Guidance Document for the Development of 3-A Sanitary Standards and Accepted Practices With Examples of Text for Criteria

<u>Drafter's Note</u>: 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.

TABLE OF CONTENTS

Section I, How to Use Th	his Manual	3
Section II, Preparation of	f a 3-A Document1	7

Section I

How to Use This Manual

<u>Drafter's Note</u>: 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

Each type or class of equipment shall be covered by a single 3-A Sanitary Standard ("B Level" Standard). The format of all standards shall include a Normative Reference Section to identify all other 3-A Sanitary Standards, Accepted Practices and associated documents that are considered as an integral part of the Standard. Each specific "B Level" 3-A Sanitary Standard shall reference 3-A Sanitary Standard for General Requirements, 00-.

3-A Sanitary Standard for General Requirements, 00- provides general criteria applicable to all equipment. The specific "B Level" 3-A Sanitary Standard for a type or class of equipment shall include only those additional criteria that are equipment specific; and any clarification of, modification of, exceptions to, or exclusion of criteria in the base "A Level" *3-A Sanitary Standard for General Requirements, 00-*. The equipment specific criteria may include, but is not limited to, definitions, materials, fabrication, installation, and cleaning validation, as appropriate.

This guidance document provides a framework for the development of equipment-specific "B Level" 3-A Sanitary Standards or 3-A Accepted Practices and describes the sanitary concepts found in a 3-A Sanitary Standard or Accepted Practice. 3-A Sanitary Standards or 3-A Accepted Practices do not cover machine safety, cost, efficiency, or any other non-sanitary 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 criteria found herein are to be used as a guide for preparing revisions or amendments to existing 3-A documents and writing new "B Level" 3-A Sanitary Standards or 3-A Accepted Practices, which use the "A Level" *3-A Sanitary Standard for General Requirements, 00-* as a normative reference. 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 (WGs) 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.

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: <u>www.3-a.org</u>.

The following is the required sequence for the text of "B Level" 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 Standard for {**Name of Equipment**}" or "3-A Accepted Practice for {**Name of System**}," followed by 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. The serial number -00 is used for a first edition. 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 "B-" (indicating a "B Level" document) preceding the document number, followed by a letter designation to indicate the proposed revision; for example, B-03-05-A or B-600-01-C. These tentative documents will list two date lines: (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 publication. Tentative documents shall be so noted on each page. During development and approval phases, "B Level" draft documents are prepared in a single column per page format. The next few lines identifying 3-A SSI, USPHS/USFDA, USDA, and EHEDG, when 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. When 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 guidance document, 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 guidance document 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. When 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. <u>Only those documents that have specific application to the document being prepared are to be included</u>. 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.
- 2.6.2 All equipment-specific 3-A Sanitary Standards and Accepted Practices covered by this guidance document shall include as a normative reference the 3-A Sanitary Standard for General Requirements, 00-.
- 2.6.2.1 When it is necessary to modify any criteria from *3-A Sanitary Standard for General Requirements,* 00-, it shall be presented in the following manner:
- 2.6.2.1.1 The original wording from the 3-A Sanitary Standard for General Requirements, 00- shall be shown in its entirety in strike out red type and the proposed modifications shall be shown in underlined blue type.
- 2.6.2.1.2 This color coding shall be maintained throughout the Working Group deliberations and voting processes to clarify the intent of the modification to the stakeholder groups.
- 2.6.2.1.3 Upon successful ballot by the 3-A SSI Working Group and Steering Committee, only the agreed upon (modification) wording shall be published.

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 Specific Equipment Standard. Terms necessary to describe specific equipment or systems should be included when the terms are not defined in the 3-A Sanitary Standard for General Requirements, 00-. 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, when 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 All materials (metals, plastics, rubbers, etc.), which are unique to the Specific Equipment Standard, not referenced in the *3-A Sanitary Standard for General Requirements*, *00-*, shall be listed in this section. The specific application(s) of the material(s) shall be identified.

- 2.8.3 All exclusions of materials listed in the *3-A Sanitary Standard for General Requirements, 00-*, should also be identified.
- 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).

2.9 Fabrication of Product and Solution Contact Surfaces (Section E)--Required

- 2.9.1 All equipment is to be designed to be 100% cleanable and to preclude the contamination of the product. 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.
- 2.9.2 All fabrication criteria which are unique to the Specific Equipment Standard, not referenced in the *3-A Sanitary Standard for General Requirements, 00-*, shall be listed in this section. The specific application(s) of the fabrication criteria shall be identified.
- 2.9.3 When fabrication criteria, permitted by the *3-A Sanitary Standard for General Requirements, 00-*, are to be used in a Specific Equipment Standard, the application shall be identified.
- 2.9.3.1 Note: We want to add a list of possible allowed items here, as it appears in the 3-A Sanitary Standard for General Requirements, 00- in the same section.
- 2.9.4 All exclusions or modifications of fabrication criteria listed in the *3-A Sanitary Standard for General Requirements, 00-*, should also be identified.

2.10 Fabrication of Nonproduct Contact Surfaces (Section F)—Required

2.11 Special Considerations (Section G)--Optional

2.11.1 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.

2.12 Installation (Section H)--Optional for Standards but Required for Most Practices

2.12.1 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, when used, it may be in either the body or the Appendix.

2.13 Appendix--Optional

- 2.13.1 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. Only necessary Appendix items, not listed in the *3-A Sanitary Standard for General Requirements, 00-*, Appendix, should be included. Although generally optional, this section is usually found in 3-A documents.
- 2.13.2 Even when not considered as normative by reference, Regulatory Agencies under their procedures and authority may use the non-normative appendix information during inspections when no other guidance on appendix items is available from the fabricator or the processor.

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. When 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 NIST 1038.

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 NIST 1038 *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.

TABLE 5 - Base SI Units					
Quantity	Unit	Symbol			
Length	meter	m			
Mass	kilogram	kg			
Time	second	S			
Electric current	ampere	А			
Thermodynamic	kelvin	K			
Amount of substance	mole	mol			
Luminous intensity	candela	cd			

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

TABLE 6- Derived SI Units

Quantity	Unit	Symbol	Formula
Frequency	hertz	Hz	1/s
Force	newton	Ν	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

Guidance Document

Quantity	Unit	Symbol	Definition
Plane Angle	degree	0	$1^{\circ} = (\Pi/180) \text{ rad}$
	minute ^a	'	$1' = (1/60)^\circ = (\Pi/10,800)$ rad
	second	"	$1'' = (1/60)' = (\Pi/648,000)$ rad
Volume	liter ^b	L	1 L = 10 dL = 1000 mL
Pressure	Kilopascal	kPa	psi x 6.897 = kPa
	Pounds per in ²	psi	kPa x 0.145 = psi
Mass	metric ton	Т	1 t = 1000 kg

TABLE 8 - Units In Use With SI

.

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

Multiplication Factor	Scientific Notation	Prefix	Symbol
1,000,000,000,000,000,000	1x10 ¹⁸	exa	E
1,000,000,000,000,000	1×10^{15}	peta	Р
1,000,000,000,000	1x10 ¹²	tera	Т
1,000,000,000	1x10 ⁹	giga	G
1,000,000	1x10 ⁶	mega	М
1000	1x10 ³	kilo	k
100	1x10 ²	hecto ^a	h
10	1x10 ¹	deca ^a	da
0.1	1x10 ⁻¹	deci ^a	d
0.01	1x10 ⁻²	centi ^a	с
0.001	1x10 ⁻³	milli	m
0.000001	1x10 ⁻⁶	micro	μ
0.00000001	1x10 ⁻⁹	nano	n
0.00000000001	1x10 ⁻¹²	pico	р
0.000000000000001	1x10 ⁻¹⁵	femto	f
0.0000000000000000000000000000000000000	1x10 ⁻¹⁸	atto	а

TABLE 9 - SI Prefixes

^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 NIST 1038. 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.
- 4.2.3.2 To round to fewer digits, when 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 when 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 when it is odd and remains the same when 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.

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 For mechanical engineering drawings, use millimeters for all linear dimensions.

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.

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 10

IP (in.)	SI (cm)	IP (in.)	SI (cm)
45	114	75	190
48	122	80	203
50	127	84	213
55	140	85	216
60	152	90	229
65	165	95	241
70	178	96	244
72	183	100	254

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

IP (ft)	SI (m)	IP (ft)	SI (m)
10	3.05	35	10.7
12	3.66	36	11.0
15	4.57	40	12.2
18	5.49	50	15.2
20	6.10	60	18.3
24	7.32	70	21.3
25	7.62	80	24.4
30	9.14	90	27.4

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

	SI
IP (in.)	(µm)
0.0002	5.
0.002	50.
0.003	80.

	SI
IP (in.)	(mm)
0.005	0.125
0.008	0.200
0.01	0.25
0.04	1.00
0.08	2.00

TABLE 13 - Volumetric Capacity Conversion (gal to L)

IP		IP		IP			
(gal)	SI(L)	(gal)	SI(L)	(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)

Copyright[©] 3-A Sanitary Standards, Inc., McLean, VA

IP	1.0 ft ²	$2.0 \ {\rm ft}^2$	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	$45.2\pm0.1~\mathrm{cm}^2$

IP (psig)	1	2	15.3	250	300	30,000
SI (kPa)	6.89	13.72	105.5	1724	2068	206,843
SI (Bar)	0.07	0.14	1.06	1.72	2.07	20.7

TABLE 15 - Pressure Conversion (psig to kPa)

TABLE 16 - Flow Rate Conversion (gpm to Lpm)								
IP (gpm)	9.4	24.0	43.0	69.0	102.0	182.0		
SI (Lpm)	35.6	90.8	163.0	261.0	386.0	689.0		

TABLE 17 - Flow Rate to achieve 5 f/s (1.52 m/s)*

					<u>``</u>				
Nominal size (inches)	1/2	3/4	1	1 1/2	2	2 1/2	3	4	6
ID (inches)	0.37	0.62	0.87	1.37	1.87	2.37	2.87	3.834	5.782
Flow rate to achieve 5 f/s (gpm)	1.7	4.7	9.3	23.0	42.8	68.8	100.8	179.9	409.2
Flow rate to achieve 1.52 m/s	6.3	17.8	35.1	87.0	260.2	260.2	381.6	681.1	1549.0
(Lpm)									

CIP flow rate guidelines for process lines.*

- (a) Pipelines should be fully flooded and ensure turbulent flow during cleaning.
- (b) CIP shall be performed at a flow rate that maintains a fully flooded process line and ensures turbulent flow.
- (c) The flow direction, line orientation, line size, and presence and orientation of branches, fittings, and other equipment can have a significant influence on the flow rate required to fully flood a process line. Consequently, designers should take these into account when determining suitable flow paths and CIP flow rates.
- (d) CIP flow rate requirements should not be considered exclusively of other CIP variables.
- (e) Table 17 details flow rate recommendations that should ensure air removal in straight horizontal and vertical lines for line sizes up to 2 in. These flow rates correspond to a flow velocity of 5 ft/sec (1.52 m/s), which is characterized by turbulent flow for all CIP solutions that are within the scope of this section and all line sizes referenced in Table 17.

* Courtesy of ASME BPE 2012

TABLE 18 - Other

Pitch:

Pitch or Slope is calculated as Rise (h) divided by Run (d). The result of this may be interpreted in two ways to communicate the angle a.

Method 1:

Where pitch or slope (h / d) is communicated in degrees, where h / d = 1 = 45 $^{\circ}$

Method 2:

Where pitch or slope is communicated in percent, where h / d = 1 = 100%



Temperature: Calculate by using $\Box C = (\Box F-32) \times 5/9$.

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.

Executive Director 3-A Sanitary Standards, Inc. 6888 Elm Street, Suite 2D McLean, VA 22101-3829 Phone: 703-790-0295 Fax: 703-761-6284 E-mail: <u>3-ainfo@3-a.org</u>

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: <u>3-ainfo@3-a.org</u> URL: <u>www.3-a.org</u>

6.2 3-A Sanitary Standards and 3-A Accepted Practices are available for purchase in English from: <u>www.3-a.org</u>.

Guidance Document

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) European Hygienic Engineering & Design Group (EHEDG)

Proposal	(Date)
Second Draft	(Date)
Third Draft	(Date)

TABLE OF CONTENTS

TITI	LE			
TAB	LE O	F CONTENTS		
DIS	CLAI	MERS		
FOR	EWO	PRD		
Α	SCO	PE		
B	NOR	RMATIVE REFERENCES		
С	DEF	INITIONS		
-				
D	MAT	FERIALS		
-	D1	Product Contact Surfaces		
	D 1	D1 1 Metals		
		D1.1 Metals		
	D2	Nonproduct Contact Surfaces		
	D2	Nonproduct Contact Surfaces		
Г	БЛВ	ΔΙCATION OF ΦΦΟΡΙΙCT ΑΝΌ SOI ΙΙΤΙΟΝ CONTACT		
Ľ		FACES		
	SUN E1	races Torrange		
	EI E2	Surface Texture		
	E2	Joints		
		E2.1 Permanent Joints		
		E2.2 Non-Permanent Joints		
	E3	Coatings		
	E4	Cleaning and Inspectability		
	E5	Draining		
	E6	Dead Ends		
	E7	Gaskets, Gasket Retaining Grooves, O-rings and Seals		
	E8	Radii		
	E9	Threads		
	E10	Perforated Surfaces		
	E11	Coil Springs		
	E12	Shafts		
	E13	Bearings		
	E14	Openings and Covers (Other Than Personnel Access Ports)		
	E15	Temperature-Sensing Device Connections		
	E16	Agitators		
	E17	Instruments		
	E18	Sanitary Tuhing		
	E10			
F	блв	RICATION OF NON-PRODUCT CONTACT SURFACES		
T,	FADRICATION OF NON-I RODUCT CONTACT SURFACES			
	Г I Г 2	Jui latta		
	ľ 2	JOINTS		

		F3	Coatings
		F4	Cleaning and Inspectability
		F5	Draining
		F6	Threads
		F7	Service Piping and Lines
		F8	Panels, Doors, or Access Ports
		F9	Guards and Other Safety Devices
		F10	Supports
		F11	Nameplates
		F12	Sterilizing Chambers
		F13	Bearings
	G H	SPEC	CIAL CONSIDERATIONS
APPE	NDIX	-	
1	STA	INLE	SS STEEL AND EQUIVALENT MATERIALS
2	PRO	DUC	Г CONTACT SURFACE FINISH
3	AIR	VEN	ГING
4	CIP	Clean	ing
5	EDT	°CF	
6	INST MA	FRUC INTE	TION HANDBOOK FOR INSTALLATION, NANCE, AND CLEANING
7	SUG	GEST	TED CLEANING PROCEDURES
8	ILLU	USTR	ATIONS
9	SLA	BS OI	R ISLANDS
10	ELE	CTRO	DLESS NICKEL ALLOY
11	HAR	RMON	JIZATION

Disclaimers

3-A Sanitary Standards and 3-A Accepted Practices are developed through the efforts of experts, working on a volunteer basis, using science-based information and their professional experiences to reach consensus decisions on the sanitary (hygienic) criteria in these 3-A documents.

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

3-A Sanitary Standards and 3-A Accepted Practices do not include provisions for mechanical, electrical, or personnel safety. Such safety criteria are established by government regulations and other standards development organizations (SDOs). Other SDO standards may be referenced.

Drawings and illustrations contained herein are examples to assist in understanding the criteria in this 3-A Sanitary Standard. 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.

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

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

Foreword

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

This 3-A Sanitary Standard is for use on a voluntary basis by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies, and by other SDOs to assure adequate public health protections exist for the equipment or systems and covered products. 3-A SSI uses these documents as its source of sanitary criteria for 3-A Symbol authorization.

This 3-A Sanitary Standard was developed jointly by 3-A SSI, the United States Public Health Service (USPHS), United States Food and Drug Administration (USFDA), the United States Department of Agriculture – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our 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: <u>3-ainfo@3-a.org</u>.

A SCOPE

A1 This 3-A {Sanitary Standard or Accepted Practice} applies to 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}.

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

A2 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 applicable, 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.

<u>Drafter's Note</u>: 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. Reference the 3-A Sanitary Standard for General Requirements, 00- to identify any Normative Reference that needs to be modified or exempted. DO NOT include this entire listing. Select for inclusion only those documents that are necessary and applicable to the document being prepared.

B2 **3-A Sanitary Standards**

Doc. No. <u>Title (3-A Sanitary Standard for:)</u>

- 00- General Requirements
- 01- Insulated Tanks
- 02- Centrifugal and Positive Rotary Pumps
- 04- Homogenizers and Reciprocating Pumps
- 05- Stainless Steel Automotive Transportation Tanks

Guidance Document

- 10- Filters Using Single Service Filter Media
- 11- Plate Type Heat Exchangers
- 12- Tubular Heat Exchangers
- 13- Farm Milk Cooling and Holding Tanks
- 16- Product Evaporators and Vacuum Pans
- 17- Formers, Fillers, and Sealers of Containers for Fluid Products
- 18- Multiple-Use Rubber and Rubber-Like Materials
- 19- Batch and Continuous Freezers for Ice Cream, Ices and Similarly Frozen Foods
- 20- Multiple-Use Plastic Materials
- 21- Centrifugal Separators and Clarifiers
- 22- Silo-Type Storage Tanks
- 23- Equipment for Packaging Viscous Products
- 24- Non-Coil Type Batch Pasteurizers
- 25- Non-Coil Type Batch Processors
- 26- Sifters for Dry Products
- 27- Equipment for Packaging Dry Products
- 28- Flow Meters
- 29- Air Eliminators
- 30- Farm Milk Storage Tanks
- 31- Scraped Surface Heat Exchangers
- 32- Uninsulated Tanks
- 33- Metal Tubing
- 34- Portable Bins for Dry Products
- 35- Blending Equipment
- 36- Inline Rotor-Stator Mixers
- 38- Cottage Cheese Vats
- 39- Pneumatic Conveyors for Dry Products
- 40- Bag Collectors
- 41- Mechanical Conveyors for Dry Products
- 42- In-Line Strainers
- 44- Diaphragm Pumps
- 45- Crossflow Membrane Modules
- 46- Refractometers and Energy-Absorbing Optical Sensors
- 49- Air-Driven Sonic Horns for Dry Products
- 50- Level Sensing Devices for Dry Products
- 51- Plug-Type Valves
- 52- Plastic Plug-Type Valves
- 53- Compression-Type Valves
- 54- Diaphragm-Type Valves
- 55- Boot Seal-Type Valves
- 56- Inlet and Outlet Leak-Protector Plug-Type Valves
- 57- Disc-Type Valves
- 58- Vacuum Breakers and Check Valves

Guidance Document

- 59- Automatic Positive Displacement Samplers for Fluid Products
- 60- Rupture Discs Assemblies
- 61- Steam Injection Heaters
- 62- Hose Assemblies
- 63- Sanitary Fittings
- 64- Pressure Reducing and Back Pressure Regulating Valves
- 65- Sight and/or Light Windows and Sight Indicators in Contact With Product
- 68- Ball-Type Valves
- 70- Italian-Type Pasta Filata Style Cheese Cookers
- 71- Italian-Type Pasta Filata Style Cheese Moulders
- 72- Italian-Type Pasta Filata Style Moulded Cheese Chillers
- 73- Shear Mixers, Mixers, and Agitators
- 74- Sensors and Sensor Fittings and Connections 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
- 95- Transportation Tank Vents
- 101- Pipeline Product Recovery Equipment Using Projectiles

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

B4 **Other References and Standards**

The most current approved version of the 3-A Sanitary Standard for General Requirements, 00- shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modifications, or exclusions.

<u>Drafter's Note</u>: All Normative References from *3-A Sanitary Standard for General Requirements, 00-* apply, any additional reference or standards may be listed herein.

C **DEFINITIONS**

The most current approved version of the 3-A Sanitary Standard for General Requirements, 00- shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modifications, or exclusions.

Drafter's Note: Choose or propose only those definitions appropriate to the standard or practice being written. Unless otherwise noted, the most current approved version of the 3-A Sanitary Standard for General Requirements, 00- shall apply. Definitions not applicable to the standard shall be excluded, clarified, or modified.

<u>Drafter's Note</u>: Specific processes, words or phrases, not listed below, may be included as a new Definition. Example definitions are given below, and should be added to a specific standard, along with new definitions, when applicable.

Dynamic Seal: The seal established between components that move relative to each other. The seal is formed using a combination of compression, pressure, and the geometrical shapes of the joined materials to create a seal at the interface of the components.

Processing Air: Air used in contact with the product and containers, except Environmental Air.

<u>Staff Note</u>: The following examples are for the items that could appear in the B-Level Standards. Examples include heating, cooling, drying, ice cream overrun, agitating, product line purging, conveying of line recovery projectiles, opening or expanding containers, for checking product container integrity, conveying packaging or lids, or similar purposes.

Inspectable: (Refer to 3-A Sanitary Standard for General Requirements, 00-)

<u>Drafter's Note</u>: 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.

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

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

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

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 B1, Reference No. 1)

Safe Water: Water that meets the requirements of the National Primary Drinking Water Regulation of the Environmental Protection Agency (EPA), The Code of Federal Regulations (CFR). (Refer to 3-A Sanitary Standard for General Requirements, 00-)

Sanitizing or Sanitization: (Refer to 3-A Sanitary Standard for General Requirements, 00-)

Sealed: (Refer to 3-A Sanitary Standard for General Requirements, 00-)

Shadow Areas: Obstructed areas on product contact surfaces where cleaning solutions will not flow or impinge directly across or on the surface.

Processing Air Contact Surfaces: Surfaces in contact with processing air, commencing with the discharge of the air treatment apparatus and ending at the first contact with product or product contact surface.

Exhaust Air Contact Surfaces: Surfaces of air ducts, plenum chamber(s) or appurtenances, from the final product contact surface to the exhaust discharge.

Unitized: Assembly of connected or attached functional subunits to form a complete machine.

D MATERIALS

Drafter's Note: The following paragraph shall be included in each Standard

The most current approved version of the 3-A Sanitary Standard for General Requirements, 00- shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modifications, or exclusions.

<u>Drafter's Note</u>: Include only materials appropriate to the Standard or Practice being written or updated. Materials shown in the *3-A Sanitary Standard for General Requirements, 00-* that are not applicable to the Standard being written or updated shall be excluded, clarified, or modified.

<u>Drafter's Note</u>: When materials are permitted only by specific inclusion in the individual 3-A Sanitary Standard, add "except that:" to the heading and format the clause(s) as listed in the individual criteria below.

D1 **Product Contact Surfaces** (Refer to 3-A Sanitary Standard for General Requirements, 00-)

<u>Drafter's Note</u>: When appropriate for the document being prepared, Splash Contact, Solution Contact, or Air Contact surfaces may be added to the heading.

Guidance Document

- D1.1 Metals (Refer to 3-A Sanitary Standard for General Requirements, 00-), except that:
- D1.1.1.2 xxxxxxx components may be made of stainless steel of Type 302, 400 series or other metal alloy which has adequate corrosion resistance for the intended application.
- D1.1.2 Components may be made of nontoxic metal(s) that have their product contact surfaces modified by coating(s).
- D1.1.3 Solder or brazing filler metal may be used for xxxxxxx components.
- D1.1.4 Powdered metal and metal alloys may be used for xxxxxxx components.
- D1.2 Non-Metals (Refer to 3-A Sanitary Standard for General Requirements, 00-), except that:
- D1.2.1 Plastic, rubber and rubber-like materials may be used for xxxxxxxxx components.
- D1.2.2 Adhesives may be used for bonding materials.
- D1.2.3 Carbon and ceramic materials may be used for xxxxxxxx components.
- D2 Nonproduct Contact Surfaces (Refer to 3-A Sanitary Standard for General Requirements, 00-)

E FABRICATION OF PRODUCT AND SOLUTION CONTACT SURFACES

Drafter's Note: The following paragraph shall be included in each Standard

The most current approved version of the 3-A Sanitary Standard for General Requirements, 00- shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modifications, or exclusions.

<u>Drafter's Note</u>: Include only fabrication criteria appropriate to the standard or practice being written or updated. Fabrication criteria shown in the 3-A Sanitary Standard for General Requirements, 00- that are not applicable to the standard being written or updated shall be excluded, clarified, or modified.

<u>Note</u>: The illustrations shown in this Fabrication Clause 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.

<u>Drafter's Note</u>: 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.

<u>Drafter's Note</u>: When fabrication methods are permitted only by specific inclusion in the individual 3-A Sanitary Standard, add "except that:" to the heading and format the clause(s) as listed in the individual criteria below.

E1 **Surface Texture** (Refer to 3-A Sanitary Standard for General Requirements, 00-)

<u>Drafter's Note</u>: When appropriate for the document being prepared, Splash Contact, Solution Contact, or Air Contact surfaces may be added to the heading.

- E2 Joints
- E2.1 **Permanent Joints** (Refer to 3-A Sanitary Standard for General Requirements, 00-), except that:
- E2.1.1.1 Soldering or brazing may be used for attaching xxxxxxxx components.
- E2.1.1.2 Interference fits may be used to assemble xxxxxxxx components.
- E2.1.1.3 Bonded joints may be used to assemble components.
- E2.1.1.4 Thermoplastics may be welded by friction, heat, solvents, or other suitable methods.
- E2.2 Non-Permanent Joints (Refer to 3-A Sanitary Standard for General Requirements, 00-), except that:
- E2.2.1 Mechanical force seals may be used for xxxxxxx components.
- E3 **Coatings** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- E4 **Cleaning and Inspectability** (Refer to 3-A Sanitary Standard for General Requirements, 00-)

<u>Drafter's Note</u>: Some equipment may have large appurtenances that are designed for CIP cleaning and do not require frequent dismantling. These appurtenances may be identified as being "removable" rather than "readily removable" if required.

- E5 **Draining** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- E6 **Dead Ends** (Refer to 3-A Sanitary Standard for General Requirements, 00-)

<u>Drafter's Note</u>: The appropriate optional wording when referring to vessels may be as follows: 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.

E7 **Gaskets, Gasket Retaining Grooves, O-rings and Seals** (Refer to 3-A Sanitary Standard for General *Requirements, 00-*)

<u>Drafter's Note</u>: In some standards, two gaskets are used sequentially and leak detection may be required between them, even when they are designed for manual cleaning.

E8 **Radii** (Refer to 3-A Sanitary Standard for General Requirements, 00-)

<u>Drafter's Note</u>: 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.

<u>Drafter's Note</u>: The appropriate wording for vessels may be included as follows: 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) for horizontal tanks, 1/2 in. (12.7 mm) for vertical tanks.

<u>Drafter's Note</u>: There are no minimum radius requirements for:

- A. Retaining grooves for mechanical force seals
- B. The juncture between product contact surfaces and the exposed part of an O-ring.
- E9 **Threads** (Refer to 3-A Sanitary Standard for General Requirements, <u>00-</u>), except that:
- E9.1 **Exposed Threads** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- E9.1.1 Exposed threads may be used for xxxxxxxx components.
- E9.2 Enclosed Threads (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- E9.2.1 Enclosed threads may be used for xxxxxxx components.
- E10 **Perforated Surfaces** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- E10.1 Perforated surfaces may be used for xxxxxxxx components.
- E11 **Coil Springs** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- E11.1 Coil springs may be used for xxxxxxx components.
- E12 Shafts (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- E13 **Bearings** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- E13.1 Bearings may be used for xxxxxxx components.
- E14 **Openings and Covers (Other Than Personnel Access Ports)** (Refer to 3-A Sanitary Standard for General Requirements, 00-)

- E15 **Temperature-Sensing Device Connections** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- E15.1 A product temperature-sensing device may be used.
- E16 Agitators
- E17 Instruments
- E18 Sanitary Tubing

F FABRICATION OF NON-PRODUCT CONTACT SURFACES

Drafter's Note: The following paragraph shall be included in each Standard

The most current approved version of the 3-A Sanitary Standard for General Requirements, 00- shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modifications, or exclusions.

<u>Drafter's Note</u>: When fabrication methods are permitted only by specific inclusion in the individual 3-A Sanitary Standard, add "except that" to the heading and format the clause as listed in the individual criteria listed below.

- F1 Surfaces (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- F2 Joints (Refer to 3-A Sanitary Standard for General Requirements, 00-)

<u>Drafter's Note</u>: When external lap joints over insulated areas are used, the work group shall consider appropriate criteria.

- F3 **Coatings** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- F4 **Cleaning and Inspectability** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- F5 Draining (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- F6 **Threads** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- F7 Service Piping and Lines (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- F8 Panels, Doors, or Access Ports (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- F9 Guards and Other Safety Devices (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- F10 **Supports** (Refer to 3-A Sanitary Standard for General Requirements, 00-)

F10.1 Casters

Casters, when provided, shall provide a clearance between the lowest part of the base of the equipment and the floor of at least 4 in. (102 mm). Casters shall be durable under normal use and when exposed to the conditions encountered in the environment of intended use, including cleaning sanitizing and/or sterilization, and of a size that will permit easy movement of the equipment. Exposed surfaces of casters shall be cleanable and of a material at least as corrosion resistant as 304 stainless steel, and relatively nonabsorbent.

Drafter's Note: Greater clearance may be required for large equipment.

F10.2 Slabs or Islands

When equipment is to be mounted on a slab or island, the mounting surface of the equipment shall be designed for sealing to the slab or island surface. Also, information shall be provided to the user about construction requirements for the slab or island and installation of equipment. See *3-A Sanitary Standard for General Requirements*, Appendix 6.

- F11 Name and/or Information Plates (Nameplates) (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- F11.1 An information plate, when necessary to convey special information, shall be attached in juxtaposition to the nameplate. Alternatively, the following information may appear on the nameplate:

<u>Drafter's Note</u>: 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.

<u>Drafter's Note</u>: This is of special importance when optional metals are used that are susceptible to acid cleaners.

3. "This equipment* designed for heat 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:

Guidance Document

- (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 {every day 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 Farm Milk 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"
- F12 Sterilizing Chambers (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- F12.1 Sterilizing chambers may be used for seal components.
- F13 **Bearings** (Refer to 3-A Sanitary Standard for General Requirements, 00-)

G SPECIAL CONSIDERATIONS

<u>Drafter's Note</u>: As appropriate for the document being prepared, include criteria of a special nature.

H INSTALLATION

<u>Drafter's Note</u>: Include only installation criteria appropriate to the standard or practice being written or changed. Installation criteria shown in the 3-A Sanitary Standard for General Requirements, 00- that are not applicable to the standard being written or changed shall be excluded, clarified, or modified.

<u>Drafter's Note</u>: As appropriate for the document being prepared, include criteria for installation. This clause is most commonly used for 3-A Accepted Practices, but may also be included in 3-A Sanitary Standards.

APPENDIX

The most current approved version of the 3-A Sanitary Standard for General Requirements, 00- shall apply, unless otherwise noted herein with additions, clarifications, exceptions, modifications, or exclusions.

<u>Drafter's Note</u>: Include only information appropriate to the Standard or Practice being written or changed. Information shown in the *3-A Sanitary Standard for General Requirements, 00-* that are not applicable to the standard being written or changed shall be excluded, clarified, or modified.

- 1 **STAINLESS STEEL AND EQUIVALENT MATERIALS** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- 2 **PRODUCT CONTACT SURFACE FINISH** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- 3 **AIR VENTING** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- 4. **CIP CLEANING** (Refer to 3-A Sanitary Standard for General Requirements, 00-)
- 5 ENGINEERING DESIGN AND TECHNICAL CONSTRUCTION FILE (Refer to 3-A Sanitary Standard for General Requirements, 00-)

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. Where indicated in the following examples, appropriate information should be completed by the fabricator.

6 **INSTRUCTION HANDBOOK FOR INSTALLATION, MAINTENANCE, AND CLEANING** (Refer to 3-A Sanitary Standard for General Requirements, 00-)

7 SUGGESTED CLEANING PROCEDURES

<u>Drafter's Note</u>: When necessary, write appropriate procedures for the equipment specified in the scope. This may include dry cleaning, additional mechanical cleaning, or manual cleaning procedures.

8 ILLUSTRATIONS

These illustrations 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:

Drafter's Note: Usually a list of illustrations titles, numbers, and pages follows.

9 SLABS, ISLANDS, OR FLOORS

When the equipment is designed to be installed on a slab, an island, or floor, the mounting should be of sufficient height that the bottom of all product connections are not less than 24 in. (610 mm) above the floor. The surface of the slab or island should be coated with a thick layer of waterproof mastic material, which will harden without cracking. The junction of the equipment base and the slab, island, or floor should be effectively sealed.

10 ELECTROLESS NICKEL ALLOY

<u>Drafter's Note</u>: When necessary write appropriate description for the application and use limits for Electroless Nickel Alloy. This may include special cleaning procedures.

11 HARMONIZATION (Refer to 3-A Sanitary Standard for General Requirements, 00-)