptying; it is not adequate during CIP cleaning. During the cleaning cycle the {Name of Equipment}, when CIP cleaned, should be vented adequately by opening the personnel access door to prevent vacuum or pressure buildup due to sudden changes in temperature of very large volumes of air. For example, when a 6,000 gal (22712 l) tank (with 800 cu ft (22.65 cu m) of 135°F (57°C) hot air after cleaning) is suddenly flash cooled by 50°F (10°C) water sprayed at 100 gpm, the following takes place: Within one second, the 800 cu ft (22.65 cu m) of hot air shrinks approximately 51 cu ft (1.44 cu m) in volume. This is the equivalent in occupied space of approximately 382 gal (1446 l) of product. The shrinkage creates a vacuum sufficient to collapse the tank unless the vent, access port, or other openings allow the air to enter the tank at approximately the same rate as it shrinks. It is obvious, therefore, that a very large air vent such as the personnel access opening is required to accommodate this air flow.

K3 Appurtenances of sanitary design should be provided to prevent excess loss of cleaning solution through the access opening. The use of tepid water of about 95°F (35°C) for both pre-rinsing and post-rinsing is recommended to reduce the effect of flash heating and cooling. Provisions should be made to prevent overfilling with resultant vacuum or pressure damage to the equipment.

L **CIP CLEANING**

The CIP system should be designed so that solution is applied to all product contact surfaces except those areas requiring manual cleaning. When being cleaned, the equipment should have a fast flushing action across the bottom. The slope should be a minimum of 1/4 in. per ft (20.0 mm per m). Cleaning and/or sanitizing solutions

should be made up in a separate tank, not in the equipment. **{This or Other Appropriate Verbiage for CIP Cleaning.}**

M SUGGESTED CLEANING PROCEDURES

Drafters Note: When necessary write appropriate procedures for the equipment specified in the scope. This may include dry cleaning, additional mechanical cleaning, or manual cleaning procedures.

N DIAGRAMS

These diagrams are intended to demonstrate general principles only, and are not intended to limit individual ingenuity. The design used should conform to the sanitary requirements set forth in this **{3-A Sanitary Standard or 3-A Accepted Practice; Choose One}**. The following examples are included in this Appendix:

Drafters Note: Usually a list of diagram titles, numbers, and pages follows.

O ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE

The following is an example of an Engineering Design and Technical Construction File (EDTCF) to be maintained by the fabricator as evidence of conforming to 3-A Sanitary Standards or 3-A Accepted Practices. (The file may contain more or less information as applicable to the equipment or system.)

The maintenance of this file is required for an application for Authorization to Display the 3-A Symbol and will be evaluated during the required Third Party Verification (TPV) evaluation of the equipment.

O1 Purpose

O1.1 To establish and document the material, fabrication, and installation (where appropriate) requirements for the engineering design and technical construction files for all products, assemblies, and sub-assemblies supplied by the manufacturer thereof to be in conformance to the sanitary criteria found in 3-A Sanitary Standards or 3-A Accepted Practices.

O2 Scope

O2.1 This EDTCF applies to equipment specified by:

O2.1.1 3-A Sanitary Standards for **{Full Title}**, Number **{Document Number XX-XX}**.

O2.1.2 3-A Accepted Practices for **{Full Title}**, Number **{Document Number XXX-XX}**.

O2.1.3 List all applicable 3-A Sanitary Standards and 3-A Accepted Practices.

O3 Responsibilities

- O3.1 The EDTCF is maintained by {**Name and Title of Responsible Official**} who is responsible for maintaining, publishing, and distributing the EDTCF.
- O3.2 Implementation: All divisions, specifically development engineering, standards engineering, sales engineering, and product departments are responsible for implementing the EDTCF.

O4 Applicability

- O4.1 The 3-A Sanitary Standards and 3-A Accepted Practices are voluntarily applied as suitable sanitary criteria for dairy and food processing equipment. 3-A Sanitary Standards are referenced in the Grade A PMO, which provides that equipment manufactured in conformity to 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance. The 3-A Sanitary Standards and Accepted Practices are also referenced in 7 CFR 58 Subpart B-- General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service. This subpart requires all new, replacement or modified equipment and all processing systems, cleaning systems, utensils, or replacement parts to comply with the most current, appropriate 3-A Sanitary Standards or 3-A Accepted Practices.

O5 References

- O5.1 List any additional regulations that apply to the equipment or system covered by this EDTCF.
- O5.2 The date of conformity or 3-A Symbol Authorization and certificate number, if authorized.

O6 EDTCF

- O6.1 The Engineering Design and Technical Construction File contents:

- O6.1.1 The Engineering Design and Technical Construction File shall contain the following items:
- a. Table of Contents (listing all documents within the EDTCF or the locations where the items may be found);
 - b. A copy of the 3-A Sanitary Standard to be applied to the Subject Equipment;
 - c. An Overall Drawing or General Arrangement Drawing of the Subject Equipment;
 - d. Full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment to the 3-A Sanitary Standard or 3-A Accepted Practice;
 - e. If essential, any technical report or certificate obtained from a competent testing body or laboratory;

- f. Instructions for Cleaning of the Subject Equipment or Item referenced by the standard (including a listing, as may be applicable, for all manually cleaned components or appurtenances and the procedures for cleaning of these items. (Example: Silo Tank Door Gasket)
 - g. Material Certifications for all materials of construction included in the equipment.
 - h. For serial manufacturing, the internal measures that will be implemented to insure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Sanitary Standards or 3-A Accepted Practices;
 - i. Change records;
 - j. Copy of the 3-A Symbol authorization, if applicable.
- O6.1.2 The Engineering Design and Technical Construction File may optionally contain the following:
- a. A list of the essential requirements of the standards or practices;
 - b. Other technical specifications, which were used when the equipment was designed;
 - c. A copy of the instructions for the product (Instruction Manuals/Instruction Books);
 - d. A description of methods adopted;
 - e. Any technical report giving the results of tests carried out internally by Engineering or others;
 - f. Documentation and test reports on any research or tests on components, assemblies and/or the complete product to determine and demonstrate that by its design and construction the product is capable of being installed, put into service, and operated in a sanitary manner;
 - g. A determination of the foreseeable lifetime of the product;
 - h. Engineering reports;
 - i. Laboratory reports;
 - j. Bills of material;
 - k. Wiring diagrams, if applicable;
 - l. Purchase order engineering files;
 - m. Hazard evaluation committee reports, if executed;
 - n. Customer specifications;
 - o. Any notified body technical reports and certification tests.
- O6.2 The EDTCF file does not have to include detailed plans or any other specific information regarding the sub-assemblies, tooling, or fixtures used for the manufacture of the product unless knowledge of them is essential for the verification of conformity to the basic sanitary requirements found in 3-A documents.
- O6.3 The documentation referred to in O6.1, above, need not permanently exist in a material manner in the EDTCF, but it must be possible to assemble them and make them available within a period of time commensurate with their importance (one week is considered reasonable time). As a minimum, each product EDTCF must contain an index of the applicable document of O6.1, above.

O6.4 The EDTCF may be in hard copy or software form.

O7 **Confidentiality**

O7.1 The EDTCF is the property of the manufacturer and is shown at their discretion, except that all or part of this file will be available to 3-A SSI or a regulatory agency for cause and upon request.

O8 **File Location**

O8.1 The EDTCF is maintained at **{Location}**.

O9 **File Retention**

O9.1 The EDTCF (including all documentation referred to in O6.1) shall be retained and kept available for 12 years following the date of placing the equipment in use or from the last unit produced in the case of series manufacture.

P **INSTRUCTION HANDBOOK, MAINTENANCE, AND CLEANING**

P1 **Instruction Handbook**

The instruction handbook includes the following items:

P1.1 **Installation of the Equipment and Associated Equipment**

Information is provided so that, after the equipment is installed, it maintains its hygienic integrity (e.g., drainability and inspectability).

P1.2 **Instructions for Use**

Measures are described on the use of the equipment so that when used correctly the product is not exposed to factors that can lead to contamination.

P2 Maintenance and Cleaning

P2.1 Maintenance

A system of measures is recommended to ensure that the hygienic integrity of the equipment is maintained during its intended lifetime. This information should include specific gasket, seal or O-ring materials where they are used because of product characteristics (e.g., high fat or high acid) or operational characteristics (e.g., vacuum or steam applications or when used to create a bacterial tight seal between product contact surfaces and non-sanitary threads).

P2.2 Cleaning

The instructions specify typical routine procedures for cleaning, sanitizing, rinsing, and inspection for cleanliness and, where appropriate, sterilization. Recommended cleaning and sanitizing procedures, materials, implements, and agents should be specified. Recommended cleaning and sanitizing procedures, materials, implements, and agents shall be compatible with the materials of construction. Where dismantling is required, specific instructions shall be provided.