



ASME BPE-2009
(Revision of ASME BPE-2007)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD



**The American Society of
Mechanical Engineers**





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FOREWORD

At the 1988 ASME Winter Annual Meeting (WAM), many individuals expressed interest in developing standards for the design of equipment and components for use in the biopharmaceutical industry. As a result of this interest, the ASME Council on Codes and Standards (CCS) was petitioned to approve this as a project. The initial scope was approved by the CCS on June 20, 1989, with a directive to the Board on Pressure Technology to initiate this project with the following initial scope:

This standard is intended for design, materials, construction, inspection, and testing of vessels, piping, and related accessories such as pumps, valves, and fittings for use in the biopharmaceutical industry. The rules provide for the adoption of other ASME and related national standards, and when so referenced become part of the standard.

(a) At the 1989 WAM, an ad hoc committee was formed to assess the need to develop further the scope and action plan. The committee met in 1990 and there was consensus concerning the need to develop standards that would meet the requirements of operational bioprocessing, including:

- (1) the need for equipment designs that are both cleanable and sterilizable
- (2) the need for special emphasis on the quality of weld surfaces once the required strength is present
- (3) the need for standardized definitions that can be used by material suppliers, designers/fabricators, and users
- (4) the need to integrate existing standards covering vessels, piping, appurtenances, and other equipment necessary for the biopharmaceutical industry without infringing on the scopes of those standards

(b) The BPE Main Committee was structured with six functioning subcommittees and an executive committee comprising the main committee chair and the subcommittee chairs. The subcommittees are

- (1) General Requirements
- (2) Design Relating to Sterility and Cleanability of Equipment
- (3) Dimensions and Tolerances
- (4) Material Joining
- (5) Surface Finishes
- (6) Seals

(c) Throughout the development of the Standard, close liaison was made with the European CEN, ASTM, and the AAA Dairy Standards. The purpose was to develop an ASME standard that would be distinctive, germane, and not in conflict with other industry standards. Wherever possible, the Committee strived to reference existing standards that are applicable to biopharmaceutical equipment design and fabrication.

This Standard represents the work of the BPE Standards Committee and includes the following Parts:

- (1) General Requirements
- (2) Design for Sterility and Cleanability
- (3) Dimensions and Tolerances for Stainless Steel Automatic Welding and Hygienic Clamp Tube Fittings
- (4) Material Joining
- (5) Stainless Steel and Higher Alloy Product Contact Surface Finishes
- (6) Equipment Seals
- (7) Polymer-Based Materials
- (8) Certification
- (9) Metallic Materials of Construction

The first edition of this Standard was approved as an American National Standard on December 22, 2005. The second edition was approved by ANSI on October 9, 2007. This edition was approved by ANSI on August 31, 2009.

Requests for interpretations or suggestions for revision should be sent to Secretary, BPE Committee, The American Society of Mechanical Engineers, Three Park Avenue, New York, NY 10016.



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ASME BPE-2009 SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2009 was approved by the American National Standards Institute on August 31, 2009.

ASME BPE-2009 includes editorial changes, revisions, and corrections introduced in ASME BPE-2007, as well as the following changes identified by a margin note, **(09)**.

<i>Page</i>	<i>Location</i>	<i>Change</i>
1–6	GR-1(b)	Revised
	GR-4	Revised in its entirety
	GR-9	Revised
	Table GR-1	Added
7–13	GR-10	Revised
14	SD-2	Revised
	SD-3	Revised
	SD-3.1.7	Revised
	SD-3.1.8	Revised
	SD-3.2	Revised in its entirety
15	SD-3.4	Subparagraphs SD-3.4.1 through SD-3.4.3 revised
	SD-3.5.2	Second paragraph revised
	SD-3.6.1	Last paragraph revised
	SD-3.6.4	Revised
	SD-3.7.8	Revised
16	SD-3.7.9	Revised
	SD-3.7.10	Added
	SD-3.7.11	Added
	SD-3.8(m)	Revised
	SD-3.10	Revised in its entirety
17	SD-3.11.1	First paragraph revised
	SD-3.11.6	Revised
	SD-3.12.1	First paragraph revised
18	SD-4.1.1(d)	Revised
	SD-4.1.2	Revised in its entirety
	SD-4.1.3(b)	Revised



<i>Page</i>	<i>Location</i>	<i>Change</i>
	SD-4.1.4(a)(4)	Revised
	SD-4.2.1(d)	Revised
	SD-4.2.2(c)	Revised
20	SD-4.3.1	Subparagraphs (a) through (d) and (g) revised
	SD-4.3.2	Subparagraphs (a) and (b) revised
	SD-4.4	Subparagraphs (a), (c), and (d) revised
	SD-4.5	Revised in its entirety
21	SD-4.6	Title revised
	SD-4.6.1(b)	Revised
	SD-4.6.4	Added
22	SD-4.7.1(h)	Revised
	SD-4.7.2	(1) Subparagraphs (b), (d), (h), (j), and (m) revised (2) Subparagraph (q) deleted (3) Fig. SD-14-1 deleted (4) Subparagraphs (r) through (t) redesignated as (q) through (s) (5) New subparagraph (r) revised
	SD-4.7.3(c)	Revised
	SD-4.7.4(c)	Revised
23	SD-4.8.1(f)	Revised in its entirety
25	SD-4.9.1	Subparagraphs (c), (c)(2), (g)(2), (g)(3), and (i) revised
	SD-4.9.2	Revised in its entirety
26	SD-4.11.1(e)	Revised
	SD-4.11.3(c)	Revised
	SD-4.11.4(a)	Revised
27–32	SD-4.14	Revised in its entirety
	SD-4.15	Revised in its entirety
	SD-4.16.1(b)	Revised
	SD-4.16.2	Subparagraphs (b) and (d) revised
33–36	SD-4.16.6	Subparagraphs (b) through (d) revised
	SD-4.17	Added
	SD-4.18	Added
37	SD-5.2	Revised in its entirety
	SD-6	Third paragraph revised
39	Fig. SD-1	Revised in its entirety
40	Fig. SD-2	Illustration (f) revised
45	Fig. SD-7-1	Fig. SD-7 redesignated as Fig. SD-7-1



<i>Page</i>	<i>Location</i>	<i>Change</i>
	Fig. SD-7-2	Added
46	Fig. SD-7-3	Added
	Fig. SD-7-4	Added
47	Fig. SD-7-5	Added
52	Fig. SD-14	Fig. SD-14-2 redesignated as Fig. SD-14
53	Fig. SD-15	Illustration (c) added
66	Fig. SD-23-1	Fig. SD-23 redesignated as Fig. SD-23-1
67	Fig. SD-23-2	Fig. SD-23-1 redesignated as Fig. SD-23-2
	Fig. SD-23-3	Added
68	Fig. SD-23-4	Added
	Fig. SD-23-5	Added
69	Fig. SD-23-6	Added
73	Fig. SD-27-1	Added
74	Fig. SD-27-2	Added
	Fig. SD-28-1	Added
75	Fig. SD-28-2	Added
76	Fig. SD-28-3	Added
	Fig. SD-28-4	Added
77	Fig. SD-29-1	Added
	Fig. SD-29-2	Added
	Fig. SD-30	Added
80	Table SD-5	Added
81	Table SD-6	Added
82, 83	DT-1	Third paragraph moved to DT-6
	DT-6	(1) First paragraph revised (2) Last paragraph added
	DT-8	First and third paragraphs revised
	DT-10	Revised in its entirety
85	DT-V-4	Second paragraph revised
	DT-V-8	Revised
86	Fig. DT-1	Added
87	Table DT-2	Title and General Notes revised
88	Table DT-4	General Note revised
89	Table DT-5-1	(1) Table DT-5 redesignated as Table DT-5-1 (2) Last two columns added (3) General Note revised
90, 91	Table DT-5-2	(1) Table DT-5-1 redesignated as Table DT-5-2



<i>Page</i>	<i>Location</i>	<i>Change</i>
92	Table DT-5-3	(2) Revised in its entirety
93	Table DT-8	Added
95	Table DT-11	Callout added to illustration
96	Table DT-13	Twelve rows deleted
98	Table DT-17	Callout added to illustration
101	Table DT-21	Callout added to illustration
104	Table DT-26	Nine rows deleted
105	Table DT-30	Nine rows deleted
		(1) Illustration revised
		(2) General Note added
		(3) Note (1) deleted
106	Table DT-31	Added
108	MJ-2	(1) Subparagraphs MJ-2.3 through MJ-2.6 redesignated as MJ-2.4 through MJ-2.7, respectively
		(2) New subparagraph MJ-2.3 added
110	MJ-6.4.1	Revised
112	Table MJ-2	In fourth column, last entry revised
116	MJ-7.2.3	Last paragraph revised
117, 118	MJ-8.4	Added
	Table MJ-5	Added
	Table MJ-6	Added
	MJ-9.2	Revised
	MJ-9.3	Revised in its entirety
120	SF-5	Subparagraphs (c) and (d) revised
121	Table SF-1	Title and General Note (b) revised
123–125	Table SF-4	Added
	SF-7	Revised
	SF-8	Revised
	SF-9	Added
	SF-10	Added
	Subsection SF-P	Added
127	SG-3.1.6	Revised
	SG-3.1.8	Added
128	SG-3.4.1	Revised
	SG-3.4.2	(1) Subparagraphs (e) and (h) revised
		(2) Penultimate paragraph revised
132	SG-4.2	Added
	SG-4.3	Added
142	Fig. SG-18	Added
150	PM-4	Revised
151–154	PM-6	Added
	PM-7	Added
	Table PM-2	Added
	PM-8	Added
155–158	Part CR	Added
159–167	Part MMOC	Added
176–184	Nonmandatory Appendix D	Added
185–194	Nonmandatory Appendix E	Added
195–197	Nonmandatory Appendix F	Added
198	Nonmandatory Appendix G	Added
199, 200	Nonmandatory Appendix H	Added
201–204	Nonmandatory Appendix I	Added
205–208	Nonmandatory Appendix J	Added
209, 210	Nonmandatory Appendix K	Added
211–213	Index	Updated



BIOPROCESSING EQUIPMENT

Part GR General Requirements

GR-1 INTRODUCTION

This Standard provides the requirements applicable to the design of equipment used in the bioprocessing, pharmaceutical, and personal care product industries, including aspects related to sterility and cleanability, materials, dimensions and tolerances, surface finish, material joining, and seals. These apply to

- (a) components that are in contact with the product, raw materials, or product intermediates during manufacturing, development, or scale-up
- (09) (b) systems that are a critical part of product manufacture [e.g., water-for-injection (WFI), clean steam, filtration, and intermediate product storage]

This Standard applies to new construction only. It is not intended to apply to the operation, examination, inspection, testing, maintenance, or repair of piping/tubing, or equipment that has been placed in service. The provisions of this Standard may be optionally applied for those purposes, although other considerations may be necessary. For installations between new construction that ties into an existing system that has been placed in service, the boundaries and requirements must be agreed to between the owner/user and contractor and inspection contractor.

This Standard does not apply to those components of the system that are not in contact with the finished product or are a part of the intermediate manufacturing stages (e.g., computer systems, electrical conduits, and external system support structures).

Steam sterilized systems normally meet pressure vessel design codes. Other equipment or systems as agreed to by the manufacturer and owner/user may not require adherence to these codes.

When operating under pressure conditions, the systems shall be constructed in accordance with the ASME Boiler and Pressure Vessel Code (BPVC), Section VIII, Division 1, and the ASME B31.3, Process Piping Code, respectively. The owner/user can stipulate additional specifications and requirements. When an application is covered by laws or regulations issued by an Enforcement Authority (e.g., municipal, provincial, state, or federal), the final construction requirements shall comply with

these laws. However, all the previously mentioned construction codes shall be satisfied including those instances where these codes are not referred to in the current BPE Standard (e.g., weld acceptance criteria, inspection requirements, pressure testing, etc.).

GR-2 SCOPE

This Standard deals with the requirements of the bioprocessing, pharmaceutical, and personal care product industries as well as other applications with relatively high levels of hygienic requirements, covering directly or indirectly the subjects of materials, design, fabrication, pressure systems (vessels and piping), examinations, inspections, testing, and certifications. Items or requirements that are not specifically addressed in this Standard cannot be considered prohibited. Engineering judgments must be consistent with the fundamental principles of this Standard. Such judgments shall not be used to override mandatory regulations or specific prohibitions of this Standard.

GR-3 INSPECTION

The inspection requirements are specified in each Part of this Standard. If an inspection or examination plan is required, it shall be developed and agreed to by the owner/user, contractor, inspection contractor, and/or engineer ensuring that the systems and components meet this Standard.

GR-4 INSPECTOR/EXAMINER

(09)

Inspector and examiner in this Standard shall be defined for the following:

(a) *Pressure Vessels*. Authorized Inspector, as defined in ASME BPVC, Section VIII, Division 1, para. UG-91.

(b) *Piping, Tubing, and Non-Code Vessels*. Owner's inspector, as defined in ASME B31.3, paras. 340.4(a) and (b). Inspector's Delegate, as defined in GR-10, meets the additional requirements listed in GR-4.1.



(c) *Piping and Tubing*. Examiner, defined as a person who performs quality control examinations for a manufacturer as an employee of the manufacturer as defined in ASME B31.3, para. 341.1.

When local regulations require that pressure equipment be designed and constructed in accordance with standards other than ASME codes/standards, the inspector in this Standard is defined as one who is acceptable to the relevant regulatory authority.

GR-4.1 Inspector's Delegate

Inspector's Delegate qualifications shall be in accordance with the requirements listed herein. The employer of the Inspector's Delegate shall have documented training and qualification programs to ensure the qualifications and capabilities of personnel are met.

The capabilities requirements are listed in Table GR-1. It is required that a capability listed for a lower level of qualification is also required for subsequent higher levels of qualification.

GR-4.1.1 Levels of Qualification. There are four levels of qualification for Inspector's Delegate. Examination personnel qualifications are not covered in this section but shall be in accordance with ASME B31.3, para. 342.

(a) *Trainee*. An individual who is not yet certified to any level shall be considered a trainee. Trainees shall work under the direction of a certified Quality Inspector Delegate and shall not independently conduct any tests or write a report of test results.

(b) *Quality Inspector Delegate 1 (QID-1)*. This individual shall be qualified to properly perform specific calibrations, specific inspections, and specific evaluations for acceptance or rejection according to written instructions. A QID-1 may perform tests and inspections according to the capabilities' requirements under the supervision of, at a minimum, a QID-2.

(c) *Quality Inspector Delegate 2 (QID-2)*. This individual shall be qualified to set up and calibrate equipment and to interpret and evaluate results with respect to applicable codes, standards, and specifications. The QID-2 shall be thoroughly familiar with the scope and limitations of the inspection they are performing and shall exercise assigned responsibility for on-the-job training and guidance of trainees and QID-1 personnel. A QID-2 may perform tests and inspections according to the capabilities requirements.

(d) *Quality Inspector Delegate 3 (QID-3)*. This individual shall be capable of establishing techniques and procedures; interpreting codes, standards, specifications and procedures; and designating the particular inspection methods, techniques, and procedures to be used. The QID-3 shall have sufficient practical background in applicable materials, fabrication, and product technology to establish techniques and to assist in establishing acceptance criteria when none are otherwise available. The QID-3 shall be capable of training personnel. A

QID-3 may perform tests and inspections according to the capabilities requirements.

GR-4.1.2 Qualification Requirements. The qualification requirements listed herein shall be met prior to consideration for examination/certification.

(a) *Trainee*

(1) be a high school graduate or hold a state or military approved high school equivalency diploma

(2) receive a minimum of 8 hr of relevant documented training (total: 8 hr), including as a minimum the requirements shown in Table GR-1

(b) *QID-1*. To be considered as a QID-1, personnel shall meet the following:

(1) be a trainee for a minimum of 6 mo of documented relevant industry experience. Alternate methods for meeting the work experience requirement are at least one of the following:

(a) prior or current certification as a QID-1

(b) completion with a passing grade of at least 2 yr of engineering or science study in a university, college, or technical school

(c) possess an AWS-CWI certificate¹ or ACCP Level II VT certificate² or international equivalent

(d) 2 yr of documented relevant experience in inspection, examination, or testing activities

(2) receive a minimum of 16 additional hours of relevant documented training (minimum total = 24 hr), including as a minimum the requirements shown in Table GR-1

(3) pass a written test and practical performance examination, including as a minimum the requirements shown in Table GR-1 for this level

(c) *QID-2*. To be considered as a QID-2, personnel shall meet the following:

(1) be a QID-1 for a minimum of 6 mo of documented relevant industry experience. Alternate methods for meeting the work experience requirement are at least one of the following:

(a) prior or current certification as a QID-2

(b) completion with a passing grade of at least 4 yr of engineering or science study in a university, college, or technical school

(c) possess an AWS-CWI certificate¹ or ACCP Level II VT certificate² or international equivalent

(d) 2 yr of documented relevant experience in inspection, examination, or testing activities of high purity/hygienic systems

(2) receive a minimum of 16 additional hours of relevant documented training (minimum total = 40 hr),

¹ Certifications from the American Welding Society (AWS). CAWI is a Certified Associate Welding Inspector and CWI is a Certified Welding Inspector.

² Certifications from the American Society of Nondestructive Testing (ASNT). ACCP is the ASNT Central Certification Program.



including as a minimum the requirements shown in Table GR-1

(3) pass a written test and practical performance examination, including as a minimum the requirements shown in Table GR-1 for this level

(d) QID-3. To be considered as a QID-3, personnel shall meet the following:

(1) be a QID-2 for a minimum of 24 mo of documented relevant industry experience. Alternate methods for meeting the work experience requirement are at least one of the following:

(a) prior or current certification as a QID-3

(b) 3 yr of documented relevant experience in inspection, examination, or testing activities of high purity/hygienic systems

(2) receive a minimum of 40 additional hours of relevant documented training, including as a minimum the requirements shown in Table GR-1 (minimum total = 80 hr)

(3) pass a written test and practical performance examination, including as a minimum the requirements shown in Table GR-1 for this level

GR-4.1.3 Certification. The employer is responsible for training, testing, and certification of employees. The employer shall establish a written practice in accordance with the guidelines of ASNT-SNT-TC-1A including

(a) the requirements listed in Table GR-1

(b) training programs

(c) certification testing requirements

(d) eye exam requirements

(e) certification documentation

The owner/user is responsible for verifying the requirements of this section are met.

GR-4.1.4 Recertification. A QID-1, QID-2, or QID-3 whose employment has been terminated may be recertified to their former level of qualification by a new or former employer based on examination, provided all of the following requirements are met:

(a) The employee has proof of prior certification.

(b) The employee was working in the capacity to which certified within 6 mo of termination.

(c) The employee is being recertified within 6 mo of termination.

If the employee does not meet the listed requirements, additional training as deemed appropriate by the owner's Inspector shall be required.

GR-5 RESPONSIBILITIES

The responsibilities of inspection personnel are defined as follows.

GR-5.1 Pressure Vessels

The responsibilities of the owner's Inspector shall be the same as the inspector in ASME BPVC, Section VIII, Division 1, UG-91.

GR-5.2 Piping, Tubing, and Non-Code Vessels

The responsibilities of the owner/user's inspector shall be in accordance with ASME B31.3, para. 340.2.

GR-6 ACCESS FOR INSPECTORS

Manufacturers of bioprocessing equipment and components shall allow free access of owner/user and authorized inspection personnel at all times while work on the equipment or components is being performed. The notification of an impending inspection should be mutually agreed to by the manufacturer and the inspector. Access may be limited to the area of the manufacturer's facility where assembly, fabrication, welding, and testing of the specific equipment or components is being performed. Inspectors shall have the right to audit any examination, to inspect components using any examination method specified in the Design Specification (including Purchase Order), and review all certifications and records necessary to satisfy the requirements of GR-5. The manufacturer shall provide the inspector with work progress updates.

GR-7 MANUFACTURER'S QUALITY ASSURANCE PROGRAM

The manufacturer shall implement a quality assurance program describing the systems, methods, and procedures used to control materials, drawings, specifications, fabrication, assembly techniques, and examination/inspection used in the manufacturing of bioprocessing equipment.

GR-8 METRIC

Metric units in this Standard are conversions from U.S. Customary units, and are for reference purposes only unless specified otherwise.

GR-9 REFERENCES

(09)

For the purpose of this Standard, the most recent approved version of the following referenced standards shall apply:

ANSI/AWS A3.0, Standard Welding Terms and Definitions

ANSI/AWS QC-1, Standard for AWS Certification of Welding Inspectors

AWS D18.2, Guide to Weld Discoloration Levels on the Inside of Austenitic Stainless Steel Tube

Publisher: American Welding Society (AWS), 550 NW Le Jeune Road, Miami, FL 33126

ASME Boiler and Pressure Vessel Code, Section V, Nondestructive Examination

ASME Boiler and Pressure Vessel Code, Section VIII, Division 1, Pressure Vessels



(09)

Table GR-1 Inspector's Delegate Capabilities

Capability	Trainee	QID-1	QID-2	QID-3
Materials				
(a) Identify materials				
(1) Fitting type	X	...	...	...
(2) Tube/pipe	X	...	...	...
(3) Filler materials	...	X	...	...
(4) Elastomers	...	X	...	...
(5) Process components	...	X	...	...
(b) Verify material marking to standard	X	...	...	...
(c) Measure material dimensions	X	...	...	...
(d) Measure material surface finish	X	...	...	...
(e) Verify material documentation				
(1) Material test reports (MTR)	...	X	...	...
(2) Certificates of compliance	...	X	...	...
(3) Instrument calibration records	...	X	...	...
(4) Elastomers	...	X	...	...
(f) Evaluate to acceptance criteria	...	X	...	...
(g) Verify material compliance to specification	...	X	...	...
(h) Verify material storage/handling compliance	...	...	X	...
Equipment Use				
(a) Mirrors/magnifiers	X	...	...	...
(b) Measuring devices	...	...	...	...
(1) Steel rule	X	...	...	...
(2) Calipers (dial, digital)	X	...	...	...
(3) Fillet gauge	...	X	...	...
(4) Radius gauge	...	X	...	...
(5) Temperature sensitive crayon (tempilstick)	...	X	...	...
(6) Slope level	...	X	...	...
(7) Undercut gage	...	X	...	...
(c) Borescope/fiberscope	...	X	...	...
(d) Profilometer	X	...	...	...
(e) Positive material identification (PMI)	...	...	X	...
(f) Calibration records (inspection equipment)	...	X	...	...
Knowledge and Skills				
Understand inspection fundamentals				
(a) Effective oral and written communication	...	X	...	...
(b) Quality procedures				
(1) Prepare documentation control requirements	...	...	...	X
(2) Develop inspection procedures	...	...	...	X
(c) Review of specifications	...	...	X	...
(d) Codes and Standards (training)				
(1) ASME BPE	GR/DT/SF	MJ/SD 3.12	X	...
(2) ASME B31.3	...	...	Chapter VI	X
(3) ASME BPVC Section IX	...	...	X	...
(e) Interpret welding symbols and drawings				
(1) Detail drawings (mechanical)	...	...	X	...
(2) P&ID	...	...	X	...
(3) Single line isometric drawings (weld maps)	...	X	...	...
(4) Isometric drawings (slope maps)	...	X	...	...
(5) General/fabrication arrangement drawings (details)	...	...	X	...
(6) Interpret welding symbols	...	...	X	...
(f) Prepare documents/reports in accordance with MJ 10.1 and SD-6				
(1) Material examination log	...	X	...	...
(2) Nonconformance reports	...	X	...	...
(3) Visual weld inspection	...	X	...	...
(4) Slope verification (isometric)	...	X	...	...
(5) Pressure test	...	...	X	...


Table GR-1 Inspector's Delegate Capabilities (Cont'd)

(09)

Capability	Trainee	QID-1	QID-2	QID-3
Knowledge and Skills (Cont'd)				
(g) Turnover package				
(1) Assemble	...	...	X	...
(2) Review	...	...	...	X
(h) Basic understanding of NDT/NDE				
(1) PT	...	...	X	...
(2) UT	...	...	X	...
(3) RT	...	...	X	...
(4) Eddy current	...	...	X	...
(5) Pressure/leak testing	...	...	X	...
Inspection				
(a) Perform visual inspection (other than weld inspection)	...	X	...	...
(b) Perform weld inspection	...	X	...	...
(c) Evaluate weld inspection results	...	...	X	...
(d) Perform slope verification	...	X	...	...
(e) Witness pressure tests	...	...	X	...
(f) Verify inspection compliance	...	...	X	...
(g) Review inspection reports	...	...	X	...
(h) Verify nonconformance disposition	...	...	X	...
(i) Perform installation verification				
(1) Installation per P&ID	...	...	X	...
(2) Check for cold spring	...	...	X	...
(3) Hanger verification	...	X	...	...
(4) Component installation per manufacturer's recommendations	...	...	X	...
Vessel Inspection (additional to above)				
(a) Verify surface finish	...	...	X	...
(b) Verify drainability	...	...	X	...
(c) Cleanability (CIP/riboflavin/sprayball testing)	...	...	...	X
(d) Verify dimensions and orientation	...	...	...	X
(e) Compliance with ASME Code (U-1)	...	...	...	X
(f) Documentation review	...	...	X	...
Welding Procedure Qualification				
Verify welding procedures (WPS/PQR) compliance	...	...	...	X
Welder Performance Qualification				
Verify welder qualification compliance	...	...	X	...
Project Planning				
(a) Review contract requirements	...	...	...	X
(b) Prepare weld inspection criteria	...	...	...	X
(c) Review specifications	...	...	...	X
(d) Prepare purchase specifications	...	...	...	X
(e) Develop inspection plan	...	...	...	X
Training				
(a) Provide on-the-job training for Quality Inspectors	...	...	X	...
(b) Maintain records of training	...	...	X	...
Audit				
(a) Perform vendor audits	...	...	...	X
(b) Perform fabricator audits	...	...	...	X
(c) Prepare audit and surveillance plan	...	...	...	X

ASME Boiler and Pressure Vessel Code, Section IX,
Welding and Brazing Qualifications

ASME B31.1, Power Piping

ASME B31.3, Process Piping

ASME B46.1, Surface Texture (Surface Roughness,
Waviness, and Lay)

Publisher: The American Society of Mechanical
Engineers (ASME), Three Park Avenue, New York,
NY 10016; Order Department: 22 Law Drive, Box 2300,
Fairfield, NJ 07007

ASTM A 20/A 20M, Standard Specification for General
Requirements for Steel Plates for Pressure Vessels

ASTM A 182/A 182M, Specification for Forged or Rolled
Alloy and Stainless Steel Pipe Flanges, Forged
Fittings, and Valves and Parts for High-Temperature
Service

ASTM A 213/A 213M, Specification for Seamless Ferritic
and Austenitic Alloy-Steel Boiler, Superheater, and
Heat-Exchanger Tubes

ASTM A 269, Seamless and Welded Austenitic Stainless
Steel Tubing for General Service

ASTM A 270, Specification for Seamless and Welded
Austenitic Stainless Steel Sanitary Tubing

ASTM A 312/A 312M, Seamless and Welded Austenitic
Stainless Steel Pipes

ASTM A 351/A 351M, Specification for Castings,
Austenitic, Austenitic-Ferritic (Duplex), for Pressure-
Containing Parts

ASTM A 380, Practice for Cleaning, Descaling, and
Passivation of Stainless Steel Parts, Equipment, and
Systems

ASTM A 480/A 480M, Specification for General
Requirements for Flat-Rolled Stainless and Heat-
Resisting Steel Plate, Sheet, and Strip

ASTM A 484/A 484M, Specification for General
Requirements for Stainless and Steel Bars, Billets, and
Forgings

ASTM A 666, Specification for Austenitic Stainless Steel
Sheet, Strip, Plate, and Flat Bar

ASTM A 967, Standard Specification for Chemical
Passivation Treatments for Stainless Steel Parts

ASTM B 912, Standard Specification for Passivation of
Stainless Steels Using Electropolishing

ASTM D 395, Standard Test Methods for Rubber
Property — Compression Set

ASTM D 412, Standard Test Methods for Vulcanized
Rubber and Thermoplastic Elastomers — Tension

ASTM D 471, Standard Test Method for Rubber
Property — Effect of Liquids

ASTM D 624, Standard Test Method for Tear Strength of
Conventional Vulcanized Rubber and Thermoplastic
Elastomers

ASTM D 2240, Standard Test Method for Rubber
Property — Durometer Hardness

ASTM E 112, Test Methods for Determining Average
Grain Size

Publisher: ASTM International (ASTM), 100 Barr Harbor
Drive, P.O. Box C700, West Conshohocken, PA 19428

European Hygienic Engineering & Design Group
(EHEDG), Document No. 18 — Passivation of Stain-
less Steel

Publisher: European Committee for Standardization
(CEN), Avenue Marnix 17, B-1000 Brussels, Belgium

FDA, 21 CFR, Parts 210 and 211, Current Good
Manufacturing Practices

GMP: current Good Manufacturing Practices, Title 21 of
the Food and Drug Administration

Publisher: U.S. Food and Drug Administration
(U.S. FDA), 5600 Fishers Lane, Rockville, MD 20857

ISO 34-1, Rubber, vulcanized or thermoplastic — Deter-
mination of tear strength — Part 1: Trouser, angle and
crescent test pieces

ISO 34-2, Rubber, vulcanized or thermoplastic — Deter-
mination of tear strength — Part 2: Small (Delft) test
pieces

ISO 37, Rubber, vulcanized or thermoplastic —
Determination of tensile stress-strain properties

ISO 48, Rubber, vulcanized or thermoplastic —
Determination of hardness (hardness between
10 IRHD and 100 IRHD)

ISO 815-1, Rubber, vulcanized or thermoplastic — Deter-
mination of compression set — Part 1: At ambient or
elevated temperatures

ISO 815-2, Rubber, vulcanized or thermoplastic —
Determination of compression set — Part 2: At low
temperatures

ISO 816, Superseded by ISO 34-2

ISO 1817, Rubber, vulcanized — Determination of the
effect of liquids

ISO 11137, Sterilization of health care products —
Radiation — Part 1: Requirements for development,
validation, and routine control of a sterilization
process for medical devices

Publisher: International Organization for
Standardization (ISO), 1 ch. de la Voie-Creuse, Case
postale 56, CH-1211, Genève 20, Switzerland/Suisse

ISPE Baseline® Pharmaceutical Engineering Guide for
Water and Steam Systems — Volume 4

Publisher: International Society for Pharmaceutical
Engineering (ISPE), 3109 W. Dr. Martin Luther King,
Jr. Blvd., Tampa, FL 33607

NIH (BL-1/BL-4), Biohazard Containment Guidelines

Publisher: National Institutes of Health (NIH), 9000
Rockville Pike, Bethesda, MD 20892

SNT-TC-1A, Recommended Practice for Nondestructive
Testing Personnel Qualification and Certification

Publisher: American Society for Nondestructive Testing
(ASNT), 1711 Arlingate Lane, P.O. Box 28518,
Columbus, OH 43228-0518



3-A, Sanitary Standards

Publisher: Techstreet, 1327 Jones Drive, Ann Arbor,
MI 48105

(09) GR-10 TERMS AND DEFINITIONS

annealing: a treatment process for steel for the purpose of reducing hardness, improving machinability, facilitating cold working, or producing a desired mechanical, physical, or other property.

anomaly: a localized surface area that is out of specifications to the surrounding area, and is classified as abnormal.

arc gap: for orbital GTAW, the nominal distance, measured prior to welding, from the tip of the electrode to the surface of the weld joint or insert.

arc strike: a discontinuity consisting of any localized remelted metal, heat-affected metal, or change in the surface profile of any part of a weld or base metal resulting from an arc, generated by the passage of electrical current between the surface of the weld or base material and a current source, such as a welding electrode, magnetic particle prod, or electropolishing electrode.

aseptic: free of pathogenic (causing or capable of causing disease) microorganisms.

aseptic processing: operating in a manner that prevents contamination of the process.

audit: an on-site evaluation by an ASME appointed team to review and report evidence of compliance of the applicant with regard to the requirements of the ASME BPE Standard, "after" issuance of a certificate.

autogenous weld: a weld made by fusion of the base material without the addition of filler. (See also *gas tungsten-arc welding*.)

automatic welding: welding with equipment that performs the welding operation without adjustment of the controls by a welding operator. The equipment may or may not perform the loading and unloading of the work. (See also *machine welding*.)

barrier fluid: a fluid used to separate environment from product such as water or condensate in a double mechanical seal.

bioburden: the number of viable contaminating organisms per product unit.

biofilm: a film of microorganisms or cell components adhering to surfaces submerged in or subjected to fluid environments.

biologics: therapeutic or diagnostic products generated and purified from natural sources.

biopharmaceuticals: ethical pharmaceutical drugs derived through bioprocessing.

bioprocessing: the creation of a product utilizing a living organism.

bioprocessing equipment: equipment, systems, or facilities used in the creation of products utilizing living organisms.

blind weld (or closure weld): a weld joint by design that cannot feasibly be visually inspected internally.

borescope: a device for indirect visual inspection of difficult access locations such as equipment and pipes.

break: a discontinuity in the face of a fitting.

burn-through: excessive melt-through or a hole through the root bead of a weld.

burr: excess material protruding from the edge typically resulting from operations such as cutting or facing.

butt joint: a joint between two members lying approximately in the same plane.

cartridge seal: a self-contained seal assembly.

cavitation: a condition of liquid flow where, after vaporization of the liquid, the subsequent collapse of vapor bubbles can produce surface damage.

certificate: a Certificate of Authorization issued by ASME.

Certificate of Authorization: a document issued by ASME that authorizes the use of an ASME BPE Symbol Stamp for a specified time and for a specified scope of activity.

certificate holder: an organization holding a Certificate of Authorization issued by the Society upon satisfactory completion of evaluation of ability to comply with the requirements of this Standard.

certification: documented testimony by qualified authorities that a system qualification, calibration, validation, or revalidation has been performed appropriately and that the results are acceptable.

cGMPs: current Good Manufacturing Practices. Current design and operating practices developed by the pharmaceutical industry to meet FDA requirements as published in the Code of Federal Regulations, Chapter 1, Title 21, Parts 210 and 211.

chromatography: the purification of substances based on the chemical, physical, and biological properties of the molecules involved.

clean: free of dirt, residues, detergents, or any contaminants that may affect or adulterate the product or process.

cleaning: all operations necessary for the removal of surface contaminants from metal to ensure maximum corrosion resistance of the metal, prevention of product contamination, and achievement of desired appearance.

clean-in-place (CIP): internally cleaning a piece of equipment without relocation or disassembly. The equipment is cleaned but not necessarily sterilized. The cleaning is

normally done by acid, caustic, or a combination of both, with water-for-injection (WFI) rinse.

clean steam: steam free from boiler additives that may be purified, filtered, or separated. Usually used for incidental heating in pharmaceutical applications.

closed head: for orbital GTAW, a welding head that encapsulates the entire circumference of the tube/pipe during welding and that contains the shielding gas.

cloudiness: the appearance of a milky white hue across some portion of a surface resulting from the electropolish process.

cluster of pits: two or more pits the closest distance between each being less than the diameter of any one pit.

cluster porosity: porosity that occurs in clumps or clusters.

compendial water: proportioned to comply with USP and/or any other acknowledged body of work related to the quality, manufacture, or distribution of high purity water.

compression set: permanent deformation of rubber after subscription in compression for a period of time, as typically determined by ASTM D 395.

concavity: a condition in which the surface of a welded joint is depressed relative to the surface of the tube or pipe. Concavity is measured as a maximum distance from the outside or inside diameter surface of a welded joint along a line perpendicular to a line joining the weld toes.

consumable insert: a ring of metal placed between the two elements to be welded that provides filler for the weld, when performed with fusion welding equipment. A consumable insert can also be used for the root pass in a multiple pass weld with the addition of filler wire (also called *insert ring*).

convexity: a condition in which the surface of a welded joint is extended relative to the surface of the tube or pipe. Convexity is measured as a maximum distance from the outside or inside diameter surface of a welded joint along a line perpendicular to a line joining the weld toes.

corrosion: a chemical or electrochemical interaction between a metal and its environment, which results in changes in the property of the metal. This may lead to impairment of the function of the metal, the environment, and/or the technical system involved.

cracks: fracture-type discontinuities characterized by a sharp tip and high ratio of length and width to opening displacement. A crack may not be detected with a stylus. A linear crack will produce a liquid penetrant indication during liquid penetration inspection, X-ray, or ultrasound.

crater: a depression at the termination of a weld bead.

crater cracks: cracks that form in the crater, or end, of the weld bead.

creep: a time-dependent permanent deformation that occurs under stress levels below the yield stress.

dead leg: an area of entrapment in a vessel or piping run that could lead to contamination of the product.

defects: discontinuities that by nature or accumulated effect (for example, total crack length) render a part or product unable to meet minimum applicable acceptable standards or specifications. This term designates rejectability. (See also *discontinuity*.)

deionized water: a grade of purified water produced by the exchange of cations for hydrogen ions and anions for hydroxyl ions.

delamination: separation into constituent layers.

demarcation: a localized area that is dissimilar to the surrounding areas with a defined boundary.

dent: a large, smooth-bottomed depression whose diameter or width is greater than its depth and that will not produce an indication.

descaling: the removal of heavy, tightly adherent oxide films resulting from hot-forming, heat-treatment, welding, and other high-temperature operations such as in steam systems.

dirty: a relative term indicating the condition of being contaminated.

discoloration: any change in surface color from that of the base metal. Usually associated with oxidation occurring on the weld and heat-affected zone on the outside diameter and inside diameter of the weld joint as a result of heating the metal during welding. Colors may range from pale bluish-gray to deep blue, and from pale straw color to a black crusty coating.

discontinuity: interruption of the typical structure of a weldment, such as a lack of homogeneity in the mechanical, metallurgical, or physical characteristics of the material or weldment. A discontinuity is not necessarily a defect.

distribution system: centralized system for the delivery of fluids from point of generation or supply to point of use.

downslope: that part of an automatic orbital weld sequence during which the welding current is gradually reduced prior to extinguishing of the welding arc. The downslope portion of a welded joint is seen as a tapering of the end of the weld bead with a reduction of penetration from the beginning to the end of the downslope so that the final weld bead is small with minimal penetration.

dross: a concentration of impurity formed in the weld puddle. It floats to the surface when the metal solidifies. (See also *slag*.)

duplex stainless steel: a group of stainless steels whose chemical composition is designed to produce a room-temperature microstructure that is a mixture of austenite and ferrite.

durometer: measurement of hardness related to the resistance to penetration of an indenter point in to a material as typically determined by ASTM D 2240.

dynamic seal: seal with a component that is in motion relative to a second surface.

elastomer: rubber or rubberlike material possessing elasticity. (See also *elastomeric material*.)

elastomeric material: a material that can be stretched or compressed repeatedly and, upon immediate release of stress, will return to its approximate original size.

electropolishing: a controlled electrochemical process utilizing acid electrolyte, DC current, anode, and cathode to smooth the surface by removal of metal.

etching: the process of removing a layer of metal from its surface using a chemical and/or electrolytic process.

ethical pharmaceutical: a controlled substance for the diagnosis or treatment of disease.

excessive penetration: weld penetration that exceeds the acceptance limit for inside diameter convexity. (See also *convexity*.)

fermentation: the biochemical synthesis of organic compounds by microorganisms or cultivated cells.

fermentor (fermenter): a vessel for carrying out fermentation.

fluoropolymer: polymer material having a carbon chain either partially or completely bonded to fluorine atoms.

flushing (rinsing): the flowing of water over the product and/or solution contact surfaces of system components for the removal of particulates or water soluble contaminants.

full penetration: A weld joint is said to be fully penetrated when the depth of the weld extends from its face into the weld joint so that the joint is fully fused. For a tube-to-tube weld, no unfused portions of the weld joint shall be visible on the inside diameter of a fully penetrated weld.

fusion: the melting together of filler metal and base metal, or of base metal only, that results in coalescence.

fusion welding: welding in which the base material is fused together without the addition of filler material to the weld. (See also *gas tungsten-arc welding*.)

gas tungsten-arc welding (GTAW): an arc welding process that produces coalescence of metals by heating them with an arc between a tungsten (nonconsumable) electrode and the work. Shielding is obtained from a gas or gas mixture. (This process is sometimes called TIG welding, a nonpreferred term.) GTAW may be performed by adding filler material to the weld, or by a fusion process in which no filler is added.

gasket: static seal made from deformable material compressed between two mating surfaces.

GMP facility: a facility designed, constructed, and operated in accordance with cGMP guidelines established by the FDA.

harvesting: the separation of cells from growth media. This can be accomplished by filtration, precipitation, or centrifugation.

heat number: an alphanumeric identification of a stated tonnage of metal obtained from a continuous melting in a furnace.

heat-affected zone: that portion of the base metal that has not been melted, but whose microstructure or mechanical properties have been altered by the heat of welding or cutting.

heat tint: coloration of a metal surface through oxidation by heating. (See also *discoloration*.)

higher alloy: a metal containing various alloying constituents formulated to provide enhanced corrosion resistance and possibly improved mechanical properties beyond those that are typically observed in UNS S31603 stainless steel.

hold-up volume: the volume of liquid remaining in a vessel or piping system after it has been allowed to drain.

hydrotest: a pressure test of piping, pressure vessels, or pressure-containing parts, usually performed by pressurizing the internal volume with water at a pressure determined by the applicable code.

hygienic: of or pertaining to equipment and piping systems that by design, materials of construction, and operation provide for the maintenance of cleanliness so that products produced by these systems will not adversely affect human or animal health.

hygienic clamp joint: a tube outside diameter union consisting of two neutered ferrules having flat faces with a concentric groove and mating gasket that is secured with a clamp, providing a nonprotruding, recessless product contact surface.

hygienic joint: a tube outside diameter union providing a nonprotruding, recessless product contact surface.

icicles: localized regions of excessive penetration, which usually appear as long, narrow portions of weld metal on the weld underbead. (See also *convexity* and *excessive penetration*.)

inclusions: particles of foreign material in a metallic or polymer matrix.

incomplete fusion (or lack of fusion): a weld discontinuity in which fusion did not occur between weld metal and faces or between adjoining weld beads. Also, in welding of tubing, when the weld fully penetrates the wall thickness but misses the joint, leaving some portion of the inner (inside diameter) weld joint with unfused edges.

incomplete penetration (or lack of penetration): a groove weld in which the weld metal does not extend completely through the joint thickness.

indication: a condition or an anomaly of a localized area that has not been classified as being accepted or rejected.

inspector's delegate: a person who is delegated by an owner's inspector to perform inspection functions as referenced in ASME B31.3, para. 340.4(c).

joint penetration: the depth that a weld extends from its face into a joint, exclusive of reinforcement.

lack of fusion after reflow: a discontinuity in welding of tubing where, after a reflow or second weld pass has been made, the original joint has still not been consumed, leaving the weld joint with unfused edges on the inner surface.

lamellar tears: terrace-like fractures in the base metal with a basic orientation parallel to the wrought surface; caused by the high stress in the thickness direction that results from welding.

laminations: elongated defects in a finished metal product, resulting from the rolling of a welded or other part containing a blowhole. Actually, the blowhole is stretched out in the direction of rolling.

linear porosity: porosity that occurs in a linear pattern. Linear porosity generally occurs in the root pass from inadequate joint penetration.

liquid penetrant indication: refer to ASME BPVC, Section V, Article 6, para. T-600, for testing an anomaly or an indication.

machine welding: welding with equipment that performs the welding operation under the constant observation and control of a welding operator. The equipment may or may not perform the loading and unloading of the works. (See also *automatic welding*.)

manual welding: welding in which the entire welding operation is performed and controlled by hand.

material type: a commercial designation for a given chemistry range.

maximum working pressure: the pressure at which the system is capable of operating for a sustained period of time.

maximum working temperature: the temperature at which the system must operate for a sustained period of time. The maximum working temperature should relate to the maximum working pressure and the fluids involved.

meandering: of or pertaining to a weld bead that deviates from side to side across the weld joint rather than tracking the joint precisely.

mechanical seal: a device used for sealing fluids with rotating shafts. A mechanical seal is a prefabricated or packaged assembly that forms a running seal between flat surfaces.

micron or micrometer (μm): one-millionth of a meter.

misalignment (mismatch): axial offset of the joint members.

miter: two or more straight sections of tube matched and joined in a plane bisecting the angle of junction so as to produce a change of direction.

mold flash: excess material that is greater than the designed geometry of a part that is formed in the molding process.

molded seal: a seal that is manufactured by forming in a mating cavity.

nick: a surface void anomaly caused by material removal or compression from the surface, whose bottom surface is usually irregular.

nominal outside diameter: a numerical identification of outside diameter to which tolerances apply.

nominal wall thickness: a numerical identification of wall thickness to which tolerances apply.

nonuniform mechanical polishing marks: a localized surface polishing pattern that is dissimilar to the surrounding area.

off angle: a measurement of face-to-face squareness.

off plane: a measurement of the offset between part centerlines or two planes.

open head: for orbital GTAW, a welding head that is open to the atmosphere external to the tube/pipe being welded and that does not enclose the shielding gas, which is still provided through the torch.

orange peel: an appearance of a pebbly surface.

orbital welding: automatic or machine welding of tubes or pipe in-place with the electrode rotating (or orbiting) around the work. Orbital welding can be done with the addition of filler material or as a fusion process without the addition of filler.

O-ring: ring seal of circular cross section.

outboard seal: a seal that is outside the product area in the outermost part of a mechanical seal assembly.

overlap: the protrusion of weld metal beyond the weld toes or weld root. Also, in an orbital weld, that amount by which the end of the weld bead overlaps the beginning of the weld bead (not including the downslope) on a single-pass weld.

owner/user: the body upon which final possession or use rests.

oxidation: a common form of electrochemical reaction that is the combining of oxygen with various elements and compounds.

oxide layer: an area usually located in the heat-affected zone of the weldment where an oxidation reaction has taken place.

packing: a type of shaft seal formed into coils, spirals, or rings that is compressed into the seal cavity.

passivation: removal of exogenous iron or iron from the surface of stainless steels and higher alloys by means of a chemical dissolution, most typically by a treatment with an acid solution that will remove the surface contamination and enhance the formation of the passive layer.

passive layer: a chromium enriched oxide layer on a stainless steel surface, that improves the corrosion resistance of the base metal.

passivity: the state in which a stainless steel exhibits a very low corrosion rate. The loss (or minimizing) of chemical reactivity exhibited by certain metals and alloys under special environmental conditions.

PE: polyethylene, polymer material composed of carbon and hydrogen.

penetration: see *full penetration*, *incomplete penetration*, *joint penetration*.

personal care products: products used for personal hygiene or cosmetic care.

PFA: perfluoroalkoxy, copolymer of perfluoroalkoxy and tetrafluoroethylene.

pharmaceutical: relating to the use and/or manufacture of medical drugs or compounds used to diagnose, treat, or prevent a medical condition.

pickling: a chemical process for cleaning and descaling stainless steel and other alloy parts, equipment, and systems.

pipe: pipe size is determined by diameter and either schedule, series, or SDR. For bioprocessing equipment, *pipe* does not include *tube*.

pit: a small surface void resulting from a localized loss of base material.

pitch: to cause to be set at a particular angle or slope. Degree of slope or elevation.

polymer: a molecule consisting of many smaller groups. They can be synthesized either through chain reactions or by templating. Some examples of polymers are plastics, proteins, DNA, and dendrimers.

polymeric materials: a natural or synthetic material whose molecules are linked in a chain.

polypropylene (PP): polymer material composed of carbon and hydrogen.

porosity: cavity-type discontinuities formed by gas entrapment during solidification.

pressure rating: pressure at which a system is designed to operate, allowing for applicable safety factors.

product contact surface: a surface that contacts raw materials, process materials, and/or product.

profilometer: an instrument for the measurement of the degree of surface roughness.

progressive polishing: a mechanical grinding procedure where a coarse grit material is used first and the successive operations use a finer and finer grit until the desired surface roughness is achieved.

PTFE: polytetrafluoroethylene, homopolymer material of tetrafluoroethylene.

pure steam: steam that is produced by a steam generator which, when condensed, meets requirements for water-for-injection (WFI).

purified water (PW): a classification of water according to compendial standards.

PVDF: polyvinylidene fluoride, homopolymer and/or copolymer material composed of carbon, hydrogen, and fluorine.

pyrogen: a fever-producing substance.

R_a: log of the arithmetic mean of the surface profile.

R_a max.: the highest value of a series of *R_a* readings.

reflow: a second weld pass made to correct a lack of fusion or missed joint.

reinforcement: see *convexity*.

rouge: a general term used to describe a variety of discolorations in high purity stainless steel biopharmaceutical systems. It is composed of metallic (primarily iron) oxides and/or hydroxides. Three types of rouge have been categorized.

class I rouge: a rouge that is predominantly particulate in nature. It tends to migrate downstream from its origin point. It is generally orange to red-orange in color. These particles can be wiped off a surface and are evident on a wipe. Surface composition of the stainless steel under the rouge remains unchanged.

class II rouge: a localized form of active corrosion. It occurs in a spectrum of colors (orange, red, blue, purple, gray, black). It can be the result of chloride or other halide attack on the surface of the stainless steel.

class III rouge: a surface oxidation condition occurring in high temperature environments such as pure steam systems. The system's color transitions to gold, to blue, to various shades of black, as the layer thickens. This surface oxidation initiates as a stable layer and is rarely particulate in nature. It is an extremely stable form of magnetite (iron sesquioxide, Fe₃O₄).

sanitary: see *hygienic*.

sanitary (hygienic) weld: generally considered to be a groove weld in a square butt joint made by the GTAW (or plasma) process as a fusion weld without the addition of filler material. A sanitary weld must be completely penetrated on the weld ID, with little or no discoloration due to oxidation, and be otherwise without defects that would interfere with maintenance in a clean and sterile condition.

schedule: dimensional standard for pipe as defined by ASTM.

SDR: standard dimension ratio, a sizing system for polymer piping systems that relates wall thickness to pressure rating as defined by ISO.

seal chamber: see *stuffing box*.

seal face: surface point on which a seal is achieved.

seal point: location of process boundary created by components in contact (seal), having sufficient contact stress/load to create media or environmental isolation.

seal weld: a weld used to obtain fluid tightness as opposed to mechanical strength.

self-draining: the elimination of all fluid from the system due to the force of gravity alone.

SEM: scanning electron microscope.

semi-automatic arc welding: arc welding with equipment that controls only the filler metal feed. The advance of the welding is manually controlled.

service life: the life expectancy or number of cycles for which the unit will maintain its performance.

size classification: The size of surface deficits is classified in two groups: macro, referring to indications that can be seen in adequate lighting without magnification, and micro, referring to indications that can be seen only with the aid of magnification.

slag: a concentration of nonmetallic impurities (often oxides or nitrides) that forms in the weld pool and solidifies on the underbead or weld top surface. Sometimes referred to as "dross."

slope: an incline or deviation from the horizontal. A tube or pipe installed in the horizontal plane is said to slope if one end is positioned higher than the other.

sparger: a device used to agitate, oxygenate, or aerate a liquid by means of compressed air or gas.

spatter: the metal particles expelled during welding that do not form part of a weld.

square cut: a tube end cut perpendicular to the tangent plane.

squareness: face-to-face perpendicularity.

star burst: a type of indication created during the reaction of electrochemical etching process on the foreign or refractory material (dross) on the welds or base metal.

static seal: a stationary sealing device.

steam in place (SIP): the use of steam to sanitize or sterilize a piece of equipment without the use of an autoclave.

stem seal: a seal element that is used on a shaft.

sterile: free from living organisms.

sterility: the absence of all life forms.

stuffing box: in shaft seals, the casing containing the sealing material. Seal chamber for shaft seals. (See also *packing*.)

super austenitic stainless steel: a subgroup of austenitic stainless steels having elevated levels of nickel, chromium, and molybdenum compared with standard austenitic stainless steels, e.g., UNS S31603, and that may have other additions, e.g., nitrogen and/or copper, to increase strength and resistance to pitting corrosion and stress corrosion cracking in the presence of chlorides.

super duplex stainless steel: those duplex stainless steels whose chemical composition is designed to result in a pitting resistance equivalent number (PREN) of at least 40.

surface finish: all surfaces as defined by Part SF of the current ASME BPE Standard and/or the owner/user or manufacturer and referred in R_a $\mu\text{in.}$ or $\mu\text{m.}$

surface inclusion: particles of foreign material in a metallic matrix. The particles are usually compounds such as oxides, sulfides, or silicates, but may be a substance foreign to and essentially insoluble in the matrix.

surface residual: a foreign substance that adheres to a surface by chemical reaction, adhesion, adsorption, or ionic bonding (for example, corrosion, rouging, and staining).

survey: an announced on-site evaluation by an ASME appointed team to review and report evidence of compliance of the applicant with regard to the requirements of the ASME BPE Standard "before" issuance or renewal of a certificate.

system volume: total volume of liquid in the system, including equipment, piping, valving, and instrumentation.

thermoplastic: long chain polymers that are usually not connected by crosslinks. Once formed, these materials can be reshaped.

thermoset: long chain polymers that are usually connected by crosslinks. Once formed, these materials cannot be reshaped.

transfer panel: a panel to which process and/or utilities are piped that mechanically precludes erroneous cross-connections.

tube: tube is sized by its nominal outside diameter. For bioprocessing equipment, *tube* does not include *pipe*.

tungsten inclusions: tungsten particles transferred into the weld deposit by occasional touching of the tungsten electrode used in the gas tungsten-arc process to the work or to the molten weld metal. These inclusions are often considered defects that must be removed and the weld repaired prior to final acceptance. Tungsten inclusions may be invisible to the unaided eye, but are readily identified in a radiograph.

unacceptable leakage: leakage level above which the system performance is considered unacceptable by the system user and applicable regulating body.

undercut: a groove melted into the base metal adjacent to the weld toe or weld root and left unfilled by weld metal.

underfill: a depression on the weld face or root surface extending below the adjacent surface of the base metal. (See also *concavity*.)

uniformly scattered porosity: porosity that is distributed in a weldment in a uniform pattern.

user: see *owner/user*.

validation: establishing documented evidence that the system does what it purports to do.

waviness: undulations or rippling of the surfaces.

weld joint design: the shape, dimensions, and configuration of the weld joint.

welding operator: one who operates machine or automatic welding equipment.

WFI: water for injection, a classification of water according to compendial standards.

Part SD

Design for Sterility and Cleanability

SD-1 INTRODUCTION

This Part establishes design guidelines applicable to bioprocessing equipment, components, assemblies, and systems. This Part shall be used in conjunction with other Parts of this Standard along with applicable references. Wherever “equipment” is stated in this Part, it shall mean all bioprocessing equipment, components, assemblies, and systems.

(09) SD-2 SCOPE AND PURPOSE

This Part covers closed bioprocessing systems and ancillary equipment designs. The purpose of this Part is to create a design framework using proven practices, for maintaining clean and bioburden controlled systems. Preferred methods suggested in this Part represent industry’s accepted design practices, should be regarded only as a guideline, and are not intended to limit the choice of alternative designs. The parties (owner/user, designer, and manufacturer) are free to impose their own design criteria for achieving the necessary requirements. Figures in this Part show several levels of design and fabrication. The preferred designation represents an industry accepted design. The alternate designation represents an industry design for use when physical constraints prevent the implementation of the preferred design. They are not intended to limit new and possibly better designs. Similarly, there may be equipment being successfully used that corresponds to the sketches labeled “not recommended.” This Part covers new construction and should not be used to evaluate the acceptability of existing equipment. Cleaning can be performed either by disassembling the system [clean out-of-place (COP)] or in situ [clean in-place (CIP)]. This Part will only apply to CIP and steam-in-place (SIP) processes.

This Part does not cover designs relating to hot water [176°F (80°C)], ethylene oxide sanitizing/sterilizing, or other chemical methods. Nevertheless, the basic concepts presented in this Part could be applied to those applications.

This Part does not address the issue of software/hardware as it relates to the automation of the cleaning or steaming process.

(09) SD-3 GENERAL GUIDELINES

All equipment shall be designed for the bioprocessing application, requirements, and specifications of the

owner/user. It shall be the responsibility of the owner/user to specify the cleaning and/or sanitization requirements of the equipment.

SD-3.1 Cleanability

SD-3.1.1 All surfaces shall be cleanable. Surface imperfections (e.g., crevices, gouges, obvious pits) shall be eliminated whenever feasible.

SD-3.1.2 Internal horizontal product contact surfaces shall be minimized.

SD-3.1.3 The equipment shall be drainable and free of areas where liquids may be retained and where soil or contaminants could collect.

SD-3.1.4 The equipment shall be free of areas of low flow and low velocity or impact where soil or contaminants could collect.

SD-3.1.5 All product contact surfaces shall be accessible to the cleaning solutions and shall be accessible to establish and determine efficacy of the cleaning protocol.

SD-3.1.6 Fasteners or threads shall not be exposed to the process, steam, or cleaning fluids. The use of threads within the process requires owner/user agreement. Bolted attachments should be eliminated whenever possible.

SD-3.1.7 No engraving or embossing of materials (for identification or traceability reasons) should be made on the process contact side. When markings are required on process contact surfaces, other methods of identification shall be used. (09)

SD-3.1.8 Design of corners and radii should meet the following requirements: (09)

All internal angles of 135 deg or less on product contact surfaces shall have the maximum radius possible for ease of cleanability. Where possible, these surfaces shall have radii of not less than $\frac{1}{8}$ in. (3.2 mm) except where required for functional reasons, such as the bonnet/body connection. For special cases, the radii may be reduced to $\frac{1}{16}$ in. (1.6 mm) when agreed to by the owner/user. When the $\frac{1}{16}$ in. (1.6 mm) radii cannot be achieved for essential functional reasons such as flat sealing surfaces and flow control apertures, the product contact surfaces of these internal angles shall be readily accessible for cleaning and examination.

(09) **SD-3.2 Steaming for Bioburden Control**

SD-3.2.1 While recognizing that there are various methods for controlling bioburden in equipment (see SD-2), this Standard will refer only to SIP.

SD-3.2.2 Equipment parts and components subjected to SIP should withstand continuous flow of saturated steam at a minimum temperature of 266°F (130°C) for a duration of 100 hr minimum under continuous steady-state conditions. However, at the discretion of the owner/user, conditions that are more stringent may be imposed. The use of elastomers/fluorelastomers (within a piece of equipment or certain process instrumentation) that may thermally degrade during SIP will need to be thoroughly evaluated by the owner/user or manufacturer. The overall life of the equipment may be shortened significantly if the correct elastomer or process instrument is not selected.

SD-3.2.3 All product contact surfaces shall reach the required temperatures during the SIP cycle.

SD-3.3 Surface Finishes

SD-3.3.1 The finishes of product contact surfaces shall be specified by the owner/user in accordance with the definitions of Part SF in this Standard.

SD-3.3.2 Residual polishing compounds shall be removed after the polishing operations are completed.

SD-3.3.3 Exterior, nonproduct contact surfaces are described in SD-3.8.

(09) **SD-3.4 Materials of Construction**

SD-3.4.1 Materials of construction shall be capable of withstanding the temperature, pressure, and chemical corrosiveness ensuring the purity and integrity of the product. Generally, materials such as 316, 316L, stainless steels, duplex stainless steels, and higher alloys have proven to be acceptable. The owner/user shall be responsible for the selection of the appropriate materials of construction for the specific process.

SD-3.4.2 When nonmetallic materials are used (e.g., plastics, elastomers, or adhesives), the owner shall specify which one of these materials shall carry a certificate of compliance. The conformance of material shall be explicitly stated (e.g., conforming to FDA, 21CFR, 177, and USP Section 88 Class VI).

SD-3.4.3 Materials shall be compatible with the stated bioprocessing conditions, cleaning solutions, and SIP conditions, etc., as specified by the owner/user.

SD-3.4.4 Clad or electroplated surface coatings, plating, and surface preparatory chemicals may be used provided approval from the owner/user has been obtained. All surface coatings shall remain intact and be tolerant to the process, SIP and CIP fluids, and temperatures, without peeling or cracking.

Surfaces exposed to bioprocessing fluids, cleaning, and SIP conditions must be

- (a) homogeneous in nature
- (b) impervious
- (c) inert
- (d) nonabsorbent
- (e) nontoxic
- (f) insoluble by process or cleaning fluids
- (g) resistant to corrosion, scratching, scoring, and distortion

SD-3.4.5 Materials that are in contact with bioprocessing fluids shall be identified by an industry recognized standard (see GR-9).

SD-3.4.6 Transparent materials (e.g., glass, polymer) that are used in viewing ports shall be rated for the applicable pressure, temperature range, and thermal shock.

SD-3.4.7 Internally coated glass shall only be used if the coating complies with FDA or other regulatory authority and approved by the owner/user.

SD-3.5 Fabrication

SD-3.5.1 Fabrication shall be performed in facilities where the product contact surfaces are protected from contamination. During field welding and assembly, surface contamination shall be prevented.

SD-3.5.2 Systems, equipment, and components shall be cleaned with a suitable cleaning agent and covered for protection before shipment. The use of preservative fluids is not recommended. (09)

Any product contact surfaces that require shipment with preservatives or coatings shall be

- (a) mutually agreed to, in advance, by the owner/user and manufacturer
- (b) clearly identified to all parties
- (c) in compliance with FDA or other applicable regulations, as appropriate for the process

SD-3.5.3 The use of blind welds in piping systems shall be avoided when possible. Proper installation sequencing of the piping system, in most cases, can eliminate most blind welds. See MJ-7.2.3 for further details.

SD-3.6 Static O-Rings, Seals, and Gaskets (See Fig. SD-1)

SD-3.6.1 Static seals (in piping, tubing, and similar fittings) should be designed with O-rings as the sealing elements. O-ring grooves should be shaped in accordance with the O-ring manufacturer recommendation for functionality. (09)

O-ring grooves shall be designed with cleaning in mind without diminishing their functionality.

SD-3.6.2 Gaskets and O-ring seals generally should be flush with the interior surface of the pipeline or the equipment.

SD-3.6.3 When O-ring seals are used, they shall be set back so the gap between sealing surfaces is as deep as it is wide to ensure flushing of the cavity at ambient temperature.

(09) **SD-3.6.4** All O-rings, seals, and gaskets in the product zones shall be compatible with the CIP cleaning media and SIP (e.g., steam-resistant elastomers/fluorelastomers).

SD-3.6.5 O-rings and gaskets shall be self-aligning and self-positioning.

SD-3.7 Connections and Fittings

SD-3.7.1 Design of equipment should minimize the number of connections. Butt welded connections should be used wherever practical.

SD-3.7.2 Hygienic design of connections and fittings implies

(a) a joint and gasket assembly that will maintain the alignment of the interconnecting fittings

(b) a design that ensures pressure on each side of the gasket at the interior surface to avoid product buildup in crevices that might exist in joints otherwise watertight (see Fig. SD-1)

SD-3.7.3 Connections to equipment shall use acceptable hygienic design connections, mutually agreeable to the owner/user and manufacturer.

SD-3.7.4 All connections shall be capable of CIP and SIP. Fittings shall be so designed that there will not be any crevices or hard-to-clean areas around the gasketed joint. ANSI raised face or flat face flanged joints should be avoided where possible (see Fig. SD-3).

SD-3.7.5 Ferrules and ferrule connections should be as short as possible to minimize dead legs. The use of short welding ferrules should be incorporated into the design.

SD-3.7.6 All product contact fittings should be self-draining when properly installed.

SD-3.7.7 Fittings should be selected or designed to minimize deformation of the seals into the product stream due to increased temperature or over-compression.

(09) **SD-3.7.8** Threaded fittings, exposed to process fluid, are not recommended [Fig. SD-2, illustration (c)]. O-ring connections are available [see Fig. SD-1, illustration (e)] in threaded, flanged, or clamped styles that do not impact process contact surfaces. The O-ring connections shall be manufactured to a hygienic standard (e.g., DIN 11864 part 1 to 3) or shall be accepted as a hygienic

connection by a recognized independent organization (e.g., EHEDG: European Hygienic Engineering and Design Group). O-ring connections shall comply with SD-3.6 and SD-3.7. The construction of the fitting shall be such that excessive deformation of the seal will not be caused as a result of overtightening the nut.

SD-3.7.9 The use of flat gaskets may be acceptable, (09) when agreed to by the owner/user and manufacturer, for applications where it is considered self-sanitizing (i.e., in pure steam distribution systems).

SD-3.7.10 Connections shown in Fig. SD-2 are not (09) recommended.

SD-3.7.11 The centerline radius of factory bent (09) tubes shall be in accordance with Table DT-5-1, CLR(r).

SD-3.8 Exterior Design

Equipment located in clean areas is periodically cleaned by wash-down or manually cleaned by wipe-down with harsh cleaning solutions. Such equipment shall conform to the following:

(a) Materials of construction should be corrosion resistant, easily maintained, cleaned, and sanitized without flaking or shedding.

(b) Finishes shall be compatible with the area/room classification as agreed to by the owner/user and manufacturer.

(c) Components shall be capable of being chemically cleaned, steam cleaned, or pressure washed.

(d) All burrs or weld marks shall be removed.

(e) Hinges should be easily removable and/or cleanable.

(f) Equipment mounted on cabinets that are exposed to the environment should be mounted flush.

(g) Skids should have no openings in the frame allowing water retention. Supporting skid frame structures and modules should be constructed from fully sealed tubes or pipes, which are easily cleaned. Frames should have rounded rather than sharp edges.

(h) Motors, gearboxes, and similar equipment should not retain fluids or cleaning solutions on their external surfaces.

(i) Nameplates for tagging equipment should be constructed from corrosion-resistant material such as stainless steel or plastic, and have minimum crevices. The nameplates should be attached and sealed or attached with a corrosion-resistant wire loop.

(j) There should be adequate clearance below or under the equipment for cleaning, and a clearance for discharge should be provided. Elevated equipment under open frames should have a minimum clearance of 6 in. (150 mm) for wash-down and cleaning. In other cases a minimum of 4 in. (100 mm) would be adequate.

(k) Joints and insulation materials shall be sealed and impervious to moisture and cleaning agents.

(l) Electrical cabinets should have a sloped top. Conduit should be polyvinyl chloride (PVC) coated, stainless steel, or easy to clean material. Ventilation panels and ducts should be easily accessible for cleaning.

- (09) (m) Painted surfaces shall be identified by the fabricator and have the advance approval of the owner/user. All paint systems shall be FDA compliant.

SD-3.9 Containment

The containment level of the system or individual pieces of equipment should be specified by the owner/user.

It will be the responsibility of the owner/user to determine the containment level for the particular type of equipment or system, in accordance with National Institutes of Health (NIH) guidelines and applicable local codes or environmental regulations.

(09) SD-3.10 Miscellaneous Design Details

SD-3.10.1 Grease and other lubricating fluids that are used in gear boxes, drive assemblies, etc., shall be contained to prevent leakage of the lubricants or process, either directly or indirectly (e.g., through seepage, seal leaks, etc.).

SD-3.10.2 The equipment manufacturer shall specify the type of lubricants that are to be used for maintenance. If the specified lubricant is not accepted by the owner/user, the choice of an alternative shall be agreed to by the owner/user and the equipment manufacturer.

SD-3.10.3 The owner/user shall give his approval for the lubricants that could come in contact with the product. These lubricants shall be identified by name, manufacturer, and grade and shall conform to FDA or other applicable regulatory codes.

SD-3.11 System Design

- (09) **SD-3.11.1** Dead legs will be measured by the term L/D , where L is the leg extension from the I.D. wall normal to the flow pattern or direction, and D is the I.D. of the extension or leg of a tubing fitting or the nominal dimension of a valve or instrument. For valves, L shall be measured to the seal point of the valve. Tables SD-1 and SD-2 indicate L/D values based on the BPE definition for various tubing geometries and configurations. If a branch from a primary pipeline has demonstrated flow during cleaning and SIP, it does not constitute a dead leg.

For high-purity water and clean steam systems, an L/D ratio of 2:1 is attainable with today's manufacturing and design technology. For other bioprocessing systems, such as purification, filtration, and fermentation having cluster, block, and multiport valves, an L/D of 2:1 is achievable. However, it may not be achievable with certain equipment and process configurations as they are currently manufactured. For this part, an L/D of 2:1 or

less shall be considered a target ratio, and shall not be construed to be an absolute requirement. The system designer and manufacturer shall make every attempt to eliminate system dead legs. It will be the responsibility of the system manufacturer or designer to identify where exceptions exist or where the target ratio of 2:1 cannot be met.

The target ratio may not be achievable for weir-type valves clamped to tees and certain sizes of close welded point-of-use valves, as shown in Fig. SD-4, illustrations (a) and (d). For the header and valve size combinations where the target value cannot be met using these configurations, a specific isolation valve design, as shown in Fig. SD-4, illustrations (b) and (c), may be required to achieve the target ratio.

SD-3.11.2 Hygienic support systems shall maintain the required pitch and alignment under all operating conditions taking into account thermal cycling, contractions, distortion, settling, etc.

If piping support is required within a classified space, a hygienic support system shall be used. Preferred hygienic support design shall incorporate rounded geometry to facilitate draining and cleanability, with minimal potential for the collecting and retaining of dust and residual cleaning solution or spillage on the hanger. Consideration should be given, in the design of the support, for ease of setting the correct tubing drain or slope angle. Materials of construction shall be corrosion resistant and compatible with chemical and physical performance and designed for steam service.

SD-3.11.3 Product hold-up volume in the system should be minimized.

SD-3.11.4 Bioprocessing piping and tubing design should have routing and location priority over process and mechanical support systems.

SD-3.11.5 Piping and connections to in-line valves should be of all-welded construction where feasible, practical, and agreed to by the owner/user and manufacturer. To ensure the highest degree of hygienic design, the piping systems should utilize welded connections except where make-break connections are necessary.

- (09) **SD-3.11.6** The flow balance between the spray devices in a multiple spray arrangement should be maintained to ensure meeting the specified cleaning criteria. Pipe sizes shall be specified to guarantee adequate supply and pressure to the spray devices.

SD-3.11.7 Pipeline should be fully flooded and ensure turbulent flow during cleaning.

SD-3.11.8 Routing of piping should be as direct and short as possible to ensure a minimal quantity of CIP solution to fill a circuit, and eliminate excessive piping and fittings.

SD-3.11.9 Cross contamination of product streams shall be physically prevented. Methods of separation used in industry are

- (a) removable spool piece
- (b) U-bend transfer panel
- (c) double block-and-bleed valve system (see Fig. SD-5)
- (d) mix-proof valving

SD-3.11.10 The use of fluid bypass piping (around traps, control valves, etc.) is not recommended.

SD-3.11.11 The use of redundant in-line equipment is not recommended due to the potential creation of dead legs.

SD-3.11.12 The use of check valves for hygienic process piping systems requires caution and is not recommended.

SD-3.11.13 Orifice plates, when required and used in hygienic piping systems, shall be installed in a drainable position.

SD-3.11.14 Eccentric reducers shall be used in horizontal piping to eliminate pockets in the system. See illustration in Table DT-27 for the proper orientation.

SD-3.11.15 The system shall be designed to eliminate air pockets, and prevent or minimize air entrainment.

SD-3.11.16 The centerline radius of bent tubes should be not less than 2.5 times the nominal tube diameter to prevent the deterioration of interior surfaces, (wrinkling, striations, and potential cracking). Tighter bends may be used with the approval of the owner/user when appropriate inspection techniques and procedures (borescope, sectioning, etc.) are used.

SD-3.11.17 Ball valves are not recommended in fluid hygienic piping systems. See SD-4.11.2(b) for further comments.

SD-3.11.18 Plate and frame type heat exchangers should be used only by agreement between owner and designer due to the difficulty of CIP and SIP.

SD-3.12 Drainability

- (09) **SD-3.12.1** For the purpose of sterility and cleaning, gravity is an effective way to facilitate drainage. To achieve gravity drainage, lines should be pitched to designated points at a specific slope. Refer to Nonmandatory Appendix C for suggested method of slope measurement. For gravity-drained piping/tubing systems, the owner/user may define the system slope in accordance with one of the designations listed in Table SD-3. Gravity-drained piping/tubing systems shall have a continuous pitch that is equal to or greater than the slope designation. Line sections up to 10 in. (25 cm) in length (or longer with advance approval of

owner/user) that are level or have a positive slope less than the slope designation are acceptable if the section is fitting-bound.

The system's process requirements should be considered in the selection of slope designation.

(a) Product-contact lines should be sloped to minimize pooling of product in the system.

(b) Lines that are steam sterilized in-place should be sloped to facilitate gravity drainage of condensate.

(c) Lines that are cleaned in-place should be sloped to facilitate gravity drainage of cleaning fluids.

The physical characteristics of the system (e.g., line size, materials, fluid viscosity, fluid surface tension) will influence drainability at a given slope and should also be considered. The owner/user may apply additional criteria in the selection of slope designation to address issues such as product recovery or maintenance. Fluid retention due to capillary action should be considered when using tubing less than $\frac{3}{4}$ in. (20 mm). System leveling should be considered for mobile equipment that is gravity drained.

SD-3.12.2 Piping and equipment should be installed with designated drain points to maximize self-draining properties. The number of drain points should be minimized. The equipment manufacturer shall indicate the proper orientation to optimize drainability. The installer and user shall ensure that proper orientation is achieved.

SD-3.12.3 The recommended minimum slope designation for gravity-drained product-contact process lines is GSD2.

SD-3.12.4 Lines connected to pumps should have a continuous pitch toward the pump.

SD-3.12.5 Systems or equipment that cannot be gravity-drained shall utilize forced expulsion with pressurized gas where line drainability is required (see Fig. SD-6).

SD-4 SPECIFIC GUIDELINES

SD-4.1 Instrumentation

SD-4.1.1 General

(a) Liquid filled elements in measuring devices should not contain materials that are harmful to the product.

(b) Gage siphons (pigtales) should not be used. The number of isolation valves should be minimized.

(c) All instruments, valves, and in-line devices where appropriate should be permanently marked for proper installation (e.g., flow direction, orientation, etc.).

(d) Measurement elements shall be designed in a way that a failure will not cause contamination hazards to the process and environment. (09)

(e) The internal volume of the instrument's sensing element should be minimized.

(f) Instruments should have integral hygienic fittings. Threaded ferrules are not acceptable to convert standard instrumentation to hygienic standards.

(09) SD-4.1.2 Relief Devices

(a) Rupture discs (or other hygienic pressure relief devices approved by the owner/user) on pressure vessels should be installed as close as possible to the system's highest point.

(b) The cleaning system design shall ensure that the rupture disc (or other hygienic pressure relief devices approved by the owner/user) will not be damaged by cleaning media impact.

(c) Rupture disc (or other hygienic pressure relief devices approved by the owner/user) installation shall comply with the *L/D* ratios mentioned in SD-3.11.1.

(d) Discharge piping shall comply with the appropriate code.

(e) If a reclosing hygienic pressure relief valve is used, the owner/user shall evaluate and, if necessary, mitigate the risk of product contamination associated with a leak across the valve seat.

SD-4.1.3 Liquid Pressure Regulators

(a) Regulators should be installed to be fully drainable through the outlet and/or inlet ports.

(09) (b) There shall be no voids or crevices within the area wetted by the fluid. Regulator designs, where a portion of the valve stem penetrates the sensing diaphragm, shall be avoided unless provisions are made to avoid entrapment of foreign matter and any leakage through the interface between stem and diaphragm, especially after SIP.

(c) Due to the inherent design characteristics of self-contained regulators, manual means of override may be required to allow full cleanability and drainability.

SD-4.1.4 Optical Components

(a) *Process Lighting/Light Glasses*

(1) Lights for use with vessels, sight flow indicators, instrumentation, and other equipment should be designed to minimize areas that can collect liquids and contaminants.

(2) The preferred design integrates light with sight glass. The light housing shall be designed to eliminate exposed threads and areas that collect contaminants. The light fixture shall be sealed.

(3) Mounting of a light with integral sight glass and hygienic fitting shall meet Part SG requirements.

(09) (4) Switches and cable glands shall be constructed of appropriate noncorrosive material.

(5) Cable glands are preferred for electrical connections at the light fixture.

(6) Heat generated by the light should be kept to a minimum to avoid adversely affecting the process and/or causing buildup of material on the process side

of the fixture. A thermal switch, timer, momentary switch, IR filter, or some other suitable means should be considered.

(b) A sight glass used with optical instruments, as well as cameras and camera/light combinations used for process viewing and measurement (e.g., temperature, pH, particle sizing) shall be subject to the same design criteria as stand-alone sight glasses.

(c) Preferred light glass mountings are shown in Fig. SD-13.

SD-4.2 Hose Assemblies

SD-4.2.1 General

(a) Permanently installed hose assemblies shall be installed and supported so that the entire hose is self-draining [see Fig. SD-7-1, illustrations (a) and (b)]. In temporary runs, hose assemblies may be manually drained after disconnecting.

(b) Hose assemblies shall be installed so that strain on the end connections is minimized. Hose assemblies shall not be used as substitute for rigid tube fittings or as tension or compression elements.

(c) Hose assembly length should be minimized and fitted for purpose.

(d) Hose assemblies shall be easy to remove for examination and/or cleaning. (09)

(e) Hose assembly shall be clearly marked or tagged with the design allowable working pressure/vacuum and design temperature range.

(f) Hose assemblies shall be inspected and maintained on a scheduled basis.

SD-4.2.2 Flexible Element

(a) The flexible element of the hose assembly shall be constructed of materials that will permit the appropriate degree of movement or drainable offset at installation.

(b) The interior surface of the flexible element shall be smooth and nonconvoluted.

(c) The materials used shall comply with the applicable requirements in Part PM and/or Part SG with regard to biocompatibility. The materials used must also be compatible with cleaning and/or SIP conditions. (09)

SD-4.2.3 End Connections

(a) End connections shall be of a material and design sufficiently rigid to withstand the combined forces of the burst pressure rating of the flexible element, the compression forces required to affect the secure assembly with the flexible element. [Refer to Fig. SD-7-1, illustrations (c) and (d).]

(b) End connections shall be of a material compatible with the process fluid, cleaning solutions, and steam where applicable. Materials shall meet the requirements of SD-3.4 or Part PM.

(c) End connections shall meet all surface finish requirements of Part SF or Part PM.

(d) End connections shall be a hygienic connection design per SD-3.7.

SD-4.3 Centrifuges

(09) SD-4.3.1 General

(a) Centrifuges designed for CIP and SIP shall have all product contact surfaces accessible to the CIP and SIP fluids, and be accessible for examination.

(b) Centrifuges that are not designed for CIP or SIP should be easily disassembled and reassembled for cleaning and examination.

(c) The owner/user shall inform the manufacturer of the cleaning requirements and the bioburden control method (e.g., temperature, pressure, chemistry).

(d) All crevices and corners, etc., should be accessible for visual examination and cleaning.

(e) Hexagon socket head cap screws shall not be used if they are in contact with the product.

(f) No exposed lubricated bearings shall be allowed in product contact zones.

(g) The centrifuge manufacturer should minimize all unwanted areas where solids may accumulate. These should include threads, gaps between parts, crevices, etc. The centrifuge manufacturer shall identify all areas of primary and incidental product contact that require manual cleaning in addition to CIP.

(09) SD-4.3.2 Product Contact Surface Finishes (Process Contact/Wetted Surfaces)

(a) Surface finish specifications shall comply with Parts SF and MJ of this Standard.

(b) The owner/user and manufacturer shall agree on the required finishes for the various parts. The surface finish of machined components or parts shall be specified by the manufacturer and agreed upon by the owner/user.

(c) Provisions should be made for inspection prior to assembly into larger assemblies of subcomponents and parts. Provisions shall be made to enhance the cleanability of the machined surface by use of sloping, draining, electropolishing of surface, or other means.

(09) SD-4.4 Filtration Equipment

(a) All wetted surfaces should be accessible for cleaning and examination.

(b) The filter housing shall be designed to allow for complete venting and draining. Liquid tee-type filter housings should be installed vertically, and vent type in-line filter housings should be installed vertically with the condensate/drain port directed downward (see Fig. SD-8).

(c) All nozzle connections shall be of a hygienic design.

(d) Baffle plates, when used, should be cleanable and designed for SIP.

(e) The housing assembly, tube-sheets, end plates, and connections should be designed to prevent bypassing of the product around the element.

(f) Parts forming internal crevices should be easily disassembled to enable access for cleaning.

(g) Vent filters for hot process services should be heat traced or steam jacketed. Other methods for preventing moisture accumulation in vent filters, such as vent heaters or condensers, could be considered.

SD-4.5 Hygienic Pumps

(09)

SD-4.5.1 General

(a) Pumps shall be cleanable. Pumps shall be selected according to the operating conditions determined by the end-user/owner (e.g., process, CIP, SIP, passivation).

(b) All product contact connections to the pump shall be of a hygienic design (see Fig. SD-1).

SD-4.5.2 Hygienic Centrifugal Pumps

(a) Hygienic centrifugal pumps shall be capable of CIP.

(b) All process contact surfaces shall be drainable without pump disassembly or removal.

SD-4.5.2.1 Impeller and Impeller Fastening Devices

(a) Shrouded/closed impellers should not be used. Figure SD-7-2 illustrates open, semi-open, and closed impeller configurations.

(b) Impeller shall be attached to shaft in a way that all crevices and threads are not exposed to product. Threads, such as in an impeller nut/bolt, shall be sealed by an O-ring or hygienic gasket. Refer to Fig. SD-7-3. The use of O-rings or hygienic gaskets shall be consistent with Part SG.

SD-4.5.2.2 Casing and Casing Drain

(a) Suction, discharge, and casing drain connections shall be an integral part of the pump casing.

(b) Casing drains shall be at the lowest point of the casing, to ensure drainage (see Fig. SD-7-4).

(c) The use of an elbow type casing drain is not recommended without the use of an automatically controlled drain. The casing drain connection shall be designed to minimize the L/D ratio as shown in Fig. SD-7-5.

(d) Pump discharge connection should be tilted to allow for full venting of the casing (see Fig. SD-7-4).

SD-4.5.2.3 Shaft Seal

(a) All pump seals should be designed to minimize seal material degradation.

(b) Shaft seals shall conform to Part SG.

SD-4.5.3 Hygienic Positive Displacement Pumps

(a) When possible, positive displacement pumps should be configured with vertically mounted inlets and outlets to promote drainability and venting.

(b) When using internal bypass pressure relief devices, they shall be of a hygienic design. It is preferred

that an external, piping mounted relief device (hygienic rupture disc) rather than a pump mounted bypass be used.

(09) SD-4.6 Process Valves

SD-4.6.1 General: Valves

(a) Process flow valves (e.g., diaphragm valves) should be of a body and port design so that the body will optimize drainability when properly installed. All hygienic valves should be welded into the process line.

(09) (b) Valve surfaces that may become product contact surfaces if a component (e.g., diaphragm) fails in service shall be readily accessible for examination, maintenance, and cleaning.

(c) Tee-body and cross-body sanitary valves shall be positioned to ensure that the valve body will optimize drainability when installed in a piping system.

(d) Isolation and block valves, which are located on bosses or tees, should be installed close-coupled to reduce or eliminate dead legs. (When the stem of a three-port valve moves from one position to the other such that all ports are connected for a brief period of time, this will cause mixing at first and then a resultant dead-end in the previous path while the current path is in use.) If this is not acceptable, two shutoff valves may be used instead.

(e) Multiport divert valves shall be installed to optimize drainability.

(f) The internal volume of the valve should be kept to a minimum.

(g) All cavities shall be easily accessible for cleaning by CIP fluids and SIP steam, and shall be designed to optimize drainability.

(h) Any crevices, void volumes, and/or gaps between mating parts should be minimized.

(i) Any guiding of valve trim and operating mechanisms shall be minimized in areas in contact with bioprocessing fluids.

(j) All valves shall be capable of being fully opened or exposed during CIP.

(k) A secondary stem seal should be fitted with a telltale connection between the primary and secondary stem seal to indicate primary seal leakage.

SD-4.6.2 Diaphragm Valves

(a) Diaphragm-type valves are specifically preferred for bioprocessing fluid applications.

(b) Valves will be designed so that complete drainage of fluid from inlet to outlet is optimized when mounted in the position specified by the manufacturer. Drain marks permanently marked on both sides of the valve body will show the correct mounting position to optimize drainability.

(c) Valve design will eliminate entrapment zones within the valve fluid cavity.

SD-4.6.3 Stem Seal Valves. Valve seals should comply with Part SG of this Standard.

SD-4.6.4 Ball Valves. The ball valve (Fig. SG-17) is a quarter-turn valve used in on/off fluid flow applications in which the controlling mechanism is a machined ball. While the ball valve should not be considered hygienic for product-contact applications, there are fluid service applications (e.g., clean steam, process gases) in which its use may be considered if the following requirements are met:

(a) The body and port of the ball valve shall facilitate drainability.

(b) The valve shall be maintainable in place. All wetted surfaces of a valve shall be accessible for examination, maintenance, and cleaning.

(c) All liquid contact surfaces shall be compatible with SIP.

(d) All seats and seals shall comply with the requirements in Part SG, or as agreed upon between the manufacturer and end user.

(e) The metallic fluid-contact surfaces of the valve, including the body cavity, shall comply with the applicable requirements in Part SF.

(f) The valve bore I.D. shall match the I.D. of the connecting tubing.

(g) Cavity fillers should not be used.

SD-4.7 Vessels, Tanks, Bioreactors, Fermenters, and Columns

SD-4.7.1 General

(a) This section defines the minimum requirements that are to be met in the design, fabrication, and supply of biopharmaceutical vessels, tanks, bioreactors, fermenters, and columns. This section will refer to all of the above as vessels whether they are pressurized or not.

(b) Design and fabrication of vessels and internal parts shall ensure that surfaces are free of ledges, crevices, pockets, and other surface irregularities. If more restrictive tolerances are required, they shall be included as part of the fabrication specifications for the project.

(c) All heat transfer surfaces should be drainable and ventable.

(d) Breastplates, reinforcing pads, doubler plates, position pads, etc., which are required for welding dissimilar material to the vessel should be of the same material as the vessel. No telltale holes are allowed on product contact surfaces and those, which are outside, should be cleanable.

(e) Vessels that are to handle above 176°F (80°C) [e.g., SIP, hot water-for-injection (WFI), hot U.S. Pharmacopeia (USP) waters, and hot CIP solutions] should be designed for full vacuum service.

(f) Top and bottom heads on vessels should be free-draining. Dished heads such as ASME flanged and dished (F&D), elliptical, and hemispherical are the usual

choice; however, flat and conical heads should slope at not less than $\frac{1}{8}$ in./ft (10 mm/m) to a common drain point.

(g) All internal surfaces should be sloped or pitched for drainability.

(09) (h) Test protocols for drainability shall be agreed upon in advance, by all the parties (see SD-5.4). All vessels should be checked for drainability during fabrication.

(09) SD-4.7.2 Vessel Openings

(a) Nozzles that are designed to be cleaned by a spray device should have the smallest L/D ratio possible. For non-flow through nozzles, the target L/D ratio is 2:1 (see Fig. SD-9).

(b) Bottom-mounted agitators, pads, etc., shall not interfere with the drainability of the vessel.

(c) All instrument probes and any sidewall penetrations (see Fig. SD-14) shall be sloped for drainage, unless the instruments used require horizontal mounting (see Fig. SD-10).

(d) Blank covers shall have the same finish as the vessel internals.

(e) Drain valves should optimize drainability and minimize dead legs.

(f) All CIP devices should be drainable and self-cleaning.

(g) The location and number of spray devices should be chosen to eliminate shadowing at internal parts such as mixer shafts, dip tubes, and baffles.

(h) Sparger and dip tubes shall be designed in accordance with SD-4.7.1(a), (b), (e), (g), and (h). Sparger and dip tubes shall incorporate low point drains (where applicable, i.e., horizontal lines) and be supported to ensure drainability.

(i) The number of shell side nozzles and connections should be minimized.

(j) Manways on the side shell of a vessel shall be installed only by agreement of the owner/user. If side-shell manways are required, they shall be sloped for drainage.

(k) Sample valves should be designed for CIP and SIP. Sample valves located on vessels shall be of a hygienic design, either flush with the inside wall of the vessel or with a target L/D ratio of 2:1.

(l) Sample valves should not be located on bottom heads.

(m) Dip tubes and spargers mounted in the nozzle neck should have an annular space between the O.D. of the dip tube or sparger and the I.D. of the nozzle neck in accordance with Table SD-4. An L/A ratio of 2:1 or less is recommended (see Fig. SD-11). If a larger L/A ratio exists, a method for cleaning this space shall be specified. In all cases sufficient annular space to allow access for CIP coverage shall be provided.

(n) As required by the process, inlet nozzles tangential to the vessel surface may be used (see Figs. SD-12 and 13).

(o) Nozzle connections less than 1 in. (25 mm) in diameter are not recommended unless agreed to by the owner/user and manufacturer.

(p) Sight glasses on the vessels should be designed with reference to SD-4.7.2(a). Sight glasses on vessels should be designed with the smallest L/D ratio possible, and incorporate cleanable O-ring designs when applicable (see Fig. SD-16).

(q) Manway covers should be dished rather than a flat design.

(r) Flanges that have metal-to-metal contact on the product side shall not be used. See Fig. SD-10 for possible designs that minimize the crevice on the internal side-wall of the vessel.

(s) All side-shell and vessel head nozzles should be flush with the interior of the vessel (see Fig. SD-19). Additional ports may require a minimum projection to ensure additives are directed into the vessel fluid.

SD-4.7.3 Internal Components

(a) When expansion joints are used internally, the surface in contact with the process fluids shall have open convolutes without guides as the preferred design.

(b) Internal support members shall be solid, rather than hollow, which have a higher risk of fatigue and contamination problems (see Fig. SD-17).

(c) Mitered fittings for internal pipe work shall only be fitted with the prior agreement between the owner/user and manufacturer. When mitered joints are used, they shall be designed and fabricated in accordance with the appropriate codes (see Fig. SD-18). (09)

(d) Vessels shall drain to a common point and shall not have multiple draining points, unless agreed to between the owner/user and manufacturer.

(e) The number of components inside the vessel should be minimized to ensure the proper drainability and cleanability of the vessel, and when used, if possible, should be supported by a solid support structure.

SD-4.7.4 Fabrication

(a) Butt welds should be used, if possible, minimizing lap joint welds and eliminating stitch welding.

(b) Flanges are not recommended, and their use shall be minimized. The bore of weld neck flanges shall be the same as the I.D. of the connected pipe or tubing to prevent ledges and nondrainable areas.

(c) Where it is inevitable and Class 150 slip-on flanges are used, the bore side bevel weld shall be designed in a way to eliminate potential CIP difficulties. (09)

(d) During handling and transportation, vessels and their parts and piping assemblies shall be suitably protected to prevent damage to polished surfaces.

SD-4.7.5 Finishes

(a) Surface finishes shall be specified and measured as required by Part SF. Surface finish coupons shall be submitted when agreed to by the owner/user and manufacturer.

(b) Product contact surface finish specifications shall pertain to all the wetted or potentially wetted surfaces (e.g., vapor space, nozzle necks, agitators, thermowells, dip tubes, baffles, etc.).

(c) The polishing of a connection face, body flange, etc., shall extend up to the first seal point.

SD-4.7.6 Sight Glasses

(a) When glass is used as the sight glass material, the preferred method is glass fused-to-metal hermetic compression seal. The fused glass shall be circular in shape within the metal frame.

(b) Bubbles in the fused sight glass are acceptable but the size and quantity should be kept to a minimum. Any bubbles at the glass surface are not acceptable.

(c) The seal point of the glass fused-to-metal sight glass is at the surface. The surface of the sight glass shall be integral, continuous, and free of cracks, crevices, and pits.

(d) Cracked glass shall not be used and is cause for rejection and removal.

(e) Surface finish for the metal frame shall meet the requirements of SD-3.3.

(f) Sight glasses shall be marked with the glass type, maximum pressure, and temperature rating per DT-3.2 and DT-3.3.

(g) Part SG requirements shall be met when mounting a sight glass.

(h) Preferred sight glass mountings are shown in Fig. SD-16.

SD-4.8 Agitators and Mixers

SD-4.8.1 General

(a) All product contact surfaces of agitators and mixers with their associated components shall be accessible to the cleaning fluids as specified by the end-user for clean in-place service (CIP; e.g., via spray, directed flow, immersion, etc.).

(b) Product contact surfaces should be self-draining and shall not inhibit drainage of the vessel.

(c) Machined transitions (shaft steps, coupling surfaces, wrench flats, etc.) should be smooth, with 15 deg to 45 deg sloped surfaces.

(d) The annular space between the agitator shaft and the agitator nozzle shall, for cleaning purposes, have the target maximum L/A ratio of 2:1 or a minimum of 1 in. (25 mm) gap, whichever is larger, to facilitate CIP spray coverage [see Fig. SD-11, illustration (b)].

(e) Cleaning and sterilization parameters shall be provided by the owner/user prior to design of the agitator. The manufacturers of agitators and mixers shall verify the cleanability of their equipment as specified and agreed to with the end-user.

(f) Top-entering mixers with shaft seals are typically mounted to a vessel using a flanged or hygienic clamp connection [see Fig. SD-15, illustrations (a) and (b)]. The designer shall ensure that

(1) the use of O-rings or hygienic gaskets to seal between mating surfaces shall be consistent with the current guidance provided in Part SG

(2) the selected mounting arrangement will support the agitator mounting design loads while achieving an appropriate seal

(3) the flange and nozzle construction is consistent with requirements of other applicable codes and standards [e.g., ASME BPVC, Section VIII, Division 1; ASME B31.3; etc. — see Fig. SD-15, illustration (c)]

(g) Socket head cap screws shall not be used in contact with the product.

(h) The design of agitator product contact parts should minimize the occurrence of void spaces. All voids should be closed by either fabrication (welding) or approved sealing techniques (O-ring seals, etc.).

(i) The use of in-tank nonwelded connections (shaft couplings, impeller hub-to-shaft, impeller blade-to-hub, etc.) should be avoided to minimize potential cleanability issues.

SD-4.8.2 In-Tank Shaft Couplings

(a) Welded in-tank shaft connections are preferred.

(b) The use of in-tank shaft couplings shall be agreed to by the owner/user.

(c) In-tank couplings shall be of an acceptable hygienic design. See examples in Fig. SD-21-1.

(d) In-tank coupling location should be driven by process and mechanical considerations.

(e) Threaded shaft connections are preferred for in-tank couplings (see Fig. SD-21-1).

(1) Shaft rotation is limited to a single direction for threaded shaft connections to ensure that shaft sections do not separate.

(2) The designer will ensure that the use of a threaded shaft connection is appropriate for the selected shaft diameter and design loads.

(3) Hygienic bolted coupling construction may be used where appropriate for the particular application (see Fig. SD-21-1).

(f) Threads shall not be exposed in any type of shaft or coupling hardware connection.

(g) The preferred location for fastener hardware is on the underside of couplings. Recommended fastener types include

(1) hex-head cap screws

(2) acorn-head cap screws

(3) threaded studs with acorn nuts

Fastener heads shall be free of raised or engraved markings that might inhibit cleanability.

(h) O-rings rather than flat gaskets are preferred to seal coupling mating surfaces. Figure SD-21-2 presents

the following acceptable approaches for seal applications:

(1) O-ring located in groove inboard of the coupling outside diameter; outboard clearance space provided to facilitate flow of CIP fluid

(2) O-ring located in groove inboard of the coupling outside diameter; O-ring fully confined by the coupling halves

(3) flat or sanitary gasket located between coupling faces; process-side gasket intrusion to be consistent with current guidance per Part SG

(4) O-ring located at the outer circumference of the coupling; O-ring restrained by lip at coupling outside diameter

(i) Bolted flanges shall be sealed. Examples of sealed fasteners are shown in Fig. SD-21-3.

(1) O-ring seal

(2) O-ring seal alternate

(3) seal washer with metal core

SD-4.8.3 Shafts and Keyways

(a) One-piece shaft construction, without mechanical couplings, are preferred.

(b) Solid shafts are preferred over hollow shafts.

(c) Hollow shafts, if used, shall be of sealed (welded) construction, inspected for integrity, and accepted per criteria given in Part MJ prior to installation.

(d) Keyways exposed to product are not recommended.

(e) Keyways, where employed due to mechanical design considerations, shall have edge radii as specified by SD-3.1.8.

(f) Keyways may require additional design and/or cleaning practice to ensure drainage and cleanability, e.g., spray ball and/or wand additions, increased CIP flow, and adjusted spray coverage.

(g) Permanent shaft hardware that may be required for routine maintenance (e.g., support collars for mechanical seal installation and removal, lifting eyes for shaft and/or impeller installation and removal, etc.) shall be fully drainable and cleanable as noted for other features in contact with the product.

SD-4.8.4 Hubs and Impellers

(a) All-welded impeller assemblies (e.g., hubs, blades) are preferred.

(b) Impeller hubs welded to the shaft are preferred over removable hubs.

(c) Removable, hygienic impellers may be used where impeller adjustment or substitution is required for process reasons or where impeller removal is required due to mechanical design and/or installation considerations.

(1) Removable impellers may be one-piece or split construction.

(2) Hub-to-shaft clearance for removable impellers shall be sufficient to preclude shaft surface finish damage during installation and removal.

(3) Removable hardware (e.g., impeller hub and shaft, impeller set-screws and hub, etc.) should be sealed in a manner consistent with the guidance provided for in-tank couplings (see SD-4.8.2).

(d) Removable impellers and impellers with flat, horizontal surfaces (e.g., flat-blade disc turbines, concave-blade disc turbines, etc.) may require additional design and/or cleaning practice to ensure drainage and cleanability, e.g., drain holes, spray ball and/or wand additions, increased CIP flow, adjusted spray coverage, impeller rotation.

SD-4.8.5 Impeller and Shaft Support Bearings

(a) Normal operation of a shaft-steady bearing or a magnetically driven mixer with in-tank impeller or shaft support bearings (see Figs. SD-21-4 and SD-21-5) generate particulate debris. It is the responsibility of the end-user to establish compliance with applicable standards (e.g., USP limits for particulate material in injectibles) as appropriate.

(b) Tank plates that support bottom-mounted magnetically driven mixers shall not interfere with drainage of the vessel.

(c) When an application mandates the use of steady/foot bearings, design features and/or procedures are required to ensure cleanability (e.g., drain holes, spray ball and/or wand additions, increased CIP flow, operating the steady bearing immersed in CIP fluid).

(d) Shaft-steady bearings, where used, shall not interfere with the drainage of the vessel.

(e) Shaft-steady bearing pedestal support members may be of solid or hollow construction. Hollow pedestal supports, if used, shall be of sealed (welded) construction, inspected for integrity, and accepted per criteria given in Part MJ after installation.

(f) Magnetically driven mixers require design features and/or procedures to ensure cleanability (e.g., drain holes, spray ball and/or wand additions, increased CIP flow, operating the agitator with the magnetically driven impeller immersed in CIP fluid).

(g) The arrangement of wear surfaces (bushing, shaft, or shaft sleeve) shall facilitate drainage.

SD-4.8.6 Mechanical Seals

(a) Mechanical shaft seals shall incorporate design features for drainability, surface finish, material of construction, etc., as outlined in Part SD, and shall be suitable for the application (e.g., Process, CIP, SIP, Passivation).

(b) Normal operation of a mechanical seal generates particulate debris. It is the responsibility of the end-user to establish compliance with applicable standards (e.g., USP limits for particulate material in injectibles) as appropriate.

(c) Seal debris wells or traps (see Fig. SD-21-6) may be used to prevent ingress of seal face wear particles that could contaminate the process fluid.

(e) Refer to Part SG of this Standard for specific seal design details.

SD-4.9 Heat Exchange Equipment

(09) SD-4.9.1 General

(a) Straight tube heat exchangers are easier to clean and inspect. The tubes can be seamless or full-finish welded, as specified by the owner/user or manufacturer.

(b) The heat exchanger product and non-product contact surface inspection shall be possible by conventional means.

(c) The technique used to form U-bend tubes shall ensure the bending process does not create structural imperfections (e.g., cracks, voids, delaminations). The technique should minimize surface imperfections (e.g., orange peel, rippling). If requested by the end-user, the manufacturer shall supply a sectioned sample of the bend area.

(1) The sectioned sample should be from the same tube batch or heat that was used to fabricate the heat exchanger.

(2) The sectioned sample shall be the smallest bend radius in the exchanger.

(3) The sample shall be sectioned so that bend's centerline is visible.

(d) The internal surface of the U-bends shall be free of relevant liquid penetrant indications, as defined by ASME BPVC, Section VIII.

(e) The I.D. of the U-bends shall be large enough for a borescopic inspection.

(f) Minimum recommended bend radii for heat exchangers should be as follows:

Nominal Tube O.D.		Min. Bend Radius	
in.	mm	in.	mm
0.375	9.5	0.625	15.8
0.500	12.7	0.750	19.1
0.625	15.8	0.938	23.8
0.750	19.1	1.125	28.6
1.000	25.4	1.500	38.1

(g) Welded shell and tube heat exchangers shall be of a double tubesheet design to prevent product contamination in the case of a tube joint failure (see Fig. SD-20).

(1) During fabrication, when the tubes are to be expanded into the inner and outer tubesheets, the product contact surface must not be scored.

(2) Tubes shall be seal welded to the outer tubesheet.

(3) The distance between inner and outer tubesheets shall be sufficient to allow leak detection and examination.

(4) Tubesheets and channels shall be drainable.

(h) The purchaser shall specify the orientation of the exchanger (i.e., horizontal or vertical), and the manufacturer shall ensure the complete product drainability,

other than the natural cohesive properties of the product, at the specified orientation. If this hold-up is unacceptable, then the system needs to be designed with some type of assist to aid draining, such as an air blowdown.

(1) In the specified orientation, the shell side shall also be drainable (e.g., WFI condensers).

(2) Transverse baffles with notches should be provided, when necessary, to drain the shell.

(3) The heat exchanger bonnet shall be match marked for proper orientation to ensure drainability or cleanability.

(i) Heat exchanger thermal and mechanical calculations shall be performed for both operating and SIP cycles.

(j) In shell and tube heat exchangers, the design pressure for the product side shall be no less than the design pressure of the utility side.

(k) The type of connections to the utility side (shell side) shall be agreed to between the owner/user and manufacturer.

SD-4.9.2 Cleaning and Steaming

(09)

(a) The product contact surfaces shall be constructed to withstand CIP and SIP or other cleaning/bioburden control methods specified by the owner/user.

(b) The cleaning and steaming conditions shall be provided by the owner/user prior to the design of the heat exchanger.

SD-4.9.3 Gaskets and Seals

(a) Gaskets that are in contact with product shall be removable and self-positioning, and shall have readily cleanable grooves.

(b) Channel/bonnet gaskets shall be of a cleanable design.

SD-4.10 Cell Disrupters

SD-4.10.1 Product contact material shall not affect product quality or integrity.

SD-4.10.2 The device shall be designed with the ability to optimize drainability.

SD-4.10.3 The design shall incorporate nonshedding components and parts.

SD-4.10.4 Safety rupture discs shall be oriented for drainability, while maintaining system integrity and safety.

SD-4.10.5 The disrupter shall be designed for ease of disassembly to allow for COP.

SD-4.11 Compensial Water and Steam Systems

SD-4.11.1 Clean Steam Distribution System (Includes: Pure Steam)

(a) The clean steam distribution system shall have adequate provision to remove air during start-up and normal operations. The use of clean steam air vents

installed at locations where air is prone to collect, such as at the ends of steam headers, can assist in this requirement.

(b) The horizontal distribution lines should be sloped in the direction of flow as indicated in SD-3.12.1. Where necessary, increases in height should be achieved by vertical risers (see Fig. SD-22-1).

(c) Adequate provision should be made to allow for line expansion and to prevent sagging of the distribution lines, so that line drainage is not reduced.

(d) Clean steam distribution systems shall not be directly connected to any nonhygienic steam systems, e.g., plant steam systems.

(09) (e) Trap legs for the collection of condensate from the steam distribution system should be of equal size to the distribution line for sizes up to 4 in. (100 mm), and one or two line sizes smaller for lines of 6 in. (150 mm) or larger. These shall be trapped at the bottom. The line size reduction can be made after the branch to the trap leg (see Fig. SD-22-2).

(f) Trap legs should be installed at least every 100 ft (approximately 30 m), upstream of control and isolation valves, at the bottom of vertical risers, and at any other low points.

(g) Condensate shall be allowed to drain to and from steam traps. The use of overhead, direct-coupled, pressurized condensate return systems should be avoided (see Fig. SD-22-2).

(h) Where possible, all components within the pure steam distribution system should be self-draining.

(i) Dead legs should be avoided by design of runs and the use of steam traps to remove condensate (see Figs. SD-22-1 and SD-22-2).

(j) Steam distribution branches and points-of-use should be routed from the top of the steam header to avoid excessive condensate loads at the branch (see Fig. SD-22-2).

(k) Clean steam condensate sampling, using a sample cooler/condenser, should be employed to collect representative sample(s) of the system (e.g., generator outlet, distribution header ends, critical points-of-use, auto-claves, and SIP stations).

SD-4.11.2 Clean Steam Valves. This section covers isolation, regulation, and control valves that are part of the clean steam system and are subject to continuous steam service.

(a) Where possible, valves for clean steam service shall be designed for drainability, and in all cases shall have minimal fluid hold-up volumes.

(b) Ball valves are an acceptable industry standard for isolation purposes on continuous clean steam service. Three-piece-body ball valves should be used instead of single-body designs for both cleanability and maintainability. The bore of the ball valve assembly shall match the inside diameter of the tube (see Fig. SG-17).

(c) All clean steam service components shall be suitable for continuous steam service at the temperatures and pressures specified by the owner/user.

(d) Requirements for operation under CIP and SIP conditions [see SD-4.6(j) and (k)] can be relaxed when agreed to by the owner/user.

(e) Secondary stem seals with telltale connections are not required for steam service.

(f) Steam service valves shall be accessible for maintenance.

SD-4.11.3 Steam Traps

(a) Steam traps are not considered hygienic. Steam trap bodies shall have an internal surface finish (excluding the bellows assembly) as agreed to by all parties. Surface finish specification shall match the clean steam condensate tube finish specification unless the condensate downstream of the trap is used in the process or sampled for quality assurance.

(b) Where used in process systems, the traps shall be capable of effectively venting air.

(c) Where installed on process systems, traps shall be maintainable to allow easy examination and cleaning. Welded traps are acceptable if agreed to by the owner/user. (09)

(d) The trap design and mode of operation shall be such that the risk of soil attachment to the wetted surfaces is minimized, especially around the bellows and seat (see Fig. SD-22-3).

(e) The trap shall be sized and installed to operate such that there is no backup of condensate into the process equipment and clean steam system under operating conditions. Operating conditions include heat-up, hold, and cooldown.

(f) The trap shall be designed such that the normal mode of mechanical failure will be in the open position.

(g) Thermostatic steam traps, installed in vertical trap legs, are preferred for use in clean steam systems (see Fig. SD-22-3).

(h) Trap operation/reactivity should be improved by the installation of an uninsulated section of tubing upstream of the trap [suggested 12 in. (30 cm) as recommended by supplier] (see Fig. SD-22-2).

SD-4.11.4 Compensial Water Systems

(a) Compensial water systems, such as USP Grade Water-for-Injection (WFI), USP Grade Purified Water, and Highly Purified Water, shall be designed as looped circulatory systems, rather than noncirculating, dead-ended, branched systems. (09)

(b) Loops shall be designed to provide fully developed turbulent flow in the circulating sections, and prevent stagnation in any branches.

SD-4.11.5 Point-of-Use Piping Design for Compensial Water Systems. Point-of-use (POU) can be defined as a location in a compensial water loop where water is accessed for the purpose of processing and/or sampling.

Typically, the point-of-use assemblies are composed of the following elements:

(a) piping associated with a compendial water loop at the physical POU

(b) POU valves, equipment, and instruments

Additional process components and equipment may be added to satisfy application and/or system requirements and will be discussed further in this Part (see Fig. SD-23-1).

SD-4.11.6 Critical Design Criteria for Point-of-Use Assemblies

(a) All POU assemblies will be designed to optimize drainability through the POU valve.

(b) Assemblies will be designed to promote the ability to CIP, SIP, and/or purge with clean gasses.

(c) Valves used in point-of-use applications should be welded into the water distribution loop where possible. Current industry designs are available to achieve a target L/D ratio of 2:1 or less (see SD-3.11.1).

(d) Sample valves should be integral to the design of the primary valve in order to reduce dead legs in the system.

(e) Sample valves should be installed only as needed on the main loop.

(f) Sample valves should be installed where water is utilized for the process to demonstrate water quality compliance to compendial monographs.

(g) Any valve used to provide clean utility processes to the POU assembly (e.g., steam or clean gas) should be fabricated in such a manner as to achieve a target L/D ratio of 2:1 or less downstream from the primary POU valve [see Fig. SD-23-1, illustrations (a) and (c)].

(h) The length of tubing from POU valves to process equipment should be minimized [see Fig. SD-23-1, illustrations (a) and (b)].

(i) If evacuating the system is not possible, appropriate porting of the primary POU valve should be accomplished to facilitate sanitization.

(j) When heat exchangers are used as point-of-use coolers [see Fig. SD-23-1, illustration (c)], the design should be hygienic in design (e.g., double tubesheet shell and tube) and optimize drainability.

(k) Physical breaks shall be employed between hoses, drain valves, or any other component leading to drains or sinks to avoid back siphoning into the POU assembly [see Fig. SD-23-1, illustrations (d) and (e)]. The distance H of the physical break should be at least twice the inner diameter of the hoses, drain valves, or any other component leading to drains or sinks to avoid back siphoning into the POU assembly. The break shall be at least 1 in. (25 mm) for hoses, drain valves, or other components with internal diameters less than or equal to $\frac{1}{2}$ in. (13 mm) (see Fig. SD-23-2).

(l) Tubing and other piping materials (except for sample valve assemblies) should be a minimum of $\frac{3}{4}$ in.

(19 mm) in diameter to facilitate free drainage of water after use.

(m) Slope of tubing is the primary mechanism to aid in drainability. Paragraph SD-3.12 provides information on appropriate minimum tubing support.

(n) A POU may include a venturi or orifice plate, if the restriction of water flow is required. Where used, the additions of these components will require a blow-down to ensure drainability.

(o) When compendial water systems are constructed of 316L stainless steel or other alloy steels, the surface finish should be less than or equal to 25 $\mu\text{in.}$ R_a or 0.6 μm (see Part SF) and may be internally electropolished. All internal surfaces shall be passivated.

(p) When compendial water systems are constructed of polymer materials, the surface finish should be less than or equal to 25 $\mu\text{in.}$ R_a or 0.6 μm .

SD-4.12 WFI Generators and Clean/Pure Steam Generators

(a) All surfaces that shall come into direct contact with the product, feedwater, or condensate/blowdown produced by the units shall be constructed of 316 stainless steel with all welded parts of 316L stainless steel or other material as specified by the owner/user.

(b) Connections to the product, feedwater, or condensate/blowdown produced by the units shall be made by the use of hygienic design fittings. All gasketed fittings should be constructed in such a manner as to avoid dead legs and crevices.

(c) Units should be completely drainable and should not contain any areas where chemicals used to clean and passivate the units are trapped or not easily flushed during rinsing operations.

SD-4.13 Micro/Ultrafiltration and Chromatography Systems

(a) Skid pumps designed for both process and CIP shall be designed to provide turbulent flow for cleaning. All process piping systems that include piping, tubing, and fluidic components shall be sloped for adequate drainage. For all low points in the system, a drain port shall be installed. A common drain port on the skid is preferred.

(b) Piping and equipment hold-up volume shall be minimized.

(c) Ultrafiltration cartridge housings shall be designed with connections and covers that will allow the unit to drain completely.

SD-4.14 Steam Sterilizers/Autoclaves

(09)

SD-4.14.1 General. For the purpose of this section, autoclaves and steam sterilizers shall be used synonymously. This section describes the requirements of autoclaves that are used in bioprocessing for the steam sterilization of hard, dry-wrapped, and liquid materials.

Autoclave chambers are pressure vessels and shall be pressure and temperature rated per the owner/user's design criteria with a minimum pressure rating of 25 psig at 266°F (1.7 barg at 130°C). The chambers shall also be vacuum rated.

For systems used in the processing of materials used in the European market, autoclaves may also be required to comply with Pressure Equipment Directive (PED) 97/23/EC and/or EN-285. Special conditions such as bio-seals may be required for autoclaves used in BSL-3 and BSL-4 applications. Please refer to the Biosafety in Microbiological and Medical Labs (BMBL) and Centers for Disease Control (CDC) guidelines for these special conditions.

This section does not pertain to pasteurizers, ETO- (ethylene oxide), VHP- (vaporized hydrogen peroxide), or ClO₂- (chlorine dioxide) type sterilization equipment.

The Manufacturer shall define the sterile boundary of the system.

SD-4.14.2 Cycle Types. Autoclaves should be capable of multiple cycle types for various load conditions. Autoclaves shall only be used to sterilize the types of goods for which they are designed. The most common load types are specified in SD-4.14.2.1 through SD-4.14.2.3.

SD-4.14.2.1 Hard Goods Cycles. Hard goods refer to goods such as metallic instruments, containers, and glassware. Effective removal of noncondensable gases is required for effective autoclaving of hard goods. Hard goods may be wrapped or unwrapped. Unwrapped goods can often be effectively autoclaved using either a single vacuum pull or gravity air displacement. These goods can sometimes be autoclaved at higher temperatures. Multiple vacuum pulse preconditioning is required for wrapped goods to ensure proper evacuation of noncondensable gases from both the autoclave chamber and autoclaved goods. Steam sterilizers used for the processing of wrapped or porous goods shall be able to pull vacuum to levels below 1 psia [69 mbar(a)] and maintain the vacuum with a maximum leak rate of 0.1 psi/5 min (6.9 mbar/5 min). Cooling, drying (pulse, vacuum) is an optional cycle step used to dry goods at the end of the autoclave cycle. Heated pulse drying is also recommended for the drying of porous goods such as rubber stoppers. Exhaust rates and heating rates should be adjustable for pressure-sensitive materials.

SD-4.14.2.2 Liquid Cycles. Forced air removal preconditioning is an optional cycle used to evacuate the noncondensable gases from the autoclave chamber. Liquid cooling cycles should be provided to efficiently cool the autoclave chamber. Providing the chamber with over-pressure helps prevent the liquid goods from boiling over during the cool down phase. Liquids can also be cooled by slow rate exhaust. Heating rates should be

adjustable to help compensate for differences in heating profiles of items in mixed loads.

SD-4.14.2.3 Air Filter Sterilization. An independent air filter steam in place sterilization (SIP) cycle should be provided for the in situ sterilization of the chamber vent filters ensuring supply of sterile air for cool down phases of autoclave loads.

SD-4.14.3 Components

SD-4.14.3.1 General

(a) *Materials of Construction.* Materials in contact with steam shall resist corrosion from steam and steam condensate. The materials shall not affect steam quality and shall not release any substances known to be toxic or that could adulterate the product. Piping/tubing and fittings shall be pressure and vacuum tight. The piping/tubing layout should be designed to minimize dead-legs within the sterile boundary. Tubing within the sterile boundary should be orbital-welded stainless steel tubing where possible and shall comply with Part MJ (MJ-6 and Table MJ-3) acceptance criteria. All process contact surfaces within the sterile boundary including tubing, chamber, and components shall be passivated.

The autoclave shall be enclosed with paneling that is resistant to corrosion and is cleanable.

(b) *Surface Finish.* The surface finish within the sterile boundary need not exceed 35Ra μ in. (0.89 μ m). Electro-polishing is not required for steam sterilization systems.

(c) *Elastomers.* Elastomers shall comply with SG-3.1.1 (Service Temperature), SG-3.1.2 (Service Pressure), and SG-3.3 (Seal Construction). Elastomers shall be resistant to corrosion and to chemical and thermal degradation. Elastomers used in autoclave applications shall be capable of withstanding pressures of a minimum of 25 psig at 266°F (1.7 barg at 130°C). Seals should meet the testing requirements specified in SG-3.1.8.

(d) *Insulation.* External surfaces should be insulated to minimize heat transmission.

SD-4.14.3.2 Doors. Autoclave door(s) shall be accessible, cleanable, and replaceable, and should be capable of undergoing inspection without dismantling. The door seal shall be resistant to clean steam and clean steam condensate. The door on the nonsterile side shall be capable of reopening after closing without undergoing a cycle. The door(s) shall not be capable of opening during a sterilization cycle. The doors shall be constructed of materials that are resistant to clean steam and clean steam condensate. For multiple-door systems, the doors shall be interlocked to allow the opening of only one door at a time. The unloading ("sterile-side") door shall remain sealed in standby mode. Refer to Part SG for specifications of seals used in bioprocessing.

SD-4.14.3.3 Sterile Air/Vent Filters. Where the sterilization cycle requires admission of air into the chamber, the air should be filtered with a sterilizing filter

(0.22 μm or less). The filter element shall be replaceable. Provisions for the steam in place (SIP) of the vent filter elements should be provided.

SD-4.14.3.4 Steam Traps. Refer to SD-4.11.3 for requirements of steam traps.

SD-4.14.3.5 Loading Carts/Trays. Carts and trays exposed to clean steam shall be constructed of materials resistant to clean steam and clean steam condensate. Carts, trays, and chamber shall be accessible or removable and cleanable.

SD-4.14.3.6 Valves. Valves and sealing materials located within the sterile boundary shall comply with SD-4.6.1 and Part SG. Valves within the sterile boundary are typically only exposed to clean steam service and chemical(s) used during passivation. Exposure to these conditions should be considered when selecting a valve type for this application.

SD-4.14.3.7 Check Valves. Provisions to prevent back-siphoning into the service feed systems should be considered.

SD-4.14.3.8 Jacket. The jacket shall be constructed using materials that are resistant to corrosion and degradation from steam or clean steam and clean steam condensate, as applicable.

SD-4.14.4 Other Features

SD-4.14.4.1 Drain Temperature. Waste to drain temperature shall comply with user specifications. The owner/user must specify discharge temperature requirements to the manufacturer.

SD-4.14.4.2 Instrumentation. Autoclave pressure and temperature shall be displayed at all doors. All instruments within the sterile boundary should be of hygienic design. Instruments shall be capable of being calibrated and replaced. The instrumentation shall include

(a) *Temperature.* Independent temperature elements (one or two for monitoring and recording and an independent one for controlling temperature) shall be provided. The chamber temperature recording element should be located in the chamber drain. Each temperature element shall be accurate to $\pm 0.1^\circ\text{C}$ (0.18°F) with a sensor response time < 5 sec. The element installation shall not affect the maximum leak rate. The temperature elements shall be temperature and clean steam resistant.

(b) *Pressure/Vacuum.* Pressure/vacuum instruments shall be provided. The pressure instruments shall monitor the chamber and jacket pressures. Provisions for recording chamber pressure during active autoclave cycles shall be included.

(c) *Date/Time.* Provisions for recording the date and time during an autoclave cycle shall be included.

(d) Recording may be achieved by paper or 21CFR Part 11 compliant electronic means.

SD-4.15 Clean in Place (CIP) Systems

(09)

SD-4.15.1 General

SD-4.15.1.1 Scope and Definitions

(a) The following terms are defined for the purpose of this section:

(1) *Clean in place (CIP) system:* a system used in the preparation, distribution, delivery, and subsequent removal of cleaning solutions to soiled equipment.

(2) *CIP cycle:* the executed recipe of rinses, washes, and air blows used to clean soiled equipment.

(3) *CIP circuit:* the sum of paths within a process unit operation that are cleaned as part of a single CIP cycle (e.g., bioreactor, buffer hold vessel).

(4) *CIP path:* the specific destination contacted with cleaning solution/rinse water during a CIP cycle (e.g., spray device path, inoculum line path, addition line path). Multiple paths within a circuit may be cleaned simultaneously.

(b) All in-circuit components of the CIP system (e.g., filter housings, pumps, vessels, heat exchangers, transfer panels, instrumentation, valving, piping) shall be designed to be cleanable, drainable, and of hygienic design appropriate for use in contact with process fluids per the applicable sections of this Standard.

SD-4.15.1.2 CIP System Operating Capabilities

(a) The CIP system shall be capable of delivering and subsequently removing cleaning solutions to soiled equipment in a verifiable and reproducible manner.

(b) The CIP system shall be capable of removing process soils to a user determined acceptance criteria.

(c) The CIP system shall be capable of removing cleaning chemicals to a verifiable amount characteristic of the final rinse solution.

SD-4.15.1.3 CIP System Functionality

(a) A CIP system is a distributed system of properly integrated components including the following:

(1) CIP skid (CIP preparation equipment) designed to prepare the cleaning solution. The CIP skid should be designed to deliver feed water, inject cleaning chemicals, heat, and supply the cleaning solution to the soiled equipment. The skid shall also be designed to remove all residual cleaning chemicals added during the cycle.

(2) CIP distribution equipment designed to transport the cleaning solution to and from the soiled equipment. The distribution equipment may also return the solution to the CIP skid, if applicable.

(3) Spray devices (if applicable) designed to deliver the cleaning solutions throughout the soiled process equipment.

(4) Instrumentation and controls architecture (if applicable) designed to communicate, monitor, and synchronize the CIP cycle, and report CIP variables.

(b) The following cleaning variables should be considered in the design of the CIP system and CIP cycle:

(1) time of exposure (contact time) to wash and rinse solutions

(2) temperature of wash and rinse solutions

(3) chemical concentration of wash solutions

(d) fluid hydraulics

(c) A CIP system should include the capability to directly or indirectly control (monitor and record if applicable) the following CIP variables:

(1) timing of CIP cycle

(2) path being cleaned (e.g., valve position indication, pressure/flow verification, manual setup verification)

(3) CIP supply temperature (or return if applicable)

(4) conductivity, volume of cleaning chemical added, or cleaning chemical concentration for wash solutions

(5) final rinse conductivity or residual cleaning chemical concentration

(6) CIP supply flow rate

(7) totalized flow (if timing not monitored)

(8) CIP supply pressure

(9) spray device rotation (if used)

(10) interruption or unacceptable decrease in flow to a path

(11) pressure of clean compressed air supply (if used in airblow)

SD-4.15.2 CIP Skid Design

(a) For the purpose of this section, a CIP skid consists of a wash and/or rinse tank with all requisite valves, pumps, and instrumentation. Provision for separation of feed waters and wash solutions should be considered. CIP skids may be located in a fixed, centralized location or may be portable and used adjacent to the soiled equipment.

(b) The CIP skid design should consider the CIP circuit volume for water consumption, location of skid in facility (if fixed), chemical consumption, waste effluent, and energy required to clean a given circuit.

(c) The wash/rinse tank(s) shall be designed and fabricated per SD-4.7. The tank(s) shall be designed for cleanability per SD-4.15.4 and shall be equipped with a spray device(s) per SD-4.15.6.

(d) If used on wash/rinse tanks, a hydrophobic vent filter shall be designed to prevent moisture accumulation in the vent filters and shall be fabricated per SD-4.4.

(e) Heat exchange equipment shall be designed and fabricated per SD-4.9.1.

(f) The CIP skid should have flow control, either via pump output or by means of flow control valves.

(g) CIP supply pumps shall be designed and fabricated per SD-4.5. The pump design should consider the handling of a gas/liquid mixture.

(h) The design should consider hazardous operation of cycle considering choice of cleaning chemicals. Chemical segregation, spill control, addition handling, material compatibility, secondary containment, and personnel safety should be considered.

SD-4.15.3 CIP Flow Rate Guidelines for Process Lines

(a) CIP shall be performed at a flow rate that maintains a fully flooded process line and ensures turbulent flow.

(b) The flow direction, line orientation, line size, and presence and orientation of dead legs, 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.

(c) CIP flow rate requirements should not be considered exclusively of other CIP process variables.

(d) Table SD-5 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 Part DT.

SD-4.15.4 Design Guidelines for Cleaning Process Vessels

(a) Process vessels should be cleaned via internal spray device(s) designed to consistently expose all internal surfaces to the cleaning variables described in SD-4.15.1.

(b) The use and application of a particular spray device design to satisfy these requirements is to be decided by the owner/user. Spray devices shall be designed and fabricated per SD-4.15.6 (also see Fig. SD-23-3 for static spray device design considerations).

(c) Dished-head vertical vessels should have cleaning solutions delivered with the majority of flow directed toward the upper head and sidewall area at the upper knuckle radius. Cylindrical horizontal vessels should have cleaning solutions delivered with the majority of flow directed toward the upper one-third of the vessel.

(1) If a static sprayball is used, gravity provides a solution sheeting over the side wall and bottom head (vertical vessels) or lower surfaces (horizontal vessels).

(2) If a dynamic spray device is used, the device may directly spray areas throughout the vessel or rely on sheeting action.

(3) Table SD-6 details ranges of flow recommendations for static sprayballs on vertical process vessels under typical cleaning loads. The recommendations in Table SD-6 ensure sufficient coverage.

(4) The criteria to ensure sufficient coverage on horizontal process vessels varies with geometry and size.

(5) Sufficient exposure shall be confirmed by coverage testing per SD-5.1 at site of equipment manufacture and/or installation.

(d) Spray device design and location shall ensure appurtenances such as manways, baffles, dip tubes, agitator impellers, and nozzles are contacted with cleaning solution. Some appurtenances may require additional provisions for cleaning.

(e) Spray devices only ensure coverage of the exterior of installed appurtenances and equipment. If not removed during CIP, cleaning solutions shall flow through appurtenances to clean their interior.

(f) The fluid level should be minimized in the process vessel during CIP. Proper hydraulic balance (supply and return flow) of the CIP circuit and sizing of the bottom outlet valve should be considered to minimize fluid level.

(g) Vortex formation during CIP may adversely affect the operation. The installation of a vortex breaker may be required.

(h) Vortex breaker design is to be decided by the owner/user. Vortex breaker surfaces shall be sloped to eliminate pooling during CIP and positioned to not adversely affect the hydraulic balance of the CIP circuit.

(i) For process vessels equipped with an agitator, the impeller should be rotated at an appropriate speed during the CIP cycle.

SD-4.15.5 CIP Distribution Design

SD-4.15.5.1 CIP Distribution Guidelines (Supply and Return)

(a) General

(1) The use and application of a particular distribution design or combination of designs is to be decided by the owner/user. SD-4.15.5 discusses design and installation considerations for a series of CIP distribution options.

(2) All CIP distribution designs shall be sloped for drainability as per SD-3.12.1. Slope designation GSD2 is recommended.

(3) The use of looped headers, transfer panels, and valve types (e.g., divert, mix-proof, multiport, zero-static, diaphragm) should all be considered in the design of the CIP distribution system.

(b) Looped Headers (See Fig. SD-23-4)

(1) For the purpose of this section, a CIP distribution looped header shall be defined as a piping ring surrounded by circuit-specific isolation valves. The entire ring path is cleaned during a CIP cycle.

(2) The dimension from the looped header to the isolation valve weir or seat should conform to SD-3.11.1 (see Fig. SD-4 for details). The use of short-outlet tees or zero-static valves is to be decided by owner/user.

(3) Future connections (if applicable) on the looped header should utilize capped short-outlet tees or capped installed zero-static valves.

(4) Looped header connections should be oriented horizontally when used in CIP return applications.

(5) CIP supply header design should provide for adequate velocity in parallel cleaning paths (e.g., line size reduction in loop header).

(c) *Transfer Panels.* Transfer panels shall be designed and fabricated per SD-4.16.

(d) *Multiport Valves.* For the purposes of this section, a CIP distribution multiport valve shall be defined as a multiple valve assembly fabricated as a single body to minimize distances and maximize drainability (see SD-4.6.1 for details).

(e) Zero-Static Chains (See Fig. SD-23-5)

(1) For the purposes of this section, a CIP distribution zero-static chain shall be defined as a manifold of circuit-specific zero-static valves.

(2) Provision shall be made to flush the manifold in a zero-static chain.

(f) Swing Elbows and Piping Spools (See Fig. SD-23-6)

(1) For the purposes of this section, a swing elbow or piping spool shall be defined as a removable section of pipe used to provide a positive break between two paths.

(2) Swing elbows or piping spools shall be connected to adequately supported piping to maintain line slope and connection alignment.

SD-4.15.5.2 CIP Distribution Piping

(a) The distribution piping and components in a recirculated CIP circuit shall be hygienic for design and fabrication as per SD-3.11 and SD-3.12.

(b) The distribution piping and components in a once-through CIP circuit or path (not recirculated) shall be hygienic for design and fabrication as per SD-3.11 and SD-3.12 upstream of the location of cleaning performance verification.

(c) CIP supply piping should be sized to ensure that the fluid flow meets or exceeds the guidelines stated in sections SD-4.15.3 and SD-4.15.4.

(d) The distribution circuits shall be designed such that fluid flow will maintain a positive pressure relative to the process drain, preventing backflow.

(e) CIP return piping shall be designed to maintain hydraulic balance (supply and return flow) of the CIP circuit.

SD-4.15.5.3 CIP Return Pumps

(a) CIP return pumps (if required) shall be designed and fabricated per SD-4.5. Centrifugal pumps are preferred for CIP return applications. If a gas/liquid mixture is anticipated, then hygienic liquid ring pumps are recommended.

(b) When a vessel is included in the circuit, CIP return pumps should be placed as close as possible to the vessel bottom outlet and at the low point of the circuit.

(c) Provision shall be made to flush through the casing drain of CIP return pumps.

(d) CIP return pumps shall be designed to maintain hydraulic balance (supply and return flow) of the CIP circuit.

SD-4.15.5.4 CIP Return Eductors. For the purpose of this section, a CIP return eductor shall be defined as a device that uses a motive fluid to create a pressure differential that returns the CIP solution.

(a) CIP return eductors shall be designed and installed to be drainable.

(b) CIP return eductors shall be designed to be removable for examination.

(c) Special design factors shall be considered when using CIP return eductors (e.g., vapor pressure, return line size).

SD-4.15.6 CIP Spray Device(s)

(a) Spray device(s) shall produce uniform spray coverage over a defined area of the equipment.

(b) The spray device shall be self-cleaning and self-draining.

(c) The spray device shall be manufactured of materials compatible with the processing system.

(d) The effective coverage of the spray device should not be affected by variations from the design conditions in flow rate or pressure of $\pm 20\%$ or otherwise agreed upon by the end user/owner.

(e) The spray device shall be removable.

(f) Static spray device(s) shall have a positioning device (preferred) or mark to allow for proper orientation.

(g) Provision shall be made to ensure proper orientation of slip-joint/clip-on style static spray device(s).

(h) All spray devices shall have unique identifiers to ensure proper installation location.

(i) Figure SD-23-3 represents a typical static spray device.

SD-4.16 Transfer Panels

SD-4.16.1 General

(a) The transfer panel shall be constructed so that the product contact surfaces can be cleaned by a CIP fluid or other method specified by the owner/user. The product contact surfaces shall be free of crevices, pockets, and other surface irregularities.

(09) (b) The transfer panel nozzle elevation shall be properly designed with respect to the connecting equipment such as tank, pump, etc., to ensure drainability, cleanability, and bioburden control during process transfer, CIP, and SIP.

(c) Design and fabrication of the transfer panel and associated components must ensure that the piping system can be fully drained when properly installed. This is not to imply that panel nozzles and/or subheaders should be sloped (see Fig. SD-25).

(d) Tagging/labeling of the transfer panel and its components shall be per SD-3.8(i). Tagging nozzles on

the backside of panels will help reduce the number of incorrect piping connections during field installation.

SD-4.16.2 Nozzles or Ports

(09)

(a) Nozzle construction shall accommodate a design feature that will assist in the elimination of internal surface anomalies caused in part by joining the nozzle to the panel structure.

(b) The method of joining a nozzle into a panel structure shall be of hygienic design. Acceptance criteria for these welds shall meet the requirements of Table MJ-4.

(c) Each front nozzle connection shall be of a hygienic design and the horizontal projection minimized to optimize drainability.

(d) To ensure proper panel functionality and joint connection integrity, panel nozzles shall not be sloped (see Fig. SD-24).

(e) Nozzle-to-nozzle clearance shall be such that jumper drain valve interference, if applicable, will not occur when jumpers are connected in all possible operating and cleaning configurations.

(f) Nozzles shall be capable of being capped. Caps may include bleed valves or pressure indicators for safety or operating purposes.

(g) Nozzle center-to-center and flatness tolerances are extremely critical to proper panel functionality and shall be agreed upon by the manufacturer and end-user. Recommended tolerances are per Table SD-7 and Fig. SD-24.

SD-4.16.3 Headers or Prepiping

(a) When a looped header design is employed, the dead leg at capped or unused nozzles should be minimized. The dimension of the subheader leg to the nozzle face should be specified as not to exceed the target L/D ratio of 2:1 where feasible (see Fig. SD-25). A dead-ended and/or unlooped subheader is not recommended.

(b) To optimize the drainability at all nozzles, regardless of use, subheaders and pre-piped manifolds shall not be sloped. All encompassing lines including long runs with the exception of subheaders, manifolds, and nozzles may be sloped as defined in SD-3.12.1.

SD-4.16.4 Jumpers or U-Bends

(a) Jumpers shall be constructed with hygienic connections on both ends designed to mate with the panel nozzles.

(b) Jumpers may have a low point drain to provide both complete drainage and vacuum break after the liquid transfer has been completed (see Fig. SD-26). Jumpers may include drain valves or pressure indicators for safety or operating purposes. The low point drain connection shall project a minimum distance approaching the target L/D ratio of 2:1 where feasible. Zero static diaphragm valves are recommended for low point drains if available from the manufacturer [see Fig. SD-26, illustrations (a) and (d)]. Low point drain designs that incorporate a spool piece allow for full rotation of the drain valve [see Fig. SD-26, illustrations

(a), (b), and (c)]. This design ensures that the drain valve is always at the true low point of the assembled jumper connection in any specified orientation.

(c) Jumper center-to-center and flatness tolerances are extremely critical to proper panel functionality. Recommended tolerances are per Table SD-7 and Fig. SD-24.

(d) The use of reducing jumpers is not recommended due to drainability concerns based on jumper orientation. Any reduction in line size should be made behind the primary nozzle connection (behind panel structure), thus allowing all connections to be the same size on the front of the panel.

(e) The overall panel design shall be such that the quantity of unique jumper centerline dimensions is minimized.

(f) The same jumper should be used for process transfer, CIP, and SIP.

(g) If a pressure indicator is installed on a jumper, it must be a hygienic design and mounted in a manner that maintains drainability in all jumper positions. A target L/D is achievable and recommended.

SD-4.16.5 Drain or Drip Pans

(a) Drain pans, if utilized, shall be built as an integral part of the transfer panel. The intended function is to collect spilled fluids that can occur during jumper or cap removal.

(b) Drain pans shall slope [preferred minimum of $\frac{1}{4}$ in./ft (21 mm/m)] to a low point and be piped to the process drain. The depth of the drain pan is determined by calculating the largest spill volume and accommodating it with a sufficient pan holding volume. Consideration should be given to increasing the drain port connection size in lieu of increasing pan depth. The preferred drain port location is central bottom draining or central back draining.

(c) The elevation of the pan should take into account the clearance required for the jumper drain valve position when a connection is made to the bottom row of nozzles. The pan should extend horizontally to accommodate the furthest connection and/or drain point from the face of the panel.

(09) SD-4.16.6 Proximity Switches

(a) Proximity switches are used to detect the presence or absence of a jumper with a stem positioned between selected nozzles.

(b) The use of magnetic proximity switches, which are mounted behind the panel structure avoiding the need to penetrate the panel face, are preferred. This elimination of structural penetration will remove any unnecessary cracks, crevices, or threads at the point of attachment, thus removing the risk of product entrapment and/or contamination concerns.

(c) Jumpers will contain a magnetic stem to activate the corresponding proximity switch. The use of a ferrous magnetic material is required; however, it must be fully

encapsulated to ensure that the ferrous material does not contaminate the classified manufacturing area. The acceptance criteria for welds joining the sensor stem to the jumper shall meet the requirements of Table MJ-4.

(d) The magnet should be of sufficient gauss rating to properly activate the corresponding proximity switch. In addition, the temperature rating of the magnet should withstand the specified temperature ranges for process and SIP without compromising the magnet performance.

(e) The proximity switch mounting shall be of hygienic design and structurally sound to maintain the specified design location.

SD-4.17 Bioreactors and Fermentors

(09)

SD-4.17.1 General

(a) *Scope.* For the purpose of this section, the terms “fermentors” and “bioreactors” are interchangeable. A bioreactor or fermentor shall be defined as a vessel-based system used in the growth of microorganisms, plant, mammalian, or insect cells.

(b) The area within the bioreactor sterile envelope or boundary shall be designed for cleanability and bioburden control. As a minimum, the bioreactor sterile envelope or boundary shall include the following (see Figs. SD-27-1 and SD-27-2):

(1) vessel internals.

(2) inlet gas piping from the filter element(s) to the vessel and any installed isolation valving. If redundant sterilizing grade filters are used in series, the inlet filter element farthest from the reactor vessel shall define the sterile boundary.

(3) exhaust gas piping from the vessel side of the exhaust filter(s) to the vessel and any installed isolation valving. If redundant sterilizing grade filters are used in series, the exhaust filter farthest from the reactor vessel shall define the sterile boundary.

(4) agitation assembly including all internal surfaces of the impellers, and shaft up to the mechanical shaft seal in contact with the product.

(5) feed systems from the vessel to the seat of the isolation valve nearest to the bioreactor vessel or if the feed stream is being filter sterilized, the sterilizing grade filter element.

(6) sampling system.

(7) product harvesting system from the vessel to the seat of the isolation valve nearest to the bioreactor vessel.

(c) A bioreactor is made up of a number of subassemblies, with those subassemblies potentially in contact with product, requiring special design consideration for cleaning and bioburden control.

(d) The bioreactor design for cleanability and sterility shall take into consideration the biosafety level requirement for the system. A bioreactor shall be designed in accordance with a biosafety level requirement as defined

by the National Institutes of Health or equivalent organization (e.g., BSL-1, BSL-2, BSL-3, or BSL-4). The biosafety level requirement should be determined based on the organism, the process, the product being produced, and/or the end user's preferences. To meet a specific biosafety level requirement, special operational considerations (e.g., steam blocks) may have to be addressed within the bioreactors' subassembly designs. If the bioreactor has been used to grow an organism that requires biohazard containment, provision shall be made to decontaminate all surfaces that may have come in contact with product prior to CIP, or to contain and decontaminate the fluids used for CIP.

(e) The bioreactor vessel should be pressure/vacuum and temperature rated per the owner/user's design criteria. The vessel shall be constructed, tested, inspected, and stamped in accordance with local ordinances, regulations, and codes.

(f) The area within the sterile envelope should be designed for CIP. For components that cannot be CIP'd, the design shall allow removal for manual cleaning out of place or replacement.

(g) The area within the sterile envelope should be designed for SIP. For those components or assemblies that cannot be SIP'd, the design shall allow removal for steam sterilization using an autoclave as long as additional provisions are provided for sterilizing the interface (e.g., steam block) once the components or assemblies are reconnected to the remainder of the bioreactor system. Autoclaved components or assemblies shall be capable of being steam sterilized without degradation to any of the elastomers or polymers that make up the components or assemblies.

SD-4.17.2 Inlet Gas Assembly

(a) The inlet gas assembly shall be defined as a piping assembly that has the ability to deliver controlled amounts of filtered gases into a bioreactor vessel. The assembly shall include but is not limited to the following:

(1) Flow Control Devices

(a) Flow control devices (e.g., rotameters, mass flow controllers, modulating control valves) shall be installed outside of the sterile boundary; therefore, piping requirements within this section may not apply. However, provisions shall be included within the design to prevent instrumentation damage due to SIP procedures and backflow.

(b) Flow control devices should be sized to prevent a vacuum condition, or a provision to bypass the flow control device shall be provided to maintain positive pressure in the vessel.

(2) Inlet Filter Assembly

(a) For the purpose of this section, an inlet filter shall be defined as a filter element installed in a housing of suitable material. The inlet filter assembly shall be defined as the filter(s) local to the bioreactor.

(b) Inlet filter assemblies shall be designed for SIP with provisions to remove entrapped air and condensate.

(c) If multiple inlet filters are used in series, then the filter assembly closest to the bioreactor shall be a sterilizing filter.

(d) Provisions shall be made for integrity testing of the filter assembly in situ or out of place.

(e) If the housings are included in a cleaning circuit, the filter elements shall be removed prior to introduction of cleaning solutions.

(f) Gas filters should be installed above the bioreactor liquid level.

(3) *Gas Sparging Assemblies (Spargers)*. Spargers shall be defined as mechanical devices normally located below an impeller used to disperse gases within a charged bioreactor. This section applies to sparge lances, wands, rings, and other devices (see Figs. SD-28-1 through SD-28-4) that may be mounted in the bioreactor vessel to introduce various gas streams for process operations. Sparge device assemblies shall meet the requirements of SD-4.7.2.

(a) Spargers shall be designed for SIP with the vessel.

(b) Spargers should be designed for CIP. If the sparge element cannot be CIP'd, provisions shall be made to remove the sparge assembly from the bioreactor for cleaning out of place or replacement.

(c) The removable sparger shall be supplied with the means to ensure that the installation orientation is in compliance with design intent.

(d) If the bioreactor is sterilized with media in the vessel, the SIP operation shall direct steam flow through the sparge device.

(e) CIP for sparge devices that use porous material for gas distribution requires particular attention. These devices should be evaluated for CIP cleanability, and should be removed from the bioreactor for external cleaning and/or replacement when CIP is not feasible.

(f) All wetted surfaces shall be sloped to drain by gravity into the vessel.

(g) If a check valve is installed in the sparge line within the sterile envelope, it shall be designed for CIP and SIP.

(4) Piping

(a) Overlay piping is defined as piping that directs filtered gases to the vessel headspace.

(b) Inlet gas assembly piping (sparge and overlay) within the sterile envelope shall meet the requirements as defined in SD-3.11.

(c) Inlet gas piping within the sterile envelope shall meet slope requirements as defined for GSD3 in Table SD-3.

SD-4.17.3 Exhaust Gas Assembly

(a) The exhaust gas assembly is defined as a piping assembly that maintains the integrity of the sterile

boundary with respect to sterility and pressure. The assembly shall include but is not limited to the following:

(1) *Exhaust Filter*

(a) For the purpose of this section, an exhaust filter shall be defined as a filter element installed in a housing of suitable material.

(b) Exhaust filters shall be designed for SIP. The housings shall be installed in such a way as to prevent the collection of condensate in the elements due to SIP.

(c) If redundant sterilizing grade exhaust filters are used in series, then the filter farthest from the bioreactor shall have a maximum rating of 0.2 μm absolute. In addition, provisions shall be included for draining condensate from the piping between the filters.

(d) Consideration should be made for CIP or removal in the case of cleaning out of place.

(e) Provisions shall be made for integrity testing of the exhaust filter.

(f) Filter elements shall be removed prior to introduction of cleaning solutions into exhaust gas assemblies.

(g) To prevent the exhaust filters from becoming blinded by condensate saturation during operation, the exhaust gas assembly may include exhaust condensers (Fig. SD-29-1), exhaust heaters (Fig. SD-29-2), steam jacketed or electrically heated traced filter housings (Fig. SD-30). These items shall be designed for SIP and CIP.

(2) *Exhaust Gas Piping*

(a) The exhaust gas assembly within the sterile envelope shall meet the requirements as defined in SD-3.11.

(b) Exhaust gas piping within the sterile envelope shall meet slope requirements as defined for GSD3 in Table SD-3.

(c) The design of exhaust gas piping from the bioreactor should ensure that there is no condensate accumulation in the line downstream of the system.

(3) *Backpressure Control Devices*

(a) If required, backpressure control devices (e.g., modulating control valves or regulators) should be installed outside of the sterile boundary.

(b) Backpressure control devices shall not hinder the bioreactor's capability of being SIP'd and CIP'd.

(c) If a vapor-liquid separator is used in the exhaust within the sterile envelope, it shall be designed for CIP and SIP.

SD-4.17.4 Piping Systems

(a) *Feed Lines.* This section applies to bioreactor piping systems used to feed liquid ingredients (e.g., pH control reagents, antifoam reagents, media, nutrient, inoculum).

(1) Feed lines shall be designed with the appropriate piping system to allow CIP and SIP of the bioreactor vessel and the feed line itself. CIP and SIP of the

feed line may be done independently or simultaneously with the bioreactor.

(2) If CIP of the ingredient feed system is performed during active culture operations, then the design should include provisions to prevent cross contamination between CIP solutions and product.

(3) Valve and piping orientation shall be designed to provide complete drainage during CIP and SIP.

(b) *Dip Tubes.* This section applies to all bioreactor port tube-extensions within the vessel.

(1) Bioreactor dip tubes shall meet the requirements of SD-4.7.2.

(2) Removable dip tubes (see Fig. SD-11) shall be inserted through a hygienic fitting. The removable dip tube shall be supplied with the means to ensure that the installation orientation is in compliance with design intent.

(3) All wetted surfaces shall be sloped to drain by gravity into the vessel.

(4) The SIP operation shall direct or balance steam distribution to establish and maintain sterilization temperature within the tube during the sterilization hold period.

(5) If the bioreactor is sterilized with media in the vessel and the dip tube extends below the working level of the media, the SIP operation shall direct steam flow through the dip tube into the vessel.

(6) Bioreactor dip tubes shall be designed for CIP or COP.

(7) If the dip tube is installed in the vessel during CIP, both the inside and outside of the dip tube shall be cleaned.

(c) *Harvest Valves/Bottom Outlet Valve*

(1) This section applies to all valves installed in the vessel bottom head.

(2) Harvest valves shall meet the requirements of SD-4.6.

(3) Bottom outlet valves shall be drainable and installed in such a way as to ensure complete drainage of the bioreactor contents.

(4) Bioreactor harvest valves shall be designed for SIP and CIP or COP.

SD-4.17.5 Miscellaneous Internal Components

(a) *Agitation Assemblies*

(1) This section applies to mechanical agitator assemblies mounted in the bioreactor for the purpose of achieving one or more mixing-related unit operations (e.g., blending, mass transfer, heat transfer, solids suspension).

(2) Agitators shall meet the requirements of SD-4.8.

(3) Agitators with double mechanical seals (Fig. SD-21-6) or magnetic couplings (Fig. SD-21-5) are recommended to isolate bioreactor contents from the environment.

(4) Agitator seal or magnetic coupling components shall be designed for CIP and SIP.

(5) Provisions shall be included in the design to clean the product-contact surfaces of impellers. Additional spray elements may be required to achieve coverage.

(6) Bottom-mounted agitators shall not interfere with free and complete drainage of bioreactor contents.

(b) Mechanical Foam Breaker Assemblies

(1) This section applies to mechanical foam breaker assemblies that may be mounted in the bioreactor for the purpose of reducing or eliminating foam accumulation in the vapor space of the bioreactor.

(2) Foam breaker assemblies shall meet the requirements of SD-4.8.

(3) Foam breakers with either double mechanical seals (Fig. SD-21-6) or magnetic couplings (Fig. SD-21-5) are recommended to isolate bioreactor contents from the environment.

(4) Foam breaker seal or magnetic coupling components shall be designed for CIP and/or SIP as appropriate.

(c) Internal Coils

(1) Internal coils should be avoided where possible.

(2) Product-contact surfaces of internal coils require provisions for CIP and SIP.

(d) Baffles. Baffle assemblies shall meet the requirements of SD-4.8.

(e) Sprayballs/Devices/Wands

(1) This section applies to sprayballs, wands, and other devices (see Fig. SD-23-3) that may be mounted in the bioreactor vessel for the purpose of distributing cleaning solution during CIP operations.

(2) Spray device assemblies shall meet the requirements of SD-4.7.2 and SD-4.15.6.

(3) If not removed during processing, spray device assemblies shall be designed for SIP.

(a) The SIP operation shall direct or balance steam distribution to establish and maintain sterilization temperature within the spray device during the sterilization hold period.

(b) With the exception of a combination sparger/spray device, internal spray devices should be located above the bioreactor operating liquid level.

(c) If the bioreactor is sterilized with media in the vessel and the spray device assembly extends or is located beneath the working level of the media, the SIP operation shall direct steam flow through the device into the vessel.

SD-4.17.6 Instrumentation

(a) Instruments installed within the sterile envelope or boundary shall be designed for SIP. Consideration should be made in the design for instrument removal for calibration.

(b) Instruments installed within the sterile envelope or boundary shall be designed for CIP or removed for COP. In the case of COP, blind caps or plugs should be provided to maintain the integrity of the system.

(c) Temperature sensing elements should be installed in thermowells. Piping associated with in-line thermowells shall be sized to allow sufficient steam and condensate flow.

SD-4.18 Process Gas Distribution Systems

(09)

For the purpose of this section, a process gas distribution system is one that extends from the bulk supply source (including cylinders) to the points of use (POU) as defined by the owner/user. Owners/users and their Quality Assurance personnel shall demonstrate that their systems comply with 21 CFR 211, Subpart D.

(a) The installation of process gas delivery and distribution systems for use within the scope of this Standard requires appropriate selection of piping materials. All components shall be supplied or rendered both hydrocarbon free (e.g., oil free) and particulate free prior to installation and/or use.

(b) For materials of construction, the owner shall specify all materials. When copper is used, it should be hard drawn and installed in accordance with the current edition of NFPA 99, Chapter 5. When copper is specified in a clean room or area, the owner shall confirm that all planned cleaning and sanitizing agents are compatible with copper and all materials of construction. When stainless steel tubing is specified, the materials of choice are alloys 316L or 304L. Orbital welding is the recommended joining method. Inside clean rooms, the piping materials of choice are 316L or 304L stainless steel tubing and fittings. The owner and manufacturer shall agree on all joining methods, levels of inspection, and acceptance criteria for all joints prior to installation.

(c) Compression fittings may be used for valves, regulators, mass flow controllers, and other instrumentation systems at the source and/or within system boundaries.

(d) Gas systems are not designed or configured with the intent or provisions to be cleaned, passivated, or chemically treated after installation. Features such as slope, high point vents, and low point drains need not be incorporated into these systems.

(e) There shall be no nonvolatile residue. The system design shall ensure that gas will remain pure throughout its delivery.

(f) It is important to select appropriate pre-filters and final system filters. The final point of use gas purity shall comply with the process requirements.

(g) Gas systems testing and sampling shall comply with 21 CFR 211 and ICH Q7 (International Conference on Harmonization, Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients).

SD-5 TESTING

All testing shall be performed using systems that avoid surface contamination of the equipment.

There are two types of testing and quality assurances performed: performance/calibration and sterility/cleaning. All testing and quality assurance documentation will be stamped with date and time. For each test documentation sheet, signatures of the test personnel and a supervisor shall be required, confirming the test results.

SD-5.1 Spray Ball Test

The purpose of a spray ball test is to document proper fluid coverage of the internal surface and parts of a tank or piece of equipment. The results give information about fluid coverage, a requirement for cleanability. All internal instruments shall be installed (e.g., agitators, level probes, dip pipes) during the spray ball testing. If it is not practical to conduct the test with all interior equipment in place, dummy shafts and dip tubes may be used to check shadowing. Cleaning of impellers may have to be verified during production CIP validation (i.e., hot WFI, cleaning agents, etc.). Spray balls shall be drainable, shall provide hole patterns to ensure that complete coverage is attained, and shall be properly manufactured to minimize corrosion.

The test shall be performed by spraying a dye (e.g., riboflavin) on the entire interior of the equipment product/process contact walls, nozzles, and miscellaneous surfaces. The test may be performed with ambient temperature water and before the riboflavin dye has dried. This test will confirm coverage of the sprayballs, but may not verify cleanability. Cleanability should be checked using the full CIP protocol at the facility where the vessel is installed including cleansers and temperatures. Water used for the following rinse shall meet the requirements of SD-5.3:

- (a) pressure
- (b) flow (per spray device)
- (c) burst duration and delay sequence between bursts

Acceptance shall be determined when all (100%) of the dye has been removed via the rinse. This shall be visually determined using an ultraviolet lamp, or by other verification methods as agreed to by the owner/user and manufacturer.

(09) SD-5.2 Cleaning, Steaming, and Bioburden Control Testing

Cleaning, steaming, and bioburden control testing (in addition to spray device testing) shall be as agreed to by the owner/user and manufacturer, and in accordance with accepted industry standards.

SD-5.3 Hydrostatic Test

Where applicable, all product contact surfaces shall be hydrostatically tested with clean purified or deionized

water filtered at 0.2 μm . If purified or deionized water is not available, then the water quality for testing shall be agreed to by the owner/user and manufacturer.

SD-5.4 Drainability Test

A drainability test for vessels shall be conducted as agreed to by all parties. As a proposed test procedure, the following shall be considered. The bottom head of the vessel shall be leveled with the outlet nozzle flange face (to within a tolerance agreed to) and shall be filled approximately to the weld seam. The outlet valve shall be opened, and the vessel allowed to drain by gravity. There shall be no puddles of water left on the bottom of the vessel greater than 5 mm in diameter (or as agreed to by the owner/user and manufacturer). If there are any puddles greater than the agreed-upon diameter, a thumb or soft rubber dowel is to be pushed into the center of the puddle, displacing the water. If water returns to the puddle, that area shall be repaired to the satisfaction of the owner/user.

SD-6 DOCUMENTATION

(09)

Documentation requirements shall be agreed to at the outset of a design project and shall be available upon request or submitted at the agreed-upon time to support the requirements of this Standard, as agreed to by the owner/user and manufacturer.

For all bioprocessing ASME Code stamped vessels, National Board registration is recommended to maintain vessel data on file.

Technical documentation to support the design of equipment and verify conformance with cleaning and SIP criteria may include, but not be limited to, the following:

- (a) material handling procedures
- (b) welding procedures
- (c) mechanical and electrochemical polishing procedures
- (d) standard operating and maintenance procedures and manuals
- (e) installation procedures
- (f) piping and instrumentation diagrams and technical references
- (g) original equipment manufacturer's data
- (h) surface finish certifications
- (i) detail mechanical drawings and layouts
- (j) certificates of compliance
- (k) technical specification sheets of components
- (l) manufacturer's data and test reports
- (m) NDE reports
- (n) shop passivation procedure
- (o) material approvals and certifications from suppliers
- (p) any additional documentation required by the user



Manufacturing documentation shall be maintained throughout the design and manufacture for each component, assembly, part, or unit.

All documentation shall be retained by the owner/user. As agreed to by the owner/user and manufacturer, documentation from the manufacturer will be retained for the agreed-upon duration of time, but not less than 3 yr after manufacture.

SD-7 RESPONSIBILITIES

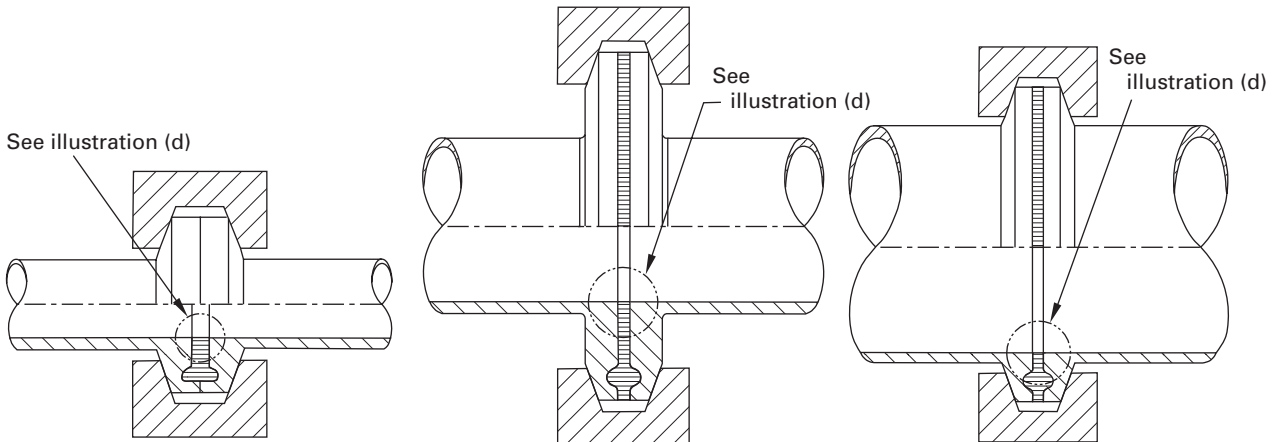
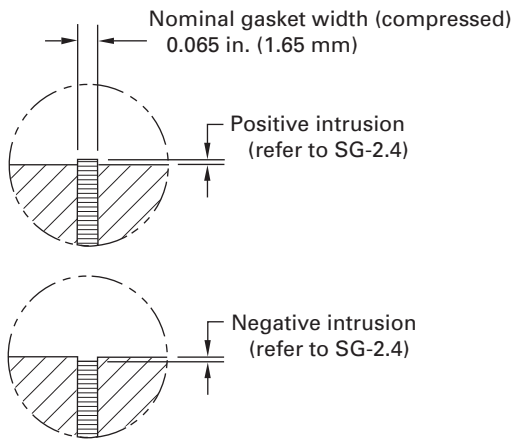
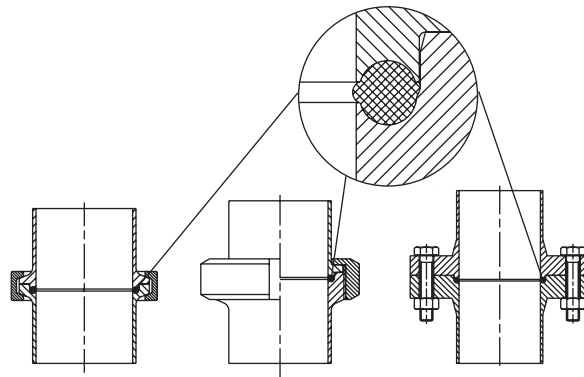
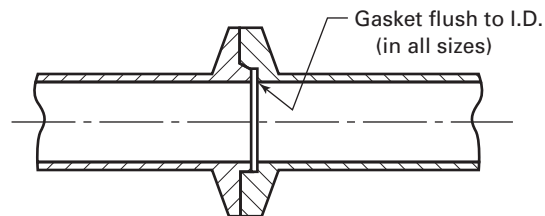
When designing, specifying, or selecting equipment and systems that will be sterilizable and cleanable, it is

necessary and important that all parties coordinate all phases of the project (design, specification, fabrication, testing, installation, start-up, validation, and actual production) to ensure sterilizable and cleanable equipment and systems.

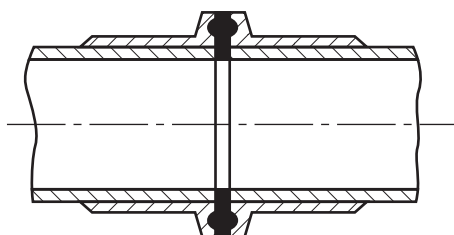
It shall be the responsibility of all parties involved to adhere to the concepts of this Part (as they apply) to advance the knowledge and database for sterilizable and cleanable equipment and systems.

Fig. SD-1 Hygienic Connections

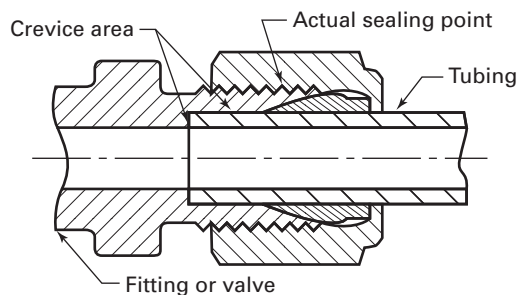
(09)


(a) Typical Hygienic Clamp Union — 1 in. and Smaller (Style A) per Table DT-5.1 (Recommended)
(b) Typical Hygienic Clamp Union — 1 in. (Style B) per Table DT-5.1 (Recommended)
(c) Typical Hygienic Clamp Union — 1.5 in. and Larger (Style A) per Table DT-5.1 (Recommended)

(d) Typical Hygienic Clamp Union — Allowable Gasket Intrusion

(e) O-Ring Fitting (Recommended)

(f) Typical High-Pressure Hygienic Fitting (Recommended)

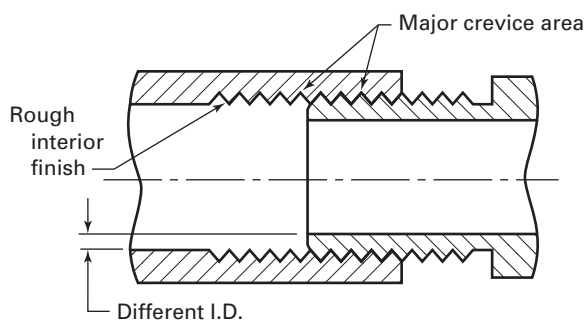
(09)

Fig. SD-2 Nonhygienic Connections


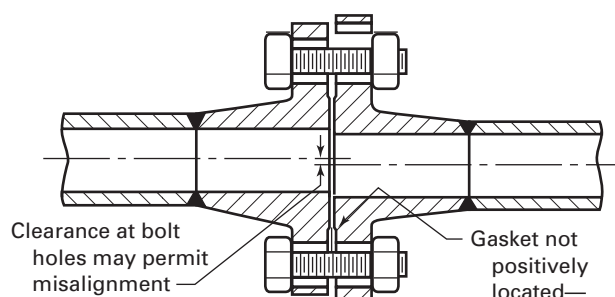
**(a) Typical Roll-On Fitting
(Not Recommended)
[Notes (1)–(3)]**



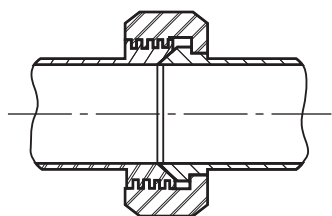
**(b) Typical Compression Fitting
(Not Recommended)**



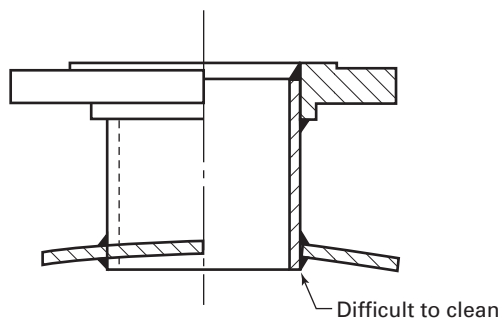
**(c) Typical Threaded Joint
(Not Recommended)**



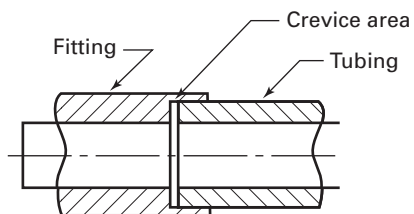
**(d) Typical Flanged Joint
(Not Recommended)**



**(e) Bevel Seat
(Not Recommended)**



**(f) Nozzle Detail
(Not Recommended)**

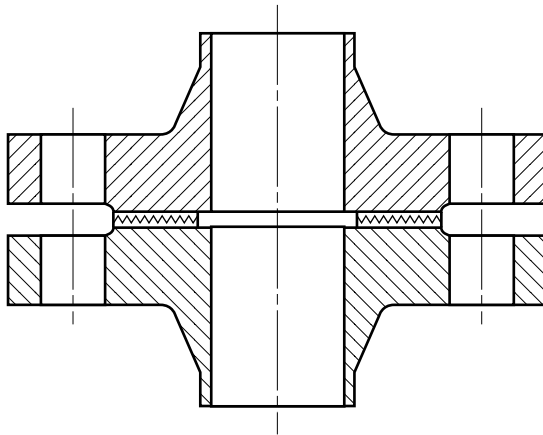


**(g) Typical Socket Joint
(Not Recommended)**

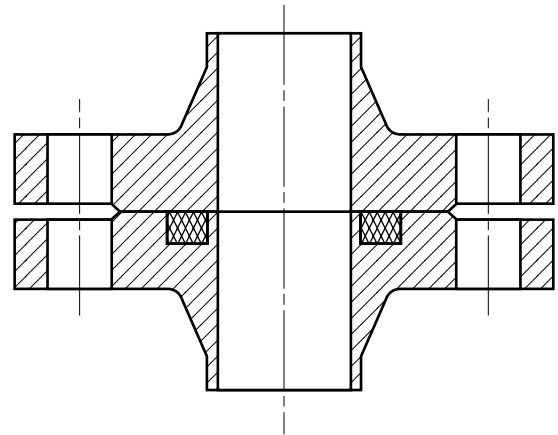
NOTES:

- (1) Tubing is expanded into the ferrule through use of rollers.
- (2) Leakage may occur, especially during temperature cycling.
- (3) Product may enter the crevice between ferrule and tubing.

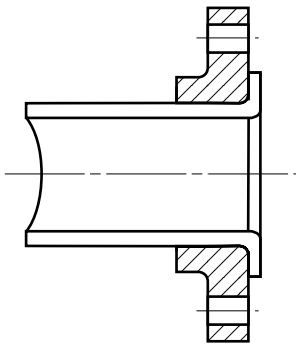
Fig. SD-3 Flat Gasket Applications



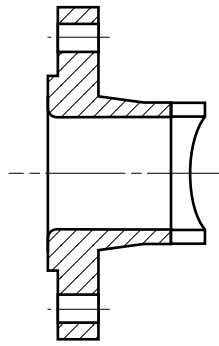
(a) Not Recommended



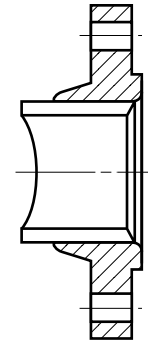
**(b) Not Recommended
(Has Been Acceptable in Certain Applications)**



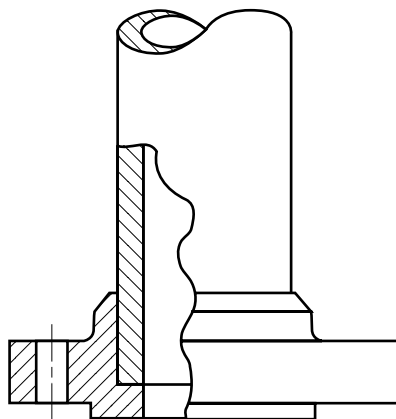
**(c) Stub-End/Lap Joint
(Not Recommended)**



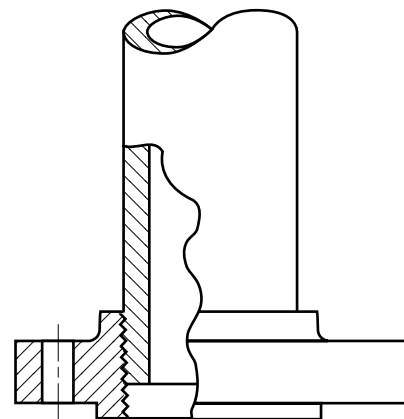
**(d) Weld Neck
(Not Recommended)**



**(e) Slip On
(Not Recommended)**

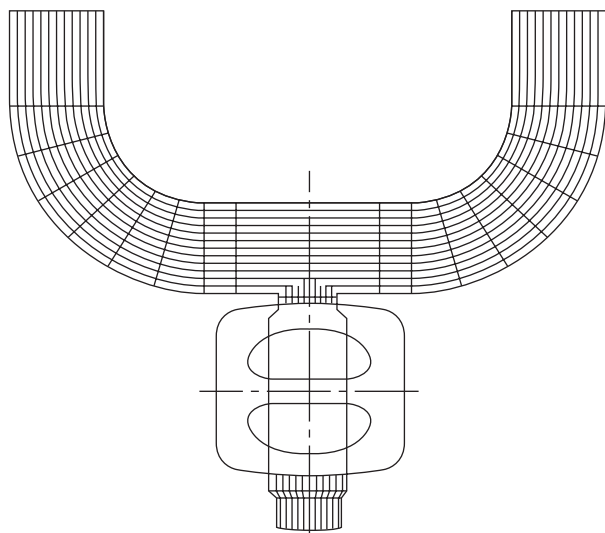


**(f) Socket Welding Flanges
(Not Recommended)**

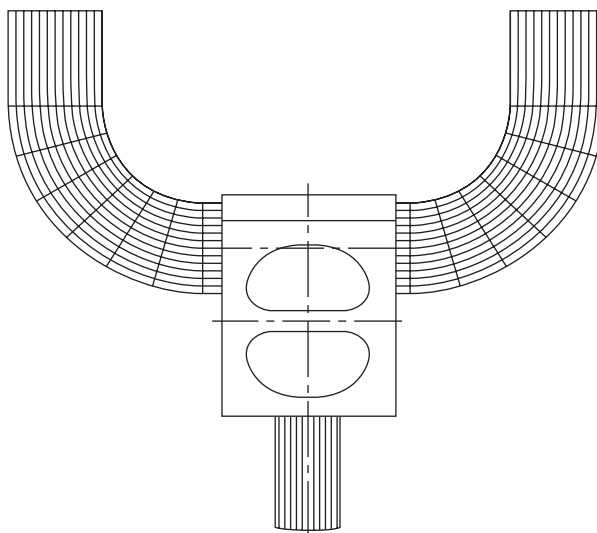


**(g) Threaded Flanges
(Not Recommended)**

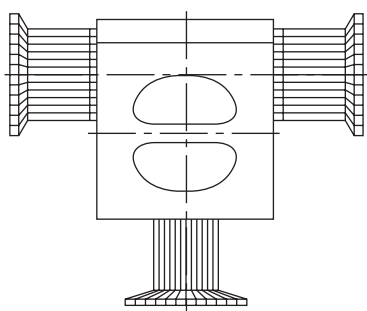
Fig. SD-4 Recommended and Preferred Drop Designs



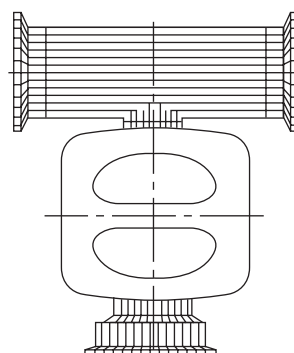
(a) Recommended
(with 2.0 Target L/D)



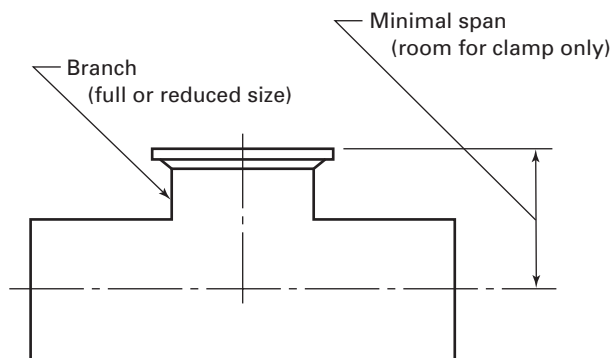
(b) Preferred



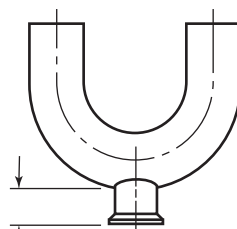
(c) Preferred



(d) Recommended

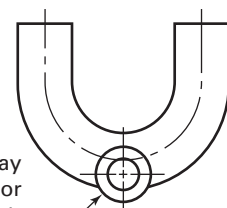


Typical short-outlet tee
(e) Recommended



Short outlet
(to minimize dead leg)

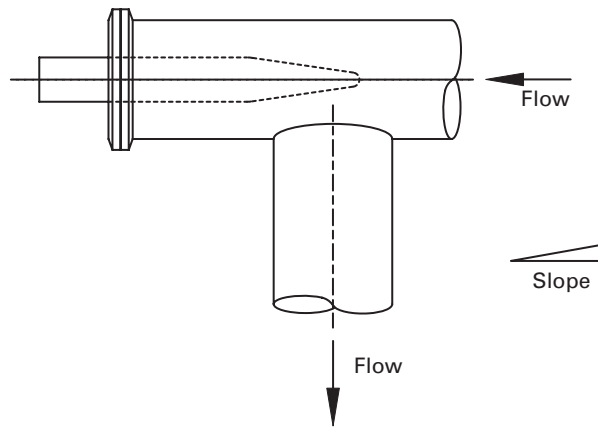
(f) Recommended



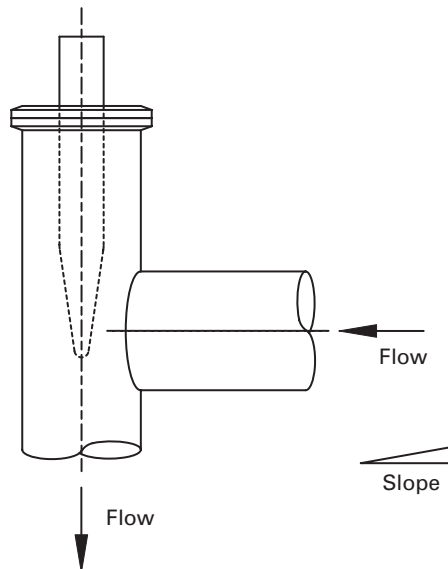
Outlet may be full or reduced size
Tangential side outlet (to provide full drainage)

(g) Preferred

Fig. SD-6 Instrument Location Detail: Hygienic Design



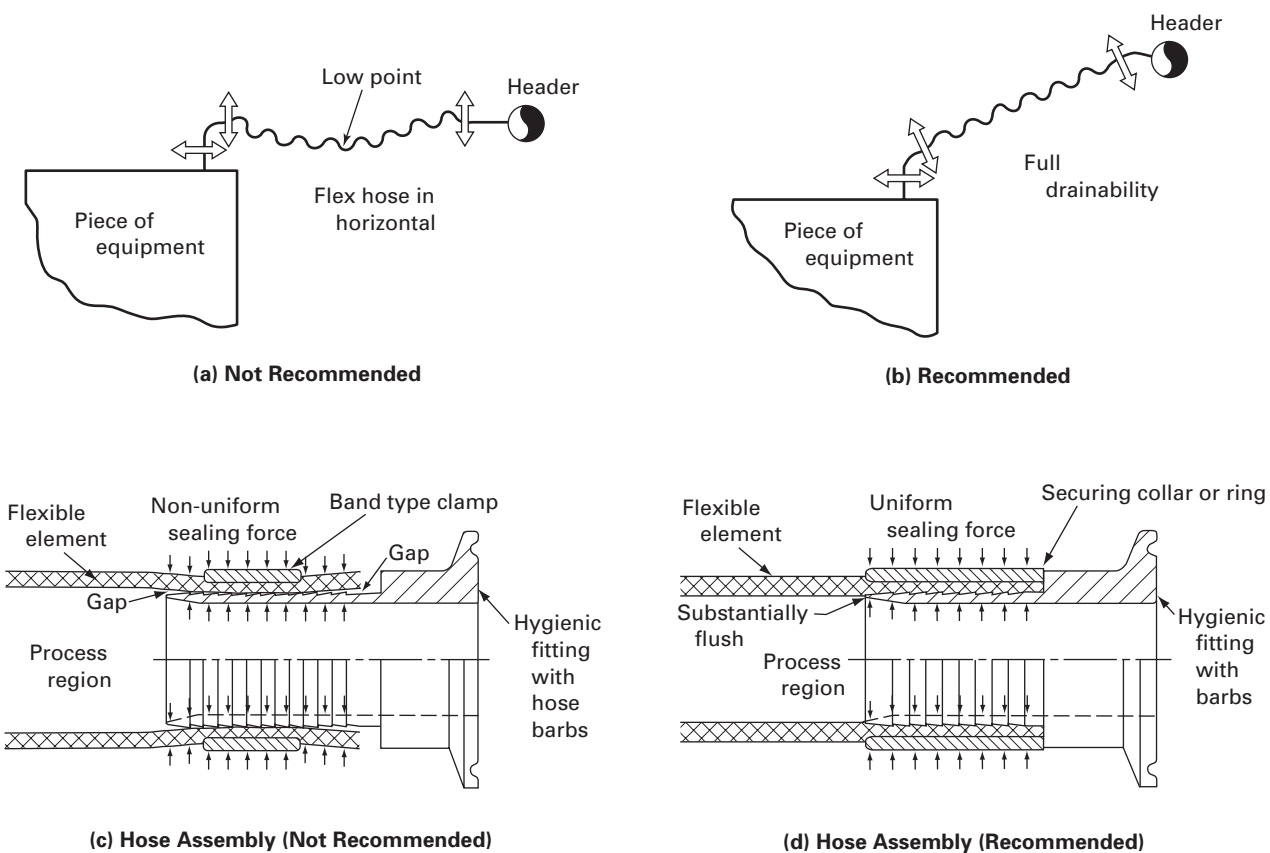
(a) Not Recommended



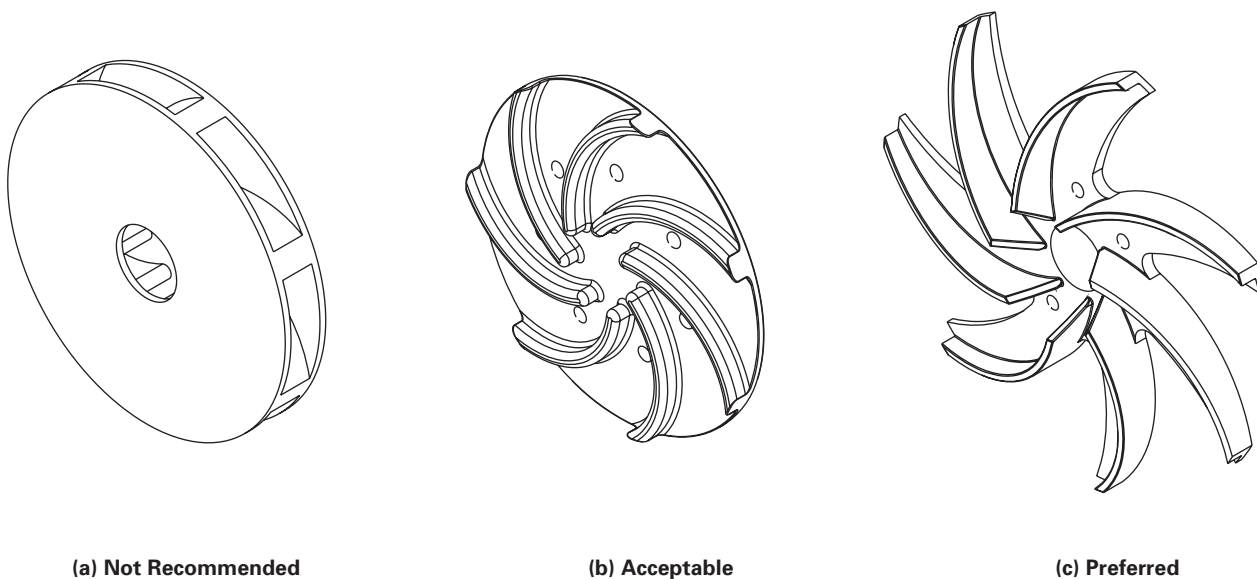
(b) Recommended

Fig. SD-7-1 Flexible Hygienic Hose Design

(09)

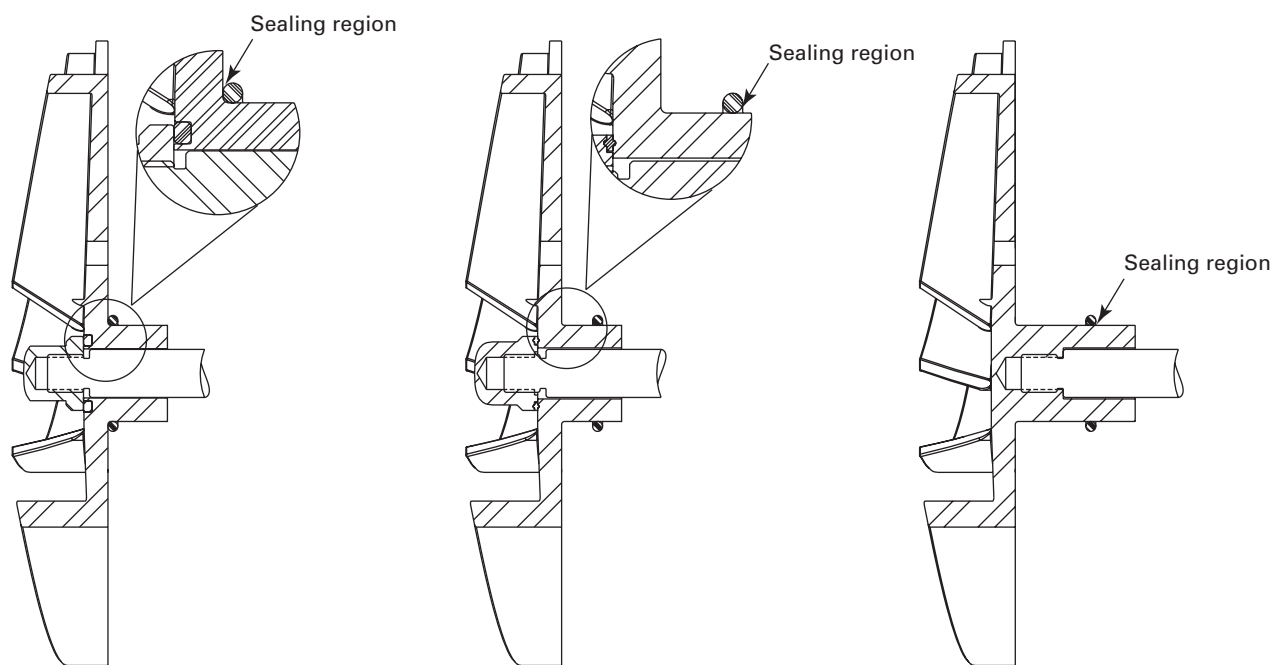

Fig. SD-7-2 Pump Impeller Configurations

(09)



(09)

Fig. SD-7-3 Acceptable Impeller Attachments



(a) Impeller Nut With O-Ring

(b) Impeller Nut With Hygienic Gasket

(c) No Impeller Nut

(09)

Fig. SD-7-4 Casing Drain Configurations

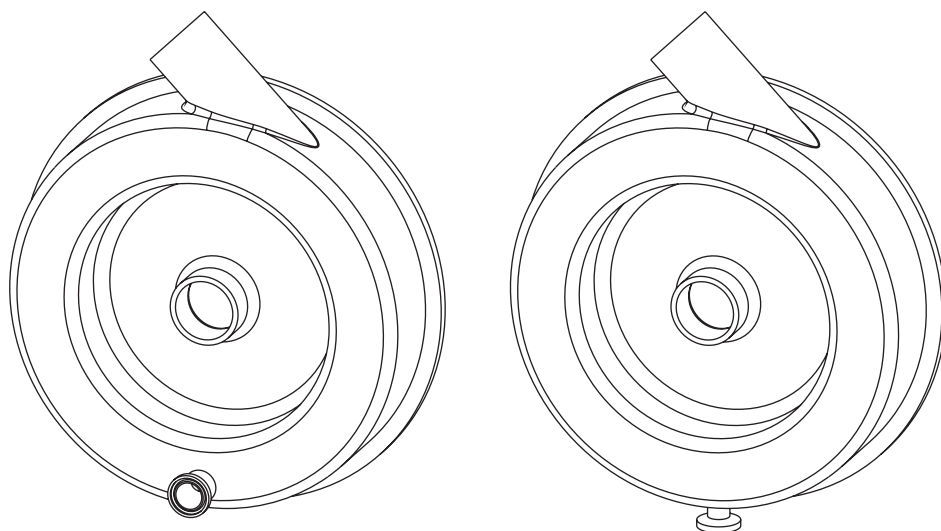


Fig. SD-7-5 Casing Drain L/D Ratios

(09)

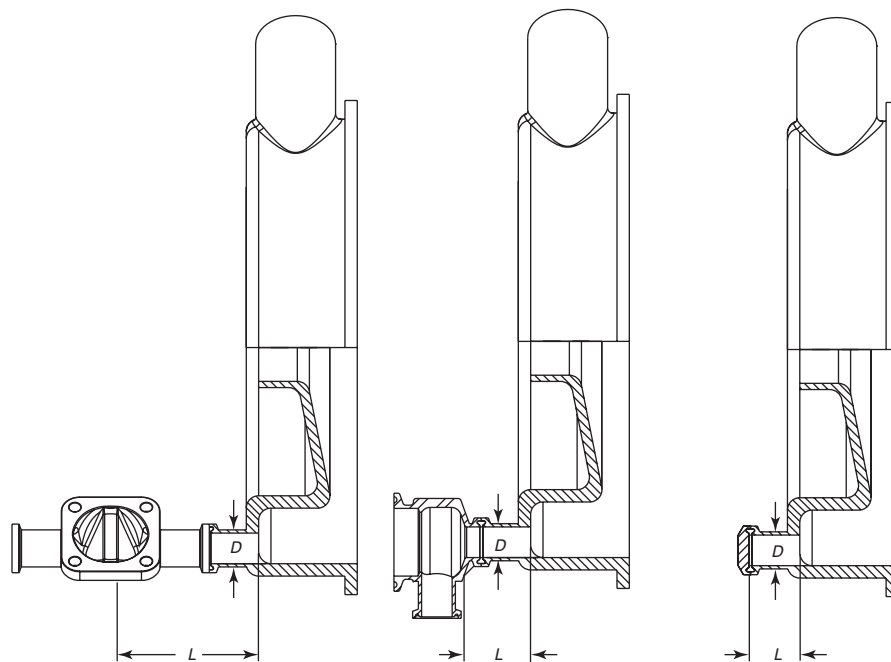
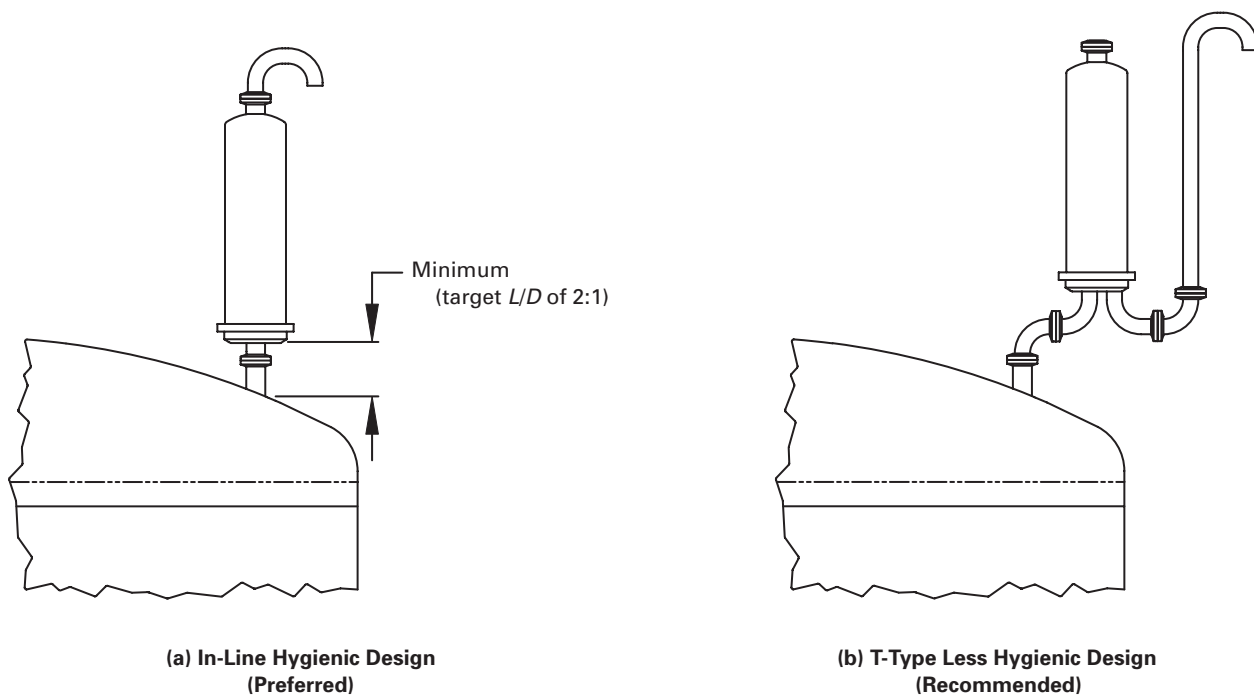
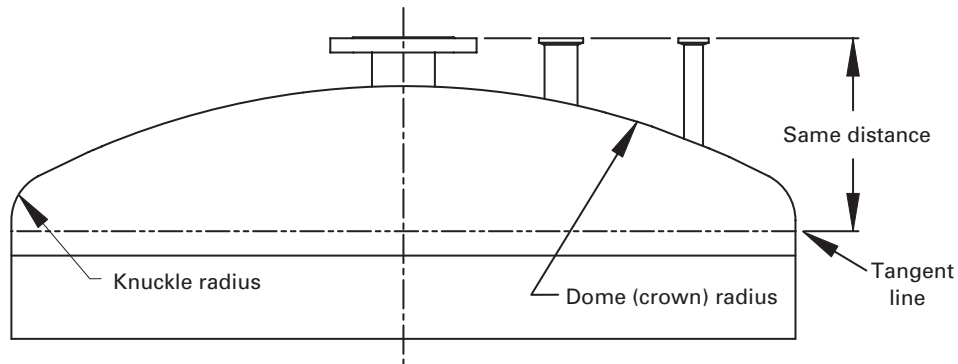
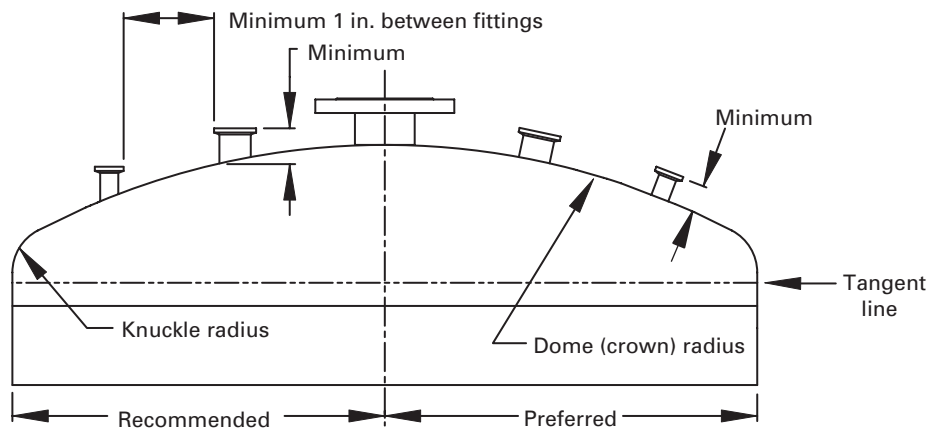
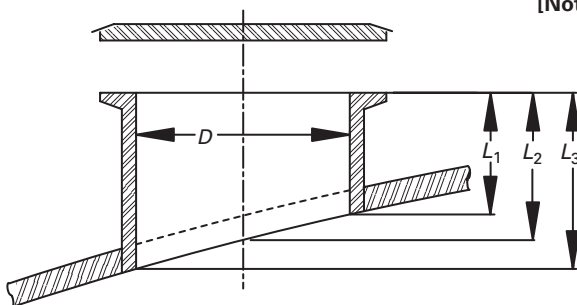
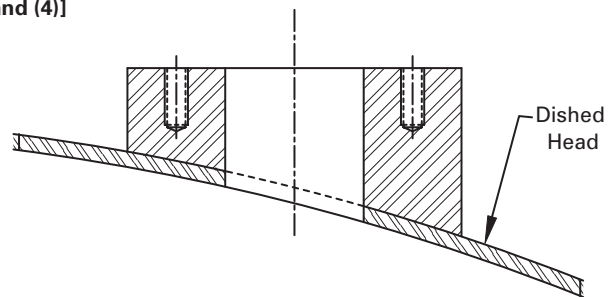
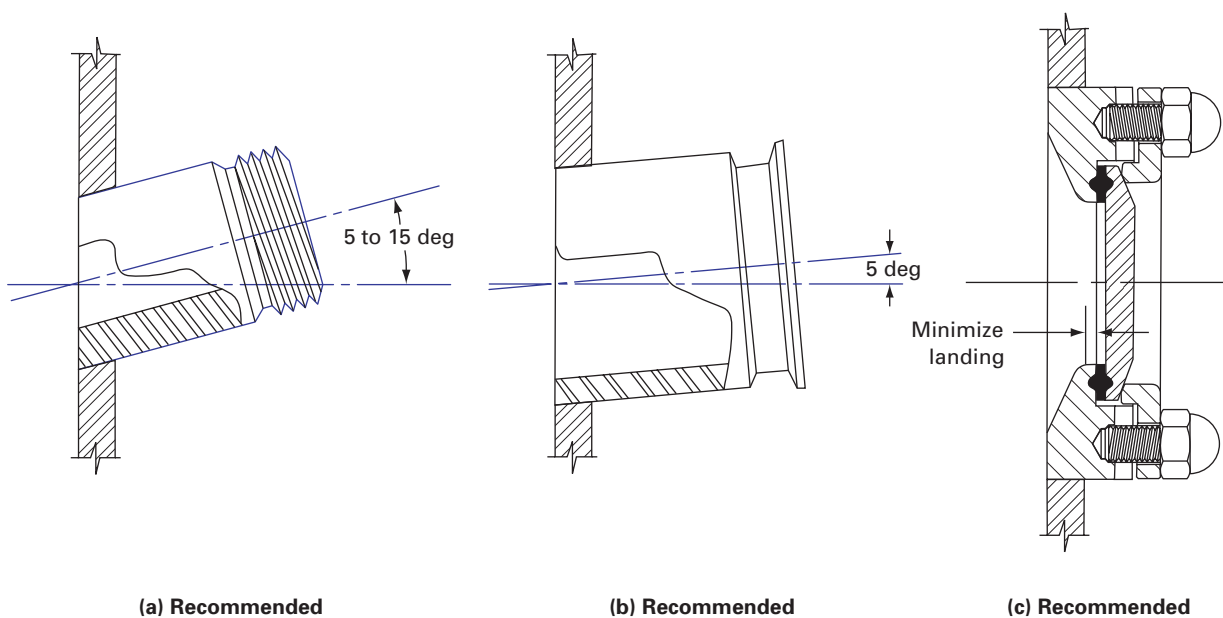
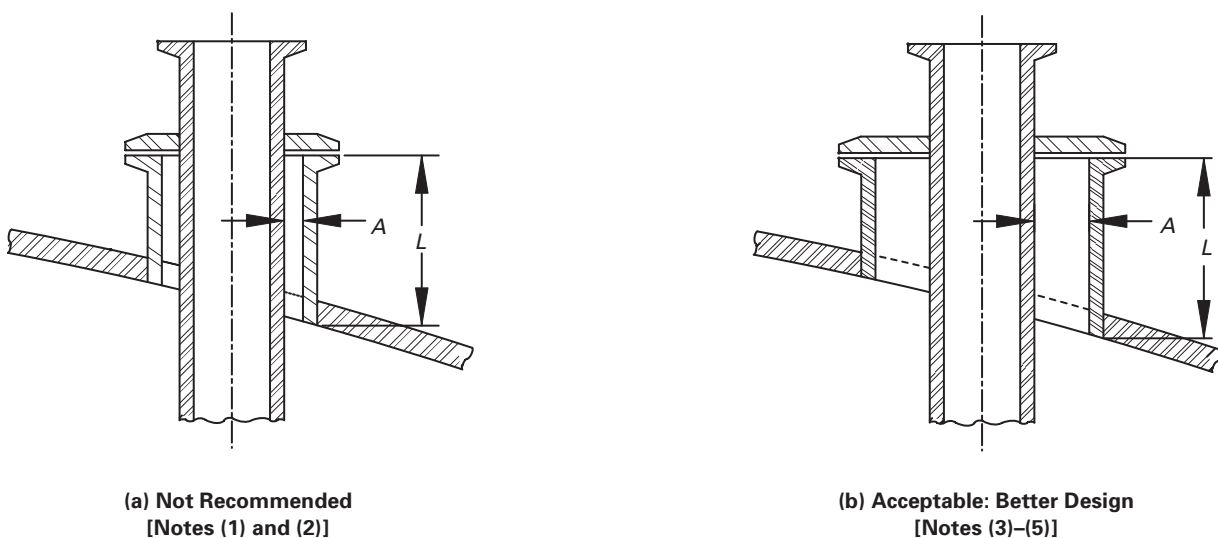

Fig. SD-8 Tank/Vessel Vent Filters


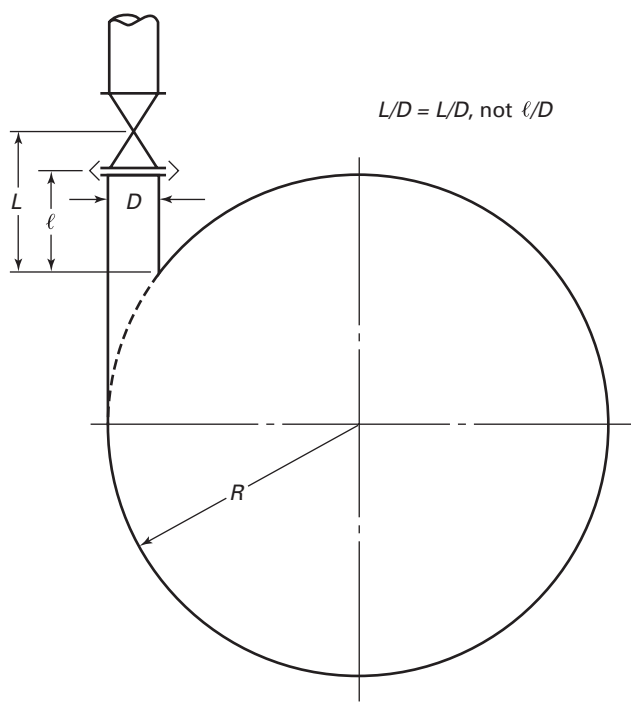
Fig. SD-9 Nozzle Design

(a) Not Recommended
[Notes (1) and (2)]

(b) Allow for Clamps/Bolt-Up
(Target L/D of 2:1)
[Notes (3) and (4)]

(c) $L/D = L_3/D$ (Target 2:1)
[Notes (5) and (6)]

(d) Instrument Connection Vessel
(Not Recommended)
[Notes (7)–(11)]
NOTES:

- (1) Potential problems with CIP and SIP with capped connections.
- (2) Dead space: stagnant areas.
- (3) Less dead space.
- (4) Better CIP/SIP capabilities.
- (5) All L/D ratios to be calculated on long-side dimensions for vessel heads.
- (6) D = inside diameter.
- (7) Thermal mass.
- (8) L/D may exceed 2:1 ratio.
- (9) Hard to clean.
- (10) Sharp edge at internal corner.
- (11) Possible crack site at internal corner.

Fig. SD-10 Sidewall Instrument Ports

Fig. SD-11 Dip Tube

NOTES:

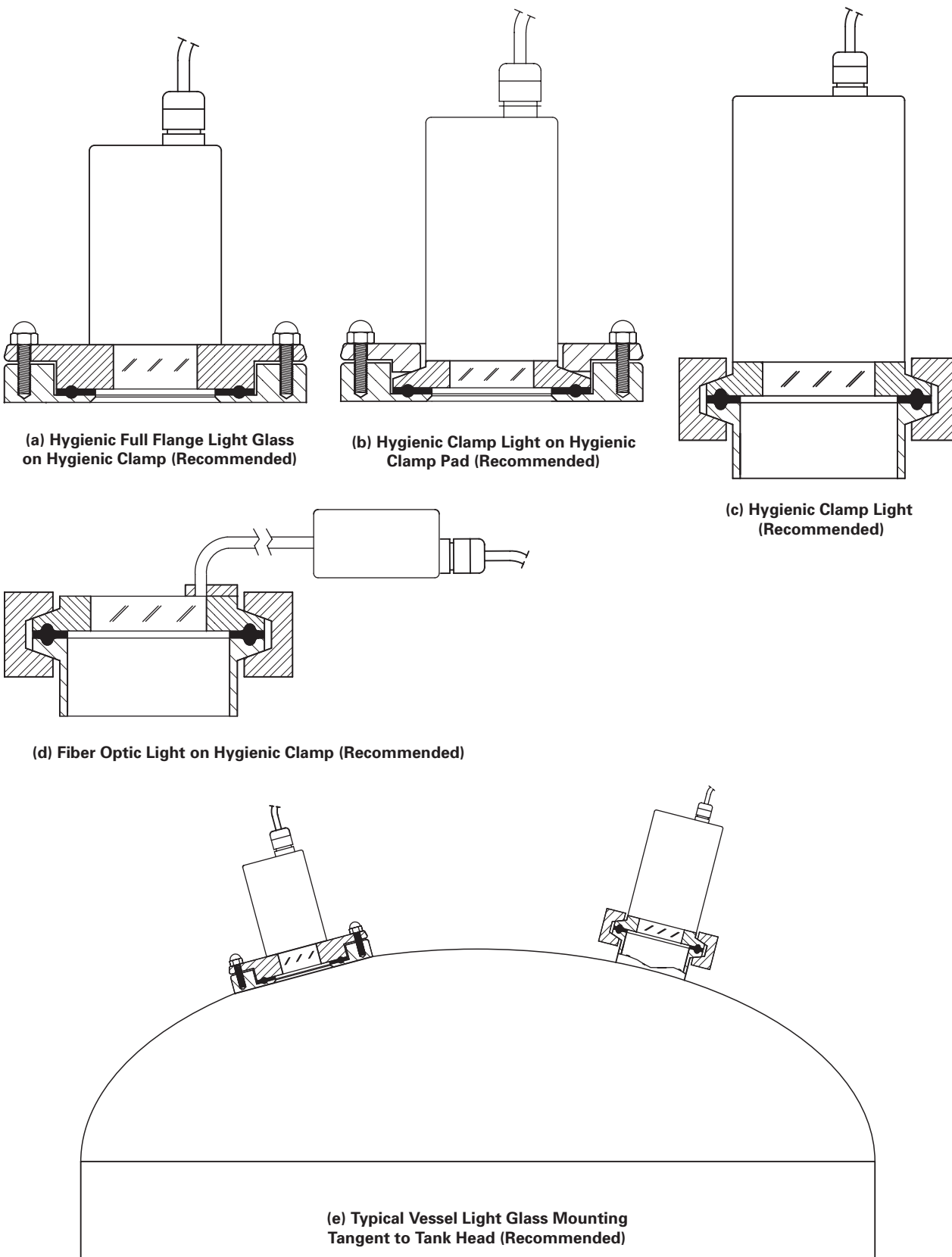
- (1) Potential problems with CIP and SIP.
- (2) Dead space: stagnant areas.
- (3) Less dead space.
- (4) Better CIP/SIP capabilities.
- (5) L/A target of 2:1 more easily attained.

Fig. SD-12 Vessel Design Tangential Nozzles

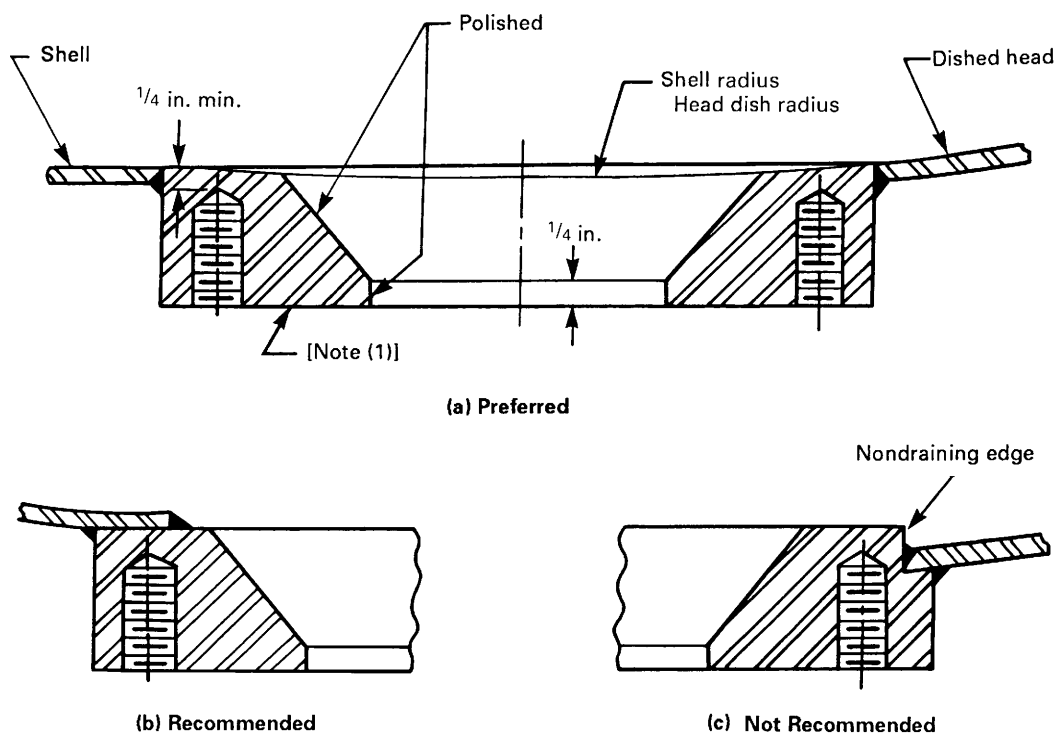


**Definition of L/D for Tangential
Inlet: Top View**

Fig. SD-13 Vessel Sight Glass Design



(09)

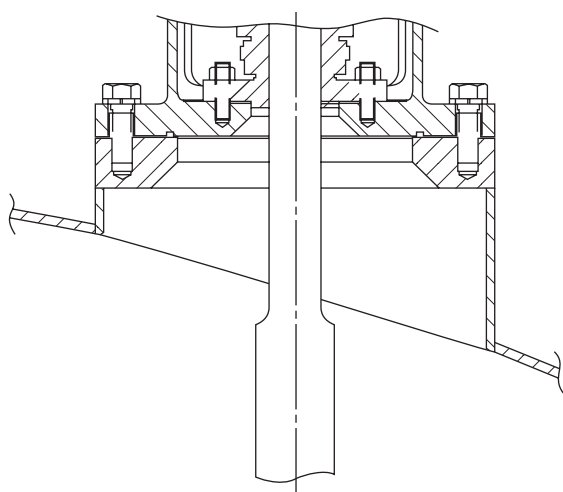
Fig. SD-14 Side and Bottom Connections


NOTE:

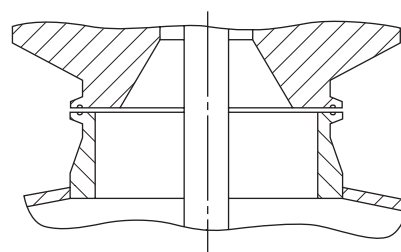
(1) If a flat gasket is used, mismatch of diameters can result in crevices.

Fig. SD-15 Agitator Mounting Flanges

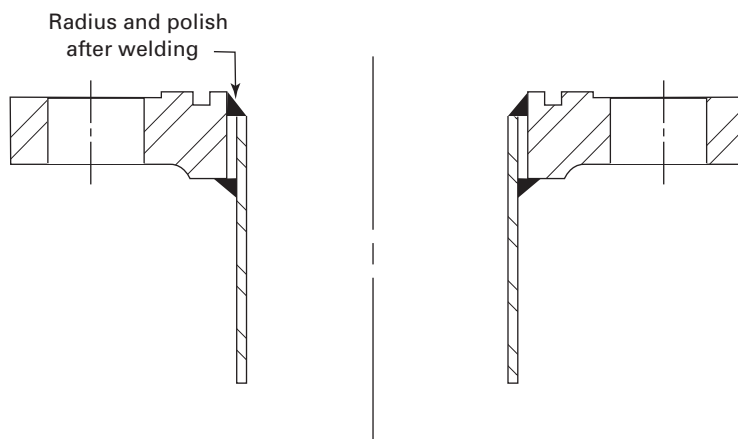
(09)



(a) Bolted Flange With O-ring

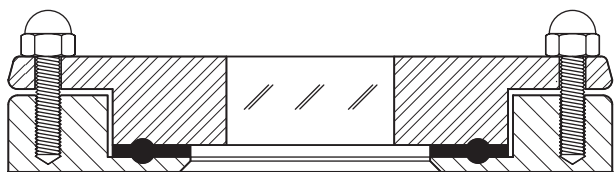


(b) Hygienic Union With Gasket

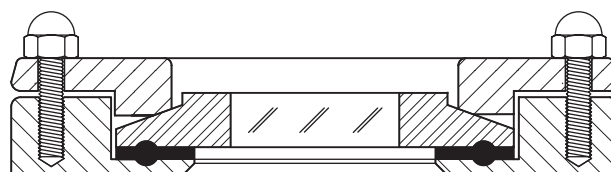


**(c) Typical Nozzle Construction
for Slip-On Flange**

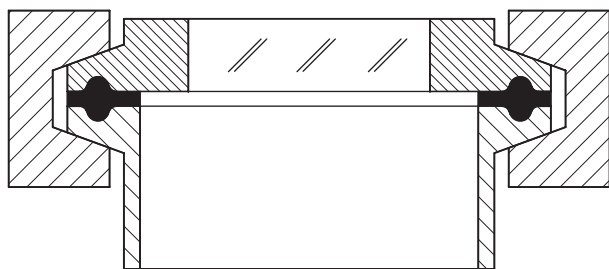
Fig. SD-16 Sight Glass Design



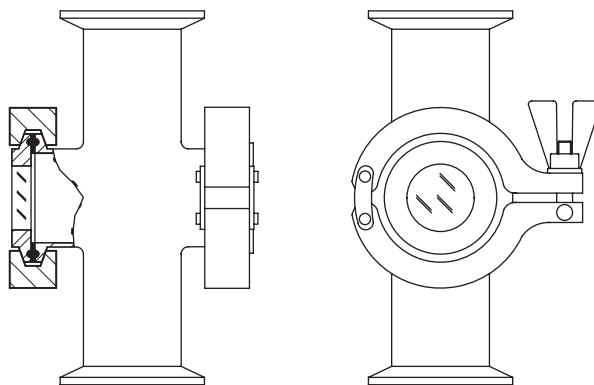
**(a) Full Flange Sight Glass on Hygienic Pad Connection
(Recommended)**



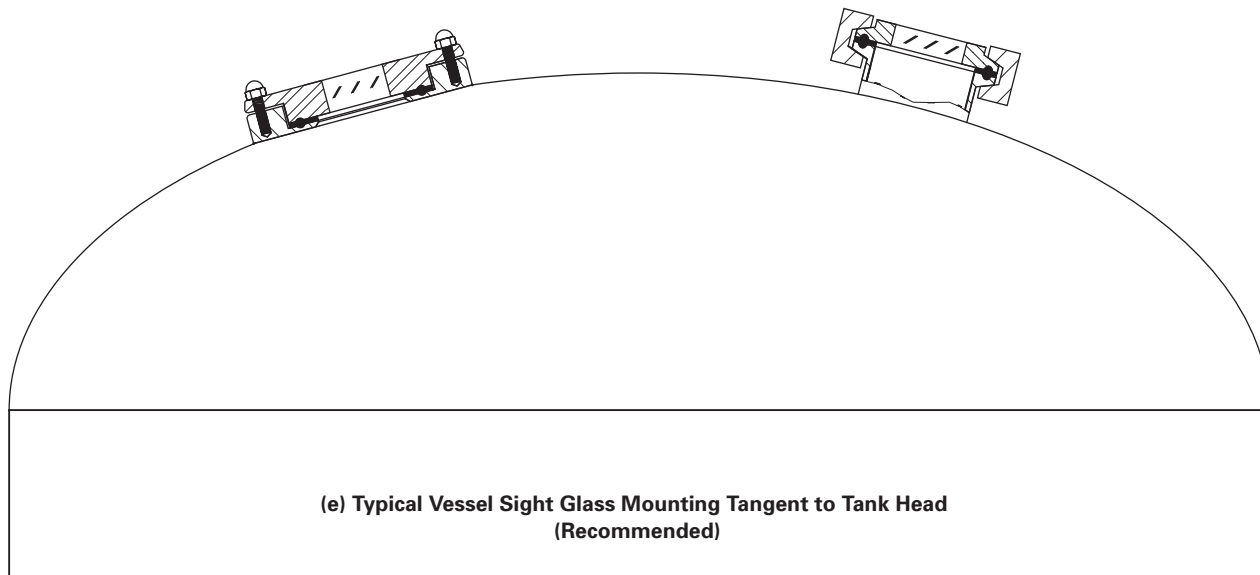
**(b) Hygienic Clamp on Hygienic Pad Connection
(Recommended)**



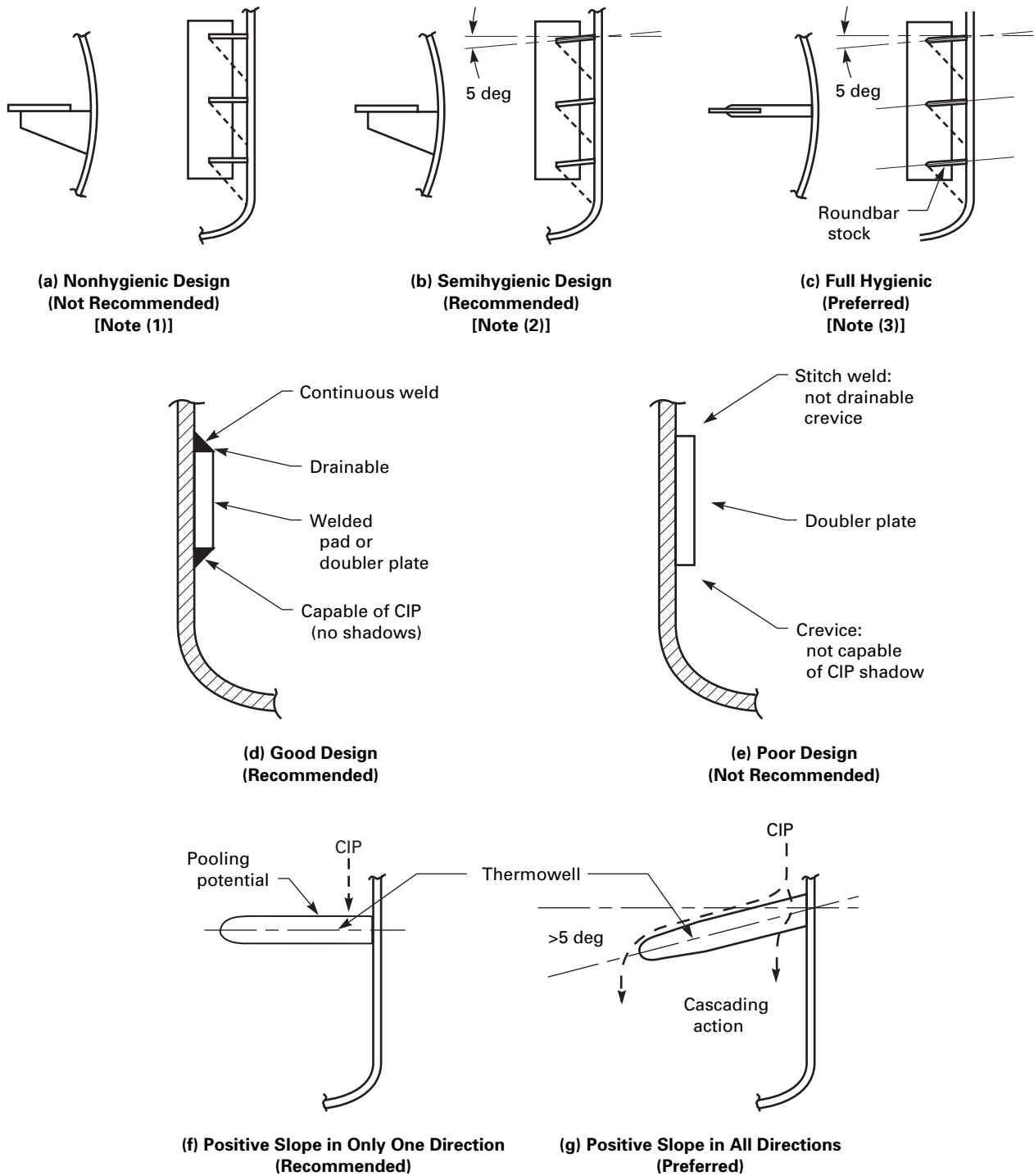
**(c) Hygienic Clamp Sight Glass
(Recommended)**



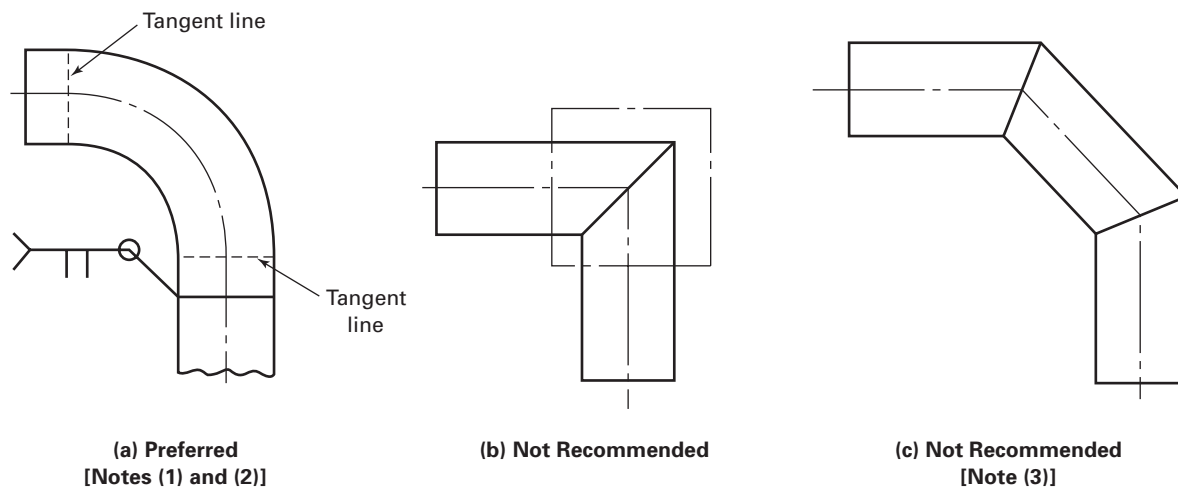
**(d) Hygienic Cross Sight Flow Indicator
(Recommended)**



**(e) Typical Vessel Sight Glass Mounting Tangent to Tank Head
(Recommended)**

Fig. SD-17 Internal Support Members

NOTES:

- (1) Flat surfaces, ledges, and CIP shadows.
- (2) Still flat surfaces, sloped for drainage, and still CIP shadows.
- (3) Sloped, minimum shadow, and curved surface.

Fig. SD-18 Mitered Fittings

NOTES:

- (1) Fittings with no extension are marginally acceptable for manual welding.
- (2) An extension is needed for automatic orbital welding.
- (3) Acceptable only if back purged and full penetration is confirmed.

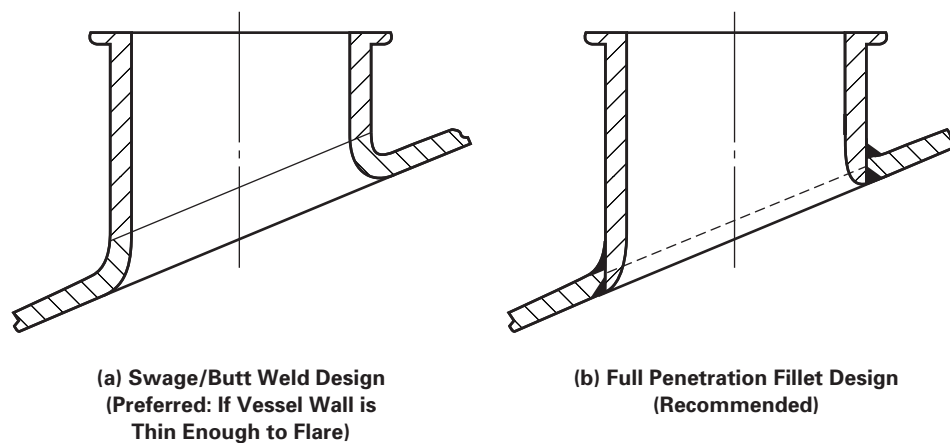
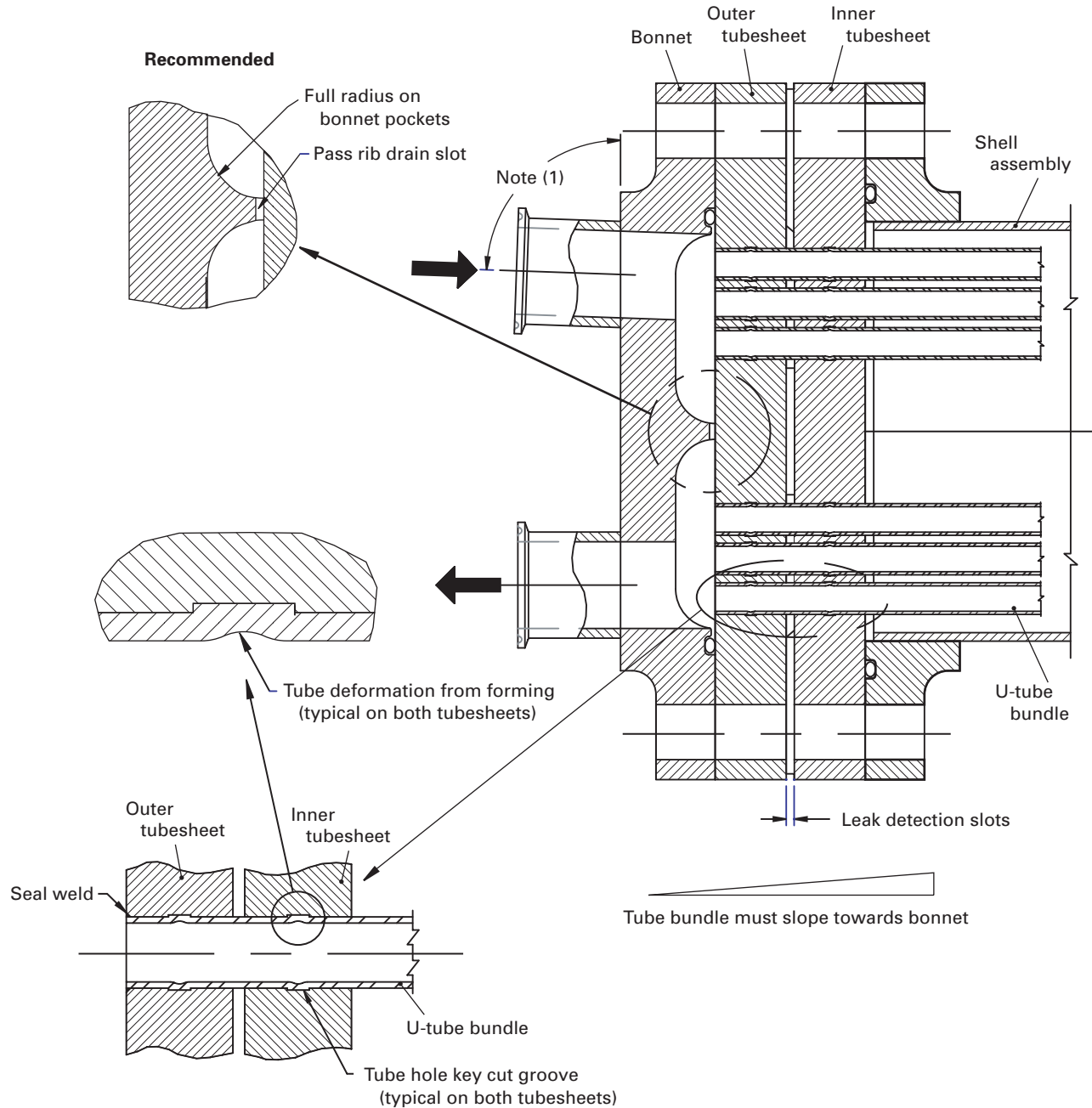
Fig. SD-19 Typical Nozzle Detail


Fig. SD-20 Double Tubesheet Heat Exchanger Bonnet Design



NOTE:

(1) Owner to specify inlet tubing slope. Heat exchanger manufacturer to slope inlet on bonnet to match inlet tubing slope.

Fig. SD-21-1 Shaft Coupling Construction

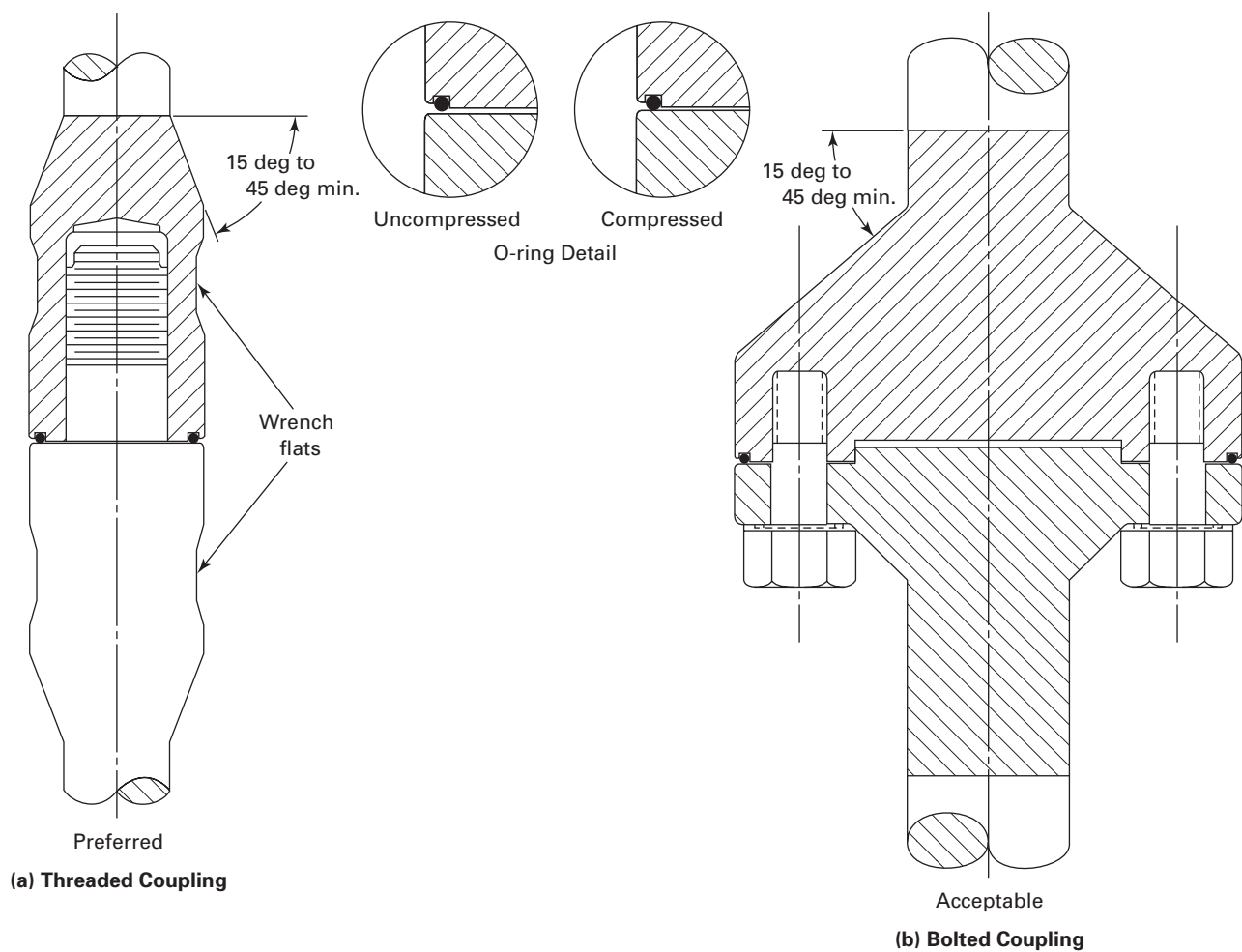


Fig. SD-21-2 Shaft Coupling Seal Arrangements

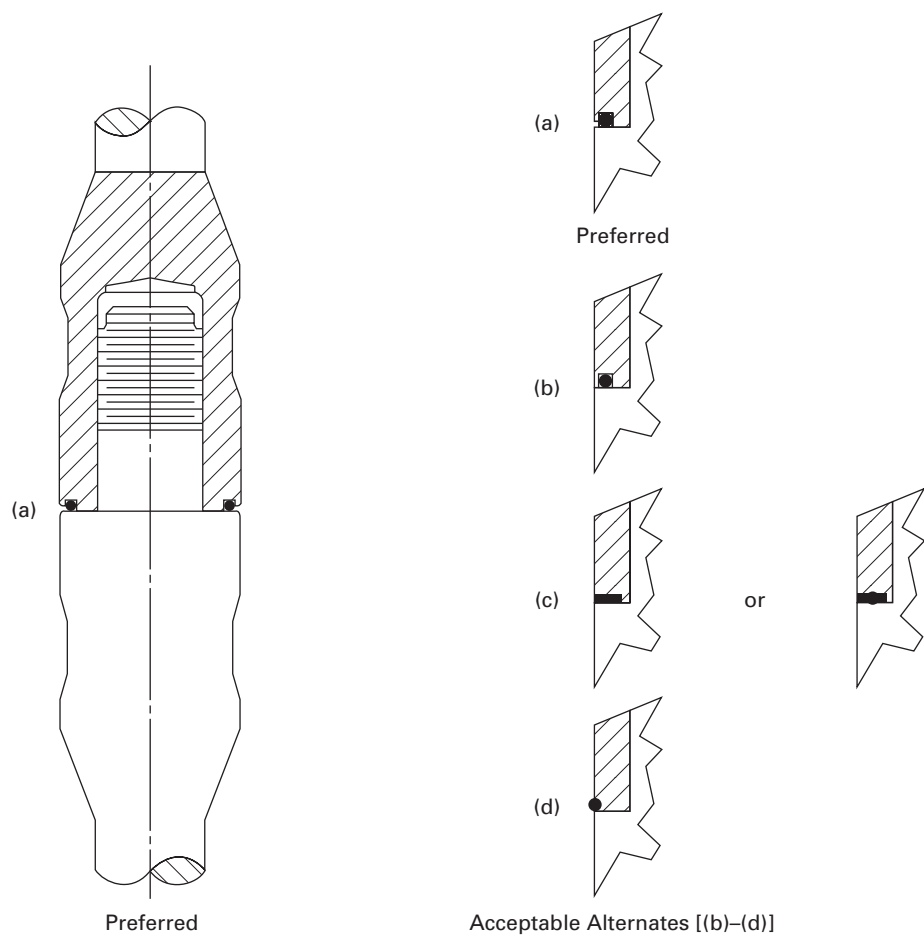


Fig. SD-21-3 Fastener Seal Arrangements

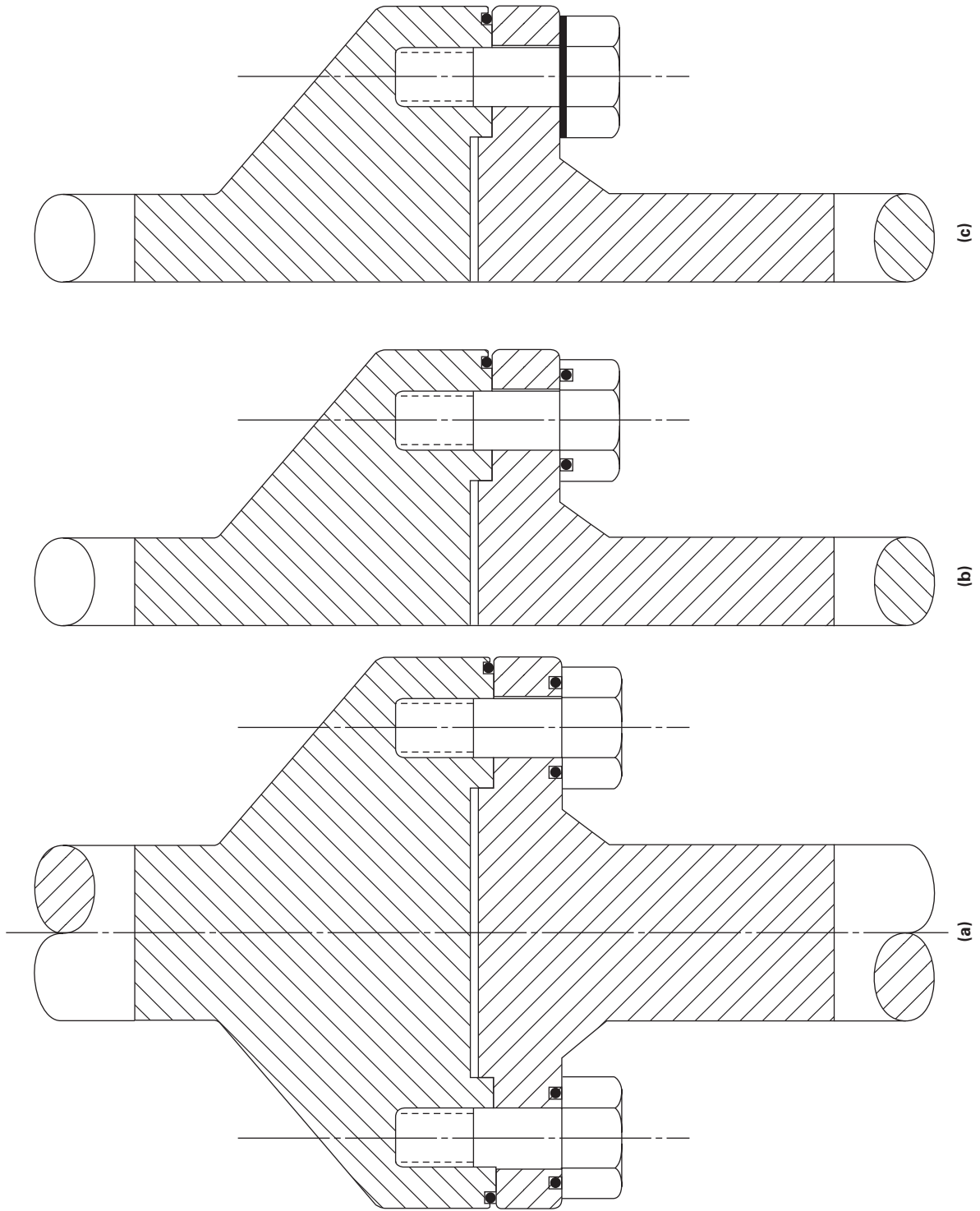
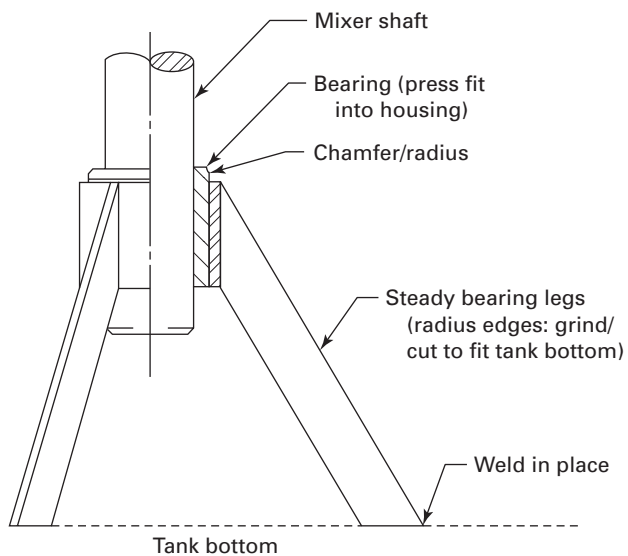
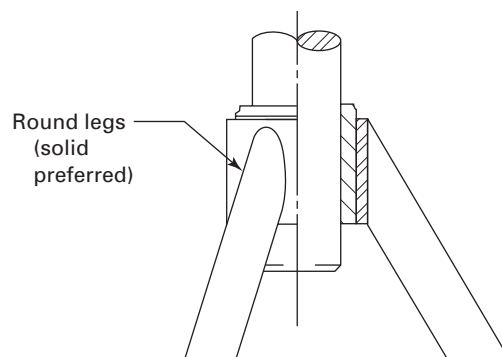


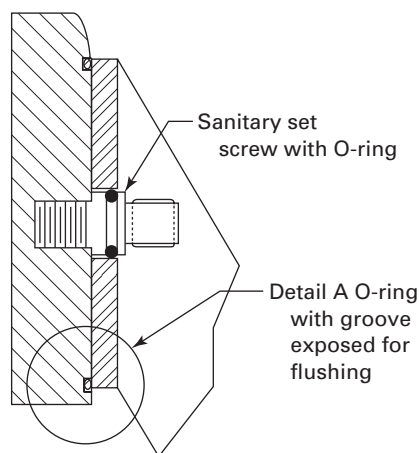
Fig. SD-21-4 Shaft Steady Bearing



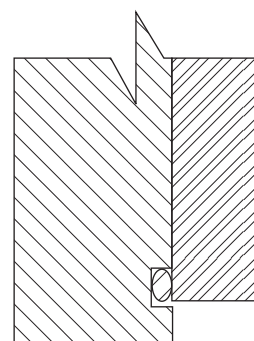
(a) Sanitary Tripod Steady Bearing



(b) Alternative Leg Design



(c) Alternative Bearing Securing Method



Detail A



Fig. SD-21-6 Double Mechanical Cartridge Seal With Debris Well

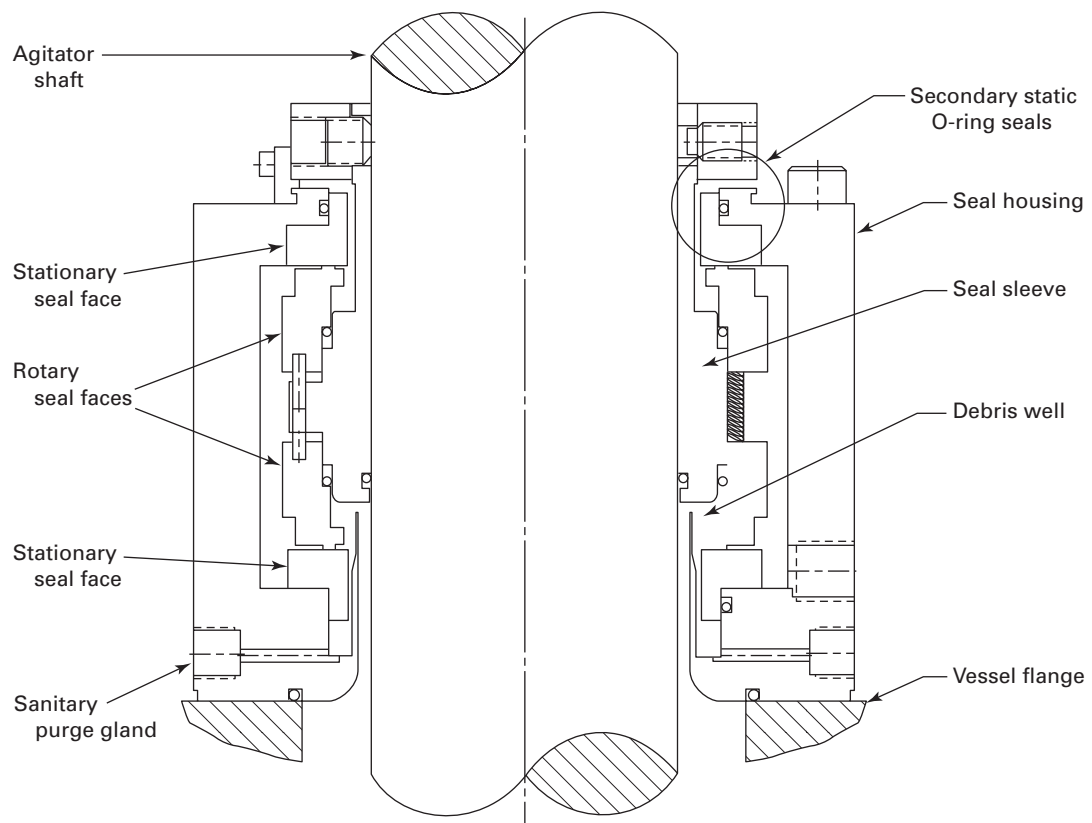
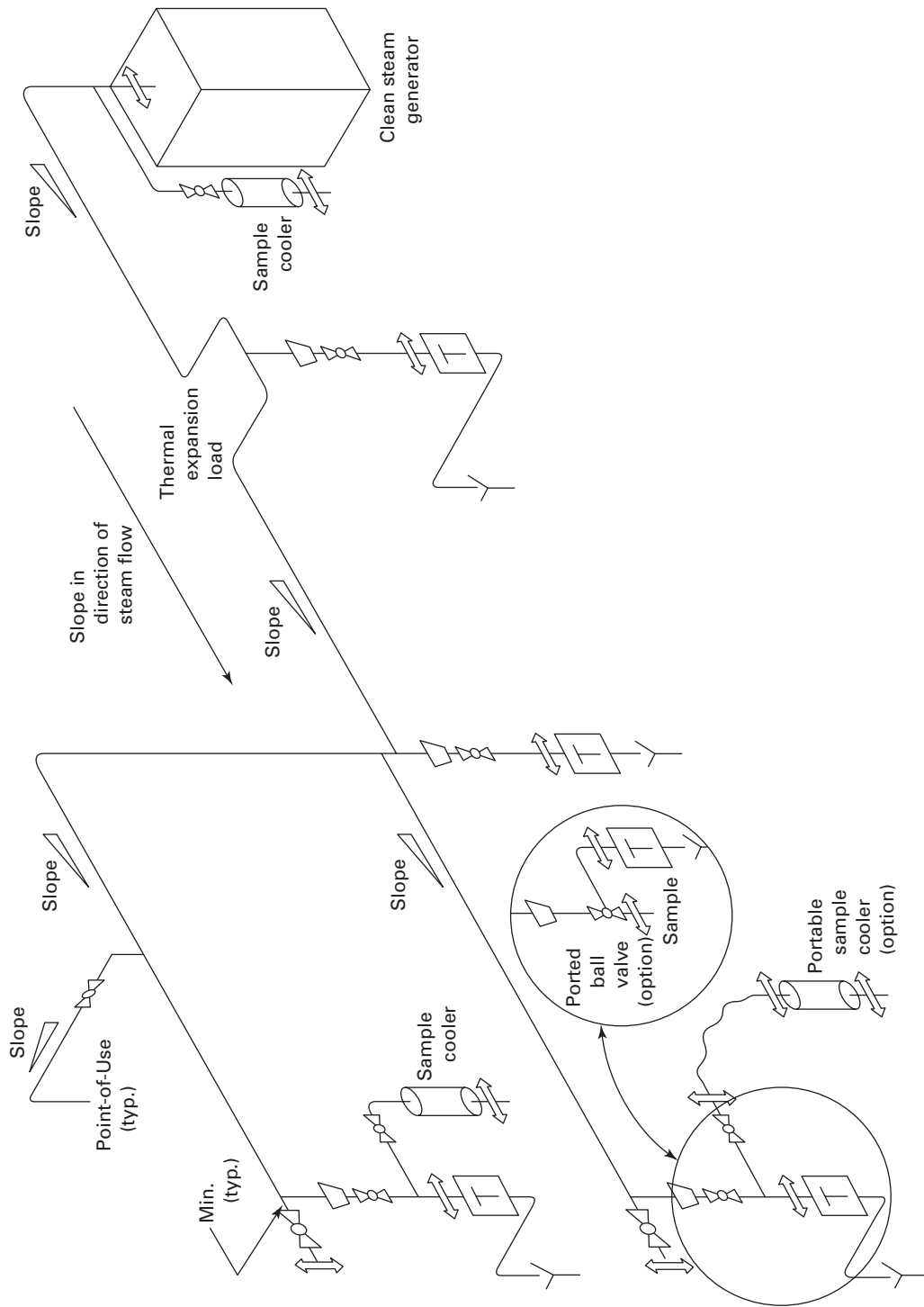
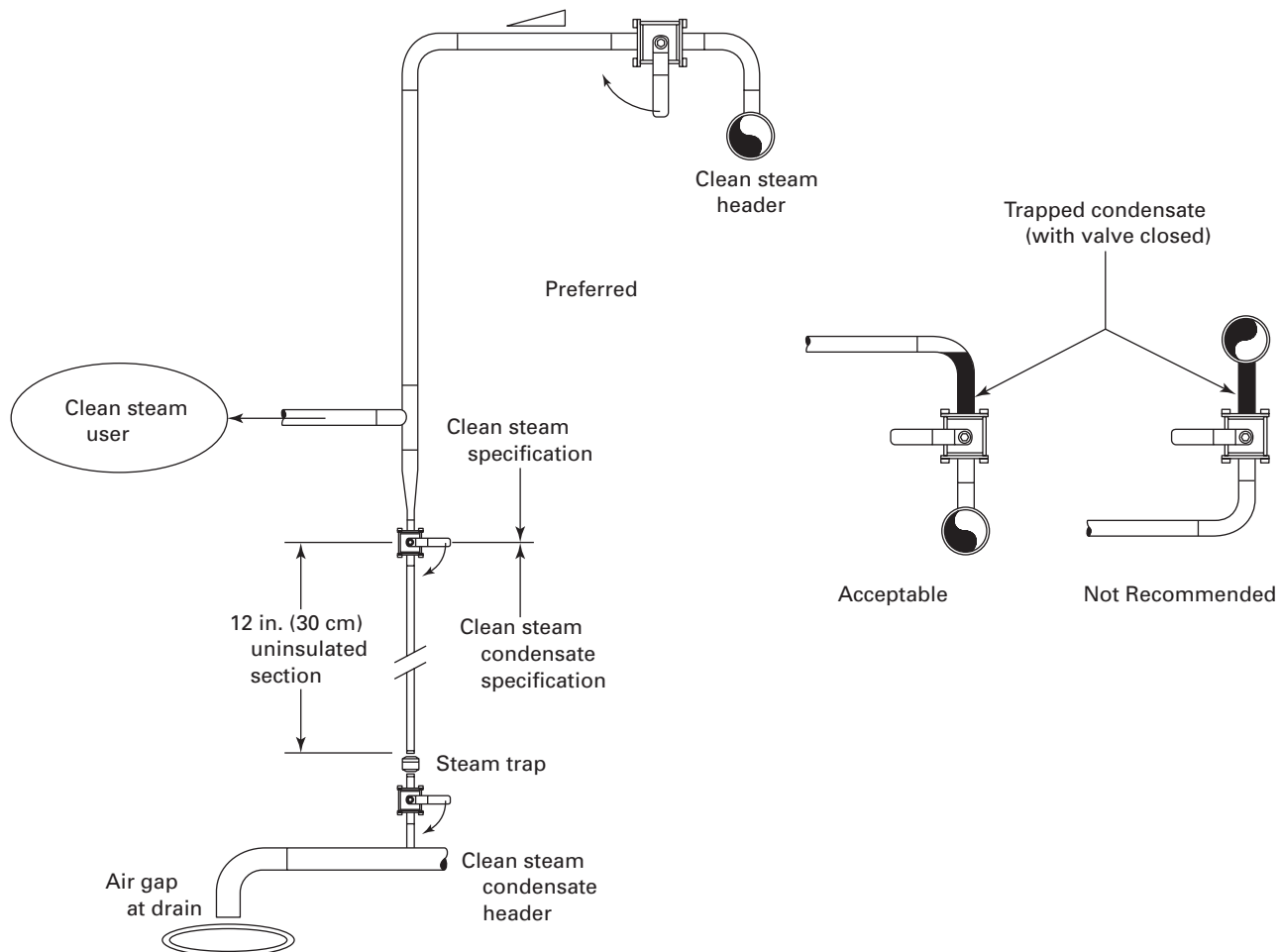
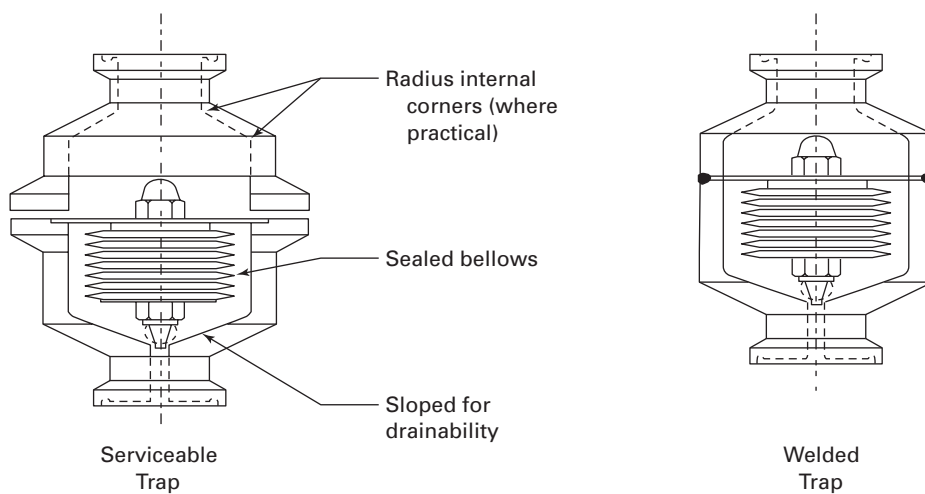


Fig. SD-22-1 Typical Clean Steam System Isometric



GENERAL NOTE: Provide steam traps

- where line transitions from horizontal to vertical (at the bottom of the vertical riser)
- at least every 100 ft (30 m)
- at end of each header or branch
- at thermal expansion loops or transitions
- where steam is sampled

Fig. SD-22-2 Clean Steam Point-of-Use Design

Fig. SD-22-3 Steam Traps for Clean Steam Systems


(09)

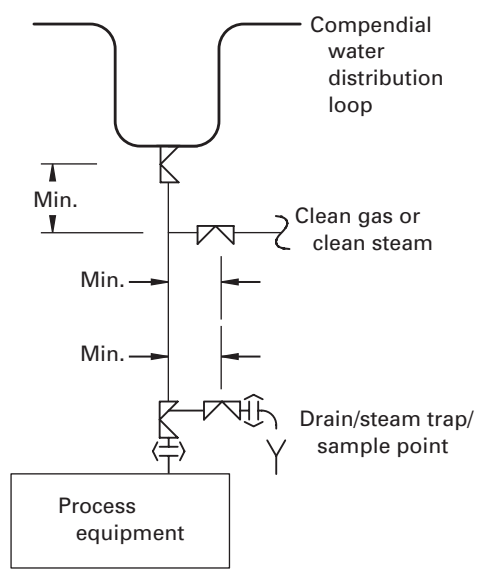
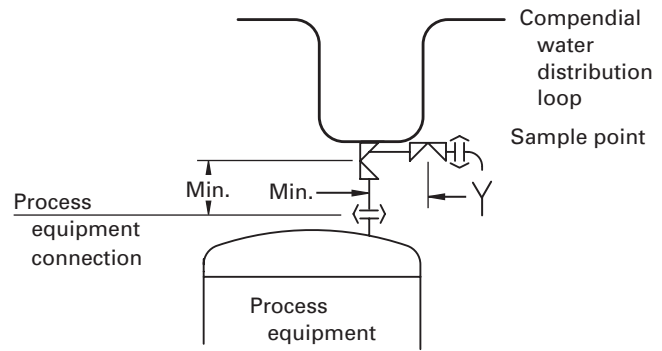
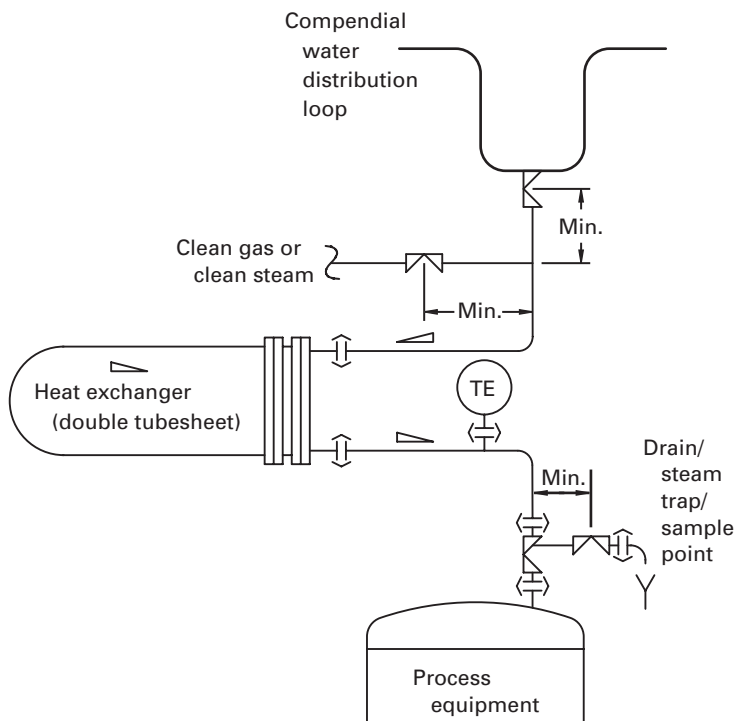
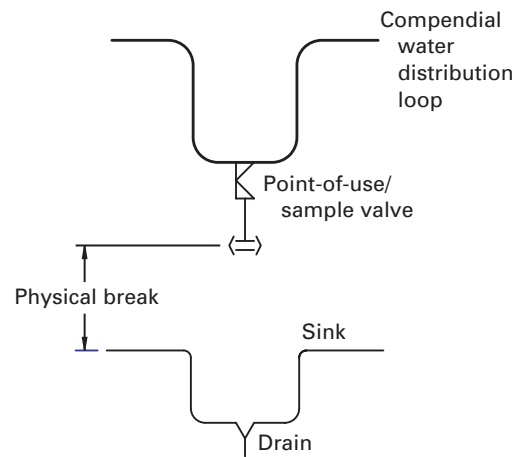
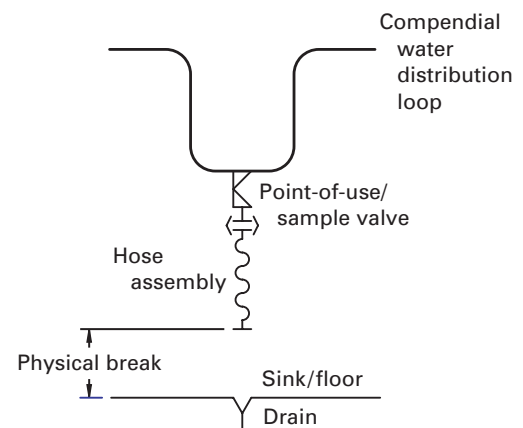
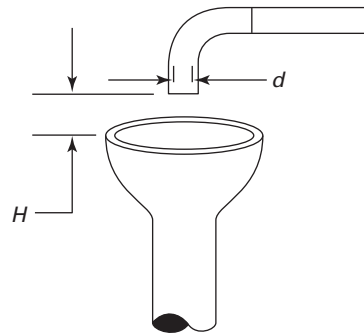
Fig. SD-23-1 Point-of-Use Piping

(a) Hard Piped to Equipment

(b) Direct Connect to Equipment

(c) Integral Heat Exchanger

(d) Sink

(e) Hose

Fig. SD-23-2 Physical Break in Point-of-Use Piping

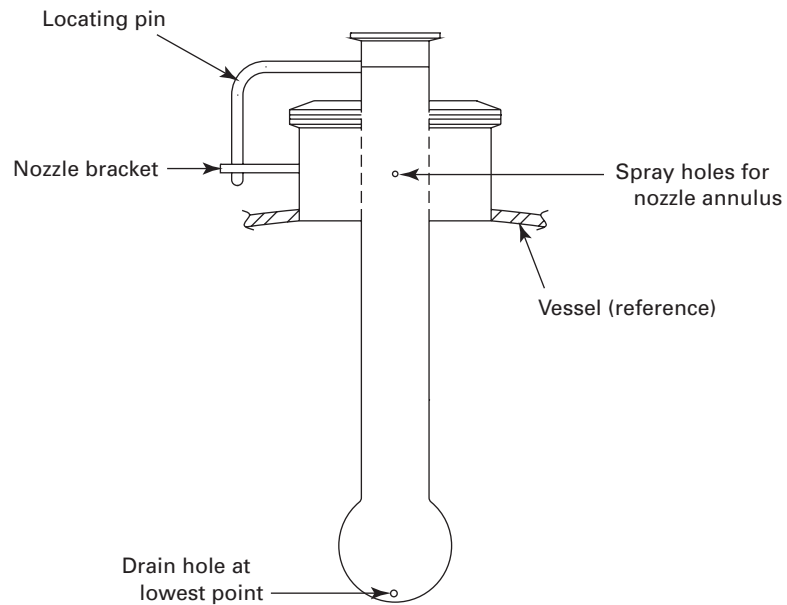
(09)



GENERAL NOTE: $H = 2 \times d$ or $H = 1$ in. (25 mm) if $d < \frac{1}{2}$ in. (13 mm)

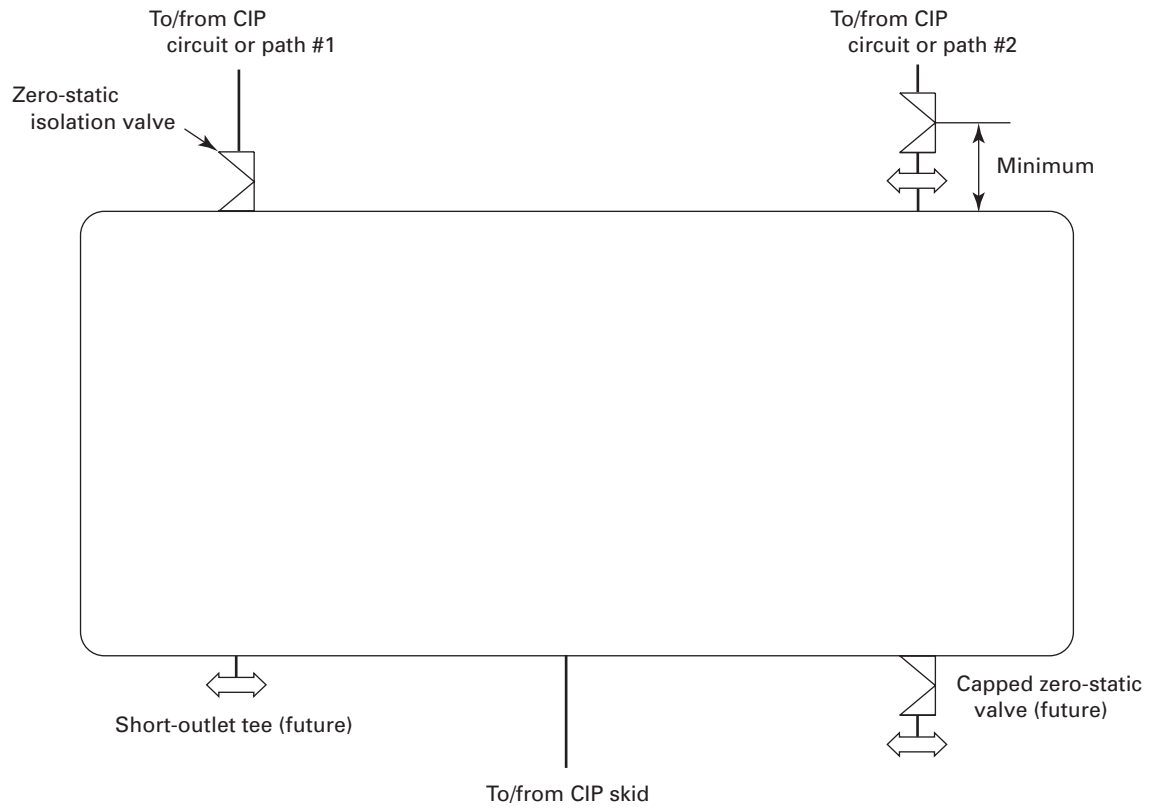
Fig. SD-23-3 Static Spray Device

(09)



(09)

Fig. SD-23-4 CIP Looped Header (Supply or Return)



(09)

Fig. SD-23-5 Zero-Static Chain

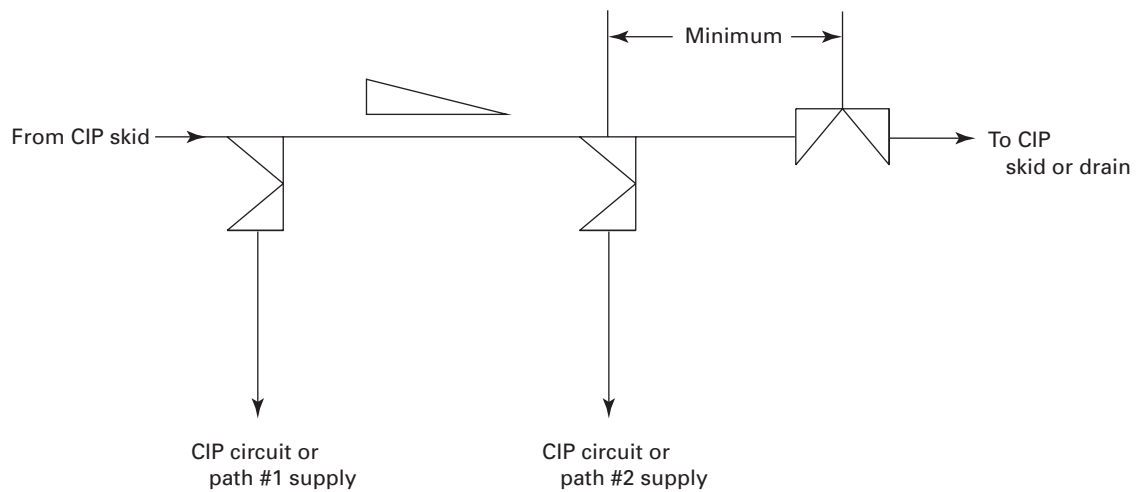


Fig. SD-23-6 Swing Elbow Arrangement

(09)

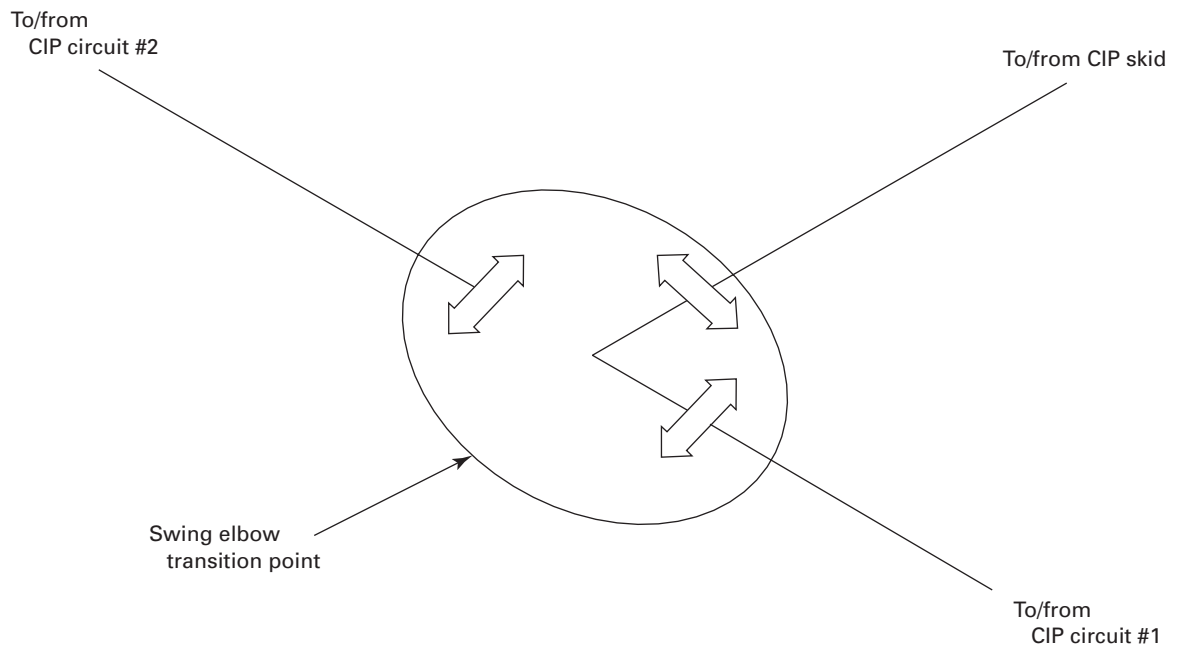


Fig. SD-24 Transfer Panel Tolerances

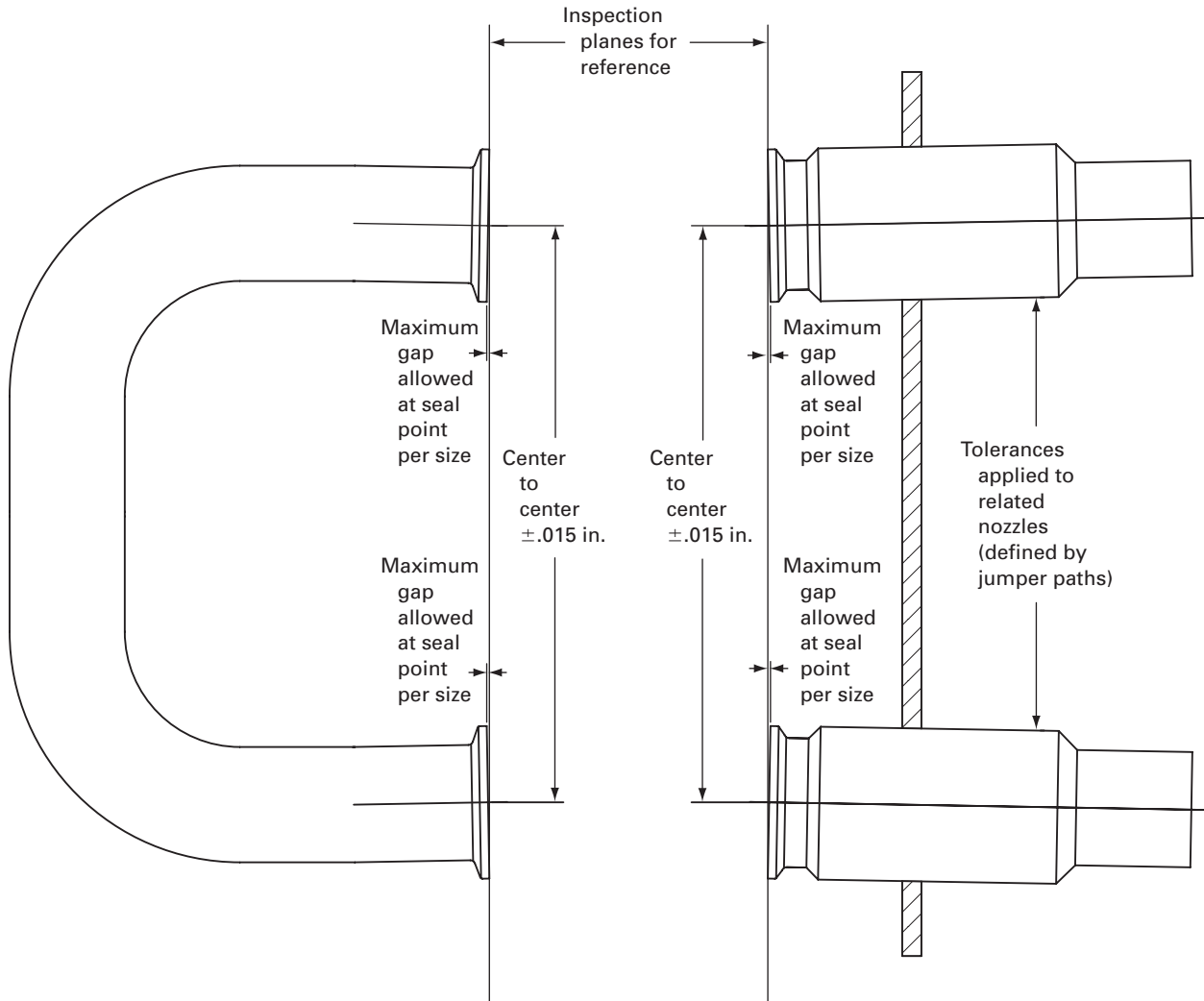
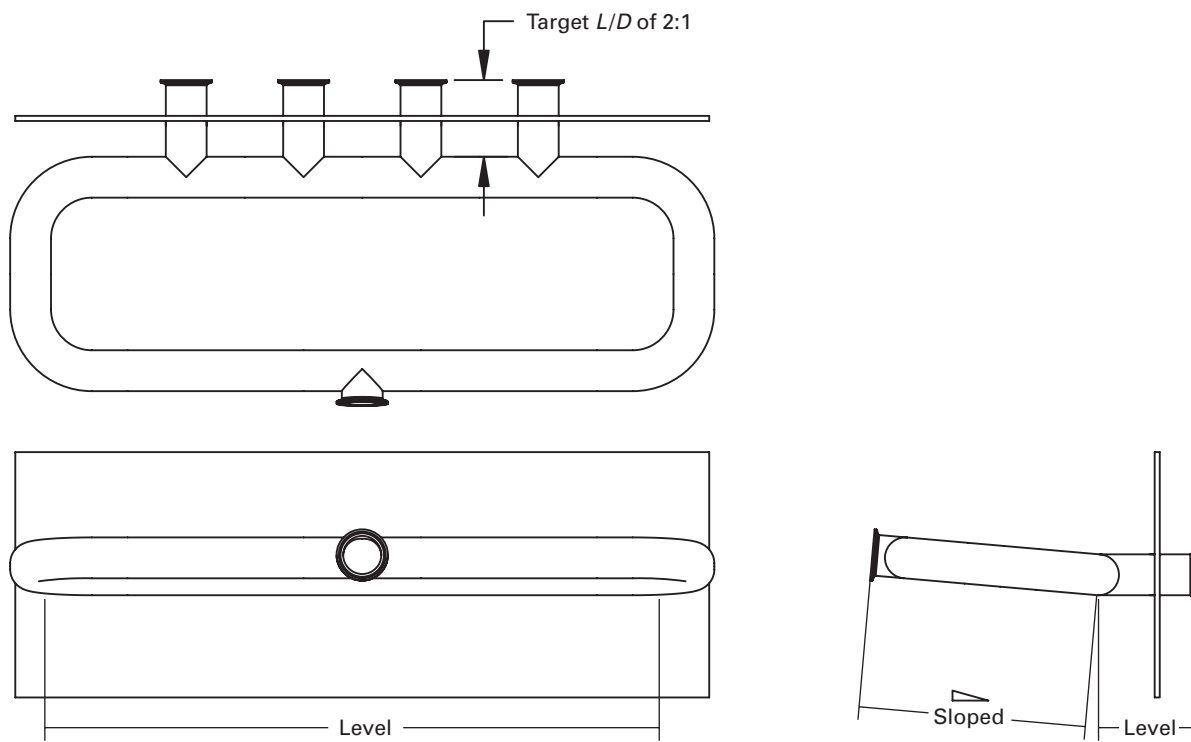
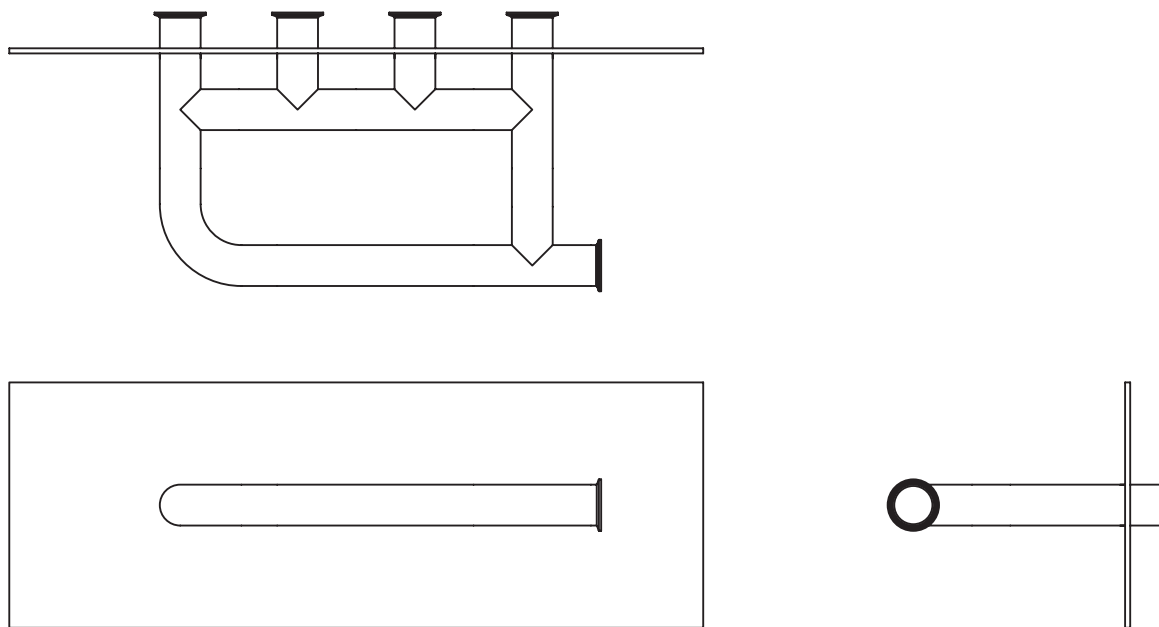


Fig. SD-25 Transfer Panel Looped Headers



(a) Recommended



(b) Not Recommended

Fig. SD-26 Transfer Panel Jumpers

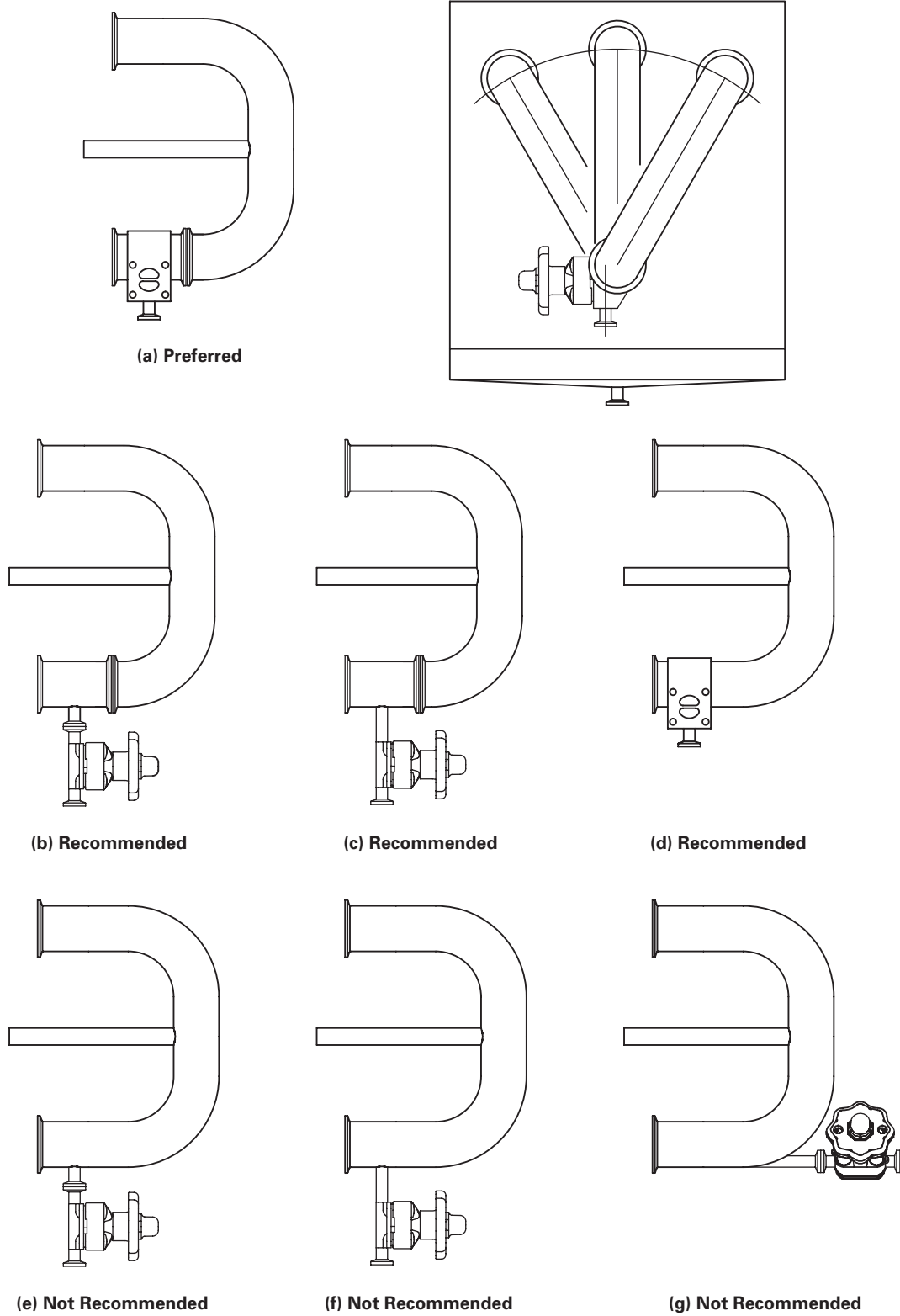
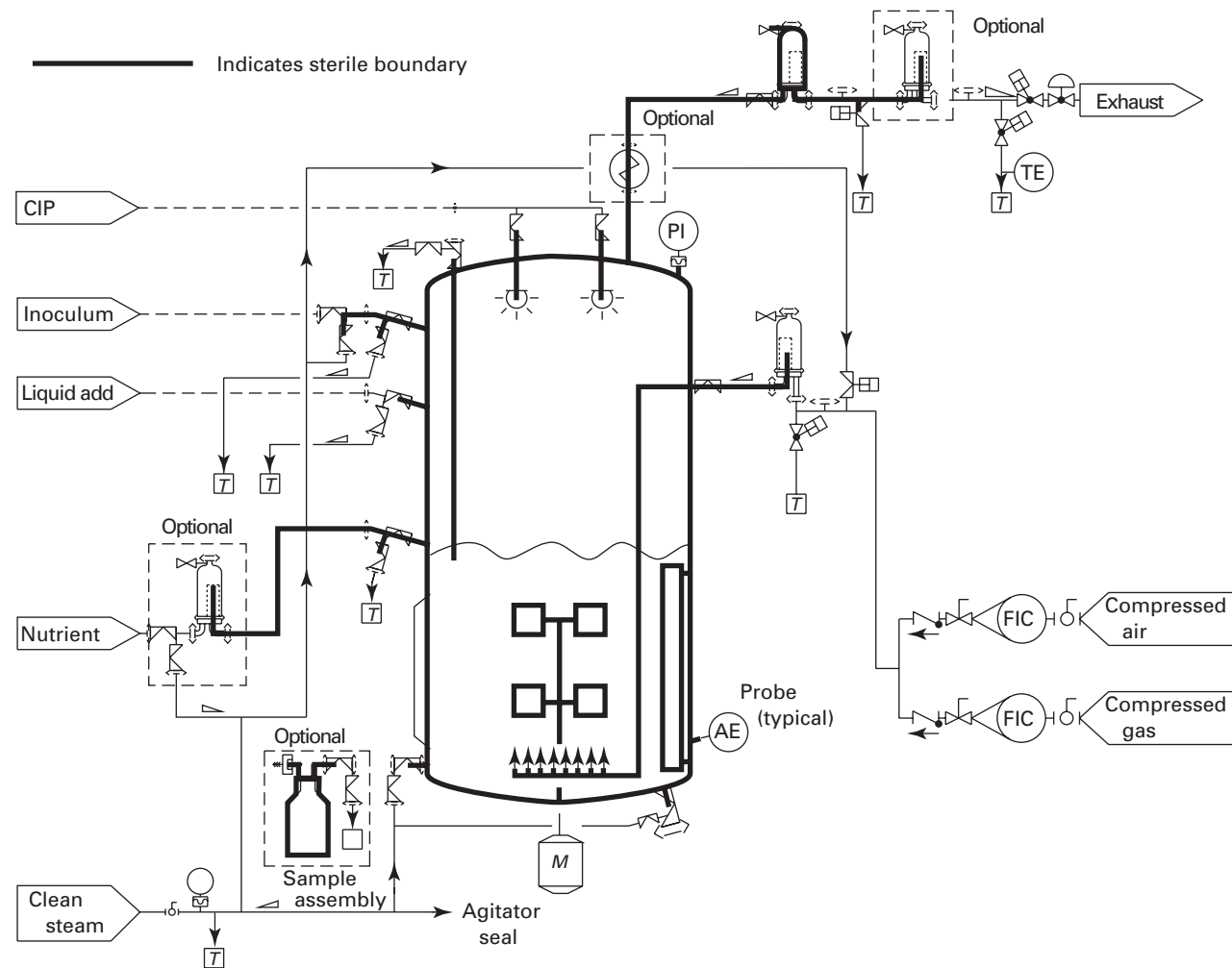


Fig. SD-27-1 Fermentor Sterile Envelope

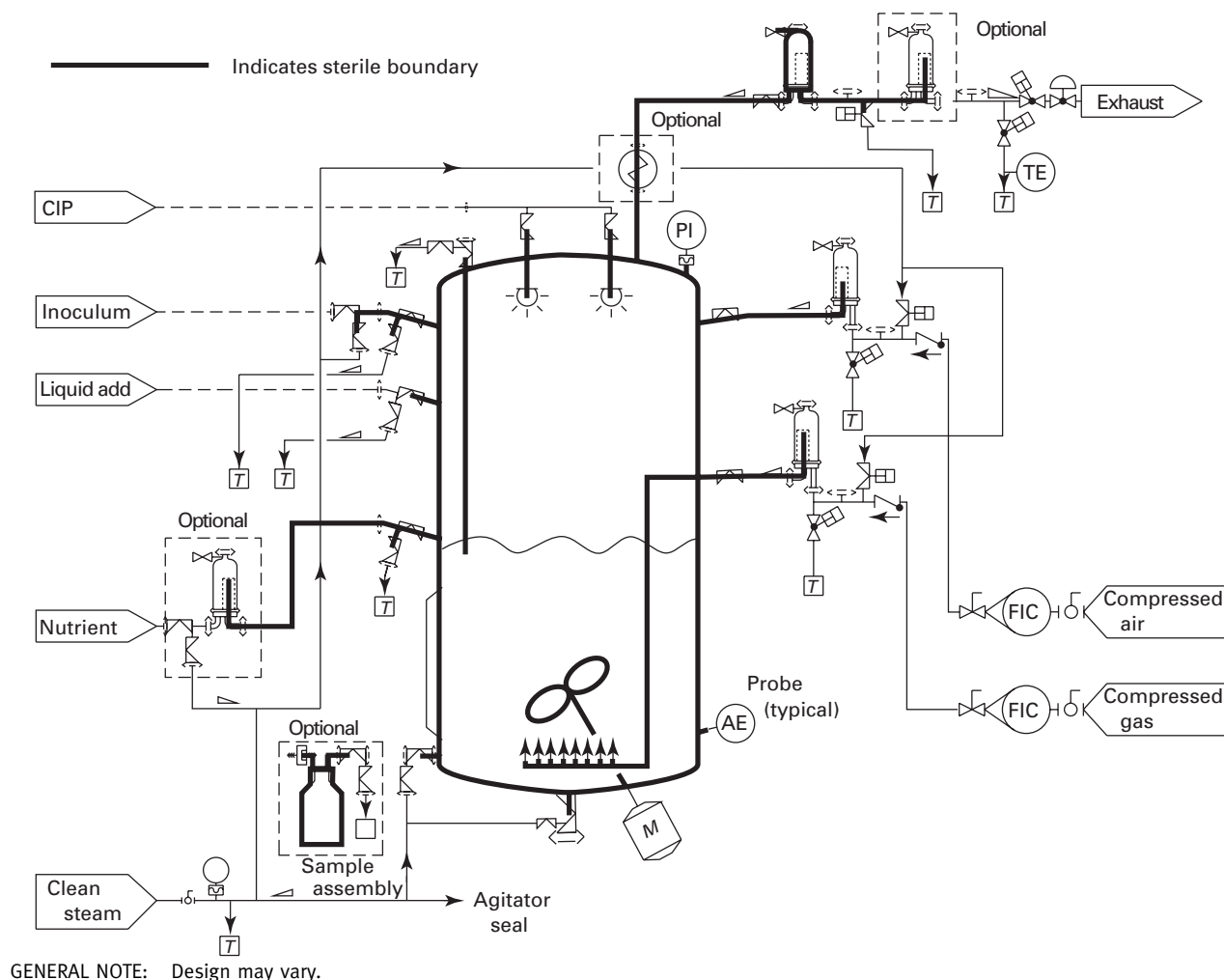
(09)



GENERAL NOTE: Design may vary.

(09)

Fig. SD-27-2 Bioreactor Sterile Envelope



(09)

Fig. SD-28-1 Gas Sparging Assembly — Lance

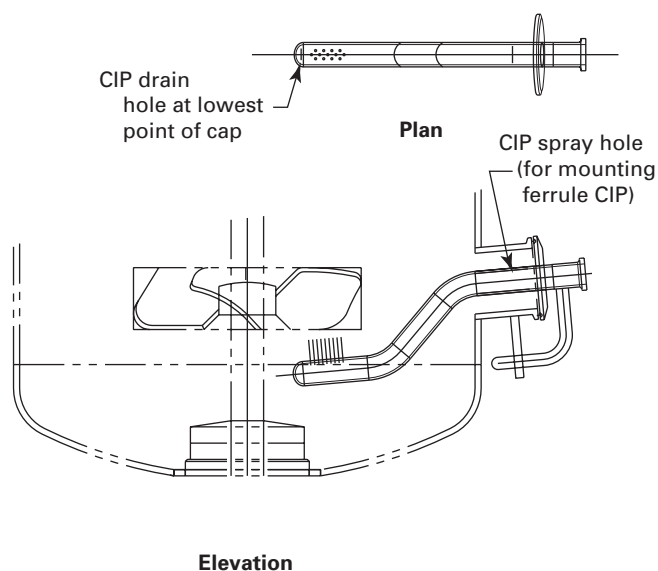
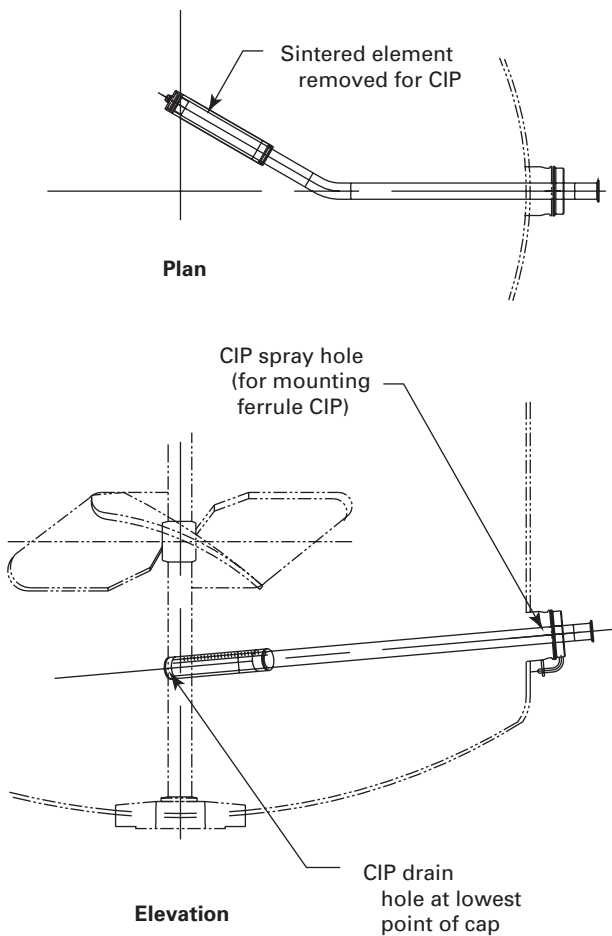


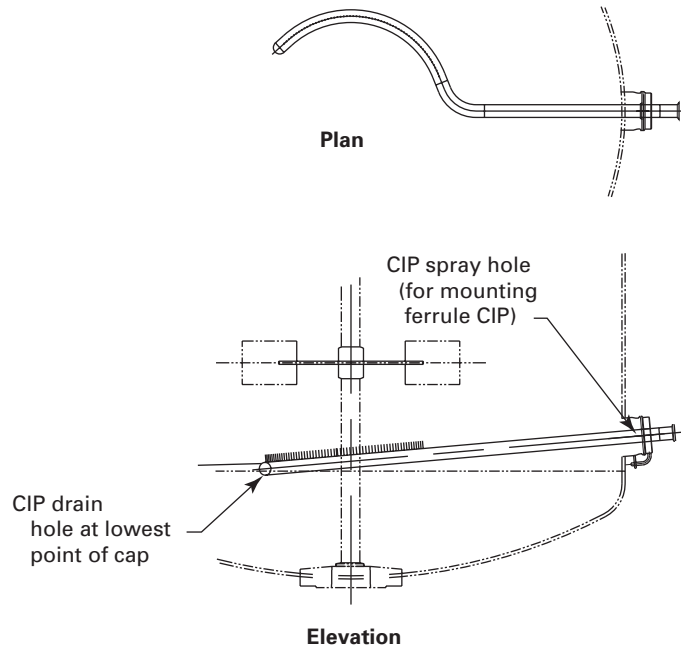
Fig. SD-28-2 Gas Sparging Assembly — Sintered

(09)



(09)

Fig. SD-28-3 Gas Sparging Assembly — Ring



(09)

Fig. SD-28-4 Gas Sparging Assembly — Single Orifice

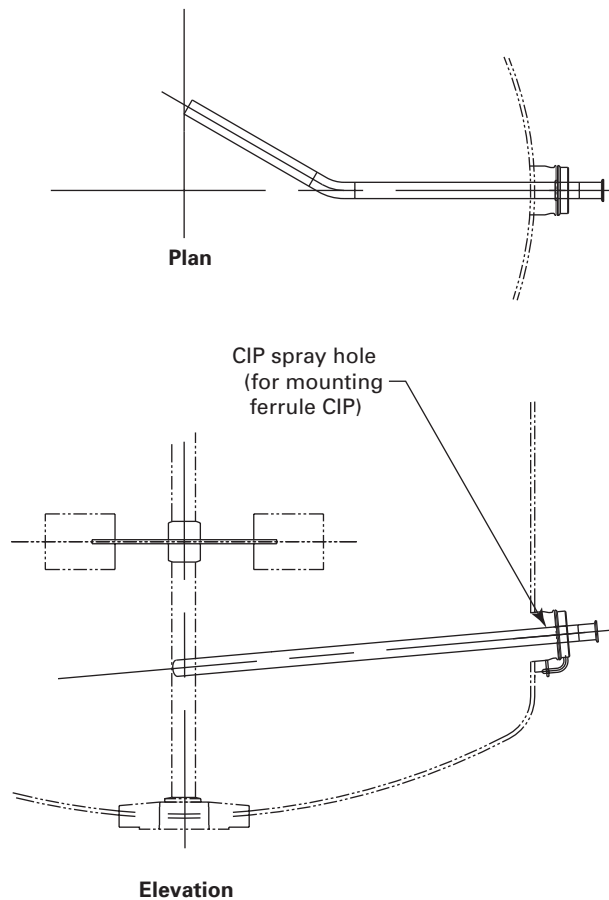
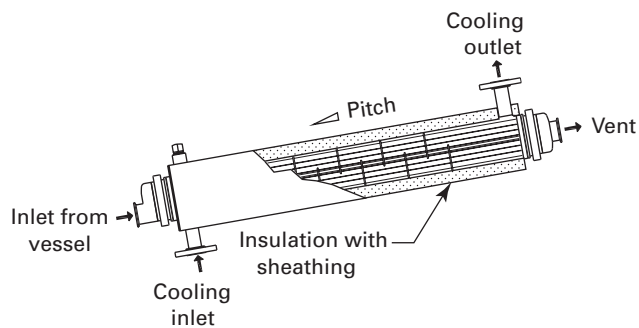
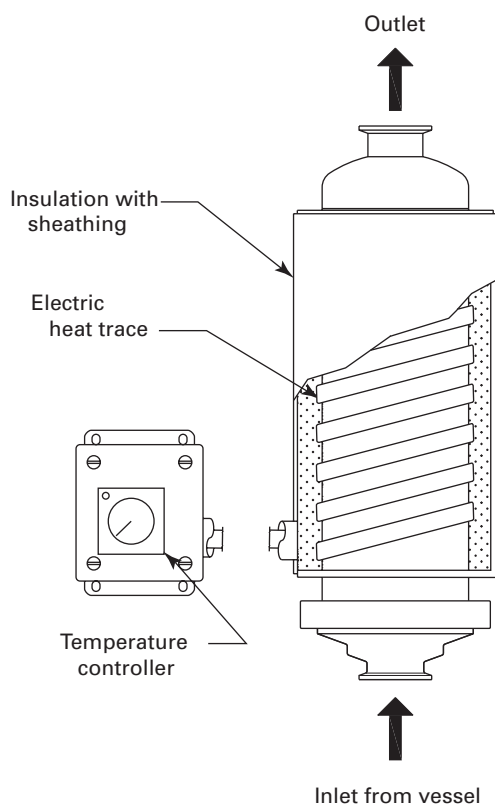


Fig. SD-29-1 Exhaust Gas Condenser

(09)


Fig. SD-29-2 Exhaust Gas Heater

(09)


Fig. SD-30 Electrically Heat Traced Filter Housing

(09)

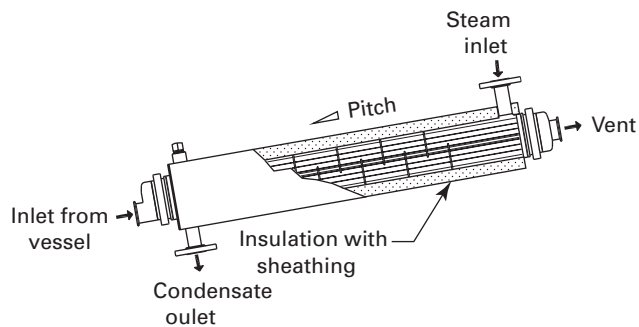
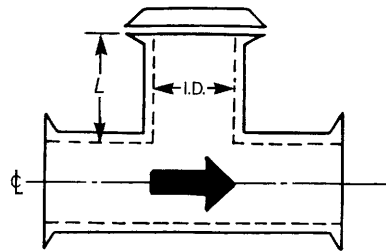
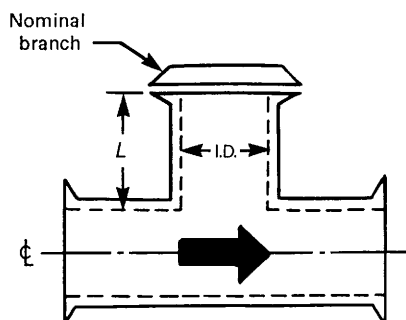


**Table SD-1 L/D Dimensions for Flow-Through Tee:
Full-Size Standard Straight Tee With Blind Cap**



Nominal Size, in.	Wall Thickness	I.D. (D)	Dead Leg, L	L/D (Dead Leg)
$\frac{1}{4}$	0.035	0.180	2.16	12.00
$\frac{3}{8}$	0.035	0.305	2.10	6.88
$\frac{1}{2}$	0.065	0.370	2.07	5.58
$\frac{3}{4}$	0.065	0.620	2.07	3.33
1	0.065	0.870	2.19	2.52
$1\frac{1}{2}$	0.065	1.370	2.14	1.56
2	0.065	1.870	2.44	1.30
$2\frac{1}{2}$	0.065	2.370	2.44	1.03
3	0.065	2.870	2.44	0.85
4	0.083	3.834	2.83	0.74
6	0.109	5.782	4.24	0.73

**Table SD-2 L/D Dimensions for Flow-Through Tee:
Short Outlet Reducing Tee With Blind Cap**



Nominal Size Tee, in.	Nominal Branch Size, in.	Tee Wall Thickness	Branch Wall Thickness	Branch I.D., D	Dead Leg, L	L/D (Dead Leg)
$\frac{3}{8}$	$\frac{1}{4}$	0.035	0.035	0.180	0.85	4.71
$\frac{1}{2}$	$\frac{1}{4}$	0.065	0.035	0.180	0.82	4.53
$\frac{1}{2}$	$\frac{3}{8}$	0.065	0.035	0.305	0.82	2.67
$\frac{3}{4}$	$\frac{1}{4}$	0.065	0.035	0.180	0.69	3.83
$\frac{3}{4}$	$\frac{3}{8}$	0.065	0.035	0.305	0.69	2.26
$\frac{3}{4}$	$\frac{1}{2}$	0.065	0.065	0.370	0.69	1.86
1	$\frac{1}{4}$	0.065	0.035	0.180	0.69	3.83
1	$\frac{3}{8}$	0.065	0.035	0.305	0.69	2.26
1	$\frac{1}{2}$	0.065	0.065	0.370	0.69	1.86
1	$\frac{3}{4}$	0.065	0.065	0.620	0.69	1.11
$1\frac{1}{2}$	$\frac{1}{4}$	0.065	0.035	0.180	0.69	3.83
$1\frac{1}{2}$	$\frac{3}{8}$	0.065	0.035	0.305	0.69	2.26
$1\frac{1}{2}$	$\frac{1}{2}$	0.065	0.065	0.370	0.69	1.88
$1\frac{1}{2}$	$\frac{3}{4}$	0.065	0.065	0.620	0.69	1.11
$1\frac{1}{2}$	1	0.065	0.065	0.870	0.69	0.79
2	$\frac{1}{4}$	0.065	0.035	0.180	0.69	3.83
2	$\frac{3}{8}$	0.065	0.035	0.305	0.69	2.26
2	$\frac{1}{2}$	0.065	0.065	0.370	0.69	1.86
2	$\frac{3}{4}$	0.065	0.065	0.620	0.69	1.11
2	1	0.065	0.065	0.870	0.69	0.79
2	$1\frac{1}{2}$	0.065	0.065	1.370	0.69	0.50
$2\frac{1}{2}$	$\frac{1}{4}$	0.065	0.035	0.180	0.69	3.83
$2\frac{1}{2}$	$\frac{3}{8}$	0.065	0.035	0.305	0.69	2.26
$2\frac{1}{2}$	$\frac{1}{2}$	0.065	0.065	0.370	0.69	1.86
$2\frac{1}{2}$	$\frac{3}{4}$	0.065	0.065	0.620	0.69	1.11
$2\frac{1}{2}$	1	0.065	0.065	0.870	0.69	0.79
$2\frac{1}{2}$	$1\frac{1}{2}$	0.065	0.065	1.370	0.69	0.50
$2\frac{1}{2}$	2	0.065	0.065	1.870	0.69	0.37
3	$\frac{1}{4}$	0.065	0.035	0.180	0.69	3.83
3	$\frac{3}{8}$	0.065	0.035	0.305	0.69	2.26
3	$\frac{1}{2}$	0.065	0.065	0.370	0.69	1.86
3	$\frac{3}{4}$	0.065	0.065	0.620	0.69	1.11
3	1	0.065	0.065	0.870	0.69	0.79



**Table SD-2 L/D Dimensions for Flow-Through Tee:
Short Outlet Reducing Tee With Blind Cap (Cont'd)**

Nominal Size Tee, in.	Nominal Branch Size, in.	Tee Wall Thickness	Branch Wall Thickness	Branch I.D., <i>D</i>	Dead Leg, <i>L</i>	<i>L/D</i> (Dead Leg)
3	1½	0.065	0.065	1.370	0.69	0.50
3	2	0.065	0.065	1.870	0.69	0.37
3	2½	0.065	0.065	2.370	0.69	0.29
4	¼	0.083	0.035	0.180	0.71	3.93
4	⅜	0.083	0.035	0.305	0.71	2.32
4	½	0.083	0.065	0.370	0.71	1.91
4	¾	0.083	0.065	0.620	0.71	1.14
4	1	0.083	0.065	0.870	0.71	0.81
4	1½	0.083	0.065	1.370	0.71	0.52
4	2	0.083	0.065	1.870	0.71	0.38
4	2½	0.083	0.065	2.370	0.71	0.30
4	3	0.083	0.065	2.870	0.71	0.25
6	¼	0.109	0.035	0.180	0.86	4.77
6	⅜	0.109	0.035	0.305	0.86	2.82
6	½	0.109	0.065	0.370	0.86	2.32
6	¾	0.109	0.065	0.620	0.86	1.39
6	1	0.109	0.065	0.870	0.86	0.99
6	1½	0.109	0.065	1.370	0.86	0.63
6	2	0.109	0.065	1.870	0.86	0.46
6	2½	0.109	0.065	2.370	0.86	0.36
6	3	0.109	0.065	2.870	0.86	0.30
6	4	0.109	0.083	3.834	0.86	0.22

**Table SD-3 Slope Designations for
Gravity-Drained Lines**

Slope Designation	Minimum Slope, in/ft	Minimum Slope, mm/m	Minimum Slope, %	Minimum Slope, deg
GSD1	1/16	5	0.5	0.29
GSD2	1/8	10	1.0	0.57
GSD3	1/4	20	2.0	1.15
GSD0	Line slope not required			

**Table SD-5 Flow Rates to Achieve 5 ft/sec
(1.52 m/s)**

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Sanitary Tube Size					
O.D.		I.D.		Flow Rate	
in.	mm	in.	mm	gpm	Lpm
0.5	12.7	0.37	9.4	1.7	6.3
0.75	19.1	0.62	15.7	4.7	18
1.0	25.4	0.87	22.1	9.3	35
1.5	38.1	1.37	34.8	23	87
2	50.8	1.87	47.5	42.8	162

**Table SD-4 Annular Spacing Recommendations
for Hygienic Dip Tubes**

Dip Tube Size Tube O.D.		Mount Nominal Size	
in.	mm	in.	mm
½	12.7	2	50
¾	19.1	2	50
1	25.4	3	75
1½	38.1	3	75
2	50.8	4	100
2½	63.5	4	100
3	76.2	6	150
4	101.6	6	150



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Table SD-6 Recommended Flow Rates to Static Spray Devices to Ensure Coverage of Vertical Process Vessels

Vessel I.D.		Flow Rate	
ft	mm	gpm	Lpm
1.5	450	12 to 14	45 to 54
2	600	16 to 19	60 to 72
3	900	24 to 28	90 to 106
4	1 200	31 to 38	117 to 144
5	1 500	39 to 47	148 to 178
8	2 500	63 to 75	238 to 285
10	3 000	79 to 94	297 to 357

GENERAL NOTE: Flow rate calculated from 2.5 gpm/ft to 3 gpm/ft of vessel inner circumference.

Table SD-7 Transfer Panel and Jumper Tolerances

Connection Nominal Size, in.	Flatness Tolerance	Center-to-Center Dimensional Tolerance, in.
	Maximum Gap Allowed, in.	
0.50	0.010	±0.015
0.70	0.010	±0.015
1.00	0.020	±0.015
1.50	0.020	±0.015
2.00	0.025	±0.015
2.50	0.025	±0.015
3.00	0.030	±0.015
4.00	0.040	±0.015



Part DT

Dimensions and Tolerances for Stainless Steel Automatic Welding and Hygienic Clamp Tube Fittings and Process Components

(09) DT-1 SCOPE

This Part describes the overall dimensions, tolerances, and markings for commercial stainless steel tube automatic weld and hygienic clamp fittings and process components. In addition to fittings, this Part also covers the tolerances and marking of commercial stainless steel process components including, but not limited to, tubing, vessels, valves, pumps, filter housings, and instrumentation.

This Part describes the fittings made for use with nominal outside diameter (O.D.) tubing for the sizes listed in Table DT-1. The dimensions in metric units are conversions from the U.S. Customary units, and are listed for reference only. For nominal metric size tubing and fittings, refer to the appropriate international standards.

DT-2 PRESSURE RATING

Fittings manufactured to this Part shall meet or exceed the pressure ratings shown in Table DT-2, and shall have an ambient temperature bursting strength of at least three times the 100°F rated internal working pressure as shown in Table DT-2 (see also Fig. DT-1).

Fabricated components employing welds shall be rated at 100% of the above ratings.

DT-3 MARKING

DT-3.1 Marking Information

Except as specified in DT-3.2, each fitting and process component shall be permanently marked by any suitable method not injurious to the product contact surface to show the following:

- (a) heat number/code traceable to material test report for each product contact surface component
- (b) material type
- (c) manufacturer's name, logo, or trademark
- (d) reference to this Standard (ASME BPE)
- (e) product contact surface designation for the appropriate BPE specification

DT-3.2 Exceptions

- (a) Where the size of the fitting or process component does not permit complete marking, the identification

marks may be omitted in reverse of the order presented above. However, the heat number and material type shall be marked on the fitting or process component.

- (b) Where the size of the fitting or process component does not permit complete marking of the heat number, a manufacturer's code number is acceptable under this Standard.

DT-4 MATERIALS

Generally, materials furnished to this Standard shall be Type 316, Type 316L, or other material agreed to by the purchaser and manufacturer.

Where Type 316L is specified, the material of the automatic weld end shall conform to the requirements for chemical composition as prescribed in Table DT-3.

For nonautomatic weld ends, the chemical composition shall meet the requirements of the applicable ASTM specification.

DT-5 METAL THICKNESS

As these fittings and process components are to match tube dimensions, the thickness of the weld ends shall conform with the tolerances listed in Table DT-5-1 and Table DT-6. The nominal wall thickness of the fittings and process components shall be the same as the tube to which they are welded.

After fabrication and surface treatment, the wall thickness in any formed part of the fitting or process component, beyond the control portion as defined in DT-8, shall be a minimum of 65% of the nominal wall thickness. For guidelines regarding all shop and field welds, refer to Part MJ. All welds shall meet the provisions of MJ-6 and Fig. MJ-1.

DT-6 FITTING DIMENSIONS

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Dimensions for the fittings depicted by this Standard are given in Tables DT-7 through DT-31.

All fittings shall have minimum tangent lengths for automatic welding per Table DT-4. The tangent length *T* is defined as the straight length measured from the welding end.

All sizes shown are nominal O.D. tube sizes.

Fittings not specifically described in Tables DT-7 through DT-31 may be constructed using combinations of centerline-to-end dimensions from the tables.

For tees and crosses, use Tables DT-18 and DT-19 for standard clamp leg lengths, Tables DT-14 and DT-15 for short outlet branch clamp lengths, Table DT-25 for short outlet run clamp lengths, and Table DT-9 for weld end lengths. Adjacent legs less than 180 deg apart cannot be constructed using more than one short outlet sanitary hygienic clamp.

Elbows furnished to this Standard shall not be mitered.

DT-6.1 Special Angle Fittings

Special angle fittings can be offered if in accordance to all DT tables, with the exception of O (off angle) in Table DT-5-1.

DT-7 TESTS

Hydrostatic testing of each fitting is not required in this Standard; however, fittings shall be capable of withstanding a hydrostatic test pressure of 1.5 times the pressure rating shown in Table DT-2 at 100°F (38°C).

(09) DT-8 TOLERANCES

Tables DT-1, DT-5-1, DT-5-2, and DT-6 list the required tolerances for fittings and process components depicted by this Standard. For tubing tolerances, refer to ASTM A 270, Supplement 2.

These tolerances shall apply after heat and surface treatment.

The control portion of the fitting or process components (refer to C Table DT-5-1 illustration) is defined as the length from the welding end over which tolerances for wall thickness and O.D. are maintained. The length of the control portion is fixed for all sizes at 0.75 in. (19 mm). For exceptions, see Table DT-22 for ferrule lengths and Table DT-30 for automatic tube weld caps.

DT-9 WELDING ENDS

Automatic weld ends furnished to this Standard shall be furnished with square-cut ends, free from burrs and breaks.

(09) DT-10 HYGIENIC CLAMP UNIONS

DT-10.1 Typical Hygienic Clamp Unions

Typical hygienic clamp unions illustrated in Fig. SD-1, illustrations (a) through (d) and include the ferrules, gasket seal, and clamp.

DT-10.2 Hygienic Gaskets

Fittings and process components with hygienic clamp unions furnished to this Standard shall employ gasket

materials and gasket designs that meet the requirements of Table DT-2 and Part SG. Gasket seal performance in the clamp union shall be based on the principles of SG-2.4 and shall comply with the dimensional requirements of Fig. SD-1, illustration (d) when the union assembly is tightened to an amount recommended by the manufacturer. Gasket seal width as shown in Fig. SD-1, illustration (d) shall be a maximum of 0.085 in. in the uncompressed condition prior to installation.

DT-10.3 Connections

Connections meeting all dimensions of Table DT-5-2 are considered interchangeable. Alternative sealing designs are acceptable, provided dimensions A, B, C, and D of Table DT-5-2, as well as A and B of Table DT-5-3, are met. All connections shall be made in accordance with SD-3.7.

DT-10.4 Hygienic Clamps

Clamps shall be designed and manufactured to accomplish the items specified in DT-10.4.1 through DT-10.4.5 through the entire range of all union component dimensional tolerances.

DT-10.4.1 Completely retain all components in a fully sealed state to meet the requirements of DT-2.

DT-10.4.2 Maintain proper component alignment during installation and operation per SD-3.7.

DT-10.4.3 Cause the ferrules to be aligned to meet a uniform nominal gap per Fig. SD-1, illustration (d) when installed and tightened to the proper design specifications.

DT-10.4.4 Cause the gauging and contact diameter between the ferrules and the mating surfaces of the clamp to occur at the gauging diameter (A) specified in Table DT-5-3 when installed and tightened to achieve the nominal gap per Fig. SD-1, illustration (d).

NOTE: As this is a nominal design condition, manufacturing tolerances of the components will cause some variation in the actual gauging and contact diameter at assembly.

DT-10.4.5 When assembled with all components, the clamp shall not have any interference with any clamp union components or itself that would prevent proper assembly (see Fig. DT-1).

DT-11 HEAT TREATMENT

Heat treatment of fittings is not a requirement of this Standard.

Where annealing is used, the annealing procedure shall consist of heating the material to a minimum temperature of 1,900°F (1 040°C) and quenching in water or rapid cooling by other means.

**DT-12 SURFACE CONDITION**

Refer to Part SF for surface condition requirements.

DT-13 PACKAGING

All end connections of fittings or process components shall be protected with end caps. Additionally, for fittings, they shall be sealed in transparent bags or shrink wrapped. Additional packaging for process components, other than fittings, shall be as agreed to by the purchaser and manufacturer.

DT-14 MINIMUM EXAMINATION REQUIREMENTS**DT-14.1 Visual Inspection**

For fittings and process components including, but not limited to, tubing, valves, pumps, filter housings, and instrumentation, each item shall be visually examined for the following criteria, as a minimum. It is not a requirement that the packaged components be removed from the original packaging, provided the following can be verified:

- (a) manufacturer's name, logo, or trademark
- (b) alloy/material type
- (c) description including size and configuration
- (d) heat number/code
- (e) product contact surface finish symbol
- (f) reference to ASME BPE
- (g) pressure rating for valves
- (h) no damage or other noncompliances

DT-14.2 Documentation Verification

Verification of Material Test Reports for fittings and process components including, but not limited to, tubing, valves, pumps, filter housings, and instrumentation, shall be examined for the following criteria, as a minimum:

- (a) Material Test Report verified to the applicable specification(s)
- (b) heat number/code traceable to a Material Test Report

DT-14.3 Physical Examination

For the purposes of this Section, a "lot" shall be defined as a specific combination of size, configuration, and heat number for fittings and process components including, but not limited to, tubing, valves, pumps, filter housings, and instrumentation in a single shipment.

If required by the owner/user, a percentage of each lot may be physically examined by the manufacturer, installing contractor, inspection contractor, or owner/user for the following criteria:

- (a) wall thickness (for weld ends only)
- (b) outside diameter (O.D.) (for weld ends only)

- (c) surface finish (as specified)
- (d) visual

When required examination reveals a defect(s), an additional 10% of that lot shall be examined for the specific defect(s). If this examination reveals another defect, an additional 10% of that lot shall be examined for the specific defects(s). If additional defects are found, perform 100% examination or reject the balance of the lot. All examined and accepted material in this lot may be retained and utilized.

The completed Material Examination Log shall describe all of the features listed above. The results of the examination shall be recorded on a Material Examination Log. This documentation may be one line item for the total quantity of a particular size, configuration, and heat number. The information required to be on the Material Examination Log may be in any format, written or tabular, to fit the needs of the manufacturer, installing contractor, inspection contractor, and owner/user as long as all information is included or referenced.

Refer to Forms MEL-1 and MEL-2, which have been provided as a guide for the Material Examination Log (see Nonmandatory Appendix B).

**SUBSECTION DT-V
DIMENSIONS AND TOLERANCES FOR STAINLESS
STEEL VALVES WITH AUTOMATIC WELDING AND
HYGIENIC CLAMP TUBE ENDS****DT-V-1 SCOPE**

This Subsection describes the dimensions, tolerances, and markings for stainless steel valves and valve fabrications.

This Subsection describes valves and valve fabrications made for use with nominal outside diameter (O.D.) tubing for the sizes listed in Table DT-1. The dimensions in metric units are conversions from the U.S. Customary units and are listed for reference only. For nominal metric size valves, please refer to the appropriate international standards.

DT-V-2 PRESSURE RATING

Valves manufactured to this Subsection shall be per the manufacturer's marked pressure-temperature recommendations.

Fabricated components employing welds shall be rated at 100% of the ratings in the preceding paragraph.

DT-V-3 MARKING**DT-V-3.1 Marking Information**

Except as specified in DT-V-3.2, each valve shall be permanently marked by any suitable method not injurious to the product contact surface to show the following:

- (a) heat number/code traceable to material test report for all wetted metal component parts of the valve or valve fabrication, if more than one heat is used
- (b) valve pressure rating
- (c) material type
- (d) manufacturer's name, logo, or trademark
- (e) reference to this Standard (ASME BPE)
- (f) product contact surface designation for the appropriate BPE specification

DT-V-3.2 Exceptions

- (a) Where the size of the valve does not permit complete marking, the identification marks may be omitted in reverse of the order presented above. However, the heat number, valve pressure rating, and material type shall be marked on the valve.
- (b) Where the size of the valve does not permit complete marking of the heat number, a manufacturer's code number is acceptable under this Standard.

(09) DT-V-4 MATERIALS

Generally, materials furnished to this Standard shall be Type 316, Type 316L, or other material agreed to by the purchaser and manufacturer.

Where Type 316L is specified for valve bodies, materials shall be per ASTM A 182, ASTM A 240, ASTM A 276, ASTM A 479, ASTM A 511, or ASTM A 351. The material of the automatic weld end shall conform to the requirements for chemical composition as prescribed in Table DT-3. For nonautomatic weld ends, the chemical composition shall meet the requirements of the applicable ASTM specification.

DT-V-5 METAL THICKNESS

As valve and valve fabrications are to match tube dimensions, the thickness of the weld ends within the control portion shall conform to the tolerances listed in Table DT-5-1 or DT-6. The nominal wall thickness of the valve ends shall be the same as the tube to which they are to be welded.

After fabrication and surface treatment, tube extension wall thickness, beyond the control portion, as defined in DT-8 shall be a minimum of 65% of the nominal wall thickness. For requirements regarding all shop and field welds, refer to Part MJ. All welds shall meet the provisions of MJ-6 and Fig. MJ-1.

DT-V-6 VALVE DIMENSION

The dimensions of the valve or valve fabrication shall conform to manufacturer's standards, or as agreed to by the purchaser and manufacturer.

Standard dimensions for valve weld end connections covered by this Standard are given in Table DT-1. All sizes shown are nominal O.D. tube sizes.

Standard dimensions for two-way weir style diaphragm valves with hygienic clamp ends covered by this Standard are given in Table DT-V-1.

DT-V-7 TESTS

Hydrostatic testing of each valve or valve fabrication is not required in this Standard; however, valves or valve fabrications shall be capable of withstanding a hydrostatic test pressure of a minimum of 1.2 times the marked pressure rating of the valve, as qualified by SG-4.1.1.6.

DT-V-8 TOLERANCES

Tables DT-1, DT-5-1, DT-5-2, and DT-6 list the required tolerances for all end connections of valves and valve fabrications depicted by this Standard.

DT-V-9 WELDING ENDS

Valves with weld ends furnished to this Standard shall be furnished with square-cut ends, free from burrs and breaks. All weld end connections for weir style diaphragm valves shall have a minimum unobstructed weld end length equal to or greater than the minimum control portion as per DT-V-8.

DT-V-10 HYGIENIC CLAMP ENDS

Valves furnished to this Standard with hygienic clamp ends shall employ a design that meets the requirements as prescribed in DT-10. For overall length dimensions of two-way weir style diaphragm valves, refer to Table DT-V-1.

DT-V-11 SURFACE CONDITION

Refer to Part SF for surface condition requirements.

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Fig. DT-1 Clamp Conditions at Installation

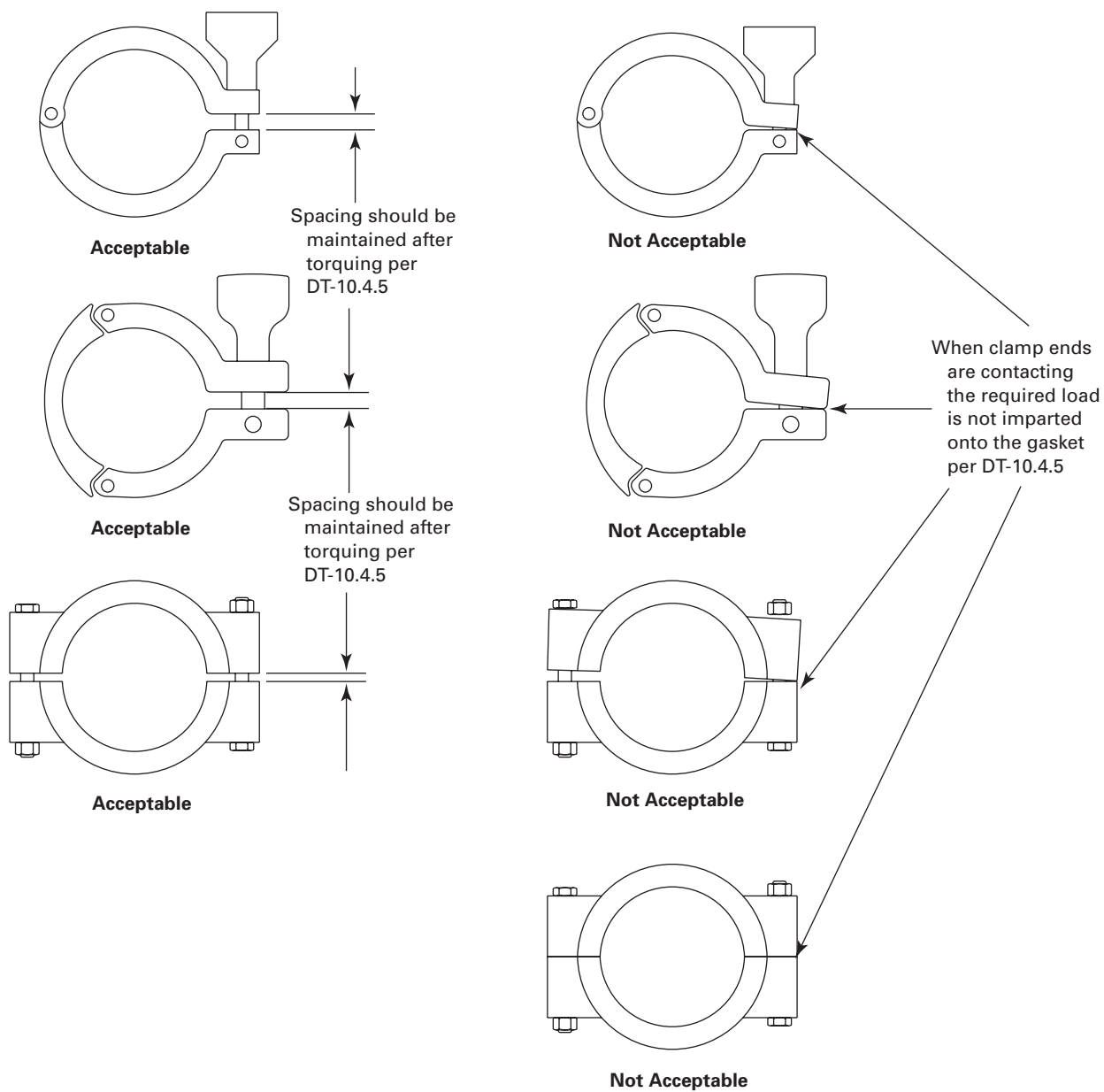


Table DT-1 Nominal O.D. Tubing Sizes

Nominal Size, in.	Tube O.D.		Tube Wall Thickness		Hygienic Clamp Size, in.
	in.	mm	in.	mm	
$\frac{1}{4}$	0.250	6.35	0.035	0.89	$\frac{3}{4}$
$\frac{3}{8}$	0.375	9.53	0.035	0.89	$\frac{3}{4}$
$\frac{1}{2}$	0.500	12.70	0.065	1.65	$\frac{3}{4}$
$\frac{3}{4}$	0.750	19.05	0.065	1.65	$\frac{3}{4}$
1	1.000	25.40	0.065	1.65	$1\frac{1}{2}$
$1\frac{1}{2}$	1.500	38.10	0.065	1.65	$1\frac{1}{2}$
2	2.000	50.80	0.065	1.65	2
$2\frac{1}{2}$	2.500	63.50	0.065	1.65	$2\frac{1}{2}$
3	3.000	76.20	0.065	1.65	3
4	4.000	101.60	0.083	2.11	4
6	6.000	152.40	0.109	2.77	6

GENERAL NOTE: Refer to ASTM A 270, Supplement 2 for tubing tolerances.

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Table DT-2 Hygienic Unions: Rated Internal Working Pressure

Temperature		Weld Joint, All Sizes		< 3 in. Clamp		3 in. Clamp		4 in. Clamp		6 in. Clamp	
°F	°C	psig	kPa (gage)	psig	kPa (gage)	psig	kPa (gage)	psig	kPa (gage)	psig	kPa (gage)
100	38	200	1,379	200	1,379	200	1,379	200	1,379	150	1,034
250	121	200	1,379	165	1,138	150	1,034	125	862	75	517

GENERAL NOTES:

- These pressure ratings apply to the hygienic clamp and gasket. For information on pressure ratings, see the manufacturer's guidelines for the components.
- For installation practices, refer to Fig. DT-1.



Table DT-3 Chemical Composition for Automatic Weld Ends, %

Material	%
Carbon, max.	0.035
Chromium	16.00–18.00
Manganese, max.	2.00
Molybdenum	2.00–3.00
Nickel	10.00–15.00
Phosphorus, max.	0.045
Silicon, max.	1.00
Sulfur	0.005–0.017

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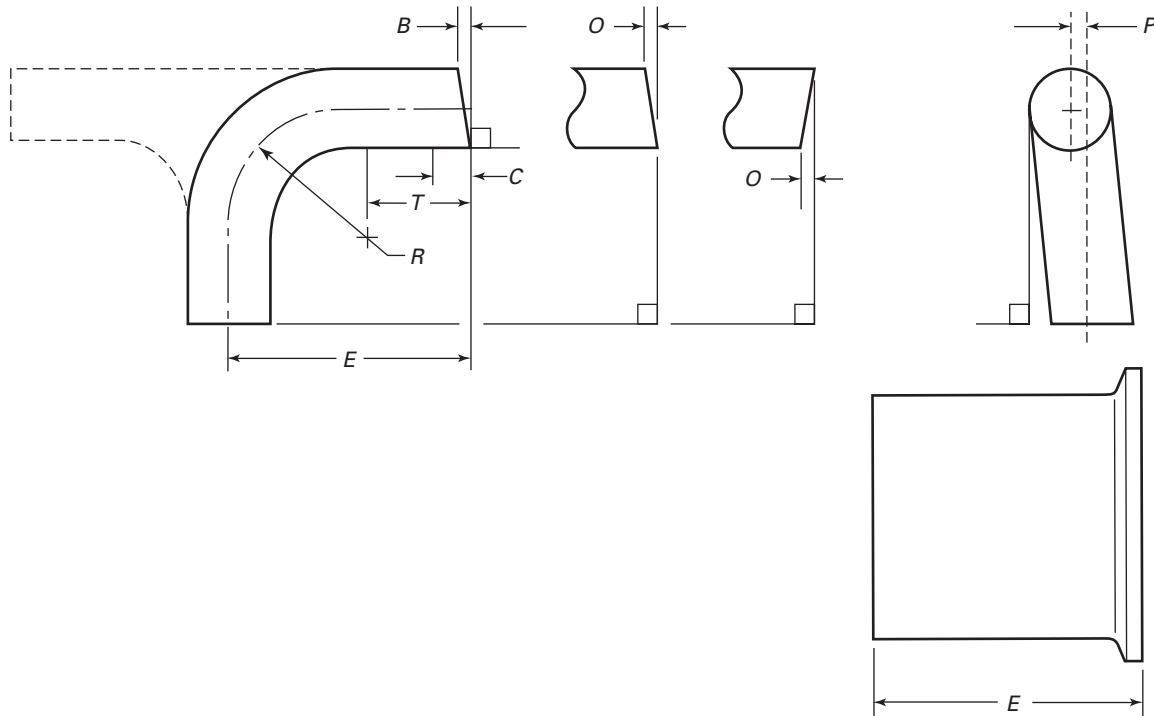
Table DT-4 Tangent Lengths

Nominal O.D. Tube Size, in.	Tangent, <i>T</i>	
	in.	mm
1/4	1.50	38.10
3/8	1.50	38.10
1/2	1.50	38.10
3/4	1.50	38.10
1	1.50	38.10
1 1/2	1.50	38.10
2	1.50	38.10
2 1/2	1.50	38.10
3	1.75	44.45
4	2.00	50.80
6	2.50	63.50

GENERAL NOTE: Minimum tangent lengths for ferrules do not apply. See Table DT-22, dimensions *B* and *C*, for available length options. Minimum tangent length for 1/4 in. to 3/4 in. size automatic tube weld: 180 deg return bend does not conform (see Table DT-23, Dimension *B*). Minimum tangent lengths for Tables DT-14, DT-15, and DT-25 do not apply.

Table DT-5-1 Final Tolerances for Mechanically Polished Fittings and Process Components

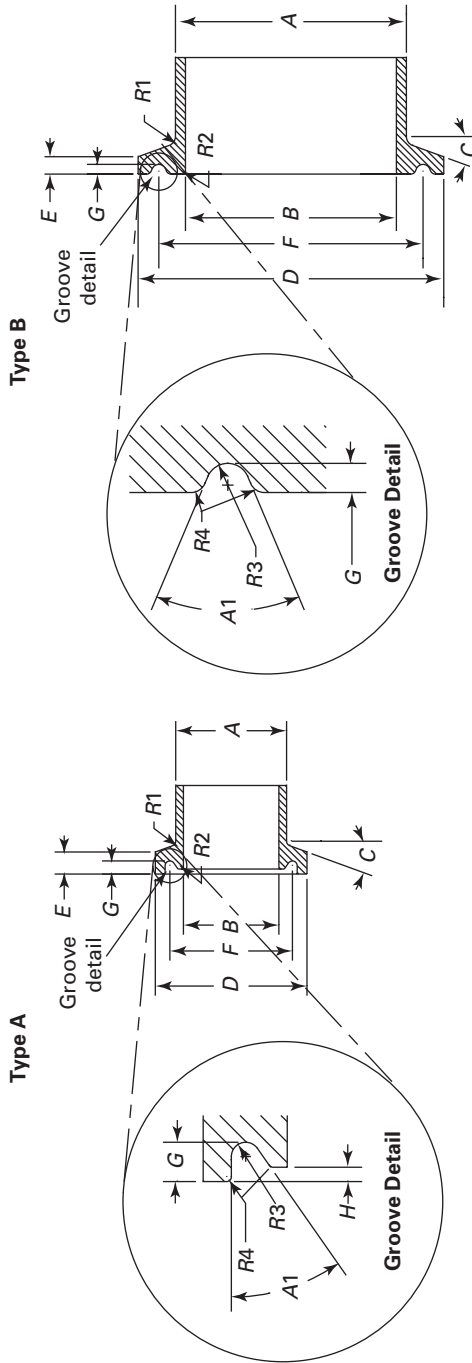
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Nominal Size, in.	O.D.		Wall Thickness		Squareness Face to Tangent, <i>B</i>		Off Angle, <i>O</i>		Equivalent Angle (for <i>O</i>) deg	Off Plane, <i>P</i>		Centerline Radius (CLR), <i>R</i>	
	in.	mm	in.	mm	in.	mm	in.	mm		in.	mm	in.	mm
1/4	± 0.005	± 0.13	+0.003/-0.004	+0.08/-0.10	0.005	0.13	0.009	0.23	2.1	0.030	0.76	0.563	14.30
3/8	± 0.005	± 0.13	+0.003/-0.004	+0.08/-0.10	0.005	0.13	0.012	0.30	1.8	0.030	0.76	1.125	28.58
1/2	± 0.005	± 0.13	+0.005/-0.008	+0.13/-0.20	0.005	0.13	0.014	0.36	1.6	0.030	0.76	1.125	28.58
3/4	± 0.005	± 0.13	+0.005/-0.008	+0.13/-0.20	0.005	0.13	0.018	0.46	1.4	0.030	0.76	1.125	28.58
1	± 0.005	± 0.13	+0.005/-0.008	+0.13/-0.20	0.008	0.20	0.025	0.64	1.4	0.030	0.76	1.500	38.10
1 1/2	± 0.008	± 0.20	+0.005/-0.008	+0.13/-0.20	0.008	0.20	0.034	0.86	1.3	0.050	1.27	2.250	57.15
2	± 0.008	± 0.20	+0.005/-0.008	+0.13/-0.20	0.008	0.20	0.043	1.09	1.2	0.050	1.27	3.000	76.20
2 1/2	± 0.010	± 0.25	+0.005/-0.008	+0.13/-0.20	0.010	0.25	0.054	1.37	1.2	0.050	1.27	3.750	95.25
3	± 0.010	± 0.25	+0.005/-0.008	+0.13/-0.20	0.016	0.41	0.068	1.73	1.3	0.050	1.27	4.500	114.30
4	± 0.015	± 0.38	+0.008/-0.010	+0.20/-0.25	0.016	0.41	0.086	2.18	1.2	0.060	1.52	6.000	152.40
6	± 0.030	± 0.76	+0.015/-0.015	+0.38/-0.38	0.030	0.76	0.135	3.43	1.3	0.060	1.52	9.000	228.60

GENERAL NOTE: Tolerance on end-to-end and center-to-end dimension "E" is ±0.050 in. (1.27 mm) for all fittings and process components depicted. For those not depicted in this Standard, see manufacturer for standards. See Table DT-6 for electropolished wall thickness tolerances. See DT-8 (Tolerances) for "C" control portion lengths. See Table DT-4 for "T" tangent length dimensions.

Table DT-5-2 Hygienic Clamp Ferrule Standard Dimensions and Tolerances



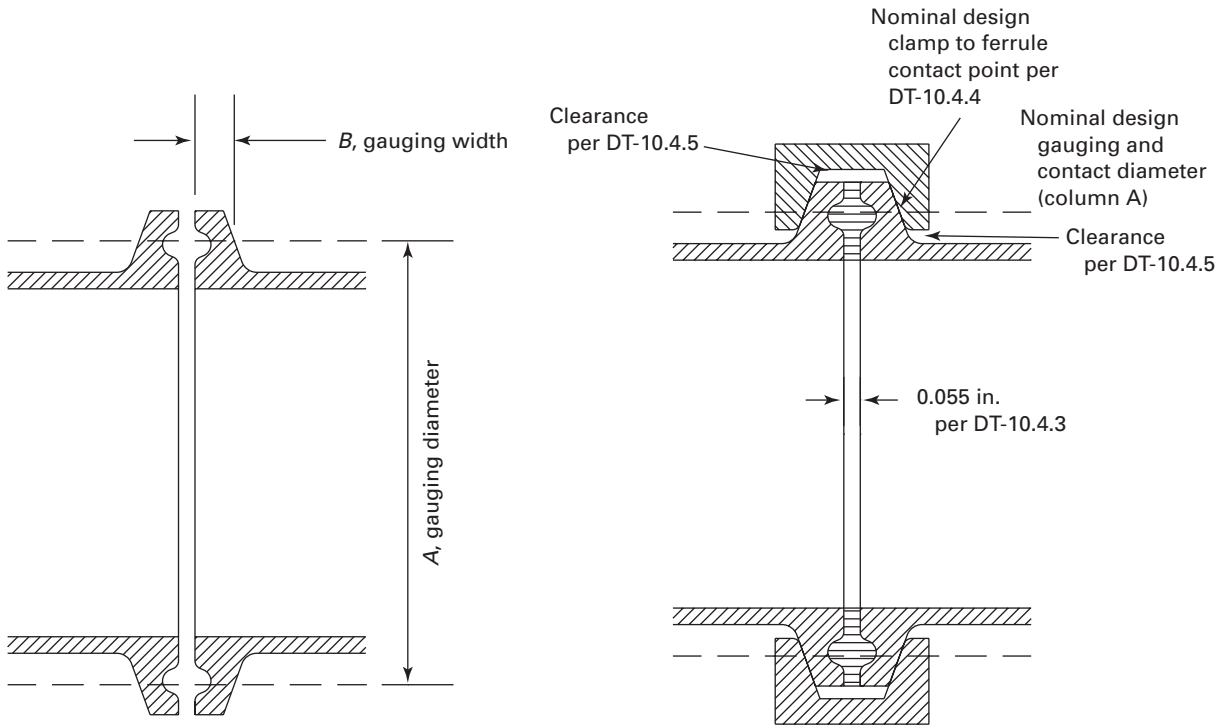
Nominal Size, in.	Type	Tube Diameter, A, in.		I.D. Bore, B, in.		Flange Angle, C, °		Flange Diameter, D, in.		Flange Thickness, E, in. ref.		Groove Diameter, F, in.	
		Dimension	Tolerance, ±	Dimension	Tolerance, ±	Dimension	Tolerance, ±	Dimension	Tolerance, +	Dimension	Tolerance, -	Dimension	Tolerance, ±
1/4	A	0.250	0.005	0.180	0.005	20	0.5	0.984	0.005	0.143	0.005	0.800	0.005
3/8	A	0.375	0.005	0.305	0.005	20	0.5	0.984	0.005	0.143	0.005	0.800	0.005
1/2	A	0.500	0.005	0.370	0.005	20	0.5	0.984	0.005	0.143	0.005	0.800	0.005
3/4	A	0.750	0.005	0.620	0.005	20	0.5	0.984	0.005	0.143	0.005	0.800	0.005
1	A	1.000	0.005	0.870	0.005	20	1.0	1.339	0.005	0.143	0.005	1.160	0.005
1	B	1.000	0.005	0.870	0.005	20	1.0	1.984	0.008	0.112	0.005	1.718	0.005
1 1/2	B	1.500	0.008	1.370	0.005	20	1.0	1.984	0.008	0.112	0.005	1.718	0.005
2	B	2.000	0.008	1.870	0.005	20	1.0	2.516	0.008	0.112	0.008	2.218	0.005
2 1/2	B	2.500	0.010	2.370	0.005	20	1.0	3.047	0.008	0.112	0.008	2.781	0.005
3	B	3.000	0.010	2.870	0.005	20	1.0	3.579	0.010	0.112	0.010	3.281	0.005
4	B	4.000	0.015	3.834	0.005	20	1.0	4.682	0.015	0.112	0.015	4.344	0.005
6	B	6.000	0.030	5.782	0.005	20	1.0	6.570	0.030	0.220	0.030	6.176	0.005

Table DT-5-2 Hygienic Clamp Ferrule Standard Dimensions and Tolerances (Cont'd)

Nominal Size, in.	Type	Groove Depth, G, in.		Face Offset, H, in.		Groove Detail, R3, in.		Groove Detail, R4, in.		Groove Detail, A1, deg	Radius R1, in.		Radius R2, in.	
		Dimen- sion	Tol- erance, ±	Dimen- sion	Tol- erance, ±	Dimen- sion	Tol- erance, ±	Dimen- sion	Tol- erance, ±		Max.	Min.	Max.	Min.
1/4	A	0.085	0.005	0.031	0.005	0.031	0.005	0.020	0.005	35	0.031	0.031	0.005	0.005
3/8	A	0.085	0.005	0.031	0.005	0.031	0.005	0.020	0.005	35	0.031	0.031	0.005	0.005
1/2	A	0.085	0.005	0.031	0.005	0.031	0.005	0.020	0.005	35	0.031	0.031	0.005	0.005
3/4	A	0.085	0.005	0.031	0.005	0.031	0.005	0.020	0.005	35	0.031	0.031	0.005	0.005
1	A	0.085	0.005	0.031	0.005	0.031	0.005	0.020	0.005	35	0.031	0.031	0.005	0.005
1	B	0.063	0.005	N/A	N/A	0.047	0.005	0.020	0.005	46	0.063	0.031	0.005	0.005
1 1/2	B	0.063	0.005	N/A	N/A	0.047	0.005	0.020	0.005	46	0.063	0.031	0.005	0.005
2	B	0.063	0.005	N/A	N/A	0.047	0.005	0.020	0.005	46	0.063	0.031	0.005	0.005
2 1/2	B	0.063	0.005	N/A	N/A	0.047	0.005	0.020	0.005	46	0.063	0.031	0.005	0.005
3	B	0.063	0.005	N/A	N/A	0.047	0.005	0.020	0.005	46	0.063	0.031	0.005	0.005
4	B	0.063	0.005	N/A	N/A	0.047	0.005	0.020	0.005	46	0.063	0.031	0.005	0.005
6	B	0.063	0.005	N/A	N/A	0.047	0.005	0.020	0.005	46	0.063	0.031	0.005	0.005

(09)

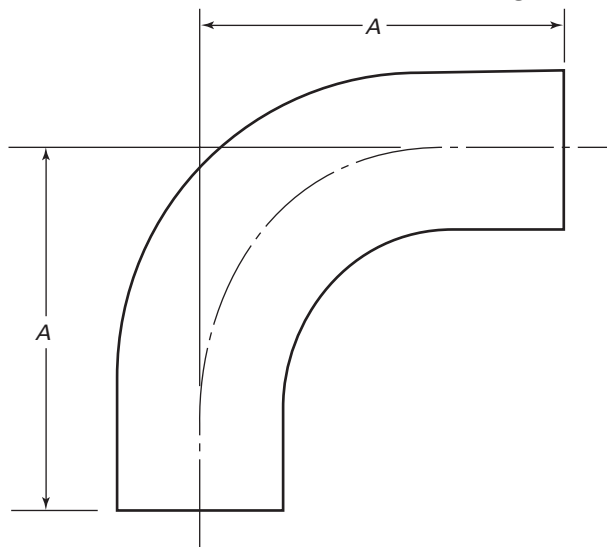
(09)

Table DT-5-3 Hygienic Clamp Ferrule: Design Criteria


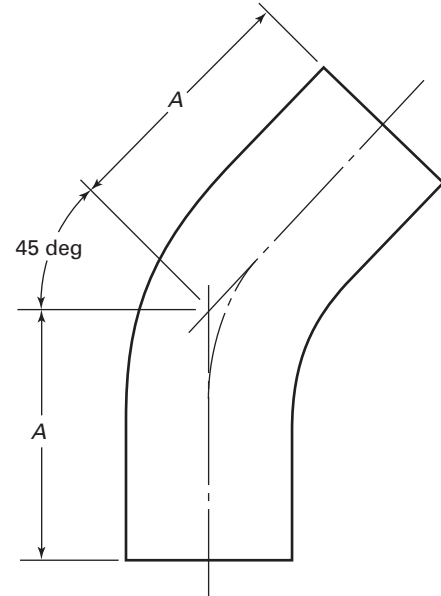
Nominal Size, in.	Type (From Table DT 5.1)	Basic Gauging and Contact Diameter, A, in. ref	Gauging Width, B, in.	
		Dimension	Dimension	Tolerance, ±
1/4	A	0.867	0.164	0.004
3/8	A	0.867	0.164	0.004
1/2	A	0.867	0.164	0.004
3/4	A	0.867	0.164	0.004
1	A	1.222	0.164	0.004
1	B	1.748	0.155	0.005
1 1/2	B	1.748	0.155	0.005
2	B	2.280	0.155	0.005
2 1/2	B	2.811	0.155	0.005
3	B	3.264	0.169	0.005
4	B	4.288	0.184	0.005
6	B	6.255	0.277	0.005

Table DT-6 Final Tolerances for Electropolished Fittings and Process Components

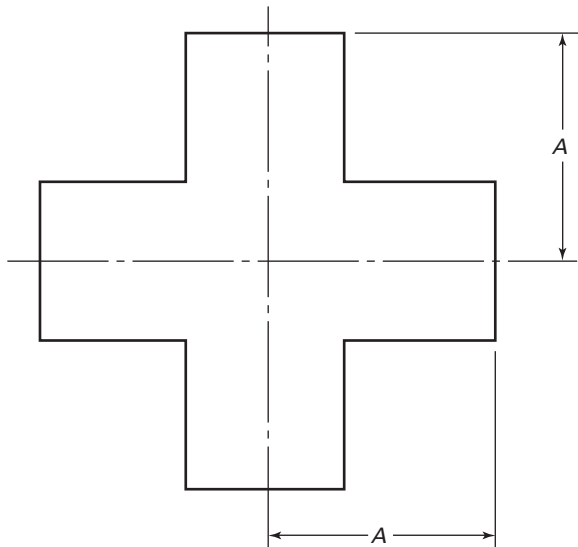
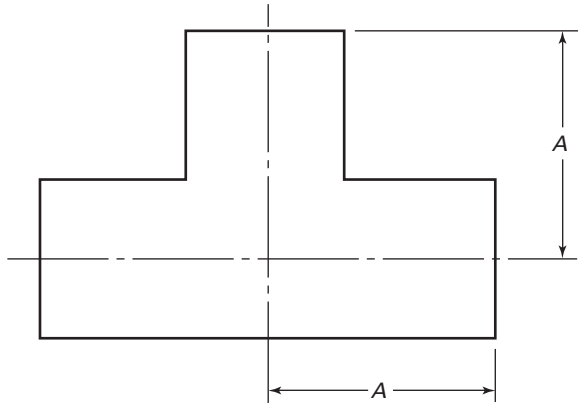
Nominal Size, in.	Wall Thickness	
	in.	mm
1/4	+0.003/-0.006	+0.08/-0.15
3/8	+0.003/-0.006	+0.08/-0.15
1/2	+0.005/-0.010	+0.13/-0.25
3/4	+0.005/-0.010	+0.13/-0.25
1	+0.005/-0.010	+0.13/-0.25
1 1/2	+0.005/-0.010	+0.13/-0.25
2	+0.005/-0.010	+0.13/-0.25
2 1/2	+0.005/-0.010	+0.13/-0.25
3	+0.005/-0.010	+0.13/-0.25
4	+0.008/-0.012	+0.20/-0.30
6	+0.015/-0.017	+0.38/-0.43

Table DT-7 Automatic Tube Weld: 90 deg-Elbow


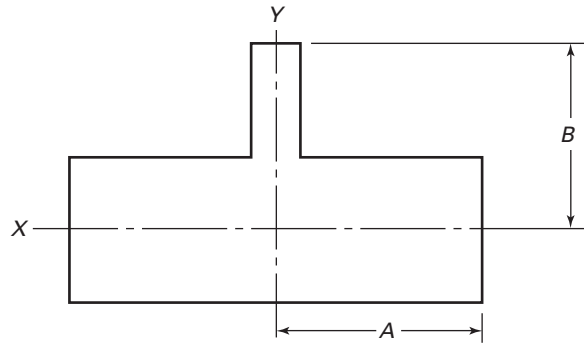
Nominal Size, in.	A	
	in.	mm
1/4	2.625	66.7
3/8	2.625	66.7
1/2	3.000	76.2
3/4	3.000	76.2
1	3.000	76.2
1 1/2	3.750	95.3
2	4.750	120.7
2 1/2	5.500	139.7
3	6.250	158.8
4	8.000	203.2
6	11.500	292.1

Table DT-8 Automatic Tube Weld: 45-deg Elbow (09)


Nominal Size, in.	A	
	in.	mm
1/4	2.000	50.8
3/8	2.000	50.8
1/2	2.250	57.2
3/4	2.250	57.2
1	2.250	57.2
1 1/2	2.500	63.5
2	3.000	76.2
2 1/2	3.375	85.7
3	3.625	92.1
4	4.500	114.3
6	6.250	158.8

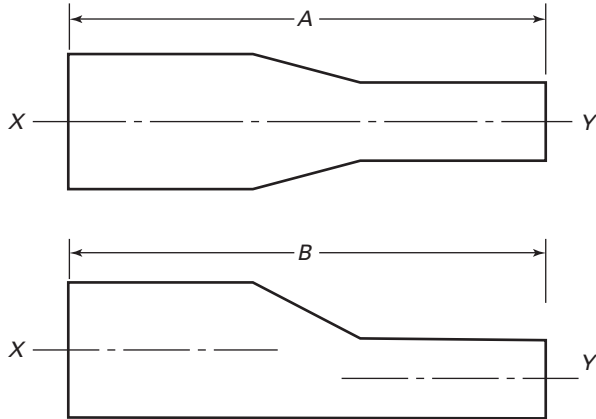
Table DT-9 Automatic Tube Weld: Straight Tee and Cross


Nominal Size, in.	A	
	in.	mm
1/4	1.750	44.5
3/8	1.750	44.5
1/2	1.875	47.6
3/4	2.000	50.8
1	2.125	54.0
1 1/2	2.375	60.3
2	2.875	73.0
2 1/2	3.125	79.4
3	3.375	85.7
4	4.125	104.8
6	5.625	142.9

Table DT-10 Automatic Tube Weld: Reducing Tee


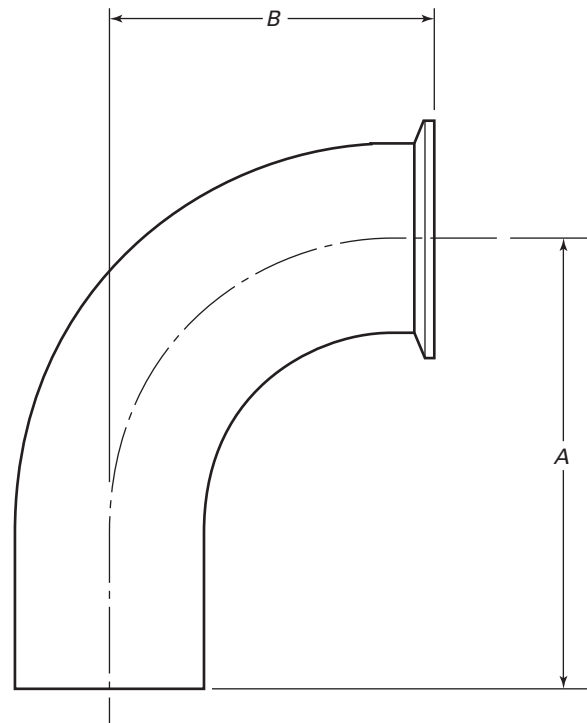
Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
3/8	1/4	1.750	44.5	1.750	44.5
1/2	1/4	1.875	47.6	1.875	47.6
1/2	3/8	1.875	47.6	1.875	47.6
3/4	1/4	2.000	50.8	2.000	50.8
3/4	3/8	2.000	50.8	2.000	50.8
3/4	1/2	2.000	50.8	2.000	50.8
1	1/4	2.125	54.0	2.125	54.0
1	3/8	2.125	54.0	2.125	54.0
1	1/2	2.125	54.0	2.125	54.0
1	3/4	2.125	54.0	2.125	54.0
1 1/2	1/2	2.375	60.3	2.375	60.3
1 1/2	3/4	2.375	60.3	2.375	60.3
1 1/2	1	2.375	60.3	2.375	60.3
2	1/2	2.875	73.0	2.625	66.7
2	3/4	2.875	73.0	2.625	66.7
2	1	2.875	73.0	2.625	66.7
2	1 1/2	2.875	73.0	2.625	66.7
2 1/2	1/2	3.125	79.4	2.875	73.0
2 1/2	3/4	3.125	79.4	2.875	73.0
2 1/2	1	3.125	79.4	2.875	73.0
2 1/2	1 1/2	3.125	79.4	2.875	73.0
2 1/2	2	3.125	79.4	2.875	73.0
3	1/2	3.375	85.7	3.125	79.4
3	3/4	3.375	85.7	3.125	79.4
3	1	3.375	85.7	3.125	79.4
3	1 1/2	3.375	85.7	3.125	79.4
3	2	3.375	85.7	3.125	79.4
3	2 1/2	3.375	85.7	3.125	79.4
4	1/2	4.125	104.8	3.625	92.1
4	3/4	4.125	104.8	3.625	92.1
4	1	4.125	104.8	3.625	92.1
4	1 1/2	4.125	104.8	3.625	92.1
4	2	4.125	104.8	3.875	98.4
4	2 1/2	4.125	104.8	3.875	98.4
4	3	4.125	104.8	3.875	98.4
6	3	5.625	142.9	4.875	123.8
6	4	5.625	142.9	5.125	130.2

(09) **Table DT-11 Automatic Tube Weld: Concentric and Eccentric Reducer**



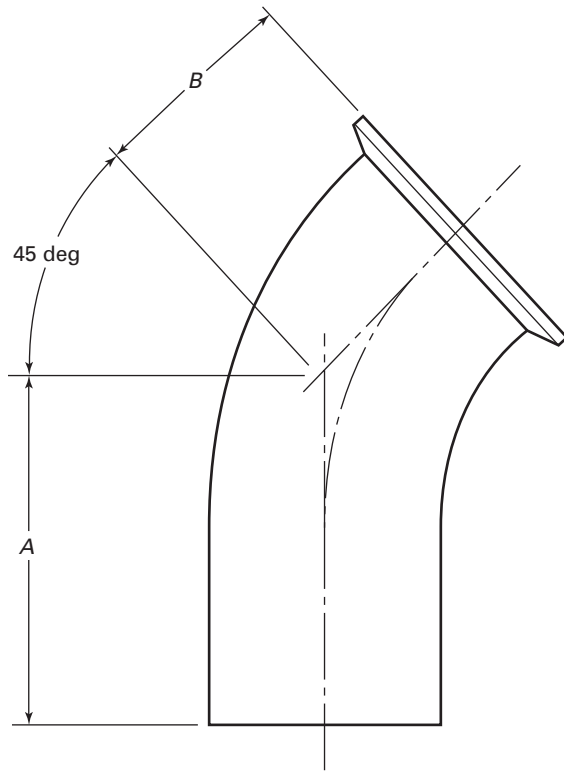
Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
3/8	1/4	3.250	82.6	4.000	101.6
1/2	1/4	3.250	82.6	4.000	101.6
1/2	3/8	3.250	82.6	4.000	101.6
3/4	3/8	3.250	82.6	4.000	101.6
3/4	1/2	4.000	101.6	4.000	101.6
1	1/2	4.500	114.3	4.500	114.3
1	3/4	4.000	101.6	4.000	101.6
1 1/2	3/4	5.000	127.0	5.000	127.0
1 1/2	1	5.000	127.0	5.000	127.0
2	1	7.250	184.2	7.250	184.2
2	1 1/2	5.250	133.4	5.250	133.4
2 1/2	1 1/2	7.250	184.2	7.250	184.2
2 1/2	2	5.500	139.7	5.500	139.7
3	1 1/2	9.250	235.0	9.250	235.0
3	2	7.500	190.5	7.500	190.5
3	2 1/2	5.500	139.7	5.500	139.7
4	2	11.750	298.5	11.750	298.5
4	2 1/2	9.750	247.7	9.750	247.7
4	3	7.750	196.9	7.750	196.9
6	3	10.000	254.0	9.750	247.7
6	4	10.000	254.0	10.000	254.0

Table DT-12 Automatic Tube Weld: Hygienic Clamp Joint, 90-deg Elbow



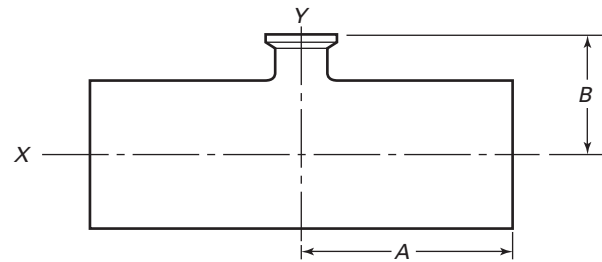
Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/4	2.625	66.7	1.625	41.3
3/8	2.625	66.7	1.625	41.3
1/2	3.000	76.2	1.625	41.3
3/4	3.000	76.2	1.625	41.3
1	3.000	76.2	2.000	50.8
1 1/2	3.750	95.3	2.750	69.9
2	4.750	120.7	3.500	88.9
2 1/2	5.500	139.7	4.250	108.0
3	6.250	158.8	5.000	127.0
4	8.000	203.2	6.625	168.3
6	11.500	292.1	10.500	266.7

(09) **Table DT-13 Automatic Tube Weld: Hygienic Clamp Joint, 45-deg Elbow**



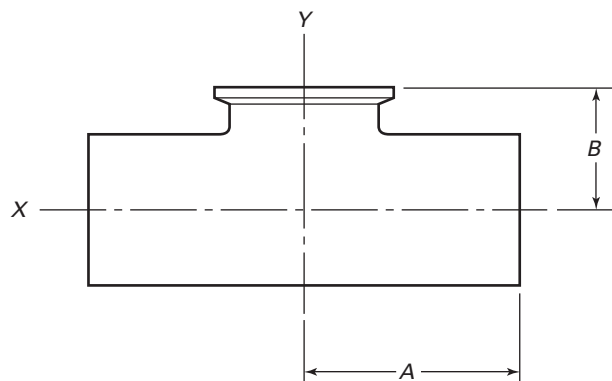
Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/4	2.000	50.8	1.000	25.4
3/8	2.000	50.8	1.000	25.4
1/2	2.250	57.2	1.000	25.4
3/4	2.250	57.2	1.000	25.4
1	2.250	57.2	1.125	28.6
1 1/2	2.500	63.5	1.438	36.5
2	3.000	76.2	1.750	44.5
2 1/2	3.375	85.7	2.063	52.4
3	3.625	92.1	2.375	60.3
4	4.500	114.3	3.125	79.4
6	6.250	158.8	5.250	133.4

Table DT-14 Automatic Tube Weld: Short Outlet Hygienic Clamp Joint Reducing Tee



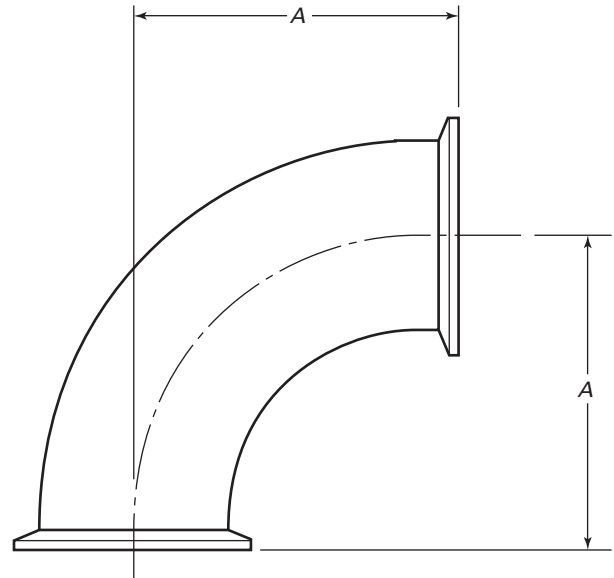
Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
3/8	1/4	1.750	44.5	1.000	25.4
1/2	1/4	1.875	47.6	1.000	25.4
1/2	3/8	1.875	47.6	1.000	25.4
3/4	1/4	2.000	50.8	1.000	25.4
3/4	3/8	2.000	50.8	1.000	25.4
3/4	1/2	2.000	50.8	1.000	25.4
1	1/4	2.125	54.0	1.125	28.6
1	3/8	2.125	54.0	1.125	28.6
1	1/2	2.125	54.0	1.125	28.6
1	3/4	2.125	54.0	1.125	28.6
1 1/2	1/2	2.375	60.3	1.375	34.9
1 1/2	3/4	2.375	60.3	1.375	34.9
1 1/2	1	2.375	60.3	1.375	34.9
2	1/2	2.875	73.0	1.625	41.3
2	3/4	2.875	73.0	1.625	41.3
2	1	2.875	73.0	1.625	41.3
2	1 1/2	2.875	73.0	1.625	41.3
2 1/2	1/2	3.125	79.4	1.875	47.6
2 1/2	3/4	3.125	79.4	1.875	47.6
2 1/2	1	3.125	79.4	1.875	47.6
2 1/2	1 1/2	3.125	79.4	1.875	47.6
2 1/2	2	3.125	79.4	1.875	47.6
3	1/2	3.375	85.7	2.125	54.0
3	3/4	3.375	85.7	2.125	54.0
3	1	3.375	85.7	2.125	54.0
3	1 1/2	3.375	85.7	2.125	54.0
3	2	3.375	85.7	2.125	54.0
3	2 1/2	3.375	85.7	2.125	54.0
4	1/2	4.125	104.8	2.625	66.7
4	3/4	4.125	104.8	2.625	66.7
4	1	4.125	104.8	2.625	66.7
4	1 1/2	4.125	104.8	2.625	66.7
4	2	4.125	104.8	2.625	66.7
4	2 1/2	4.125	104.8	2.625	66.7
4	3	4.125	104.8	2.625	66.7
6	1/2	5.625	142.9	3.625	92.1
6	3/4	5.625	142.9	3.625	92.1
6	1	5.625	142.9	3.625	92.1
6	1 1/2	5.625	142.9	3.625	92.1
6	2	5.625	142.9	3.625	92.1
6	2 1/2	5.625	142.9	3.625	92.1
6	3	5.625	142.9	3.625	92.1
6	4	5.625	142.9	3.750	95.3

**Table DT-15 Automatic Tube Weld:
Short Outlet Hygienic Clamp Joint Tee**



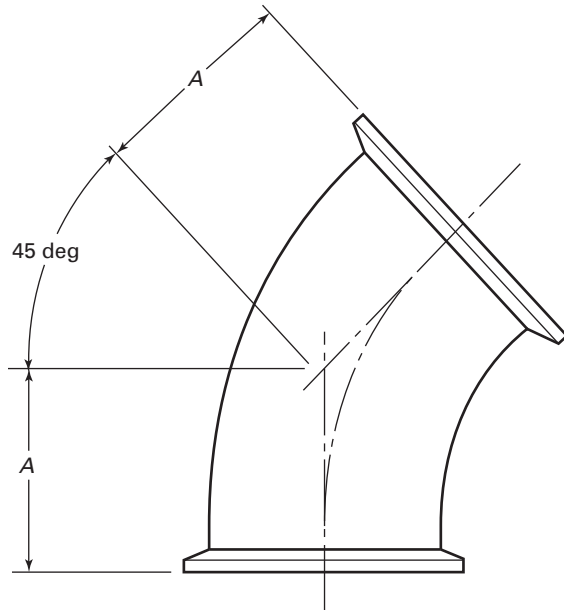
Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/4	1.750	44.5	1.000	25.4
3/8	1.750	44.5	1.000	25.4
1/2	1.875	47.6	1.000	25.4
3/4	2.000	50.8	1.125	28.6
1	2.125	54.0	1.125	28.6
1 1/2	2.375	60.3	1.375	34.9
2	2.875	73.0	1.625	41.3
2 1/2	3.125	79.4	1.875	47.6
3	3.375	85.7	2.125	54.0
4	4.125	104.8	2.750	69.9
6	5.625	142.9	4.625	117.5

Table DT-16 Hygienic Clamp Joint: 90 deg-Elbow



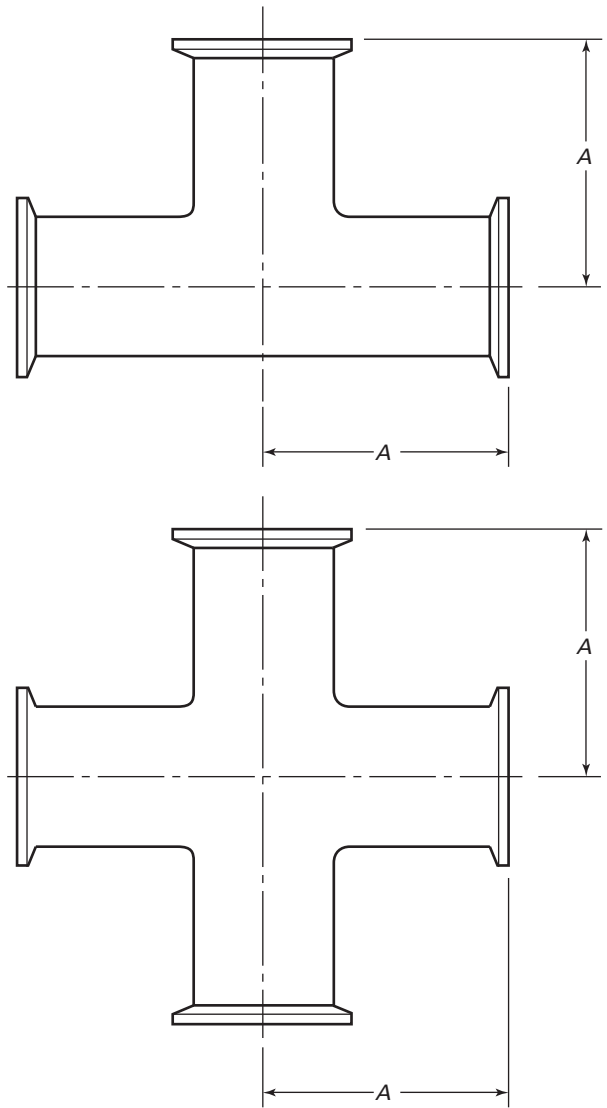
Nominal Size, in.	A	
	in.	mm
1/4	1.625	41.3
3/8	1.625	41.3
1/2	1.625	41.3
3/4	1.625	41.3
1	2.000	50.8
1 1/2	2.750	69.9
2	3.500	88.9
2 1/2	4.250	108.0
3	5.000	127.0
4	6.625	168.3
6	10.500	266.7

(09) Table DT-17 Hygienic Clamp Joint: 45-deg Elbow

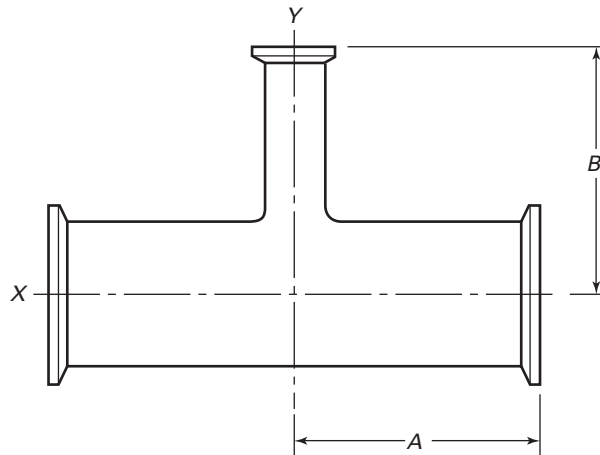


Nominal Size, in.	A	
	in.	mm
1/4	1.000	25.4
3/8	1.000	25.4
1/2	1.000	25.4
3/4	1.000	25.4
1	1.125	28.6
1 1/2	1.438	36.5
2	1.750	44.5
2 1/2	2.063	52.4
3	2.375	60.3
4	3.125	79.4
6	5.250	133.4

Table DT-18 Hygienic Clamp Joint: Straight Tee and Cross

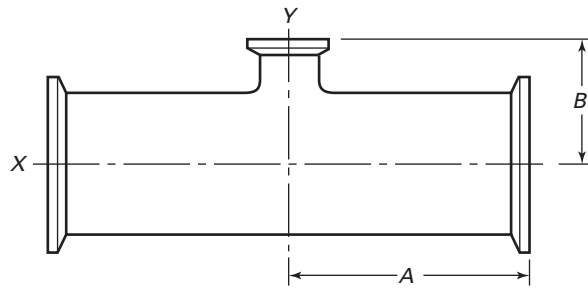


Nominal Size, in.	A	
	in.	mm
1/4	2.250	57.2
3/8	2.250	57.2
1/2	2.250	57.2
3/4	2.375	60.3
1	2.625	66.7
1 1/2	2.875	73.0
2	3.375	85.7
2 1/2	3.625	92.1
3	3.875	98.4
4	4.750	120.7
6	7.125	181.0

Table DT-19 Hygienic Clamp Joint: Reducing Tee


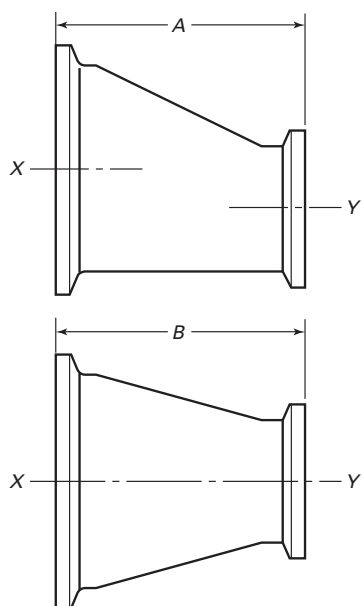
Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
$\frac{3}{8}$	$\frac{1}{4}$	2.250	57.2	2.250	57.2
$\frac{1}{2}$	$\frac{1}{4}$	2.375	60.3	2.375	60.3
$\frac{1}{2}$	$\frac{3}{8}$	2.375	60.3	2.375	60.3
$\frac{3}{4}$	$\frac{1}{4}$	2.500	63.5	2.500	63.5
$\frac{3}{4}$	$\frac{3}{8}$	2.500	63.5	2.500	63.5
$\frac{3}{4}$	$\frac{1}{2}$	2.500	63.5	2.500	63.5
1	$\frac{1}{4}$	2.625	66.7	2.625	66.7
1	$\frac{3}{8}$	2.625	66.7	2.625	66.7
1	$\frac{1}{2}$	2.625	66.7	2.625	66.7
1	$\frac{3}{4}$	2.625	66.7	2.625	66.7
$1\frac{1}{2}$	$\frac{1}{2}$	2.875	73.0	2.875	73.0
$1\frac{1}{2}$	$\frac{3}{4}$	2.875	73.0	2.875	73.0
$1\frac{1}{2}$	1	2.875	73.0	2.875	73.0
2	$\frac{1}{2}$	3.375	85.7	3.125	79.4
2	$\frac{3}{4}$	3.375	85.7	3.125	79.4
2	1	3.375	85.7	3.125	79.4
2	$1\frac{1}{2}$	3.375	85.7	3.125	79.4
$2\frac{1}{2}$	$\frac{1}{2}$	3.625	92.1	3.375	85.7
$2\frac{1}{2}$	$\frac{3}{4}$	3.625	92.1	3.375	85.7
$2\frac{1}{2}$	1	3.625	92.1	3.375	85.7
$2\frac{1}{2}$	$1\frac{1}{2}$	3.625	92.1	3.375	85.7
$2\frac{1}{2}$	2	3.625	92.1	3.375	85.7
3	$\frac{1}{2}$	3.875	98.4	3.625	92.1
3	$\frac{3}{4}$	3.875	98.4	3.625	92.1
3	1	3.875	98.4	3.625	92.1
3	$1\frac{1}{2}$	3.875	98.4	3.625	92.1
3	2	3.875	98.4	3.625	92.1
3	$2\frac{1}{2}$	3.875	98.4	3.625	92.1
4	$\frac{1}{2}$	4.750	120.7	4.125	104.8
4	$\frac{3}{4}$	4.750	120.7	4.125	104.8
4	1	4.750	120.7	4.125	104.8
4	$1\frac{1}{2}$	4.750	120.7	4.125	104.8
4	2	4.750	120.7	4.375	111.1
4	$2\frac{1}{2}$	4.750	120.7	4.375	111.1
4	3	4.750	120.7	4.375	111.1
6	3	7.125	181.0	5.375	136.5
6	4	7.125	181.0	5.750	146.1

Table DT-20 Hygienic Clamp Joint: Short Outlet Reducing Tee

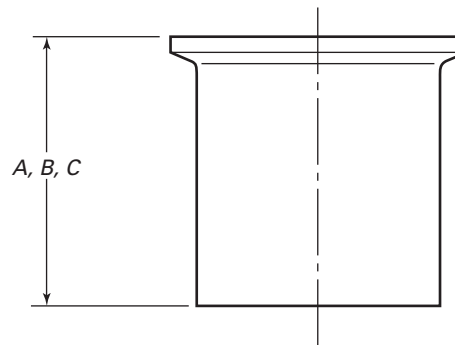


Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
3/8	1/4	2.250	57.2	1.000	25.4
1/2	1/4	2.375	60.3	1.000	25.4
1/2	3/8	2.375	60.3	1.000	25.4
3/4	1/4	2.500	63.5	1.000	25.4
3/4	3/8	2.500	63.5	1.000	25.4
3/4	1/2	2.500	63.5	1.000	25.4
1	1/4	2.625	66.7	1.125	28.6
1	3/8	2.625	66.7	1.125	28.6
1	1/2	2.625	66.7	1.125	28.6
1	3/4	2.625	66.7	1.125	28.6
1 1/2	1/2	2.875	73.0	1.375	34.9
1 1/2	3/4	2.875	73.0	1.375	34.9
1 1/2	1	2.875	73.0	1.375	34.9
2	1/2	3.375	85.7	1.625	41.3
2	3/4	3.375	85.7	1.625	41.3
2	1	3.375	85.7	1.625	41.3
2	1 1/2	3.375	85.7	1.625	41.3
2 1/2	1/2	3.625	92.1	1.875	47.6
2 1/2	3/4	3.625	92.1	1.875	47.6
2 1/2	1	3.625	92.1	1.875	47.6
2 1/2	1 1/2	3.625	92.1	1.875	47.6
2 1/2	2	3.625	92.1	1.875	47.6
3	1/2	3.875	98.4	2.125	54.0
3	3/4	3.875	98.4	2.125	54.0
3	1	3.875	98.4	2.125	54.0
3	1 1/2	3.875	98.4	2.125	54.0
3	2	3.875	98.4	2.125	54.0
3	2 1/2	3.875	98.4	2.125	54.0
4	1/2	4.750	120.7	2.625	66.7
4	3/4	4.750	120.7	2.625	66.7
4	1	4.750	120.7	2.625	66.7
4	1 1/2	4.750	120.7	2.625	66.7
4	2	4.750	120.7	2.625	66.7
4	2 1/2	4.750	120.7	2.625	66.7
4	3	4.750	120.7	2.625	66.7
6	1/2	7.125	181.0	3.625	92.1
6	3/4	7.125	181.0	3.625	92.1
6	1	7.125	181.0	3.625	92.1
6	1 1/2	7.125	181.0	3.625	92.1
6	2	7.125	181.0	3.625	92.1
6	2 1/2	7.125	181.0	3.625	92.1
6	3	7.125	181.0	3.625	92.1
6	4	7.125	181.0	3.750	95.3

(09)

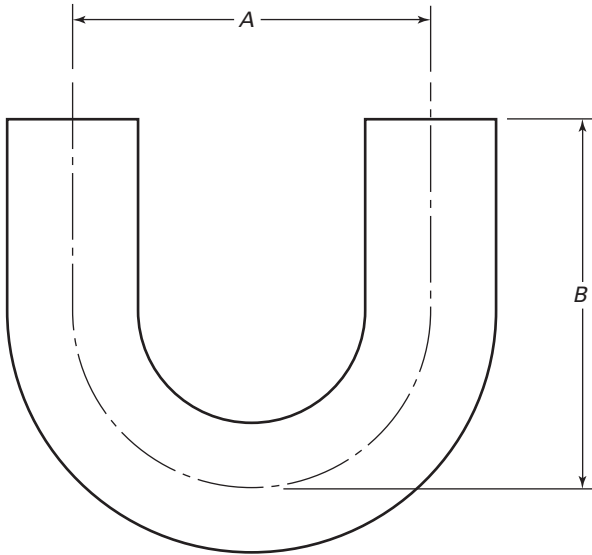
Table DT-21 Hygienic Clamp Joint: Concentric and Eccentric Reducer


Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
3/4	1/2	2.000	50.8	2.000	50.8
1	1/2	2.500	63.5	2.500	63.5
1	3/4	2.000	50.8	2.000	50.8
1 1/2	3/4	3.000	76.2	3.000	76.2
1 1/2	1	3.000	76.2	3.000	76.2
2	1	5.000	127.0	5.000	127.0
2	1 1/2	3.000	76.2	3.000	76.2
2 1/2	1 1/2	5.000	127.0	5.000	127.0
2 1/2	2	3.000	76.2	3.000	76.2
3	1 1/2	7.000	177.8	7.000	177.8
3	2	5.000	127.0	5.000	127.0
3	2 1/2	3.000	76.2	3.000	76.2
4	2	9.125	231.8	9.125	231.8
4	2 1/2	7.125	181.0	7.125	181.0
4	3	5.125	130.2	5.125	130.2
6	3	7.625	193.7	7.500	190.5
6	4	7.625	193.7	7.625	193.7

Table DT-22 Automatic Tube Weld: Ferrule


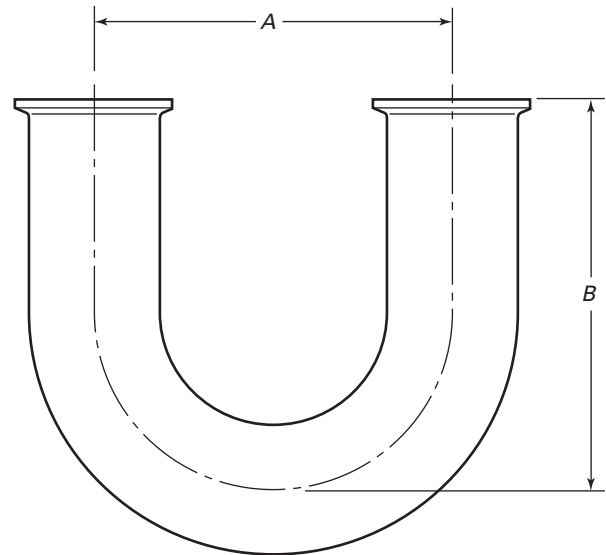
Nominal Size, in.	<i>A</i>		<i>B</i>		<i>C</i>	
	in.	mm	in.	mm	in.	mm
$\frac{1}{4}$	1.750	44.5	1.130	28.7	0.500	12.7
$\frac{3}{8}$	1.750	44.5	1.130	28.7	0.500	12.7
$\frac{1}{2}$	1.750	44.5	1.130	28.7	0.500	12.7
$\frac{3}{4}$	1.750	44.5	1.130	28.7	0.500	12.7
1	1.750	44.5	1.130	28.7	0.500	12.7
$1\frac{1}{2}$	1.750	44.5	1.130	28.7	0.500	12.7
2	2.250	57.2	1.130	28.7	0.500	12.7
$2\frac{1}{2}$	2.250	57.2	1.130	28.7	0.500	12.7
3	2.250	57.2	1.130	28.7	0.500	12.7
4	2.250	57.2	1.130	28.7	0.625	15.9
6	3.000	76.2	1.500	38.1	0.750	19.1

Table DT-23 Automatic Tube Weld: 180-deg Return Bend



Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/4	4.500	114.3	2.625	66.7
3/8	4.500	114.3	2.625	66.7
1/2	4.500	114.3	3.000	76.2
3/4	4.500	114.3	3.000	76.2
1	3.000	76.2	3.000	76.2
1 1/2	4.500	114.3	4.500	114.3
2	6.000	152.4	5.000	127.0
2 1/2	7.500	190.5	5.750	146.1
3	9.000	228.6	6.500	165.1
4	12.000	304.8	8.500	215.9
6	18.000	457.2	11.500	292.1

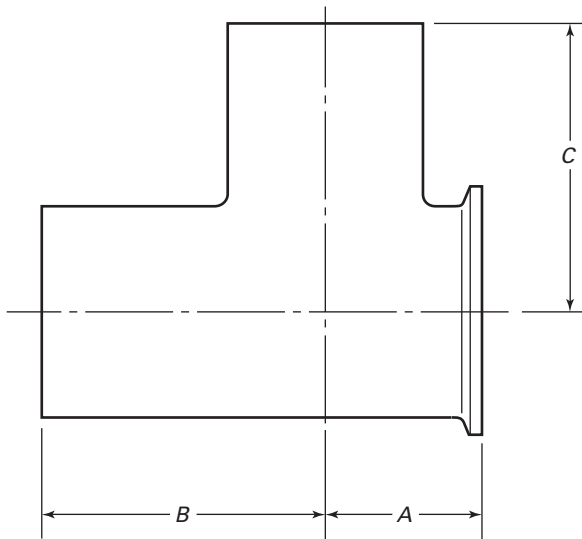
Table DT-24 Hygienic Clamp Joint: 180-deg Return Bend



Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/4	4.500	114.3	3.125	79.4
3/8	4.500	114.3	3.125	79.4
1/2	4.500	114.3	3.500	88.9
3/4	4.500	114.3	3.500	88.9
1	3.000	76.2	3.500	88.9
1 1/2	4.500	114.3	5.000	127.0
2	6.000	152.4	5.500	139.7
2 1/2	7.500	190.5	6.250	158.8
3	9.000	228.6	7.000	177.8
4	12.000	304.8	9.125	231.8
6	18.000	457.2	13.000	330.2

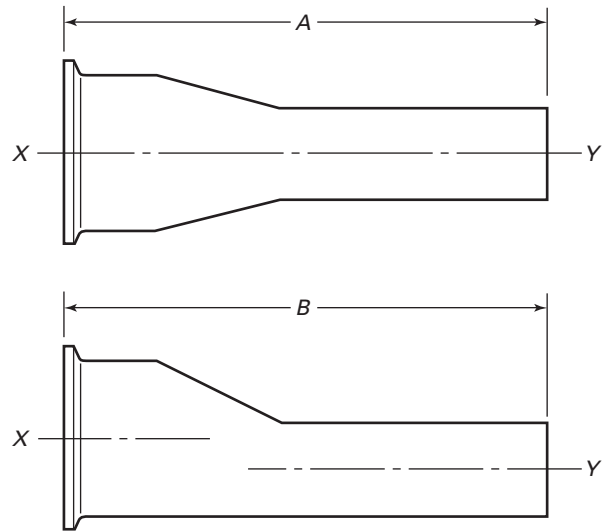
GENERAL NOTE: 1/4 in.-3/4 in. sizes do not conform to Table DT-4.

Table DT-25 Hygienic Mechanical Joint: Short Outlet Run Tee

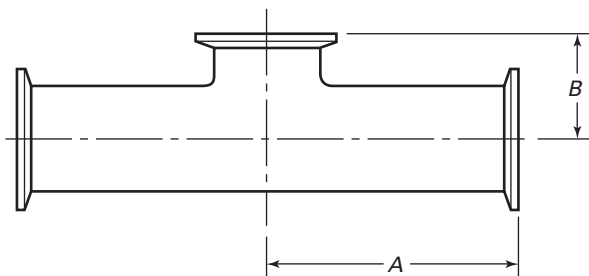


Nominal Size, in.	A		B		C	
	in.	mm	in.	mm	in.	mm
1/4	0.875	22.2	1.750	44.5	1.750	44.5
3/8	0.875	22.2	1.750	44.5	1.750	44.5
1/2	0.875	22.2	1.875	47.6	1.875	47.6
3/4	1.000	25.4	2.000	50.8	2.000	50.8
1	1.125	28.6	2.125	54.0	2.125	54.0
1 1/2	1.375	34.9	2.375	60.3	2.375	60.3
2	1.625	41.3	2.875	73.0	2.875	73.0
2 1/2	1.875	47.6	3.125	79.4	3.125	79.4
3	2.125	54.0	3.375	85.7	3.375	85.7
4	2.750	69.9	4.125	104.8	4.125	104.8
6	4.625	117.5	5.625	142.9	5.625	142.9

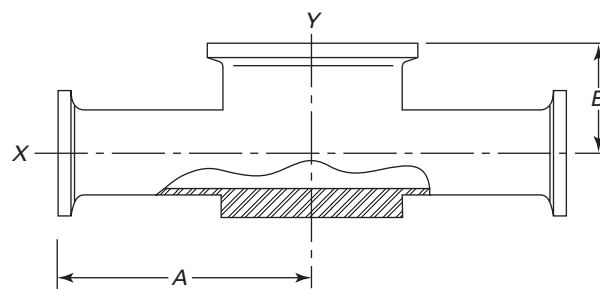
Table DT-26 Hygienic Clamp Joint: Tube Weld Concentric and Eccentric Reducer (09)



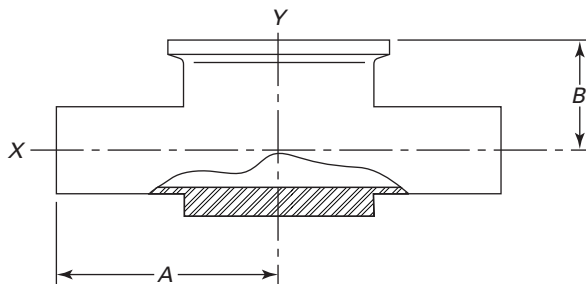
Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
3/4	1/2	3.000	76.2	3.000	76.2
1	1/2	3.500	88.9	3.500	88.9
1	3/4	3.000	76.2	3.000	76.2
1 1/2	3/4	4.000	101.6	4.000	101.6
1 1/2	1	4.000	101.6	4.000	101.6
2	1	6.000	152.4	6.000	152.4
2	1 1/2	4.000	101.6	4.000	101.6
2 1/2	1 1/2	6.000	152.4	6.000	152.4
2 1/2	2	4.250	107.9	4.250	108.0
3	1 1/2	8.000	203.2	8.000	203.2
3	2	6.250	158.8	6.250	158.8
3	2 1/2	4.250	108.0	4.250	108.0
4	2	10.375	263.5	10.375	263.5
4	2 1/2	8.375	212.7	8.375	212.7
4	3	6.375	161.9	6.375	161.9
6	3	9.000	228.6	8.750	222.3
6	4	9.000	228.6	9.000	228.6

Table DT-27 Hygienic Clamp Joint: Short Outlet Tee


Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/2	2.250	57.2	1.000	25.4
3/4	2.375	60.3	1.125	28.6
1	2.625	66.7	1.125	28.6
1 1/2	2.875	73.0	1.375	34.9
2	3.375	85.7	1.625	41.3
2 1/2	3.625	92.1	1.875	47.6
3	3.875	98.4	2.125	54.0
4	4.750	120.7	2.750	69.9
6	7.125	181.0	4.625	117.5

Table DT-29 Hygienic Clamp Joint: Instrument Tee


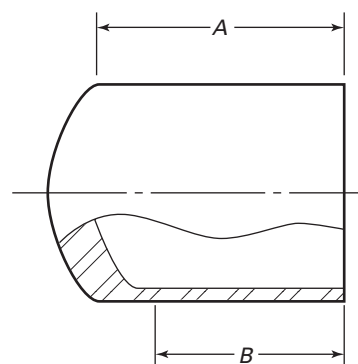
Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
1/2	1 1/2	3.000	76.2	0.875	22.2
3/4	1 1/2	3.000	76.2	1.000	25.4
1	1 1/2	3.000	76.2	1.125	28.6
1 1/2	2	3.250	82.6	1.000	25.4
3/4	2	3.250	82.6	1.125	28.6
1	2	3.250	82.6	1.250	31.8
1 1/2	2	3.250	82.6	1.500	38.1

Table DT-28 Automatic Tube Weld: Instrument Tee


Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
1/2	1 1/2	2.500	63.5	0.875	22.2
3/4	1 1/2	2.500	63.5	1.000	25.4
1	1 1/2	2.500	63.5	1.125	28.6
1 1/2	2	2.750	69.9	1.000	25.4
3/4	2	2.750	69.9	1.125	28.6
1	2	2.750	69.9	1.250	31.8
1 1/2	2	2.750	69.9	1.500	38.1

Table DT-30 Automatic Tube Weld: Cap

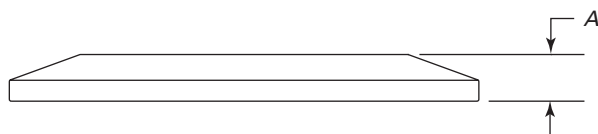
(09)



Nominal Size, in.	A, Min.	
	in.	mm
1/2	1.500	38.1
3/4	1.500	38.1
1	1.500	38.1
1 1/2	1.500	38.1
2	1.500	38.1
2 1/2	1.500	38.1
3	1.750	44.5
4	2.000	50.8
6	2.500	63.5

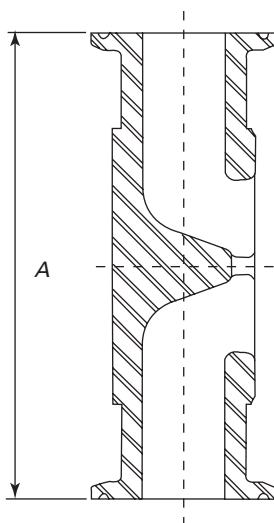
GENERAL NOTE: Minimum I.D. control portion length, B, is 0.375 in. (9.53 mm) for all sizes.

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Table DT-31 Hygienic Clamp Joint: Solid End Cap


Nominal Size, in.	A, min.	
	in.	mm
$\frac{1}{4}$	0.187	4.7
$\frac{3}{8}$	0.187	4.7
$\frac{1}{2}$	0.187	4.7
$\frac{3}{4}$	0.187	4.7
1	0.250	6.4
$1\frac{1}{2}$	0.250	6.4
2	0.250	6.4
$2\frac{1}{2}$	0.250	6.4
3	0.250	6.4
4	0.312	7.9
6	0.437	11.1

Table DT-V-1 Hygienic Clamp Joint: Weir Style Diaphragm Valve



Nominal Size, in.	A	
	in.	mm
$\frac{1}{4}$ Fractional	2.500	63.5
$\frac{3}{8}$ Fractional	2.500	63.5
$\frac{1}{2}$ Fractional	2.500	63.5
$\frac{1}{2}$	3.500	88.9
$\frac{3}{4}$	4.000	101.6
1	4.500	114.3
$1\frac{1}{2}$	5.500	139.7
2	6.250	158.8
$2\frac{1}{2}$	7.630	193.8
3	8.750	222.3
4	11.500	292.1



Part MJ

Material Joining

MJ-1 SCOPE

The requirements of this Part are applicable to the joining of equipment used in the bioprocessing, pharmaceutical, and personal care product industries, including pressure vessels and tanks [which includes heat exchangers, atmospheric tanks, pumps, and any vessels designed and built to the ASME Boiler and Pressure Vessel Code (BPVC), Section VIII, Division 1], piping (built to ASME B31.3), tubing, and fittings, and shall be used in conjunction with the requirements of ASME BPVC, Sections VIII and IX, and ASME B31.3, as applicable. These materials, joining methods, examinations, etc., are limited to process systems that contact bioprocessing products or product-process streams.

(09) MJ-2 MATERIALS

MJ-2.1 Stainless Steels

Material for process surfaces shall conform to AISI 316L (UNS S31603) and a published ASTM or other recognized specification, unless otherwise agreed to by the purchaser and supplier. All materials (tubing and fittings) shall conform with Table DT-3. However, a process component or tube with a sulfur content either below the lower limit or above the upper limit of Table DT-3 can be used in a welded connection, provided that all of the following conditions are met:

- (a) Use of the process component or tube is agreed to by the owner/user.
- (b) The process component or tube meets 0.030 wt. % maximum sulfur limit.
- (c) The process component or tube meets all other requirements of Table DT-3.
- (d) All welds on the component or tube are internally inspected and meet the requirements of MJ-6.4.

Material for supporting structures shall conform to AISI 304 or 304L (UNS S30400 or S30403) unless otherwise agreed to by the purchaser and supplier.

MJ-2.2 Nickel Alloys

The use of nickel alloys shall be subject to agreement by the purchaser and supplier. The alloy shall conform to a published ASTM or other recognized specification. It is recommended that weld and finish samples be made from the actual heat or lot of material in question, in order to guarantee the desired results.

MJ-2.3 Duplex Stainless Steels

Production welds shall not be made on thicknesses greater than that which passes the requirements of ASTM A 923 Methods A and/or C.

MJ-2.4 Mechanically Polished Material

Mechanically polished material shall be ready for welding (i.e., free of grit and residues). Polished material shall meet the dimensional tolerances of the applicable specifications, and the surface finish requirements of this Standard, after polishing has been completed.

MJ-2.5 Electropolished Material

Electropolished material shall be ready for welding and shall be free of chemical residues and water stains. Surfaces shall meet the surface finish requirements of Part SF for stainless steel or higher alloys.

MJ-2.6 Other Materials

Other materials (for example, titanium, tantalum, thermoplastic, and glass) may be used, based upon agreement by owner/user and contractor.

MJ-2.7 Weld and Finish Samples

Weld and finish samples, when required, shall be made from the same material specification and grade to be used in production in order to demonstrate the desired results.

MJ-3 JOINING PROCESSES AND PROCEDURES

MJ-3.1 Welds Finished After Welding

For pressure vessels, tanks, and piping and tubing systems where the process-contact surface of the weld is to be finished after welding, the welding processes used shall be limited to the arc or high energy beam (electron beam and laser beam) processes as defined in ANSI/AWS A3.0. All welding procedures must be qualified per MJ-8 of this Standard. The owner/user and contractor shall agree that the welding process selected will provide the desired results.

MJ-3.2 Welds Used in the As-Welded Condition

For pressure vessels, tanks, and piping and tubing systems where the process-contact surface of the weld is to be used as is, welding processes shall be limited to the inert-gas arc processes (such as gas tungsten-arc

welding and plasma arc welding) or the high energy beam processes (such as electron beam or laser beam welding), as defined in ANSI/AWS A3.0. All welding procedures must be qualified per MJ-8 of this Standard. Every effort shall be made to use an automatic or machine welding process. Autogenous welds, welds with filler wire, or consumable inserts are acceptable for this Standard provided they meet the requirements for all applicable codes. The owner/user and contractor shall agree that the welding process selected will provide the desired results.

MJ-3.3 Nonmetallics

Joining of polymers (e.g., thermoplastics) shall be performed in accordance with Part PM. Joining of other nonmetallic materials shall be in accordance with procedures and processes recommended by the material manufacturer, and approved by the owner/user, using materials or compounds that are inert to the intended service.

MJ-3.4 Mechanical Connections

Mechanical connections shall conform to SD-3.7.

MJ-4 WELD JOINT DESIGN AND PREPARATION

MJ-4.1 General

All butt joints in which one or both weld faces is a product contact surface shall have continuous complete weld joint penetration. This requirement exists for welds made from either one side or from both sides of the weld joint. All weld joints must have the product contact surfaces properly purged or protected for the prevention of discoloration or contamination. External attachments (e.g., lift lugs, dimple jackets, ladder clips, etc.) must have any discoloration of the product contact surface removed.

Welds attaching any connection that passes through the wall of a tank or vessel, or a branch connection on a pipe or tube system, in which one or both sides of the weld joint is a product contact surface, shall either be joined with a full penetration groove weld with a reinforcing fillet weld [similar to Fig. SD-14, illustration (a)], or have at least one telltale hole provided if double fillet welded only [similar to Fig. SD-14, illustration (b)]. A telltale hole is required on all lap, tee, corner, or edge joints that have one or both welds as a product contact surface and are not attached by full penetration welds. The telltale hole shall provide a path for product or test media flow in the event of inner weld containment failure. Telltale holes are not required when all welds are on product contact surfaces [e.g., Fig. SD-17, illustration (d) detail or similar]. The telltale hole shall be no larger than NPS ¼ in. (6.35 mm) and may be tapped for a preliminary compressed air and soapsuds test for tightness of inside welds. These telltale holes may be

plugged when the vessel is in service. The plugging material used shall not be capable of sustaining pressure between the lapped surfaces.

Socket welding is not permitted in process stream systems or where CIP or SIP requirements are defined.

MJ-4.2 Pressure Vessels and Tanks

Joint designs shall be those permitted by ASME BPVC, Section VIII, and shall comply with MJ-4.1.

MJ-4.3 Piping

Joint designs shall be those permitted by ASME B31.3, and shall comply with MJ-4.1.

MJ-4.4 Tubing

Joint designs for hygienic tubing and fittings shall be square butt joints. The tubing and fittings shall have ends prepared by machining or facing to provide a square end that meets the requirements of Tables DT-5-1 and DT-6. The butt weld joints shall be properly cleaned within ½ in. (13 mm) of the joint area on the inside and outside surfaces prior to welding. Welding on tubing shall be done using automatic (or machine) welding techniques (such as orbital tube welding or lathe welding), except where size or space will not permit. In that case, manual welding can be performed, but must be agreed to by the owner/user and contractor.

MJ-4.5 Tube-Attachment Welds

(a) Tube-attachment welds, as addressed in this Standard, are those that

(1) make branch connections other than those used to fabricate the fittings described in Part DT of this Standard

(2) attach tubes to other product forms

(3) attach nozzles to transfer panels

(4) attach a tube to any part of a hygienic system

(b) Tube-attachment welds not governed by this Part of the Standard include

(1) those governed by MJ-6.4 of this Standard

(2) tube-to-tubesheet welds that are governed by ASME BPVC, Section VIII, Division 1, in addition to the visual inspection requirements of Part SF and MJ-6.2 of this Standard

These welds may be performed by the manual, machine, or an automatic welding process. Joint designs shall comply with MJ-4.1. The weld joints for complete penetration welds shall be prepared by means compatible with hygienic service. The weld joints shall be properly cleaned within ½ in. (13 mm) on the inside and outside surfaces, where accessible, prior to welding. Either fillet welds, groove welds, or a combination of both may be used.



MJ-5 FILLER MATERIAL

Filler material shall conform to a published AWS specification, or to a proprietary specification agreed to between the filler manufacturer, equipment supplier, and end owner/user. Proprietary fillers require special attention; see MJ-8 of this Standard and QW-250 and QW-350 of ASME BPVC, Section IX. Filler metals may be in the form of welding wire, consumable inserts, or other shapes or forms.

The use of filler metals is neither required nor prohibited. When used, filler metals shall be selected to provide deposited weld metal compatible with the materials to be joined and the service conditions anticipated. For stainless steel base metals, only low carbon grades of stainless steel filler metals shall be used (e.g., for 316L base metal only 316L or 316LSi filler metal shall be used; for 304L base metal 308L or 316L filler metals shall be used). Stainless steel or nickel alloy with high molybdenum content may require special filler metals. The base metal manufacturer should be consulted.

MJ-6 WELD ACCEPTANCE CRITERIA

MJ-6.1 General

Welding for a sterile environment requires that the weld shall not result in a surface that will contribute to microbiological growth and contamination of the product. The weld shall not have any discontinuities such as cracks, voids, porosity, or joint misalignment that will promote contamination of the product. All welding procedures shall be qualified to MJ-8.

MJ-6.2 Pressure Vessels and Tanks

Weld acceptance criteria for pressure vessels and tanks shall be in accordance with ASME BPVC, Section VIII, Division 1, with the additional requirements of Table MJ-1. Where "None" is specified in Table MJ-1, the limits of ASME BPVC Section VIII, Division 1 will apply.

MJ-6.3 Piping

Weld acceptance criteria for piping shall be in accordance with ASME B31.3, paras. 341.3.2 through 341.3.4 and Table 341.3.2, along with the criterion value notes for the applicable fluid service category in Table 341.3.2 for pipe welds and the additional requirements of Table MJ-2.

MJ-6.4 Tubing

Weld acceptance criteria (including borescopic acceptance criteria) for tubing and fittings shall be in accordance with Table MJ-3 (see Fig. MJ-1).

Preproduction sample welds, when required, shall be submitted by the contractor to the owner/user to establish weld quality. Owner/user, contractor, and inspection contractor shall agree to the number and type of sample welds.

During construction, sample welds shall be made on a regular basis to verify that the equipment is operating properly and that the purging setup is adequate to prevent discoloration beyond the level agreed upon by the owner/user and contractor. Owner/user and contractor shall agree to the frequency of sample welds. It is strongly recommended that these sample welds be made at the beginning of each work shift, whenever the purge source bottle is changed, and when the automatic or machine welding equipment is changed (such as when the orbital tube weld head is changed).

The sample welds described in the preceding paragraphs, and any associated welding machine printed records (e.g., welding parameter printouts directly from welding machine or downloaded from a welding machine), if any, may be disposed of after written acceptance of the coupons by the owner, the owner's representative, or the inspector.

MJ-6.4.1 Sample Welds. Sample welds for tubing shall meet all the acceptance criteria of Table MJ-3. An internal bead width of 1.0 to 2.5 times the nominal wall thickness is required. (09)

MJ-6.4.2 Rewelding. Rewelding (reflow) may be attempted one time only for the following defects:

- (a) incomplete penetration (lack of penetration)
- (b) incomplete fusion (lack of fusion)
- (c) unconsumed tack welds that can be inspected on the product contact side

All rewelds shall either totally consume the original weld or overlap the original weld with no base metal between the welds.

MJ-6.5 Tube-Attachment Welds

The acceptance criteria for tube-attachment welds shall be in accordance with Table MJ-4.

MJ-6.5.1 Sample Welds. Sample welds are not required for tube-attachment welds or seal welds.

MJ-6.5.2 Rewelding. Rewelding is allowed, except for welds that are product contact surfaces, for which the rewelding restrictions of MJ-6.4.2 apply.

MJ-7 INSPECTION, EXAMINATION, AND TESTING

MJ-7.1 Scope

These paragraphs provide for the inspection/examination of bioprocessing equipment and components including pressure vessels, tanks, skids, pumps, piping, tubing, fittings, and clamps. Examination methods, terms, and definitions shall be as defined in Part GR of this Standard and in other existing recognized codes and standards, including ASME BPVC, Section VIII, Division 1; ASME B31.3; and AWS-QC1 and SNT-TC-1A requirements for examiner and inspector certifications.

Table MJ-1 Acceptance Criteria for Welds on Pressure Vessels and Tanks

Discontinuities	Welds on Product Contact Surfaces			Welds on Nonproduct Contact Surfaces	
	Welds Left in the As-Welded Condition [Note (1)]	Prior to Finishing (As Welded)	After Postweld Finishing [Note (1)]	As Welded	After Postweld Finishing
Cracks	None	None	None	None	None
Lack of fusion	None	None	None	None	None
Incomplete penetration	None on product contact side; otherwise, see Note (2)	None on product contact side; otherwise, see Note (2)	None on product contact side; otherwise, see Note (2)	See Notes (2) and (5)	See Notes (2) and (5)
Porosity	None open to the surface; otherwise, see Note (2)	See Note (2)	None open to the surface; otherwise, see Note (2)	None open to the surface; otherwise, see Note (2)	None open to the surface; otherwise, see Note (2)
Inclusions (metallic or nonmetallic)	None open to the surface; otherwise, see Note (2)	See Note (2)	None open to the surface; otherwise, see Note (2)	None open to the surface; otherwise, see Note (2)	None open to the surface; otherwise, see Note (2)
Undercut	None	See Note (2)	None	See Note (2)	See Note (2)
Groove weld concavity	See Note (3)	See Note (2)	Maximum of 10% of the wall thickness of thinner member	See Note (2)	See Note (2)
Reinforcement	See Note (3)	See Note (2)	$\frac{1}{32}$ in. (0.8 mm) max.	See Note (2)	See Note (2)
Fillet weld convexity	$\frac{1}{16}$ in. (1.6 mm) max.	Per applicable design and fabrication code	$\frac{1}{32}$ in. (0.8 mm) max.	See Note (2)	See Note (2)
Discoloration [see Note (4)]	Per Table MJ-3	N/A	Per Table MJ-3	Per customer specification	Per customer specification

GENERAL NOTE: All repairs shall comply with ASME Section VIII, Division 1.

NOTES:

- (1) Must comply with paras. SF-5 and MJ-3.2.
- (2) The limits of ASME Section VIII, Division 1 will apply.
- (3) Acceptable if the following requirements are achieved:
 - (a) the requirements of ASME Section VIII, Division 1 are met.
 - (b) any feathering must not reduce wall thickness below the minimum required.
 - (c) the requirements of para. SD-5.4 are met.
- (4) Also applies to heat-affected zone.
- (5) Does not apply to insulation sheathing and similar welds.



(09)

Table MJ-2 Acceptance Criteria for Welds on Pipe

Discontinuities	Welds on Product Contact Surfaces			Welds on Nonproduct Contact Surfaces	
	Welds Left in the As-Welded Condition	Prior to Finishing (As Welded)	After Postweld Finishing	As Welded	After Postweld Finishing
Cracks	None	None	None	None	None
Lack of fusion	None	None	None	None	None
Incomplete penetration	None	None on product contact side; otherwise, see Note (1)	None on product contact side; otherwise, see Note (1)	See Notes (1) and (4)	See Notes (1) and (4)
Porosity	None open to the surface; otherwise, see Note (1)	See Note (1)	None open to the surface; otherwise, see Note (1)	None open to the surface; otherwise, see Note (1)	None open to the surface; otherwise, see Note (1)
Inclusions (metallic or nonmetallic)	None open to the surface; otherwise, see Note (1)	See Note (1)	None open to the surface; otherwise, see Note (1)	None open to the surface; otherwise, see Note (1)	None open to the surface; otherwise, see Note (1)
Undercut	None	See Note (1)	None	See Note (1)	See Note (1)
Concavity	See Note (2)	See Note (1)	See Note (2)	See Note (1)	See Note (1)
Reinforcement	See Note (1)	See Note (1)	$\frac{1}{32}$ in. (0.8 mm) max.	See Note (1)	See Note (1)
Fillet weld convexity	$\frac{1}{16}$ in. (1.6 mm) max.	See Note (1)	$\frac{1}{32}$ in. (0.8 mm) max.	See Note (1)	See Note (1)
Discoloration	Per Table MJ-3, see Note (3)	N/A, see Notes (2) and (3)	Per Table MJ-3	Per customer specification	Per customer specification

GENERAL NOTE: All repairs shall comply with ASME B31.3.

NOTES:

- (1) The limits of ASME B31.3, paras. 341.3.2 through 341.3.4 and Table 341.3.2, along with the criterion value notes for Table 341.3.2 will apply.
- (2) Acceptable if the following requirements are achieved:
 - (a) the requirements of ASME B31.3 are met.
 - (b) any feathering shall not reduce wall thickness below the minimum required.
 - (c) the requirements of para. SD-3.11.2 are met for complete drainage.
- (3) Special surface preparation may be needed to meet the criteria of Table MJ-3. Welds on piping that has been in service may require unique criteria.
- (4) Does not apply to insulation sheathing and similar welds.

Table MJ-3 Acceptance Criteria for Welds on Tube

Discontinuities	Product Contact Surfaces	Nonproduct Contact Surfaces
Misalignment (mismatch) [see Note (1)]	Maximum of 15% of nominal wall thickness [see Fig. MJ-1, illustration (b)], except that 4 in. tube may have a maximum of 0.015 in. (0.38 mm) misalignment on the O.D. and 6 in. tube may have a maximum of 0.030 in. (0.76 mm) misalignment on the O.D. Figure MJ-1, illustration (b) does not apply to 4 in. and 6 in. tube.	Same as product contact surfaces
Concavity [see Note (1)]	Maximum of 10% of the nominal wall thickness [see Figs. MJ-1, illustrations (c) and (d)]. However, O.D. and I.D. concavity shall be such that the wall thickness is not reduced below the minimum thickness required in DT-5.	Maximum of 10% of the nominal wall thickness [see Fig. MJ-1, illustrations (c) and (d)] over entire circumference with up to 15% of the nominal wall thickness permitted over a maximum of 25% of the circumference.
Convexity [see Note (1)]	Maximum of 10% of the nominal wall thickness [see Fig. MJ-1, illustration (f)]	Maximum of 0.015 in. (0.38 mm) [see Fig. MJ-1, illustration (f)]
Cracks	None allowed	None allowed
Lack of fusion	None allowed	None allowed
Undercut	None allowed	See Note (2)
Arc strikes	None allowed	See Note (3)
Incomplete penetration	None [see Fig. MJ-1, illustration (e)]	None [see Fig. MJ-1, illustration (e)]
Tack welds	Must be fully consumed by final weld bead [see Note (4)]	Same as product contact side [see Note (4)]
Discoloration (weld bead)	None allowed. For welds in nickel alloys, and for welds in super-austenitic alloys made with nickel alloy inserts or filler metals, slag is permitted as long as it is silver to light gray in color and adherent to the surface.	Discoloration level will be agreed upon between the owner/user and contractor. AWS D18.2 may be used as a reference for this purpose. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user.
Discoloration (Heat-affected zone)	Heat-affected zone (HAZ) may be permitted to have light straw to light blue color (for example, AWS D18.2 samples 1 through 3 may be used as a guide). Any discoloration present must be tightly adhering to the surface such that normal operations will not remove it. In any case, the HAZ shall have no evidence of rust, free iron, or sugaring. See Note (5).	Discoloration level will be agreed upon between the owner/user and contractor. AWS D18.2 may be used as a reference for this purpose. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user. See Note (5).
Tungsten inclusions	None open to the surface; otherwise, see Note (2).	See Note (2)
Weld bead width	No limit provided that complete joint penetration is achieved on groove welds.	If product contact surface cannot be inspected (such as I.D. of a tube beyond the reach of remote vision equipment), then the non-product contact surface weld bead shall be straight and uniform around the entire weld circumference [see Fig. MJ-1, illustration (g)]. The minimum weld bead width shall not be less than 50% of the maximum weld bead width [see Fig. MJ-1, illustration (h)]. The maximum weld bead meander shall be 25% of the weld bead width, measured as a deviation from the weld centerline, as defined in Fig. MJ-1, illustration (i).
Porosity	None open to the surface; otherwise, see Note (2).	None open to the surface; otherwise, see Note (2).

GENERAL NOTE: All repairs shall comply with ASME B31.3.

NOTES:

- (1) In the case of two different wall thicknesses, any acceptance criteria listed in terms of nominal wall thickness shall be based on the nominal wall thickness of the thinner tube.
- (2) The limits of ASME B31.3, paras. 341.3.2 through 341.3.4 and Table 341.3.2, along with the criterion value notes for Table 341.3.2, will apply.
- (3) Arc strikes on the non-product contact surface may be removed by mechanical polishing as long as the minimum design wall thickness is not compromised.
- (4) Any welds which show unconsumed tack welds on the non-product contact surface must be inspected on the product contact surface; otherwise they are rejected. If the weld cannot be inspected on the product contact surface, rewelding per MJ-6.4.2 is not allowed. Rewelding per MJ-6.4.2 is allowed if the weld can be inspected on the product contact surface after rewelding.
- (5) Welds on tubing that has been in service may require unique criteria.


Table MJ-4 Acceptance Criteria for Tube-Attachment Welds

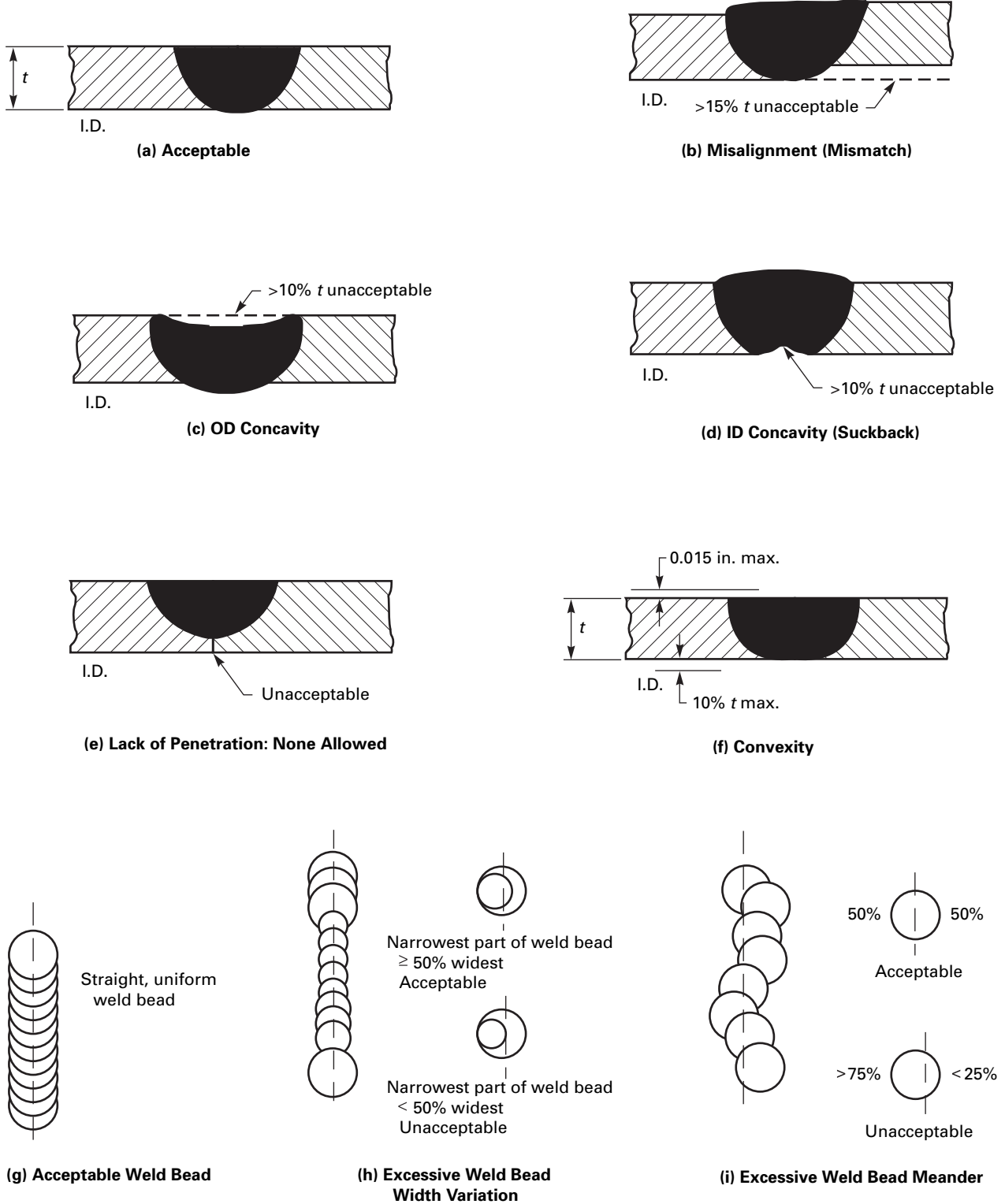
Discontinuities	Groove Welds		Fillet Welds	
	Product Contact Surface	Nonproduct Contact Surface	Product Contact Surface	Nonproduct Contact Surface
Cracks	None	None	None	None
Lack of fusion	None	None	None	None
Incomplete penetration	None	None	N/A [Note (1)]	N/A
Porosity	None open to the surface; otherwise, see Note (2)	None open to the surface; otherwise, see Note (2)	None open to the surface; otherwise, see Note (2)	None open to the surface; otherwise, see Note (2)
Convexity	10% T_w max.	0.015 in. (0.38 mm) max. and Note (3)	10% T_w max.	N/A
Undercut	None	See Note (2)	None	See Note (2)
Concavity	See Table MJ-3	See Table MJ-3	See Table MJ-3	N/A
Tack welds	Must be fully consumed by final weld bead; see Note (4)	Must be fully consumed by final weld bead; see Note (5)	Must be fully consumed by final weld bead; see Note (4)	Must be fully consumed by final weld bead; see Note (5)
Tungsten inclusions	None open to surface	None open to surface	None open to surface	None open to surface
Discoloration HAZ	See Table MJ-3	See Table MJ-3	See Table MJ-3	See Table MJ-3
Discoloration weld bead	See Table MJ-3	See Table MJ-3	See Table MJ-3	See Table MJ-3
Overlap	None	None	None	None
Minimum throat	N/A	N/A	Per Client Spec. and Note (6)	Per Client Spec. and Note (6)

GENERAL NOTES:

- (a) T_w is the nominal thickness of the thinner of the two members being joined. Weld metal must blend smoothly into base metal.
(b) Any NDE method may be used to resolve doubtful indications.

NOTES:

- (1) Penetration to the product contact surfaces is neither required nor prohibited. Welds that penetrate through to the product contact surface may exhibit intermittent penetration. Weld penetration through to the product contact surface must meet all other product contact surface requirements of this table and Table MJ-3.
(2) The limits of ASME B31.3, para. 341.3.2 through 341.3.4 and Tables 341.3.2, along with the criterion value notes for Table 341.3.2 will apply.
(3) For $T_w \geq \frac{1}{4}$ in. (6 mm), convexity (reinforcement) is $\frac{1}{8}$ in. (3 mm).
(4) Rewelding per MJ-6.5.2 is allowed.
(5) Any weld showing unconsumed tack weld(s) on the nonproduct contact surface can be rewelded per MJ-6.5.2 if the product contact surface can be reinspected. Otherwise, it is rejected.
(6) For welds designated by the owner/user as seal welds, there is no minimum throat requirement.

Fig. MJ-1 Acceptable and Unacceptable Weld Profiles for Tube Welds


MJ-7.2 Types of Examinations

Owner/user, contractor, inspection contractor, and/or engineer shall agree to the types of examinations, unless otherwise specified in the applicable code.

MJ-7.2.1 Pressure Vessels and Tanks. Examinations including visual, liquid penetrant, radiographic, and ultrasonic shall be performed in accordance with the provisions of ASME BPVC, Section VIII, Division 1. Fabricators of tanks and pressure vessels must visually examine all welds on product contact surfaces. Personnel performing examinations of pressure vessels and tanks designed to ASME BPVC, Section VIII, Division 1, shall meet requirements of the appropriate section of that Code.

MJ-7.2.2 Piping. Examinations including visual and any special method (as defined in ASME B31.3, Chapter VI, para. 344.1.2) shall be performed in accordance with the provisions of ASME B31.3, Section 344. Personnel performing examinations of piping systems shall meet the requirements of ASME B31.3, para. 342.1, Personnel Qualification and Certification, and 342.2, Specific Requirement.

Owner/user, installing contractor, inspection contractor, and/or engineer shall agree to the minimum percentage of product contact welds to be selected for visual examination. The contractor shall submit an inspection plan to ensure that welds meet the acceptance criteria of this Part. This plan shall include borescopic or direct visual inspection of the product contact surfaces on a minimum percentage of welds agreed to by the owner/user and contractor. In no case shall this minimum percentage be less than 20% of each system installed. A representative sample of each welder or welding operator's work must be included. The inspection required for compliance with ASME B31.3 may be included in the minimum percentage provided those inspections were direct visual or borescopic and of the product contact surface.

(09) **MJ-7.2.3 Tubing.** Examinations including visual, liquid penetrant, radiographic, ultrasonic, and any supplementary examinations (as defined in ASME B31.3, Chapter VI, para. 344.1.2) shall be performed in accordance with the provisions of ASME B31.3, Section 344. The external surfaces of all welds shall be visually examined. This Standard does not require radiography unless specified by the owner/user or other applicable code.

Personnel performing examinations of tubing systems shall meet the requirements of ASME B31.3, para. 342.1, Personnel Qualification and Certification, and 342.2, Specific Requirement.

Owner/user, installing contractor, inspection contractor, and/or engineer shall agree to the minimum percentage of welds to be selected for borescopic or other internal visual examination. The contractor shall submit

an inspection plan to ensure that welds meet the acceptance criteria of this Part. This plan shall include borescopic or direct visual inspection of the internal surfaces of an agreed-to minimum percentage of welds by the owner/user and contractor, but a minimum of 20% of all welds shall be randomly selected in each separate system. A procedure shall also be submitted for examining blind welds. The random selection of the accessible welds to be examined shall be up to the owner/user's inspector's discretion. There shall also be a plan for checking each operator's first shift of production.

Examiners shall be qualified in accordance with the requirements of ASME B31.3, paras. 342.1 and 342.2. Owner's inspectors and inspectors' delegates shall be qualified in accordance with GR-4.

MJ-7.2.4 Tube-Attachment Welds. Examinations including visual, liquid penetrant, radiographic, ultrasonic, and any supplementary examinations (as defined in ASME B31.3, Chapter VI, para. 344.1.2) shall be performed in accordance with the provisions of ASME B31.3, Section 344. The external surfaces of all welds shall be visually examined. This Standard does not require radiography unless specified by the owner/user or other applicable code.

Personnel performing examinations of tubing systems shall meet the requirements of ASME B31.3, para. 342.1, Personnel Qualification and Certification, and para. 342.2, Specific Requirement.

Visual inspection shall be performed on all product contact surfaces penetrated by or affected by welding.

MJ-7.3 Examination Procedures

MJ-7.3.1 Pressure Vessels and Tanks. Examination procedures for pressure vessels and tanks shall be in accordance with ASME BPVC, Section VIII, Division 1.

MJ-7.3.2 Piping. Examination procedures for piping systems shall be in accordance with the requirements of ASME B31.3, para. 343.

MJ-7.3.3 Tubing. Examination procedures for tubing systems shall be in accordance with the requirements of ASME B31.3, para. 343.

MJ-7.4 Supplementary Examinations

The execution of supplementary examinations and testing (such as borescopic and surface finish) for any system shall be in accordance with ASME B31.3, para. 341.5.

MJ-7.5 Testing

MJ-7.5.1 Pressure Vessels and Tanks. Testing of pressure vessels designed to code specifications shall be performed in accordance with ASME BPVC, Section VIII, para. UG-99 or UG-100.

MJ-7.5.2 Piping. Hydrostatic or pneumatic testing of piping systems shall be performed in accordance with ASME B31.3, Chapter VI, Section 345.

MJ-7.5.3 Tubing. Hydrostatic or pneumatic testing of tubing systems shall be performed in accordance with ASME B31.3, Chapter VI, Section 345.

MJ-7.6 Records

MJ-7.6.1 Pressure Vessels and Tanks. Records and retention of records for code vessels shall be in accordance with ASME BPVC, Section VIII, paras. UW-51 for radiographs, UG-120 for manufacturer's data reports, and UW-52 for spot examination of welds.

MJ-7.6.2 Piping. Records and retention of records associated with piping shall be in accordance with ASME B31.3, Chapter VI, Section 346.

MJ-7.6.3 Tubing. Records and retention of records associated with hygienic tubing shall be in accordance with ASME B31.3, Chapter VI, Section 346.

MJ-8 PROCEDURE QUALIFICATION

MJ-8.1 Pressure Vessels and Tanks

Welding procedures for pressure vessels and tanks shall be qualified in accordance with ASME BPVC, Section IX, except as modified by the specific code section under which the vessels or tanks are designed.

MJ-8.2 Piping

Welding procedures for piping systems shall be qualified in accordance with ASME BPVC, Section IX, except as modified in ASME B31.3.

MJ-8.3 Tubing

Welding procedures for welding of hygienic tubing systems shall be qualified in accordance with ASME BPVC, Section IX, except as modified in ASME B31.3, with the following additions:

(a) A change in the type or nominal composition of the backing (purge) gas shall require requalification (see QW-250).

(b) If filler metal is used, a change from one AWS classification of filler metal to another, or to a proprietary filler metal, shall require requalification (see QW-250).

(09) MJ-8.4 Duplex Stainless Steels

In addition to the welding procedure specification test requirements of ASME BPVC, Section IX, the weld metal and heat-affected zones from qualification test coupons of duplex stainless steels shall also meet the requirements of ASTM A 923 Methods A and/or C.

Table MJ-5 Tube/Pipe Diameter Limits for Orbital GTAW Performance Qualification (09)

Outside Diameter of Test Coupon, in. (mm)	Outside Diameter Qualified, in. (mm)	
	Min.	Max.
$\frac{1}{2}$ (13) and less	None	$\frac{1}{2}$ (13)
$>\frac{1}{2}$ (13) to $3\frac{1}{2}$ (89)	$>\frac{1}{2}$ (13)	$3\frac{1}{2}$ (89)
$>3\frac{1}{2}$ (89)	$>3\frac{1}{2}$ (89)	Unlimited

Table MJ-6 Weld Thickness Limits for Orbital GTAW Performance Qualification (09)

Thickness of Test Coupon, <i>t</i> , in. (mm)	Deposited Weld Thickness Qualified, in. (mm)	
	Min.	Max.
$<\frac{1}{16}$ (1.5)	<i>t</i>	2 <i>t</i>
$\frac{1}{16}$ (1.5) $\leq t \leq \frac{3}{8}$ (10)	$\frac{1}{16}$ (1.5)	2 <i>t</i>
$t > \frac{3}{8}$ (10)	$\frac{3}{16}$ (5)	Unlimited

MJ-9 PERFORMANCE QUALIFICATION

MJ-9.1 Pressure Vessels and Tanks

Welder and welding operator performance qualifications for pressure vessels and tanks shall be in accordance with ASME BPVC, Section IX, except as modified by the specific code section under which the vessels or tanks are designed.

MJ-9.2 Piping (09)

Welder and welding operator performance qualifications for piping systems shall be in accordance with ASME BPVC, Section IX, except as modified in ASME B31.3. When the piping is to be used for hygienic systems, the additional rules in MJ-9.3 shall apply in addition to those of Section IX. The qualification ranges shall be governed by Tables MJ-5 and MJ-6.

MJ-9.3 Tubing (09)

Welder and welding operator performance qualifications for welding of hygienic tubing systems shall be in accordance with ASME BPVC, Section IX, except as modified in ASME B31.3.

For the qualification of welding operators, the following essential variables also apply in addition to those of Section IX:

(a) welding of a joint using an edge preparation other than a square groove.

(b) the addition or deletion of solid backing.

(c) a change in the fit-up gap from that qualified.

(d) a change in pipe/tube diameter. See Table MJ-5.

(e) the addition or deletion of filler metal.

(f) the addition or deletion of consumable inserts.



(g) a change in the thickness of the deposited weld metal. See Table MJ-6.

(h) the addition or deletion of backing gas (purge gas).

(i) a change in the current type or polarity.

(j) a change in the weld head type from open head to closed head or vice versa.

(k) a change from single pass to multipass welding or vice versa, when using filler wire.

In addition to the tests required by Section IX of the ASME BPVC, either the original qualification test or a single test coupon must meet all the requirements of Table MJ-3 of this Standard.

Any change in the variables listed in MJ-9.3 requires welding of a new test coupon, for which only visual inspection in accordance with Table MJ-3 is required. Compliance with the variables in MJ-9.3 shall be documented.

MJ-10 DOCUMENTATION REQUIREMENTS

MJ-10.1 Turn Over Package Documentation Required

For cGMP-validated distribution systems (including the tubing systems on modules, super skids, and skids, and the shop or field fabrication of tubing, etc.) the following documentation shall be provided to the owner/user or their designee, as a minimum:

(a) *Materials Documentation*

- (1) Material Test Reports (MTRs)
- (2) Certified Material Test Reports (CMTRs)
- (3) Certificates of Compliance (C of Cs)
- (4) Material Examination Logs

(b) *Welding, Inspection, and Examination Qualification Documentation* (not required for standard fittings, valves, and components unless specifically required by the owner/user)

- (1) Welding Procedure Specifications (WPSs)
- (2) Procedure Qualification Records (PQRs)
- (3) Welder Performance Qualifications (WPQs)
- (4) Welding Operator Performance Qualifications (WOPQs)

(5) Examiner Qualifications

(6) documentation of approval of the above by the owner's representative prior to welding

(7) Inspector Qualifications

(8) documentation of the approval of (b)(7) above by the Owner prior to welding

(c) *Weld Documentation* (not required for standard fittings, valves, and components unless specifically required by the owner/user)

- (1) Weld Maps
- (2) Weld Logs
- (3) Weld Examination and Inspection Logs
- (4) Coupon Logs

(d) *Testing and Examination Documentation* (as applicable)

(1) passivation reports

(2) sprayball testing

(3) pressure testing

(4) final slope check documentation

(5) calibration verification documentation

(6) purge gas certifications

(7) signature logs

(8) number of welds — both manual and automatic

(9) number of welds inspected expressed as a percentage (%)

(10) heat numbers of components must be identified, documented, and fully traceable to the installed system

MJ-10.2 Materials Documentation

MJ-10.2.1 Materials Examination. The requirements for materials examination/inspection and documentation are listed in DT-14.

MJ-10.2.2 Material Test Reports. The combination of documents, including Certificates of Compliance (C of Cs), Material Test Reports (MTRs), and/or Certified Material Test Reports (CMTRs) for all metallic equipment and component product contact surfaces defined in the scope of this Standard shall include the following information, as a minimum:

(a) ASME BPE Standard, including year date

(b) material type

(c) heat number

(d) chemical composition

(e) AWS Classification of filler metal, if used

(f) alloy designation and material specification of insert, if used

(g) postweld heat treatment documentation, if applicable

(h) mechanical properties are not required, but if included, must be accurate to the raw material specification

MJ-10.3 Weld Log

The results of the welding, examination, and inspection shall be recorded on a Weld Log. The information required to be on the Weld Log may be in any format, written or tabular, to fit the needs of the manufacturer, installing contractor, inspection contractor, and owner/user as long as all required information is included or referenced. Form WL-1 (see Nonmandatory Appendix B) has been provided as a guide for the Weld Log. This form includes the required data plus some other information that is not required. The minimum requirements are listed below.

(a) isometric drawing number (including revision number)

(b) weld number

(c) date welded

(d) welder/welding operator identification



- (e) size
- (f) examination
 - (1) date
 - (2) type of examination
 - (3) acceptance/rejection
 - (4) initials
- (g) inspection
 - (1) date
 - (2) type of examination
 - (3) acceptance/rejection
 - (4) initials
- (h) identification of blind welds

- (i) identification of manual welds

- (j) basis of rejection

The following information shall be recorded on the Weld Log, an isometric drawing, or other owner/user approved documentation:

- (aa) heat numbers

- (ab) slope

MJ-11 PASSIVATION

If agreed to by the owner/user and the manufacturer, all welded systems shall be passivated after cleaning and prior to use.



Part SF

Stainless Steel and Higher Alloy Product Contact Surface Finishes

SF-1 SCOPE

The purpose of this Part is to provide criteria for stainless steel and higher alloy product contact surface finishes for bioprocessing, pharmaceutical, and personal care products equipment and distribution system components. This Part shall be referenced when specifying product contact surface finishes for the specific systems, including, but not limited to, vessels and distribution system components.

SF-2 OBJECTIVE

The objective is to describe an acceptable product contact surface finish on selected materials of construction to enhance their cleaning, sterilization, and corrosion resistance.

SF-3 APPLICATIONS

This Part shall be applicable to all systems designated by the owner/user or representative thereof.

Product contact surface requirements shall apply to all accessible and inaccessible areas of the systems that directly or indirectly come in contact with the designated product.

These systems shall include, but are not limited to, one or more of the following:

- (a) USP Water-for-Injection (WFI)
- (b) USP Purified Water
- (c) USP Pure Steam
- (d) other product/process contact surface systems

SF-4 MATERIAL

The preferred material of construction for these systems is austenitic stainless steel, type 316L alloy. Other materials may be specified by the owner/user. They may be of the following form:

- (a) *Tubing*. ASTM A 213/A 213M, ASTM A 269, ASTM A 270 (including Supplementary Requirements S2. Pharmaceutical Quality Tubing)
- (b) *Piping*. ASTM A 312/A 312M
- (c) *Fittings*. To be made to the tube and/or pipe fitting specifications shown in Part DT and/or GR
- (d) *Plate, Sheet, and Strip*. ASTM A 240/A 240M, ASTM A 666

(e) *Forged Wrought and Casting*. ASTM A 182/A 182M, ASTM A 351/A 351M, and ASTM A 484/A 484M.

SF-5 INSPECTION AND TECHNIQUES EMPLOYED IN THE CLASSIFICATION OF PRODUCT CONTACT SURFACE FINISHES (09)

Product contact surface finish inspections shall be made by one or more of the following methods:

- (a) *Visual Inspection*
 - (1) direct visual inspection
 - (2) indirect visual inspection (e.g., borescopes, mirrors)
- (b) *Liquid Penetrant*
- (c) *Surface Roughness Measurement Device (Profilometer)*
- (d) *Scanning Electron Microscopy*
- (e) *Electron Spectroscopy for Chemical Analysis*
- (f) *Auger Electrospectroscopy for Chemical Analysis*
- (g) *Replicas*. ASTM E 1351

Acceptance criteria of stainless steel and higher alloy mechanically polished product contact surface finishes are shown in Table SF-1.

Acceptance criteria of stainless steel and higher alloy electropolished product contact surface finishes shall meet requirements shown in Table SF-2 in addition to those shown in Table SF-1.

Visual inspection shall be performed under adequate room lighting. Additional lighting shall be used when appropriate to illuminate blind or darkened areas and to clarify questionable areas.

SF-6 SURFACE CONDITION

Product contact surfaces of tubing, fittings, valves, vessels, and other process components furnished to this Standard shall be finished using mechanical polishing, chemical polishing, cold working, machining, and/or electropolishing processes at the request of the owner/user, in conformance with applicable sections of this Part. In addition, all surfaces shall be clean (free of oils, grease, particulates, grinding compounds, or electrolytes).

SF-7 ELECTROPOLISHING PROCEDURE QUALIFICATION (09)

Electropolishing service providers shall maintain and implement a quality assurance/control program for

Table SF-1 Acceptance Criteria for Stainless Steel and Higher Alloy Mechanically Polished Product Contact Surface Finishes

(09)

Anomaly or Indication	Acceptance Criteria
Pits	If diameter <0.020 in. and bottom is shiny [Notes (2) and (4)]. Pits <0.003 in. diameter are irrelevant and acceptable.
Cluster of pits	No more than 4 pits per each $\frac{1}{2}$ in. x $\frac{1}{2}$ in. inspection window. The cumulative total of all relevant pits shall not exceed 0.040 in.
Dents	None accepted [Note (1)].
Finishing marks	If R_a max. is met.
Welds	As welded shall meet requirements of MJ-6. If welds are finished, then shall be smooth and blended.
Nicks	None accepted.
Scratches	For tubing, if cumulative length is <12.0 in. per 20 ft tube length or prorated and if depth is <0.003 in. For fittings, valves, and other process components, if length is <0.25 in. cumulatively, depth <0.003 in. and R_a max. is met. For vessels, if length < 0.50 in. at 0.003 depth and if <3 per inspection window [Note (3)].
Surface cracks	None accepted.
Surface inclusions	If R_a max. is met.
Surface residuals	None accepted, visual inspection
Surface roughness (R_a)	See Table SF-3.
Weld slag	For tubing, up to 3 per 20 ft length or prorated, if <75% of the width of the weld bead. For fittings, valves, vessels, and other process components, none accepted (as welded shall meet the requirements of MJ-6 and Table MJ-3).
Porosity	None open to the surface.

GENERAL NOTES:

- This table replaces previously published Tables SF-1, SF-3, SF-5, SF-7, and SF-9.
- Mechanically polished or any other finishing method that meets the R_a max.

NOTES:

- For vessels, dents in the area covered by and resulting from welding dimple heat transfer jackets are acceptable.
- Black bottom pit of any depth is not acceptable.
- An inspection window is defined as an area 4 in. x 4 in.
- Pits in super-austenitic and nickel alloys may exceed this value. Acceptance criteria for pit size shall be established by agreement between owner/user and manufacturer. All other pit criteria remain the same.



Table SF-2 Acceptance Criteria for Mechanically Polished and Electropolished Product Contact Surface Finishes

Anomaly or Indication	Acceptance Criteria
Blistering	None accepted
Buffing	None accepted (following electropolishing)
Cloudiness	None accepted
End grain effect	Acceptable if R_a max. is met
Fixture marks	Acceptable if electropolished
Haze	None accepted
Orange peel	Acceptable if R_a max. is met
Stringer indication	Acceptable if R_a max. is met
Weld whitening	Acceptable if R_a max. is met

GENERAL NOTE: Mechanically polished or any other finishing method that meets the R_a max.

Table SF-3 R_a Readings for Product Contact Surfaces

Surface Designation	Mechanically Polished [Note (1)]	
	R_a Max.	
	μ -in.	μ m
SF0	No finish requirement	No finish requirement
SF1	20	0.51
SF2	25	0.64
SF3	30	0.76
	Mechanically Polished [Note (1)] and Electropolished	
	R_a Max.	
	μ in.	μ m
SF4	15	0.38
SF5	20	0.51
SF6	25	0.64

GENERAL NOTES:

- This table replaces previously published Tables SF-2, SF-4, SF-6, SF-8, and SF-10.
- All R_a readings are taken across the lay, wherever possible.
- No single R_a reading shall exceed the R_a max. value in this table.
- Other R_a readings are available if agreed upon between owner/user and manufacturer, not to exceed values in this table.

NOTE:

- Or any other finishing method that meets the R_a max.

Table SF-4 Acceptance Criteria for Passivated Product Contact Surface Finishes

(09)

Anomaly or Indication	Acceptance Criteria
Surface particles	No particles observed under visual inspection, without magnification, and using adequate room lighting.
Stains	None accepted (weld discoloration to comply with Part MJ, Tables MJ-1 through MJ-4).
Visible construction debris	None accepted
Visible oils or organic compounds	None accepted

GENERAL NOTES:

- Surface condition must meet Tables SF-1 and/or SF-2, as applicable.
- Additional tests/acceptance criteria may be selected from Table E-3, Test Matrix for Evaluation of Cleaned and/or Passivated Surfaces in Nonmandatory Appendix E, Passivation Procedure Qualification.

their electropolishing procedures. They shall also qualify their electropolishing method(s) in accordance with a written procedure. This procedure shall specify the acceptable ranges of the electropolishing essential variables.

Nonmandatory Appendix H, Electropolishing Procedure Qualification, has been provided as a guide.

Flash electropolishing shall not be acceptable. Spot electropolishing shall be acceptable if it meets the requirements in this section.

(09) SF-8 PASSIVATION PROCEDURE

Passivation for this Part shall be limited to newly installed or newly modified sections of systems and components. Passivation shall be performed in accordance with an approved quality assurance/control program. The passivation method(s) including procedures for initial water flushing, chemical cleaning and degreasing, passivation, and final rinse(s) shall be qualified in accordance with a written procedure and documentation package. This procedure shall specify the acceptable ranges of the passivation essential variables. Nonmandatory Appendix E, Passivation Procedure Qualification, has been provided as a guide to passivation practices and evaluation of passivated surfaces. Spot passivation is permitted. The pickling process shall not be accepted as a substitute for passivation. There is no universally accepted nondestructive test for the presence of a passive layer.

For passivated product contact surfaces, the acceptance criteria in Table SF-4 apply in addition to Table SF-1 and/or Table SF-2, as applicable. Tests to ensure the presence of a passive layer shall be agreed to between the owner/user and contractor.

(09) SF-9 NORMATIVE REFERENCES

The following standards contain provisions that, through reference, specify terms, definitions, and

parameters for the determination of surface texture (roughness, waviness, and primary profile) by profiling methods:

(a) ASME B46.1, Surface Texture (Surface Roughness, Waviness, and Lay), an American National Standard.

(b) ISO 3274, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Nominal characteristics of contact (stylus) instruments.

(c) ISO 4287, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters.

(d) ISO 4288, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture.

(e) ISO 11562, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Metrological characterization of phase correct filters.

SF-10 ROUGE AND STAINLESS STEEL

(09)

Rouge is a naturally occurring phenomenon in existing stainless steel high purity process systems (including water or pure steam). The degree to which it forms depends upon

(a) the stainless steel material used for each component within the system

(b) how the system was fabricated (e.g., welding, surface finish, passivation treatment)

(c) what process service conditions the system is exposed to (e.g., water purity, process chemicals, temperatures, pressures, mechanical stresses, flow velocities, and oxygen exposure)

(d) how the system is maintained

The presence of rouge in a system needs to be evaluated against its potential to affect the product, process, and/or long-term operation of the system. Nonmandatory Appendix D, Rouge and Stainless Steel, provides the methods to measure rouge in a system in both the process solution and on the actual product contact surface. It also suggests various fabrication and operation



practices to minimize rouge formation and methods/techniques for its remediation.

For more information, refer to the ISPE Water and Steam Systems Baseline® Pharmaceutical Engineering Guide.

(09) **SUBSECTION SF-P**
POLYMER PRODUCT CONTACT SURFACE FINISHES
SF-P-1 SCOPE

The purpose of this Subsection is to provide criteria for polymer product contact surface finishes for bio-processing, pharmaceutical, and personal care products equipment and distribution system components. This Subsection shall be referenced when specifying product contact surface finishes for the specific systems, including, but not limited to, vessels whether coated/lined or not, and distribution system components.

SF-P-2 OBJECTIVE

The objective is to describe an acceptable product contact surface finish on selected materials of construction to enhance their cleaning, sterilization, and ability to convey purified flow streams with limited potential for containment buildup.

SF-P-3 APPLICATIONS

This Subsection shall be applicable to all systems designated by the owner/user or representative thereof.

Product contact surface requirements shall apply to all accessible and inaccessible areas of the systems that directly or indirectly come in contact with the designated product.

These systems shall include process systems and clean utilities.

SF-P-4 MATERIALS

The preferred materials of construction for these systems shall be as described in PM-5.2, Thermoplastic Materials.

SF-P-5 INSPECTION AND TECHNIQUES EMPLOYED IN THE CLASSIFICATION OF PRODUCT CONTACT SURFACE FINISHES

Product contact surface finish inspections shall be made by one or more of the following methods:

(a) *Visual Inspection*

(1) direct visual inspection (e.g., illumination through pipe/tube wall)

(2) indirect visual inspection (e.g., borescopes, mirrors)

(b) *Surface Roughness Measurement Device*

(1) profilometer or other surface measurement devices

Acceptance criteria of polymer product contact surface finishes are shown in Table SF-P-1.

Visual inspection shall be performed under adequate room lighting. Additional lighting shall be used when appropriate to illuminate blind or darkened areas and to clarify questionable areas.

SF-P-6 SURFACE CONDITION

The following surface finishes of polymer materials are available:

(a) *Piping/Tubing and Fittings*

(1) as molded

(2) as extruded

(3) as machined

(4) as fabricated from molded, extruded, or machined components

(b) *Sheet, Rod, and Block*

(1) as molded

(2) as extruded

(3) as machined after molding or extrusion

These are generally utilized terms and may not be applicable in all cases. The final criteria shall be determined by the R_a values shown in Table SF-P-2.

Table SF-P-1 Acceptance Criteria for Polymer Product Contact Surface Finishes

Anomaly or Indication	Acceptance Criteria
Scratches	For rigid tubing/piping, if cumulative length is <12.0 in. per 20 ft tube/pipe length or prorated and if depth <0.003 in. For other process components, surface finish must be agreed upon by supplier and owner/user.
Surface cracks	None accepted
Surface inclusions	None accepted
Surface roughness, R_a	See Table SF-P-2.

GENERAL NOTE: All product contact surface finishes shall be defined by the owner/user and manufacturer using the criteria described in SF-P-1, Scope.

Table SF-P-2 R_a Readings for Product Contact Surfaces

Surface Designation	R_a , Max.	
	μ in.	μ m
SFP0	No finish required	No finish required
SFP1	15	0.38
SFP2	25	0.64
SFP3	30	0.76
SFP4	40	1.01
SFP5	50	1.27
SFP6	60	1.52

GENERAL NOTES:

- No single R_a reading shall exceed the R_a maximum value in this table.
- Other R_a readings are available if agreed upon between owner/user and manufacturer, not to exceed values in this table.

Part SG

Equipment Seals

SG-1 SCOPE AND PURPOSE

SG-1.1 Scope

This Part defines the design and materials of construction of seals in equipment used in the bioprocessing, pharmaceutical, and personal care products industries. For this purpose, seals are defined as those elements that create or maintain process boundaries between system components and/or subassemblies in order to ensure system integrity in validated process and utility systems. It is not the intent of this Part to inhibit the development or use of new technologies.

SG-1.2 Purpose

The purpose of this Part is to enable equipment manufacturers, system designers, and end-users to specify the required seal type and performance for a specific application.

SG-2 SEAL CLASSES

Seal classes define the level of seal integrity for a given service condition with regard to the average effect that leakage by the seal or catastrophic failure of the seal can have on the product within the system or on the environment exterior of a fluid system.

SG-2.1 Class I Seals

Seals defined under this class may experience some minute leakage due to sliding interaction with stems or shafts such as O-rings [SG-4.1.1.2(a)] or some packings [SG-3.5.6.3(a)]. Class I seals shall be allowed only in a continuously sterilizing environment. Examples are valves handling sterile steam. Mechanical seals may be of single seal arrangement (SG-3.5.3.1) such as packing [SG-3.5.6.3(a)], lip seals [SG-3.5.6.3(b)], and labyrinth seals [SG-3.5.6.3(c)].

SG-2.2 Class II Seals

Seals defined under this class shall include only non-sliding types of valve seals such as diaphragms [SG-4.1.1.2(b) and (c)]. Mechanical systems shall have multiple seals (SG-3.5.3.2). Examples of uses of Class II seals are for water-for-injection (WFI) and sucrose solutions.

SG-2.3 Class III Seals

Valve seals defined under this class shall have no sliding surfaces and shall exhibit a minimum degree of

permeation. Examples of uses of Class III seals are for toxic fluids, highly dangerous fluids, and fluids containing pathogenic or recombinant DNA organisms. Shafts or stems shall have a secondary seal [SG-4.1.1.1(b)], while mechanical shaft seals shall have multiple seals [SG-3.5.3.2(a)] with a barrier fluid.

SG-2.4 Hygienic Fitting Seals

Hygienic fitting seals are used to form a sealed union between two ferrules described in SD-3.7. A sealed flange assembly, illustrated in one of many configurations in Fig. SD-1, shall result in a nearly flush interface between the gasket and the ferrule I.D.

The seal manufacturer shall designate the seal intrusion as Intrusion Category I or Intrusion Category II, per SG-2.4.1. The purpose of a flush interface is to minimize the entrapment of the material in a dead space that can lead to microbial growth and contamination. Furthermore, excessive intrusion into the process stream may lead to erosion of elastomeric seals, thereby contaminating the process stream. The amount of intrusion depends upon the dimensional control of the seal, the hygienic clamp ferrule dimensions [see Table DT-5-2 and Fig. SD-1, illustrations (a) through (c)], the amount of torque applied to the flange, the material properties of the seal, the application of steam, and the surface of the seal (wet or dry) during installation.

When choosing a seal material, the end-user should consider the biocompatibility, cleanability, steam stability, low temperature flexibility, creep resistance, sealability, leak resistance, solvent resistance, lot traceability, and other factors, depending upon the application requirements. Service intervals should be determined by the end-user and will depend on the duty cycle.

SG-2.4.1 Hygienic Fitting Seal Intrusion. Hygienic seals shall meet and be designated by one of the following categories when tested by the seal manufacturers in accordance with SG-3.4.3:

(a) *Intrusion Category I.* Seals having a maximum intrusion/recess of 0.025 in. (0.6 mm).

(b) *Intrusion Category II.* Seals having a maximum intrusion/recess of 0.008 in. (0.2 mm).

The user/owner is responsible for selecting the appropriate seal to meet their particular process requirements. Seal intrusion is one of many factors to consider in choosing a hygienic union.

SG-3 GENERAL PROVISIONS FOR SEALS IN BIOPROCESSING SERVICE: USER BASIC DESIGN REQUIREMENT

SG-3.1 Seal Performance

The equipment supplier shall be informed of all the conditions under which the seal may be expected to operate. These shall include, in addition to the service temperature and pressure, any parameters that may affect the seal performance. It is up to the equipment supplier to inform the end-user of the life cycle expectancy and the methods that will ensure that the seal operates within its design classification (e.g., routine maintenance).

SG-3.1.1 Service Temperature. Seals shall be capable of preventing unacceptable leakage when thermally cycled between the rated upper and lower temperature limits. The number of allowable thermal cycles shall be stated by the manufacturer.

SG-3.1.2 Service Pressure. The service pressure is the maximum permissible usage pressure for which the seal meets the maximum permissible leakage rate. The service pressure and acceptance level for pressure rating shall be furnished by the seal supplier.

SG-3.1.3 Bioburden. Bioburden is the concentration of microbial matter per unit volume. Microbial matter includes viruses, bacteria, yeast, mold, and parts thereof.

SG-3.1.4 Cavitation Resistance. The seal shall be placed so as to minimize damage by cavitation.

SG-3.1.5 Sterilization. The complete sterilization procedure shall be supplied by the end-user. This shall include the methods, frequency, and length of operation.

(09) **SG-3.1.6 Cleaning.** The complete cleaning procedure shall be supplied by the end-user to the fabricator/vendor for evaluation and selection of compatible material. This shall include the methods, frequency, and length of operation.

SG-3.1.7 Passivation. The complete passivating procedure shall be supplied by the end-user. The equipment supplier shall inform the end-user whether the seal will be able to perform as specified after passivation, or whether a new seal is required before the start of operation.

(09) **SG-3.1.8 Testing.** Testing by the equipment supplier and/or the end-user is encouraged to help determine a hygienic fitting seal's fitness for use in the process applications. These tests are to simulate routine operational periods with no intervention (e.g., retorquing of clamps or fasteners), beyond initial installation procedures. Nonmandatory Appendix J defines the standard process test conditions (SPTC), as well as an approach to perform these tests.

SG-3.2 System Requirements

Cleaning and sterilization of a seal occurs on a regular basis. This is necessary to ensure elimination of any bacterial growth, which could harm future products or the environment. The methods of cleaning are listed in SG-3.2.1 through SG-3.2.3:

SG-3.2.1 Cleaning Systems

(a) *Clean-In-Place (CIP).* The wetted part of a seal shall be designed so that accumulation of system media can be removed through the action of a cleaning solution. The seal should be placed to allow for best drainability.

(b) *Clean-Out-of-Place (COP).* Disassembly for cleaning.

SG-3.2.2 Sterilizing Systems. Seal requirements shall be based on the sterilization method utilized. All wetted seal surfaces shall be designed to minimize cracks and crevices. When cracks and crevices cannot be avoided, sterilization testing shall be performed to validate sterility within the system boundaries. All seals and seal contact surfaces shall be designed to accommodate expansion and contraction during sterilization and cooling-down stage. Seal materials shall be used that are corrosion-resistant to saturated steam and pure steam. The seal should be placed to allow for drainage of fluid. The following are typical sterilizing systems:

(a) *Steam-In-Place (SIP).* All seals and their assemblies shall have a minimum temperature rating meeting the requirements of SD-3.2.2.

(b) Chemical sterilization.

(c) Hot air sterilization at 160°C.

SG-3.2.3 Passivation Systems. The following are typical passivation systems:

(a) acid treatments

(b) proprietary trade formulations

Full information shall be provided as to the corrosive or erosive effect on the seal.

SG-3.3 Seal Construction

SG-3.3.1 Materials

(a) *Biocompatibility.* Biocompatibility is defined here as the ability of a substance or material to be in contact with living matter such as bacteria or mammalian cells without interfering in any way with its metabolism or ability to live and procreate. Seal materials shall be biocompatible with the system fluid to ensure that the system fluid is not adversely affected by the seal material. The biocompatibility and proper material selection shall be the responsibility of the system user.

Biocompatibility testing of candidate seals for qualification requires both in-vivo (animal testing) and in-vitro (testing in glass) tests. In-vivo testing is described in the United States Pharmacopeia (USP) in Chapter 88 and involves intramuscular implantation, intracutaneous injection, and systemic toxicity testing. In-vitro testing,

on the other hand, is described in the United States Pharmacopeia in Chapter 87 and is used to place extract from candidate seals in direct contact with living cells (typically mouse cells) for a prescribed period of time. The amount of cell lysing (death) is recorded and reported for that particular seal material. Seal manufacturers must provide, upon customer request, documentation (test report) of the in-vivo USP Class VI <88> and the in-vitro USP <87> testing on final manufactured seals. Failure of either test indicates unacceptable biocompatibility of the candidate seal. Such failures are often attributed to adverse reaction to extractables from cured elastomeric seals. Extractables may include catalyst residues, cross linking agents, process aids, plasticizers, etc.

Qualification testing of final manufactured seals (actual seals, not generic compounds) can be performed on any given size seal (or combination thereof) within a product group as long as the materials used and the manufacturing process are representative of the entire group. Biocompatibility testing must be repeated for significant changes in raw materials or processes used to fabricate seals. Otherwise, biocompatibility testing is used upon initial qualification of the material and process by the seal manufacturer.

(b) *Process Compatibility.* Seal materials shall be resistant to corrosion from process, cleaning, and sterilization fluids. Selection shall be based on all media that could come in contact with the seal, including cleaning and sterilization media. Special consideration shall be made when the exposure is at elevated temperatures.

(c) *Permeation Resistance.* Seal permeation shall be included in seal leakage criteria and not addressed as an individual topic.

(d) *Surface Finish*

(1) Seals shall be free of molding imperfections or burrs within the system boundary and on sealing surfaces.

(2) Seals shall be free of foreign matter on surfaces within the system boundary and on sealing surfaces.

(3) Surfaces to be sealed shall meet specifications provided by seal supplier based on performance and the requirements in Part SF.

(4) Molded seals and components shall have molding flash removed to prevent contact with the product stream.

(e) *Particle Generation.* Seal designs should minimize wear that generates particles that could enter the product.

(f) *Extractables.* Compounds not conforming to the applicable sections of 21 CFR 177 and having potential product contact shall be tested for chemical extractables. Candidate materials shall be tested for chemical extractables using the U.S. Pharmacopeia <661> or <381> to assess the amount of total extractables, residue on ignition, buffering capacity, and the amount of heavy metals.

Extractables results shall be available upon user request. Additional analytical techniques may be used to quantify specific compounds or elements extracted from seal materials if requested by the user.

SG-3.3.2 Crevices. A smooth, contoured, pocketless interior surface shall be created when seals are placed between the seal contact surfaces. Gaskets and O-ring seals generally should be flush with the interior surface of the pipeline or the equipment; refer to Fig. SD-1, illustrations (e) and (f). All recessed seal contact surfaces shall avoid sharp corners, and be easily cleanable with seal removed. All seal and seal contact surfaces shall be designed to minimize cracks or crevices that might harbor system media, refer to SD-3.6.

SG-3.3.3 Dead Spaces. Dead spaces are defined here as a void in the wetted portion of the structure not completely occupied by a seal, usually required to allow for thermal expansion of the seal material. These should be avoided; all seal and seal contact surfaces shall be designed so that the system is self-draining when seals are properly installed.

SG-3.4 Compliance Requirements

SG-3.4.1 General Requirements. A certificate of compliance shall be issued by the seal manufacturer to certify compliance to this Standard when required by the end-user. Additional agreements may be required; refer to SD-3.4.3. At a minimum, seals exposed to process contact fluids and/or that have a high probability of exposure will comply to the United States Pharmacopeia (USP) directive with regard to USP <87> (or ISO 10993-5) and USP <88> Class VI (or ISO 10993-6, ISO 10993-10, and ISO 10993-11) on biological reactivity [see SG-3.3.1(a)]. Examples of seals coming in direct contact with a process stream include gaskets, O-rings, diaphragms, pinch tubes, and valve stem seals.

SG-3.4.2 Certificate of Compliance. The Certificate of Compliance shall contain the following information:

- (a) manufacturer's name
- (b) part number
- (c) lot number
- (d) material of construction
- (e) compound number or unique identifier
- (f) cure date or date of manufacture
- (g) intrusion category (hygienic seals only; see SG-2.4.1)
- (h) compliance to USP <87> (or ISO 10993-5) and USP <88> Class VI (or ISO 10993-6, ISO 10993-10, and ISO-10993-11)

(i) packaging and storage recommendation (this may be of another document and not a certificate of compliance)

Marking on the seal package should include items (a) through (i) above.

Manufacturer's name and lot number shall be marked on either the seal itself or the seal package containing the seal. The lot number should enable the manufacturer to identify the raw material and processing conditions used to fabricate the article. Manufacturers are encouraged to mark the seal itself to avoid potential loss of traceability and to aid in positive identification of seals after removal from a process stream.

SG-3.4.3 Test Requirements. Conformance testing is done upon initial qualification of the hygienic union. Testing is intended to show design conformance and is not required on every seal. Testing must be repeated for significant changes in raw materials or processes used to fabricate seals. The seal manufacturer shall provide, upon request of the end-user, a certificate of design conformance that the sealed union meets the intrusion requirements of SG-2.4. The intrusion value is defined as the measured quantity that provides the maximum radial distance from the fitting I.D. to the point of maximum intrusion under the manufacturer's specified conditions (i.e., torque, fitting design, clamp design, etc.). The point of maximum intrusion/recess shall be measured using a method that does not cause deformation of the components being measured.

SG-3.5 Sealing Systems

Sealing of rotating shafts, i.e., on pumps, agitators, and compressors, is accomplished with a system made up of a mechanical seal or seals and the necessary support equipment.

SG-3.5.1 Mechanical Seal. Basic components are the primary and mating rings held together to form the dynamic sealing surfaces perpendicular to the shaft as shown in Fig. SG-1. Seal faces shall be cooled and lubricated (e.g., by the sealed fluid and/or an exterior barrier fluid).

SG-3.5.2 Types of Seal Systems Based on Lubrication. Effective operation of a seal depends on the lubricating film between the faces. There are four types as follows:

(a) *Liquid Lubricated Contacting.* Seal faces are cooled and lubricated by the fluid being sealed, i.e., process or barrier liquid. This system is normally applied to pumps.

(b) *Liquid Lubricated Noncontacting.* Seal faces are cooled and lubricated by a barrier liquid. In this system, the design of the seal faces is such that a generated lubricating film has a pressure greater than the liquid being sealed. This results in a noncontacting liquid seal design. This system is normally supplied to pumps.

(c) *Gas Lubricated Contacting.* Lightly loaded seal faces that are running dry are cooled and lubricated by the process or barrier gas being sealed as shown in Fig. SG-2. This is normally applied to top-entering agitators or fermentors.

(d) *Gas Lubricated Noncontacting.* Seal faces are cooled and lubricated by the process gas or a neutral barrier fluid like nitrogen or purified air to cool and lubricate the seal faces. The design of the seal faces is such that the generated gas film has a pressure greater than the pressure being sealed, creating a noncontacting design. This sealing concept is the most energy efficient and zero emissions control seal available to industry. This sealing concept is normally applied to pumps and compressors.

SG-3.5.3 Seal Arrangement. Seal arrangement is used to describe the design of a particular seal installation and the number of seals used on a piece of equipment. Single and multiple seal arrangements have been developed for emissions control and the development of various lubrication systems. Sealing arrangements are classified into two groups.

SG-3.5.3.1 Single Seal

(a) *Internally Mounted, Process Lubricated.* A single seal mounted inside the seal chamber is shown in Fig. SG-3. Process fluid pressure acts with the spring load to keep the seal faces in contact. The spring load shall be sufficient to provide adequate sealing pressure when fluid pressure is negative (vacuum).

(b) *Externally Mounted, Process Lubricated.* Outside mounted seals should be considered for low pressure applications. An external seal installation is lubricated by the process fluid being sealed as shown in Fig. SG-4. The purpose of using an outside mounted seal is to minimize the effects of corrosion that might occur if metal parts are directly exposed to the process fluid being sealed.

Externally mounted seals shall be lubricated such as by steam or gas depending on the process conditions. This type of design requires a seal face geometry to provide for the development of a gas or steam film at the seal faces. This type of installation is normally used on pumps having a repeller. Constant steam lubrication has the benefit of maintaining a sterile environment for low pressure applications. All external seal designs are intended for light duty service where the products are not considered hazardous to the plant environment.

SG-3.5.3.2 Dual Seals. Dual seal installations shall be used in applications requiring a neutral barrier fluid for lubrication, plant safety, and improved corrosion resistance.

(a) *Double Seals.* Double seals consist of two assemblies that will operate with a barrier fluid, always at higher pressure than the process fluid. Installation may be liquid or gas lubricated.

(b) *Tandem Seals.* This seal arrangement is made up of two single seals mounted in the same direction. The inboard seal carries the full differential pressure of the process fluid to atmosphere. The outboard seal contains a neutral barrier fluid that creates a buffer zone between

the inboard seal and plant atmosphere. Normally the buffer fluid is maintained at atmospheric pressure. Developed heat at the inboard seal is removed with a seal flush similar to a single seal installation. The outboard seal chamber fluid shall be circulated to remove unwanted heat. In special cases the outboard seal may be gas lubricated. Examples of double and tandem seals are shown in Figs. SG-5 and SG-6.

SG-3.5.4 Cartridge Seals. Cartridge seals are a preferred assembly of the seal components and adaptive hardware. These assemblies are bench testable and can validate the seal before installation.

SG-3.5.5 Materials of Construction. All seal components shall be selected on the basis of the product being sealed and the fluids used for sanitation, cleaning, or sterilization. Material selection should also comply with FDA fluid additive regulations (see GR-9). Carbon seal faces are acceptable providing the ingredients are not health threatening. The surface structure of any materials should not be porous. Pores in any materials should not be permitted since the product sealed or the media used to clean the structure may become entrapped, resulting in contamination. Common materials of construction are identified in Table SG-1.

SG-3.5.6 Seal Piping and Lubrication Support Equipment

SG-3.5.6.1 Single Seal

(a) *Dead-Ended Seal Chamber With Internal Circulation for Seal Cooling.* The seal chamber shall be self-draining, as shown in Fig. SG-7, illustration (a), and is intended for use on light duty applications. Design of the seal chamber shall provide for the circulation of process fluid.

(b) Product flush shall be circulated to the seal faces for cooling. Circulation of process fluid shall be accomplished by a recirculation line from the pump discharge to the seal chamber as shown in Fig. SG-7, illustration (b). The seal chamber shall also be self-draining.

(c) External flush of a buffer or barrier fluid shall be circulated to the seal faces for cooling. Used where the process fluid is abrasive, a fluid compatible with the process shall be injected into the seal chamber at a pressure higher than the process fluid, as shown in Fig. SG-7, illustration (c).

SG-3.5.6.2 Dual Seals

(a) Double Seals

(1) *Pressurized With External Liquid Compatible With the Process.* The seal system is a thermosyphon for light duty service. Minimum size of the reservoir shall be determined by the seal manufacturer. The seal system shall be capable of being cleaned and steam-sterilized in place.

(2) *Pressurized With External Liquid Compatible With the Process.* The seal system shall have a forced circulation when service conditions are beyond a thermosyphon system. All parts of this system shall be capable of being cleaned and sterilized in place.

(3) *Pressurized With Gas or Purified Air.* Circulation of gas is not required for cooling. Gas is dead-ended in the seal chamber as shown in Fig. SG-8. The seal system shall be capable of being cleaned and sterilized in place.

(b) Tandem Seals

(1) Nonpressurized barrier liquid shall be circulated in the outboard seal chamber. Movement of liquid could be accomplished with a pumping ring. A minimum sized reservoir by the seal manufacturer shall be required (see Fig. SG-9). The seal system shall be capable of being cleaned and sterilized in place.

(2) Outboard seals shall be capable of running dry with or without a nitrogen or purified air purge gas. Seal chamber shall be dead-ended. The seal system purge flow rate shall be sized by the seal manufacturer. System shall meet clean and sterilization requirements.

In each case described, if the process liquid will crystallize out on the atmospheric side of the seal, a quench fluid, water or steam, may be required. If a quench fluid cannot be used due to clean room operations of the biotech facility, then a noncontacting gas lubricated seal shall be used. Consult the seal manufacturer.

SG-3.5.6.3 Basic Review of Rotary Sealing Systems

(a) *Packing.* Packing may be used to seal a rotating or reciprocating shaft. Compression packing is most commonly used to seal a rotating shaft. The seal is formed by the packing being squeezed between the inboard end of a stuffing box and the gland (see Fig. SG-10). A static seal is formed at the inside diameter of the stuffing box and at the ends of the packing rings. The dynamic seal is formed between the packing and shaft or shaft sleeve. Under load, the packing deforms down against the shaft, controlling leakage. Some leakage along the shaft is necessary to cool and lubricate the packing.

The design of the packing utilizes soft resilient braided polytetrafluoroethylene (TFE) rings. Five rings are commonly used. This type of seal is limited to speeds of 1,800 ft/min (550 m/min or 10 m/s) and pressures to 250 psig [1 724 kPa (gage)]. Packing is not compatible with CIP technology. When the machine is cleaned, the packing shall be replaced.

Floating or automatic types of packings are used to seal reciprocating shafts. These seals take the shape of V-rings, U-cups, and O-rings. Speeds are limited to 150 ft/sec (46 m/s) and pressures to 1,000 psig [7 000 kPa (gage)]. TFE is a preferred material of construction. This type of seal is shown in Fig. SG-11.

(b) *Lip Seals.* Lip seals are another form of low duty radial shaft seals. The design for biochemical and sterile

processes requires an open cross-sectional design. Loading to the shaft is accomplished through the design of the elastomer lip, as shown in Fig. SG-12. These seals are limited to a minimum pressure of 5 psia [35 kPa (absolute)] and a maximum of 15 psig [100 kPa (gage)]. Maximum speed capability is 2,000 ft/sec (10 m/s). A range of elastomers is available.

(c) *Labyrinth Seals.* Labyrinth seals consist of one or more knife edges that are attached to either the housing or shaft. Design clearance between the knives and the mating surfaces are maintained at a low, closely controlled value. This type of seal has no speed limit and can be used at high temperatures. Pressure limit is typically low, 5 psig [35 kPa (gage)] per knife edge. Leakage from this device is high, 0.1 scfm to 100 scfm (2.8 L/min to 2 800 L/min). When leakage of process gas must be prevented, a buffer gas is introduced between two labyrinths, as shown in Fig. SG-13.

SG-4 SPECIAL PROVISIONS FOR SEALS IN BIOPROCESSING SERVICE

SG-4.1 Group 2 (Dynamic Seals)

SG-4.1.1 Type 1 (Reciprocating Valve Stem Seals)

SG-4.1.1.1 Seals for reciprocating valve stems are classified as follows:

(a) *Primary Stem Seals.* Primary stem seals serve as pressure barriers for process fluids. Such seals shall meet the pressure and temperature requirements of the specified material as outlined in SG-3.1 and the aseptic and sterilizing requirements specified by the owner/user. In addition, they shall meet all of the general requirements for seals outlined in SG-3.2 to SG-3.4.

(b) *Secondary Stem Seals.* Secondary seals serve as backup to the primary stem seal. These seals shall be designed to serve as pressure barriers for the process and/or sterilizing fluid in case of primary seal failure. Such seals, therefore, shall meet the pressure and temperature requirements of the specified material outlined in SG-3.1. However, such seals do not have to meet any aseptic or sterilizing requirements specified for the primary seal unless the enclosed area between the primary and secondary seals is designed to permit periodic cleaning, draining, and sterilization (see Fig. SG-14).

(c) *Other Seals.* These seals are not intended to come in contact with the process fluid. They may be commercial in nature and need only to meet respective functional requirements such as withstanding actuating air pressure, unless they have to withstand special ambient temperature requirements. In such cases, special elastomer material has to be selected. However, suitable open areas or drainage ports shall be located in such a way that contact with the process fluid is avoided in case of primary or secondary stem seal failure.

SG-4.1.1.2 Types of Primary Valve Stem Seals and Their Requirements. Primary valve stem seals as defined in SG-4.1.1.1(a) may be classified as follows:

(a) *Sliding Seals.* Seals that are statically retained within a valve component and that undergo sliding motion between the seal and a cooperating surface. Typical examples are O-rings and uniformly loaded sliding seals (see Fig. SG-15).

(b) *Nonsliding Seals.* Seals that may undergo an elastic or geometric deformation in order to accommodate the stem motion. An example of this type is a convoluted diaphragm whose inner and outer peripheries are statically retained by the stem and valve housing respectively.

(c) *Other Nonsliding Seals.* Seals that simultaneously fulfill the functions of stem sealing, statically seal part of the body cavity, and selectively serve as a closure member to interrupt the flow of process fluid through the valve. An example of this type is a diaphragm that is statically retained at its outer periphery and is able to seal against a weir or orifice with portions of its central surface area (see Fig. SG-16). For the purposes of this definition, such diaphragms shall have no openings to connect to stems or other devices within the pressurized surface area.

SG-4.1.1.3 Seals, as defined in SG-4.1.1.1 and made of elastomeric or polymeric material, shall meet all the requirements as specified in SG-3.3.

Wherever elastomeric or polymeric seals are retained under static compression, adjoining metal surfaces shall be machined to a roughness specified by the seal manufacturer to ensure required performance, and shall meet the requirements of Part SF, Tables SF-1 and SF-3, if surface can become exposed to the system fluid under the normal course of system operation. The compression has to be sufficiently uniform to minimize voids. The surface compression load per square meter must exceed the stress equal to $E\epsilon$, where E = modulus of elasticity and ϵ = strain (fractional change in original seal thickness). The resultant stress shall not be less than twice the maximum working pressure of the process fluid.

The design of the static retention shall allow for unrestrained volumetric expansion of the given elastomer or polymer during temperature cycles that the material may experience during normal operation.

SG-4.1.1.4 O-ring seals as defined in SG-4.1.1.1(a) shall be fitted in grooves located at a distance of less than $6d$ from the major valve body cavity where the stem is at its point of maximum valve travel, and where d = radial gap between stem and the stem passage within the valve housing in order to meet adequate sterilization requirements. Grooves shall be able to accommodate seal expansion without causing extrusion.

SG-4.1.1.5 When made from metal, nonsliding seals [as defined in SG-4.1.1.2(c)] shall meet the surface finish requirements for the valve housing interior on the side facing the process fluid. The portion of the seals

being retained under static compression shall have adjoining metal surfaces meeting the requirements of Part SF, Tables SF-1 and SF-3, and compression shall be sufficiently uniform to eliminate voids. The surface compression shall be at least 60% of the yield strength of the retaining metal, in no case less than 70 000 kPa.

SG-4.1.1.6 Additional Requirements for Elastomeric or Polymeric Seals Used as Valve Closure Members.

The valve manufacturer shall recommend material for the intended service and pressure, and comply with the URS (User Requirement Specification), but material selection is the responsibility of the end-user.

(a) The valve manufacturer shall test each valve assembly as part of the production process or shall validate the design and manufacturing process. One hundred percent leak testing is not required for validated manufacturing processes. Testing shall include integrity testing, beyond the sealing portion of the housing.

(b) Leakage rates shall comply with MSS-SP-88 or ANSI/FCI Standard 70-2, as applicable, and shall meet the URS.

(c) The integrity of the pressure boundary design shall be capable of passing a test as required by MSS-SP-88, category "C," or applicable regional specifications.

SG-4.1.1.7 Diaphragm Marking. Diaphragms shall be marked in accordance with Section 12.3 of MSS-SP-88, but only on those portions of the diaphragm that are exposed beyond the sealing portion of the housing.

SG-4.1.1.8 Elastomeric or polymeric seals used as ball or butterfly valve closure members shall meet the requirements of SG-4.1.1.6. Ball valve closure members (seats) shall be considered static seals.

(a) Special consideration shall be given to cleaning the body cavity between adjacent seals (seats). Valve seals shall be arranged so that the internal body cavity will be self-draining when properly installed (see Fig. SG-17).

(b) Ball or butterfly valve closure members shall not be pressure dependent. Seal integrity shall be tested using dry, oil-free air or an inert gas at a pressure of 50 psi to 80 psi (345 kPa to 550 kPa) and meet the leakage criteria of SG-4.1.1.6(b).

SG-4.1.2 Type 2 (Rotary Valve Stem Seals). This type shall meet all requirements of SG-4.1.1.2.

(09) SG-4.2 O-Rings Fabricated From Molded or Extruded Section Using Vulcanized Molded Joints

SG-4.2.1 O-Rings. Fully molded O-rings should be used, wherever possible.

SG-4.2.2 Vulcanized Bonded Joints. When the fully molded seal diameters are not available, O-rings fabricated from molded section using molded vulcanized joints can be fitted as long as the following parameters are kept.

SG-4.2.2.1 Materials. All bonded joint seal materials shall be compliant with SG-3.3.1, and any additional requirements specified by the end-user. The vulcanized bonded joint should consist of either an unvulcanized portion of the seal material or a compatible material where this gives an improved joint. In both cases, the joining material shall meet the same requirements as the seal material.

SG-4.2.2.2 Joint Integrity. The joint integrity shall meet the strength requirements of the application. A vulcanized O-ring should only contain one joint. Where tooling availability limits seal diameter, extra joints can be included by prior arrangement with the end-user.

SG-4.2.2.3 Excessive Material and Toolmarks. All excessive joint material shall be removed. The surface finish and any residual material, tool marks, or reductions in cross-sectional tolerances should not be at a level that compromises seal performance and cleanability.

SG-4.2.3 Adhesive-Bonded Joints. Adhesive-bonded joints should be avoided and their use must be agreed to between the supplier and the end-user.

SG-4.3 Seals for Centrifugal Compensial Water Pumps (09)

(a) *Mechanical Seal Configuration.* Single mechanical seals are preferred for their simplicity, observable leakage path to the atmosphere, and lack of need for an additional seal support system. When applicable, the seal should be designed in accordance with this Standard to withstand CIP and/or SIP.

(b) *Process Contact of Primary Faces and Secondary Seals.* Springs and pins shall be located on the atmospheric side of the seal faces and secondary seals.

(c) *Secondary Seals Shall be Drainable.* Secondary seal cavities shall be located and designed so that the process side is accessible to fluid flow and it is drainable. Figure SG-18 illustrates one possible design used for an O-ring secondary seal in a groove.

(d) *Mechanical Seal Mounting Hardware Drainability.* Auxiliary components used to mount the mechanical seal to the pump shall be consistent with nonpooling and drainability requirements of Part SD.

(e) *Materials of Construction.* Materials of construction shall meet SG-3.3.1 for polymers and SG-3.5.5 for seal face materials.

Fig. SG-1 Basic Components of a Seal

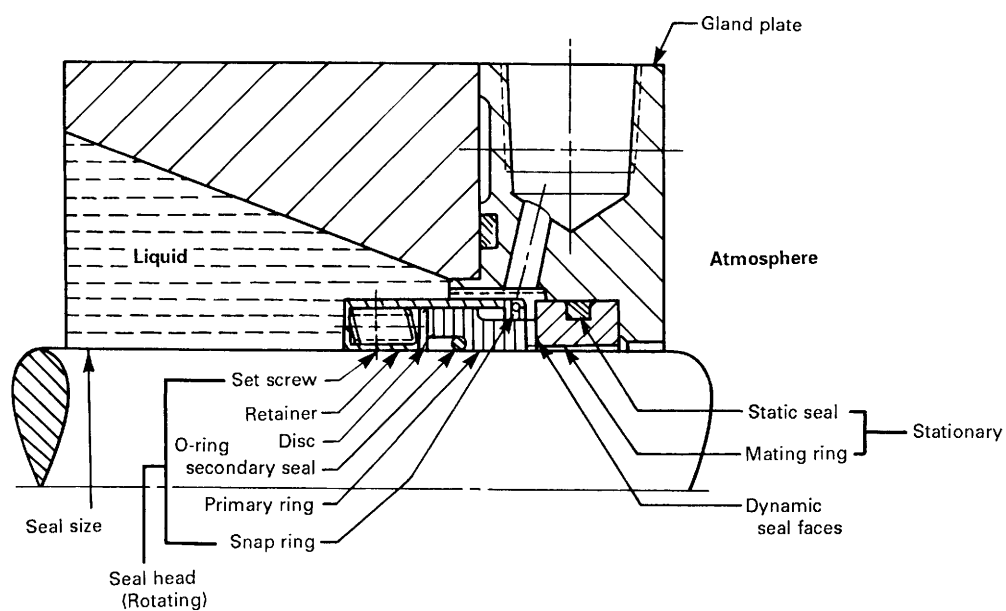


Fig. SG-2 Single Dry Running Contacting Seal

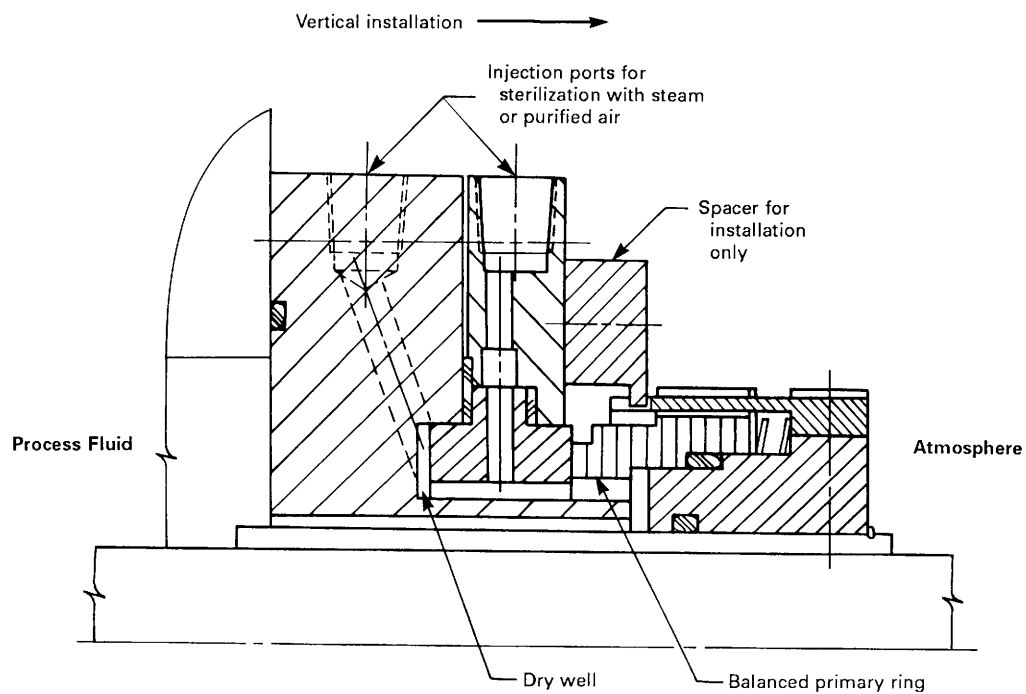


Fig. SG-3 Internally Mounted, Process Lubricated Contact Seal

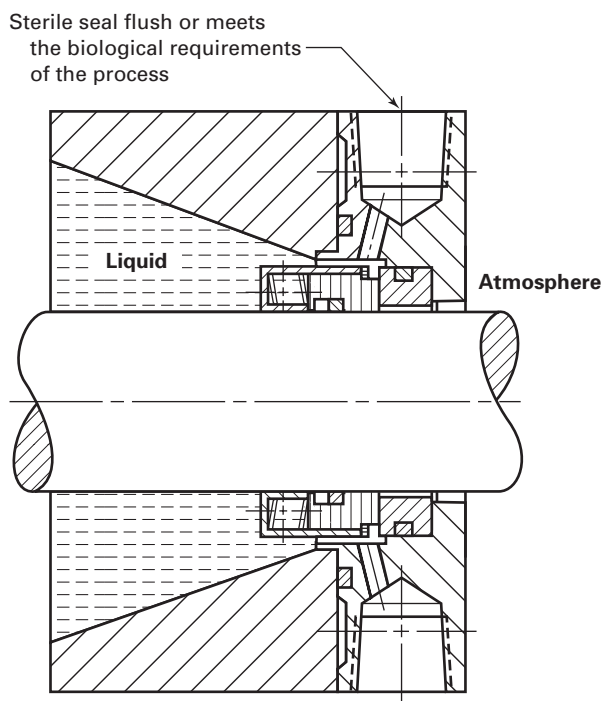


Fig. SG-4 Externally Mounted, Process Lubricated Contact Seal

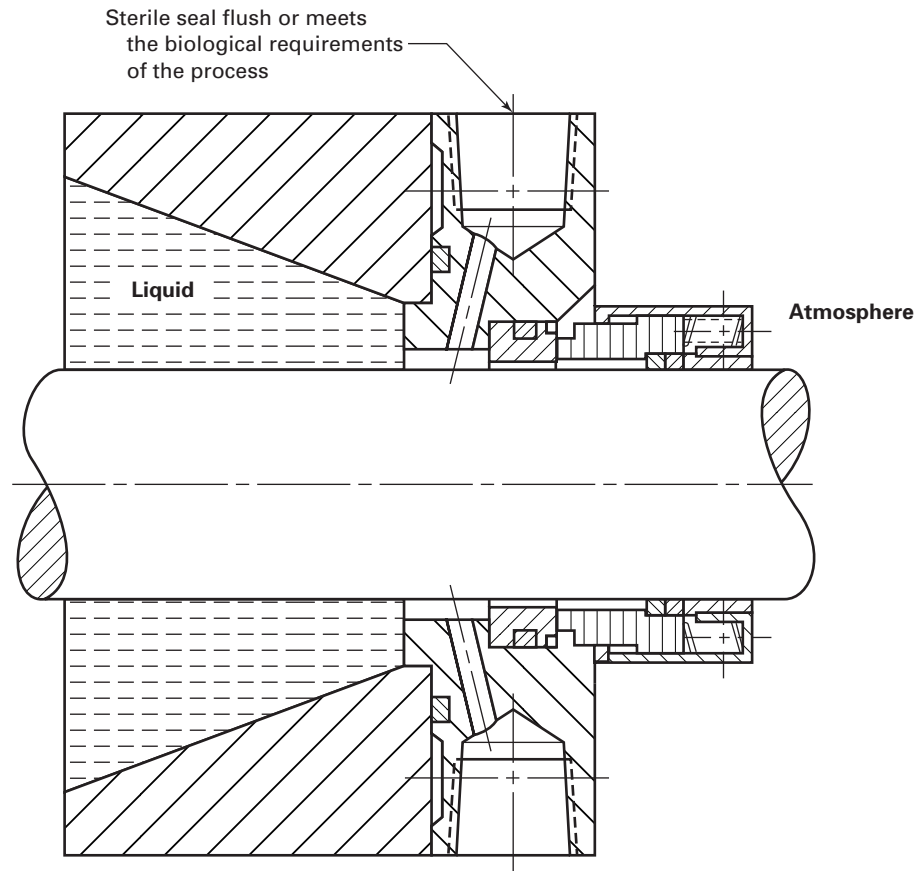
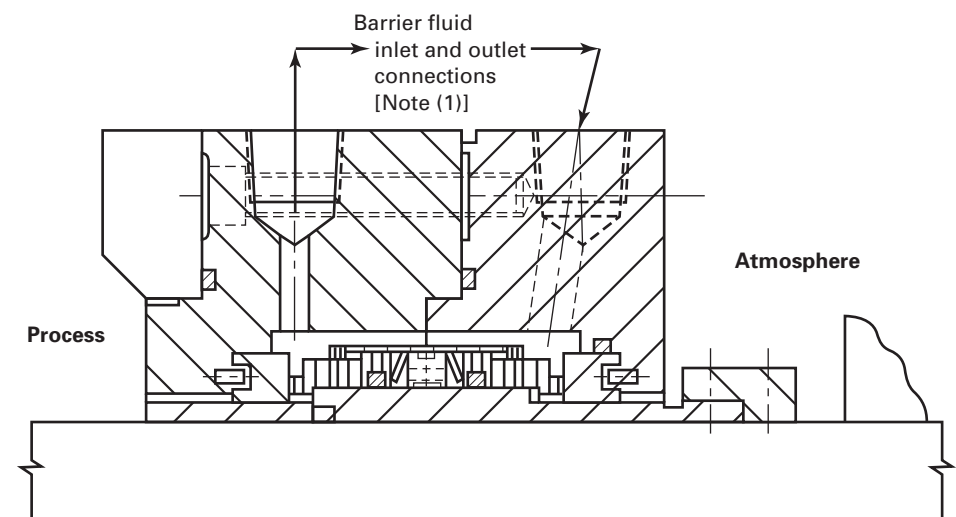


Fig. SG-5 Double Seal Installation



NOTE:

(1) Barrier fluid should meet or exceed the quality of the process side fluids (pathogens and particulates).

Fig. SG-6 Tandem Seal Installation

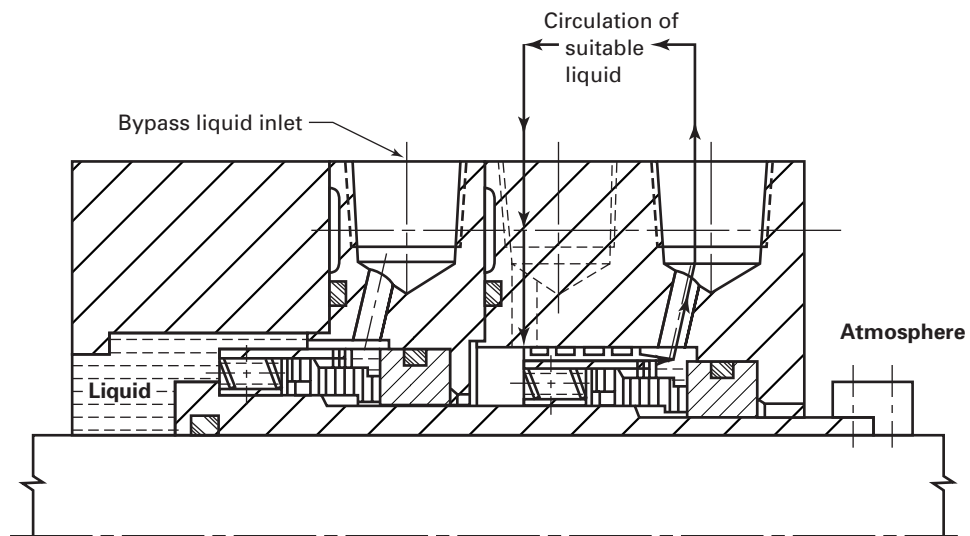
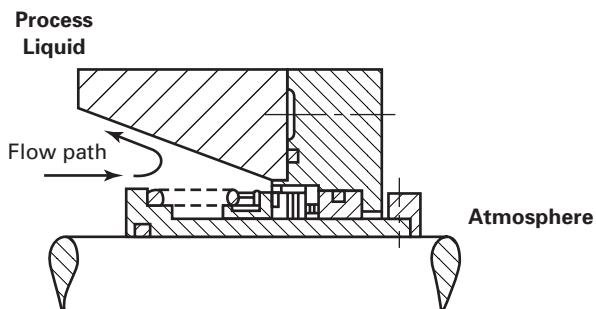
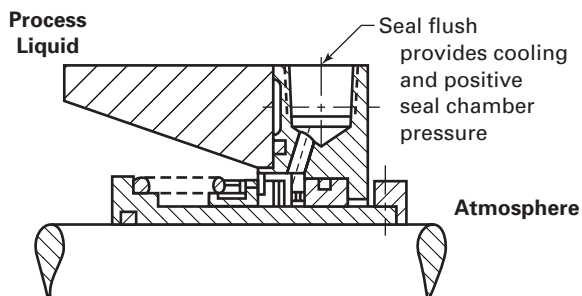


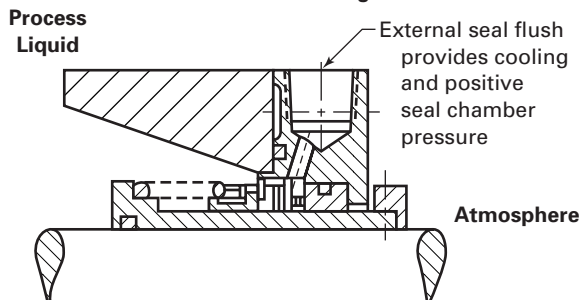
Fig. SG-7 Seal Piping and Lubrication Plans



(a) Dead-Ended Seal Chamber With Internal Circulation



(b) Recirculation Line Provides Cooling



(c) External Flush Provides Cooling

Fig. SG-8 Gas Lubricated Noncontacting Double Seal

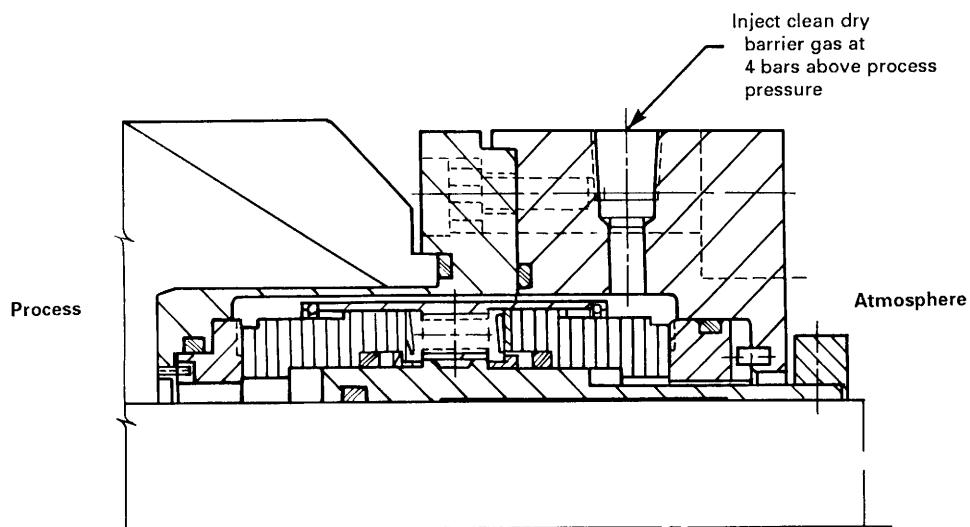


Fig. SG-9 Tandem Seal With Barrier System

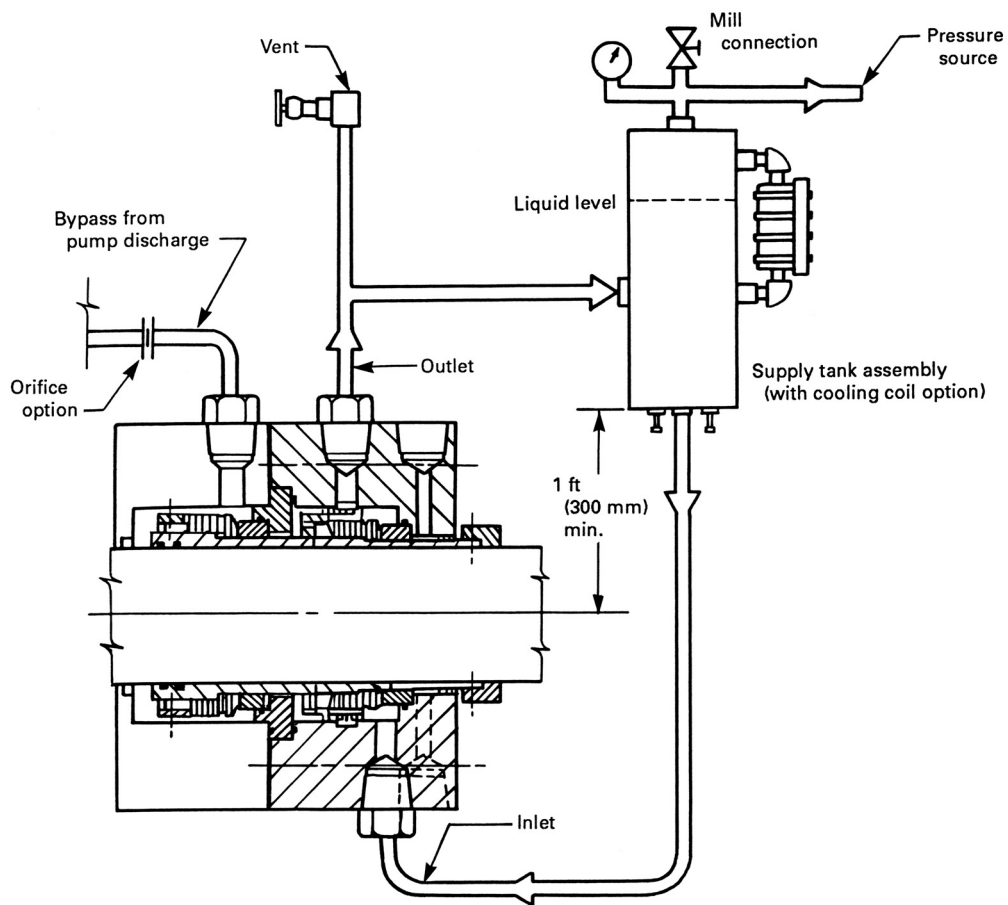


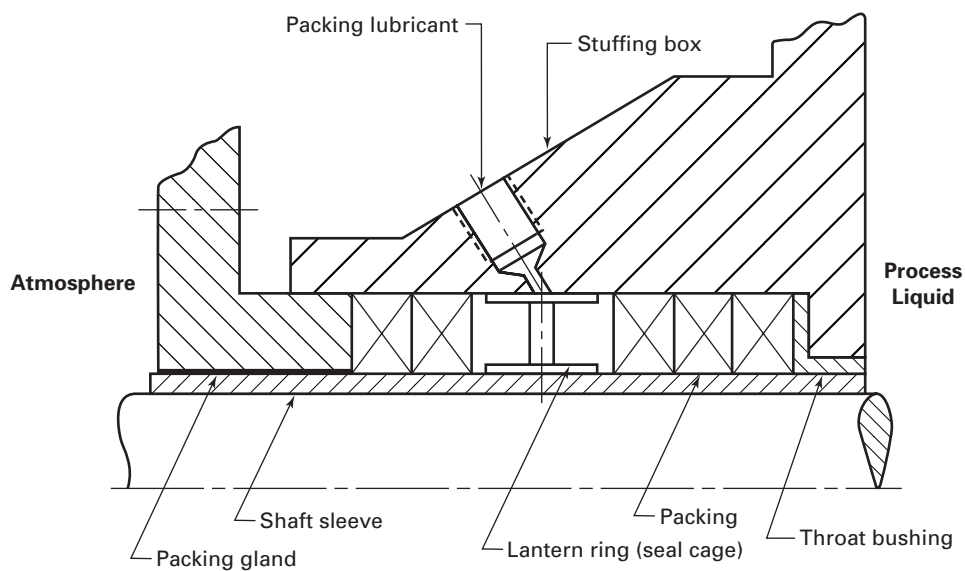
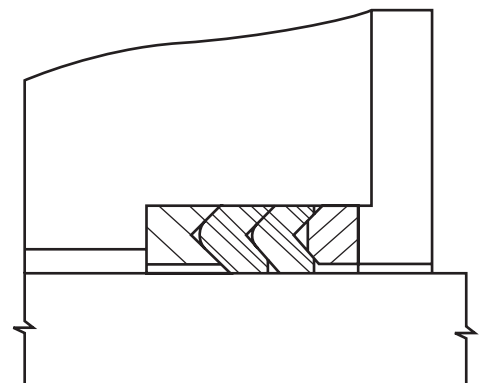
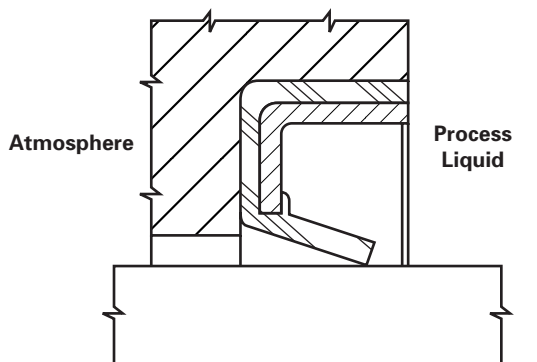
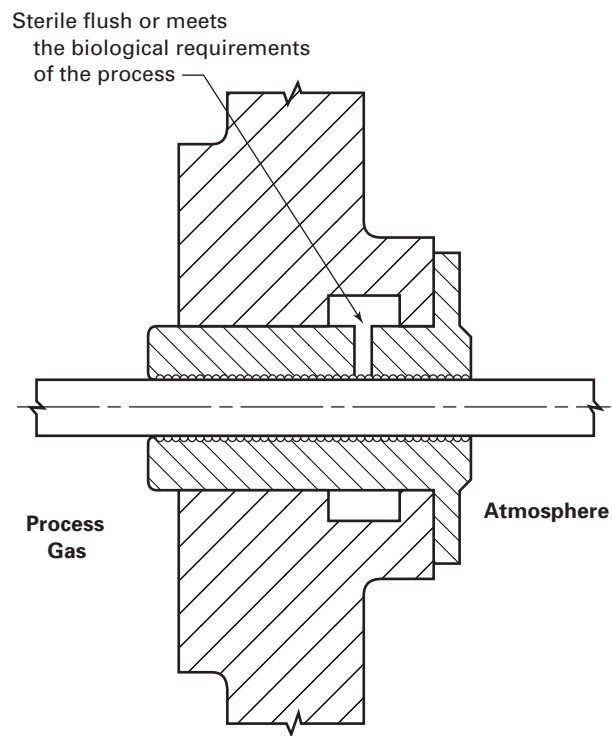
Fig. SG-10 Typical Packing Installation

Fig. SG-11 V-Ring Packing for Reciprocating Applications

Fig. SG-12 Open Cross-Sectional Lip Seal

Fig. SG-13 Labyrinth Seal


Fig. SG-14 Typical Angle Valve With Rolling Diaphragm and Orifice

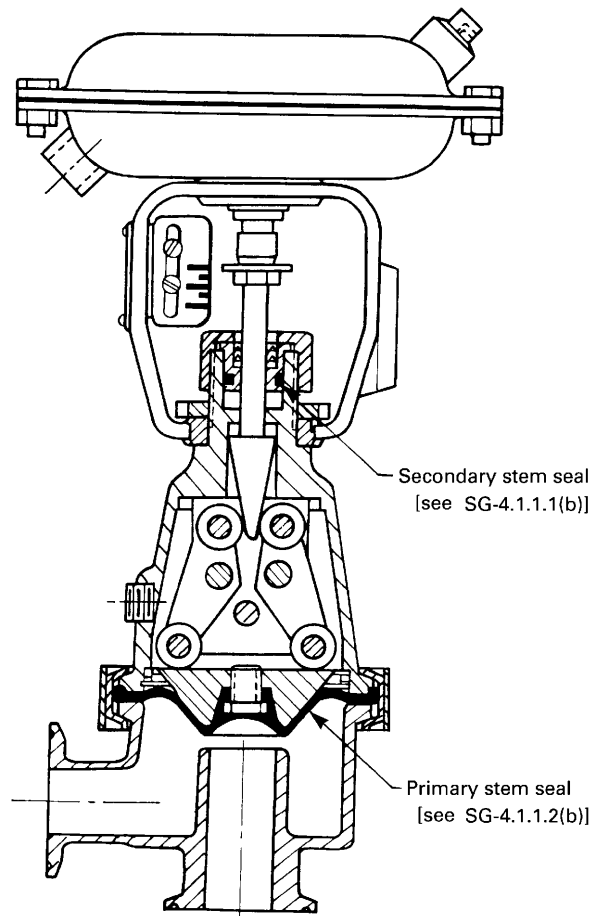


Fig. SG-15 Example of Sampling Valve With Uniformly Loaded Sliding Seal

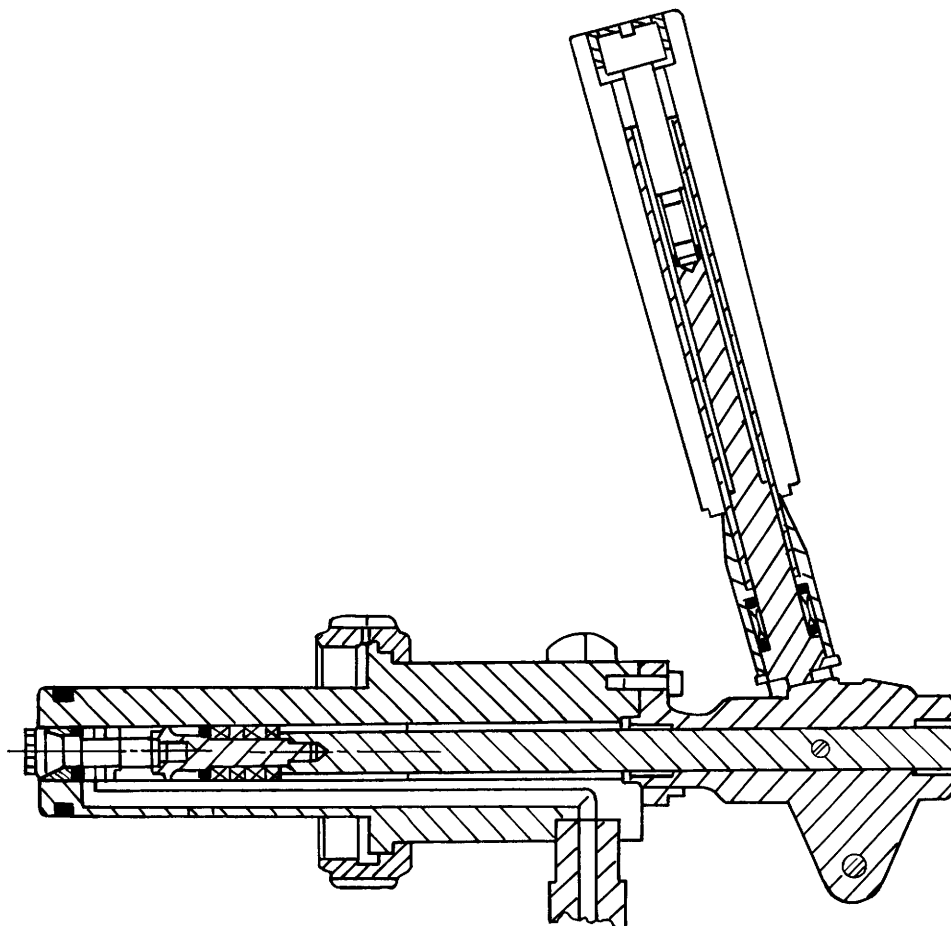


Fig. SG-16 Typical In-Line Diaphragm Valve With Weir

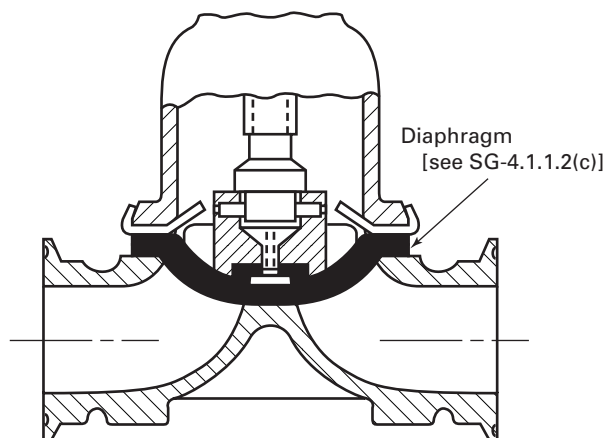
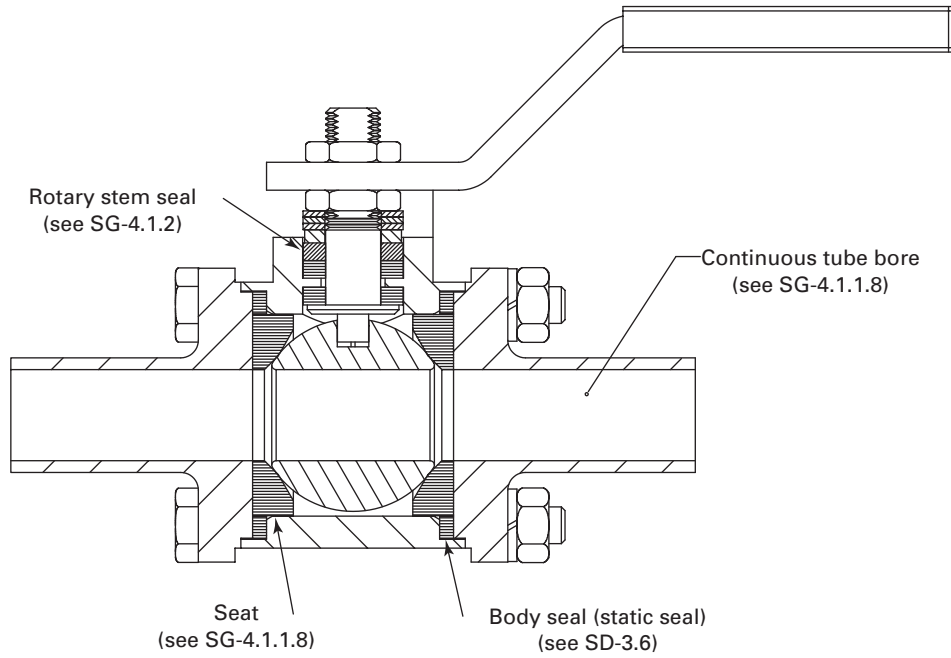


Fig. SG-17 Typical Ball Valve Configuration



(09)

Fig. SG-18 Example of Secondary Seal Design

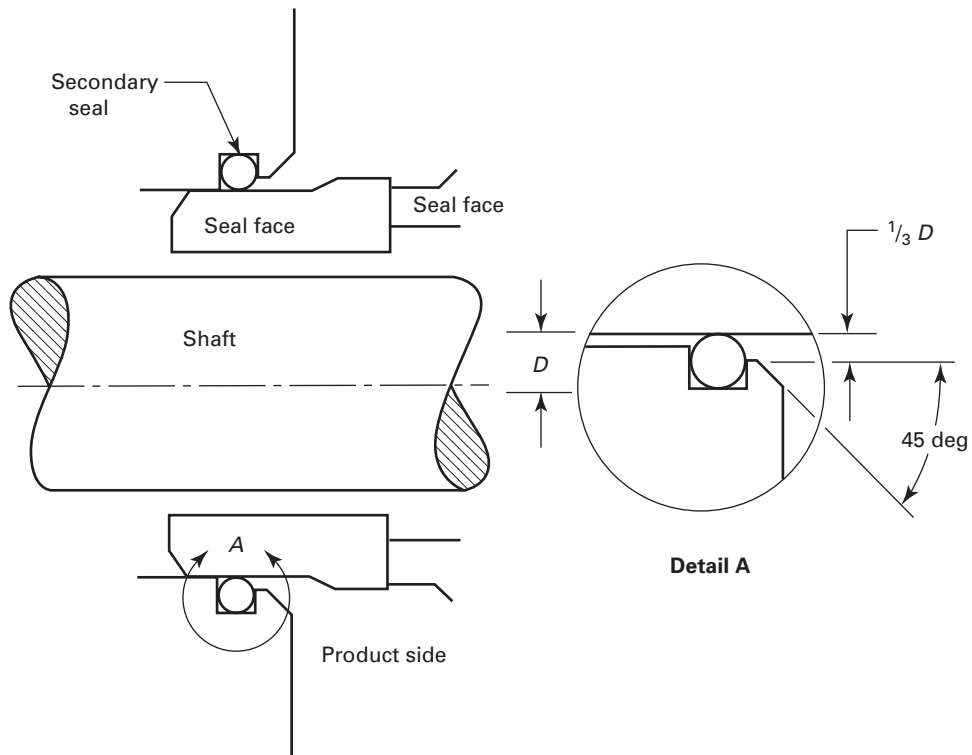


Table SG-1 Common Rotary Seal Materials for Biochemical and Sterile Service

Component	Materials of Construction
Secondary seals, (O-rings, bellows, and gaskets)	Nitrile [Note (1)] Ethylene propylene [Note (1)] Fluorocarbon [Note (1)]
Primary ring	Carbon Tungsten carbide Silicon carbide
Hardware (retainer, disc, springs, set screws, etc.)	316 Stainless steel
Mating ring	Carbon Ceramic Tungsten carbide Silicon carbide

NOTE:

- (1) Compound satisfies FDA requirements (see GR-9) for use with food, beverage, and drug service. Although the FDA does not approve compounds for use in this service, they have sanctioned certain ingredients that are considered nontoxic and noncarcinogenic.

Part PM

Polymer-Based Materials

PM-1 INTRODUCTION

This Part defines the requirements that are applicable to and unique to the use of polymer-based materials used in bioprocessing, pharmaceutical, and personal care products, equipment, components, assemblies, and bioprocessing systems in conjunction with requirements of other applicable parts of this Standard along with applicable references. Polymer-based materials include thermoplastics and thermosetting materials, both virgin and composite forms. Wherever equipment is referred to in this Part, it shall mean all bioprocessing, pharmaceutical, and personal care products, equipment, components, assemblies, and systems.

PM-1.1 Scope and Purpose

The scope and purpose of this Part is to provide requirements for the specification and documentation of bioprocessing, pharmaceutical, and personal care products, equipment constructed with polymer-based materials that are required to be cleaned, sterilized, and to be operated in a clean and sterile manner.

NOTE: The design of the equipment and systems should reference Part SD of this Standard. For requirements relating to polymer seals and gaskets, refer to Part SG.

The objective of this Part is to describe and outline accepted practices for the use of polymer-based materials that have demonstrated their merit in attaining cleanliness and sterility as they relate to bioprocessing equipment. Although acceptable requirements are indicated throughout this Part, more stringent requirements may be imposed as agreed to by the owner/user and manufacturer. Figures in this Part show ranges of usage and fabrication. There may be equipment being successfully used that corresponds to sketches labeled "not recommended." This Part covers new construction and shall not be used to evaluate the acceptability of existing equipment.

PM-2 DESIGN CONSIDERATIONS FOR POLYMERIC PIPING, TUBING, FITTINGS, VALVE BODIES, AND OTHER COMPONENTS

PM-2.1 Sizing Comparisons

Thermoplastic piping systems are available in a variety of sizing standards. Tube (e.g., Schedule 40, Schedule 80), Standard Dimensional Ratio (SDR) 11, and SDR 21 are some of the most common standards used.

Table PM-1 is a reference that compares the outside and inside dimensions of these standards. It is important to consider these standards when performing system-sizing calculations to enhance dimensional alignment of pipe/tube inner diameters to allow for sterility, cleanliness, and drainability. Tube inside dimensions are critical for alignment to stainless steel systems.

PM-2.2 Pressure Ratings

Polymer piping systems have varying pressure ratings depending on material and sizing standard. Valves and mechanical connections such as sanitary adapters, flanges, or threads may carry pressure ratings independent of pipe and fittings. Elevated operating temperatures will decrease overall system rating. Consult material manufacturers for specific details.

PM-2.3 Thermal Expansion

Polymer materials will expand and contract with changing temperature conditions. The effect of thermal expansion must be considered and designed for in each and every thermoplastic system.

To compensate for thermal expansion it is recommended to use loops, offsets, and changes in direction. By using the pipe itself to relieve the stress, the integrity of the pipe system is maintained. The use of bellows or pistons are not recommended due to the formation of pockets and gaps where liquids may be held up. The amount of thermal expansion growth in a pipe system is generally calculated by the following formula:

(U.S. Customary Units)

$$\Delta L = 12 \times L \times \alpha \times \Delta T$$

where

L = length of the pipe run, ft

α = coefficient of thermal expansion, in./in./°F
material and temperature dependent

ΔL = change in length, in.

ΔT = temperature change, °F

(SI Units)

$$\Delta L = L \times \alpha \times \Delta T$$

where

L = length of the pipe run, mm

α = coefficient of thermal expansion, mm/m/°C
material and temperature dependent

ΔL = change in length, mm

ΔT = temperature change, °C

Table PM-1 Size Comparison of Common Thermoplastic Sizing Standards

Nominal Size System	SS Tube				Sch 40				Sch 80				SDR 11				SDR 21			
	O.D.		I.D.		O.D.		I.D.		O.D.		I.D.		O.D.		I.D.		O.D.		I.D.	
	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm
1/2	0.5	12.7	0.37	9.4	0.84	21.3	0.61	15.4	0.84	21.3	0.53	13.4	0.79	20	0.59	16.2	0.79	20	0.64	16.2
3/4	0.75	19.1	0.62	15.7	1.05	26.7	0.81	20.6	1.05	26.7	0.74	18.8	0.98	25	0.77	20.4	0.98	25	0.83	21.2
1	1	25.4	0.87	22.1	1.32	33.4	1.03	26.2	1.32	33.4	0.94	23.7	1.26	32	1.02	24.2	1.26	32	1.07	27.2
1 1/4	1.375	34.9	1.125	28.6	1.66	42.2	1.36	34.6	1.66	42.2	1.26	31.9	1.57	40	1.28	32.6	1.57	40	1.38	35.2
1 1/2	1.5	38.1	1.37	34.8	1.9	48.3	1.59	40.4	1.9	48.3	1.48	37.5	1.97	50	1.61	40.8	1.97	50	1.73	44
2	2	50.8	1.87	47.5	2.38	60.3	2.05	52	2.38	60.3	1.91	48.6	2.48	63	2.02	51.4	2.48	63	2.24	57
2 1/2	2.5	63.5	2.37	60.2	2.88	73	2.45	62.1	2.88	73	2.29	58.1	2.95	75	2.41	61.4	2.95	75	2.67	67.8
3	3	76.2	2.87	72.9	3.5	88.9	3.04	77.3	3.5	88.9	2.86	72.7	3.54	90	2.9	73.6	3.54	90	3.07	81.4
4	4	102	3.84	97.5	4.5	114	3	76.1	4.5	114	3.79	96.2	4.33	110	3.54	90	4.33	110	3.8	99.4
6	6	152	5.78	147	6.63	168	6.03	153	6.63	168	5.71	145	6.3	160	5.14	131	6.3	160	5.69	145



Typical coefficients of thermal expansion at room temperature by material type are found below. Consult manufacturer for exact coefficient values.

(U.S. Customary Units)

PVDF	6.6×10^{-5} , in./in./°F
PFA	7.0×10^{-5} , in./in./°F
PP	8.33×10^{-5} , in./in./°F

(SI Units)

PVDF	1.2×10^{-5} , mm/m/°C
PFA	1.2×10^{-5} , mm/m/°C
PP	1.5×10^{-5} , mm/m/°C

ΔT is the maximum (or minimum) temperature minus the installation temperature. If the installation temperature or time of year is unknown, it is practical to increase the ΔT by 15% for safety. It is not necessary or practical to use the maximum temperature minus the minimum temperature unless it will truly be installed in one of those conditions.

PM-2.4 System Support Criteria

PM-2.4.1 Support Distances. Supports shall be placed based on the spacing requirements provided by system manufacturers. Hanging distances are based on system material as well as the specific gravity and temperature of the process media. Operating conditions of all applicable processes, including CIP and SIP, must also be considered. Hanging criteria generally increases with system operating temperatures. The placement of hangers, guides, and anchors is critical in systems exposed to thermal cycling. Hanger locations should be identified by the system engineer and laid out to allow for expansion and contraction of the pipe over its life of operation.

PM-2.4.2 Hanger and Clamp Types. Avoid using hangers that place a pinpoint load on the pipe when tightened. A U-bolt hanger is not recommended for thermoplastic piping. Hangers that secure the pipe 360 deg around the pipe are preferred. Thermoplastic clamps are also recommended over metal clamps, as they are less likely to scratch the pipe in the event of movement. Clamps should be evaluated to avoid rough edges that could damage the pipe. Ideally, if a metal clamp is being used, an elastomer material should be used in between the pipe and the clamp. Refer to Part SD for exterior cleanability.

PM-2.5 Connections and Fittings

Design of equipment should minimize the number of mechanical connections. Fusion welded connections should be used wherever practical. Hygienic design of

connections shall comply with SD-3.7, Connections and Fittings.

PM-2.6 Materials

Materials of construction shall not affect the purity or integrity of the product. It will be the owner/user's responsibility to select the appropriate materials of construction for the bioprocessing conditions. Materials shall be compatible with the stated bioprocessing conditions, cleaning solutions, and sterilizing conditions, etc., as specified by the owner/user.

Materials shall be capable of withstanding the temperature, pressure and chemical conditions.

Polymer surfaces may be used provided approval from the owner/user has been obtained. All polymer product contact surfaces shall be designed to remain intact and be tolerant of applicable SIP and CIP. In general, product contact surfaces requirements should consider the following characteristics:

- (a) homogeneous in nature
- (b) impervious
- (c) inert
- (d) nonabsorbent
- (e) nontoxic
- (f) insoluble by process or cleaning fluid
- (g) resistant to degradation, scratching, scoring, and distortion when exposed to bioprocessing fluids and sterilizing conditions

All polymer materials in contact with bioprocessing fluids or that may have contact with the processing fluid shall be identified by referenced industry standards. Refer to PM-5.

The use of elastomers (within a piece of equipment) that may thermally degrade during sterilization will need to be thoroughly investigated by the owner/user and manufacturer. The overall life of the equipment may be shortened significantly if the correct polymer is not selected.

PM-2.6.1 Extractables and Leachables. The determination of extractables/leachables, from polymer-based materials into a product or intermediate, shall be determined jointly by both the owner/user and the manufacturer of the completed polymer equipment/container (refer to SG-3.3.1). The owner/user shall be responsible for determining the impact of the extractables/leachables on the drug product/intermediates. The owner/user shall be responsible for the determination of the suitability of the usage of polymer equipment in their drug production manufacturer.

PM-3 POLYMER MATERIAL JOINING

PM-3.1 Scope

The requirements of this Part are applicable to the fusion welding of polymeric materials used for bioprocessing equipment. Equipment includes but is not

limited to valves, fittings, tubing, piping, other components, pumps and lined tanks, reactors, and pressure vessels. These materials, joining methods, examinations, etc., are limited to surfaces in process systems that contact bioprocessing products or product-process streams.

PM-3.2 Joining Processes and Procedures for Tube and Pipe Systems

Polymer tube and pipe systems are joined by a variety of heat fusion welding methods. Available techniques include various beadless technologies, noncontact IR fusion, butt fusion, and socket fusion.

NOTE: All joining techniques may not be available for all materials, nor are all methods acceptable for all processes. Care should be taken in selecting material of construction and joining technique based upon application requirement. A brief description of some available joining techniques follows.

PM-3.2.1 Beadless Welding. Beadless welding (material-dependent) is compatible with SIP systems and must be used where system, in-place drainage is required. Beadless welding may be used in the process stream or where CIP requirements are defined. Beadless welding is the preferred method for system joining.

A variety of beadless welding techniques exists in which resultant joints are free from internal beads and crevices. The primary method of beadless welding involves careful diffusion of heat through the external surfaces while maintaining internal support of material as it becomes molten. Once heated to desired temperature and duration, the molten material flows and readily joins as a single piece. An internal support device is inserted in the weld area to prevent the formation on an internal bead. Refer to manufacturers' written procedures for the complete beadless welding process.

PM-3.2.2 Noncontact IR Butt Fusion. IR fusion is not suitable for SIP systems for it is not considered in-line drainable as required by accepted current Good Manufacturing Practices (cGMP).

IR welding is similar to butt fusion with the significant difference being the joining material does not come into direct contact with the heating element. Instead, the material is held close to the heating element and is heated by radial heat. IR welding uses the same critical welding parameters of heat soak time, change over time, and joining force as found with butt fusion. However, by avoiding direct contact with the heating element, IR fusion produces a cleaner weld with more repeatable and smaller bead sizes. Refer to manufacturers' written procedures for the complete noncontact, IR fusion welding process.

PM-3.2.3 Contact Butt Fusion. Butt fusion is not suitable for SIP systems for it is not considered in-line drainable as required by accepted cGMP.

The principle of butt fusion, as described in ASTM D 2657, "Standard Practice for Heat Fusion Joining of Polyolefin Pipe and Fittings," is to heat two surfaces at the melt temperature, then make contact between the two surfaces and allow the two surfaces to fuse together by application of force. The force causes flow of the melted materials to join. Upon cooling, the two parts are united. Nothing is added or changed chemically between the two components being joined. Butt fusion does not require solvents or glue to join material. Butt fusion joints result in external and internal beads, which may assist with weld quality and inspection criteria.

Refer to manufacturers' written procedures and ASTM D 2657, DVS 2207-11, "Welding of Thermoplastics — Heated Tool Welding of Pipes, Pipeline Components and Sheets Made of PP," and DVS 2207-15, "Welding of Thermoplastics — Heated Tool Welding of Pipes, Pipeline Components and Sheets Made of PVDF."

PM-3.2.4 Socket Fusion. Socket fusion is not suitable for SIP systems for it is not considered in-line drainable as required by accepted cGMP.

In socket welding, as described in ASTM D 2657, the pipe end and socket fittings are heated to the welding temperature by means of a socket and spigot heater inserts. Socket welding may be manually performed on pipe diameters up to 2.0 in. (63 mm). Sizes above that require a Bench Socket Tool due to the required joining forces. In sizes greater than 1 in. (13 mm), a bench-style machine may be preferred for ease of operation.

Refer to manufacturers' written procedures and ASTM D 2657, DVS 2207-11, and DVS 2207-15.

PM-3.3 Joint Design and Preparation

The quality of polymeric weld joints depends on the qualification of the welders, the suitability of the equipment used, environmental influences, and adherence to applicable weld standards.

Every welder must be trained and possess a valid qualification certificate. Weld component and equipment manufacturer, or its representative, shall provide certification training and a valid qualification certificate.

The welding zone must be protected against adverse environmental influences including excessive moisture, extreme temperature conditions, excessive drafts, and contamination sources (i.e., dirt, dust, oil, foreign material shavings). Environmental condition recommendations shall be included in the Bonding Procedure Specification (BPS) provided by the material/equipment manufacturer and approved by the owner/user.

PM-3.3.1 Tubing and Pipe. Joint designs for tubing, pipe, and fittings shall be square butt joints. Joining surfaces shall have ends prepared by molding, cutting, machining, or facing to provide a square end that meets requirements of Table DT-5-1 for applicable squareness. The butt weld joints must be completed in accordance

with the BPS. The owner/user and contractor shall agree that the welding process selected will provide the desired results.

PM-3.4 Weld Acceptance Criteria

Inspection criteria and methods are dictated by material type and joining method. Common visual inspection criteria includes complete bonding of joining surface, straight and aligned joints, and exclusion of dirt and foreign substances in weld zone.

PM-3.4.1 Weld Acceptance for Beadless Welds.

Visual weld acceptance (including borescopic and light illumination at 1X magnification) for beadless polymer hygienic pipe, tubing, valves, and fittings that are internally and externally inspected shall be in accordance with the weld acceptance criteria of this section. This Part does not require radiography for polymer materials. Preproduction sample welds, when required, shall be submitted by the contractor to the owner/user to establish weld quality. Owner/user, contractor, and inspection contractor shall agree to the number and type of sample welds. During construction, sample welds shall be made on a regular basis to verify that the equipment is operating properly and that the setup is adequate to prevent discoloration beyond the level agreed upon by the owner/user and contractor. Owner/user and contractor shall agree to the frequency of sample welds. It is strongly recommended that these sample welds be made at the beginning of each work shift and when changing the operator or welding equipment.

PM-3.4.1.1 Cracks and Crevices. Any crack or crevice would generally indicate lack of full penetration welds. No internal or external cracks or crevices shall be permitted in the weld zone. See Fig. PM-1, illustration (b).

PM-3.4.1.2 Pits and Pores. Pits and pores shall not be present in the weld zone on the interior surface. See Fig. PM-1, illustration (c).

PM-3.4.1.3 Voids. Voids or microbubbles in the weld zone are the result of molten material shrinking as it cools leaving small voids, usually in the center of the weld, due to volume displacement. They are not uncommon in beadless welding and their presence alone is not reason for rejection. Large voids [limited by PM-3.4.1.3(a)] or excessive voids [limited by PM-2.4.1.3(b)] are not acceptable according to the following guidelines:

(a) Any single void larger in diameter than 10% of nominal pipe wall thickness is not acceptable.

(b) The total for all void diameters in a given cross-sectional inspection shall not exceed 10% of nominal pipe wall thickness.

See Fig. PM-1, illustration (d).

PM-3.4.1.4 Fit-Up and Mismatch. Components shall be aligned so as to prevent hold-up volume areas that would contribute to contamination of the product. The maximum misalignment is 10% of nominal wall thickness [see Fig. PM-1, illustration (e)]. It is not recommended to join two polymer components of different wall thicknesses.

PM-3.4.1.5 Inclusions. Any dark, visible inclusion or specks on the product contact surface of the weld zone are considered foreign materials and are not acceptable. See Fig. PM-1, illustration (f).

PM-3.4.1.6 Discoloration. Slight discoloration in the weld zone is not uncommon in beadless welding. Slight discoloration would include up to a light “straw” color in the weld zone. Dark color change on the surface or at weld interface could indicate improper cleaning or joint preparation and should be rejected. See Fig. PM-1, illustration (g).

PM-3.4.1.7 Concavity. Maximum inside diameter (I.D.) concavity shall be limited to 10% of the nominal pipe wall thickness. See Fig. PM-1, illustration (h).

PM-3.4.2 Examination Procedures for Nonbeadless Welds. Weld acceptance criteria for piping shall be in accordance with ASME B31.3, A341.3.2 through A341.3.4; DVS 2202-1, “Imperfections in Thermoplastic Welding Joints; Features, Descriptions, Evaluations”; and American Welding Society (AWS) G1.10M, “Guide for the Evaluation of Hot Gas, Hot Gas Extrusion, and Heated Tool Butt Thermoplastic Welds” criteria. These standards contain detailed, nondestructive inspection requirements for fabrication of sheets and piping systems by heat welding, socket and butt fusion. Refer to manufacturers’ inspection criteria for noncontact IR and beadless welding techniques.

Borescoping of product contact surface weld areas on polymer systems is not an absolute requirement although it may be preferred by owner and inspector.

PM-3.4.3 Testing. Hydrostatic testing of piping and rigid tubing systems shall be performed in accordance with ASME B31.3, Chapter VI, Section 345. Pneumatic testing shall not be used for polymer systems.

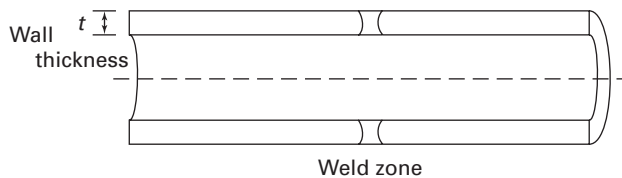
PM-3.4.4 Records. Weld equipment should monitor and record critical weld parameters such as heat, cool time, and temperature. If the equipment does not have monitoring or recording capabilities, weld data shall be recorded in welding protocols or on data carriers.

Additional requirements of records and retention of records associated with piping and tubing shall be in accordance with ASME B31.3, Chapter VI, Section 346.

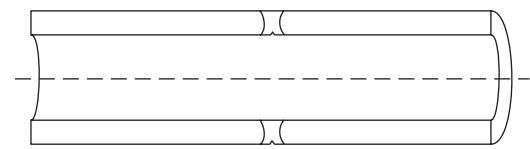
PM-3.5 Documentation Requirements

The following documentation shall be presented to the owner/user or his/her designee, as a minimum:

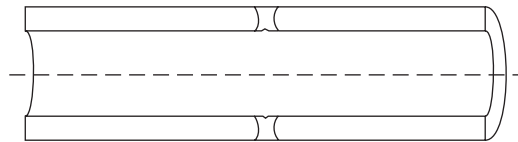
Fig. PM-1 Acceptable and Unacceptable Weld Profiles for Beadless Welds



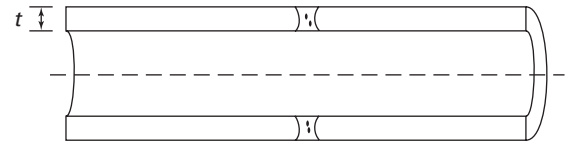
(a) Acceptable Bead Free Weld



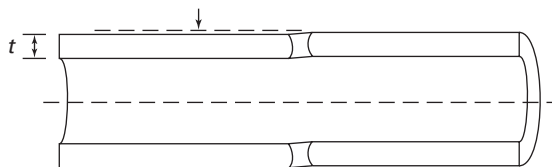
(b) Crack or Crevice on Inside or Outside Unacceptable



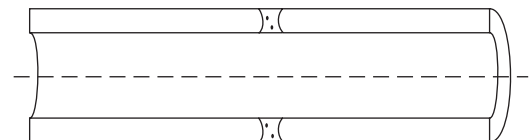
(c) Pits or Pores on Wetted Surface Are Unacceptable



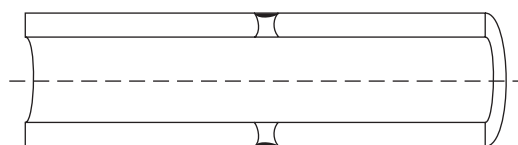
**(d) Voids (Microbubbles) in Weld Area
[Notes (1) and (2)]**



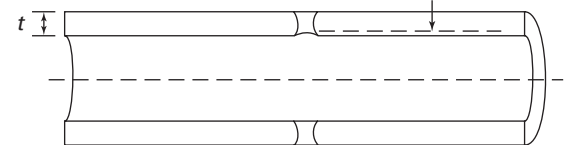
(e) Misalignment [Note (3)]



(f) Inclusions in the Weld Zone Are Unacceptable



(g) Discoloration in Weld Area [Notes (4) and (5)]



(h) Concavity [Note (6)]

NOTES:

- (1) Unacceptable if:
 - (a) any single void diameter is $> 10\%$ wall thickness (t)
 - (b) or the total for all void diameters in a cross-sectional view is $> 10\%$ wall thickness (t)
- (2) A few small voids are acceptable and are usually localized in the center of the weld zone.
- (3) Unacceptable if wall offset is $> 10\%$ wall thickness (t).
- (4) Slight discoloration is normal and acceptable (straw color).
- (5) Dark color is unacceptable (brownish).
- (6) Unacceptable if $> 10\%$ wall thickness (t).



(a) *Welding Documentation.* Welding Procedure Specifications/Parameters (WPS/P) used, their Procedure Qualification Records (PQR), and Welder Performance Qualifications/Certification (WPQ/C) or Welding Operator Performance Qualifications/Certifications (WOPQ/C).

(b) *Weld Maps.* When required by the owner/user, weld maps of bioprocessing components, weld inspection logs of bioprocessing components (including type and date of inspection), and welder identification of each weld shall be provided either on the weld map or on the inspection log.

It is recommended to utilize fusion equipment that electronically stores welding histories and serializes welds. Welding history shall be turned over, in printed or electronic format, to owner/user upon completion of work and as part of the Installation Qualification (IQ) process.

(c) *Materials.* All molded fittings, molded valves, and extruded pipe shall be intrinsically identified to provide, as a minimum, material of construction, lot number, and date of production to ensure traceability. Certificate of compliance shall be provided for molded/extruded components not properly labeled.

(d) *Testing Records.* Other records (e.g., pressure test, surface finish) shall be provided as required by owner/user.

(09) **PM-4 POLYMER INTERIOR PRODUCT CONTACT SURFACES OF PIPING, TUBING, FITTINGS, VALVE BODIES, AND COATED OR LINED VESSELS**

Polymer material contact surface requirements are found in Subsection SF-P, Polymer Product Contact Surface Finishes.

PM-5 MATERIALS OF CONSTRUCTION

PM-5.1 Scope

The scope and purpose of this section is to provide information related to polymer materials used in bioprocessing. Included is information about various types of materials such as tubing, piping, sheets, weld rods, and other shapes used in such equipment as storage tanks, reactors, agitators, piping, valves, pumps, and hoses.

PM-5.2 Thermoplastic Materials

Polymeric materials for process contact surfaces shall conform to a published ASTM Standard or other recognized specification, unless otherwise agreed to by purchaser and supplier. Material shall also meet the standard requirements of the Food and Drug Administration (FDA) 21 CFR Part 177 and United States Pharmacopoeia (USP) Class VI.

For fusion-welded components, it is the responsibility of the manufacturer to supply polymeric components manufactured using resins having Melt Flow Rates (MFR) as measured by ASTM D 1238, "Standard Test Method for Melt Flow Rates of Thermoplastics by Extrusion Plastometer," suitable for the intended method of joining.

Selection of material of construction shall be decided by owner and shall be dependent upon factors such as intended application, specified process quality, and cleaning requirements. Not all materials and joining methods are preferred for all applications. Polymer stock material used for product contact, custom fabrication components shall be virgin, unpigmented, and should be compatible with the material used in the rest of the process piping/tubing application. Weld rod used in the application shall be virgin and unpigmented.

PM-5.2.1 Fluorinated Ethylene-Propylene (FEP). All FEP resin shall be virgin, of the same type and class as described in ASTM D 2116, and listed in the United States Code of Federal Register (CFR) Title 21, Chapter 1, Part 177.1550 for food contact.

PM-5.2.2 Perfluoroalkoxy (PFA). All PFA resin shall be virgin, of the same type and class as described in ASTM D 3307, and listed in the United States Code of Federal Register (CFR) Title 21, Chapter 1, Part 177.1550 for food contact.

PM-5.2.3 Polypropylene (PP). All PP resin shall be virgin, of the same type and class as described in ASTM D 4101, and listed in the United States Code of Federal Register (CFR) Title 21, Chapter 1, Part 177.1520 for food contact.

PM-5.2.4 Polytetrafluoroethylene (PTFE) and Modified Polytetrafluoroethylene (M PTFE). All PTFE, and modified PTFE, resin shall be virgin, of the same types and classes as described in ASTM D 4894 and ASTM D 4895, and listed in the United States Code of Federal Register (CFR) Title 21, Chapter 1, Part 177.1550 for food contact.

PM-5.2.5 Polyvinylidene Fluoride (PVDF) and Polyvinylidene Fluoride/Hexafluoropropylene (PVDF/HFP). All PVDF resin shall be virgin as described in ASTM D 3222 or ASTM D 5575 and listed in the United States Code of Federal Register (CFR) Title 21, Chapter 1, Part 177.2510 or 177.2600 for food contact.

PM-5.2.6 Filler Materials. Filler materials may be utilized with the preceding materials to enhance properties for uses such as, but not limited to, gaskets and seals. Final fabricated products made with filler materials shall be USP Class VI compliant.

PM-5.3 Thermoset Elastomers

Original physical properties and other properties required for satisfactory performance of the elastomer

shall be agreed upon by the user and supplier. Appropriate documentation, regarding such properties, such as a certificate of compliance, shall be furnished to the user. Performance properties may include, for example, hardness specification, compression set limits, minimum tensile strength at break, resistance to media (time, temperature, concentration), etc. The elastomer material used shall conform to relevant Food and Drug Administration (FDA) and USP Class VI requirements.

PM-5.3.1 Ethylene Propylene (EPM and EPDM). Ethylene propylene or ethylene propylene diene monomer elastomer shall be made from 100% virgin polymer as the sole elastomer component.

PM-5.3.2 Silicone (VMQ). Silicone elastomer shall be made from 100% virgin polymer as the sole elastomer component.

PM-5.3.3 Fluoroelastomer (FKM). Fluoroelastomer shall be made from 100% virgin polymer as the sole elastomer component.

PM-5.3.4 Perfluoroelastomer (FFKM). Perfluoroelastomer shall be made from 100% virgin polymer as the sole elastomer component.

PM-5.4 New Materials

New materials or significant reformulations of existing materials shall at a minimum conform to USP Class VI requirements (also consider USP 661 and USP 381) and PM-2 of this document.

(09) PM-6 ELASTOMER PERFORMANCE PROPERTIES

PM-6.1 Scope

The purpose of this section is to provide information related to the physical and dimensional properties or changes that may occur to elastomer materials after contact with a range of test fluids. This information will assist in the selection of suitable elastomer materials for applications. These fluids are representative of products typically used during cleaning of bioprocessing equipment.

PM-6.2 Normative References

ASTM D 395 or ISO 815, Standard Test Methods for Rubber Property — Compression Set
ASTM D 471 or ISO 1817, Standard Test Method for Rubber Property — Effect of Liquids
ASTM D 2240 or ISO 48, Standard Test Method for Rubber Property — International Hardness or Durometer Hardness
ASTM D 412 or ISO 37 — Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension
ASTM D 624, ISO 34, or ISO 816, Tear Strength

Publisher: American Society of Testing and Materials (ASTM International), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959

PM-6.3 Samples

Sample parts shall be prepared according to ASTM D 412 (ISO 37). Samples tested per this specification shall be from the same formulation as finished parts.

PM-6.4 Immersion Fluids

Test fluids and test temperatures for fluid immersions are as follows:

(a) sodium hydroxide — 8% V/V, 2M (or appropriate commercial substitute) at 70°C (158°F)

(b) phosphoric acid — 4% V/V (or appropriate commercial substitute) at 70°C (158°F)

(c) sodium hypochlorite — 0.05% V/V at 70°C (158°F)

(d) saturated clean steam at 130°C (266°F)

Rinse samples with water to a neutral pH, or minimum conductivity, and dry before testing.

Additional test fluids and conditions may be specified.

PM-6.5 Qualification Testing

Qualification testing should be performed on samples from each product formulation. Product properties shall be tested in accordance with the specifications listed in PM-6.2, as applicable.

PM-6.6 Elastomer Testing — Property Retention

Elastomer material testing requirements are listed in Table PM-2. The test durations are 70 hr, 166 hr, and 502 hr. These tests indicate a minimum standard of acceptance and provide a guide regarding property changes with exposure time.

PM-6.7 Elastomer Test Result Interpretation

Elastomer test interpretation is greatly dependent on the specific application. A significant property change, after fluid exposure, may impact an elastomer's performance. In such cases, a different material will be more suitable for the application. Refer to Nonmandatory Appendix K, Interpretation of Elastomer Material Property Changes. The end-user must ultimately decide on the relevance of the test results for the applicable process.

PM-7 SINGLE-USE COMPONENTS AND ASSEMBLIES

(09)

PM-7.1 Scope

This subsection defines the requirements that are applicable and unique to the use and manufacturing of single-use components and assemblies. These products are intended for one time use and may be referred to as disposables. In this subsection, "component" is defined as an individual unit and "assembly" is defined

(09)

Table PM-2 Thermoset Elastomers Test Properties

Property Change (From Original Value)	Test Designation	Description and Application (Reference Nonmandatory Appendix K, Interpretation of Elastomer Material Property Changes)
Fluid immersion (70 hr, 166 hr, and 502 hr at specified temperature) [Note (1)], (reference PM-6.3)	...	...
Compression set	ASTM D 395B or ISO 815	Measure of recovery after deformation
Volume and/or weight	ASTM D 471 or ISO 1817	Absorption of solvent or extraction of soluble constituents from elastomer
Hardness, IRHD, or shore (pts)	ASTM D 1415 or ISO 2240	Changes related to solvent and/or temperature; higher numbers indicate harder material
100% modulus	ASTM D 412 or ISO 37	Measure of force required to extend sample by 100%
Tensile strength at break	ASTM D 412 or ISO 37	Force needed to stretch part to breaking point
Elongation at break	ASTM D 412 or ISO 37	Percent elongation at break
Tear strength	ASTM D 624, ISO 34, or ISO 816	Elastomer resistance to tear

NOTE:

(1) Test duration times are $-0/+2$ hr.

as the combination of two or more individual components. This subsection will address the methods for identifying, inspecting, packaging, joining, biocompatibility, and sterilization applicable to single-use polymers, components, and assemblies.

PM-7.2 Identification

Single-use components and assemblies shall be designed and packaged to provide lot traceability. The traceability shall enable the end-user to identify the raw material(s), processing conditions critical to support the manufacturer's specifications, and the date of manufacture.

PM-7.2.1 Labeling. The primary packaging of single-use components and assemblies shall be labeled with the following information:

- (a) manufacturer
- (b) part identifier
- (c) lot identifier

Additional information can be included on the label upon agreement between manufacturer and end-user.

PM-7.2.2 Certificate of Compliance. The single-use component or assembly manufacturer shall issue a Certificate of Compliance that contains the following information:

- (a) manufacturer's name and contact information
- (b) part identifier
- (c) lot identifier
- (d) date of manufacturing and/or expiration date
- (e) compliance information

Additional information can be included in the Certificate of Compliance upon agreement between manufacturer and end-user.

PM-7.3 Inspection and Packaging

The packaging of single-use components and assemblies shall be performed to help control the potential introduction of bioburden, particulate, or other contaminants to the component, assembly, or the end-user's system. Inspection shall be performed to confirm the quality of the packaging and the contents meet the specified criteria between supplier and end-user.

PM-7.3.1 Inspection. Single-use components and assemblies shall be inspected for the presence of particulate or other contamination before primary packaging as agreed upon by manufacturer and end-user. This inspection shall take place in a controlled environment in accordance with the intended use of the final component or assembly.

PM-7.3.2 Packaging. The purpose of packaging of single-use components and assemblies is to control the potential introduction of bioburden, particulate, or other contamination. The packaging shall not adulterate the component and assembly. Primary packaging shall take place in a controlled environment at a level suitable for the final use of the component or assembly. The packaging of single-use components and assemblies shall be labeled according to PM-7.2.1.

PM-7.4 Joining Methods

The joining of polymers may be performed in many ways for single-use applications. Examples of these joining techniques include, but are not limited to, welding, heat sealing, overmolding, solvent bonding, mechanical connections, and adhesives. With any of these methods, the procedure for the joining of polymers, components, or assemblies shall be controlled to ensure repeatable results. The joint shall not leak, shall meet the pressure requirements for the intended use, and shall maintain the integrity of the component or assembly's contact surface.

PM-7.5 Biocompatibility

The biocompatibility of single-use components and assemblies must be considered carefully due to the potential for large product contact areas and long contact times. Many of these components and assemblies are composed of multiple materials or multilayer structures, and the primary concern is how the product interacts with the contact surfaces. The design of the component and assembly shall not compromise the integrity, safety, or efficacy of the process fluid. The focus of evaluations should be on the material of construction of the product contact surface, but it is preferred to evaluate the complete component and assembly. At a minimum, the product contact surface shall comply with the following tests:

(a) biological reactivity, in vitro (cytotoxicity, i.e., USP <87>)

(b) biological reactivity, in vivo (i.e., USP <88>) or equivalent per recognized compendia agreed to by end-user and manufacturer

Additionally, the user should consider protein adsorption, preservative absorption, leaching of low molecular weight compounds, endotoxins, and presence of animal-derived compounds in single-use components and assemblies.

PM-7.6 Sterilization

Where single-use components and assemblies are required to be sterile, validation of sterility shall be conducted according to recognized standards (e.g., ISO 11137).

(09) PM-8 HOSE ASSEMBLIES

PM-8.1 Scope

The scope and purpose of this section is to define the requirements for flexible hose assemblies intended for repeated use. Hose assemblies are defined here as a length of a flexible, polymeric element with at least one end connection securely affixed and capable of containing fluids under specified conditions (e.g., pressure and temperature.)

PM-8.2 Hose Construction

PM-8.2.1 Flexible Elements. Elements may be constructed from a single, homogeneous material or multiple layers. Multilayer elements may consist of an inner contact layer surrounded by one or more additional reinforcement layers and an outer cover. Reinforcement layers may include fabric braiding, metal wire or braiding, and various elastomeric materials. The liner design shall allow for drainability and cleanability as required by the end-user.

PM-8.2.2 Mechanically Affixed and Reusable End Connections. Metallic and nonmetallic end connections are attached to the flexible element by mechanical compression. The design shall ensure a seal is maintained at the end of the barb [see Fig. SD-7-1, illustration (d)]. Band style hose clamps are not recommended [see Fig. SD-7-1, illustration (c)]. The fitting should be designed to minimize entrapment of liquid in the hose assembly. Dimensions and tolerances of the process connection shall be consistent with Table DT-5-2.

PM-8.2.3 Flare-Through End Connections. Flare-through end connections are connections in which the inner contact layer of the flexible element extends through the fitting and is formed into the end connector. Flare-through end connections may have integral gaskets or provisions for standard gaskets.

PM-8.2.4 Molded-in-Place End Connections. Molded-in-place end connections are secured to the flexible element by a thermal or chemical bond. Molded-in-place end connections utilizing nonrigid materials may require additional stiffening reinforcement to achieve an adequate process connection seal. Molded-in-place end connections may include an integral gasket.

PM-8.2.5 Hose Materials. Hose assembly materials shall conform to applicable sections of SD-3.4 and PM-2.6.

(a) *Biocompatibility.* The biocompatibility and proper material selection shall be the responsibility of the end-user. Biocompatibility testing of candidate hose assemblies for qualification requires USP <87> (or ISO 10993-5) and USP Class VI <88> (or ISO 10993-6, ISO 10993-10, and ISO 10993-11) tests on all polymeric process contact materials. End-users may request similar testing on non-contact layers that may come in contact with the process fluid in the event of a failure of the inner liner. Hose assembly suppliers shall provide, upon customer request, documentation of the biocompatibility testing on final manufactured hose assembly materials. Failure of either test indicates unacceptable biocompatibility of the candidate hose assembly.

(b) *Surface Finish.* Surface finish of metallic end fittings shall comply with the requirements of Part SF.



(c) *Particle Generation.* Hose assembly designs should minimize wear that generates particles that could enter the product.

(d) *Extractables.* Hose assembly materials shall conform to the requirements of PM-2.6.1.

PM-8.3 Hose Assembly Performance

The equipment supplier should be informed of all the conditions under which the hose assembly may be expected to operate. This should include the methods, frequency, and length of cleaning and sterilization procedures. In addition to the service temperature and pressure, any parameters that may affect the hose assembly performance should be provided. The equipment supplier should inform the end-user of the life cycle expectancy and the methods that will ensure that the hose assembly operates within its design specification (e.g., routine maintenance).

PM-8.3.1 Service Temperatures and Pressures. Hose assemblies shall be capable of withstanding thermal and pressure cycling between the rated upper and lower temperature and pressure limits.

PM-8.3.2 Nonroutine Events. The complete procedure for nonroutine events such as passivation, derouging, and post construction cleaning should be supplied by the end-user. The supplier should inform the end-user whether the hose assembly will perform as specified during these events. The end-user should perform a risk assessment to determine if a new hose assembly is required after nonroutine events.

PM-8.3.3 Cleaning Systems

(a) *Clean-in-Place (CIP).* Hose assemblies shall be designed in accordance with SD-3.1. The hose assembly shall be installed to allow for drainability (see SD-4.2).

(b) *Clean-Out-of-Place (COP).* External surfaces of hose assemblies subject to COP shall be compatible with cleaning agents and be nonabsorbent. Hose assemblies shall be designed to allow effective removal of cleaning agents from external surfaces.

PM-8.3.4 Sterilizing Systems. Hose assembly requirements shall be based on the sterilization method utilized. All process contact surfaces should be designed to minimize crevices. When crevices cannot be avoided,

sterilization testing shall be performed to validate sterility within the system boundaries. All hose assemblies and hose assembly process contact surfaces shall be designed to accommodate expansion and contraction during sterilization and cool-down stage.

PM-8.4 Hose Assembly Installation

Hose assemblies shall be installed per SD-4.2 and used in accordance with the supplier's guidelines (e.g., bend radius). Change in hose assembly length due to pressure and temperature cycling and the potential effect on drainability should be considered by the end-user.

PM-8.5 Compliance Requirements

PM-8.5.1 General Requirements. A Certificate of Compliance shall be issued by the hose assembly supplier to certify compliance to this Standard when required by the end-user.

PM-8.5.2 Certificate of Compliance. The Certificate of Compliance shall contain the following information:

- (a) manufacturer's name
- (b) part number
- (c) unique identifier of the hose assembly
- (d) material of construction of process contact items
- (e) compliance to USP <87> (or ISO 10993-5) and USP Class VI <88> (or ISO 10993-6, ISO 10993-10, and ISO 10993-11)
- (f) packaging and storage recommendations (this may be in another document)

Supplier's name and unique identifier shall be marked on either the hose assembly itself or the package containing the hose assembly. The unique identifier shall enable the supplier to identify the raw material and processing conditions used to fabricate the article. Suppliers shall mark the hose assembly itself to avoid potential loss of traceability and to aid in positive identification of hose assemblies.

PM-8.5.3 Test Requirements. Conformance testing is done upon initial qualification of the hose assembly. Testing is intended to show design conformance and is not required on every hose assembly. Testing shall be repeated for significant changes in raw materials or processes used to fabricate hose assemblies.

Part CR Certification

(09)

CR-1 INTRODUCTION

Part CR provides requirements for the certification of organizations providing components in accordance with this Standard. It also provides requirements for the authorization of organizations to mark with the ASME BPE Symbol Stamp.

In Part CR, the term “components” shall be limited to tubing and fittings.

CR-2 GENERAL

ASME BPE certification means that the capability to fulfill requirements of this Standard by the organization has been reviewed and accepted by ASME. The organization is responsible for ensuring that ASME BPE Symbol Stamped products meet the requirements on which the certification is based.

Certificate Holders are organizations that meet all of the requirements of this Standard and have been issued valid Certificates as described in this Part.

A Certificate Holder that is authorized to mark components with an ASME BPE Symbol Stamp is issued a Certificate of Authorization.

Certificate Holders are issued a certificate number to be used to attest to the validity of their certification. Written references indicating that an organization is a Certificate Holder are not valid without reference to the certificate number.

A current list of Certificate Holders is available from ASME upon request.

CR-2.1 ASME Procedures and Policies

ASME has procedures and policies for the issuance, withholding, withdrawing, suspension, and renewal of Certificates, and the conduct of surveys, investigations, and audits. They include provisions for confidentiality, conflict of interest, and due process. Relevant procedures and policies are available from ASME upon request.

CR-2.2 ASME BPE Certificate Holders

The ASME BPE Certificate of Authorization Holder is the provider of components that certifies that each component complies with all applicable requirements of this Standard and is authorized to apply the official ASME BPE Symbol Stamp to covered products. This can include the final manufacturer, assembler, or supplier.

CR-2.3 ASME BPE Certificate Holder's Responsibilities

When certification is granted, each applicant agrees to the requirements specified in CR-2.3.1 through CR-2.3.6.

CR-2.3.1 Use of the Certificate and ASME BPE Markings

(a) The Certificate and the ASME BPE markings are at all times the property of ASME.

(b) The Certificate and the ASME BPE markings shall be used according to the rules and regulations of this Standard.

(c) The Certificate and symbol, as appropriate, shall be promptly returned to ASME, and usage of the ASME BPE markings shall cease upon demand by ASME or when the applicant discontinues the scope of work covered by the Certificate.

(d) The holder of a Certificate shall not permit any other party, including subcontractors, to use the Certificate or ASME BPE markings.

(e) A Certificate of Authorization Holder shall mark their ASME BPE Symbol Stamp (or a facsimile of it) on their components and documentation (as applicable).

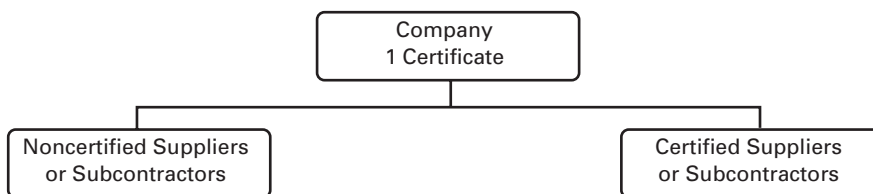
When a Certificate Holder indicates on any written documentation that they are an ASME BPE Certificate Holder, they shall include their valid certificate number on that documentation.

CR-2.3.2 Compliance With This Standard. The ASME BPE Certificate Holder shall ensure that all components and related documentation are properly marked. The Certificate Holder shall retain a valid copy of the current revision of the ASME BPE Standard. Figure CR-1 provides a graphic of several acceptable certification methodologies for companies with one or more facilities.

CR-2.3.3 Subcontracting. The ASME BPE Certificate Holder providing any component with proper ASME BPE markings compliant with the ASME BPE Standard has the responsibility of ensuring that any work provided on or in the component by others complies with all the requirements of this Standard. “Work provided by others” shall mean work provided by other corporate affiliates or work provided by nonaffiliated independent contractors. Figure CR-1 provides a graphic of several acceptable certification methodologies for subcontracting.

Fig. CR-1 Options for Certification of Organizations

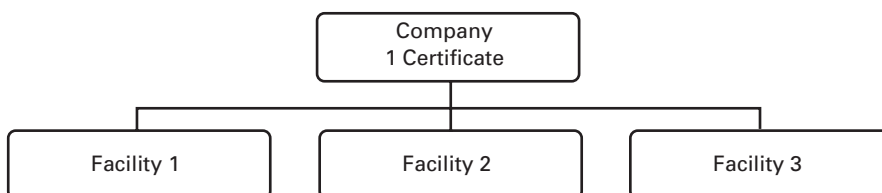
1. One company that purchases raw materials or products from either certified suppliers or subcontractors or noncertified subcontractors (where only the final company is certified).



2. One company with only one facility.



3. One company with numerous facilities — one certificate covering all facilities.



4. One company with numerous facilities — separate certificate for each facility.



CR-2.3.4 Quality Management System. The Applicant shall establish and maintain an effective Quality Management System (QMS) that addresses all of their processes to ensure that all applicable requirements of the current ASME BPE Standard are met. The current Standard shall be adopted and conformed to by the applicant within 6 mo of the date of issuance.

CR-2.3.5 Quality Management System Manual. The ASME BPE Certificate Holder shall maintain a copy of the ASME accepted Quality Management System (QMS) Manual. If the Certificate Holder wishes to change the program to a degree requiring changes to the manual, the Certificate Holder shall submit to and obtain approval of the proposed changes from ASME in writing prior to implementation. In response to the submitted proposed changes ASME may require an audit of the Certificate Holder at its discretion.

The Certificate Holder shall provide a copy of their QMS Manual to ASME as part of the document submission package.

CR-2.3.6 Requirements for Designated Oversight. The use of the ASME BPE Symbol Stamp shall be documented with data reports or certificates of conformance, or both, that are signed by a responsible representative of the Certificate Holder who is authorized to perform the designated oversight activities (i.e., Certified Individual). The data reports or certificates of conformance, or both, shall be retained for a period of not less than 5 yr.

CR-2.3.6.1 Duties of the Certified Individual. The Certified Individual shall

(a) verify that each item, or lot of items, to which the BPE Symbol is to be applied conforms with the applicable requirements of the ASME BPE Standard

(b) sign the appropriate data report or certificate of conformance or both prior to release of control of the item

CR-2.3.6.2 Requirements for the Certified Individual

(a) The Certified Individual shall be an employee of the Certificate Holder and shall be qualified and certified by the Certificate Holder. Qualifications shall include the following as a minimum:

(1) knowledge of the applicable requirements of the ASME BPE Standard for the application of the Symbol Stamp

(2) knowledge of the Certificate Holder's QMS

(3) training commensurate with the scope, complexity, or special nature of the activities to which oversight is to be provided

(b) The Certificate Holder shall maintain a record of the qualifications and training of the Certified Individual.

CR-3 ACQUIRING AN ASME BPE CERTIFICATE

CR-3.1 Application for Certification

Each Applicant shall identify the specific facility(s) covered, and state the scope and limits of any activities for which certification is requested. At its discretion, ASME may limit or extend the scope of certification. Figure CR-1 provides a graphic of several acceptable certification methodologies for companies with one or more facilities.

Application for BPE Certification shall be made to ASME.¹

CR-3.2 Verification of Qualification

An organization requesting certification shall be surveyed by an ASME assigned survey team to ensure that the requirements of this Standard are met. After issuance of the Certificate, follow-up audits will be conducted to ensure continued compliance.

CR-3.2.1 Evaluation of the Quality Management System. The Applicant's QMS Manual and related procedures shall be reviewed for conformance with the requirements of this Standard.

CR-3.2.2 Applicant's Facilities and Equipment. An on site survey shall be conducted to verify compliance with the Applicant's QMS Manual and this Standard.

The Applicant shall have, as appropriate to the scope of work performed by the organization, demonstrated controls of, or procedures for

(a) design

(b) effective material control, including

(1) segregation of noncompatible materials

(2) segregation of nonconforming material

(3) product marking/identification

(4) packaging

(5) finished product storage

(c) manufacturing processes

(d) procedures requiring special environmental conditions

(e) maintenance of equipment and tooling

(f) safe storage of nonactive equipment and tooling

(g) examination/inspection

(h) document control and storage

The Applicant's organization shall have, use, and maintain in good working order, the appropriate equipment, fixtures, machinery, and tooling that will ensure compliance of final product with this Standard.

The Applicant shall provide examples, appropriate to the scope of work to be certified, of product(s) for evaluation by the survey or audit team. Such product(s) may be either work in process or finished product as applicable. Such product(s) must be satisfactorily tested/inspected, and the results of such tests/inspections shall be reviewed and documented by the survey or audit team.

Families of similar products being of the same or similar design and function, as designated in the Applicant's scope of work, shall be audited based on tests and inspections of a representative sample of that family.

CR-3.2.3 Personnel. The Applicant's organization shall include specific personnel designated for each of the following functions as appropriate to the scope of work performed by the organization:

(a) *Design.* As an alternative or as an extension of in-house staff, this function may be performed by outside qualified engineering personnel.

(b) *Purchasing*

(c) *Contract Review*

(d) *Document Control*

(e) *Material Control.* Management of incoming, in process, finished, and discrepant materials must be provided for.

(f) *Manufacturing*

(g) *Quality Control.* Quality control personnel shall be independent of all other departments responsible for production or service processes.

(h) *Examination/Inspection.* An Applicant may perform either examination functions or examination and inspection functions. In any case, the individuals performing the final product assessment must be independent of all other departments responsible for production or service processes. Examination personnel may be responsible to production management, only if an independent inspection department is operating within the facility.

(i) *Maintenance of Equipment*

¹ The applications and related forms and information may be obtained from ASME Conformity Assessment Department, Three Park Avenue, New York, NY 10016-5990 and www.asme.org.



CR-3.3 Issuance of ASME BPE Certificate

(a) The Certificate may be granted or withheld by ASME at its discretion.

(b) Upon satisfactory completion of the survey and survey review, recommendation of the ASME BPE Certification Subcommittee, and payment of the proper administrative fee, ASME shall issue an ASME BPE Certificate of Authorization.

The 5-yr certificate is issued to an Applicant for a specific location(s) as defined in the application and accepted by ASME, and it shall describe the scope and limits of work for which the Applicant is certified.

(c) After initial certification, ASME shall institute a continuing audit program of the Certificate Holder's Quality Management System and compliance with this Standard.

(d) Each Certificate shall be signed by duly authorized ASME personnel.

(e) Should continued certification be sought, 6 mo prior to the date of expiration of any such Certificate, the Applicant shall apply for a renewal of certification.

(f) Renewal is based upon 5-yr intervals with a minimum of two audits during each 5-yr period.

(g) Failure to apply for renewal of the Certificate in time and with appropriate documentation may result in loss of certification until such time as all requirements for re-certification have been met.

(h) ASME reserves the right to withdraw or refuse to renew certification for cause.

CR-3.4 Denial or Loss of ASME BPE Certificate

Upon notification of failure to provide satisfactory evidence of compliance with this Standard and the requirements for certification after a survey, investigation or audit, the Applicant or Certificate Holder shall have the right of appeal. A copy of the appeal procedures shall be provided to the Applicant or Certificate Holder upon notification of unsatisfactory evidence of compliance.

CR-4 REQUIREMENTS SUBJECT TO CHANGE

ASME may change requirements concerning the issuance and use of Certificates and use of ASME BPE markings as it deems appropriate. Such requirements shall become binding on the Certificate Holder upon notification by ASME.

Part MMOC

Metallic Materials of Construction

(09)

MMOC-1 GENERAL

The purpose of this Part is to identify metallic materials of construction that are commonly used in hygienic service. This Part will identify materials, their associated testing standards, mechanical and chemical properties, appropriate surface finish, fabrication guidelines, and other attributes necessary for use in hygienic service. Additionally, this Part will define a method by which other metallic materials of construction, both listed and unlisted, can be submitted and evaluated for inclusion into this Standard.

MMOC-2 ALLOY DESIGNATIONS

MMOC-2.1 General

This Part identifies for use those metallic materials of construction that have demonstrated the ability to meet welding and surface finish criteria as set forth in other parts of this Standard. It is the responsibility of the owner/user to ensure that any metallic materials selected for use from those listed in Tables MMOC-1 through MMOC-3 are appropriate for its intended application. The guidelines and criteria listed in this Part of the standard indicate a general acceptability for use and do not address the specifics of fabrication or requirements of any given service.

MMOC-3 USES OF SPECIFICATIONS

MMOC-3.1 General

The documents listed in MMOC-4.2, MMOC-4.3, MMOC-4.4, MMOC-4.5, and MMOC-4.6 may contain references to codes, standards, or specifications not listed in this Part of this Standard. Such unlisted codes, standards, or specifications are to be used only in the context of the listed documents in which they are referenced. Where documents listed in MMOC-4.2, MMOC-4.3, MMOC-4.4, MMOC-4.5, and MMOC-4.6 contain design rules that are in conflict with this Standard, the design rules of this Standard shall govern.

MMOC-3.2 Listed Specifications

Materials purchased to specifications listed in the appropriate sections of MMOC-4.2, MMOC-4.3, MMOC-4.4, MMOC-4.5, and MMOC-4.6 may be used for applications governed by this Standard. Fittings must be purchased to the requirements of Part DT. Valves must

meet the requirements of Subsection DT-V. Materials used in applications governed by this Standard shall conform to a specification listed in the above paragraphs, except as provided in MMOC-3.3.

MMOC-3.3 Unlisted Specifications

Alloys in specifications not listed in MMOC-4.2, MMOC-4.3, MMOC-4.4, MMOC-4.5, and MMOC-4.6 may be used for applications governed by this Standard provided they conform to a published specification covering composition, physical and mechanical properties, method and process of manufacture, heat treatment and quality control, and otherwise meet the chemical composition requirements of one of the specifications listed in MMOC-4.2, MMOC-4.3, MMOC-4.4, MMOC-4.5, and MMOC-4.6. Alloys not listed in Tables MMOC-1 through MMOC-3 may be used for applications governed by this Standard provided the following requirements are met:

- (a) the applicable requirements of MMOC-9 are met
- (b) the specific written permission of the owner/user is obtained

MMOC-3.4 Unknown Materials

Materials of unknown origin or specification shall not be used in hygienic service.

MMOC-3.5 Reclaimed Materials

Reclaimed pipe/tube and other piping components may be used, provided they are properly identified as conforming to a published specification listed in MMOC-4.2, MMOC-4.3, MMOC-4.4, MMOC-4.5, or MMOC-4.6 or to a published specification not listed in those paragraphs and otherwise meeting the minimum requirements of MMOC-9. Sufficient cleaning and inspection shall be made to determine minimum wall thickness and freedom from imperfections that would be unacceptable in the intended service.

MMOC-3.6 Designation of Alloy and Fluid Service

The user is responsible for designating the specific alloy, from MMOC-2, to be used for each system having a product-contact or cleaning solution-contact surface. The user is also responsible for identifying the appropriate fluid service category for piping or tubing, in accordance with the definitions in the current edition of ASME B31.3, Process Piping Code.


Table MMOC-1 Wrought Stainless Steels: Nominal Compositions = (wt. %)

UNS Number [Note (1)]	EN Designation	C	N	Cr	Ni	Mo	Cu
Common Austenitic Stainless Steels							
S30400	...	0.08	0.11	18.0–20.0	8.00–10.5	...	...
...	1.4301	0.07	0.11	17.5–19.5	8.0–10.5	...	...
S30403	...	0.03	0.11	18.0–20.0	8.00–12.0	...	...
...	1.4307	0.03	0.11	17.5–19.5	8.0–10.5	...	...
S31600	...	0.08	0.11	16.0–18.0	10.0–14.0	2.00–3.00	...
...	1.4401	0.07	0.11	16.5–18.5	10.0–13.0	2.0–2.5	...
S31603	...	0.03	0.11	16.0–18.0	10.0–14.0	2.00–3.00	...
...	1.4404	0.03	0.11	16.5–18.5	10.0–14.0	2.0–2.5	...
...	1.4435	0.03	0.11	17.0–19.0	12.5–15.0	2.5–3.0	...
S31703	...	0.03	0.11	18.0–20.0	11.0–15.0	3.00–4.00	...
...	1.4438	0.03	0.11	17.5–19.5	13.0–17.0	3.0–4.0	...
6%–Mo Super-Austenitic Stainless Steels							
N08367	...	0.03	0.18–0.25	20.0–22.0	23.5–25.5	6.00–7.00	0.75
S31254	...	0.02	0.18–0.22	19.5–20.5	17.5–18.5	6.00–6.50	0.50–1.00
N08926	...	0.02	0.15–0.25	19.0–21.0	24.0–26.0	6.00–7.00	0.50–1.50
...	1.4547	0.02	0.18–0.25	19.5–20.5	17.5–18.5	6.0–7.0	0.5–1.0
Duplex Stainless Steels							
S32205	...	0.03	0.14–0.20	22.0–23.0	4.50–6.50	3.00–3.50	...
...	1.4462	0.03	0.10–0.22	21.0–23.0	4.5–6.5	2.5–3.5	...

GENERAL NOTES:

- (a) Maximum, unless range or minimum is indicated.
- (b) Values listed in this Table are primary elements only and are not complete chemical compositions as listed in specific product type material specifications. Alloy composition is typically at the low end of the ranges indicated above. Refer to appropriate product type material specification for complete material composition requirements.

NOTE:

- (1) For cross-referencing of the UNS numbers listed above to common alloy names, refer to SAE Metals and Alloys in the Unified Numbering System, latest edition.

Table MMOC-2 Wrought Nickel Alloys: Nominal Compositions = (wt. %)

UNS Designation [Note (1)]	EN Number	C	Cr	Ni	Mo	Cu	Other
N06625	...	0.10	20.0–23.0	58.0 min	8.00–10.0	...	Fe: 5.0 max., (Nb + Ta): 3.15–4.15
N10276	...	0.01	14.5–16.5	Balance	15.0–17.0	...	W: 3.0–4.5
...	2.4819	0.01	14.5–16.5	Balance	15.0–17.0	0.5	W: 3.0–4.5 Co 2.5 max., Mn 1.0 max.
N06022	...	0.015	20.0–22.5	Balance	12.5–14.5	...	W: 2.5–3.5
...	2.4602	0.01	20.0–22.5	Balance	12.5–14.5	...	W: 2.5–3.5 Fe 2.0–6.0, Co 2.5 max.

GENERAL NOTES:

- (a) Maximum, unless range or minimum is indicated
- (b) Values listed in this Table are primary elements only and are not complete chemical compositions as listed in specific product type material specifications. Alloy composition is typically at the low end of the ranges indicated above. Refer to appropriate product type material specification for complete material composition requirements.

NOTE:

- (1) For cross-referencing of the UNS numbers listed above to common alloy names, refer to SAE Metals and Alloys in the Unified Numbering System, latest edition.

Table MMOC-3 Stainless Steel and Nickel Alloy Cast Designations

ACI Designation	EN Designation	Designation	Approximate Wrought Equivalent
Cast Austenitic Stainless Steels			
CF-8	1.4308	J92600 (CF8) (CF8A) (CPF8) (CPF8A) MIL-C-24707/3 (CF8)(MIL)	S30400
CF-3	1.4306, 1.4309	J92500 (CF3) (CF3A) (CPF3) (CPF3A)	S30403
CF-8M	1.4408	J92900 (CF8M) (CPF8M) MIL-C-24707/3 (CF-8M)(MIL)	S31600
CF-3M	1.4404, 1.4435	J92800 (CF3M) (CF3MA) (CPF3M)	S31603
CG-3M	...	J92999	S31703
Cast 6%–Mo Super Austenitic Stainless Steels			
CN3MN	...	J94651	N08367
CK3MCuN	1.4529, 1.4547	J93254 (CK3MCuN)	S31254
Cast Duplex Stainless Steels			
CD-3MN	1.4470	J92205 (4A) (CD3MN) (CE3MN) (5A)	S32205
Cast Nickel-Based Alloys			
CW-6MC	2.4856	N26625 (CW6MC) (AMS)	N06625
CW-12MW	...	N30002	N10276
CW-2M	2.4610	N26455 (CW2M)	N10276
CW-6M	...	N30107	N10276
CX-2MW	2.4602	N26022 (CX2MW)	N06022

MMOC-4 REFERENCED SPECIFICATIONS

MMOC-4.1 General

Standards and specifications adopted by reference in this Standard are listed by application category in this Part. It is not considered practical to identify the specific edition of each standard and specification listed in the following listing; therefore, the most current edition is implied.

Material manufactured in accordance with earlier editions of the referenced standards and that in all other respects conforms to this Standard will be considered to be in conformance with this Standard.

MMOC-4.2 Tubing/Piping

Tubing and piping manufactured in accordance with the following specifications are acceptable.

ASTM A 213, Specification for Seamless Ferritic and Austenitic Alloy — Steel Boiler Superheater, and Heat-Exchanger Tubes

ASTM A 249, Specification for Welded Austenitic Steel Boiler, Superheater, Heat-Exchanger, and Condenser Tubes

ASTM A 269, Specification for Seamless and Welded Austenitic Stainless Steel Tubing for General Service

ASTM A 270, Specification for Seamless and Welded Austenitic and Ferritic/Austenitic Stainless Steel Sanitary Tubing

ASTM A 312/312M Specification for Seamless, Welded, and Heavily Cold Worked Austenitic Stainless Steel Pipes

ASTM B 619 Specification for Welded Nickel and Nickel–Cobalt Alloy Pipe — (Valve And Pump Manufacturers)

ASTM B 626, Specification for Welded Nickel And Nickel–Cobalt Alloy Tube — (Valve Manufacturers)

ASTM B 675, Specification for UNS N08367 Welded Pipe

ASTM B 676, Specification for UNS N08367 Welded Tube — (Valve Manufacturers)

ASTM B 690, Specification for Iron–Nickel–Chromium–Molybdenum Alloys (UNS N08366 and UNS N08367) Seamless Pipe and Tube

Publisher: American Society for Testing and Materials (ASTM International), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959

EN 10216-2, Seamless Steel Tubes for Pressure Purposes — Technical Delivery Conditions — Part 2: Non-Alloy and Alloy Steel Tubes With Specified Elevated Temperature Properties

EN 10216-3, Seamless Steel Tubes For Pressure Purposes — Technical Delivery Conditions — Part 3: Alloy Fine Grain Steel Tubes

EN 10216-4, Seamless Steel Tubes for Pressure Purposes — Technical Delivery Conditions — Part 4: Non-Alloy and Alloy Steel Tubes With Specified Low Temperature Properties

- EN 10216-5, Seamless Steel Tubes for Pressure Purposes — Technical Delivery Conditions — Part 5: Stainless Steel Tubes
- EN 10217-1, Welded Steel Tubes for Pressure Purposes — Technical Delivery Conditions — Part 1: Non-Alloy Steel Tubes With Specified Room Temperature Properties
- EN 10217-2, Welded Steel Tubes for Pressure Purposes — Technical Delivery Conditions — Part 2: Electric Welded Non-Alloy and Alloy Steel Tubes With Specified Elevated Temperature Properties
- EN 10217-3, Welded Steel Tubes for Pressure Purposes — Technical Delivery Conditions — Part 3: Alloy Fine Grain Steel Tubes
- EN 10217-4, Welded Steel Tubes for Pressure Purposes — Technical Delivery Conditions — Part 4: Electric Welded Non-Alloy Steel Tubes With Specified Low Temperature Properties
- EN 10217-5, Welded Steel Tubes for Pressure Purposes — Technical Delivery Conditions — Part 5: Submerged Arc Welded Non-Alloy and Alloy Steel Tubes With Specified Elevated Temperature Properties
- EN 10217-6, Welded Steel Tubes for Pressure Purposes — Technical Delivery Conditions — Part 6: Submerged Arc Welded Non-Alloy Steel Tubes With Specified Low Temperature Properties
- EN 10217-7, Welded Steel Tubes for Pressure Purposes — Technical Delivery Conditions — Part 7: Stainless Steel Tubes
- EN 10296-1, Welded Circular Steel Tubes for Mechanical and General Engineering Purposes — Technical Delivery Conditions — Non-Alloy and Alloy Steel Tubes
- EN 10296-2, Welded Circular Steel Tubes for Mechanical and General Engineering Purposes — Technical Delivery Conditions — Part 2: Stainless Steel
- EN 10297-1, Seamless Circular Steel Tubes for Mechanical and General Engineering Purposes — Technical Delivery Conditions — Part 1: Non-Alloy and Alloy Steel Tubes
- EN 10297-2, Seamless Circular Steel Tubes For Mechanical And General Engineering Purposes — Technical Delivery Conditions — Part 2: Stainless Steel
- EN 10312, Welded Stainless Steel Tubes for the Conveyance of Water and Other Aqueous Liquids — Technical Delivery Conditions
- Publisher: European Committee for Standardization (CEN), Avenue Marnix 17, B-1000 Brussels, Belgium

MMOC-4.3 Castings

Castings manufactured in accordance with the following specifications are acceptable.

ASTM A 351/A 351M, Specification for Castings, Austenitic, for Pressure-Containing Parts

ASTM A 743/A 743M, Specification for Castings, Iron-Chromium, Iron-Chromium-Nickel, Corrosion Resistant, for General Application

ASTM A 890/A 890M, Specification for Castings, Iron-Chromium-Nickel-Molybdenum Corrosion-Resistant, Duplex (Austenitic/Ferritic) for General Application

Publisher: American Society for Testing and Materials (ASTM International), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959

EN 10213-1, Technical Delivery Conditions for Steel Castings for Pressure Purposes — General

EN 10213-2, Technical Delivery Conditions for Steel Castings for Pressure Purposes — Steel Grades for Use at Room Temperature and at Elevated Temperatures

EN 10213-3, Technical Delivery Conditions for Steel Castings for Pressure Purposes — Steels for Use at Low Temperatures

EN 10213-4, Technical Delivery Conditions for Steel Castings for Pressure Purposes — Austenitic and Austenitic-Ferritic Steel Grades

EN 10283, Corrosion Resistant Steel Castings

Publisher: European Committee for Standardization (CEN), Avenue Marnix 17, B-1000 Brussels, Belgium

MMOC-4.4 Forgings

Forgings manufactured in accordance with the following specifications are acceptable.

ASTM A 182/A 182M, Specification for Forged or Rolled Alloy and Stainless Steel Pipe Flanges, Forged Fittings, and Valves and Parts for High-Temperature Service

ASTM B 462, Specification for Forged or Rolled UNS N06030, UNS N06022, UNS N06035, UNS N06200, UNS N06059, UNS N06686, UNS N08020, UNS N08024, UNS N08026, UNS N08367, UNS N10276, UNS N10665, UNS N10675, UNS N10629, UNS N08031, UNS N06045, UNS N06025, and UNS R20033 Alloy Pipe Flanges, Forged Fittings, and Valves and Parts for Corrosive High-Temperature Service

ASTM B 564, Specification for Nickel Alloy Forgings

Publisher: American Society for Testing and Materials (ASTM International), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959

EN 10222-5, Steel Forgings for Pressure Purposes — Part 5: Martensitic, Austenitic, and Austenitic-Ferritic Stainless Steels

EN 10250-3, Open Steel Die Forgings for General Engineering Purposes — Alloy Special Steels

EN 10250-4, Open Die Steel Forgings for General Engineering Purposes — Part 4: Stainless Steels

Publisher: European Committee for Standardization (CEN), Avenue Marnix 17, B-1000 Brussels, Belgium

MMOC-4.5 Plate, Sheet, and Strip

Plate, sheet, and strip manufactured in accordance with the following specifications are acceptable.

ASTM A 240/A 240M, Specification for Chromium and Chromium-Nickel Stainless Steel Plate, Sheet, and Strip for Pressure Vessels and for General Applications

ASTM A 666, Specification for Annealed or Cold-Worked Austenitic Stainless Steel Sheet, Strip, Plate, and Flat Bar

ASTM B 443, Specification for Nickel-Chromium-Molybdenum-Columbium Alloy (UNS N06625) and Nickel-Chromium-Molybdenum-Silicon Alloy (UNS N06219) Plate, Sheet, and Strip

ASTM B 575, Specification for Low-Carbon Nickel-Chromium-Molybdenum, Low-Carbon Nickel-Chromium-Molybdenum-Copper, Low-Carbon Nickel-Chromium-Molybdenum-Tantalum, and Low-Carbon Nickel-Chromium-Molybdenum-Tungsten Alloy Plate, Sheet, and Strip

ASTM B 688, Specification for Chromium-Nickel-Molybdenum-Iron (UNS N08366 and UNS N08367) Plate, Sheet, and Strip

Publisher: American Society for Testing and Materials (ASTM International), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959

EN 10028-1, Flat Products Made of Steels for Pressure Purposes — Part 1 — General Requirements

EN 10028-2, Flat Products Made of Steels for Pressure Purposes — Part 2: Non-Alloy and Alloy Steels With Specified Elevated Temperature Properties

EN 10028-3, Specification for Flat Products Made of Steels for Pressure Purposes — Weldable Fine Grain Steels, Normalized

EN 10028-4, Flat Products Made of Steels for Pressure Purposes — Part 4: Nickel Alloy Steels With Specified Low Temperature Properties

EN 10028-5, Flat Products Made of Steels for Pressure Purposes — Part 5: Weldable Fine Grain Steels, Thermomechanically Rolled

EN 10028-6, Flat Products Made of Steels For Pressure Purposes — Part 6: Weldable Fine Grain Steels, Quenched and Tempered

EN 10028-7, Flat Products Made of Steels for Pressure Purposes — Part 7: Stainless Steels

EN 10088-2, Stainless Steels — Part 2: Technical Delivery Conditions for Sheet/Plate and Strip of Corrosion Resisting Steels for General Purposes

EN 10088-4, Stainless Steels — Part 4: Technical Delivery Conditions for Sheet/Plate and Strip of Corrosion Resisting Steels for Construction Purposes

Publisher: European Committee for Standardization (CEN), Avenue Marnix 17, B-1000 Brussels, Belgium

MMOC-4.6 Hollow Products, Rod, and Bar Stock

Hollow products, rod, and bar stock manufactured in accordance with the following specifications are acceptable.

ASTM A 479/A 479M, Specification for Stainless Steel Bars and Shapes for Use in Boilers and Other Pressure Vessels

ASTM B 574, Specification for Low-Carbon Nickel-Chromium-Molybdenum, Low-Carbon Nickel-Molybdenum-Chromium-Tantalum, Low-Carbon Nickel-Chromium-Molybdenum-Copper, and Low-Carbon Nickel-Chromium-Molybdenum-Tungsten Alloy Rod

ASTM B 691, Specification for Iron-Nickel-Chromium-Molybdenum Alloys (UNS N08366 and UNS N08367) Rod, Bar, and Wire

Publisher: American Society for Testing and Materials (ASTM International), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959

EN 10263-1, Steel Rod, Bars and Wire for Cold Heading and Cold Extrusion — Part 1: General Technical Delivery Conditions

EN 10263-2, Steel Rod, Bars and Wire for Cold Heading and Cold Extrusion — Part 2: Technical Delivery Conditions for Steels Not Intended for Heat Treatment After Cold Working

EN 10263-3, Steel Rod, Bars and Wire for Cold Heading and Cold Extrusion — Part 3: Technical Delivery Conditions for Case Hardening Steels

EN 10263-4, Steel Rod, Bars and Wire for Cold Heading and Cold Extrusion — Part 4: Technical Delivery Conditions for Steels for Quenching and Tempering

EN 10263-5, Steel Rod, Bars and Wire for Cold Heading and Cold Extrusion — Part 5: Technical Delivery Conditions for Stainless Steels

EN 10272, Stainless Steel Bars for Pressure Purposes

EN 10088-3, Stainless Steels — Part 3: Technical Delivery Conditions for Semi-Finished Products, Bars, Rods, Wire, Sections and Bright Products of Corrosion Resisting Steels for General Purposes

EN 10088-5, Stainless Steels — Part 5: Technical Delivery Conditions for Bars, Rods, Wire, Sections and Bright Products of Corrosion Resisting Steels for Construction Purposes

For austenitic stainless steels, hollow products and bar stock are acceptable for nozzles and clamping mechanisms.

Publisher: European Committee for Standardization (CEN), Avenue Marnix 17, B-1000 Brussels, Belgium

MMOC-5 FABRICATION**MMOC-5.1 General**

This part provides fabrication requirements and guidelines for metallic components, equipment, and

distribution systems fabricated from the stainless steel grades and nickel alloys listed in Tables MMOC-1 through MMOC-3. Fabrication with metallic materials other than those listed in this Part is permitted with the owner's written approval (see MMOC-3.3). Such fabrication shall be performed in accordance with the material manufacturer's recommendations.

MMOC-5.1.1 Weld Ends. Where UNS S31603 (316L) is specified, the material of the automatic weld end shall conform to the requirements for chemical composition as prescribed in Table MMOC-4.

For nonautomatic weld ends, the chemical composition shall meet the requirements of the applicable material specification.

MMOC-5.1.2 Fitting and Component Fabrication. For standard fittings and process components employing welds, the requirements of MMOC-5.1.1 do not apply to welds made in the construction of the fitting or component, so long as the following conditions are met:

(a) The fabricator has a quality plan in place to verify full penetration of all such component welds.

(b) The chemical composition of any automatic weld end left as a final feature on the fitting or component shall comply with the requirements of Table MMOC-4.

(c) Process components or tube with a sulfur content either below the lower limit or above the upper limit of Table MMOC-4 can be used in a welded connection, provided that all conditions of MJ-2.1 are met.

(d) Welds may be finished or left in the as-welded condition.

(e) All welds must meet the requirements of MJ-2.1(d) and MJ-6.

If a filler metal or consumable insert is used during fitting and component fabrication, it must be in accordance with the required filler metals or consumable inserts listed in Table MMOC-5 or Table MMOC-6. The fabricator must also supply proof of filler metal or consumable insert compliance as part of the documentation.

MMOC-5.1.3 Castings. When cast alloys discussed in this section solidify, microsegregation of chromium and molybdenum occurs. Segregation reduces corrosion resistance and is corrected in castings by a full solution anneal as specified by the material specification or as recommended by the material manufacturer. All cast materials shall be supplied in the solution annealed condition, and the solution anneal procedure shall meet the time and temperature requirements of the product specification. Any weld repair by the casting manufacturer shall meet the requirements of the specification or shall be as specified by the owner.

MMOC-5.1.4 Ferrite. If specific ferrite levels in 316 and other common austenitic stainless steel equipment are deemed necessary to maintain certain properties, the owner/user shall specify required ferrite ranges separately for base metal, for welds in the solution annealed

Table MMOC-4 Chemical Composition for 316L Automatic Weld Ends

Element	Wt. %
Carbon, max.	0.035
Chromium	16.00–18.00
Manganese, max.	2.00
Molybdenum	2.00–3.00
Nickel	10.00–15.00
Phosphorus, max.	0.045
Silicon, max.	1.00
Sulfur	0.005–0.017

condition, and for welds left in the as-welded condition. As a general rule material with high ratios of Ni to Cr show lower ferrite levels in the base metal and subsequent to welding. See Table MMOC-7 for predicted ferrite number ranges for various 316 stainless steel product forms. These are not acceptance criteria. The listed ferrite numbers refer to as-solidified 316 stainless steels and therefore indicate predicted ferrite levels of the respective autogenous welds, welds with filler metal, or castings. Additional information regarding ferrite can be found in Nonmandatory Appendix G.

MMOC-5.2 Filler Metals and Consumable Inserts

This section applies to metallic materials of construction listed in Tables MMOC-1 through MMOC-3 that have special requirements to achieve a sound weld while maintaining an acceptable level of corrosion resistance. These requirements are in addition to the requirements specified in Part MJ. When filler metals or inserts are required, only those listed in Table MMOC-5 or Table MMOC-6, respectively, shall be used.

MMOC-5.2.1 Super-Austenitic Stainless Steels. To compensate for segregation, super-austenitic stainless steels listed in Table MMOC-5 shall be welded using either the filler metals listed in Table MMOC-5 or the consumable inserts listed in Table MMOC-6. As an alternative, valves or other fabricated components employing welds may be welded autogenously as long as the component is postweld solution heat treated in accordance with the supplier's recommendations to minimize segregation.

The super-austenitic stainless steels in Tables MMOC-5 and MMOC-6 are prone to the precipitation of undesirable secondary intermetallic phases such as sigma and chi. This precipitation typically occurs in the range of 1,000°F (540°C) to 1,900°F (1,040°C). This is a concern during welding and other thermomechanical processes such as solution annealing, and it is desirable to keep exposure time within this temperature range to a minimum.

End-users are cautioned that any service temperature, heat treatment, or welding procedure that exposes this material to these temperatures should be minimized. The material manufacturer should be consulted for specific instructions regarding heat treatment.

Table MMOC-5 Filler Metals

Base Metal			Filler Metal [Note (1)]			
UNS Designations	SMAW		UNS Designations	GTAW/GMAW/SAW/PAW		
	AWS Classification	SFA Specification		AWS Classification	SFA Specification	UNS Designations
Super-Austenitic Stainless Steels						
S31254	ENiCrMo-3	5.11	W86112	ERNiCrMo-3	5.14	N06625
N08367	ENiCrMo-4		W80276	ERNiCrMo-4		N10276
N08926	ENiCrMo-10		W86022	ERNiCrMo-10		N06022
Duplex Stainless Steels [Note (2)]						
S32205	E2209	5.4	W39209	ER2209	5.9	S39209
	E2553		W39553			
	E2593		W39593			
	E2594		W39594			
	E2595		W39595			
Nickel Alloys						
N10276	ENiCrMo-4	5.11	W80276	ERNiCrMo-4	5.14	N10276
N06022	ENiCrMo-10	5.11	W86022	ERNiCrMo-10	5.14	N06022
N06625	ENiCrMo-3	5.11	W86112	ERNiCrMo-3	5.14	N06625

NOTES:

- (1) Any filler metal listed under any filler metal column for a given alloy category may be used to weld any base metal in that category.
- (2) Any super duplex stainless steel filler metal can be used to weld any duplex stainless steel.

Table MMOC-6 Consumable Inserts for Super-Austenitic and Duplex Stainless Steels

Base Metal Alloy	Insert Alloy [Note (1)]
Super-Austenitic Stainless Steels	
UNS N08367	UNS N06625 UNS N06022 UNS N10276
UNS N08926	
UNS S31254	
CN3MN	
CK-3MCuN	
Duplex Stainless Steels	
UNS S32205	UNS N06022
CD3MN	UNS N10276

NOTE:

- (1) See MMOC-4 for listed rod, bar, or plate specifications from which these consumable inserts may be manufactured.

MMOC-5.2.2 Consumable Inserts for Orbital Welding of Listed Alloys. Table MMOC-6 lists the most common alloys from which consumable inserts are machined for use in welding specific super-austenitic and duplex stainless steels. Other nickel–chromium–molybdenum inserts may be used as long as the corrosion resistance of the final weldment meets or exceeds that of the base metal.

MMOC-5.2.3 Duplex Stainless Steels. The corrosion resistance and mechanical properties of duplex stainless steels are based on having roughly equal amounts of ferrite and austenite in the microstructure at room temperature. Welding of duplex stainless steels generally

results in an increase in the amount of ferrite in the microstructure and as a result, appropriate welding procedures should be selected to offset this.

Filler metals or consumable inserts are not required to weld duplex stainless steels, provided the weldment is given a postweld solution anneal in accordance with the manufacturer's recommendations. The balance of austenite and ferrite in the weld metal shall be maintained so that there is no less than 30% of the lesser phase.

The listed duplex stainless steel, UNS S32205, may be prone to the precipitation of undesirable secondary intermetallic phases such as sigma and chi. This precipitation occurs continually in the range of 1,200°F (650°C) to 1,830°F (1 000°C). End-users are cautioned that any service temperature, heat treatment, or welding procedure that exposes this material to these temperatures should be minimized. The material manufacturer should be consulted for specific instructions regarding heat treatment.

Any nominal thickness of 0.109 in. (2.77 mm) or greater shall be welded using a welding procedure qualified in accordance with MJ-8 and the additional requirements of ASTM A 923 Methods A and/or C. Any nominal thickness less than 0.109 in. (2.77 mm) shall be welded using a welding procedure qualified in accordance with MJ-8 and the additional requirements of ASTM A 923 Method A.

MMOC-5.2.4 Nickel Alloys. The nickel-based alloys listed in Table MMOC-5 may be welded either with or

**Table MMOC-7 Predicted Ferrite Number (FN)
Ranges for Various 316 Product Forms and Welds**

Product Form	Expected FN
Wrought product forms with sulfur levels less than 0.005%	FN = 0.5 to 4
Wrought product forms with a sulfur range of 0.005% to 0.017%	FN = 1.0 to 6
GMAW/GTAW using ER316L [Note (1)]	FN = 4 to 12 [Note (2)]
SMAW using ER316L [Notes (3), (4)]	FN = 4 to 10 [Note (5)]
CF-8M and CF-3M Castings	FN = 5 to 15

GENERAL NOTE: FN ranges determined from WRC-1992 Constitution Diagram for Stainless Steel Weld Metals¹

NOTES:

- (1) SFA 5.9/5.9M, Specification for Bare Stainless Steel Welding Electrodes and Rods
- (2) Nitrogen pickup or weld metal dilution could result in a 3 to 4 FN loss in the as deposited weld
- (3) SFA 5.4/5.4M, Specification for Stainless Steel Electrodes for Shielded Metal Arc Welding
- (4) Electrodes with a restricted FN usually require a special order, with the exception of 2 FN maximum product for cryogenic service temperatures.
- (5) FN in the as-deposited weld is influenced by welding technique and is lowered by nitrogen pickup or weld metal dilution.

without filler metal. Postweld solution annealing is not required for these alloys.

MMOC-5.3 Field Bending of Tubing

Field bending of tubing is permitted for diameters up to and including $\frac{1}{2}$ in. (12.7 mm). Post-bending heat treatment is not required. Bending of tubing of any diameter requires prior written permission from the owner/user. Consult the material manufacturer for recommended minimum bend radii.

MMOC-6 MECHANICAL PROPERTIES

MMOC-6.1 General

The specific service environment for which the alloys in Tables MMOC-1 through MMOC-3 may be used is not within the scope of this Standard. The possibility of material deterioration in service should be considered by the user. Carbide phase degradation of corrosion resistance, susceptibility to intergranular corrosion of austenitic materials, or grain boundary attack of nickel-based alloys are among those items requiring attention.

¹ D. J. Kotecki and T. A. Siewert, *WRC-1992 constitution diagram for stainless steel weld metals: a modification of the WRC-1988 diagram*, Welding Journal 71(5), pp. 171-s, 1992.

MMOC-6.2 Tubing/Piping

All tube or pipe used for product contact surfaces, cleaning solution contact surfaces, and nonproduct contact surfaces shall meet the mechanical property requirements of the specification to which they are manufactured.

MMOC-6.3 Fittings and Welded Components

Refer to DT-2 for strength requirements for fittings and DT-V-2 for pressure rating requirements for valves.

MTRs for fittings are not required to list mechanical properties; however, if they do, they must comply with the specifications for the raw materials from which the fittings were fabricated. It should be understood that the mechanical properties for worked products, such as fittings, can be expected to deviate from that of the original heat, or from the original MTR of the material.

MMOC-6.4 Toughness

Some of the materials listed in Tables MMOC-1 through MMOC-3 undergo a decrease in toughness when used at low temperatures, to the extent that other applicable Codes may require impact tests for applications even at temperatures higher than +20°F (−6.67°C). It is the responsibility of the owner/user to ensure that such testing is performed and that the requirements of all applicable codes are met.

MMOC-6.5 Testing

Refer to DT-7 for the testing requirements for fittings and DT-V-7 for the testing requirements for valves.

MMOC-7 CORROSION RESISTANCE REQUIREMENTS

MMOC-7.1 General

Resistance to corrosion is an essential characteristic of the materials used to fabricate the systems governed by this Standard. Corrosion testing is recommended whenever specific production performance characteristics must be determined. The owner/user shall have the final responsibility for proper material selection.

MMOC-7.2 Corrosion Testing

Corrosion testing may be performed for the following reasons:

- (a) to compare a number of alloys in a specific standard environment, or
- (b) to determine the compatibility of an alloy in a specific user defined environment

Once a particular alloy has been selected for an application, more extensive testing may be appropriate. This testing may involve the evaluation of any one of a number of process variables on material performance. These variables include, but may not be limited to, upset temperature conditions, varying concentrations of the corrosive agent or condition, cleaning chemical type and

concentration, various surface finishes, welding process, and filler metal alloy. It may be appropriate to use electrochemical test methods or a standard immersion test method to evaluate the effect of the various parameters. Standard ASTM corrosion tests commonly used are discussed in Nonmandatory Appendix F, Corrosion Testing.

MMOC-8 SURFACE FINISH REQUIREMENTS

MMOC-8.1 General

Alloys used for product contact surfaces that are required to be mechanically polished or electropolished must demonstrate the ability to achieve the necessary surface finish by meeting the applicable requirements in Part SF of this Standard. They must also demonstrate the ability to produce the surface characteristics generally agreed to be associated with adequately electropolished and/or passivated surfaces. When required by the owner/user, the electropolishing and/or passivation contractor may be required to qualify his procedures in accordance with the appropriate appendices as referenced in Part SF.

Material manufacturers or suppliers of components whose surfaces have been electropolished and/or passivated shall supply a "Certificate of Compliance for Passivation" and/or "Electropolishing" stating that standard industry practices, such as ASTM A 967 or ASTM B 912, as applicable, have been used. If required by the owner/user, the manufacturer or supplier may be required to demonstrate the effectiveness of their procedure by a method mutually agreed upon.

The user is cautioned that some alloys other than UNS S31603 may not meet the visual inspection requirements for product contact surfaces listed in Table SF-1 for mechanically polished surfaces and Table SF-2 for electropolished surfaces.

In such cases, visual inspection requirements, particularly concerning inclusions and pits, should be mutually agreed upon by both the user and supplier prior to ordering the material. Visual comparison charts or samples may be used to define acceptable and nonacceptable product contact surfaces.

Surface roughness values shall be in accordance with Part SF of this Standard.

MMOC-9 UNLISTED ALLOYS

MMOC-9.1 General

Unlisted alloys may be submitted for consideration for inclusion into Table MMOC-1, Table MMOC-2, or Table MMOC-3 of this Part of the Standard when the following information is submitted to and found acceptable by the MMOC Subcommittee:

(a) an industry-recognized specification or standard including tensile strength properties.

(b) certification that fittings and fabricated components meet the pressure ratings of Part DT, Table DT-2 and valves meet the pressure rating requirements of DT-V-2.

(c) data showing that the corrosion resistance of the alloy, as measured by the pitting resistance equivalent (PRE) number using the applicable equation on a typical composition, meets or exceeds that of 316L stainless steel (UNS S31603). PRE number listings can be found in Nonmandatory Appendix F, Corrosion Testing.

(d) evidence that the material can be mechanically polished, electropolished, and/or passivated to meet the applicable requirements of Part SF.

(e) a recommended welding process(es) and filler metal(s), evidence showing that the combination of base metal, filler metal(s), and recommended welding process(es) meets the requirements of MMOC-6, MMOC-7, MMOC-8, and MJ-6. Special restrictions or instructions shall be noted.



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NONMANDATORY APPENDIX A

COMMENTARY: SLAG

A-1 GENERAL

- (a) Inert-gas welding processes do not introduce slag.
- (b) Stainless steels, especially type 316L, typically produce a small, round, black spot at the termination of the weld bead, on the O.D., I.D., or both. This spot is generally unavoidable and has been found to be acceptable in most process applications.
- (c) Slag in or on welds may be the result of faulty weld preparation, such as contamination, poor cleaning, or faulty tacking procedures.

(d) Slag may also result from melting base metals of certain compositions that include elements not normally reported on Material Test Reports. These elements include, but are not limited to, aluminum, calcium, cerium, and zirconium.

(e) The owner/user and contractor should investigate the origin of any slag found during weld examination, determine its acceptability, and agree on any corrective action.

(f) The inert-gas welding processes themselves do not introduce a slag because no fluxing materials are used (see GR-10 and AWS 3.0).



NONMANDATORY APPENDIX B MATERIAL EXAMINATION LOG AND WELD LOG

(See Forms beginning on next page.)

[illegible]

GENERAL NOTES:

- (a) "A" or Acc. indicates a conformance with the applicable sections of Part DT.
(b) "R" or Rej. indicates a nonconformance with the applicable sections of Part DT.

(1) Per applicable sections of Part SF.

**Form MEL-2 Material Examination Log****Item**

Page: ____ of ____

Customer company name, _____

address, contact names, _____

and number: _____

Project Information: _____

Material Specification: _____

P.O. Number: _____

Packing List #: _____

Lot #: _____

Examiner's Information: _____

Manufacturer: _____

Material/Alloy Type: _____

Material Description: _____

Heat Number/Heat Code: _____

Wall Thickness: _____

O.D. Tolerance: _____

Surface RA: _____

Visual Examination: _____

MTR Verified: _____

Quantity Received: _____

Qty. Accepted: _____

Qty. Rejected: _____

Date Inspected: _____

Comments: _____

**Instructions for Completing the Material Examination Log**

Item	Typical Entry
Top Right Section (Suggested)	
	Customer company name, address, contact names, and number
Top Center Section (Suggested)	
Project Information:	Specifications, Codes and Standards
Material Specification:	ASTM specification, customer specification
Top Left Section (Suggested)	
Page: ____ of ____:	Sequential identifying number and total pages in package
P.O. Number:	Purchase order number which the material was ordered under
Packing List #:	Packing list identifying number
Lot #:	Lot number issued from the Material Receiving Log
Examiner's Information:	The name of the examiner, company of examiner, etc. ...
Bottom Section (Required)	
Manufacturer:	Name of manufacturer
Material/Alloy Type:	Type or grade of material (316L, AL6XN, etc.)
Material Description:	Size, material product form (tubing, 90,45, TEE, ferrule, valve, etc.)
Heat Number/Heat Code:	Record heat number(s) for the sample
Wall Thickness:	Record Accept or Reject after physical examination of the lot. (if required)
O.D. Tolerance:	Record Accept or Reject after physical examination of the lot. (if required)
Surface RA:	Record Accept or Reject after physical examination of the lot. (if required)
Visual Examination:	Record Accept or Reject after physical examination
DT-3 Compliant:	Record Accept or Reject after markings verification
MTR Verified:	Record Accept or Reject for MTR compliance with specifications
Quantity Received:	Total quantity of material received in the shipment or lot
Quantity Examined:	Total quantity of material physically inspected per DT-9 (if required)
Qty. Accepted:	Record quantity accepted
Qty. Rejected:	Record quantity rejected
Examiner's Initials:	Initials of examiner who performed the work
Date Inspected:	Date the examination(s) were performed for the samples listed
NCR Number:	The NCR report number if needed
Comments:	Record any notes for inspection area(s) requiring more description



Form WL-1 Weld Log (Weld and Examination/Inspection Log)

GENERAL NOTES:

- NOTES:

- (1) VO = Visual O.D. only, VI = Visual O.D. and BoreScope I.D.
- (2) Blind welds shall be indicated as "Blind" in the Comments section. Manual welds shall be indicated as "Manual" in the Comments section. Videotaped welds shall be indicated as "Video" in the Comments section. Any other requirements can be indicated in the Comments section.

NONMANDATORY APPENDIX C

SLOPE MEASUREMENT

C-1 GENERAL

(a) Slope measurement shall be made with a digital level or a digital protractor. The instrument used should be capable of displaying slope in degrees, percent, and in./ft (mm/m).

(b) Refer to the owner's manual for the proper procedure to perform the self-calibration routine. This must be performed immediately prior to use.

(c) Slope measurements shall only be made under the following conditions:

- (1) before insulation has been installed
- (2) after hangers/pipe supports have been installed, adjusted, and fixed in-place
- (3) before the introduction of any fluids, such as liquids or process gases (pure oxygen, nitrogen, steam, etc.)
- (4) when the system is at ambient pressure and temperature

(d) For piping or tubing systems, slope measurements shall be made at the following locations:

- (1) between hangers/pipe supports
- (2) at each change in direction
- (3) at any other location deemed necessary by the inspector, such as between welds or any apparent change in slope
- (4) Slope should be measured only on runs that are approximately horizontal.
- (e) Slope measurements may be made on either the top or bottom of the tubing/piping.
- (f) For slope measurements made on skids or modules, ensure that the base is level in all directions. Then, make sure that all slope measurements are made relative to the base.
- (g) Slope shall be verified after the fabricator has completed, or corrected, the piping installation, and set the slope.

(09)

NONMANDATORY APPENDIX D

ROUGE AND STAINLESS STEEL

D-1 GENERAL

Rouge is a naturally occurring phenomenon in existing stainless steel high purity process systems (including water or pure steam). The degree to which it forms depends upon

(a) the stainless steel material used for each component within the system

(b) how the system was fabricated (e.g., welding, surface finish, passivation treatment)

(c) what process service conditions the system is exposed to (e.g., water purity, process chemicals, temperatures, pressures, mechanical stresses, flow velocities, and oxygen exposure)

(d) how the system is maintained

The presence of rouge in a system needs to be evaluated against its potential to affect the product process and/or long-term operation of the system.

This Appendix provides the methods to measure rouge in a system in both the process solution and on the actual product contact surface. It also suggests various fabrication and operation practices to minimize rouge formation, and methods/techniques for its remediation.

For the definition of rouge and its classification into Classes I, II, and III, see Section GR-10 of this Standard.

D-2 CONSIDERATIONS FOR REDUCING ROUGE FORMATION

Tables D-1 and D-2 provide guidance on different variables and how they may contribute to the presence of rouge in a high purity system. They are listed in the following categories:

(a) *Category 1: Little Influence on the Formation of Rouge.* There are theories that suggest other factors that may have a role in the formation of rouge. These variables are not listed in Tables D-1 and D-2.

(b) *Category 2: Moderate Influence on the Formation of Rouge.* There is industry data supporting these variables, and they should be considered.

(c) *Category 3: Strong Influence on the Formation of Rouge.* There is well established industry data supporting these variables, and they should be considered.

D-2.1 System Fabrication

See Table D-1 for a discussion of fabrication variables that affect the amount of rouge formation.

D-2.2 System Operation

See Table D-2 for a discussion of operation variables that affect the amount of rouge formation.

D-3 EVALUATION METHODS TO MEASURE ROUGE

Rouge can be measured by either its presence in the process fluid, and/or its presence on the product/solution contact surface.

D-3.1 Process Fluid Analyses

Fluid analyses provide a means of identifying the mobile constituents within a subject process system. They represent the current quality status of the media, and the result of rouging.

Table D-3 provides description, pros, and cons of various tests for the identification of mobile constituents.

D-3.2 Solid Surface Analyses

Surface analyses provide information on the nature, microstructure, and composition of surface layers. They may represent the future status of the media, and the possible threat of rouging to the water quality.

Table D-4 provides description, pros, and cons of various tests for the identification of surface layers' composition.

D-4 METHODS TO REMEDIATE THE PRESENCE OF ROUGE IN A SYSTEM

Remediation (derouging) processes are designed to remove iron oxide and other surface constituents of rouge while minimizing damage to the surface finish. Rouge occurs on the surface, from corrosion or precipitates onto the surface after migrating from other locations. These conditions are easily categorized by using the standard Classes I, II, and III rouge. The following sections describe these remediation processes and the conditions under which they are performed.

D-4.1 Class I Rouge Remediation

Class I rouges are weakly attached to the surface and relatively easily removed and dissolved. This rouge is generally hematite or red ferric iron oxide with low levels of other oxides or carbon content. Phosphoric acid is useful to remove light accumulations and can be

blended with other acids and compounds including citric, nitric, formic, or other organic acids and surfactants to assist in its derouging effectiveness. Citric acid based chemistries with additional organic acids are effective at rouge removal. The use of sodium hydrosulfite is also fast and effective at removal of Class I rouge.

These chemistries are processed at elevated temperatures from 104°F (40°C) to 176°F (80°C) for between 2 hr and 12 hr. The process time and temperatures may depend upon severity of rouge accumulation, system component's material of construction, and concentration of chemistries. The concentration of each chemistry is based upon proprietary testing and process design criteria.

Electrochemical cleaning is an alternative method of rouge removal that uses phosphoric acid and applied direct current where the product contact surface is anodic. As a cathode is moved over the product contact surface to be cleaned, rouge is readily removed. This process is very effective in removing all three classes of rouge but is limited to accessible parts of a system and is primarily performed on the product contact surfaces in vessels.

For specific Class I rouge remediation processes, refer to Table D-5.

D-4.2 Class II Rouge Remediation

Class II rouge is removed with chemistries that are very similar to the above listed processes with the addition of oxalic acid, which improves the effectiveness in removal of this type of rouge. This rouge consists mostly of hematite or ferric iron oxide with some amount of chromium and nickel oxides as well as small carbon content. All of the above chemistries remove the rouge without damage to the surface finish with the exception of oxalic acid, which may etch the surface depending on conditions and concentration processed. Class II rouges are more difficult to remove than Class I, and may require additional time, even though these processes are often run at slightly higher temperatures and increased concentrations.

For specific Class II rouge remediation processes, refer to Table D-5.

D-4.3 Class III Rouge Remediation

Class III rouge is much more difficult to remove compared to Class I and Class II rouge, both due to its chemical composition difference and its structural difference. These high temperature deposits form magnetite iron oxide with some substitution of chromium, nickel, or silica in the compound structure. Significant amounts of carbon are generally present in these deposits due to reduction of organics present in the water, which

sometimes produces the "smut" or black film that may form during derouging. The chemistries used to remove this rouge are very aggressive and will affect the surface finish to some degree. Phosphoric acid based derouging systems are generally only effective on very light accumulation of the rouge. The strong organic acid blends with formic and oxalic acid are effective on some of these high temperature rouges, and being less aggressive, produce much less potential for etching of the surface finish.

The citric and nitric blends with hydrofluoric acid or ammonium bifluoride will remove these Class III rouges more quickly, but will definitely etch the surface wherever the base metal is subjected to the derouging fluid. The amount of etching or increase in surface finish roughness is dependent upon process conditions, chemical concentration, and variability of the rouge thickness and level of surface finish roughness initially. The condition of use for these processes is highly variable both in temperature and time required to effectively remove all of the rouge and leave the surface prepared for cleaning and passivation. The less aggressive chemistries are used at higher temperatures [140°F (60°C) to 176°F (80°C)] and require longer contact time (8 hr to 48 plus hours); the nitric acid based fluoride solutions are often used at lower temperatures [ambient to 104°F (40°C)], while the citric acid based fluoride solutions are used at the higher temperatures and shorter contact times (2 hr to 24 hr).

For specific Class III rouge remediation processes, refer to Table D-5.

D-4.4 Remediation Variables

The times and temperatures given above are in direct relation to the percent by weight of the base reactant(s). A change in a formulation will change those corresponding requirements. Different application methods include fluid circulation, gelled applications for welds or surfaces, and spraying methods for vessels and equipment. Rinsing of the surface after processing as well as proper waste disposal planning is critical to the derouging process. The waste fluids generated by these processes can be classified as hazardous due to chemical constituents or heavy metals content.

Rouge can effectively be removed from product contact surfaces to reduce the potential for oxide particulate generation into the process fluids. These derouging processes are required prior to proper cleaning and passivation of the stainless steel surface for restoration of the passive layer after corrosion. Analytical testing of utility fluids can be useful in identifying the level of particulate generation and levels of metal oxides contained in these fluids as corrosion degrades the surface.


Table D-1 Considerations That Affect the Amount of Rouge Formation During the Fabrication of a System

Variables	Considerations
3-Strong Influence on the Formation of Rouge [Note (1)]	
Alloy selection	Selection of the proper alloy [e.g., 316L stainless steel (S31603), 6 moly (N08367), etc.] should address the corrosive effects of the process conditions. For example, low carbon stainless steel (316L) has better corrosion resistance versus the higher carbon stainless steels (316). Beneficial alloys can mitigate premature or accelerated corrosion. Higher nickel content will enhance corrosion resistance.
Mechanical polishing/buffing	Striations from cold working techniques may include residual grinding/polishing debris in lap-ping inclusions. Cumulative increase of interior area due to surface finish inconsistency proportionally exposes more alloy to the mechanisms of corrosion and burden of passivation.
Electropolishing	Minimizes the exposure area of the native alloy to oxidizing fluids or halides, and minimizes the origins for micropitting by various mechanisms including halide attack and thermal stress corrosion. Surface occlusion from passivation fluids is minimized by the smooth, more even finish.
Passivation	Impedes or retards corrosive developments of stainless steel surfaces. The effectiveness of pas-sivation methods in terms of depth and enhancement of surface alloy ratios (i.e., chrome to iron) determine the eventual propensity of an alloy to corrode and the rates of corrosion.
Alloy composition	(% molybdenum, chromium, nickel, etc.) The microstructure quality affects precipitation of impurities at grain boundaries. Migration of impurities to the alloy surface can either support corrosion cells or seed downstream corro-sion. Weld joints on tubing and/or components with dissimilar sulfur concentrations may result in lack of penetration due to weld pool shift. The resulting crevice may become a corro-sion initiation site.
Welding, welding conditions, purging, etc.	Improper welds can result in chromium depleted heat affected zones (HAZs) and other condi-tions that reduce corrosion resistance. Weld discontinuities create opportunities to trap fluid borne impurities. Cracks resulting from poor welds will create breaches in passive layer and form active corrosion cells. Proper purging prevents weld contamination by heat tint oxides and the concurrent loss of corrosion resistance. Passivation cannot reverse the effects of improper purging.
Product form and fabrication methods	The ferrite content can be greatly affected by the forming process (e.g., a forging will typically have much lower ferrite percentages than a casting). Barstock endgrain voids at the surface can enhance the potential of the alloy to pit and corrode. Minimization of differences in sul-fur content will enhance the potential for successful welding.
2-Moderate Influence on the Formation of Rouge [Note (1)]	
Installation/storage environment	Unidentified corrosion due to the storage or installation environment, including carbon steel contamination, scratching, exposure to chemical contaminants, stagnated condensation or liq-uids, etc., may warrant a derouging step prior to passivation. Failure to detect instances of corrosion will marginalize the effect of a normal passivation.
Expansion and modifications to an established system	Oxide formations in newly commissioned systems can form at different rates than older sys-tems and initially generate migratory Class I rouge. Where oxide films exist in established sys-tems, they are likely to be more stable, producing less migratory iron or chrome oxides. Because the newer system can generate and distribute lightly held Class I migratory hematite forms throughout the system, the corrosion origin and cause can be difficult to identify.

NOTE:

(1) There is well established industry data supporting this, and it needs to be considered.

Table D-2 Considerations That Affect the Amount of Rouge Formation During the Operation of a System

Variables	Considerations
3-Strong Influence on the Formation of Rouge [Note (1)]	
Corrosive process fluid (bleach, halides, etc.)	Corrosion cell inceptions at breaches in the passive layer, as in chloride corrosion cells, will progressively catalyze the corrosion mechanism. This has a very strong influence for applications such as high salt buffer tanks, etc.
High shear/velocity environment (pump impeller, sprayball, tees, etc.)	Erosive forces deplete or erode the passive layer and introduce base metal composition particles to the remainder of the system. Severe instances can cause pitting on the tips of pump impellers, or fluid impingement spots on vessel walls. In pure steam systems, high velocity sections can scour tubing walls either preventing sustained buildup of stable magnetite layers or sloughing off fragments from developing oxide formations that are then transported downstream for possible corrosion seeding.
Operating temperature and temperature gradients	Operating temperature and temperature gradients will affect the eventual nature of oxide formations (e.g., Class I hematite versus Class III magnetite), the ease of removal, the propensity to become stationary, stable, or lightly held and migratory. The nature of restoration by passivation and derouging may be largely determined by the operating temperature of the system. Established magnetite formations in pure steam systems may require a derouging step prior to the passivation steps.
Gaseous phase composition, including dissolved gases (O ₂ , CO ₂ , N ₂ , etc.)	For monographed fluids (WFI and pure steam), the constituency of dissolved gases are generally believed to have a minor influence on rouge formation when within established conductivity and total organic carbon (TOC) limits in systems that have an adequate passive layer. It is possible for impurities to migrate across distillation and pure steam generation processes as dissolved gases. A variety of analytic spectrometry methods are available to identify these species. (Refer to Tables D-3 and D-4.)
Application, process media (pure steam, WFI, buffer, media, CIP, etc.), frequency of operation	The nature of the oxide formations, potential for corrosion, remedial methods, and period of formation are greatly influenced by the application as noted in the other impact descriptions (temperature, corrosive process, etc.). In steam-in-place (SIP) systems, velocity, temperature, and trapping can have impacts on the composition and locations of rouge formations and migratory deposits. Adequately designed systems can minimize this impact. Poorly trapped pure steam headers, regularly exposed to pressure gradients, can introduce corrosion mechanisms and products through steam condensate. Long hold periods in high salt buffer tanks and the effectiveness of the tank agitation can promote or accelerate rouge formation. SIP following inadequate CIP can create corrosion mechanisms and further aggravate removal methods.
System CIP, cleaning methods	Exposure to CIP cycles and the specific chemical cleaning solutions strongly affect the potential for rouge occurrence. System sections exposed to a cyclic CIP regime will be less likely to form or collect rouge. Significant factors include whether there is an acid or hot acid CIP cycle in the CIP recipe. The duration and temperature of the acid cycle can be important. Acid cycles with mild concentrations (e.g., 2% to 20% phosphoric acid) have been shown to maintain and restore passive layers.
Redox potential	The use of ozone to sanitize purified water or WFI systems has also demonstrated beneficial effects in impeding alloy corrosion.



Table D-2 Considerations That Affect the Amount of Rouge Formation During the Operation of a System (Cont'd)

Variables	Considerations
2-Moderate Influence on the Formation of Rouge [Note (1)]	
Maintenance of the system	System components such as worn pure steam regulator plug seats, improper or misaligned gas-kets, worn regulator and valve diaphragms, pump impellers (with worn tips), and eroded or cracked heat exchanger tube returns are believed to be sources of Class I rouge.
Stagnant flow areas	A moving oxidizing fluid can maintain the passive layer. (Studies with nitrogen blanketed WFI storage tanks have shown negative effects on passive layers as a result of minimizing oxygen in the fluid.) Liquid condensate that is not immediately removed from a pure steam conduit or that collects from improper valve sequencing can concentrate and transport surface oxidation products or steam contained solubles. These can concentrate and deposit at a branch terminus such as a vessel sprayball, dip tube, etc. These deposits are typically lightly held forms of hematite. Though easily removed, they can be difficult to remove in large vessels and appear to go against the common stipulation of "visually clean."
Pressure gradients	Pure steam systems only. Pressure changes in the distribution system will affect the amount of steam condensate as well as affect the quality of the steam. If system sections are exposed to pressure ranges, condensate that is not effectively removed from horizontal sections can be re-vaporized at higher pressures, which will lower the steam quality and transport any impurities borne in the steam condensate.
System age	This depends on how the system has been maintained in regard to frequency of passivation or derouging, CIP exposure, and formation of stable oxide layers. New systems have been observed to generate disproportionate amounts of Class I rouge formations in contrast to established systems. In pure steam systems, although oxide formations become stable with age, they can also thicken and be prone to particle sloughing in high velocity sections. It should be noted that system time in use can have both beneficial and negative effects in regard to rouge formation and that regular system monitoring is important in identification of incipient corrosion.

NOTE:

(1) There is well established industry data supporting this, and it needs to be considered.

Table D-3 Process Fluid Analyses for the Identification of Mobile Constituents of Rouge

Type of Test	Test Description	Test Criteria	
		Pros	Cons
Ultra trace inorganic analysis (ICP/MS)	Concentrations of trace metals in process solutions including pure water/steam are directly analyzed by inductively coupled plasma mass spectrometry (ICP/MS).	Noninvasive sample acquisition. Highly quantitative information. Provides strong ability to trend data.	Baseline must be determined for each system analyzed.
Standard particulate analysis (via light)	A liquid sample is subjected to a laser light, which scatters upon contact with particles. The scattered light is collected, processed, segregated by channel, and displayed as a specific count for each size range analyzed.	Noninvasive sample acquisition. Highly quantitative information. Provides strong ability to trend data.	Baseline must be determined for each system analyzed.
Ultra trace inorganic analysis (by SEM/EDX)	Fluids are filtered via vacuum filtration, and particles are collected on a fine pore filter medium. The particles are then analyzed by scanning electron microscopy for size, composition, and topographical features.	Provides highly detailed physical observation and elemental composition data for mobile particulates.	Limited with respect to organic particulate identification.
Fourier transform infrared spectroscopy (FTIR)	Organic analysis of liquid samples or extracts from wipe samples. Used to identify possible organic films or deposits.	Potentially noninvasive sample acquisition. Allows for organic identification of elastomers or alternate organic contaminants.	Organic contaminants must be profiled in a specific target compound library.

Table D-4 Solid Surface Analyses for the Identification of Surface Layers Composition

Type of Test	Test Description	Test Criteria	
		Pros	Cons
Microscopic and human visual analysis	Visual analysis via polarized light microscopy (PLM), scanning electron microscopy (SEM), or alternative microscopy instrumentation.	Good test for morphology determination. Can be coupled with energy dispersive X-ray (spectroscopy) (EDX) analysis for elemental composition information.	Invasive test. Requires the periodic removal of solid samples (e.g., coupons)
Scanning auger microanalysis (SAM) or auger electron spectroscopy (auger)	Surface metal elemental composition analysis. Provides for detailed qualitative elemental composition data on both the surface itself and the sub-surface (or base metal).	Highly accurate method for positive identification and qualification of the surface metal composition. Utilized to determine the depth and elemental composition of the surface including the passive layer itself.	Invasive and destructive test. Requires the periodic removal of solid samples (e.g., coupons)
Small spot electron spectroscopy for chemical analysis (ESCA) or X-ray photoelectron spectroscopy (XPS)	The sample is subjected to a probe beam of X-rays of a single energy. Electrons are emitted from the surface and measured to provide elemental analysis of the top surface layers.	Highly accurate method for the qualification and quantification of the surface metal composition. Utilized to determine the depth and compositional analysis of the passive layer. Provides excellent elemental analysis of the top surface layers, including which oxide(s) are present.	Invasive and destructive test. Requires the periodic removal of solid samples (e.g., coupons)
Reflection grade ellipsometry	Multicolor interferometry utilizing light and its diffractive properties to assess surface conditions.	Nondestructive analysis. Known diffractive characteristics of elements could provide for qualitative analysis of surface chemistry properties.	Invasive test. Requires the periodic removal of solid samples (e.g., coupons). Field qualification of this method is still ongoing.
Electrochemical impedance spectrometry	The analysis of electrochemical noise in order to quantify state of corrosion of a metallic surface.	Noninvasive, real time quantification of metallic corrosion. Provides strong ability to trend data.	Field qualification of this method is still ongoing.

Table D-5 Rouge Remediation Processes Summary

Derouging Processes: Specific				
Class of Rouge	Description [Notes (1), (2)]	Comments [Notes (3), (4)]	Chemistry [Note (5)]	Conditions of Process [Notes (6), (7)]
Class I Removal	Phosphoric acid	Effective at removing iron oxides without etching the product contact surface	5% to 25% phosphoric acid	2 hr to 12 hr at 40°C to 80°C
	Citric acid with intensifiers	Effective at removing iron oxides without etching the product contact surface	3% to 10% citric acid with additional organic acids	2 hr to 12 hr at 40°C to 80°C
	Phosphoric acid blends	Can be used at a variety of temperatures and conditions	5% to 25% phosphoric acid plus either citric acid or nitric acid at various concentrations	2 hr to 12 hr at 40°C to 80°C
	Sodium hydrosulfite	Effective at removing iron oxides without etching the surface, but may generate sulfide fumes	5% to 10% sodium hydrosulfite	2 hr to 12 hr at 40°C to 80°C
	Electrochemical cleaning	Useful in removing stubborn rouge without risk of etching the product contact surface	25% to 75% phosphoric acid	Limited to accessible parts of systems, primarily vessels. Process times are approximately 1 min/ft ² .
Class II Removal	Phosphoric acid	Effective at removing iron oxides without etching the surface	5% to 25% phosphoric acid	2 hr to 24 hr at 40°C to 80°C
	Citric acid with organic acids	Effective at removing iron oxides without etching the surface	5% to 10% citric acid with additional organic acids	2 hr to 24 hr at 40°C to 80°C
	Phosphoric acid blends	Can be used at a variety of temperatures and conditions	5% to 25% phosphoric acid plus either citric acid or nitric acid at various concentrations	2 hr to 24 hr at 40°C to 80°C
	Oxalic acid	Effective at removing iron oxides; may etch electropolished surfaces	2% to 10% oxalic acid	2 hr to 24 hr at 40°C to 80°C
	Electrochemical cleaning	Useful in removing stubborn rouge without risk of etching the product contact surface	25% to 75% phosphoric acid	Limited to accessible parts of systems, primarily vessels. Process times are approximately 1 min/ft ² .

Table D-5 Rouge Remediation Processes Summary (Cont'd)

Derouging Processes: Specific (Cont'd)				
Class of Rouge	Description [Notes (1), (2)]	Comments [Notes (3), (4)]	Chemistry [Note (5)]	Conditions of Process [Notes (6), (7)]
Class III Removal	Phosphoric acid blends	Can be used at a variety of temperatures and conditions	5% to 25% phosphoric acid plus either citric acid or nitric acid at various concentrations	8 hr to 48+ hr at 60°C to 80°C
	Oxalic acid	May etch electropolished surfaces	10% to 20% oxalic acid	8 hr to 48+ hr at 60°C to 80°C
	Citric acid with organic acids	May etch electropolished surfaces	5% to 10% citric acid with additional organic acids	8 hr to 48+ hr at 60°C to 80°C
	Citric acid with intensifiers	Will etch electropolished surfaces	5% to 10% citric acid with additional organic acids and fluorides	8 hr to 48+ hr at 60°C to 80°C
	Nitric/HF	Will etch electropolished surfaces	15% to 40% nitric acid with 1% to 5% HF	1 hr to 24 hr at ambient to 40°C
	Electrochemical cleaning	Useful in removing stubborn rouge without risk of etching the product contact surface	25% to 75% phosphoric acid	Limited to accessible parts of systems, primarily vessels. Process times are approximately 1 min/ft ²

NOTES:

- (1) All of these derouging processes should be followed with a cleaning and passivation process of the treated surface.
- (2) Application methods include fluid circulation, gelled applications for welds or product contact surfaces, and spraying methods for vessels and equipment.
- (3) These derouging processes may produce hazardous wastes based on metals content and local and state regulations.
- (4) Oily or loose black residue due to the carbon build-up may be present on the product contact surfaces after derouging, and require special cleaning procedures to remove.
- (5) Chemical percentages are based on weight percent.
- (6) The time and correlating temperatures given above are in direct relation to the percent by weight of the base reactant(s). A change in a formulation will change those corresponding requirements.
- (7) A water rinse shall immediately follow each of the above chemical treatments.

NONMANDATORY APPENDIX E

PASSIVATION PROCEDURE QUALIFICATION

(09)

E-1 GENERAL

This document provides basic information and offers guidelines for owners/users, equipment manufacturers, and service providers for newly manufactured or installed systems in accordance with the requirements of GR-1. This document covers the preparation and execution of procedures associated with the initial water flushing, chemical cleaning and degreasing, passivation, and final rinse(s), of specialized systems, as well as bioprocessing equipment after assembly, erection, or modification. These procedures will apply to 316L stainless steel and higher alloys.

This Appendix defines a method for qualifying the passivation process used for system and component surfaces that will be exposed to the product(s) in bioprocessing, pharmaceutical, and personal care products systems.

This Appendix provides information on passivation procedures and testing of the surface resulting from various passivation procedures.

E-2 PURPOSE OF PASSIVATION TREATMENTS

Passivation, or the forming of a passive layer on the surface of stainless steel alloys, is a naturally occurring phenomenon on a clean surface when oxygen is present. The passive layer may be augmented by chemical treatment of the stainless steel surface.

A critical prerequisite in preparation for the chemical passivation processes is a cleaning procedure. This procedure includes all operations necessary for the removal of surface contaminants (oil, grease, etc.) from the metal to ensure maximum corrosion resistance, prevention of product contamination, and achievement of desired appearance. The purpose of the final chemical passivation process is to provide an alloy surface free of iron or other contaminants allowing the alloy to be in the most corrosion resistant state.

For improved corrosion resistance in the standard stainless steel grades (e.g., Type 316L) the passivation treatment is most beneficial and important. With the more corrosion resistant stainless steels grades (e.g., 6% Mo), passivation is less critical provided the surfaces are clean and free of contaminants. At the owner/user's option, passivation may be performed to reduce the iron concentration and enhance chromium.

In a discussion on passivation, it should be realized the best passivation treatment or any surface treatment

only puts the alloy in its most corrosion resistant state for a particular environment. In other words, there are inherent corrosion resistance limitations for any alloy, and the best passivation treatment does not replace the need for a more corrosion resistant material for certain applications.

E-2.1 Why Passivation Is Necessary

Although stainless steel components may be clean and the passive layer intact prior to installation, welding destroys the passive film on the weld bead and the heat-affected zone (HAZ) of the weld. The distribution of elements across the weld and HAZ including chromium, iron, and oxygen are disturbed when the metal is melted so that the concentration of iron is elevated, while chromium, which is normally of higher percentage than iron in the passive layer, is reduced.

Heat-tint discoloration and contamination (especially iron) introduced during fabrication may also compromise corrosion resistance unless removed. Passivation after welding, by removing free iron, may help to restore the passive layer. It does not remove heat-tint discoloration. Removal of heat-tint discoloration requires a more aggressive acid than the usual nitric or citric acids used for passivation. Since the only postweld treatment normally used for installed piping systems is passivation, welding procedures that minimize the formation of heat-tint oxides (discoloration — refer to AWS D18.1/D18.2) are specified.

Fabrication, cutting, bending, etc., can result in contamination that leads to loss of corrosion resistance. Examples are embedded iron, heat tint, welding flux from covered electrodes, arc strikes, painting/markings, etc. Exposure to carbon steel or iron is particularly detrimental. By removing contamination, especially free iron, a passivation treatment can help to restore the natural passivity of stainless steel that is damaged by fabrication.

E-2.2 When Passivation Is Necessary

(a) *After Welding and Fabrication.* Welded components that are electropolished after welding may be passivated as specified by the owner/user.

(b) *After Welding of New Components Into a System.*

Table E-1 Minimum Surface Requirements for Process Qualification Samples

Material	Test Method	Cr/Fe Ratio	Oxide Depth
UNS S31600 (316 SS)	AES	1.0 or greater	15 Å, min.
and/or	GD-OES	1.0 or greater	15 Å, min.
UNS S31603 (316 L SS)	XPS/ESCA	1.3 or greater	15 Å, min.

GENERAL NOTE: Additional alternative testing methods for cleanliness and passivation are shown in Table E-3, sections 1, 2, and 3.

E-3 PASSIVATION PROCEDURE (SEE SF-8)

E-3.1 Procedure Description

The passivation provider shall obtain welded and nonwelded sample component(s) or coupons from each passivation method used (e.g., circulation, spot, bath) for the purpose of demonstrating that the procedure is capable of providing the required surface characteristics, namely, cleanliness, surface chemistry, and corrosion resistance.

The passivation process used on the qualification component(s) or coupons shall be reproducible in the system for which it is intended.

The procedure description and qualification document shall be available for review by the owner/user or his designee. The owner/user shall be responsible for verifying that the passivation procedure to be used on their system or components has been qualified.

E-3.2 Procedure Qualification

The passivation provider shall develop a passivation procedure for each method used. The procedure shall be developed to ensure that essential variables used to obtain the qualification samples can effectively remove free iron and meet the requirements of Table E-1, Minimum Surface Requirements for Process Qualification Samples. Procedure qualification, as a minimum, shall include the following:

(a) *Process Description*. The following steps shall be described as a minimum (Table E-2, Passivation Processes, may be used as a guide):

- (1) prepassivation survey and preparation
- (2) flushing
- (3) cleaning
- (4) passivation
- (5) final rinsing
- (6) verification

(b) *Essential Variables (Conditions Under Which the Samples Were Processed)*. The following essential variables shall remain within the designated range:

- (1) process time
- (2) temperature of solution during process
- (3) general chemistry of process fluids
- (4) process endpoint determination
- (5) conductivity of final deionized rinse water

(c) *Procedure Qualification Coupon Testing*

(1) ESCA (electron spectroscopy for chemical analysis) also known as XPS (X-ray photoelectron spectroscopy) testing at the weld and on the base metal to meet the requirements of Table E-1

(2) AES (auger electron spectroscopy) testing at the weld and on the base metal to meet the requirements of Table E-1

(3) GD-OES (glow discharge optical electron spectroscopy) testing at the weld and on the base metal to meet the requirements of Table E-1

Qualification of method shall be supported by documentation for each procedure. The actual values of the essential variables, and coupon testing, listed above shall be documented and maintained as part of the procedure.

E-3.3 Procedure Documentation Requirements

The passivation provider shall generate and provide the following documentation, as a minimum:

- (a) process descriptions
- (b) essential variables
- (c) ESCA/XPS or AES or GD-OES testing for each procedure qualification sample produced

E-4 PASSIVATION QUALITY CONTROL

E-4.1 Quality Control Surveillance

Quality control surveillance to ensure the written and qualified passivation procedure has been followed is essential. A thorough rinse with deionized or owner/user approved water should follow the chemical treatment. It is good practice to continue rinsing until, as determined by conductivity analysis, that ionic contaminants, process chemicals, and byproducts have been removed. This document shall be available for review by the owner/user or his designee.

(a) Written documentation that all requirements of the qualified procedure have been followed.

(b) Final rinse shall meet pre-established conductivity (quality) requirements.

E-4.2 Certificate of Passivation Conformance

The passivation provider shall supply a Certificate of Conformance for each system or set (type) of component(s) that shall include, but not be limited to

- (a) customer's name
- (b) description of system or component(s)

- (c) vendor company name
- (d) qualified passivation method used
- (e) documentation of passivation process, as follows:
 - (1) written qualified procedure
 - (2) documentation of process control of essential variables
 - (3) instrument calibration records
 - (4) certificates of analysis for all chemicals used
 - (5) process testing and verification
- (f) post-passivation verification method(s) used

E-5 EVALUATION OF CLEANED AND PASSIVATED SURFACES

There are no universally accepted tests to ensure that a component or system has been passivated or is in a passive condition. If the system/component has received the proper chemical passivation treatment, the documentation generated during the process (listed above) should give some assurance that the components or system have received the specified treatment. As a guide to owners/users and others, to help determine whether an acceptable surface has been achieved following a particular cleaning or chemical passivation procedure, Table E-3, Test Matrix for Evaluation of Cleaned and/or Passivated Surfaces, has been developed.

E-5.1 Acceptance Criteria for Cleaned and/or Passivated Product Contact Surfaces (See Table SF-4)

Table E-3 may be used as a guide for acceptance criteria for cleaned and/or passivated components or systems. This matrix is a simplified compilation of testing methodologies that an owner/user may want to use in selecting a test or as a means to interpret a proposal from a testing company.

The matrix is divided into groups of four types of testing methods

- (a) Gross Inspection of Cleaned and Passivated Parts per ASTM A 380/A 967 (Pass/Fail)
- (b) Precision Inspection of Cleaned and Passivated Parts under ASTM A 380/A 967 (Pass/Fail)
- (c) Electrochemical Field and Bench Tests
- (d) Surface Chemical Analysis Tests

Groups 1 and 2 of Table E-3 reflect the two main divisions in ASTM A 380 and ASTM A 967. The most obvious type examination of these methods is visual. The examiner shall look for a clean surface free of oxides, scale, weld discoloration/heat tint, stains, dirt, oil, grease, or any deposits that could prevent the chemical passivation solution from reaching the metal surface.

The test results from ASTM A 967, which are exclusively for passivation, are all based on visual detection of staining or discoloration indicative of the presence of free iron. These test results are subjective and non-quantifiable. However, for some applications this may be all that is required. The visual acceptance criteria in ASTM A 380 and ASTM A 967 apply.

Groups 3 and 4 of Table E-3 reflect two distinct methods of quantitative testing. These tests are not contained in either of the ASTM Standards. These tests are designed to provide a more quantifiable analysis of a passivated surface. The electrochemical field and bench tests in Group 3 — Table E-3, with the exception of Cyclic Polarization, are suitable for field tests such as those used for post-passivation testing of installed piping systems and passivated welded surfaces.

Passivation, by removal of free iron, is capable of dramatically increasing the chromium-to-iron (Cr/Fe) ratio on the surface of 316L stainless steel when properly applied. One measurement of the degree of enhancement of the layer following a chemical passivation treatment is the Cr/Fe ratio as determined by AES, GD-OES, or ESCA. However, the procedure is not readily adapted to field use, but may be useful in developing the passivation procedure.

A Cr/Fe acceptance ratio, regardless of test method, should be 1.0 or greater (see Table E-1); because of variability in accuracy, identical results obtained with the different test methods are not expected. The surface chemical analysis tests in Group 4 — Table E-3 — include methods for evaluation of the thickness and chemical state of the passive layer on stainless steel. Cyclic polarization measurements (Group 3 — Table E-3) may also be used to provide a quantitative evaluation of the level of passivation. Cyclic polarization as well as the methodologies in Group 4 — Table E-3 — might be applied to sacrificial coupons placed in systems subject to the complete passivation process.


Table E-2 Passivation Processes

Process Type	Process Description [Notes (1), (2)]	Comments [Note (3)]	Conditions of Process [Notes (4), (5)]	Chemistry [Note (6)]
Pre-Cleaning				
Water flushing/ filtration processes	High velocity DI (or owner/user chosen) water flushing for removal of particles and construction debris	Removes debris prior to the passivation process	Ambient temperature for 5 min to 30 min per section; generally includes filtration of fluids	DI water
	High velocity water flushing	Removes debris prior to the passivation pro- cess. Chlorides in water are detrimental to aus- tenitic stainless steels.	Ambient temperature for 15 min to 60 min per section	DI water (recommended)
Cleaning				
Cleaning/ degreasing processes	Phosphate cleaners	Removes light organic deposits. Can leave phosphate surface contamination.	1 hr to 4 hr at heated conditions depending on the solution and contamination level	Blends of sodium phosphates [monosodium phosphate (MSP), disodium phos- phate (DSP), triso- dium phosphate (TSP)], and surfactants
	Alkaline cleaners	Can be selected for specific organic contaminates		Blends of nonphos- phate detergents, buffers, and surfactants
	Caustic cleaners	Effective at removal of heavy organic contami- nation or degreasing		Blends of sodium and potassium hydroxides and surfactants
	Isopropyl alcohol (IPA)	Effective as a degreaser. Volatile. Highly flamma- ble and sensitive to static discharge.	Hand swab or wipe sur- face at ambient conditions	70% to 99%


Table E-2 Passivation Processes (Cont'd)

Process Type	Process Description [Notes (1), (2)]	Comments [Note (3)]	Conditions of Process [Notes (4), (5)]	Chemistry [Note (6)]
Passivation				
Passivation processes	Nitric acid	Proven method under ASTM A 380/A 967. Can be processed at ambient conditions depending on formulation.	30 min to 90 min at ambient temperature or higher, depending on concentration used	10% to 40% nitric acid
	Phosphoric acid	Effective at removing iron oxides in addition to free iron	1 hr to 4 hr at heated conditions	5% to 25% phosphoric acid
	Phosphoric acid blends	Can be used at a variety of temperatures and conditions		5% to 25% phosphoric acid plus either citric acid or nitric acid at various concentrations
	Citric acid	Specific for free iron removal. Should be processed at elevated temperatures. Takes longer to process than mineral acid systems. Meets or exceeds ASTM A 967.		10% citric acid
	Chelant systems	Should be processed at elevated temperatures; Takes longer to process than mineral acid systems. Removes iron oxides in addition to free iron. Meets or exceeds ASTM A 967.		3% to 10% citric acid with various chelants, buffers, and surfactants
	Electropolishing	This process is generally limited to components rather than installed systems. Process should be performed according to a qualified procedure. This process removes metal from the surface. Electropolishing should be performed in such way as to meet or exceed ASTM B 912.	Exposure time must be calculated to ensure 5 μm to 10 μm material removal from all surfaces requiring passivation. Rinsing must include a step to ensure removal of residual film that may adversely affect the appearance or performance of the product.	Phosphoric acid based electrolyte


Table E-2 Passivation Processes (Cont'd)

Process Type	Process Description [Notes (1), (2)]	Comments [Note (3)]	Conditions of Process [Notes (4), (5)]	Chemistry [Note (6)]
Oxidation				
Oxidation processes	Hydrogen peroxide	Oxidizes metal surface and sanitizes	30 min to 2 hr at ambient to 40°C	3% to 10% hydrogen peroxide
	Hydrogen peroxide with peracetic acid blends	Oxidizes metal surface and sanitizes		1% to 2% blend

NOTES:

- (1) Application methods include fluid circulation, gelled applications for welds or surfaces, and spraying methods for vessels and equipment.
- (2) Special attention should be directed to removal of metal shavings and construction debris from locations such as sprayballs, diaphragm valves, heat exchangers, etc.
- (3) These passivation processes may produce hazardous wastes based on metals content, and local and state regulations.
- (4) The time and correlating temperatures given above are in direct relation to the percent by weight of the base reactant(s). A change in a formulation may change those corresponding requirements.
- (5) A water rinse shall immediately follow each of the above chemical treatments.
- (6) Chemical percentages are based on weight percent.

Table E-3 Test Matrix for Evaluation of Cleaned and/or Passivated Surfaces

Type of Test	Test Description	Pros	Cons
1. Gross Inspection of Cleaned and/or Passivated Parts per ASTM A 380/A 967 (Pass/Fail)			
Visual examination [CT (test for cleanliness), RT (test for the presence of rouge)]	Bench or field test. Visual examination is the direct or indirect visual inspection of, in this case, a passivated metallic surface.	Can be performed with minimal preparation and equipment. Good general appearance review.	Not quantitative. Subjective interpretation of findings.
Wipe test ASTM A 380 (CT, RT)	Bench or field test. This test consists of rubbing a test surface with a clean, lint-free, white cotton cloth, commercial paper product, or filter paper moistened with high-purity solvent.	Useful for testing surfaces that cannot be readily accessed for direct visual examination. Removable surface contamination can be easily identified and compared.	Not quantitative. Difficult to inspect hard-to-reach areas of large tube diameters. There is also a risk of leaving errant fibers behind from the wipe or plug. Can be detrimental to electropolished surfaces.
Residual pattern test ASTM A 380 (CT)	Bench or field test. After finish-cleaning, dry the cleaned surface per ASTM A 380. The presence of stains or water spots indicates the presence of contaminants.	A simple test with rapid results.	Not quantitative. Not very sensitive.
Water-break test ASTM A 380 (CT)	Bench or field test. Spray or dip the test surface in DI quality water or better. The water will sheet off of a clean surface, but will bead on a contaminated surface.	General cleanliness of surface is easily determined. Useful in detecting hydrophobic contamination.	Not quantitative. This test identifies the presence of retained oils and greases and is not practical for detecting the presence of free iron.
A 380 water-wetting and drying; ASTM A 967 water immersion practice A [PT (test for passivation)]	Bench or field test. Immersed in, or flushed with distilled water then air dried. Repeated for a minimum of 12 times. A modified version of this test requires a solution of 3% to 7% salt water, with a final rinse prior to inspection, using DI quality water or better.	Staining is evidence of free iron, which is detected through visual examination. Identifies possible pitting corrosion sites or imbedded iron.	Not quantitative.
High humidity test ASTM A 380 and ASTM A 967 Practice B (PT)	Bench test. Sample coupon is immersed or swabbed with acetone or methyl alcohol then dried in an inert atmosphere. The coupon is then subjected to 97% humidity at 100°F for 24 hr or more.	Staining is evidence of free iron, which is detected through visual examination.	Not quantitative. Not used for installed tubing. Sample coupons can be used, but does not prove complete coverage. Lengthy test. Containment cabinet required.
Salt spray test ASTM A 967 Practice C (PT)	Bench or field test. This test is conducted in accordance with ASTM B 117 subjecting the test area to a 5% salt solution for a minimum of 2 hr.	Rust or staining attributable to the presence of free iron particles imbedded in the surface will become noticeable upon visual examination of the metal surface.	Not quantitative. Longer term testing is required to test for passive film quality or corrosion resistance. However, exposures over about 24 hr may show light staining resulting from differences in micro finish texture.

Table E-3 Test Matrix for Evaluation of Cleaned and/or Passivated Surfaces (Cont'd)

Type of Test	Test Description	Pros	Cons
2. Precision Inspection of Cleaned and/or Passivated Parts Under ASTM A 380/A 967 (Pass/Fail)			
Solvent ring test ASTM A 380 (CT)	Bench test. Place a single drop of high-purity solvent on the surface to be evaluated, stir briefly, then transfer to a clean quartz microscope slide and allow the drop to evaporate. If foreign material has been dissolved by the solvent, a distinct ring will be formed on the outer edge of the drop as it evaporates.	Good test for organic contamination on the test surface.	Not quantitative.
Black light inspection ASTM A 380 (CT)	Bench test. This test requires the absence of white light and a flood type ultra-violet light.	Suitable for detecting certain oil films and other transparent films that are not detectable under white light. Good test for organic contamination on surface.	Not quantitative. Not practical when testing for passivation.
Atomizer test ASTM A 380 (CT)	Bench test. This test is conducted in accordance with ASTM F 21 using DI quality water or better. A variation of the water-break test, this test uses an atomized spray, rather than a simple spray or dip to wet the surface.	Test for presence of hydrophobic films. This test is more sensitive than the water-break test.	Not quantitative. Requires direct visual examination.
Ferroxyl test for free iron ASTM A 380/potassium ferricyanide-nitric acid ASTM A 967 Practice E (PT)	Bench or field test. Apply a freshly prepared solution of DI water or better, nitric acid, and potassium ferricyanide to the coupon using an atomizer having no iron or steel parts. After 15 sec a blue stain is evidence of surface iron. Remove solution from the surface as soon as possible after testing, per ASTM A 380 or A 967.	Identification of free iron contamination on surface. Very sensitive test.	Not quantitative. This is a very sensitive test and must be performed by personnel familiar with its limitations. Either a sacrificial coupon is used for this test, or the test area is cleaned as described in the respective ASTM practice and/or specification. Safety and disposal issues exist with the test chemical. Easy to get a false-positive result.
Copper sulfate test ASTM A 380/ASTM A 967 Practice D (PT)	Bench test. Prepare a 250-cm ³ solution consisting of 1 cm ³ of sulfuric acid (s.g. 1.84), 4 g copper sulfate, and the balance in DI water or better. Apply this to a sacrificial coupon using a swab. Keep the surface to be tested wet for a period of 6 min with additional applications as needed.	Identification of free iron contamination on the test surface. Is effective in detecting smeared iron deposits.	Not quantitative. Imbedded iron is detected, but difficult to detect small discrete iron particles.

Table E-3 Test Matrix for Evaluation of Cleaned and/or Passivated Surfaces (Cont'd)

Type of Test	Test Description	Pros	Cons
3. Electrochemical Field and Bench Tests			
Cyclic polarization measurements	This technique uses cyclic polarization measurements similar to the ASTM G 61 test method to measure the critical pitting potential (CPP). The more noble (more positive) the CPP, the more passive the stainless steel surface. Similar results may be obtained with the ASTM G 150 test that measures critical pitting temperature (CPT).	This test method provides a direct measurement of the corrosion resistance of a stainless steel surface. The measured CPP provides a quantitative measurement of the level of passivation. The test equipment is relatively inexpensive.	The method requires a potentiostat and corrosion software package to make the measurements. To ensure reliable results, operators should be trained in electrochemical test techniques.
Electrochemical pen (ec-pen) (PT)	The result is based on pre-set values. Being the size and shape of a writing instrument, the ec-pen makes electrolytic contact when placed on the test surface. Capillary action causes electrolyte to flow from the reservoir to the surface through a porous polymer body while preventing the electrolyte from leaking out of the pen. There is a stable electrode inside the pen mechanism. By simply positioning the ec-pen on the sample surface, electrolytic contact is established and electrochemical characterization is possible. The measured area is typically 1.5 mm ² .	Easy to handle, short sample preparation time, real-time results, and the possibility to run experiments on virtually any size object with various surface geometries. The ec-pen is a portable instrument for the measurement of corrosion potential suitable for field use.	This test does not quantify the passive layer, but instead provides a pass-fail indication of passivity. The local test area needs to be cleaned and re-passivated after testing.
Koslow test kit 2026 (PT)	Similar to the ec-pen, in that it measures the corrosion potential of the metal surface, the Koslow 2026 consists of a meter, a probe, and an inter-connecting cable. An electrical charge is first applied to the test piece after which a moist pad is placed on the surface of the same test piece. The probe is pressed into the moist pad to complete the circuit. Within a couple of seconds the cell voltage result appears on the digital meter.	Measures corrosion potential at the surface.	User sensitive.

Table E-3 Test Matrix for Evaluation of Cleaned and/or Passivated Surfaces (Cont'd)

Type of Test	Test Description	Pros	Cons
4. Surface Chemical Analysis Tests			
Auger electron spectroscopy (AES) (PT, RT)	Secondary and auger electrons, in the targeted area of the test coupon, are bombarded with a primary electron beam, which is used as an excitation source. Photoelectrons are subsequently ejected from the outer orbital of atoms in the target material. The ejected photoelectrons are then detected by means of electron spectroscopy. The method by which the ejected photoelectrons are detected and analyzed is AES. This test is useful for surface analysis from 2 Å to a depth greater than 100 Å.	Provides quantitative analysis. Using a scanning primary beam, secondary electron images yield information related to surface topography. Auger electrons, when analyzed as a function of energy, are used to identify the elements present. Elemental composition of the surface to a depth of 2 Å to 20 Å is determined and can be used in depth profiling applications.	The specimen chamber must be maintained at ultra high vacuum (UHV). The specimen must be electrically conductive. Instrument is not readily available. Expertise is needed for data interpretation.
Electron spectroscopy for chemical analysis (ESCA) also known as, X-ray photoelectron spectroscopy (XPS) (PT, RT)	Using X-ray as an excitation source, photoelectrons are ejected from the inner-shell orbital of an atom from the target material. The ejected photoelectrons are then detected by means of XPS. The method by which the ejected photoelectrons are then detected and analyzed is ESCA (or XPS). Useful for surface analysis to a depth of 10 Å to 100 Å.	Provides quantitative analysis in measuring the following: (a) Elemental composition of the surface (10 Å to 100 Å usually) (b) Empirical formula of pure materials (c) Elements that contaminate a surface (d) Chemical or electronic state of each element in the surface (e) Uniformity of elemental composition across the top of the surface (also known as line profiling or mapping) (f) Uniformity of elemental composition as a function of ion beam etching (also known as depth profiling)	The specimen chamber must be maintained at ultra high vacuum (UHV). Instrument is not readily available. Expertise is needed for data interpretation.
GD-OES (glow-discharge optical emission spectroscopy) (PT, RT)	GD-OES uniformly sputters material from the sample surface by applying a controlled voltage, current, and argon pressure. Photomultiplier tube detectors are used to identify the specific concentrations of various elements based on the wavelength and intensity of the light emitted by the excited electrons in each element when they return to the ground state.	The GD-OES method is particularly useful for rapid, quantitative, depth profiling of thick and thin-film structures and coatings.	Relatively expensive. Instrument not widely available.

NONMANDATORY APPENDIX F CORROSION TESTING

(09)

F-1 GENERAL

Corrosion testing can be used to determine whether the material manufacturer has used the appropriate processing variables during the fabrication of the raw product form. These variables include those primarily related to thermomechanical processing and heat treatment. The material can be evaluated based on weight loss, electrochemical response, or even measured by destructive testing techniques such as toughness testing. The standard ASTM tests that are commonly used are shown in Table F-1. However, there is no guarantee that a tested alloy will be appropriate for a specific environment even if it performs well in an industry-accepted test.

It is often appropriate to test a number of candidate alloys in a specific environment. Ideally the test selected should reflect the corrosion mode anticipated in production. These corrosion modes include general corrosion, crevice corrosion, pitting corrosion, and stress corrosion cracking.

F-2 CORROSION TESTS

For general corrosion, the most commonly used test method is ASTM G 31, Standard Practice for Laboratory Immersion Corrosion Testing of Metals.

To rank materials based on their resistance to localized corrosion, such as pitting corrosion, the two most commonly used electrochemical methods are ASTM G 61, Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements for Localized Corrosion and ASTM G 150, Standard Test Method for Electrochemical Critical Pitting Temperature Testing of Stainless Steels.

Other methods used to screen for more specific metallurgical problems such as the presence of sigma phase, chromium carbides, or improper heat treatment are described in Table F-1.

F-3 PITTING RESISTANCE EQUIVALENT (PRE) NUMBER

Where testing is not possible or desired, end-users may use the PRE number as a guide to rank a material's corrosion resistance. Relative PRE number values for some wrought stainless steel and nickel alloys are shown in Table F-2. Notice that although different equations are used to calculate the PRE number for the two different alloy systems [see Table F-2, Notes (1) and (2)], the numbers may still be used to compare alloys for ranking purposes.

Since the PRE numbers are calculated based on composition, the listed values in Table F-2 are based on nominal composition only and are not representative of the ranges of PRE numbers that could result from the compositional ranges permitted by the applicable material specification. The values listed in Table F-2 are not representative of values that may be obtained by compositions specified by the owner/user. The owner/user is cautioned that PRE numbers should be developed from the specific composition of the heat intended for use in order to accurately rank or estimate the alloy's resistance to pitting. Consideration should be given to other factors that might reduce the corrosion resistance such as

- (a) improper heat treatment
- (b) surface finish and quality
- (c) deleterious second phases
- (d) welding

Table F-1 ASTM Corrosion Tests

ASTM Standard		Purpose of Test	Data Obtained	Typical Alloys Tested
ASTM A 262	Practice A (oxalic acid test)	Qualitative test to determine susceptibility to intergranular attack associated with chromium carbide precipitates. Tests the effectiveness of final heat treatment. Used to screen specimens intended for testing in Practices B, C, and E.	Comparative, visual examination of microstructure after testing only.	Austenitic stainless steels
	Practice B (ferric sulfate-sulfuric acid test)	Quantitative test measuring weight loss due to intergranular corrosion associated with chromium carbide precipitates. Also tests for sigma phase in 321. Tests the effectiveness of final heat treatment.	Report weight loss only.	Austenitic stainless steels
	Practice C (nitric acid test)	Quantitative test measuring weight loss due to intergranular corrosion associated with chromium carbide precipitates. Also tests for sigma phase in 316, 316L, 317, 317L, 321, and 347. Tests the effectiveness of final heat treatment.	Report weight loss only.	Austenitic stainless steels
	Practice E (copper–copper sulfate–sulfuric acid test)	Qualitative test to determine susceptibility to intergranular attack associated with chromium carbide precipitates. Tests the effectiveness of final heat treatment.	Pass or fail	Austenitic stainless steels
ASTM A 923	Method A (sodium hydroxide etch test)	Detection of the presence of detrimental intermetallic phases. Used to screen specimens intended for testing in Method B and Method C.	Visual examination. Pre-test for subsequent methods.	Duplex stainless steels
	Method B (Charpy impact test)	Used to test toughness characteristics that may result from processing irregularities.	Impact toughness energy	Duplex stainless steels
	Method C (ferric chloride test)	Detects a loss of corrosion resistance associated with a local depletion of Cr and/or Mo as a result of the precipitation of chromium-rich and possibly molybdenum-rich phases.	Report weight loss only.	Duplex stainless steels
ASTM G 48	A and B (ferric chloride test)	Resistance to pitting and/or crevice corrosion	Report weight loss	Stainless steels, Ni-based alloys and Cr-bearing alloys.
ASTM G 48	Methods C and D (ferric chloride test)	Resistance to pitting and/or crevice corrosion. Define the minimum temperature at which pitting or crevice corrosion initiates. Test the effects of alloying elements, final heat treatment, as well a surface finish of final product.	Report critical temperature	Ni-based and Cr-bearing alloys

Table F-1 ASTM Corrosion Tests (Cont'd)

ASTM Standard		Purpose of Test	Data Obtained	Typical Alloys Tested
ASTM G 48	Methods E and F (ferric chloride test)	Resistance to pitting and/or crevice corrosion. Define the minimum temperature at which pitting or crevice corrosion initiates. Test the effects of alloying elements, final heat treatment, as well a surface finish of final product.	Report critical temperature	Stainless steels
ASTM G 28	Method A	Tests the susceptibility to intergranular attack associated with composition and processing.	Report weight loss only.	Ni-based alloys
	Method B	Tests the susceptibility to intergranular attack associated with composition and processing, specifically subsequent heat treatments.	Report weight loss only.	Ni-based alloys

Table F-2 PRE Numbers for Some Alloys

UNS or EN Designation	PRE Number
Austenitic Stainless Steels [Note (1)]	
S30400	20
1.4301	19
S30403	20
1.4307	19
S31600	23
1.4401	23
S31603	23
1.4404	23
1.4435	26
S31703	28
1.4438	29
6% Mo Super-Austenitic Stainless Steels	
N08367	43
S31254	42
1.4547	42
Duplex Stainless Steels	
S32205	35
1.4462	31
Nickel-Based Alloys [Note (2)]	
N06625	41
N10276	45
2.4819	45
N06022	46
2.4602	46

GENERAL NOTE: The above are industry accepted formulae. Other formulae may be used at the owner's discretion.

NOTES:

- (1) For stainless steels: PRE Number = %Cr + 3.3[%Mo + 0.5(%W)] + 16(%N).
- (2) For nickel alloys: PRE Number = %Cr + 1.5(%Mo + %W + %Nb).

(09)

NONMANDATORY APPENDIX G FERRITE

G-1 GENERAL

Ferrite is a phase that may precipitate during solidification of austenitic stainless steels depending on the ratios of the alloying elements. The ferritic phase consists of crystals with a body centered cubic (bcc) lattice in contrast to the face centered cubic (fcc) lattice of the austenitic matrix. The presence of ferrite in 316 stainless steel welds may reduce the corrosion resistance in some corrosive environments. However, a minimum ferrite level may be required to maintain specific properties of particular product forms (e.g., castings, or is deemed necessary to prevent hot cracking of heavy wall weldments, e.g., vessels made from plate).

The ferrite level of 316 stainless steel base metal strongly depends on heat analysis, primarily the chromium to nickel ratio, product form, and final heat treatment. Whereas wrought 316 stainless steel materials in the solution annealed condition typically show very low ferrite levels of 0–3 vol.%, CF-8M and CF-3M stainless steel castings may contain 10–20 vol.% of ferritic phase in the austenitic matrix.

As-solidified 316 stainless steel welds typically have higher ferrite levels than the base metal. This is caused by rapid cooling that prevents the ferrite to austenite transformation from proceeding to thermodynamic equilibrium. The ferrite level of as-solidified 316 stainless steel welds can be determined from the WRC-1992 Constitution Diagram for Stainless Steel Weld Metals¹ using a chromium equivalent $Cr(eq) = \%Cr + \%Mo + 0.7\%Nb$ and a nickel equivalent $Ni(eq) = \%Ni + 35\%C + 20\%N + 0.25\%Cu$. Postweld heat treatment (e.g., solution annealing of welded tubing) reduces the amount of ferrite in the weld.

It should be recognized that many austenitic stainless steels with high nickel contents and nickel alloys do not contain any ferrite in as-solidified welds.

¹ D. J. Kotecki and T. A. Siewert, WRC-1992 constitution diagram for stainless steel weld metals: a modification of the WRC-1988 diagram, *Welding Journal* 71(5), pp. 171-s, 1992.

Measuring of ferrite in production welds shall be in accordance with AWS A4.2M:2006 (ISO 8249:2006MOD).

G-2 INFLUENCE OF FERRITE IN BIOPHARMACEUTICAL SERVICE

Ferrite in the base metal and welds can have a beneficial or a negative effect depending upon the particular service, but generally offers little concern for biopharmaceutical services. Laboratory corrosion tests in severe biopharmaceutical service have shown that increased amounts of weld metal ferrite somewhat lowers corrosion resistance.² However, in high purity water systems, there has been no reported system failures related to delta ferrite content in welds.

G-3 CONTROL OF FERRITE CONTENT IN WELDS OF 316 STAINLESS STEELS

Ferrite in welds of 316 stainless steels can be controlled by one or more of the following methods:

- (a) postweld solution annealing
- (b) use of weld filler with increased nickel content
- (c) increase of nickel equivalent by addition of approximately 1–3 vol.% nitrogen to shielding gas
- (d) selection of heats of materials with high nickel to chromium ratios, such as the European steel grade 1.4435 (see Table MMOC-1) with a restricted $Cr(eq)$ to $Ni(eq)$ ratio³ as per BN2⁴

² R. Morach and P. Ginter, Influence of low δ -ferrite in the corrosion behavior of stainless steels, *Stainless Steel World*, September 1997.

³ $Cr(eq) - 0.91 Ni(eq) \leq 7.70$, with

(a) $Cr(eq) = \%Cr + 1.5 \%Si + \%Mo + 2 \%Ti$, and

(b) $Ni(eq) = \%Ni + 0.5 \%Mn + 30 \%C + 30 (\%N - 0.02)$

⁴ Basler Norm BN2 (N 11.265), Nichtrostender Stahl nach BN2, 1997.



NONMANDATORY APPENDIX H

ELECTROPOLISHING PROCEDURE QUALIFICATION

(09)

H-1 SCOPE

This Appendix defines a method for qualifying the electropolishing process used for electropolishing component(s) surfaces that will be exposed to the product(s) in bioprocessing, pharmaceutical, and personal care products systems and ancillary equipment.

H-2 PURPOSE

This Appendix is intended to provide general guidelines for qualification of the electropolish methods used to achieve required surface improvements. Electropolishing is utilized to impart a surface that

- (a) shall be free of oxide contamination and undesirable metallurgical conditions
- (b) takes advantage of a material's surface chemical characteristics minus any damage or degradation from the component(s) manufacturing process
- (c) exhibits a surface that is free of the surface irregularities that result from prior machining and forming process
- (d) optimizes corrosion resistance

H-3 ELECTROPOLISH PROCEDURE QUALIFICATION

H-3.1 Method Procedure

This Appendix is intended to provide general guidelines for qualifying the electropolish process utilized to provide the surface improvements of component(s) required.

The electropolish vendor shall produce sample component(s) or coupons from each electropolish method used (e.g., submersion, spot, in situ) for the purpose of demonstrating the method is capable of providing the required surface characteristics.

The electropolish vendor should also demonstrate the ability to reproduce the method utilized on the qualification component(s) or coupons onto the production component(s) and/or equipment for which the method is being qualified.

The electropolish vendor shall have a written quality control program that shall describe, as a minimum, the following:

- (a) prepolish inspection process
- (b) precleaning process
- (c) specific gravity at operating temperature of electrolyte bath (minimum and maximum)

(d) bath analysis data (last date analyzed, iron/water concentrations of electrolyte, adjusted specific gravity value)

(e) resistivity of final deionized rinse water (minimum and maximum)

Qualification will be supported by internal documentation for each method. The actual values of the essential variables listed above shall be documented, maintained, and available for customer review.

H-3.2 Essential Variables

The electropolish vendor shall develop an electropolishing procedure for each method used. The procedure will be developed to ensure that essential variables used to produce the qualification samples can be reproduced. The electropolishing procedure, as a minimum, shall include the following essential variables:

- (a) amperage/time (minimum and maximum)
- (b) temperature range of bath during process (minimum and maximum)
- (c) electropolish process
- (d) final rinsing/cleaning process
- (e) final inspection requirements

H-3.3 Vendor Documentation

The electropolish vendor, as a minimum, shall generate and maintain the following additional information:

- (a) SEM records for each process qualification sample produced.
- (b) XPS (ESCA) records for each process qualification sample produced. These results must meet the criteria of Table H-1.
- (c) actual sample(s) used to qualify the process.
- (d) process control records.
- (e) the electropolish procedure used.
- (f) final R_a (if required).
- (g) copies of Certificate of Compliance (C of C) for each job.

H-3.4 Certificate of Compliance

The electropolish vendor, if requested by the customer, shall provide a Certificate of Compliance with each type of component(s) that shall include but is not limited to

- (a) vendor's company
- (b) customer's name
- (c) description of component(s)
- (d) identification of the electropolish procedure used
- (e) final surface finish report (R_a if required by the customer)

**Table H-1 Minimum Surface Requirements for Process Qualification Samples**

Material	Cr/Fe Ratio	Depth [Note (1)]	Surface Photo
UNS S31600 (316 SS)	1 to 1 or greater	15 Å minimum	150X [Note (2)]
UNS S31603 (316L SS)	1 to 1 or greater	15 Å minimum	150X [Note (2)]

NOTES:

- (1) Test method: X-ray photoelectron spectroscopy (XPS/ESCA) analysis.
(2) Scanning electron microscopy (SEM).



NONMANDATORY APPENDIX I VENDOR DOCUMENTATION REQUIREMENTS FOR NEW INSTRUMENTS

(09)

I-1 OVERVIEW

I-1.1 Section 1: VDR Definitions

This section identifies the vendor documentation requirements (VDR) number, document title, and definitions for the documentation.

I-1.2 Section 2: Instrument Types and Required Documents

This section identifies the major instrument types and the required documentation, by VDR number.

I-2 INSTRUCTIONS FOR USE

Together, these two sections are intended to be used by end-users, design and procurement agents, and vendors, to identify the documents required to support commissioning/qualification, installation, operation, and maintenance of instrumentation for the biopharmaceutical industry.

These documentation requirements may be modified, as necessary, to reflect the actual documents required for a particular instrument, based on the instrument's complexity, application, end-user's specific requirements, etc.


Table I-1 Vendor Documentation Requirements for New Instruments: Section 1, VDR Definitions

VDR #	Documentation	Definitions
1	Certified arrangement/assembly drawings	Provide Certified Arrangements/Assembly Drawings for the tagged component [(or tagged packaged equipment (skid))] specified on the P.O. A Certified "Arrangement" or "Assembly Drawing" means that a statement, signed and dated by an authorized company representative, is included on (or with) the drawing, certifying the component (or skid) has been manufactured in accordance with stated, applicable federal and state or internationally recognized regulatory requirements and the designated component (or skid), by tag number, complies with the established industry standards and product specifications.
2	Catalog information, cut sheets, product bulletins	This information shall include Supplier's literature for the component being purchased. The literature shall include dimensions, materials of construction, and layout considerations such as orientation, typical utility requirements, power, and instrument air.
3	Detailed parts list/bill of material	Provide a complete listing of all subassemblies, parts, and raw materials that compose the final (finished) component (or skid). Include the quantity of each item.
4	Installation, operation, maintenance, and lubrication manual(s)	Provide manuals for the components (or skid) being purchased. Manuals should include installation guidelines, detailed operating instructions with operating ranges, settings, etc. Also, include step-by-step start up, operating, and shutdown procedures and maintenance procedures for all required maintenance/repairs and lubrication schedule.
5	Recommended spare parts for 1 yr's normal maintenance	Spare parts list will include the vendors' recommended listing of spare parts required for 1 yr, assuming that the system is cycled once a week (50 times/yr); the list to include the tag number (if applicable), a description of each part sufficient for ordering and the vendor's part number.
6	Certified performance report	Provide a Certified Performance Report that states that the instrumentation by tag number and serial number complies with the stated process ranges established in the stated specification. The Certified Performance Report must be signed and dated by an authorized person from the manufacturer or sub-supplier who performed the test. Typically this testing is a destructive test, and the instrumentation being purchased was produced from the same manufacturing process with the same material supplier(s).
7	Wiring schematics	Provide drawings that show the following: (a) terminal strip/wiring numbering (b) starter, overloads, protective devices (c) ALL electrical components (d) Instrumentation (electrical connections).
8	Instrument calibration reports	Calibration certificates or reports must be traceable to NIST or other internationally recognized and agreed upon calibration standards. They must also include the procedure used, calibration data/results, the calibration date, the person who performed the calibration, along with the serial number(s) of the standards or equipment utilized in the calibration process. NOTE: All calibration certificates or reports must contain the instrument serial number.
9	Sizing calculations	Given two or three parameters below, provide the sizing calculations, designated by tag number, for the design flow: (a) type of liquid and viscosity (b) piping size (c) flow For relief devices, the calculation to show the relieving flow, set pressure, back pressure, vacuum, specific gravity, viscosity, coefficient of discharge, back pressure coefficient, viscosity (or other applicable) coefficient, calculated required area in square inches; summary to show the manufacturer, model number, and the selected area.

**Table I-1 Vendor Documentation Requirements for New Instruments: Section 1, VDR Definitions (Cont'd)**

VDR #	Documentation	Definitions
10	Material test report for metallic materials	The material test report for product-contact metallic materials shall comply with the requirements listed in DT-14.2. REQUIRED ONLY FOR HYGIENIC APPLICATIONS.
11	Certificate of compliance for elastomers	The certificate of compliance for product-contact elastomer materials shall comply with the requirements listed in SG-3.4.2. REQUIRED ONLY FOR HYGIENIC APPLICATIONS.
12	Certificate of compliance for surface finish	The certificate of compliance for surface finish must be uniquely identified by tag number, serial number, and/or model number; state the associated surface finish value in RA or BPE designation per section SF; and whether any polishing compounds have been used to meet stated specification. If polishing compounds are used they shall be inorganic and animal source material-free as stated on the Certificate of Compliance. The Certificate of Compliance must be signed and dated by an authorized person from the manufacturer. REQUIRED ONLY FOR HYGIENIC APPLICATIONS.
13	Certificate of compliance for polymer-based materials	The certificate of compliance for product-contact polymer-based materials shall comply with the requirements listed in PM-5.2. REQUIRED ONLY FOR HYGIENIC APPLICATIONS.

**Table I-2 Vendor Documentation Requirements for New Instruments:
Section 2, Instrument Types and Required Documents**

Instrument Types	Required Documents (VDR Number)
Analytical element: condition/density/pH/resistivity	2, 3, 4, 5, 7, 10, 11, 12, 13
Conservation vent valve	1, 2, 3, 4, 5, 6, 9, 10, 11, 12, 13
Control damper: flow/humidity/pressure/temperature	2, 4
Control valve: analytical/flow/humidity/level/pressure/temperature	1, 2, 3, 4, 5, 7, 9, 10, 11, 12, 13
Controllers, indicating controllers	2, 3, 4, 5, 7
D/P transmitter: flow/level/pressure	2, 4, 7, 8, 10, 12
Damper actuator	2, 4, 7, 9
Electrical components	2, 4, 7
Flow element	1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 13
Flow orifice	2, 4, 10, 11, 12, 13
Flow switch: thermal	2, 3, 4, 5, 7, 10
Flow valve, automated valve assembly	1, 2, 3, 4, 5, 7, 10, 11, 12, 13
Indicator: humidity/pressure/temperature	2, 4, 8, 10, 12
Indicator: flow/level	2, 3, 4, 5, 10, 11, 12, 13
Level element	2, 3, 4, 5, 7, 10, 11, 12, 13
Level transmitter: microwave	2, 4, 7, 10, 11, 12, 13
Lighting	2, 4, 5, 7, 10, 12
Miscellaneous instruments: alarm/element/switch/transmitter	2, 4, 7
Positioner/transducer I/P: pressure/speed/temperature	2, 4, 7
Pressure element, pressure safety element	2, 4, 6, 10, 11, 12, 13
Pressure indicator	2, 4, 8
Pressure port	2, 4
Pressure safety (relief) valve	1, 2, 3, 4, 5, 6, 9, 10, 11, 12, 13
Recorder, indicating recorder	2, 4, 5, 7
Regulator valve: temperature/pressure	1, 2, 3, 4, 5, 10, 11, 12, 13
Sight glass	2, 3, 4, 5, 10, 11, 12, 13
Smoke detector, motion detector	2, 3, 4, 5
Solenoid valve	2, 4, 7
Switch: current/limit	2, 4, 7
Switch: analytical/flow/level/pressure/vibration	2, 3, 4, 5, 7, 10, 11, 12, 13
Temperature element: RTD	2, 4, 7, 8, 10
Temperature switch	2, 4, 7, 10, 12
Thermowell	2, 10, 12
Transmitter: analytical/flow/humidity/level/pressure/temperature/weight	2, 3, 4, 5, 7
Weight element	2, 3, 4, 5, 7, 8

NONMANDATORY APPENDIX J STANDARD PROCESS TEST CONDITIONS (SPTC) FOR SEAL PERFORMANCE EVALUATION

(09)

J-1 MATERIAL EVALUATION

Evaluate the material's fitness for use. The specific material composition shall be evaluated against the specific process conditions that it may be exposed to, including routine sterilization and cleaning. Considerations for other nonroutine conditions such as allowable extreme process upset conditions and nonroutine treatments (e.g., passivation, derouging) should also be considered.

(a) Verify that the material's service temperature and pressure meet the desired process conditions, including sterilization and cleaning.

(b) Verify that the material is compatible with the intended process and cleaning chemicals at the routine concentrations used, including consideration for extreme allowable process conditions, per PM-6.1.

J-2 SIMULATED STEAM-IN-PLACE (SIP) TESTING

Expose the material to multiple SIP cycles to establish a life expectancy for the application. The testing cycles will occur without intervention (e.g., retorquing of clamps or fasteners), beyond initial installation procedures. The cycle will consist of the following:

(a) *Initial Installation and Preparation.* This typically includes assembly, cleaning, performance verification (routinely includes a steaming cycle), seating of seals, retorquing of clamps and fasteners, etc.

(b) *Pre-SIP Exposure Pneumatic Pressure Hold.* Initial test of the system to verify its ability to hold pressure prior to starting SIP exposure.

(1) *System Temperature.* Ambient, as close to 25°C (77°F) as possible

(2) *System Pressure.* At least 3.1 bar (45 psig)

(3) *Test System Volume.* A fixed volume of less than 10 L (2.6 gal)

(4) *Test Exposure Time.* At least 1 hr.

(5) *Allowable Pressure Drop.* Less than 0.0345 bar (0.5 psig) drop in 1 hr.

(c) *Steam-in-Place.* Expose the system to a simulated SIP with saturated USP Pure Steam or equivalent.

(1) *System Temperature.* Minimum of 130°C (266°F).

(2) *System Pressure.* Saturated steam pressure.

(3) *Test System Volume.* A fixed volume of less than 10 L (2.6 gal) is recommended.

(4) *Test Exposure Time.* At least one continuous hour greater than 130°C (266°F).

(d) *Cool Down.* Cool the system with ambient clean dry air.

(1) *System Temperature.* Ambient, as close to 25°C (77°F) as possible.

(2) *System Pressure.* 0 psig to 3.1 bar (45 psig).

(3) *Test System Volume.* A fixed volume of less than 10 L (2.6 gal) is recommended.

(4) *Test Exposure Time.* Until the system reaches 25°C (77°F), usually less than 1 hr.

(e) *Repeat Steps.* Repeat steps in paras. J-2(c) (Steam-in-Place) and J-2(d) (Cool Down) until 10, 100, and 500 of cycles are attained.

(f) *Post-SIP Exposure Pressure Hold.* Acceptance test of the system to verify its ability to hold pressure after the desired number of SIP cycles.

(1) *System Temperature.* Ambient, as close to 25°C (77°F) as possible.

(2) *System Pressure.* At least 3.1 bar (45 psig).

(3) *Test System Volume.* A fixed volume of less than 10 L (2.6 gal) is recommended.

(4) *Test Exposure Time.* At least 1 hr.

(5) *Allowable Pressure Drop.* Less than 0.0345 bar (0.5 psig) drop in 1 hr.

(g) *Vacuum.* The ability of the system to hold vacuum should be considered for routine process equipment, where applicable. Specific applications that require vacuum, such as autoclaves and freeze driers shall require the addition of a vacuum hold test requirement.

(h) *Cleaning Chemicals.* Integrated clean-in-place (CIP) test exposure should be considered to be added to the testing cycles. Specific cleaning chemicals and concentrations are determined by the process applications. Some systems, such as CIP systems, may be exposed to multiple cleaners. Typical cleaning solutions and concentrations used in the bioprocess industry are

(1) sodium hydroxide (8% v/v)

(2) phosphoric acid (4% v/v)

(3) sodium hypochlorite (0.05% v/v)

(i) *Hygienic Fitting Seal Acceptance Criteria.* The seal will be classified as a Level 10, 100, or 500 seal, if all of the following acceptance criteria are met after the corresponding number (10th, 100th, and or 500th) of SIP exposure/cool-down cycles:

(1) Pressure hold test shall be passed after the 10th, 100th, and/or the 500th SIP exposure cycle.



(2) Compliance with SG-2.4 shall be established after the 10th, 100th, and/or 500th SIP exposure cycle (Intrusion Category I or II).

(3) The condition of the gasket shall be examined after the 10th, 100th, and/or the 500th SIP exposure cycle, and any direct visible changes shall be recorded.

Specific pass/fail appearance criteria shall be agreed upon by both the supplier and the end-user with respect to surface defects, compression marks, discoloration, or erosion. Cracks, tears, or holes will be considered failures.



FORM J-1 APPLICATION DATA SHEET

Client: _____
Project: _____
Location: _____
Date: _____

Identification # _____
Tag # _____
P & ID # _____

Application/ Operation	Service	Application Details		Normal Operating Temperature, °C or °F [Note (1)]	Operating Low Temperature, °C or °F	(High) Design Temperature, °C or °F	Normal Operating Pressure, psig or bar [Note (2)]	(High) Design Pressure, psig or bar	Shutoff Pressure, (0%/100%) ΔP [Note (3)]	Cycle Frequency Per Day/ Week/Year	Duration, hr/day
		Size	Rupture disk set pressure								
Steam	Process Fluid Continuous ☐ Yes ☐ No Intermittent ☐ Yes ☐ No										
Purified Water/WPI	☐ Yes ☐ No										
Other	☐ Yes ☐ No										
CIP	Sodium hydroxide ☐ Yes ☐ No										
	Phosphoric acid ☐ Yes ☐ No										
	Sodium hypochlorite ☐ Yes ☐ No										
	Other ☐ Yes ☐ No										
SIP	☐ Yes ☐ No										
Autoclave	☐ Yes ☐ No										
Passivation	Check one:										
	Citric acid ☐ Yes ☐ No										
	Nitric acid ☐ Yes ☐ No										
	Phosphoric acid ☐ Yes ☐ No										
	Other ☐ Yes ☐ No										
Solids	☐ Yes ☐ No										
Valve Operation											
Mode of Operation: Valves	Manual ☐ Yes ☐ No										
	Automated ☐ Yes ☐ No										
Diaphragm material currently using? (please state in the space below)											



FORM J-1 APPLICATION DATA SHEET (CONT'D)

GENERAL NOTE: The purpose of the Application Data Sheet is to facilitate the communication of the service parameters, for a particular application, between the end-user and the manufacturer. It is also designed to act as a tool in the selection of proper materials for the process or utility service being defined. This Application Data Sheet will support paras. SD-3.4.2, SD-3.4.3, and SG-3.1.

NOTES:

- (1) Operating Temperature: the normal operating temperature for a particular service.
- (2) Operating Pressure: the normal operating pressure for a particular service.
- (3) Shutoff Pressure: the line pressure at which the valve will need to close against. Also can be stated as 0% ΔP or 100% ΔP . 0% ΔP is when closing against pressure on both the upstream and downstream side; 100% ΔP is when closing against pressure on the upstream side only.



NONMANDATORY APPENDIX K INTERPRETATION OF ELASTOMER MATERIAL PROPERTY CHANGES

(09)

Table K-1 Interpretation of Elastomer Material Property Changes

Property Change	Measurement	Test Result Interpretation	Additional Comments
Hardness	Shore A, shore D scale, shore M scale (O-rings), or IRHD hardness. Usually measured in units of points.	May indicate fluid absorption (increase) or extraction of ingredients (decrease); however, both absorption and extraction may occur simultaneously. A significant change in hardness may also indicate attack on the polymer backbone.	Relatively easy test to run. A significant decrease in hardness may result in increased abrasion. This is a macro measurement.
100% modulus	This is the stress required to reach 100% elongation.	Change may be caused by heat aging (increase) and/or chemical attack (decrease). Chemical absorption (decrease) or ingredient extraction (increase) can also affect modulus. Excessive increase in modulus may be a sign of polymeric embrittlement. Related to tensile strength and inversely related to elongation.	Requires specialized equipment for measurement. Evaluates the elastomer on the micro level. Elastomer modulus should not be confused with modulus measurements for metals.
Tensile strength at break	Ultimate tensile strength recorded at material breakage.	May indicate exposure to excessive heat (increase) and/or chemical attack (decrease).	Requires specialized equipment for measurement. Evaluates the elastomer on a micro level.
Elongation at break	Ultimate elongation of sample measured at material breakage.	May indicate exposure to excessive heat (decrease) and/or chemical attack (increase). Elongation (macro) and localized is important for sealing to avoid elastomer splits and cracks.	Requires specialized equipment for measurement. Evaluates the elastomer on a micro level. Especially important for flexing applications such as diaphragms.
Compression set	Measures the ability of an elastomer to recover dimensionally after being subjected to compressive load, at a temperature, over time.	Compression set is an indication of whether an elastomer is able to maintain sealing force. In general, the lower the compression set value, the better, especially if the application will involve temperature cycling. In this case, the elastomer has to maintain sealing through thermal expansion cycles.	Relatively easy to test to run. Preferred to run at application temperature. Most important for applications involving O-rings or gaskets.
Volume/weight	Measure weight gain/loss or volume increase/decrease	Volume swell and weight gain typically track together. Fluid exposure can result in fluid absorption (increase) or extraction of elastomer ingredients (decrease). Absorption of process fluid may or may not be a reversible process.	Weight and volume change are relatively easy to measure. May be best indicators of performance. An increase due to absorption can result in product failure due to nibbling and extrusion. A decrease can result in leakage around the seal.
Tear strength	The ease at which a tear can be initiated and propagated.	May indicate fluid absorption (decrease) or extraction of ingredients (increase). Property is typically related to change in elongation.	Requires specialized equipment for measurement. May be useful data for applications involving diaphragms.

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