

ASME BPE-2016
(Revision of ASME BPE-2014)

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 initial subcommittees were

- (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 3-A 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 this edition includes the following Parts:

- (1) General Requirements
- (2) Systems Design
- (3) Metallic Materials
- (4) Polymeric and Other Nonmetallic Materials
- (5) Dimensions and Tolerances for Process Components
- (6) Process Instrumentation
- (7) Sealing Components
- (8) Materials Joining
- (9) Process Contact Surface Finishes
- (10) Certification Requirements

The first edition of this Standard was approved as an American National Standard on May 20, 1997. This edition was approved by ANSI on June 27, 2016.

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

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ASME BPE-2016

SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2016 was approved by the American National Standards Institute on June 27, 2016.

ASME BPE-2016 has been reorganized and includes editorial changes, revisions, and corrections introduced in ASME BPE-2014, as well as the following changes identified by a margin note, **(16)**.

<i>Page</i>	<i>Location</i>	<i>Change</i>
1, 2	Chapter 1	Chapter designation added
	GR-2	Last paragraph revised
6	GR-5.2	Revised
	GR-5.2.1.1.1	Subparagraph (a)(4) revised
7	GR-5.3.1	Subparagraph (c) revised
	GR-5.3.2.1	Revised in its entirety
	GR-5.4	Name of Form revised
8, 9	GR-7	ASME PVHO-1, ISO 10993, and United States Pharmacopeia and National Formulary added
9–16	GR-8	(1) Definitions of <i>autogenous fillet weld</i> , <i>finishing marks</i> , <i>nonsliding seal</i> , <i>oxide island</i> , <i>scratch</i> , <i>seat leakage</i> , <i>shell leakage</i> , <i>sliding seal</i> , and <i>tack weld</i> added (2) Definitions of <i>blind weld</i> , <i>clean-in-place (CIP)</i> , <i>flushing (rinsing)</i> , <i>material manufacturer</i> , <i>mechanical polishing</i> , <i>orange peel</i> , <i>PFA</i> , <i>rouge</i> , and <i>slag</i> revised (3) Definition of <i>dross</i> deleted
18	Chapter 2	Chapter designation added
	SD-2	Second paragraph added
	SD-2.3.1.1	Revised in its entirety
19	SD-2.4.1.2	Subparagraph (a) revised
20	SD-2.4.3.1	Revised
	SD-2.4.4.1	Subparagraph (c) revised
27	SD-3.1.2.3	Subparagraphs (b) and (g) revised
29	SD-3.3.1	Revised in its entirety
30, 33, 39	SD-3.3.2.2	Subparagraph (d) revised
	SD-3.3.2.4	Subparagraph (c) revised
	SD-3.4	Revised in its entirety

<i>Page</i>	<i>Location</i>	<i>Change</i>
36	Fig. SD-3.4.2-4	Redesignated
	Fig. SD-3.4.2-5	Redesignated
37	Table SD-3.4.3-1	Redesignated
	Figure SD-3.4.3-1	(1) Redesignated (2) Cross reference to table in Note (1) updated
38	Figure SD-3.4.3-2	(1) Redesignated (2) Parts (a) and (b) revised
39	SD-3.5.1	(1) Figure numbers updated in subparas. (d) and (f)(1) (2) Subparagraph (g) revised
40	Fig. SD-3.4.6-1	Redesignated
41, 44	SD-3.5.3	Subparagraphs (d) and (g) revised
46, 47	SD-3.6.1	Subparagraphs (g), (h), and (j) revised
51	SD-3.7.6	Subparagraph (b) revised
53	SD-3.8.1.1	References to figures in subparas. (b)(1) and (b)(2) updated to tables
	SD-3.8.1.2	References to figures updated to tables
	Fig. SD-3.8.1.1-1	Deleted (incorporated into Table DT-4.5.1-1)
	Fig. SD-3.8.1.1-2	Deleted (incorporated into Table DT-4.5.2-1)
55	SD-3.9.2	Subparagraph (k) revised
57	Fig. SD-3.9.2.1-3	Revised
58	SD-3.11.1	Subparagraph (b) revised
	SD-3.11.2.2	Revised
60	SD-4.1.1	Subparagraphs (a) and (b) revised
	SD-4.2.1	Subparagraphs (a) and (b) revised
62, 64, 65	SD-4.3.1	Subparagraph (b) revised
	SD-4.4	Revised in its entirety
	SD-5.1.1.1	Subparagraph (c) revised
75	SD-5.1.1.4.2	Subparagraph (b) figure number updated
76, 77	SD-5.1.3	Revised in its entirety
	SD-5.2.1.1	Subparagraph (e) revised
78–81	SD-5.2.2	Added
	SD-5.3.1	Revised in its entirety
84, 85	SD-5.3.3.3	Revised in its entirety

<i>Page</i>	<i>Location</i>	<i>Change</i>
87–94	SD-5.3.4	Revised in its entirety
	Fig. SD-5.3.4.3.1-1	Added
	Fig. SD-5.3.4.3.1-2	Added
	Fig. SD-5.3.4.3.6-1	Added
	SD-5.3.5	Revised in its entirety
	SD-5.4	Title revised
	SD-5.4.1.1	First paragraph revised
100	SD-6.4	Subparagraph (a) revised
101, 104	Chapter 3	Chapter designation added
	MM-2.1	Revised
	MM-3.1	Revised
	MM-3.2	Revised
	MM-3.3	Revised
	MM-3.5	Revised
102	Table MM-2.1-1	Fifth column revised
104	Table MM-2.1-4	Revised
	MM-4.1	Revised
	MM-5	Revised in its entirety
106–108	Table MM-5.2.1.2-1	(1) Redesignated (2) Title revised (3) Third row revised
	Table MM-5.2.6-1	Redesignated
	MM-6.1	Table numbers updated
	MM-6.3	Revised
	MM-6.4	Revised
	MM-6.6	Added
109, 110	Table MM-5.3-1	Redesignated
111	Table MM-5.3-2	Redesignated
112	Table MM-5.3.3-1	Redesignated
	Table MM-5.4-1	Added
113	MM-7.2	Subparagraph (b) revised
	MM-8.1	First paragraph revised
114	PM-1	Revised
	PM-2	Revised
	PM-2.1	Revised
	PM-2.1.1	Fourth paragraph revised
	PM-2.1.2	Revised
	PM-2.1.3	Second paragraph revised

<i>Page</i>	<i>Location</i>	<i>Change</i>
116	PM-2.2.3	Added
117	Table PM-2.2.1-1	Revised
118	PM-3.2	Revised in its entirety
120	PM-4.1.2	Cross-reference added
	PM-4.1.5	Revised
	PM-4.1.5.1	First paragraph revised
	PM-4.1.6	Revised
121	PM-4.1.7	Added
125, 126	PM-4.5	Added
128	Chapter 4	Chapter designation added
	DT-2	Revised
129	DT-4.4	Second paragraph revised
	DT-4.5	Added
	DT-7	First paragraph revised
	DT-8	First paragraph revised
	DT-9.3	Revised
130	DT-9.4	Subparagraphs (c) and (d) figure number updated
132	Table DT-2-1	Title revised
134	Table DT-4.1-1	U.S. Customary column revised
135	Table DT-4.1.1-1	SI column revised
	Table DT-4.1.1-2	SI columns revised
136	Table DT-4.1.1-3	SI column revised
	Table DT-4.1.1-4	SI column revised
137	Table DT-4.1.1-5	SI columns revised
	Table DT-4.1.1-6	SI column revised
138	Table DT-4.1.1-7	SI columns revised
	Table DT-4.1.1-8	SI columns revised
139	Table DT-4.1.2-1	SI column revised
	Table DT-4.1.2-2	SI columns revised
140	Table DT-4.1.2-3	SI columns revised
	Table DT-4.1.2-4	SI column revised
141	Table DT-4.1.2-5	SI columns revised
	Table DT-4.1.2-6	SI columns revised
142	Table DT-4.1.2-7	SI columns revised
143	Table DT-4.1.2-8	SI columns revised

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144	Table DT-4.1.2-9	SI columns revised
	Table DT-4.1.2-10	SI columns revised
	Table DT-4.1.2-11	SI columns revised
145	Table DT-4.1.3-1	Revised
146	Table DT-4.1.3-2	Revised
147	Table DT-4.1.3-3	Revised
148	Table DT-4.1.4-1	Revised
	Table DT-4.1.5-1	SI column revised
149	Table DT-4.1.5-2	SI column revised
150	Table DT-4.4.1-1	SI column revised
151	Table DT-4.5.1-1	Added
152	Table DT-4.5.2-1	Added
153, 154	Table DT-7-1	Revised
155	Table DT-7-2	Revised
156	Table DT-9.3-1	Revised
157, 158	PI-1	Revised
	PI-2	Revised in its entirety
166	PI-7.3.6	Subparagraph (b) editorially revised
170	PI-7.6	Editorially revised
178	PI-9.1.1	Revised
	PI-9.1.2.1	Revised
	PI-9.1.2.2	Revised
	PI-9.1.2.3	Revised in its entirety
	PI-9.1.3	Revised
	PI-9.1.3.1	Revised
	PI-9.1.3.2	Revised
	PI-9.1.3.5	First paragraph revised
	PI-9.1.3.6	First paragraph revised
	PI-9.1.4.1	Revised
	PI-9.1.4.2	Revised
181	PI-9.1.4.4	Revised
	PI-9.1.5	Revised
	PI-9.1.6	Deleted
186	SG-2.3.1.6	Figure number updated
192, 193, 194, 198	SG-2.3.2.3	Subparagraph (b)(5) revised
	SG-2.3.2.4	Subparagraphs (a) through (d), (f), and (h) through (k) revised

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199	SG-3.3.1	Subparagraphs (a), (d)(4), and (e) revised
200	Fig. SG-3.3.2.2-1	Title revised
201	SG-3.3.2.3	Subparagraph (a)(13) revised
206, 207	SG-4.3.1.1	Revised in its entirety
	SG-5.1	Revised in its entirety
207, 208	SG-5.3	Revised in its entirety
209	Chapter 5	Chapter designation added
	MJ-2.1.1	Cross-references in subparas. (a) and (c) updated
	MJ-2.2.1	Revised
210, 211	MJ-2.2.2	Revised
	MJ-2.2.3	Revised
	MJ-2.3	Revised
	MJ-3.1	Revised
	MJ-3.2	Revised
	MJ-3.3	Revised
	MJ-3.4	Revised
	MJ-3.5	Revised in its entirety
	MJ-4	(1) New MJ-4.1 added, and remaining paragraphs redesignated (2) MJ-4.2 and MJ-4.3 revised
	Table MJ-6.3-1	Revised in its entirety
212	Table MJ-6.3-2	Revised in its entirety
213, 214	MJ-7.3.3	Subparagraph (b) revised
	MJ-8.1	Revised
	MJ-9.3	Revised
215	Table MJ-8.2-1	(1) Title and tenth row revised (2) Eleventh row added
216, 217	Table MJ-8.3-1	(1) Title and tenth and 18th rows revised (2) Eleventh row and Note (4) added
218, 219	Table MJ-8.4-1	Revised in its entirety
220	Fig. MJ-8.4-1	(1) Title and illustration (e) revised (2) Illustration (g) added
221	Fig. MJ-8.4-2	(1) Red circles added (2) Paragraph underneath figure revised
222	Fig. MJ-8.4-3	(1) Red circles added (2) Paragraph underneath figure revised
223	Fig. MJ-8.4-4	Title and General Note revised
224, 225	Table MJ-8.5-1	Revised in its entirety

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226	Fig. MJ-8.5-1	(1) Illustration (a) revised (2) Illustration (c) added
227	MJ-9.3.1	Revised
	MJ-9.3.2	Revised
	MJ-9.3.3	Revised
	MJ-9.4	Revised
228	MJ-9.6.3.2	Revised
	MJ-9.7.1	Subparagraph (d) revised
	MJ-9.8	Subparagraph (a) revised
229	Fig. MJ-9.7.1-1	Revised in its entirety
230	SF-2.4	Revised
231	Table SF-2.2-1	Last row deleted
232	Table SF-2.2-2	(1) Second row deleted (2) New second and current fifth rows revised
235	Chapter 6	Chapter designation added
	Part CR	Part title revised
251	D-4.2	Editorially revised
272	G-1	Revised
	G-3	Revised
276, 277	Table I-1.1-1	Definitions of VDRs 10, 11, and 13 revised
279–281	J-1.1	Revised
	J-1.2	Paragraph added
	J-1.2.1	Subparagraphs (b)(6), (d)(2), (e), and (f)(5) revised
	J-1.2.2	Added, and remaining paragraphs redesignated
	J-1.2.3.2	Revised
286	J-2.3	Last sentence editorially revised
290	K-5.2	Subparagraphs (a), (b), and (c) revised
291	Table K-3-1	General Note revised to Note (1)
296	N-1.1	Added
	N-2	Revised in its entirety

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297	O-1	(1) ICH Q3A updated (2) ISO 10993-18:2005(E), Part 5 added (3) Parenteral Drug Association, EDQM Council of Europe, BioProcess International, John Wiley & Sons, International Society for Pharmaceutical Engineering, and USP references added (4) NRI reference deleted
	O-2	Title revised
298	O-3	Title and subpara. (d) revised
	O-4	Added
299	Fig. O-4-1	Added
306–308	Nonmandatory Appendix S	Title revised
	S-1	(1) Title revised (2) S-1.1 designation added, and remaining paragraph redesignated
	S-2	Added
309	T-2	Subparagraph (c) revised
311, 312	Nonmandatory Appendix U	Added
313	Nonmandatory Appendix V	Added
315–328	Index	Updated

BIOPROCESSING EQUIPMENT

CHAPTER 1 INTRODUCTION, SCOPE, AND DEFINITIONS

(16)

Part GR General Requirements

GR-1 INTRODUCTION

The ASME Bioprocessing Equipment Standard was developed to aid in the design and construction of new fluid processing equipment used in the manufacture of biopharmaceuticals, where a defined level of purity and bioburden control is required.

The Standard typically applies to

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

The General Requirements Part states the scope of the ASME BPE Standard and provides references and definitions that apply throughout the document.

When operating under pressure conditions, systems shall be constructed in accordance with the ASME Boiler and Pressure Vessel Code (BPVC), Section VIII, and/or ASME B31.3 Process Piping Code or applicable local, national, or international codes or standards. The owner/user may stipulate additional or alternative specifications and requirements.

This Standard shall govern the design and construction of piping systems for hygienic service. For process piping systems designed and constructed in accordance with ASME B31.3, it is the owner's responsibility to select a fluid service category for each fluid service. Should any fluid service meet the definition of high-purity fluid service (ASME B31.3, Chapter X) it is recommended that such fluid service be selected and the requirements of this Standard and ASME B31.3, Chapter X be met.

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.

Items or requirements that are not specifically addressed in this Standard are not 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-2 SCOPE OF THE ASME BPE STANDARD

(16)

The ASME BPE Standard provides requirements for systems and components that are subject to cleaning and sanitization and/or sterilization including systems that are cleaned in place (CIP'd) and/or steamed in place (SIP'd) and/or other suitable processes used in the manufacturing of biopharmaceuticals. This Standard also provides requirements for single-use systems and components used in the above listed systems and components. This Standard may be used, in whole or in part, for other systems and components where bioburden risk is a concern.

This Standard applies to

- (a) new system (and component) design and fabrication
- (b) definition of system boundaries
- (c) specific metallic, polymeric, and elastomeric (e.g., seals and gaskets) materials of construction
- (d) component dimensions and tolerances
- (e) surface finishes
- (f) materials joining
- (g) examinations, inspections, and testing
- (h) certification

This Standard is intended to apply to new fabrication and construction. If the provisions of this Standard are optionally applied by an owner/user to existing, in-service equipment, other considerations may be necessary. For installations between new construction and an

existing, in-service system, such as a retrofit, modification, or repair, the boundaries and requirements must be agreed to among the owner/user, engineer, installation contractor, and inspection contractor.

For a system or component to be BPE-compliant, adherence to all applicable parts of this Standard is required.

GR-3 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-4 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-4.1 Inspector/Examiner

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

(a) *Pressure Vessels*. Authorized Inspector, as defined in ASME BPVC, Section VIII.

(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-8, meets the additional requirements listed in GR-4.2.

(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-4.2 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-4.2-1. It is required that a capability listed for a lower level of qualification is also required for subsequent higher levels of qualification.

GR-4.2.1 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-4.2.2 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-4.2-1

(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

Table GR-4.2-1 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 gauge	...	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 GR-5.3				
(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-4.2-1 Inspector's Delegate Capabilities (Cont'd)

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 and/or Welding Operator Performance Qualification				
Verify welder and/or welding operator performance 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

(-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 hr of relevant documented training (minimum total = 24 hr), including as a minimum the requirements shown in Table GR-4.2-1

(3) pass a written test and practical performance examination, including as a minimum the requirements shown in Table GR-4.2-1 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 hr of relevant documented training (minimum total = 40 hr), including as a minimum the requirements shown in Table GR-4.2-1

(3) pass a written test and practical performance examination, including as a minimum the requirements shown in Table GR-4.2-1 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 hr of relevant documented training, including as a minimum the requirements shown in Table GR-4.2-1 (minimum total = 80 hr)

(3) pass a written test and practical performance examination, including as a minimum the requirements shown in Table GR-4.2-1 for this level

GR-4.2.3 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-4.2-1

(b) training programs

(c) certification testing requirements

(d) eye examinations as follows:

(1) *Near Vision Acuity.* The individual shall have natural or corrected near distance acuity in at least one eye such that the individual is capable of reading a minimum of a Jaeger Number 2 or equivalent type and size letter at a distance designated on the chart but no less than 12 in. (305 mm). This test shall be administered initially and at least annually thereafter.

(2) *Color Contrast.* The individual shall demonstrate the capability of distinguishing and differentiating contrast among colors. This test shall be administered initially and, thereafter, at intervals not exceeding 3 yr.

These examinations shall be administered by an ophthalmologist, optometrist, medical doctor, registered nurse or nurse practitioner, certified physician assistant, or other ophthalmic medical personnel and shall include the state or province (or applicable jurisdictional) license number.

(e) certification documentation

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

GR-4.2.4 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 months of termination.

(c) The employee is being recertified within 6 months 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-4.3 Responsibilities

The responsibilities of inspection personnel are defined in GR-4.3.1 and GR-4.3.2.

GR-4.3.1 Pressure Vessels. The responsibilities of the owner's Inspector shall be the same as the inspector in ASME BPVC, Section VIII.

GR-4.3.2 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.

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.

GR-4.4 Access for Inspectors

Manufacturers of bioprocessing equipment and components shall allow free access to 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 are 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 to review all certifications and records necessary to satisfy the requirements of GR-5. The manufacturer shall provide the Inspector with work progress updates.

GR-5 DOCUMENTATION

GR-5.1 General

Documentation requirements shall be agreed to at the beginning of a design project and shall be made 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/contractor.

(16) GR-5.2 Document Requirements

Material Test Reports (MTRs) for all metallic process components shall be verified to be in compliance with the applicable specification. Certificates of Compliance (C of Cs) for all polymeric and other nonmetallic process components shall be provided. In addition, the following documentation shall be provided to the owner/user or their designee.

GR-5.2.1 General List of Documents

GR-5.2.1.1 Metallic Materials

(16) GR-5.2.1.1.1 Turnover Package Documentation.

Documentation required for cGMP-validated distribution systems, including the vessels, tubing systems on modules, super skids, skids, the shop or field fabrication of tubing, etc., includes the following:

(a) Materials Documentation

- (1) Material Test Reports
- (2) Certificates of Compliance
- (3) Material Examination Logs
- (4) Identification of the filler metal or consumable insert used

(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/Parameters (WPS/P)

- (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/user's representative prior to welding

- (7) Inspector qualifications

(8) documentation of the approval of para. GR-5.2.1.1.1(b)(7) by the owner/user 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) spray device coverage 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 that must be identified, documented, and fully traceable to the installed system

- (11) surface finish C of Cs

- (12) NDE (nondestructive examination) reports

(e) System/Equipment

- (1) standard operating and maintenance procedures and manuals
- (2) installation procedures
- (3) piping and instrumentation diagrams
- (4) detail mechanical drawings and layouts
- (5) technical specification sheets of components and instrumentation
- (6) original equipment manufacturer's data
- (7) manufacturer's data and test reports
- (8) any documentation that is specifically needed for the owner/user's qualification of a system

GR-5.2.1.1.2 Technical support information to support the design, operation, and maintenance of equipment may include, but is not limited to, the following:

- (a) material handling procedures
- (b) mechanical and electropolishing procedures
- (c) shop passivation procedures

GR-5.3 Material Test Reports/Certificates of Compliance

- (16) **GR-5.3.1 Metallic Materials.** The combination of documents, including C of Cs and MTRs, for all valves and fittings having process contact surfaces shall include the following information, as a minimum:

- (a) ASME BPE Standard, including year date
- (b) material type
- (c) heat number or code traceable to the original heat
- (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

MTRs for other components made to a material specification shall contain the minimum information specified by the material specification incorporated by reference.

GR-5.3.2 Polymeric and Other Nonmetallic Material Components. The manufacturer of polymeric and other nonmetallic components shall issue a Certificate of Compliance that the components meet requirements as shown in Table PM-2.2.1-1.

- (16) **GR-5.3.2.1 Seal Documentation.** Seal manufacturers shall provide, upon owner/user request, documentation (test report) of the USP <88> Biological Reactivity Test In Vivo, Class VI and the USP <87> Biological Reactivity Test In Vitro testing on final manufactured seals.

A Certificate of Compliance shall be issued by the seal manufacturer to certify compliance to this Standard when required by the owner/user. The Certificate of Compliance shall contain the information listed in Table PM-2.2.1-1. Additional agreements may be required.

GR-5.3.2.2 Sealed Unions. The seal manufacturer shall provide, upon request of the owner/user, a certificate of design conformance that the sealed union meets the intrusion requirements of SG-4.2.

GR-5.3.3 Electropolishing. The electropolishing vendor, if requested by the owner/user, shall provide a Certificate of Compliance with each type of component(s) that shall include, but is not limited to, the following:

- (a) vendor's company
- (b) owner/user's name
- (c) description of component(s)
- (d) identification of the electropolishing procedure used
- (e) final surface finish report (R_a if required by the owner/user)

GR-5.3.4 Passivation. The passivation provider shall supply a Certificate of Compliance for each system or set (type) of component(s) that shall include, but not be limited to, the following:

- (a) owner/user's name
- (b) description of system or component(s)
- (c) service provider's 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) postpassivation verification method(s) used
- (g) for material manufacturers/suppliers of components whose surfaces have been electropolished and/or passivated, a Certificate of Compliance for Passivation and/or Electropolishing stating that standard industry practices, such as ASTM A967 or ASTM B912, 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.

GR-5.4 Weld and Examination/Inspection Log (16)

The results of the welding, examination, and inspection shall be recorded on a Weld and Examination/Inspection 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/supplier, installing contractor, inspection contractor, and owner/user as long as all required information is included or referenced. Form WEL-1 (see Nonmandatory Appendix B) has been provided as a guide for the Weld and Examination/Inspection Log. This form includes the required data plus some other information that is not required. The minimum requirements are as follows:

- (a) isometric drawing number (including revision number)
- (b) weld number
- (c) date welded
- (d) welder and/or 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

In addition, heat numbers (or other identification system for material traceability) and slope shall be recorded on the Weld and Examination/Inspection Log, an isometric drawing, or other owner/user-approved document.

GR-5.5 Records Retention

GR-5.5.1 Vessel Documentation. For all Bioprocessing ASME Code-stamped vessels, National Board registration is recommended to maintain vessel data on file. 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.

GR-5.5.2 Welding Documentation

(a) *Piping and Tubing.* Records and retention of records associated with piping and tubing shall be in accordance with ASME B31.3.

(b) *Pressure Vessels and Tanks.* Records and retention of records for code vessels shall be in accordance with ASME BPVC, Section VIII.

GR-6 U.S. CUSTOMARY AND SI UNITS

This Standard uses standard units listed in Mandatory Appendix II. Nonmandatory Appendix T has been provided as a guide for U.S. Customary and SI unit conversion.

(16) GR-7 REFERENCES

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

3-A, Sanitary Standards

Publisher: 3-A Sanitary Standards, Inc., 6888 Elm Street, Suite 2D, McLean, VA 22101 (www.3-a.org)

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

ANSI/AWS QC1, Standard for AWS Certification of Welding Inspectors

AWS B2.4, Specification for Welding Procedure and Performance Qualification for Thermoplastics

AWS G1.10M, Guide for the Evaluation of Hot Gas, Hot Gas Extrusion, and Heated Tool Butt Thermoplastic Welds

Publisher: American Welding Society (AWS), 8669 NW 36 Street, No. 130, Miami, FL 33166 (www.aws.org)

ASME B31.3, Process Piping

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

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

ASME Boiler and Pressure Vessel Code, Section VIII, Rules for Construction of Pressure Vessels

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

ASME PTC 19.3 TW, Thermowells

ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy

Publisher: The American Society of Mechanical Engineers (ASME), Two Park Avenue, New York, NY 10016-5990 (www.asme.org)

Material specifications for metallic materials are listed by product form in Part MM.

ASTM A380, Practice for Cleaning, Descaling, and Passivation of Stainless Steel Parts, Equipment, and Systems

ASTM A967, Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts

ASTM B912, Standard Specification for Passivation of Stainless Steels Using Electropolishing

ASTM D395, Standard Test Methods for Rubber Property — Compression Set

ASTM D412, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension

ASTM D471, Standard Test Method for Rubber Property — Effect of Liquids

ASTM D624, Standard Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers

ASTM D2240, Standard Test Method for Rubber Property — Durometer Hardness

ASTM D2657, Standard Practice for Heat Fusion Joining of Polyolefin Pipe and Fittings

ASTM E112, Test Methods for Determining Average Grain Size

ASTM E220, Standard Test Method for Calibration of Thermocouples by Comparison Techniques

ASTM E230/E230M, Standard Specification and Temperature-Electromotive Force (emf) Tables for Standardized Thermocouples

ASTM E644, Standard Test Methods for Testing Industrial Resistance Thermometers

ASTM E1137/E1137M, Standard Specification for Industrial Platinum Resistance Thermometers

ASTM E2500, Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment

Publisher: American Society for Testing and Materials (ASTM International), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959 (www.astm.org)

DVS 2202-1, Imperfections in Thermoplastic Welding Joints; Features, Descriptions, Evaluation

Publisher: DVS-Verlag GmbH (German Welding Society), Aachener Strasse 172, D-40223 Dusseldorf, Germany (dnb.ddb.de)

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

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

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 (FDA), 10903 New Hampshire Avenue, Silver Spring, MD 20993 (www.fda.gov)

IEC 60751, Industrial Platinum Resistance Thermometers and Platinum Temperature Sensors

Publisher: International Electrotechnical Commission (IEC), 3, rue de Varembe, Case Postale 131, CH-1211 Geneva 20, Switzerland/Suisse (www.iec.ch)

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

ISO 34-2, Rubber, vulcanized or thermoplastic — Determination 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 — Determination 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 10993, Biological evaluation of medical devices

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), Central Secretariat, Chemin de Blandonnet 8, Case Postale 401, 1214 Vernier, Geneva, Switzerland (www.iso.org)

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 (www.ispe.org)

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

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

Recommended Practice (RP) No. SNT-TC-1A, Personnel Qualification and Certification in Nondestructive Testing

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

United States Pharmacopeia and National Formulary (USP-NF)

Publisher: U.S. Pharmacopeia Convention (USP), 12601 Twinbrook Parkway, Rockville, MD 20852-1790 (http://www.usp.org/usp-nf)

GR-8 TERMS AND DEFINITIONS

(16)

annealing: a treatment process for steel for 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 fillet weld: a fillet weld that is produced without the addition of filler metal. (See also *seal weld*.)

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: pharmaceuticals manufactured by biotechnology methods, with the products having biological sources, usually involving live organisms or their active components. Biopharmaceuticals generally include recombinant proteins, (monoclonal) antibodies, vaccines, blood/plasma-derived products, nonrecombinant culture-derived proteins, and cultured cells and tissues.

bioprocess: technique or operation used in the manufacture and/or purification of biopharmaceuticals or other biological materials, such as products derived from microbial fermentation (e.g., yeast, mold, bacteria), cell culture (e.g., insect, mammalian, plant), tissue culture, blood, or milk fractionation.

bioprocessing: see *bioprocess*.

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

blind weld: a weld joint by design that cannot feasibly be visually inspected internally.

blister (polymeric): a localized imperfection on a polymer surface, containing a pocket of fluid.

blistering (metallic): a localized delamination within the metal that has an appearance of chipped or flaked-off areas. Per SEMI F019-0304, section 4.2.1.

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

break: a discontinuity in the face of a fitting.

buffing: a metal finishing process for smoothing the surface using a grease-suspended abrasive.

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 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.

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.

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: a condition achieved by removal of dirt, residues, detergents, or other surface contaminants.

cleaning: operations by which dirt, residues, detergents, or other surface contaminants are removed to achieve predetermined surface attributes.

clean-in-place (CIP): cleaning of process contact surfaces of a system or component without disassembly beyond the removal of single-use components.

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: purported 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 D395.

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.

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 D2240.

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

dynamic spray device: a moving device, designed to produce a nonstationary spray pattern.

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.

end grain effect: a surface discontinuity of small diameter (or linear) cavities located perpendicular to the rolling direction of the material and appearing after electropolishing.

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*.)

expiration date: the date after which the shelf life has been exceeded.

extractables (polymeric): chemicals that can be removed from polymeric articles using appropriate solvents.

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

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

finishing marks: any surface texture or pattern resulting from cutting, machining, forming, grinding, polishing, and/or other finishing methods.

fixture marks: an area on an electropolished component where the electrical connection was made for the processing of the component.

flash electropolish: an electrochemical process done for a very short duration of time with a low current density, which neither significantly alters the surface of the material nor meets the acceptance criteria as set forth in Table H-3.3-1 in Nonmandatory Appendix H of this Standard.

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

flushing (rinsing): the flowing of water over the process 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*.)

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

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.

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

grain boundary: an interface separating two grains, where the orientation of the lattice structure changes from that of one grain to that of the other. Per SEMI F019-0304, section 4.8.2.

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

haze: a localized diminished surface brightness, commonly produced by gassing or air pockets, during electropolishing.

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

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

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.

holdup 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 process contact surface.

hygienic joint: a tube outside diameter union providing a nonprotruding, recessless process 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.

leachables (polymeric): typically a subset of extractables, these chemicals migrate from polymeric articles into the product or process fluid.

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.

luster: the state or quality of shining by reflecting light. (See also *variance in luster*.)

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 manufacturer: an organization responsible for the production of products meeting the requirements of the material specification(s).

Material Test Report (mill test report or MTR): a document in which the results of tests, examinations, repairs, or treatments required by the material specification to be reported are recorded. This document includes those of any supplementary requirements or other requirements stated in the order for the material. This document may be combined with a Certificate of Compliance as a single document. When preparing a Material Test Report, a material manufacturer may transcribe data produced by other organizations, provided he accepts responsibility for the accuracy and authenticity of the data.

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 polishing: a process by which abrasive media is applied to a surface until the specified surface roughness (R_a) is achieved.

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 (1 μ) or micrometer (1 μ m): 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.

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

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

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.

nonsliding seal: a seal that does not have transverse or rotational movement between the seal and mating surface(s).

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: large-featured, roughened type of surface visible to the unaided eye whose surface appearance pattern is like that of an orange peel.

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 island: a concentration of nonmetallic impurities (often oxides or nitrides) that may form in the weld pool and solidify on the underbead or weld top surface.

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*, and *joint penetration*.

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

PFA: perfluoroalkoxy, copolymer of tetrafluoroethylene and perfluorovinyl ether.

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 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.

process component: a component that contacts the product or process fluid. Process components include, but are not limited to, piping, fittings, gaskets, vessels, valves, pumps, filter housings, and instruments.

process contact surface: a surface under design operating conditions that is in contact with, or has the potential to be in contact with, raw materials, in-process materials, APIs, clean utilities (e.g., WFI, CIP, pure steam, process gases), or components (e.g., stoppers) and where there is a potential for the surface to affect product safety, quality, identity, strength, or purity.

product contact surface: a process contact surface that is in contact with, or has the potential to be in contact with, a product where product is defined by the owner/user. Examples of product contact surfaces may include the interior surfaces of bioreactors, transfer tubing, chromatography columns, vessels, and recirculating segments of CIP systems.

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 that, 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.

$R_a \text{ max.}$: 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 that tends to migrate downstream from its origination point and can deposit on process contact surfaces. 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 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, Fe_3O_4).

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 I.D., 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.

scratch: an elongated mark or groove cut in the surface by mechanical means, not associated with the predominant surface texture pattern.

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. (See also *autogenous fillet weld*.)

seat leakage: a quantity of test fluid passing through an assembled valve in the closed position under the defined test conditions.

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.

shelf life: the duration, under specified storage conditions, from the date of manufacture to the last date the product can be placed in service without having an unacceptable effect on performance.

shell leakage: a quantity of test fluid passing from the inside of a component externally to atmosphere under the defined test conditions.

significant change (polymeric): a change that may affect form, fit, or function.

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 nonmetallic product resulting from the mutual dissolution of flux and nonmetallic impurities in some welding and brazing operations.

sliding seal: a seal that has transverse or rotational movement between the seal and mating surface(s).

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.

spot electropolishing: a localized electrochemical process that is capable of producing the correct Cr to Fe ratios on the surface of a material and meeting the requirements of Table H-3.3-1 in Nonmandatory Appendix H.

spray device: device for the directed distribution (delivery) of liquids to defined process contact surfaces of equipment. (See also *static spray device* and *dynamic spray device*.)

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

squareness: face-to-face perpendicularity.

static seal: a stationary sealing device.

static spray device: a stationary device, designed to produce a fixed directional spray pattern.

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.

stringer indication: a linear void resulting from the removal of an elongated nonmetallic inclusion or secondary phase.

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

superaustenitic 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 expressed in R_a inches or meters.

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 (e.g., 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.

tack weld: a weld made to hold parts of a weldment in proper alignment until the final welds are made.

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.

variance in luster: the appearance of a different shine or reflectivity resulting from the examination or inspection technique or from the preconditioning or conditioning of the electropolished surface.

waviness: undulations or rippling of the surfaces.

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

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

weld whitening: a difference in appearance of grain structure between weld metal and base metal after electropolishing.

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

(16)

CHAPTER 2 DESIGN

Part SD Systems Design

SD-1 PURPOSE AND SCOPE

The purpose of Part SD is to establish design guidelines applicable to bioprocessing equipment. Wherever “equipment” is stated in this Part, it shall mean all bioprocessing equipment, components, assemblies, and systems.

The purpose of this Part is to provide requirements for the specification, design, fabrication, and verification of process equipment and systems that are fit for intended use, and to minimize risk to the product. Part SD also provides design guidelines that should be applied at the discretion of the owner/user on the basis of assessed risk to the product. Figures in this Part are intended to illustrate accepted applications of general design principles and are not intended to limit alternate designs.

The scope of Part SD encompasses requirements for equipment, process systems, and utilities that could potentially impact product quality. Specific guidance is provided for bioburden control in manufacturing processes, including design requirements for cleaning, sanitization, and/or sterilization of bioprocess systems.

(16) SD-2 GENERAL GUIDELINES

All equipment and/or systems shall be designed according to 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 and/or system.

Following installation, process contact liquid-service systems should be flushed with deionized or better-quality water and/or chemically cleaned, per owner’s requirements, before being placed into service. This does not apply to single-use or precleaned components.

SD-2.1 Containment

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

The owner/user shall determine the containment level for the particular type of equipment or system, in accordance with the Centers for Disease Control and Prevention (CDC) and guidelines of the National Institutes of Health (NIH) or directives of the European Union and other applicable local codes or environmental regulations.

SD-2.2 Bioburden Control

[Reserved for future content]

SD-2.3 Bioburden Reduction

[Reserved for future content]

SD-2.3.1 Thermal Sanitization. [Reserved for future content]

SD-2.3.1.1 Steam-in-Place. Equipment parts and components subjected to SIP should be designed and constructed to withstand continuous exposure to saturated steam at a minimum temperature of 266°F (130°C; representing 24 psig/1.65 bar under saturated steam conditions) for a duration of at least 100 hr under continuous steady-state conditions. All process contact surfaces subjected to SIP shall reach the required temperatures, under the required saturated steam pressure conditions, during the SIP cycle. Executing SIP operations at temperatures exceeding 266°F (130°C) may cause degradation of elastomers and/or damage to other components, resulting in reduction of overall equipment life. SIP conditions that are more stringent may be imposed by the owner/user. The use of elastomers (within a piece of equipment or certain process instrumentation) that could thermally degrade during SIP shall be evaluated by the owner/user or manufacturer. (16)

SD-2.3.1.2 Depyrogenation. [Reserved for future content]

SD-2.3.2 Chemical Sanitization. [Reserved for future content]

SD-2.4 Fabrication

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

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.

Any process 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-2.4.1 Materials of Construction

SD-2.4.1.1 General. Generally, materials such as stainless steels, duplex stainless steels (e.g., 316-type and 316L-type alloys), 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. Metallic materials of construction are listed in Part MM.

When nonmetallic materials are used (e.g., polymeric materials or adhesives), the owner/user 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). Polymeric materials and other nonmetallic materials of construction are listed in Part PM.

(16) SD-2.4.1.2 Process Compatibility

(a) Materials of construction shall be capable of withstanding the temperature, pressure, and chemical corrosiveness of the process.

(b) Materials shall be compatible with the stated bioprocessing conditions, cleaning solutions, and SIP conditions, etc., as specified by the owner/user.

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

- (1) homogeneous in nature
- (2) impervious
- (3) inert
- (4) nonabsorbent
- (5) nontoxic
- (6) insoluble by process or cleaning fluids
- (7) resistant to corrosion, scratching, scoring, and distortion

(d) Materials that are in contact with bioprocessing fluids shall be identified by an industry-recognized standard (see para. MM-4).

SD-2.4.1.3 Surface Coatings. 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.

SD-2.4.1.4 Transparent Materials

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

(b) Internally coated glass shall only be used if the coating complies with FDA regulations or another regulatory authority's regulations and is approved by the owner/user.

SD-2.4.2 Cleanability

(a) The following provisions are applicable to tubing, equipment, or systems intended to be cleaned:

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

(2) All surfaces shall be accessible to the cleaning solutions and shall be accessible to establish and determine efficacy of the cleaning protocol.

(3) 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.

(4) 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.

(b) The following provisions are applicable to tubing, equipment, or systems intended to be cleaned in place:

(1) Internal horizontal surfaces should be minimized.

(2) The equipment shall be drainable and free of areas where liquids may be retained and where soil or contaminants could collect. The equipment shall be free of areas of low flow and velocity or impact where soil or contaminants could collect.

(3) Design of corners and radii should meet the following requirements: All internal angles of 135 deg or less on 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

Table SD-2.4.3.1-1 Slope Designations for Gravity-Drained Lines

Slope Designation	Minimum Slope, in./ft	Minimum Slope, mm/m	Minimum Slope, %	Minimum Slope, deg
GSD1	$\frac{1}{16}$	5	0.5	0.29
GSD2	$\frac{1}{8}$	10	1.0	0.57
GSD3	$\frac{1}{4}$	20	2.0	1.15
GSD0	Line slope not required			

sealing surfaces and flow control apertures, the surfaces of these internal angles shall be readily accessible for cleaning and examination.

SD-2.4.3 Drainability

- (16) **SD-2.4.3.1 General.** For the purpose of bioburden control 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-2.4.3.1-1. 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 the owner/user) that are level or have a positive slope less than the slope designation are acceptable if the section is fitting-bound.

SD-2.4.3.2 Drainability Design Considerations.

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

(a) Process contact lines exposed to liquid should be sloped to minimize pooling 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-2.4.3.3 Slope Considerations. The recommended minimum slope designation for gravity-drained process contact lines is GSD2.

SD-2.4.3.4 Drain Points

(a) 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 owner/user shall ensure that proper orientation is achieved.

(b) Systems or equipment that cannot be gravity-drained shall use forced expulsion with pressurized gas where line drainability is required.

SD-2.4.4 Miscellaneous Design Details

SD-2.4.4.1 Lubricants

(16)

(a) Grease and other lubricating fluids that are used in gearboxes, 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.).

(b) 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.

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

SD-2.4.4.2 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 polymeric material, and should have minimal 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 enclosures and conduit should be cleanable and use materials of construction that are compatible with cleaning agents.

(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-2.4.4.3 Surface Finishes. The finishes of process contact surfaces shall be specified by the owner/user in accordance with the definitions of Part SF in this Standard.

SD-3 PROCESS COMPONENTS

SD-3.1 Connections, Fittings, and Piping

SD-3.1.1 General

(a) Design of equipment should minimize the number of connections. Butt-welded connections should be used wherever practical.

(b) Connections to equipment shall use acceptable hygienic design connections, mutually agreeable to the owner/user and manufacturer.

(c) 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. ASME raised-face or flat-face flanged joints should be avoided where possible (see Fig. SD-3.1.1-1).

(d) 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.

(e) All process contact fittings exposed to liquid should be self-draining when properly installed.

(f) Threaded fittings, exposed to process fluid, are not recommended (see Fig. SG-2.2.2-5).

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

(h) The centerline radius of factory-bent tubes shall be in accordance with Table DT-3-1, CLR(R).

(i) Piping systems described in Part SD refer to hygienic tubing systems. Caution should be exercised

if using pipe (instead of tube) to ensure that the requirements of this Standard are met. The requirements of hygienic tubing (e.g., surface finish, dimensions, and tolerances) are not typically met by pipe.

SD-3.1.2 System Design

SD-3.1.2.1 General

(a) Product holdup volume in the system should be minimized.

(b) Bioprocessing piping and tubing design should have routing and location priority over process and mechanical support systems.

(c) 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 use welded connections except where make-break connections are necessary.

SD-3.1.2.2 Dead Legs. 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-3.1.2.2-1 and SD-3.1.2.2-2 indicate L/D values based on the BPE definition for various tubing geometries and configurations.

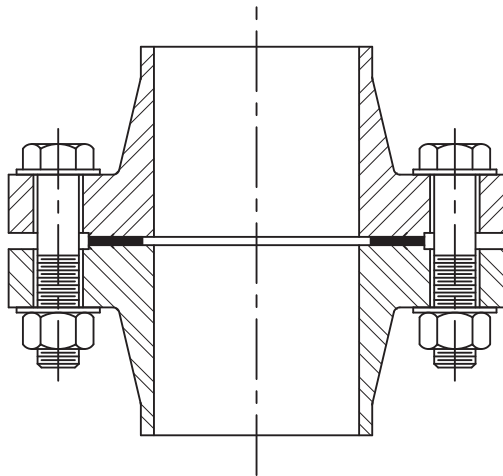
There is evidence that an L/D of 2 or less may prevent the branch from being a dead leg; however, the size and shape of the branch are also important in determining if the branch could lead to contamination. With sufficient flow through a primary pipeline, a branch may not constitute a dead leg.

The orientation of a branch is critical to the cleanability of the system. The branch shall be oriented to avoid a dead leg (e.g., a vertical branch with an L/D of 2 or less may still result in a dead leg with trapped gas or residual materials).

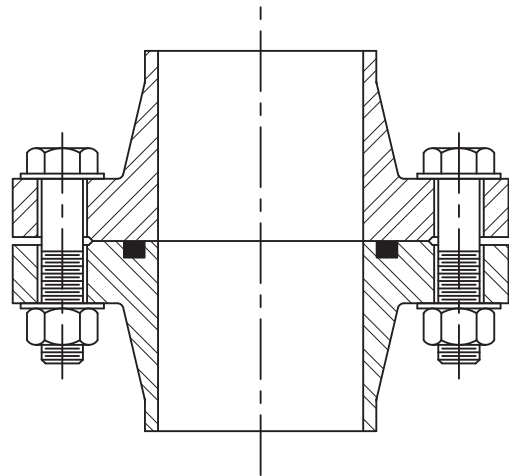
For high-purity water systems, an L/D of 2 or less is attainable with today's manufacturing and design technology. For other bioprocessing systems, such as purification, filtration, and fermentation having cluster, block, and multiport valves, an L/D of 2 or less is achievable. However, it may not be achievable with certain equipment and process configurations as they are currently manufactured. An L/D of 2 or less is recommended but shall not be construed to be an absolute requirement. The system designer and manufacturer shall make every attempt to eliminate system branches with an L/D greater than 2. It will be the responsibility of the system manufacturer or designer to identify where exceptions exist or where the L/D of 2 or less cannot be met.

An L/D of 2 or less 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-3.1.2.2-1, illustrations (a), (d), (e), (f), and (g).

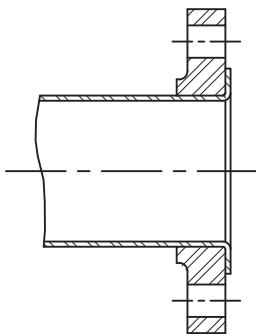
Fig. SD-3.1.1-1 Flat Gasket Applications



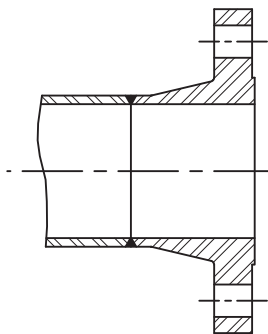
(a) Flange With Flat Gasket



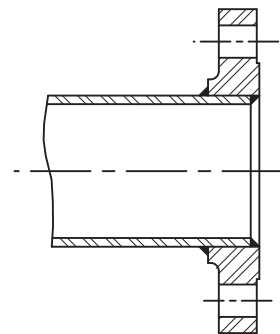
(b) Flange With O-Ring



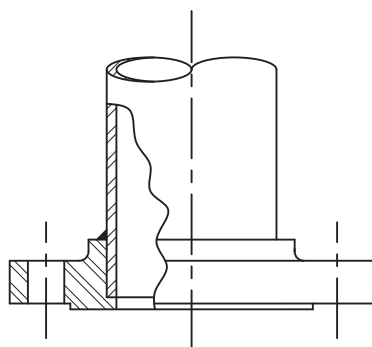
(c) Stub-End / Lap Joint



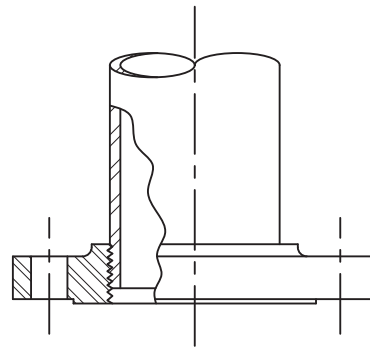
(d) Weld Neck



(e) Slip On

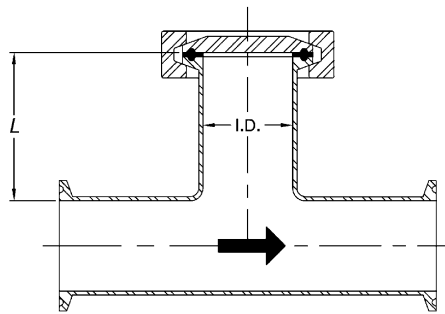


(f) Socket Weld



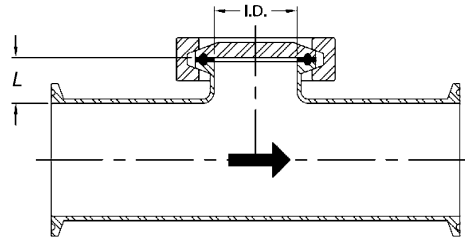
(g) Threaded

Table SD-3.1.2.2-1 L/D Dimensions for Flow-Through Tee: Full-Size Standard Straight Tee With Blind Cap



Nominal Size, in.	Wall Thickness	I.D. (D)	Branch, L	L/D (Branch)
$\frac{1}{4}$	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-3.1.2.2-2 L/D Dimensions for Flow-Through Tee:
Short-Outlet Reducing Tee With Blind Cap**

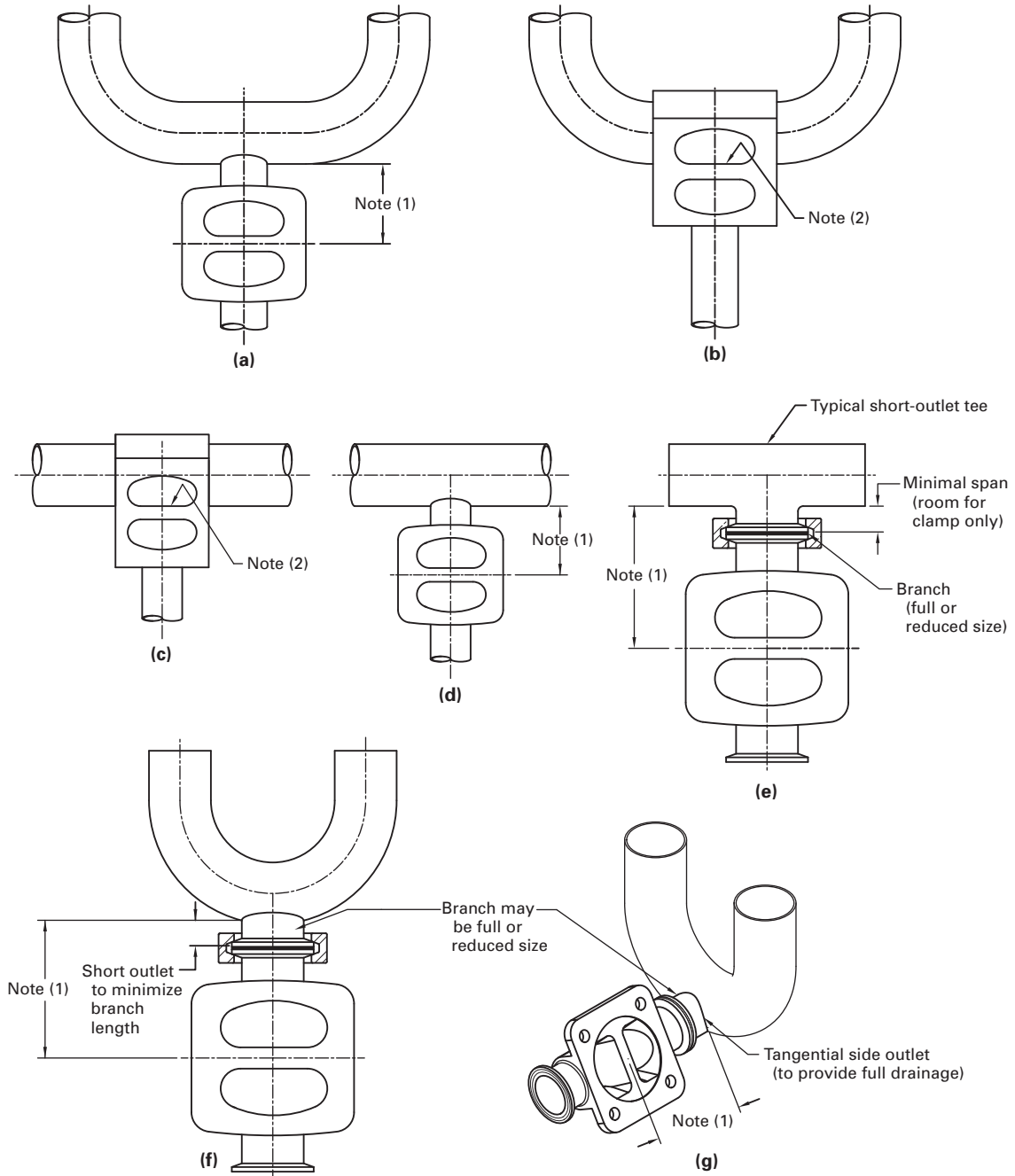


Nominal Tee Size, in.	Nominal Branch Size, in.	Tee Wall Thickness	Branch Wall Thickness	Branch I.D., D	Branch, L	L/D (Branch)
$\frac{3}{8}$	$\frac{1}{4}$	0.035	0.035	0.180	0.85	4.71
$\frac{1}{2}$	$\frac{1}{4}$	0.065	0.035	0.180	0.82	4.53
$\frac{1}{2}$	$\frac{3}{8}$	0.065	0.035	0.305	0.82	2.67
$\frac{3}{4}$	$\frac{1}{4}$	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
3	$1\frac{1}{2}$	0.065	0.065	1.370	0.69	0.50
3	2	0.065	0.065	1.870	0.69	0.37
3	$2\frac{1}{2}$	0.065	0.065	2.370	0.69	0.29

**Table SD-3.1.2.2-2 L/D Dimensions for Flow-Through Tee:
Short-Outlet Reducing Tee With Blind Cap (Cont'd)**

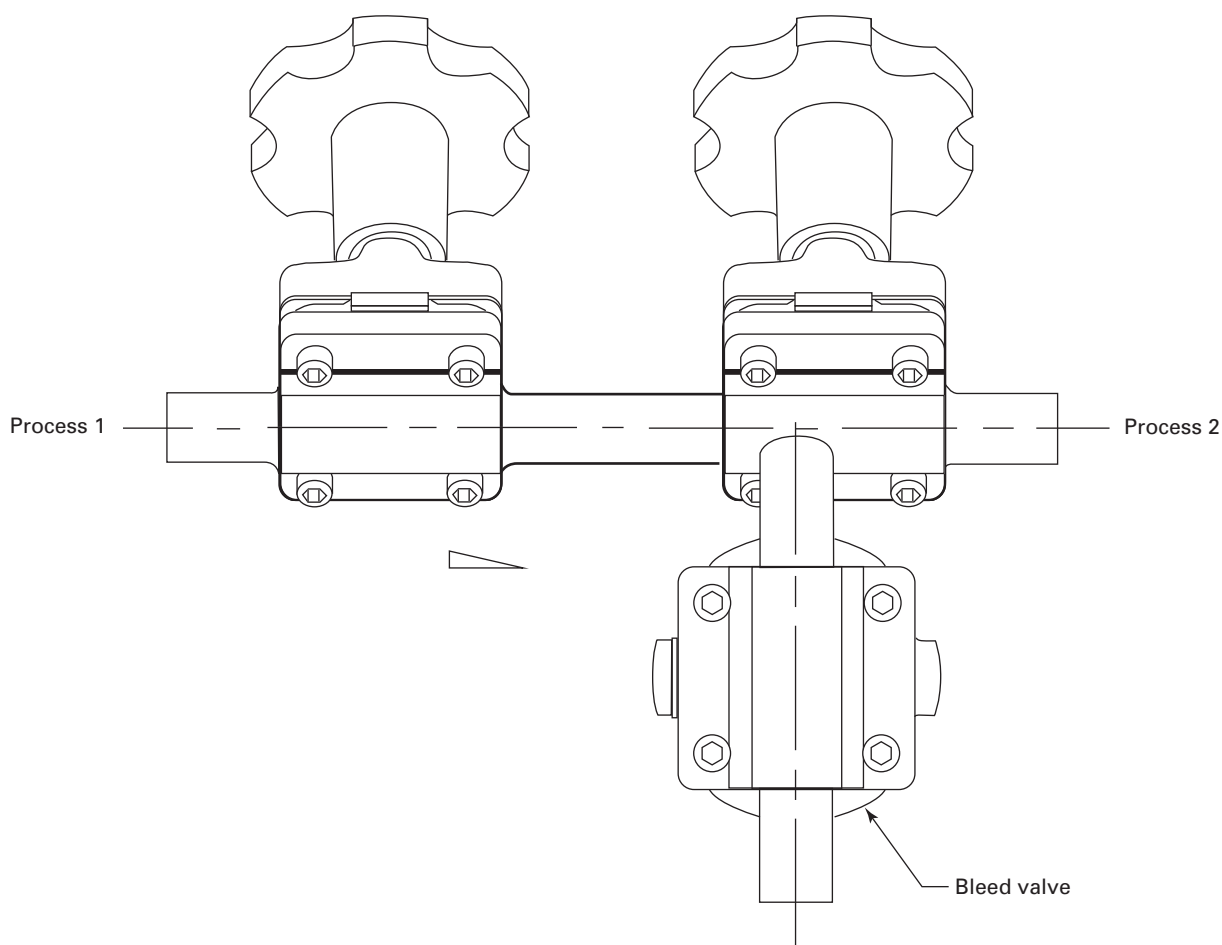
Nominal Tee Size, in.	Nominal Branch Size, in.	Tee Wall Thickness	Branch Wall Thickness	Branch I.D., D	Branch, L	L/D (Branch)
4	$\frac{1}{4}$	0.083	0.035	0.180	0.71	3.93
4	$\frac{3}{8}$	0.083	0.035	0.305	0.71	2.32
4	$\frac{1}{2}$	0.083	0.065	0.370	0.71	1.91
4	$\frac{3}{4}$	0.083	0.065	0.620	0.71	1.14
4	1	0.083	0.065	0.870	0.71	0.81
4	$1\frac{1}{2}$	0.083	0.065	1.370	0.71	0.52
4	2	0.083	0.065	1.870	0.71	0.38
4	$2\frac{1}{2}$	0.083	0.065	2.370	0.71	0.30
4	3	0.083	0.065	2.870	0.71	0.25
6	$\frac{1}{4}$	0.109	0.035	0.180	0.86	4.77
6	$\frac{3}{8}$	0.109	0.035	0.305	0.86	2.82
6	$\frac{1}{2}$	0.109	0.065	0.370	0.86	2.32
6	$\frac{3}{4}$	0.109	0.065	0.620	0.86	1.39
6	1	0.109	0.065	0.870	0.86	0.99
6	$1\frac{1}{2}$	0.109	0.065	1.370	0.86	0.63
6	2	0.109	0.065	1.870	0.86	0.46
6	$2\frac{1}{2}$	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

Fig. SD-3.1.2.2-1 Accepted Point-of-Use Designs



NOTES:

- (1) L/D of 2 or less.
- (2) $L/D = 0$ (preferred).

Fig. SD-3.1.2.3-1 Double Block-and-Bleed Valve Assembly

For the header and valve size combinations where the L/D of 2 cannot be met using these configurations, a specific isolation valve design, as shown in Fig. SD-3.1.2.2-1, illustrations (b) and (c), may be required to achieve the desired ratio.

(16) SD-3.1.2.3 System Piping

(a) 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.

(b) Cross-contamination of process streams shall be physically prevented. Methods of separation used in industry are

- (1) removable spool piece
- (2) U-bend transfer panel
- (3) double block-and-bleed valve system (see Fig. SD-3.1.2.3-1)
- (4) mix-proof valving

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

(d) The use of redundant in-line equipment is not recommended due to the potential creation of dead legs.

(e) Eccentric reducers shall be used in horizontal piping to eliminate pockets in the system.

(f) The system shall be designed to eliminate air pockets and prevent or minimize air entrainment.

(g) Field bending of tubing is permitted for diameters up to and including $\frac{1}{2}$ in. (15 mm). The centerline radius of field-bent tubes should be not less than 2.5 times the nominal tube diameter to mitigate the risk of interior surface damage (e.g., wrinkles, striations, and cracks). Field bending of tubing in larger diameters or smaller bend radii may be used with the approval of the owner/user when appropriate inspection techniques and procedures (e.g., visual, borescope, and sectioning) are used.

(h) Ball valves are not recommended in fluid hygienic piping systems. See SD-4.2.3(b) for further comments.

(i) Process contact surfaces of austenitic stainless steel, except those covered by section SD-4.3.1, should be passivated before being placed in service. Specific passivation requirements shall be defined in the engineering design documents and/or specifications and shall be in accordance with SF-2.6. Passivation of electropolished surfaces is not required unless the surface has

been altered (e.g., welded or mechanically polished) or exposed to external contamination after electropolishing.

(j) The use of blind welds in piping systems should be avoided. Proper installation sequencing of the piping system can reduce the number of blind welds. See MJ-7.3.3(b) and GR-5.3.4 for further details.

SD-3.1.2.4 Hygienic Support Systems

(a) Hygienic supports should be used within classified spaces. Hygienic support design should incorporate drainable geometry to facilitate cleanability, have no exposed threads, and have minimal potential for collecting and trapping debris or liquids on the hanger. Materials of construction shall be corrosion resistant and compatible with the chemical, thermal, and physical performance requirements of the installed location. The materials shall have adequate strength and durability to withstand the application of continuous and/or cyclic thermal exposure that may be encountered in the designed service.

(b) The piping should maintain proper continuous slope for drainability. Hygienic support systems shall assist in maintaining the required slope and alignment under all operating conditions, taking into account thermal cycling, distortion, settling, moment loads, fluid specific gravity, etc. The support system should be designed to distribute loads and stresses from any potential movement. The supports shall be installed without adding stress to the tube or pipe in an attempt to achieve a desired slope.

(c) The support systems shall provide for, and control, the intended movement of the system. The designer should take into account system and equipment movement when planning the design. Anchoring systems should be designed to avoid piping motion in any of the three Cartesian axes. Guiding systems should be designed to allow piping axial motion due to thermal or mechanical loads. An anchor serves to secure the piping in place, and a guide will allow axial motion of the piping and is used to allow for thermal expansion.

(d) Supports/hangers should be installed close to each change in direction of piping. The only exception is on short subassemblies using small-diameter tube (<1.000 in. O.D.) that is installed in a drainable position and does not bear any additional weights or loads from other process equipment. Hangers shall be of adequate strength and durability to withstand the imposed loads per MSS SP-58, Table 1. Per manufacturer's recommendations, supports/hangers should be installed as close as possible to (and on both sides of, if possible) concentrated loads including valves, instrumentation, and filter housings.

SD-3.1.2.4.1 Pipe Hangers and Supports for Metallic Piping. Metallic piping system hangers and supports shall be installed in compliance with MSS SP-58, MSS SP-69, MSS SP-89, and ASME B31.3

standards. The metallic pipe or tube to be installed shall meet the straightness criteria of ASTM A1016 to optimize drainability. The support spacing shall not exceed a distance that will permit the piping to deflect under operating conditions.

SD-3.1.2.4.2 Pipe Hangers and Supports for Nonmetallic Piping

(a) Nonmetallic piping system hangers and supports shall be engineered based on the specific materials selected. When properly installed, stress concentration points will be minimized. Considerations shall be made to ensure drainability and overcome any deflection, such that pooling is minimized. Refer to manufacturer's recommendations for spacing, which is based on calculations that take into consideration the piping material, density, modulus of elasticity, diameter and wall thickness of the pipe, specific gravity of the fluids being transported, operating temperature, and thermal expansion properties.

(b) The requirement of a continuous support shall be determined based on the operating temperatures and the specific gravity of the process fluid being transported. Support channels may be available in a "V" or "U" section and shall be manufactured with no sharp edges that may embed or cause damage to the pipe exterior. These are commonly available in stainless steel or fiberglass reinforced plastic (FRP) materials. These supports cannot restrict axial movement of the piping and shall be approved by the owner/user.

SD-3.2 Hose Assemblies

SD-3.2.1 General

(a) Permanently installed hose assemblies shall be installed and supported to be self-draining [see Fig. SD-3.2.1-1, illustrations (a) and (b)]. In temporary runs, hose assemblies may be manually drained after disconnecting.

(b) Hose assemblies shall be installed to avoid strain on end connections. Hose assemblies shall not be used as a 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.

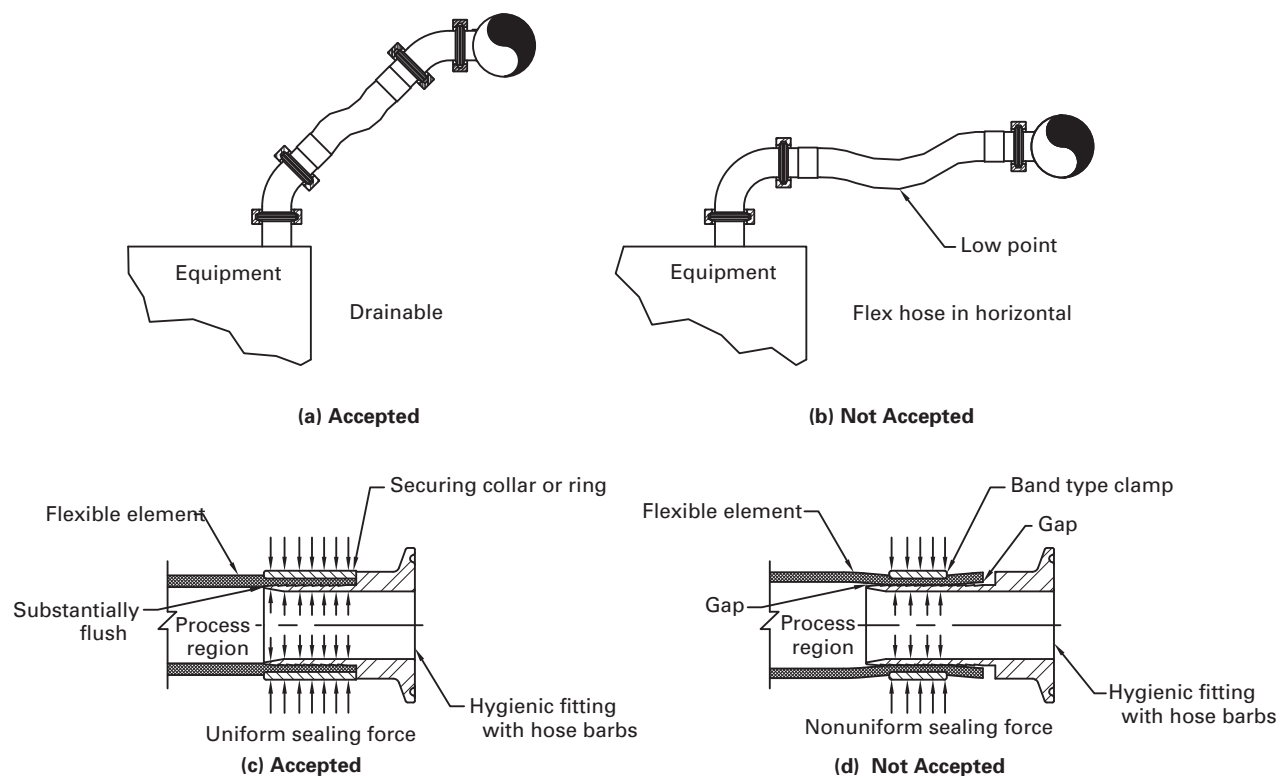
(e) Hose assembly shall be clearly marked or tagged with the design allowable working pressure/vacuum and design temperature range.

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

SD-3.2.2 Flexible Element

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

(b) The interior surface of the flexible element shall be cleanable and drainable.

Fig. SD-3.2.1-1 Flexible Hygienic Hose Design

(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.

SD-3.2.3 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 and the compression forces required to affect the secure assembly with the flexible element. [Refer to Fig. SD-3.2.1-1, 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-2.4.1 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 SG-3.3.2.

SD-3.3 Pumps

(16) SD-3.3.1 Diaphragm Pumps

(a) Diaphragm pumps may be used in positive displacement pump applications. Some diaphragm pumps are available that provide low shear, constant flow or pressure, low pulsation, high turndown ratio (e.g., 1,000:1), and/or low particle generation.

(b) The owner/user shall evaluate whether holdup volume and drainability characteristics of a diaphragm pump are acceptable for the application. Some process applications require the process system, including the diaphragm pump, to remain continuously flooded with sanitizing solution instead of being drained.

(c) Process contact diaphragms, O-rings, gaskets, and seals shall comply with Part SG. Process contact metallic materials of construction shall comply with Part MM. Nonmetallic process contact surfaces including diaphragms shall comply with Part PM.

(d) Where applicable, check valves shall comply with SD-3.13

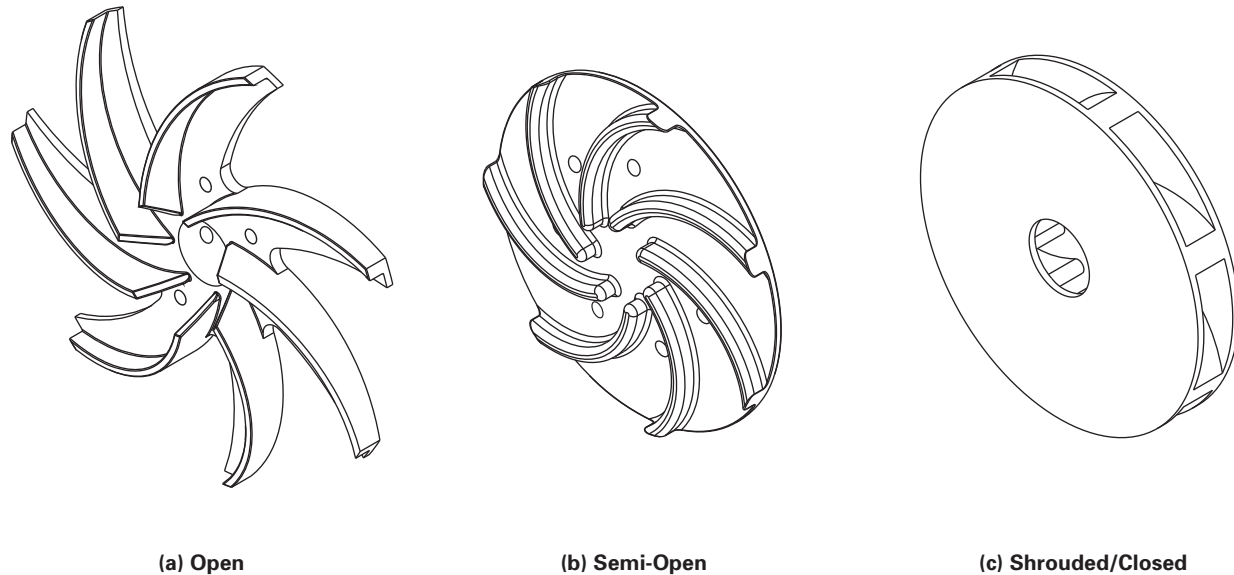
(e) Where used, diaphragm fasteners shall be attached within the pump head such that crevices or threads are not exposed to the process fluids.

(f) The owner/user should consider leak detection and/or leak path design of the pump to identify a failure that can lead to process contamination and/or biohazards.

SD-3.3.2 Hygienic Pumps

SD-3.3.2.1 General

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

Fig. SD-3.3.2.2-1 Pump Impeller Configurations

(b) All process contact connections to the pump shall be of a hygienic design (see Figs. SG-2.2.2-1, SG-2.2.2-2, SG-2.2.2-3, and SG-2.2.2-4).

(16) SD-3.3.2.2 Centrifugal Pumps

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

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

(c) Shrouded/closed impellers should not be used. Fig. SD-3.3.2.2-1 illustrates open, semi-open, and closed impeller configurations.

(d) The impeller shall be attached to the shaft in such a way that all crevices and threads are not exposed to the process. Threads, such as in an impeller nut/bolt, shall be sealed by an O-ring or hygienic gasket. Refer to Fig. SD-3.3.2.2-2. The use of O-rings or hygienic gaskets shall be consistent with Part SG.

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

(f) Casing drains shall be at the lowest point of the casing, to ensure drainage (see Fig. SD-3.3.2.2-3).

(g) 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 as shown in Fig. SD-3.3.2.2-4.

(h) The pump discharge connection should be tilted to allow for full venting of the casing (see Fig. SD-3.3.2.2-3).

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

(j) Shaft seals shall conform to Part SG.

SD-3.3.2.3 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 disk) rather than a pump-mounted bypass be used.

SD-3.3.2.4 Rotary Lobe Pumps

(16)

(a) The owner/user shall specify the chemical, thermal, and hydraulic operating conditions of the pump (e.g., process, CIP, SIP) to ensure proper component selection. Hygienic rotary lobe pumps are temperature sensitive (e.g., rotor to casing contact due to thermal expansion).

(b) The pump should be designed and installed to minimize holdup volume.

(c) Rotor fasteners shall be attached to the shaft in a way that crevices and threads are not exposed to the process. Threads and crevices shall be isolated from the process fluid by an appropriate hygienic seal, such as an O-ring or hygienic gasket (see Fig. SD-3.3.2.4-1).

(d) The pump cover shall seal against the pump body by means of an O-ring or hygienic gasket.

(e) All process contact O-rings, gaskets, and shaft seals shall comply with Part SG.

(f) If a pressure relief device is used, it shall be of hygienic design in conformance with SD-3.15.

SD-3.4 Vessels

(16)

SD-3.4.1 General. SD-3.4.1 defines the requirements that are to be met in the design, fabrication, and supply

Fig. SD-3.3.2.2-2 Acceptable Impeller Attachments

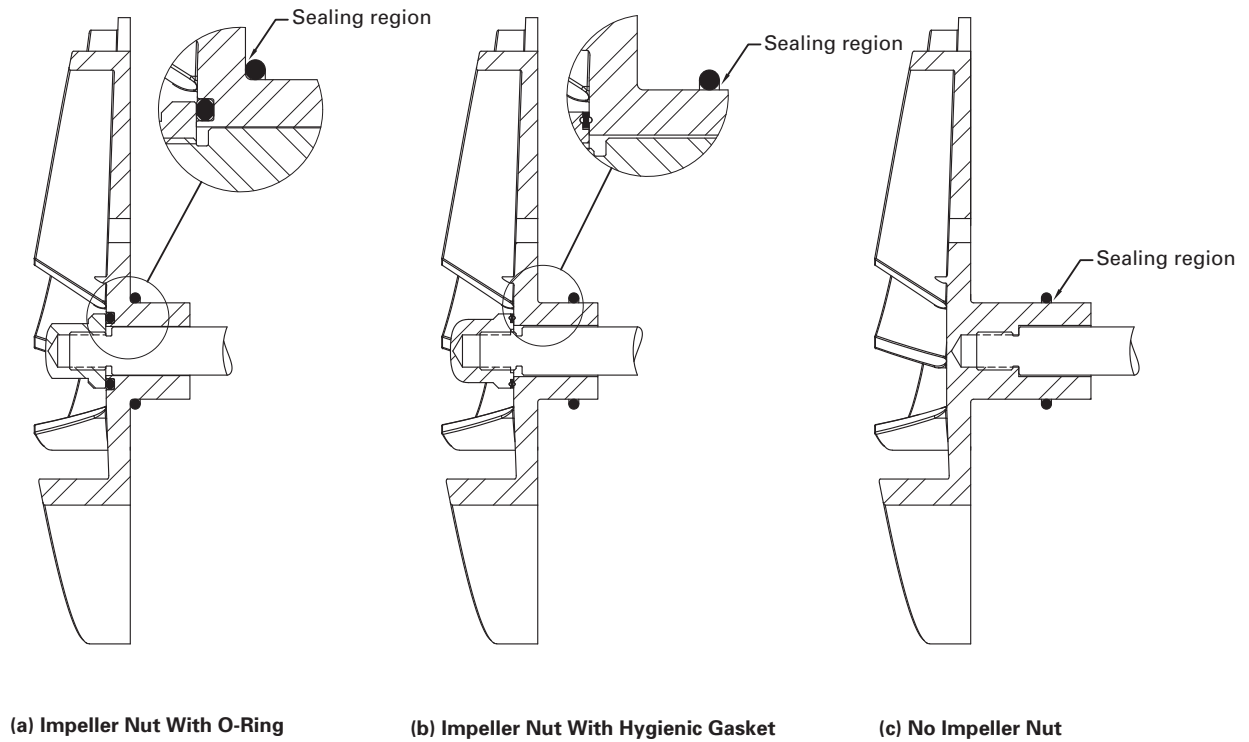


Fig. SD-3.3.2.2-3 Casing Drain Configurations

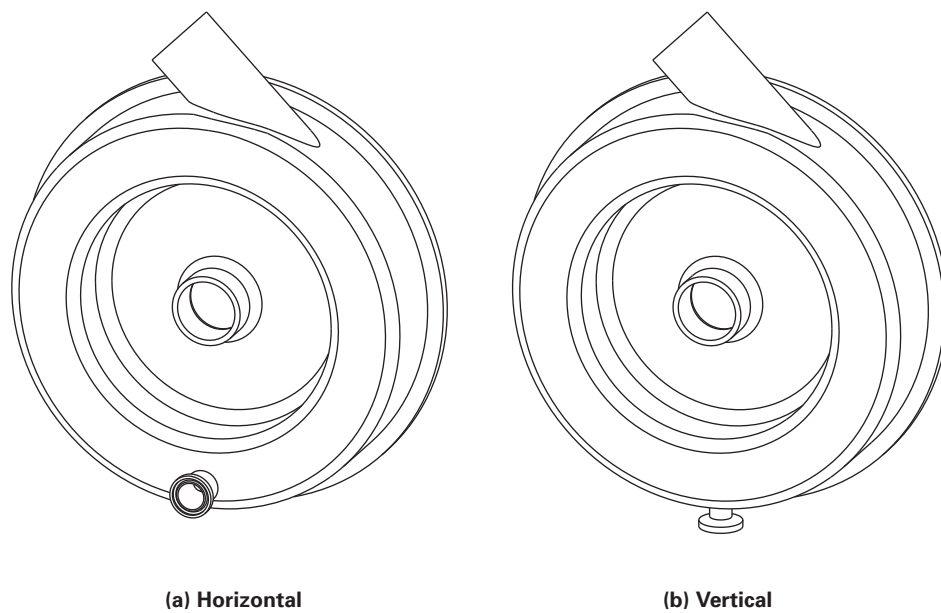


Fig. SD-3.3.2.2-4 Casing Drain L/D Ratios

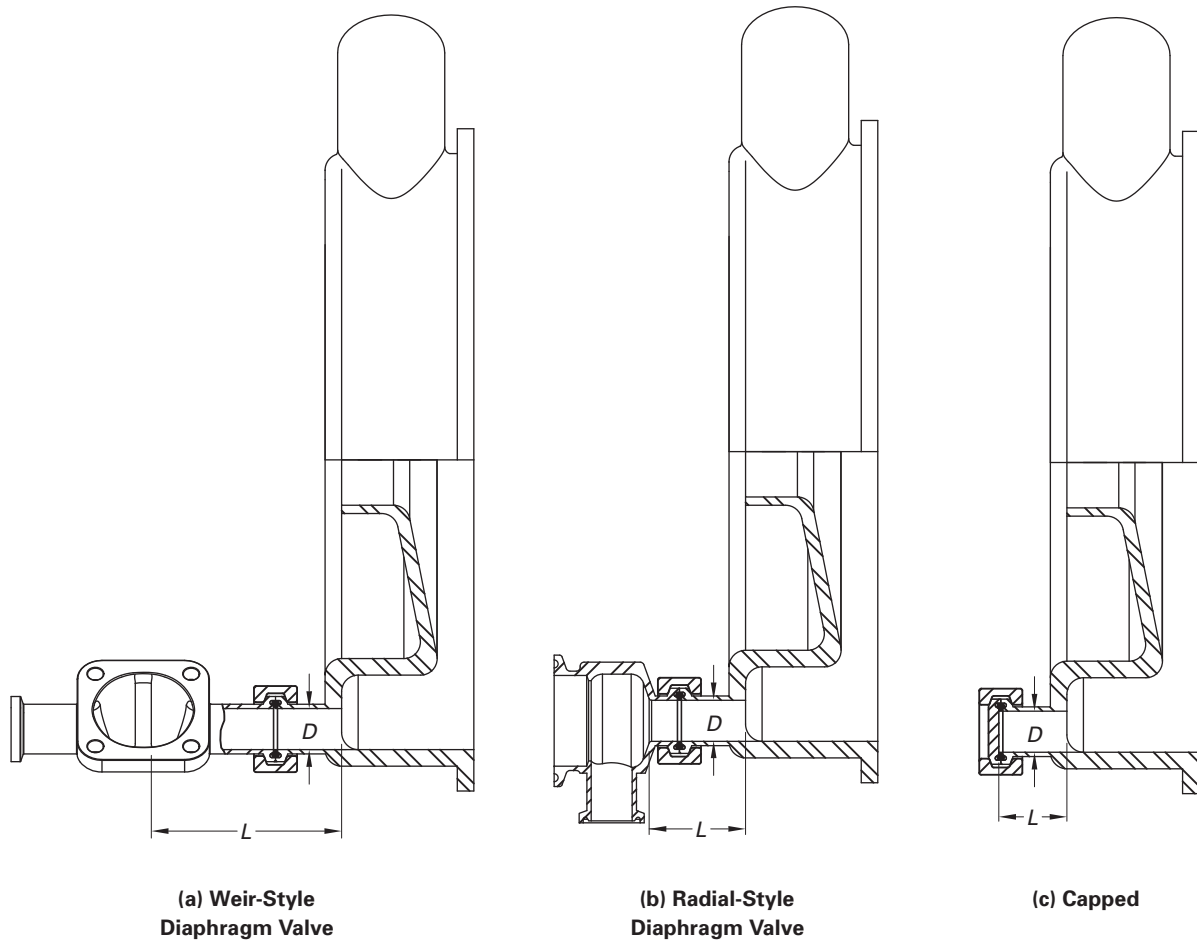
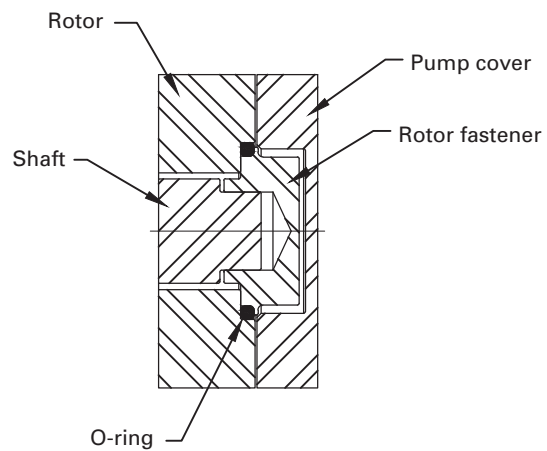


Fig. SD-3.3.2.4-1 Rotary Lobe Pump Rotor Attachment



of pressurized and nonpressurized biopharmaceutical vessels.

(a) 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.

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

(c) Reinforcing pads, doubler plates, poison pads, etc., should be constructed of the same material as the vessel. If the vessel material of construction is a superaustenitic stainless steel, 316L-type alloys or other higher alloy stainless steels may be used for these components on non-process contact surfaces only. No telltale holes are allowed on process contact surfaces and those that are outside should be cleanable.

(d) Vessels that are to be exposed to temperatures 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 [maximum allowable working pressure—external of 15 psig (1 barg)].

(e) Top and bottom heads on vessels that are cleaned in place shall be self-draining. Dished heads such as ASME flanged and dished (F&D), elliptical, and hemispherical are the most common types. Flat or conical heads should slope at not less than $\frac{1}{8}$ in./ft (10 mm/m) to a common drain.

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

(g) Test protocols for drainability shall be agreed upon in advance by all the parties (see SD-6.4). All vessels should be checked for drainability during fabrication.

SD-3.4.2 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, an L/D of 2 or less is recommended (see Fig. SD-3.4.2-1).

(b) Nozzles less than 1 in. (25 mm) in diameter are not recommended unless the system design provides for SIP and CIP through the nozzle.

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

(d) All instrument probes and any sidewall penetrations (see Fig. SD-3.4.2-2) shall be sloped for drainage, unless the instruments used require horizontal mounting (see Fig. SD-3.4.2-3).

(e) Blank covers or hygienic plugs used in process contact applications shall have the same finish as the vessel internals.

(f) Drain valves should optimize drainability and minimize branch L/D .

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

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

(i) 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.

(j) Sample valves shall be designed in accordance with SD-3.11.

(k) Sample valves shall be installed in accordance with SD-3.11.

(l) As required by the process, inlet nozzles tangential to the vessel surface may be used (see Fig. SD-3.4.2-4 and Fig. PI-9.1.3.3-1).

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

(n) Flanges that have metal-to-metal contact on the process contact side shall not be used.

(o) All nozzles should be flush with the interior of the vessel except where projections are required to ensure additives are directed into the process fluid (e.g., chemical addition) (see Fig. SD-3.4.2-5).

SD-3.4.3 Internal Components

(a) Sparger and dip tubes shall be designed in accordance with SD-3.4.1(a), (d), (f), and (g). Sparger and dip tubes shall incorporate low-point drains [where applicable, i.e., horizontal lines should slope at not less than $\frac{1}{8}$ in./ft (10 mm/m)] and be properly supported to ensure drainability. Refer to Table SD-2.4.3.1-1 to determine the appropriate slope designation.

(b) 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-3.4.3-1. An L/A of 2 or less is recommended (see Fig. SD-3.4.3-1). If a larger L/A 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.

(c) Internal support members shall be solid, rather than hollow, which have a higher risk of fatigue and contamination problems (see Fig. SD-3.4.3-2).

(d) 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.

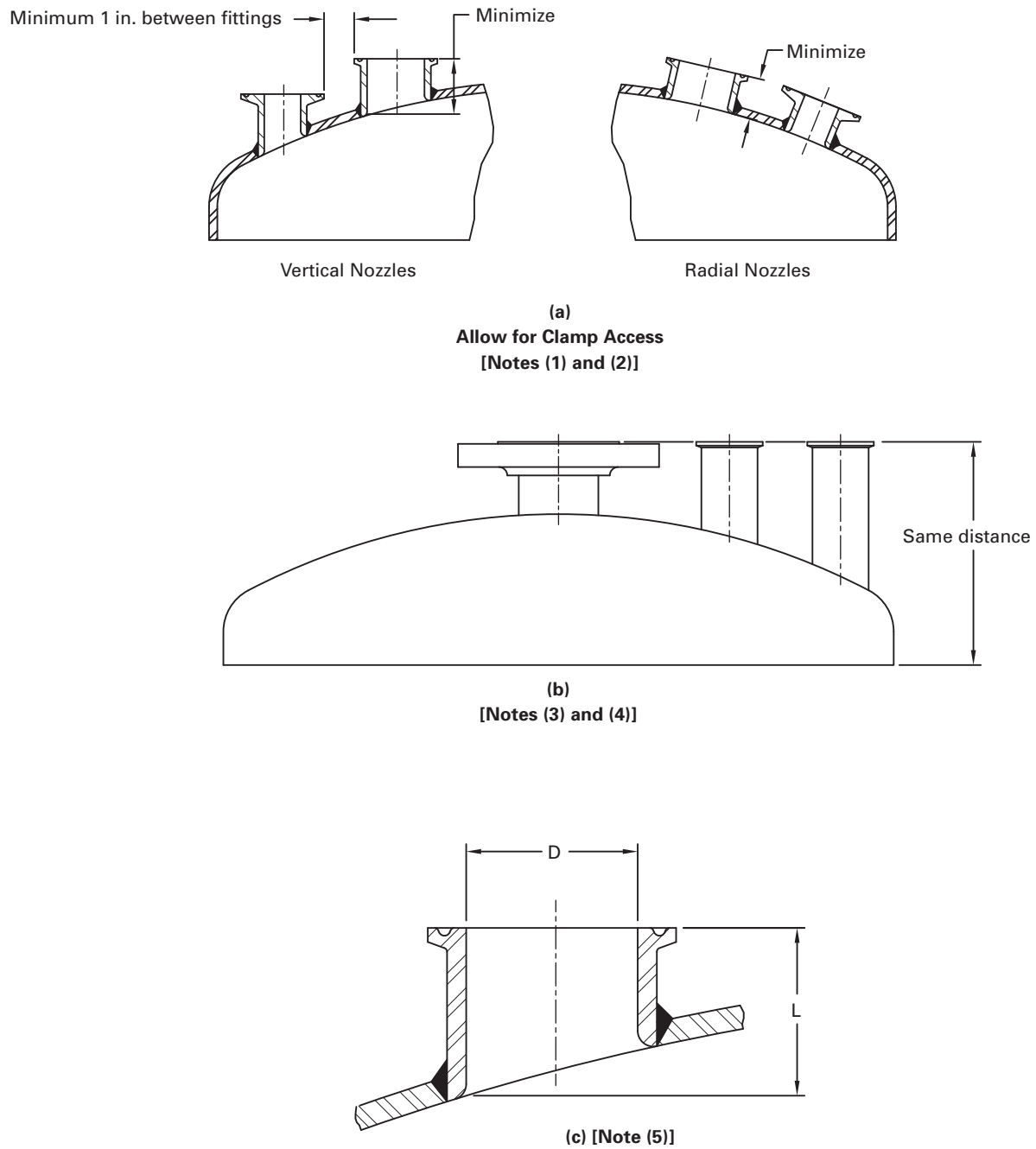
(e) Vessels shall drain to a common point and shall not have multiple draining points, unless agreed to between the owner/user and manufacturer.

SD-3.4.4 Fabrication

(a) For process contact surfaces, butt welds should be used and the use of lap joint welds should be minimized. Stitch welding shall not be used on process contact surfaces.

(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.

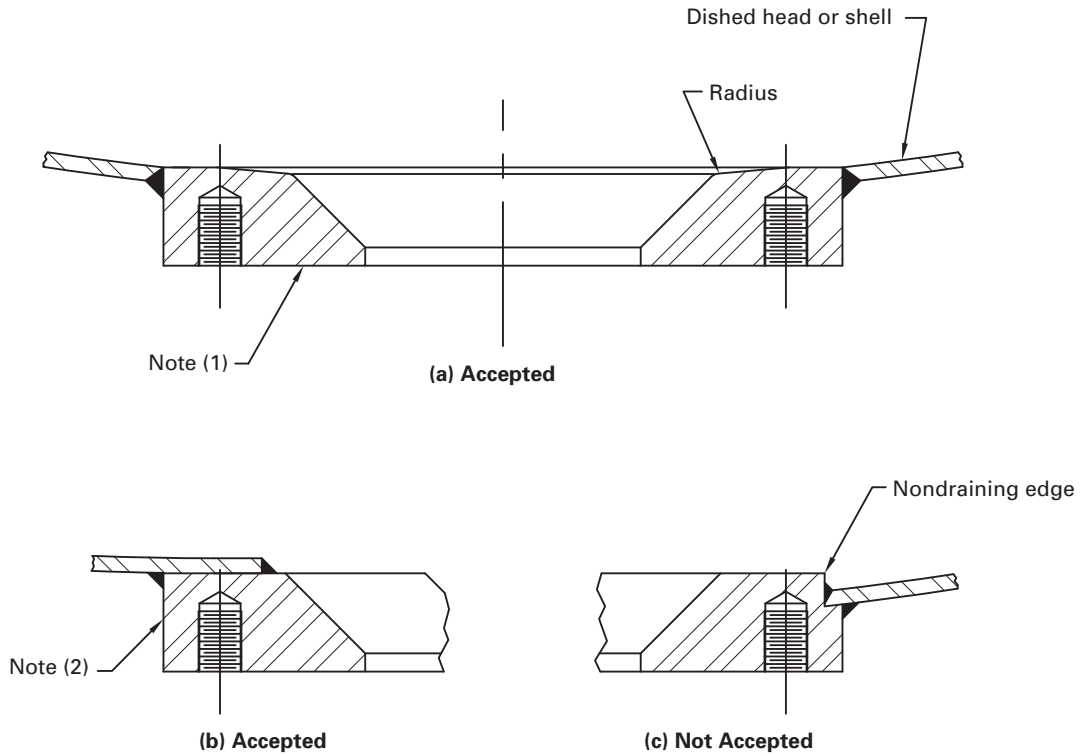
Fig. SD-3.4.2-1 Nozzle Design



NOTES:

- (1) Less dead space.
- (2) Better CIP/SIP capabilities.
- (3) Potential problems with CIP and SIP with capped connections.
- (4) Dead space: stagnant areas.
- (5) All L/D ratios to be calculated on long-side dimensions for vessel heads.

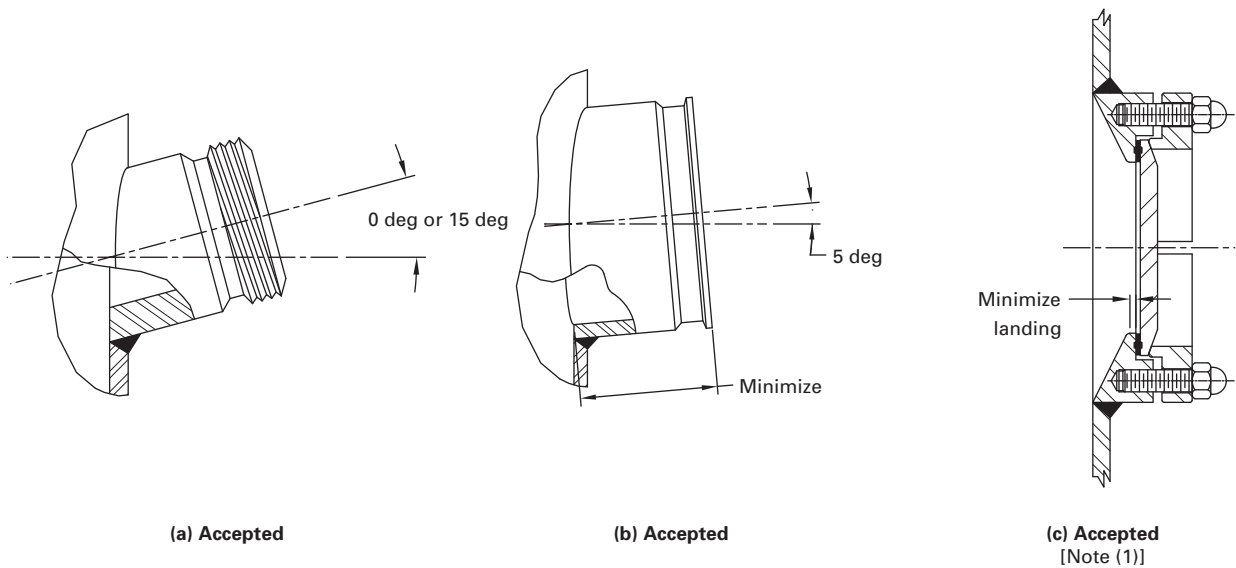
Fig. SD-3.4.2-2 Side and Bottom Connections



NOTES:

- (1) If a flat gasket is used, mismatch of diameters can result in crevices.
- (2) Telltale hole required.

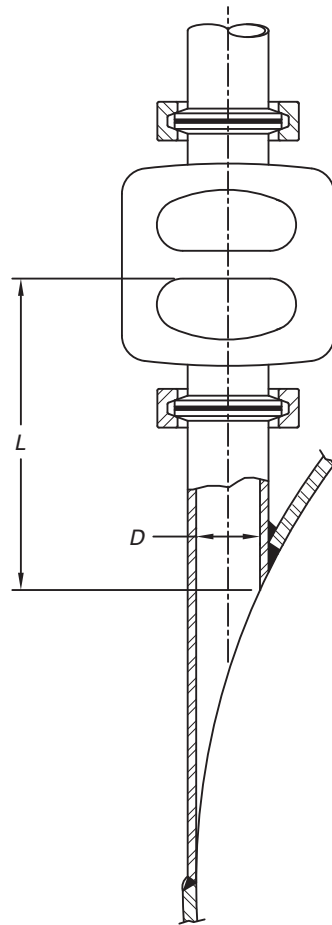
Fig. SD-3.4.2-3 Sidewall Instrument Ports



NOTE:

- (1) May also be pitched similar to illustration (b).

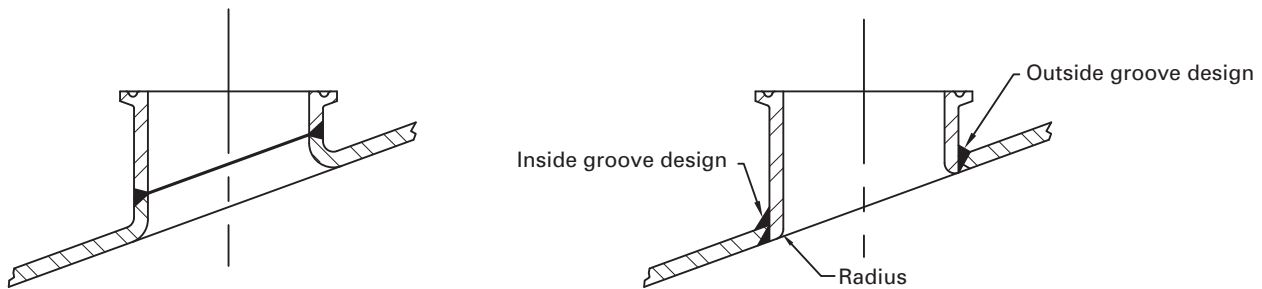
(16)

Fig. SD-3.4.2-4 Vessel Design Tangential Nozzles

**Definition of L/D for Tangential Inlet:
Top Section View**

GENERAL NOTE: CIP through nozzle is recommended.

(16)

Fig. SD-3.4.2-5 Typical Nozzle Detail

**(a) Swage/Butt Weld Design
(Accepted: If Vessel Wall Is
Thin Enough to Flare)**

**(b) Full Penetration Groove Weld
With Fillet Design
(Accepted)**

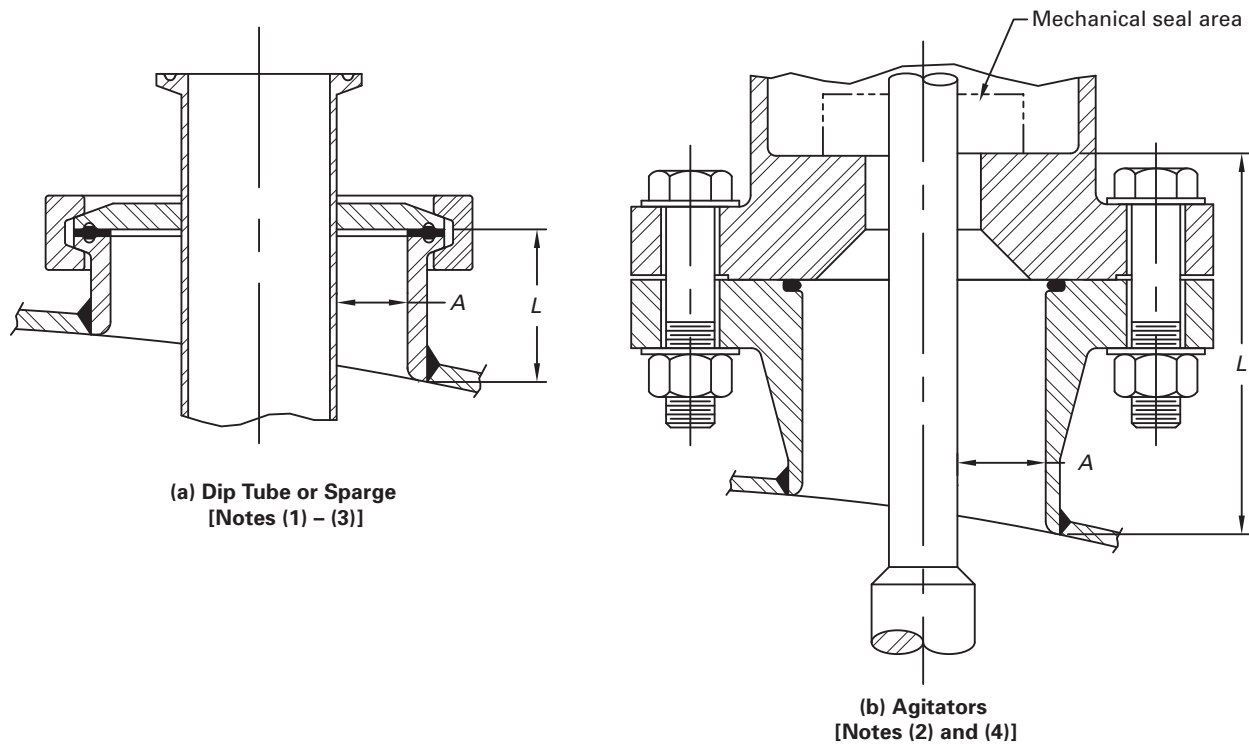
Table SD-3.4.3-1 Annular Spacing Recommendations for Hygienic Dip Tubes

(16)

Dip Tube Size Tube O.D.		Mount Nominal Size	
in.	mm	in.	mm
1/2	12.7	2	50
3/4	19.1	2	50
1	25.4	3	75
1 1/2	38.1	3	75
2	50.8	4	100
2 1/2	63.5	4	100
3	76.2	6	150
4	101.6	6	150

Fig. SD-3.4.3-1 Accepted Nozzle Penetrations

(16)

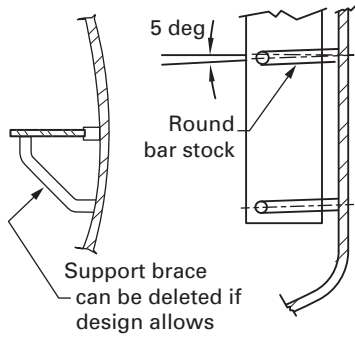


NOTES:

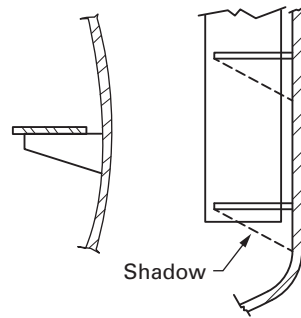
- (1) Nozzle and dip tube size per Table SD-3.4.3-1.
- (2) L/A less than 2:1.
- (3) Requirements also apply to nozzles with instrument penetrations.
- (4) $A = 1$ in. (25 mm) minimum.

(16)

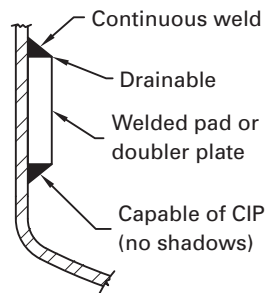
Fig. SD-3.4.3-2 Internal Support Members



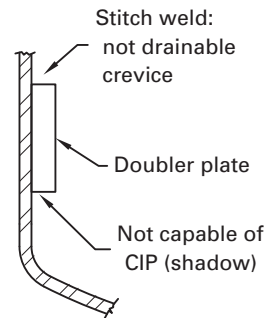
(a) Hygienic Design
(Accepted: Sloped, Minimum Shadow, and Curved Surface)



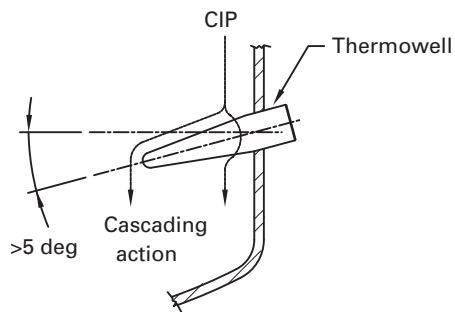
(b) Nonhygienic Design
(Not Accepted: Flat Surfaces, Ledges, and CIP Shadows)



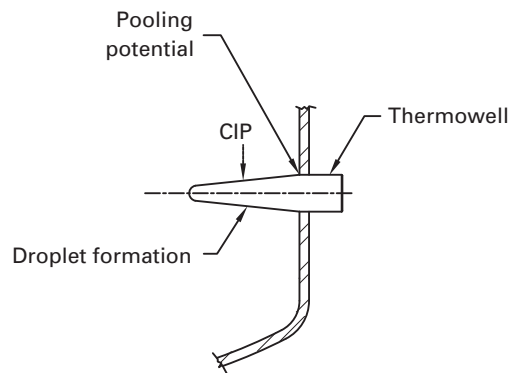
(c) Good Design
(Accepted)



(d) Poor Design
(Not Accepted)



(e) Positive Slope in All Directions
(Accepted)



(f) Positive Slope in Only One Direction
(Accepted)

(c) Where slip-on nondrainable flanges are used, the bore-side bevel weld shall be designed to eliminate potential drainability and CIP difficulties.

SD-3.4.5 Finishes

(a) Surface finishes shall be specified in R_a values (see Table SF-2.4-1) and measured as required by Part SF. Surface finish coupons shall be submitted when agreed to by the owner/user and manufacturer.

(b) Process 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-3.4.6 Sight Glasses

(a) Sight glasses on the vessels should be designed with reference to SD-3.4.2(a). Sight glasses on vessels should be designed with the smallest L/D possible and incorporate cleanable O-ring designs when applicable (see Fig. SD-3.4.6-1).

(b) Refer to PI-9.1.2.3 for additional sight glass requirements.

(c) Surface finish for the metal frame shall meet the requirements of Part SF in this Standard.

(d) Sight glasses shall be marked with the glass type, maximum pressure, and temperature rating per DT-11.1 and DT-11.1.1.

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

(f) Preferred sight glass mountings are shown in Fig. SD-3.4.6-1.

SD-3.4.7 Portable Tanks. Portable tanks shall be designed in accordance with SD-3.4.

(a) Casters shall be cleanable and compatible with cleaning solutions used for external cleaning.

(b) Casters should be designed for the environment in which the vessel will be used.

(c) Flexible hoses used to connect portable vessels shall meet the requirements of SD-3.2.

(d) Provisions for static grounding should be evaluated and incorporated into the vessel design, if required. The connections for static grounding should be designed to be cleanable.

SD-3.4.8 Media Bulk Containers. [Reserved for future content]

SD-3.4.9 Cryogenic Containers. [Reserved for future content]

SD-3.5 Agitators and Mixers

(16) SD-3.5.1 General

(a) All process 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) Process 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 an L/A of 2 or less, or a minimum of 1 in. (25 mm) gap, whichever is larger, to facilitate CIP spray coverage [see Fig. SD-3.4.3-1, 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-3.5.1-1, illustrations (a), (b), and (c)]. 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 (see Fig. SG-3.3.2.2-1).

(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; ASME B31.3, etc.]

(g) Socket head cap screws shall not be used in process contact applications.

(h) The design of agitator process 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-3.5.2 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 accepted hygienic design. See examples in Fig. SD-3.5.2-1.

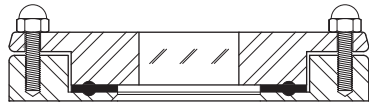
(d) In-tank coupling location should be driven by process and mechanical considerations.

(e) Threaded shaft connections are accepted for in-tank couplings [see Fig. SD-3.5.2-1, illustration (a)].

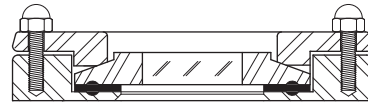
(1) Shaft rotation is limited to a single direction for threaded shaft connections to ensure that shaft sections do not separate.

(16)

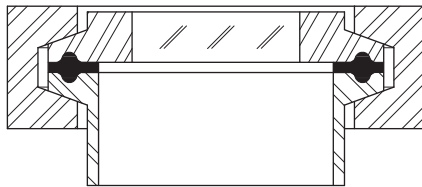
**Fig. SD-3.4.6-1 Sight Glass Design
(Accepted)**



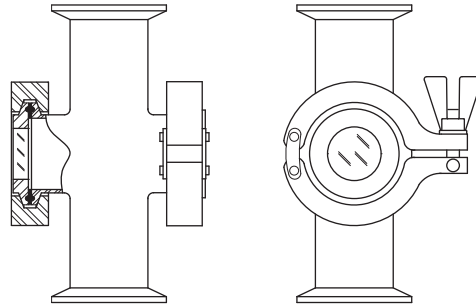
**(a) Full Flange Sight Glass
on Hygienic Pad Connection**



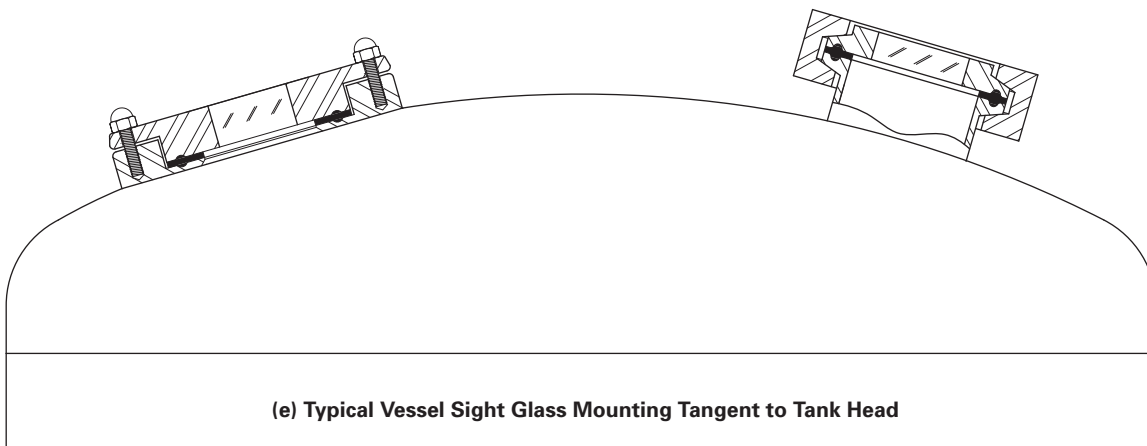
(b) Hygienic Clamp on Hygienic Pad Connection



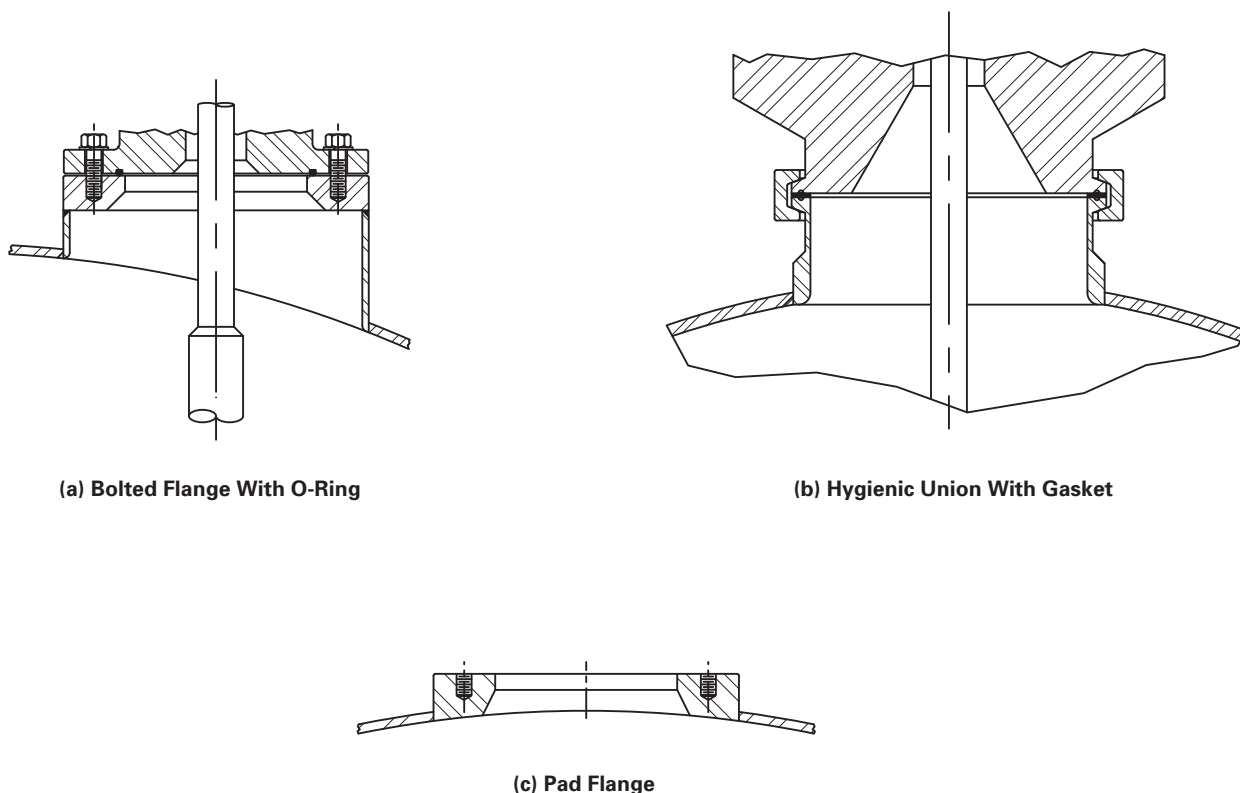
(c) Hygienic Clamp Sight Glass



(d) Hygienic Cross Sight Flow Indicator



(e) Typical Vessel Sight Glass Mounting Tangent to Tank Head

Fig. SD-3.5.1-1 Agitator Mounting Flanges

(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-3.5.2-1, illustration (b)].

(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. Accepted fastener types include

- (1) hex-head cap screws
- (2) acorn-head cap screws
- (3) threaded studs with acorn nuts

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

(i) O-rings rather than flat gaskets are preferred to seal coupling mating surfaces. Figure SD-3.5.2-2 presents the following acceptable approaches for seal applications:

(1) O-ring located in a single groove inboard of the coupling outside diameter [see Fig. SD-3.5.2-2, illustration (a)]; O-ring compression, internal space to accommodate compression, and outboard clearance space all designed to minimize the intrusion of process fluid between the coupling faces and to facilitate flow of CIP fluid.

(2) Alternate construction for O-ring located in a groove just inboard of the coupling outside diameter [see Fig. SD-3.5.2-2, illustration (b)]; O-ring restrained by lip at coupling circumference with clearance space provided as above to ensure cleanability of the coupling area.

(3) Alternate construction for O-ring located in grooves in both coupling halves inboard of the coupling outside diameter [see Fig. SD-3.5.2-2, illustration (c)]; outboard clearance space provided as above to ensure cleanability of the coupling area.

(4) O-ring with attached inboard flat segment located between coupling faces [see Fig. SD-3.5.2-2, illustration (d)]; outboard clearance space provided as above to ensure cleanability of the coupling area.

(j) Bolted flanges shall be sealed. Examples of accepted fastener seals are shown in Fig. SD-3.5.2-3 as follows:

- (1) O-ring seal [illustration (a)]
- (2) O-ring seal alternate [illustration (b)]
- (3) seal washer with metal core [illustration (c)]

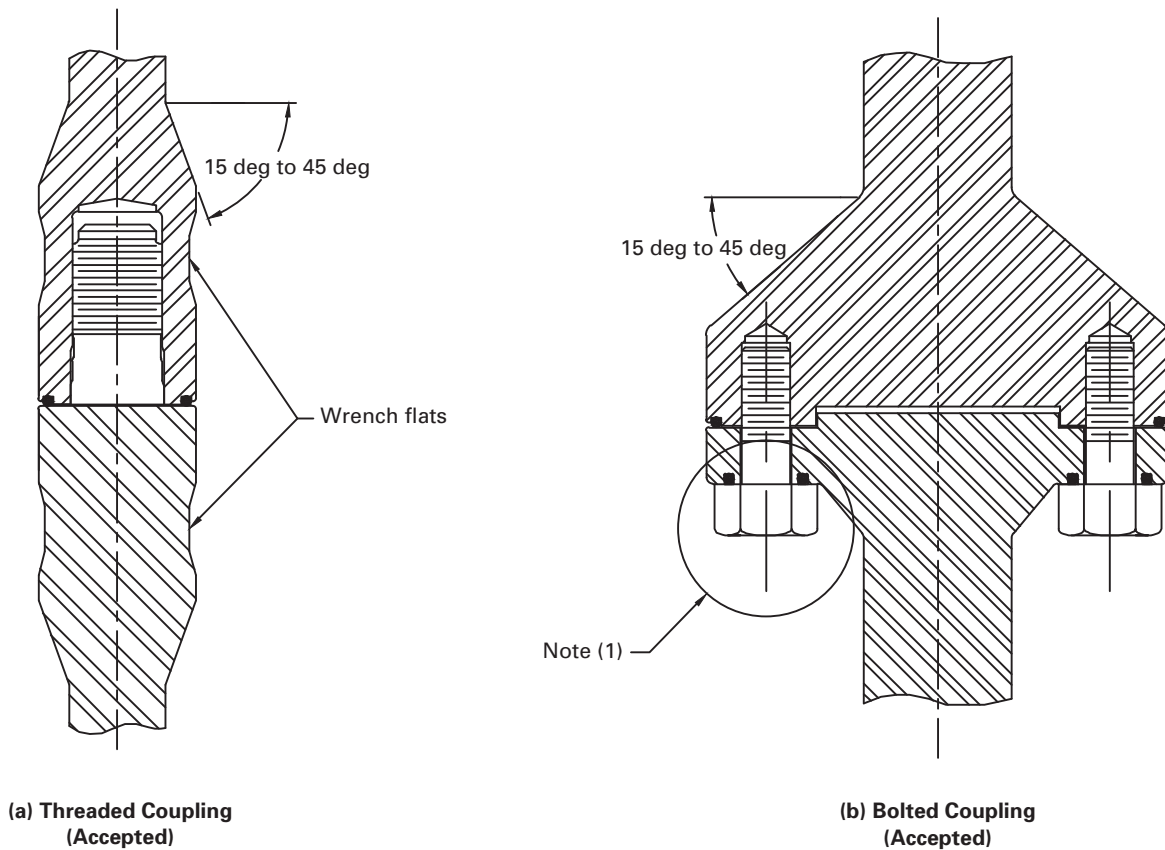
SD-3.5.3 Shafts and Keyways

(16)

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

(b) Solid shafts are preferred over hollow shafts.

Fig. SD-3.5.2-1 Shaft Coupling Construction



NOTE:

(1) See Fig. SD-3.5.2-3 for alternative bolt seals.

Fig. SD-3.5.2-2 Shaft Coupling Seal Arrangements

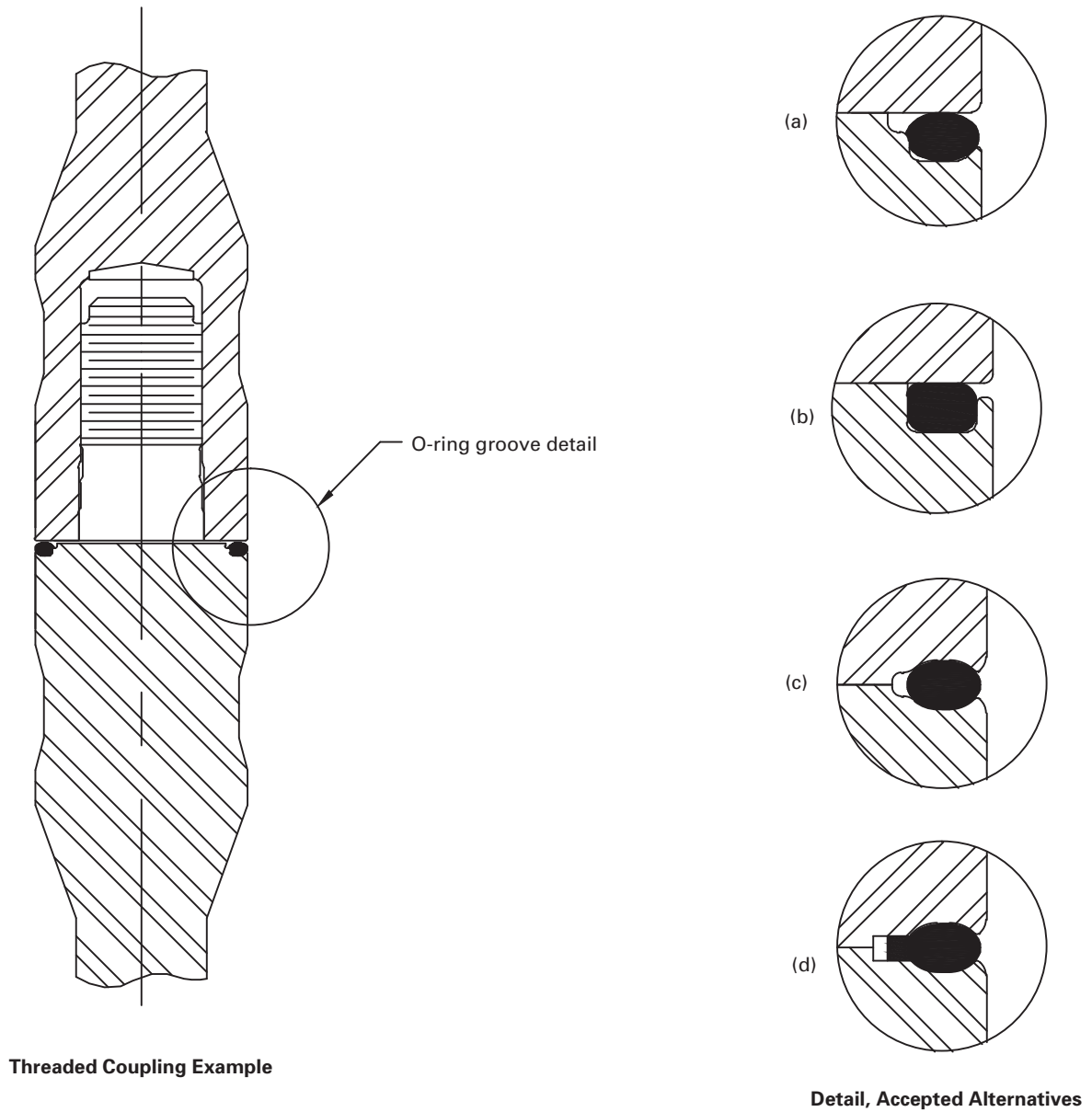
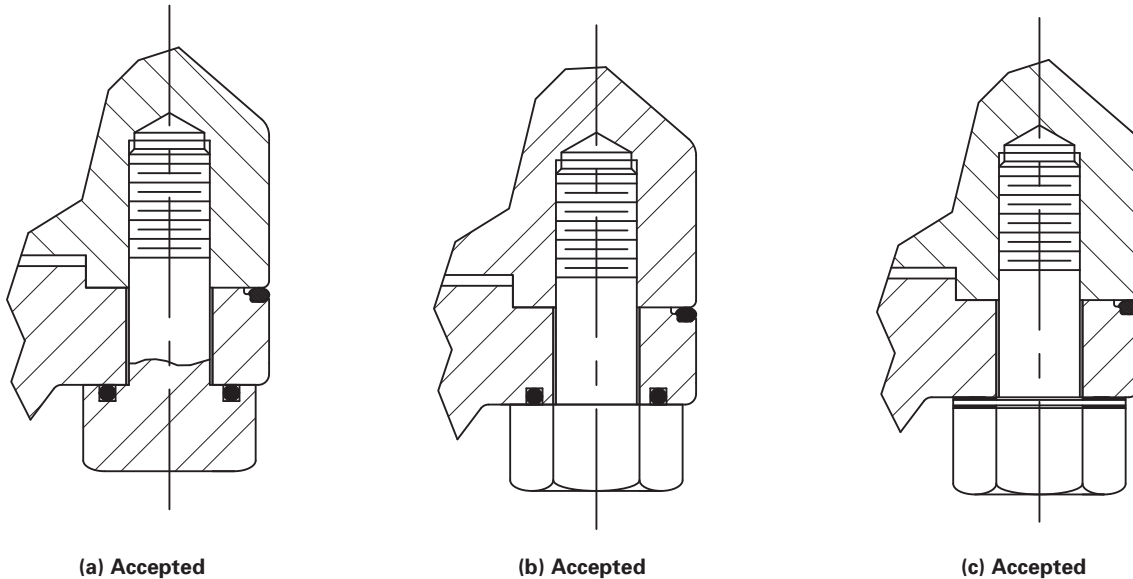


Fig. SD-3.5.2-3 Fastener Seal Arrangements: Alternative Bolting Designs

(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 the process are not recommended.

(e) Keyways, where employed due to mechanical design considerations, shall have edge radii as specified by SD-2.4.2(g).

(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, installed on the process contact side, 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.

SD-3.5.4 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 hygienic 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-3.5.2).

(d) Removable impellers and impellers with flat, horizontal surfaces (e.g., flat-blade disk turbines, concave-blade disk 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-3.5.5 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-3.5.5-1 and SD-3.5.5-2) 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 injectables) as appropriate.

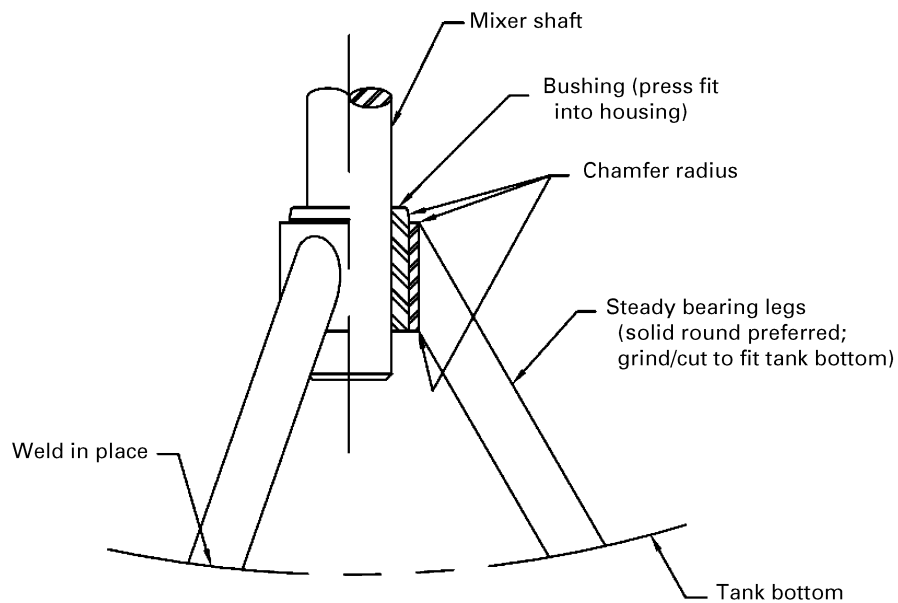
(b) Tank plates that support bottom-mounted magnetically driven mixers shall not interfere with drainage of the vessel.

(c) When an application mandates the use of shaft-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).

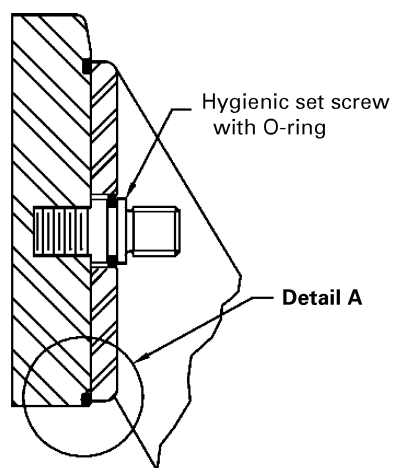
(d) Shaft-steady bearings, where used, shall not interfere with the drainage of the vessel.

(e) Shaft-steady bearing pedestal support members may be of solid or hollow construction. Hollow pedestal

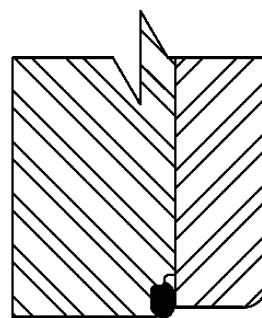
Fig. SD-3.5.5-1 Shaft-Steady Bearing



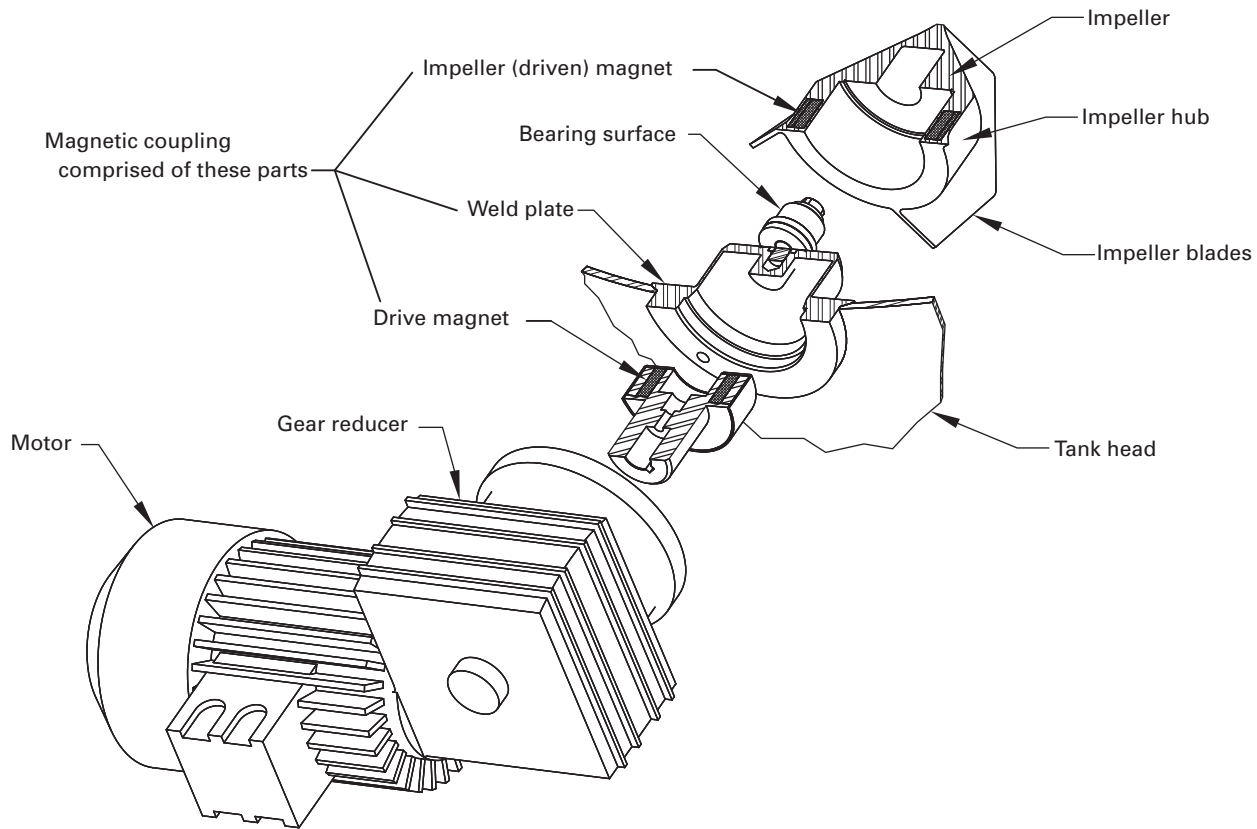
**(a) Hygienic Tripod Steady Bearing
(Alternative Design — Flat Bar Legs With Rounded Edges)**



(b) Alternative Bushing Securing Method



**Detail A
O-Ring With Groove Exposed for Flushing**

Fig. SD-3.5.5-2 Magnetically Coupled Mixer (Typical Bottom-Mount)

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-3.5.6 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 injectables) as appropriate.

(c) Seal debris wells or traps (see Fig. SG-2.3.2.3-2) may be used to prevent ingress of seal face wear particles that could contaminate the process fluid.

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

SD-3.6 Heat Exchange Equipment

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

SD-3.6.1 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 process and non-process 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 will be used to fabricate the heat exchanger.

(16)

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

(3) The sample shall be sectioned so that the 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.		Minimum Bend Radius	
in.	mm	in.	mm
0.375	9.5	0.625	15.2
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 contamination of the process in the event of a tube joint failure (see Fig. SD-3.6.1-1).

(1) During fabrication, when the tubes are to be expanded into the inner and outer tubesheets, the process contact surface shall 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 owner/user shall specify the orientation of the exchanger (i.e., horizontal or vertical), and the manufacturer shall ensure the complete draining of the process liquid from the process contact side of the heat exchanger at the specified orientation, other than the natural cohesive properties of said process liquid. If this holdup is unacceptable, then the manufacturer shall design 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 allow for proper draining of the shell.

(3) The heat exchanger bonnet shall be match marked with the outer tubesheet 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 process contact side shall be equal to or greater 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-3.6.2 Cleaning and Steaming

(a) The process 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-3.6.3 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-3.7 Transfer Panels

SD-3.7.1 General

(a) The transfer panel shall be constructed so that the process contact surfaces can be cleaned by a CIP fluid or other method specified by the owner/user. The process contact surfaces shall be free of crevices, pockets, and other surface irregularities.

(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-3.7.1-1).

(d) Tagging/labeling of the transfer panel and its components shall be per SD-2.4.4.2(i). Tagging nozzles on the back side of panels will help reduce the number of incorrect piping connections during field installation.

SD-3.7.2 Nozzles or Ports

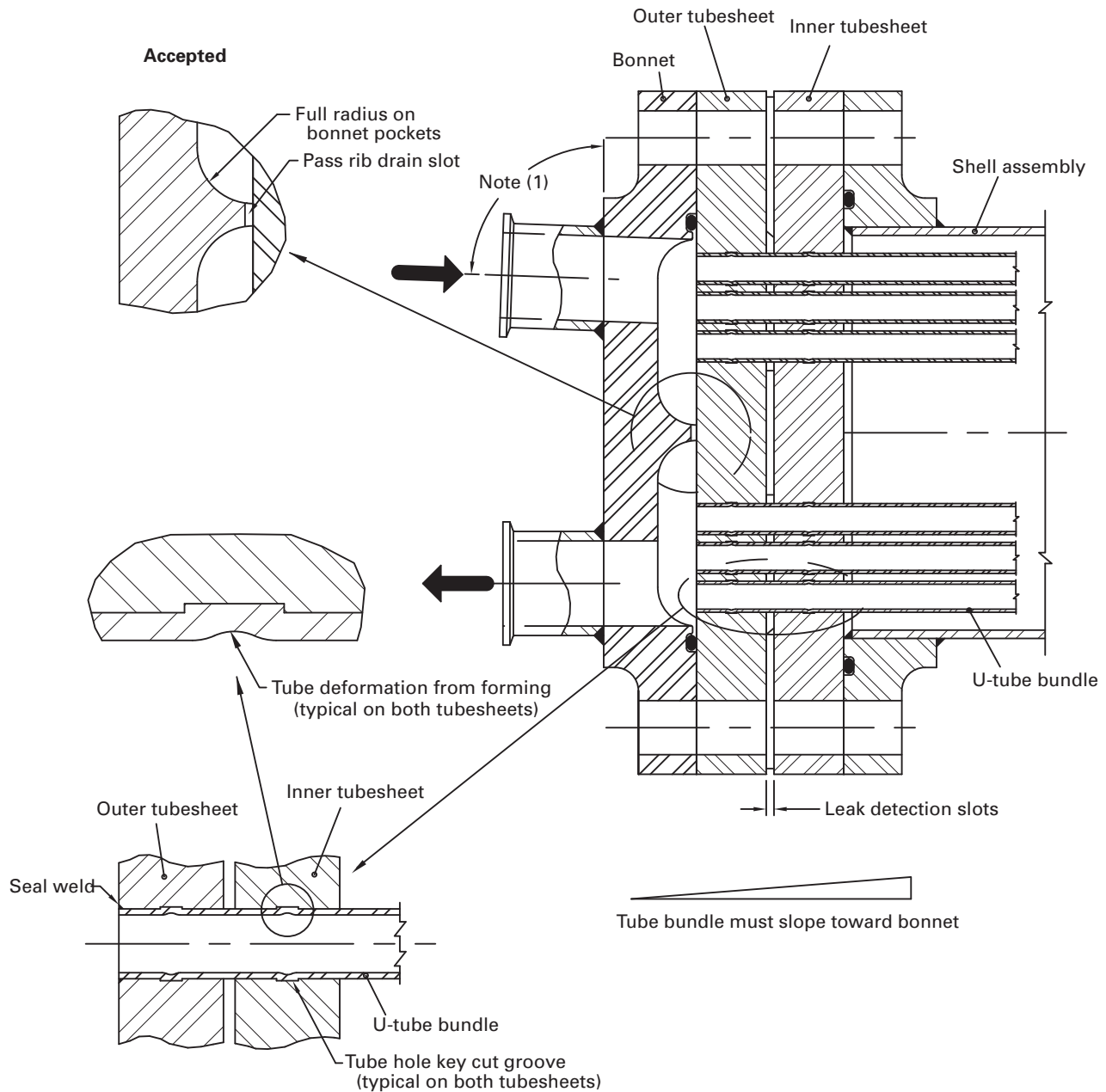
(a) Nozzle construction shall accommodate a design feature that will assist in the elimination of internal surface anomalies caused in part by joining the nozzle to the panel structure.

(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-8.5-1.

(c) Each front nozzle connection shall be of a hygienic design and the horizontal projection minimized to optimize drainability.

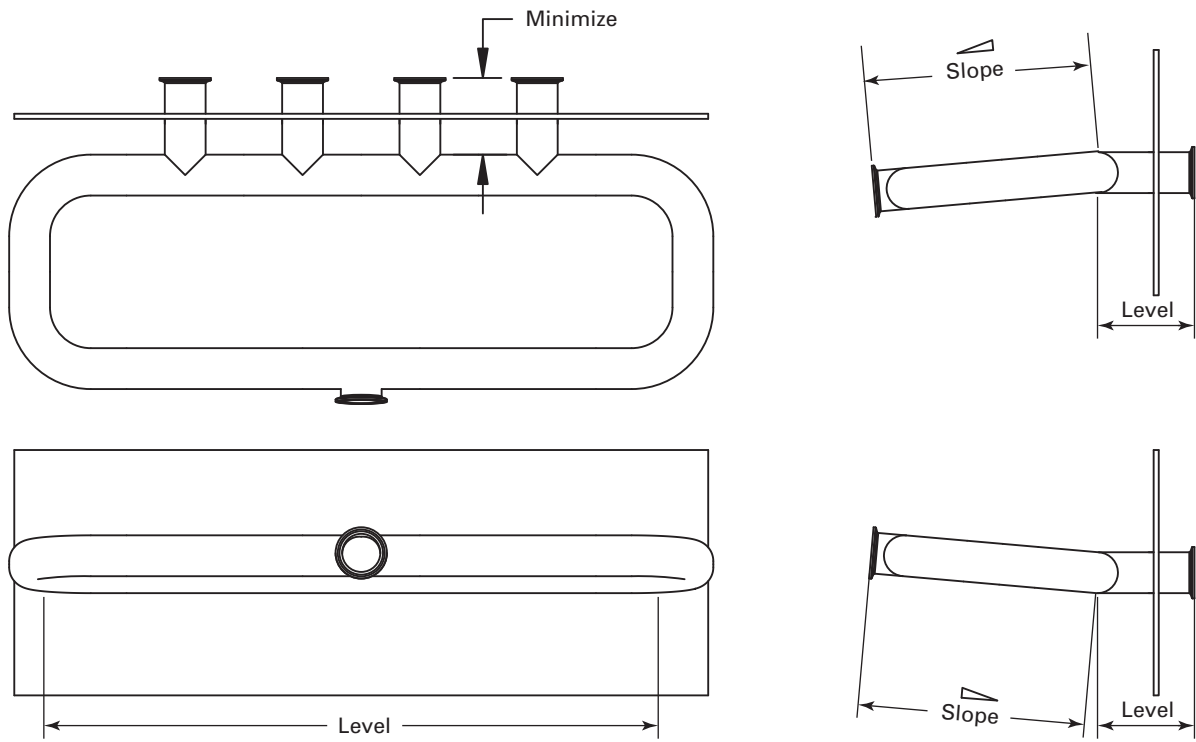
(d) To ensure proper panel functionality and joint connection integrity, panel nozzles shall not be sloped (see Fig. SD-3.7.2-1).

(e) Nozzle-to-nozzle clearance shall be such that jumper drain valve interference, if applicable, will not

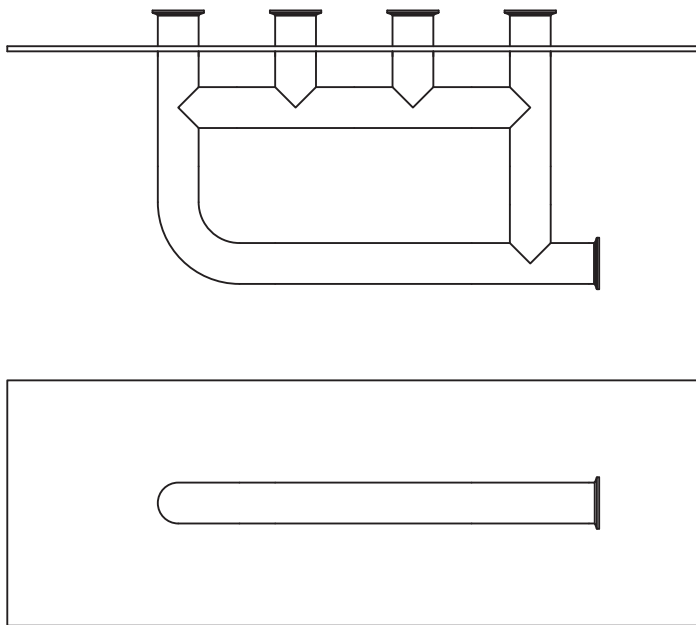
Fig. SD-3.6.1-1 Double Tubesheet Heat Exchanger Bonnet Design**NOTE:**

(1) Owner to specify inlet tubing slope. Heat exchanger manufacturer to slope inlet on bonnet to match inlet tubing slope.

Fig. SD-3.7.1-1 Transfer Panel Looped Headers

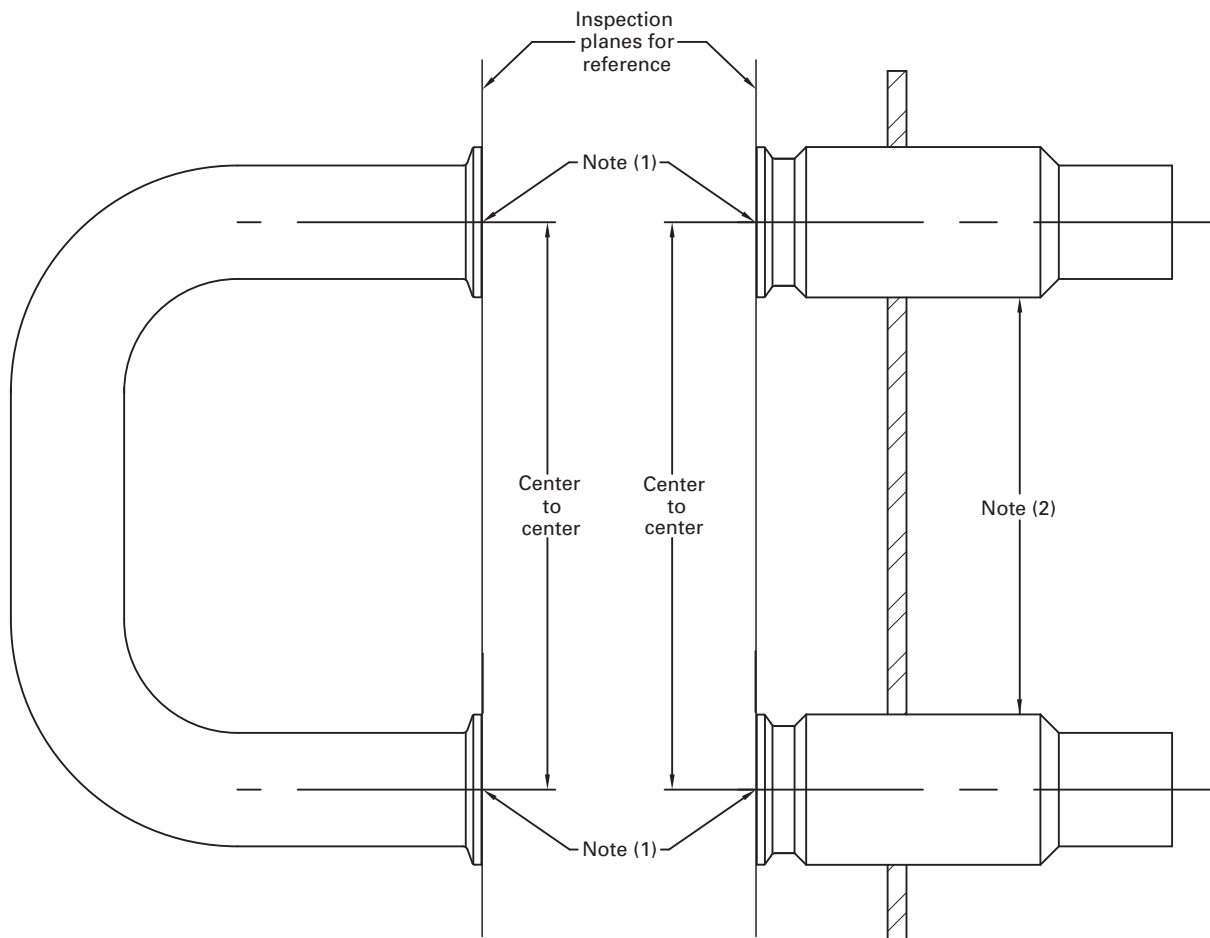


(a) Accepted



(b) Not Accepted

**Fig. SD-3.7.2-1 Transfer Panel Tolerances
(Reference Table DT-7-2)**



NOTES:

- (1) Flatness tolerance defines the maximum gap allowed across the entire sealing surface relative to the inspection planes shown above.
- (2) Tolerances applied to related nozzles (defined by jumper paths).

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 on by the manufacturer and end-user. Recommended tolerances are per Table DT-7-2 and Fig. SD-3.7.2-1.

SD-3.7.3 Headers or Pre-Piped Manifolds

(a) When a looped header design is employed, the branch length at capped or unused nozzles should be minimized. The dimension of the subheader leg to the nozzle face should not exceed an L/D of 2 (see Fig. SD-3.7.1-1). 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-2.4.3.

SD-3.7.4 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-3.7.4-1). The branch L/D of a low-point drain connection should be minimized. Zero-static diaphragm valves are recommended for low-point drains if available from the manufacturer [see Fig. SD-3.7.4-1, illustrations (a) and (d)]. Low-point drain designs that incorporate a spool piece allow for full rotation of the drain valve [see Fig. SD-3.7.4-1, 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 DT-7-2 and Fig. SD-3.7.2-1.

(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. The L/D should be 2 or less.

SD-3.7.5 Drain or Drip Pans

(a) Drain pans, if used, 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.

SD-3.7.6 Proximity Switches

(16)

(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 that are mounted behind the panel structure to avoid penetration of the panel face is preferred. This elimination of structural penetration removes any unnecessary cracks, crevices, or threads at the point of attachment, effectively mitigating risk of process fluid 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-8.5-1.

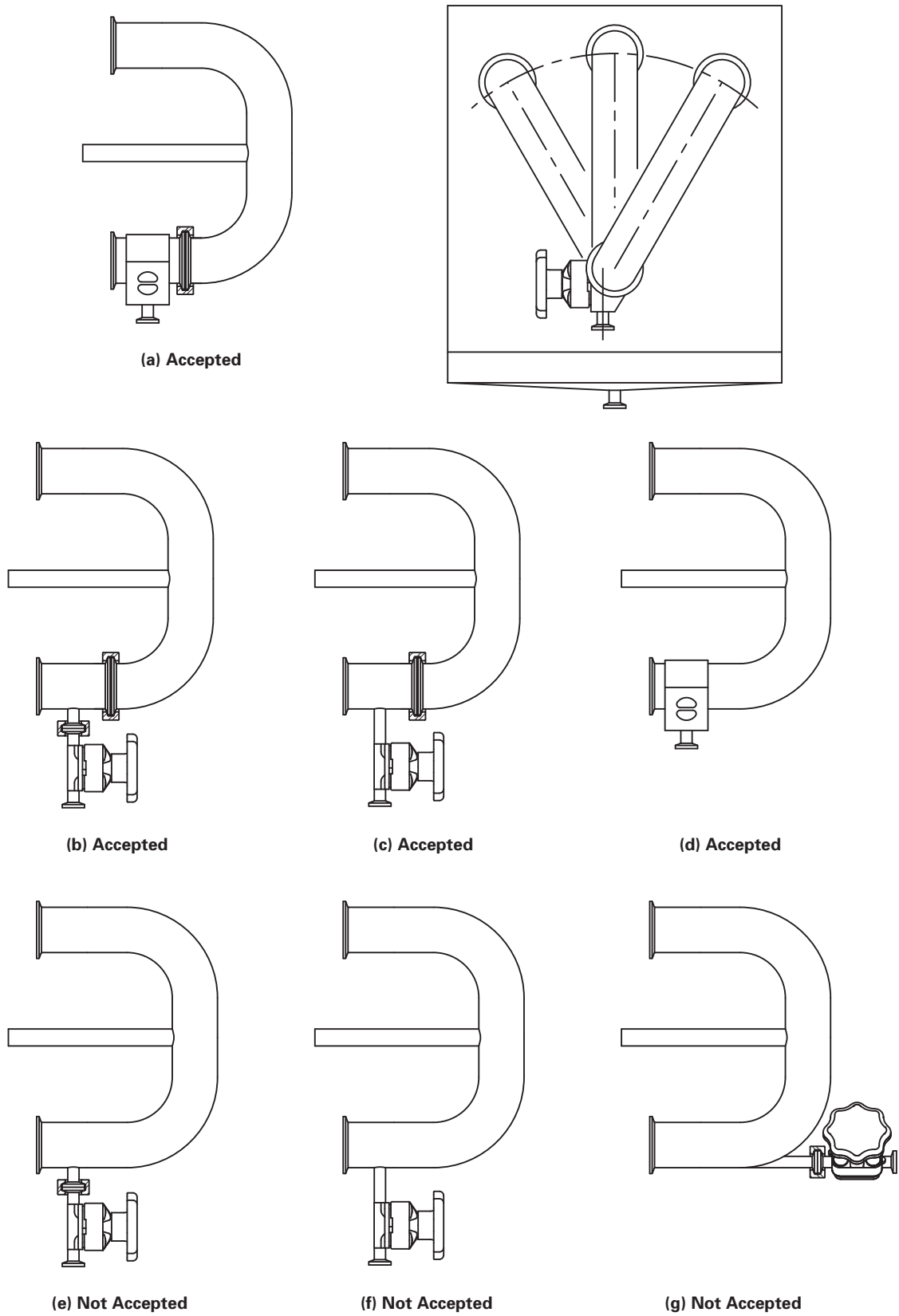
(d) The magnet should be of sufficient gauss rating to properly activate the corresponding proximity switch. In addition, the temperature rating of the magnet should withstand the specified temperature ranges for process and SIP without compromising the magnet performance.

(e) The proximity switch mounting shall be of hygienic design and structurally sound to maintain the specified design location.

SD-3.8 Filters

SD-3.8.1 Code 7 Cartridge Lock Design. The ASME BPE Code 7 lock is designed to be used with filter

Fig. SD-3.7.4-1 Transfer Panel Jumpers



cartridges using an SAE AS 568-226 double O-ring seal and a two-locking-tab design.

- (16) **SD-3.8.1.1 Design Features.** This design consists of the following features:

(a) a socket bore that is machined into a base or cartridge plate into which the filter cartridge O-ring adapter is inserted.

(b) locking tab retainer mechanism that captures the cartridge locking tabs when the cartridge is inserted into the socket bore.

(1) Table DT-4.5.1-1 shows a recessed tapered lock retainer design in which the locking tab retainers are machined into a plate and the machined recesses capture the cartridge locking tabs as the cartridge is rotated into position.

(2) Table DT-4.5.2-1 shows an external tapered lock retainer design in which a set of metal cages captures the cartridge locking tabs as the cartridge is rotated into position.

(c) the locking tab retainers shall be designed with a taper to provide a secure lock for the cartridge. The cartridge tabs shall travel through the narrowing tab retainers until a tight fit is achieved. The taper shall be on the upper portion of the tab retainer. Full capture of cartridge tabs by the locking tab retainers is not required to secure cartridges for operation.

(d) all surfaces of the cartridge socket shall meet the required finish for the wetted surfaces as specified by the owner/user.

(e) the cartridge O-ring(s) shall be completely contained within the socket bore.

- (16) **SD-3.8.1.2 Testing.** The cartridge manufacturer shall validate that its cartridge design fits, seals, and remains in place with one of the housing designs shown in Tables DT-4.5.1-1 and DT-4.5.2-1.

SD-3.9 Spray Devices

SD-3.9.1 General. SD-3.9 covers spray devices intended for use in bioprocessing equipment, intended to remain in place or be removed during production. Recommendations in this section are valid for water-based cleaning solutions. The flow rate recommendations in this section are for metallic vessels.

(a) Spray devices distribute rinse and cleaning solutions to interior surfaces of bioprocessing equipment by direct spray and use sheeting action for remaining targeted areas. Spray devices are also used in other applications [e.g., water systems to maintain coverage of the storage tank head space and in clean-out-of-place (COP) cabinet washers].

(b) The differential pressure across the spray device generates liquid velocity exiting through the spray device orifices, nozzles, or slots. Differential pressure and its resulting flow are key parameters of spray devices. Flow is the recommended control parameter

because it is independent of temperature and location of the measurement device.

(c) The spray pattern, as it exits the device, is determined by the spray device design. Spray patterns are typically streams/jets or fans.

(d) The impact pattern is determined by the interaction over time of the spray pattern and the geometry of the equipment.

(e) During design, consideration should be given to the following in the selection of spray device(s):

(1) residue characteristics

(2) equipment geometry and appurtenances

(3) physical location and orientation of spray device(s)

(4) process requirements including air-purge and steaming, if applicable

(5) cleaning system capacity

(6) installation of screen/strainer to protect the functionality of the spray device

(7) cleaning cycle time

(8) cleaning chemistry compatibility with materials of construction

(9) potential orifice erosion (e.g., from CIP and SIP)

(f) Spray devices are either static or dynamic.

(1) Static spray devices continuously produce a defined impact pattern by stationary direct spray. Static spray devices have no moving parts. Examples of static spray devices include static spray balls, stationary nozzles, and spray wands.

(2) Dynamic spray devices are either single axis or multiaxis. Both produce a defined impact pattern by moving multidirectional spray(s). Dynamic spray device rotation is rinse water/cleaning solution driven or motor driven. Dynamic spray devices have moving parts, which may include bearings, gears, and turbines.

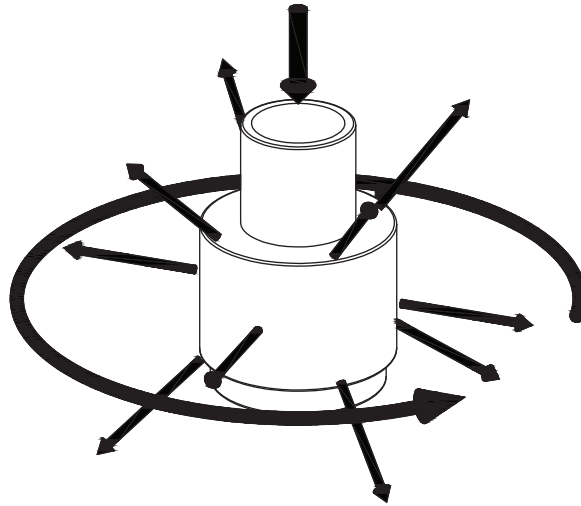
(-a) Single-axis dynamic spray devices (see Fig. SD-3.9.1-1). When the orifices/nozzles/slots are manufactured at an angle, the resulting force spins the spray head. Rotation can also be turbine or motor driven.

(-b) Multiaxis dynamic spray devices rotate in more than a single plane (see Fig. SD-3.9.1-2). When rinse water/cleaning solution driven, the flow through the spray device turns a turbine wheel, which typically turns the body around one axis as well as the nozzle(s) around a second axis, creating a repeatable indexed pattern. When motor driven, the body and nozzles are turned mechanically by the motor.

(g) Spray devices can be designed as removable, retractable, or to remain in place.

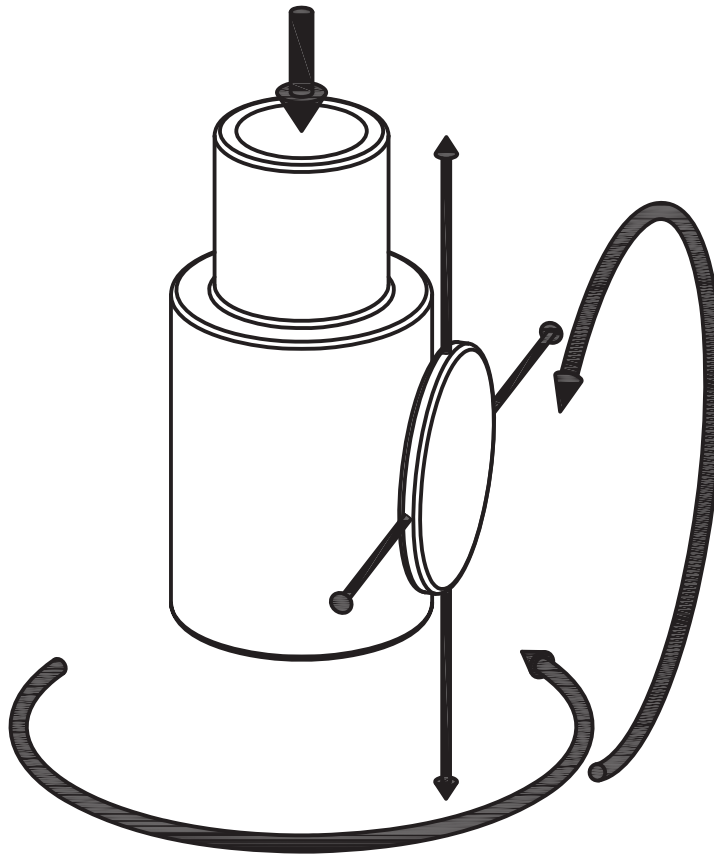
(h) Spray device(s) are specific to the application and equipment. Spray devices are generally not interchangeable without considering the specific flow, pressure, equipment design, spray pattern, and drainability of the spray device(s).

Fig. SD-3.9.1-1 Dynamic Spray Device: Single Axis



GENERAL NOTE: Spray pattern is for illustration purposes.

Fig. SD-3.9.1-2 Two Axes Dynamic Spray Device



GENERAL NOTE: Number of jets is for illustration purposes.

(16) SD-3.9.2 Spray Device Requirements

(a) Materials of construction shall comply with SD-2.4.1.2 or as otherwise agreed on with the owner/user.

(b) When installed, spray devices shall be drainable and cleanable inside and outside or otherwise as agreed on with the owner/user.

(c) Spray device(s) shall be installed per manufacturer's instructions.

(d) When operated within specification, the spray device(s) shall produce repeatable effective coverage over a defined area of the equipment.

(e) Effective coverage shall not be affected by flow rate variations of 10% or otherwise agreed on by the owner/user.

(f) Spray devices shall be accessible for functionality verification, inspection, and maintenance.

(g) Removable spray device(s) shall be capable of being re-installed in a repeatable manner by unique identifiers to ensure proper installation location.

(h) Spray device selection, orientation, and location shall be designed to ensure the equipment and the targeted surfaces of its appurtenances (e.g., manways, dip-tubes, baffles, nozzles, agitator shaft, and impellers) are exposed to rinse water/cleaning solution.

(i) Spray device(s) shall be provided with a level of documentation that is consistent with the equipment for which it is to be installed and in accordance with GR-5 documentation requirements.

(j) Process contact surface finishes of spray devices should be consistent with the equipment for which it is installed or otherwise specified by the owner/user and in accordance with the definitions of Part SF.

(k) Spray devices shall not use lubricants other than the process liquid. Dynamic devices are typically lubricated by the rinse/cleaning solution(s).

SD-3.9.2.1 Static Spray Device Requirements

(a) Static spray devices shall have a positioning device (preferred) or mark to allow for proper orientation during re-installation, as static devices are orientation sensitive (see Fig. SD-3.9.2.1-1)

(b) Weld-on or self-cleaning slip-joint/clip-on connections are acceptable. Provision shall be made to ensure proper orientation and location if a slip-joint/clip-on style static spray device(s) is used.

(c) A portion of the flow is directed toward the specific appurtenances.

(d) The flow rate guideline for vertical cylindrical vessels with dished heads is 2.5 gal/min/ft to 3 gal/min/ft (31 L/min/m to 37 L/min/m) of inner vessel circumference. Reference Fig. SD-3.9.2.1-2. The majority of the flow is directed toward the upper head to ensure coverage of appurtenances and provide the sheeting action.

(e) The flow rate guideline for horizontal cylindrical vessels with dished heads is 2 gal/min/ft to

3 gal/min/ft (25 L/min/m to 37 L/min/m) of perimeter ($2L + 2D$). Reference Fig. SD-3.9.2.1-3. The majority of the flow is directed toward the upper one-third of the vessel to ensure coverage of appurtenances and provide the sheeting action.

(f) Flow requirements for the specific application should be confirmed with the spray device and/or equipment manufacturer or other subject matter experts.

SD-3.9.2.2 Single-Axis Dynamic Spray Device Requirements

(a) Rotation and/or frequency verification shall be agreed on with the owner/user.

(b) Weld-on or self-cleaning slip-joint/clip-on connections are acceptable. Other hygienic alternatives shall be agreed on with the owner/user.

(c) The flow rate guideline for vertical cylindrical vessels with dished heads is 1.9 gal/min/ft to 2.3 gal/min/ft (23.6 L/min/m to 28.6 L/min/m) of inner vessel circumference. The majority of the flow is directed toward the upper head to ensure coverage of appurtenances and provide the sheeting action.

(d) The flow rate guideline for horizontal cylindrical vessels with dished heads is 1.4 gal/min/ft to 2.1 gal/min/ft (17.4 L/min/m to 26.1 L/min/m) of perimeter ($2L + 2D$). The majority of the flow is directed toward the upper one-third of the vessel to ensure coverage of appurtenances and provide the sheeting action.

(e) Flow requirements for the specific application should be confirmed with the spray device and/or equipment manufacturer or other subject matter experts.

(f) High-velocity gas flow from air-blows or steam passing through liquid-driven spray devices can result in wear to bearing surfaces. Consideration should be taken to restrict gas flow through the spray device according to the manufacturer's recommendation.

SD-3.9.2.3 Multiaxis Dynamic Spray Device Requirements

(a) Rotation and/or frequency verification shall be agreed on with the owner/end-user.

(b) The time to complete a full impact pattern (see Fig. SD-3.9.2.3-1) at a specified pressure or flow rate shall be provided by the manufacturer.

(c) Weld-on or self-cleaning slip-joint/clip-on connections are acceptable. Other hygienic alternatives shall be agreed upon with the owner/user.

(d) The flow rate guideline for vertical cylindrical vessels with dished heads is 1.3 gal/min/ft to 1.5 gal/min/ft (16.1 L/min/m to 18.6 L/min/m) of inner vessel circumference to ensure coverage of appurtenances and provide the sheeting action.

(e) The flow rate guideline for horizontal cylindrical vessels with dished heads is 0.8 gal/min/ft to 1.2 gal/min/ft (9.9 L/min/m to 14.9 L/min/m) of perimeter ($2L + 2D$) to ensure coverage of appurtenances and provide the sheeting action.

Fig. SD-3.9.2.1-1 Static Spray Device

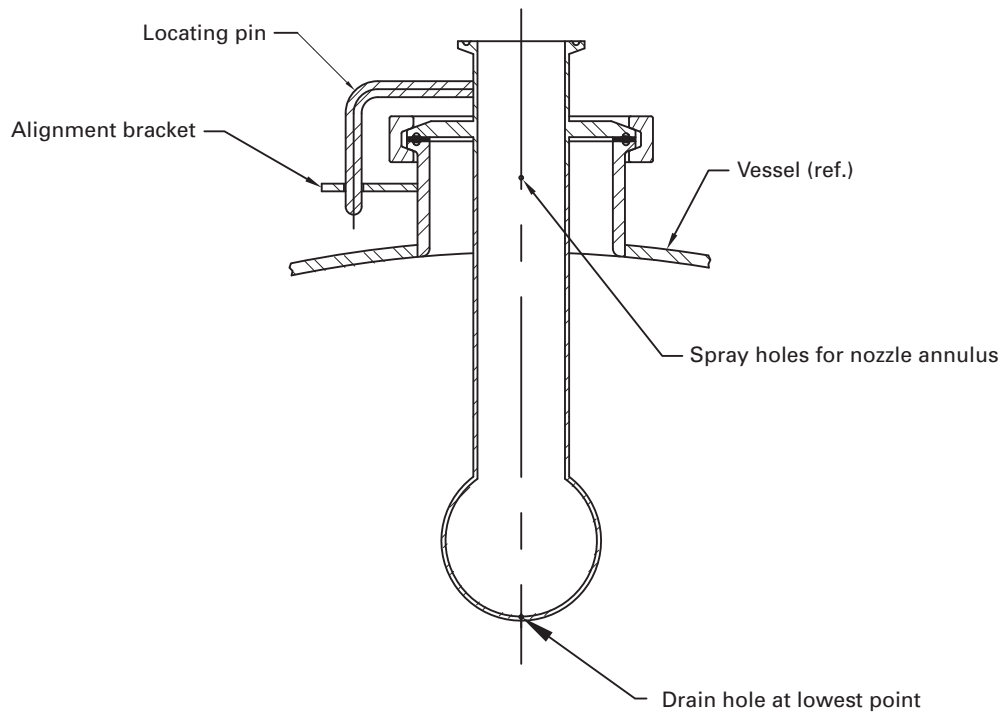


Fig. SD-3.9.2.1-2 Flow Rate Guideline for Vertical Cylindrical Vessels

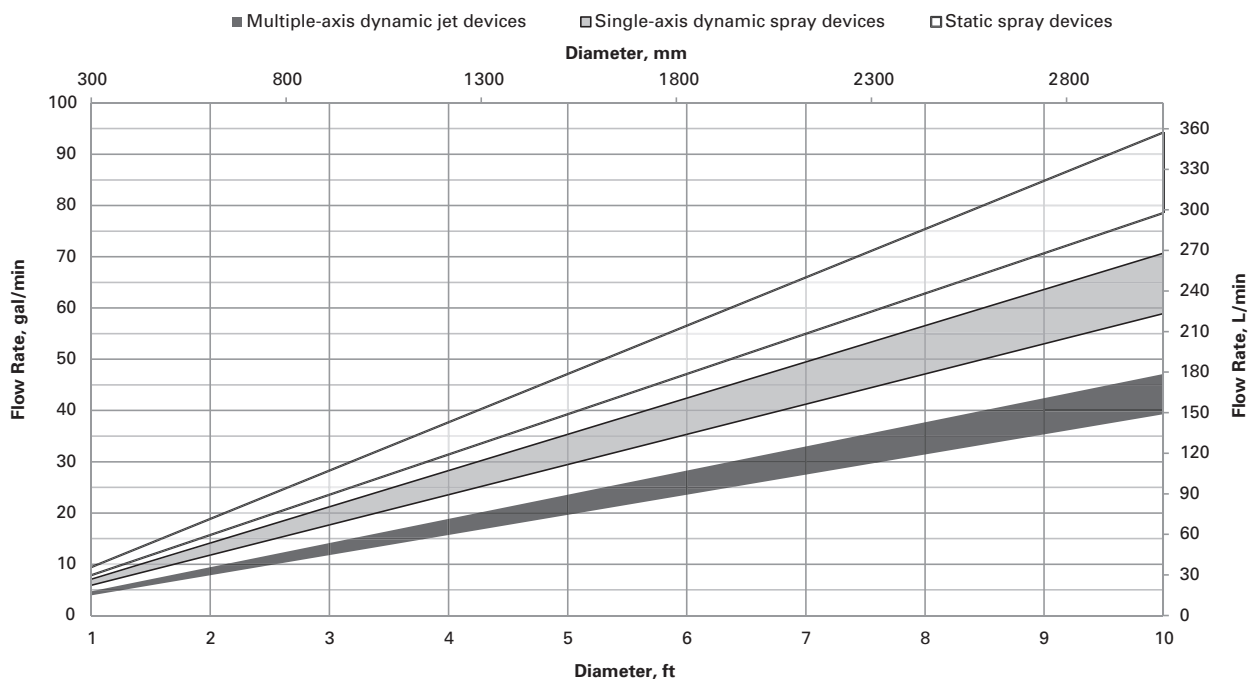
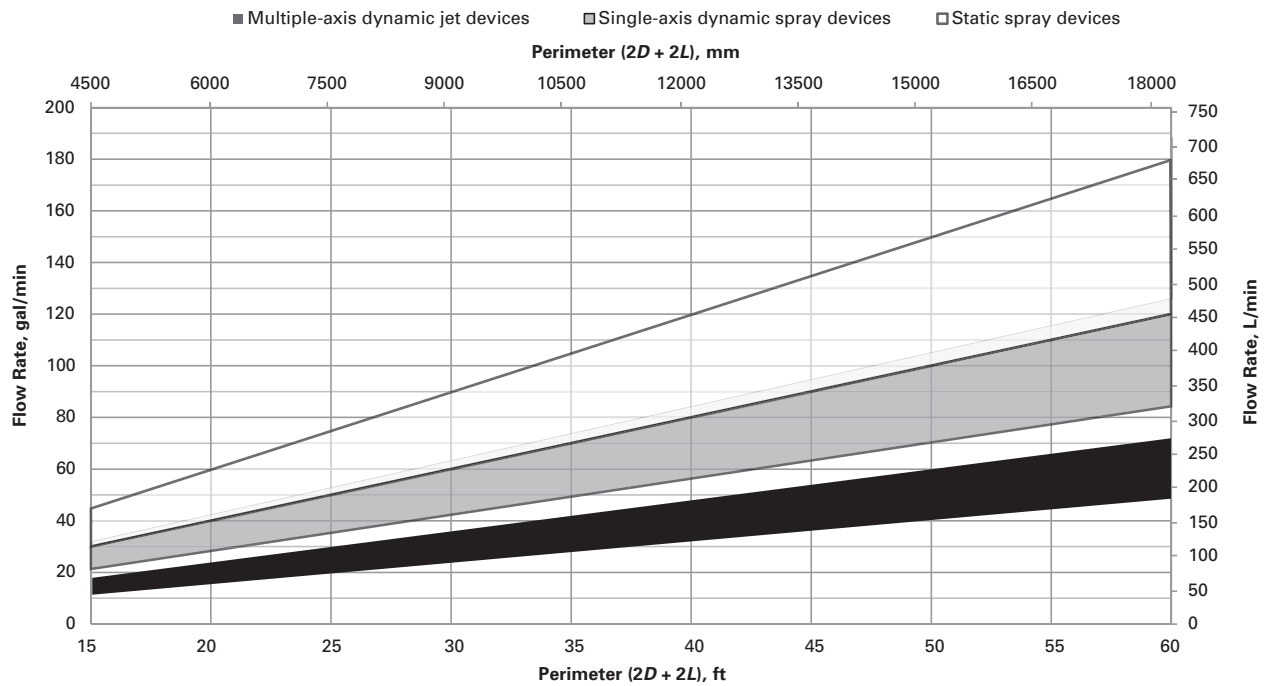
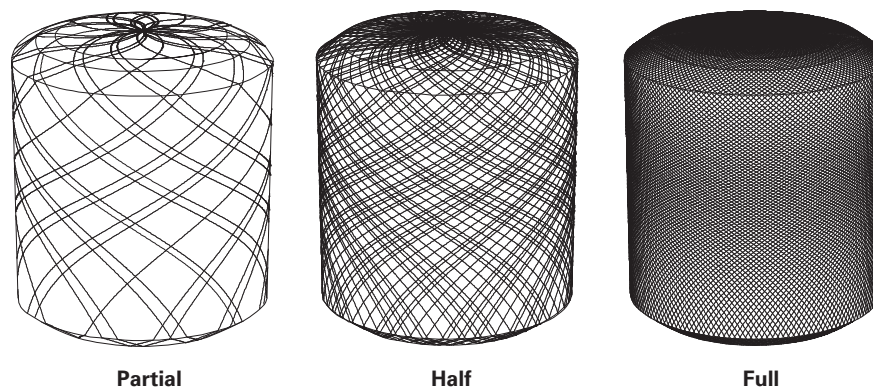


Fig. SD-3.9.2.1-3 Flow Rate Guideline for Horizontal Cylindrical Vessels

(16)

**Fig. SD-3.9.2.3-1 Impact Pattern Buildup**

(f) Flow requirements for the specific application should be confirmed with the spray device and/or equipment manufacturer or other subject matter experts.

(g) High-velocity gas flow from air-blows or steam passing through liquid-driven spray devices can result in wear to bearing surfaces. Consideration should be taken to restrict gas flow through the spray device according to the manufacturer's recommendation.

SD-3.10 Disposables That Require Presterilization or Poststerilization

[Reserved for future content]

SD-3.11 Sampling Systems

(16) SD-3.11.1 General

(a) Sampling equipment in the biopharmaceutical industry is used for the collection of samples that then undergo chemical or microbiological evaluation. Sampling may be either aseptic or nonaseptic.

(b) Sampling systems shall not adulterate the process fluid being sampled nor affect the sample characteristics being tested.

(c) Aseptic sampling systems shall be steamable or presterilized single-use.

(d) Hygienic sampling systems shall either be cleanable or single-use.

(e) Aseptic sampling systems shall be closed to isolate the process; protect the sample, sample container, and sample transfer process from the environment; and obtain representative samples.

SD-3.11.2 Aseptic Sampling Systems

SD-3.11.2.1 Basic Requirements

(a) Steamable sample systems shall meet the relevant requirements of SD-2.3.1.1.

(b) Sampling systems intended for multiple-use shall be cleanable.

(c) Sample valves shall meet the requirement of SG-3.3.2.3.

(d) In septum sample devices, the needles shall be sterilized prior to insertion into the vessel or process line.

(e) Collecting devices shall be designed, connected, and disconnected in ways that maintain the integrity of the sample.

(16) SD-3.11.2.2 Installation. The sampling device shall be installed to maintain the aseptic barrier between the process fluid being sampled and the environment. Consideration should be given to ease of assembly and subsequent handling of the sample.

SD-3.11.2.3 Sample Collecting

(a) When using single-use collecting devices, consideration shall be given to maximum pressure ratings of valves, adaptors, and bags.

(b) Consideration should be given to the impact of absorption and off-gassing that could lead to nonrepresentative samples. Polymeric material requirements for leachables and extractables are listed in Part PM.

SD-3.11.3 Nonaseptic Sampling. [Reserved for future content]

SD-3.12 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.

(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-3.12-1).

(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 cool down.

(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-3.12-1).

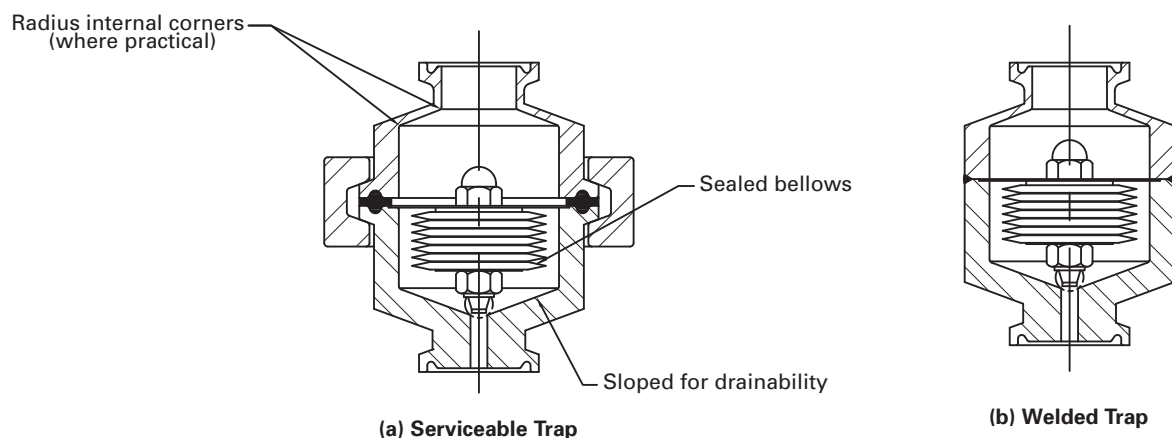
(h) Trap operation/reactivity should be improved by the installation of an uninsulated section of tubing upstream of the trap [suggested 12 in. (30 cm) as recommended by supplier] (see Fig. SD-4.2.2-2).

SD-3.13 Check Valves

(a) Check valves that are used in product contact applications shall be of hygienic design. They shall be designed for CIP. Crevices and holdup volumes should be minimized.

(b) Check valves in process contact applications should be installed in a manner that permits self-draining. Nonself-draining valves may be used for liquid streams that flow continuously (e.g., a compendial water loop) or where valves are wetted with a sanitizing medium when not in use (e.g., chromatography system that is filled with sodium hydroxide solution between uses).

(c) The flow direction and required orientation for drainability should be clearly identified on the device.

Fig. SD-3.12-1 Steam Traps for Clean Steam Systems

Where the valve is integral to equipment (e.g., diaphragm pumps, homogenizers, etc.) indication of the flow direction is not required.

(d) The use of check valves with springs in product contact should be avoided. The end-user should determine whether check valves that use a spring are acceptable for other process contact applications. Applications where spring check valves are typically acceptable include condensate removal lines and dry process gases.

(e) Check valve design shall comply with SG-3.3.2.3.

SD-3.14 Orifice Plates

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

SD-3.15 Relief Devices

(a) Rupture disks (or other hygienic pressure relief devices approved by the owner/user) shall be installed in a hygienic manner without compromising the safety or efficiency of the system.

(b) The cleaning system design shall ensure that the rupture disk (or other hygienic pressure relief devices approved by the owner/user) will not be damaged by the cleaning process (e.g., mechanical forces, chemical compatibility, etc.).

(c) Rupture disk (or other hygienic pressure relief devices approved by the owner/user) installation shall comply with the L/D ratios mentioned in SD-3.1.2.2.

(d) Rupture disks shall be installed in the manufacturer's recommended holder to ensure proper functionality and cleanability.

(e) Relief devices, including discharge piping, shall be installed in compliance with applicable codes (e.g., flammable liquids and combustibles in accordance with NFPA 30).

(f) Pressure relief valves that are used in product contact applications shall be of hygienic design on both sides of the valve seat. Cavities and holdup volumes should be minimized.

(g) Safety pressure relief valves that are used in product contact applications shall be of hygienic design up to the valve seat.

(h) Pressure and safety pressure relief valves shall be installed in a manner that permits self-draining on both the process and discharge sides of the valve seat.

(i) Pressure relief valves that are used in product contact applications shall be CIP capable. If required for CIP or SIP, an override that allows flow through the valve shall be included.

(j) Pressure relief valves that are used in product contact applications shall comply with SG-3.3.2.3.

SD-3.16 Liquid Pressure Regulators

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

(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 PROCESS UTILITIES

SD-4.1 Compendial Water Systems

(a) Compendial water systems, such as USP Grade Water-for-Injection (WFI), USP Grade Purified Water (PW), and Highly Purified Water (HPW), shall be designed as looped circulatory systems, rather than non-circulating, dead-ended, branched systems.

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

(16) SD-4.1.1 Compensial Water Generation

(a) All surfaces that shall come into direct contact with the compensial water, feed water, or condensate/blowdown produced by the units shall be constructed of 316- or 316L-type stainless steel or other material as specified by the owner/user.

(b) Connections to the compensial water, feed water, or condensate/blowdown compensial water 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 agents used to clean, de-scale, and/or passivate the units are trapped or not easily flushed during rinsing operations.

SD-4.1.2 Compensial Water Distribution Systems

SD-4.1.2.1 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 processing and/or sampling. Typically, the point-of-use assemblies are composed of the following elements:

(a) piping associated with a compensial 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-4.1.2.1-1).

SD-4.1.2.2 Critical Design Criteria for Point-of-Use Assemblies

(a) All point-of-use 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 gases.

(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 an L/D of 2 or less (see SD-3.1.2.2).

(d) Sample valves should be integral to the design of the primary valve to eliminate 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 used for the process to demonstrate water quality compliance to compensial monographs.

(g) Any valve used to provide clean utility services to the POU assembly (e.g., steam or clean gas) should be fabricated in such a manner as to achieve an L/D of 2 or less downstream from the primary POU valve [see Fig. SD-4.1.2.1-1, illustrations (a) and (c)].

(h) The length of tubing from POU valves to process equipment should be minimized [see Fig. SD-4.1.2.1-1, 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-4.1.2.1-1, illustration (c)], the design shall comply with SD-3.6.

(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-4.1.2.1-1, 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-4.1.2.2-1).

(l) Tubing and other piping materials should be a minimum of $\frac{3}{4}$ in. (19 mm) in diameter to facilitate free drainage of water after use.

(m) POU assemblies shall be drainable as indicated in SD-2.4.3.

(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 compensial water systems are constructed of metallic materials, 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 316L-type internal surfaces shall be passivated.

(p) When compensial 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-4.2 Clean/Pure Steam Systems

SD-4.2 is applicable to both clean and pure steam systems.

SD-4.2.1 Clean/Pure Steam Generation**(16)**

(a) All surfaces that come into direct contact with the clean/pure steam, feed water, or condensate/blowdown produced by the units shall be constructed of 316- or 316L-type stainless steel or other material as specified by the owner/user.

(b) Connections to the clean/pure steam, feed water, 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 agents used to clean, de-scale, and/or passivate the units are trapped or not easily flushed during rinsing operations.

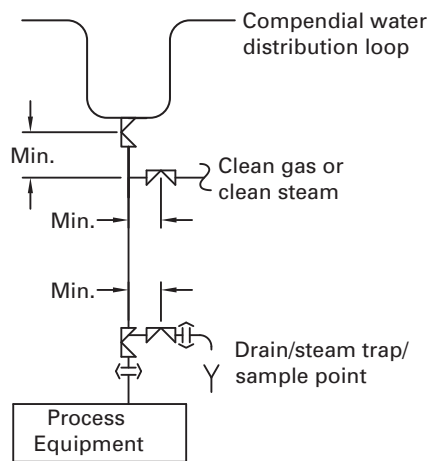
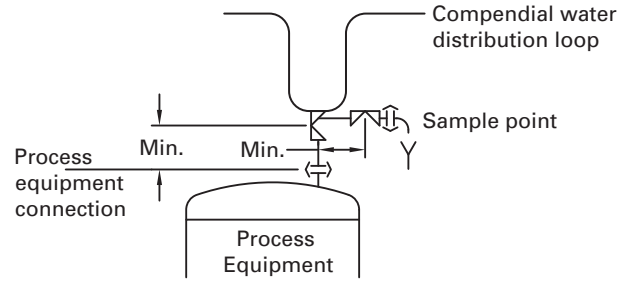
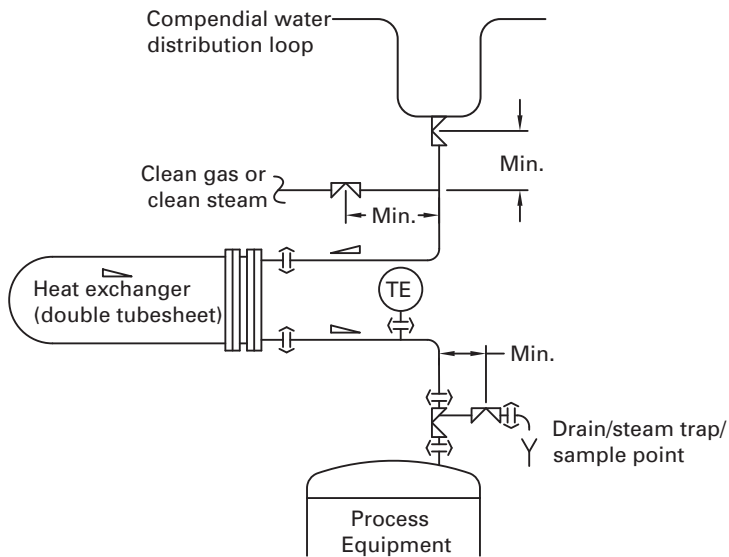
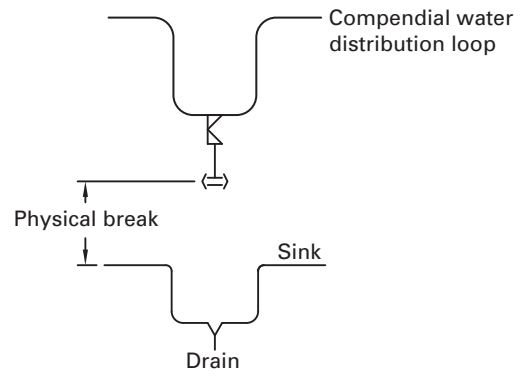
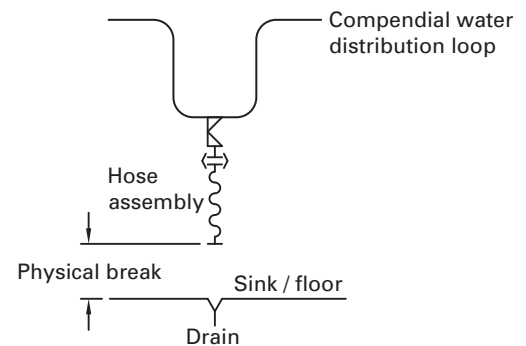
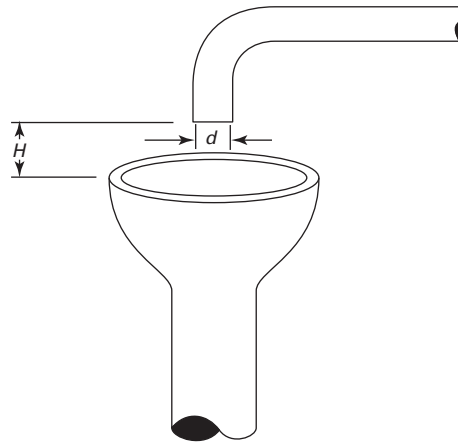
Fig. SD-4.1.2.1-1 Point-of-Use Piping**(a) Hard Piped to Equipment****(b) Direct Connect to Equipment****(c) Integral Heat Exchanger****(d) Sink****(e) Hose**

Fig. SD-4.1.2.2-1 Physical Break in Point-of-Use Piping

GENERAL NOTE: $H = 2 \times d$ or $H = 1$ in. (25 mm) if $d < \frac{1}{2}$ in. (13 mm).

SD-4.2.2 Clean/Pure Steam Distribution System

(a) The distribution system shall have adequate provision to remove air during start-up and normal operations. The use of air vents installed at locations where air is likely to be trapped, 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-2.4.3. Where necessary, increases in height should be achieved by vertical risers (see Fig. SD-4.2.2-1).

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

(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-4.2.2-2).

(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-4.2.2-2).

(h) Where possible, all components within the 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-4.2.2-1 and SD-4.2.2-2).

(j) 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-4.2.2-2).

(k) Sampling points for clean/pure steam should be located to collect representative sample(s) of the system (e.g., generator outlet, distribution header ends, critical points-of-use, autoclaves, or SIP stations).

SD-4.2.3 Clean/Pure Steam Valves. SD-4.2.3 covers isolation, regulation, and control valves that are part of the steam system and are subject to continuous steam service.

(a) Valves for steam service shall be designed for drainability and should have minimal fluid holdup volumes.

(b) Ball valves are an acceptable industry standard for isolation purposes on continuous 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-2.3.1.3-1).

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

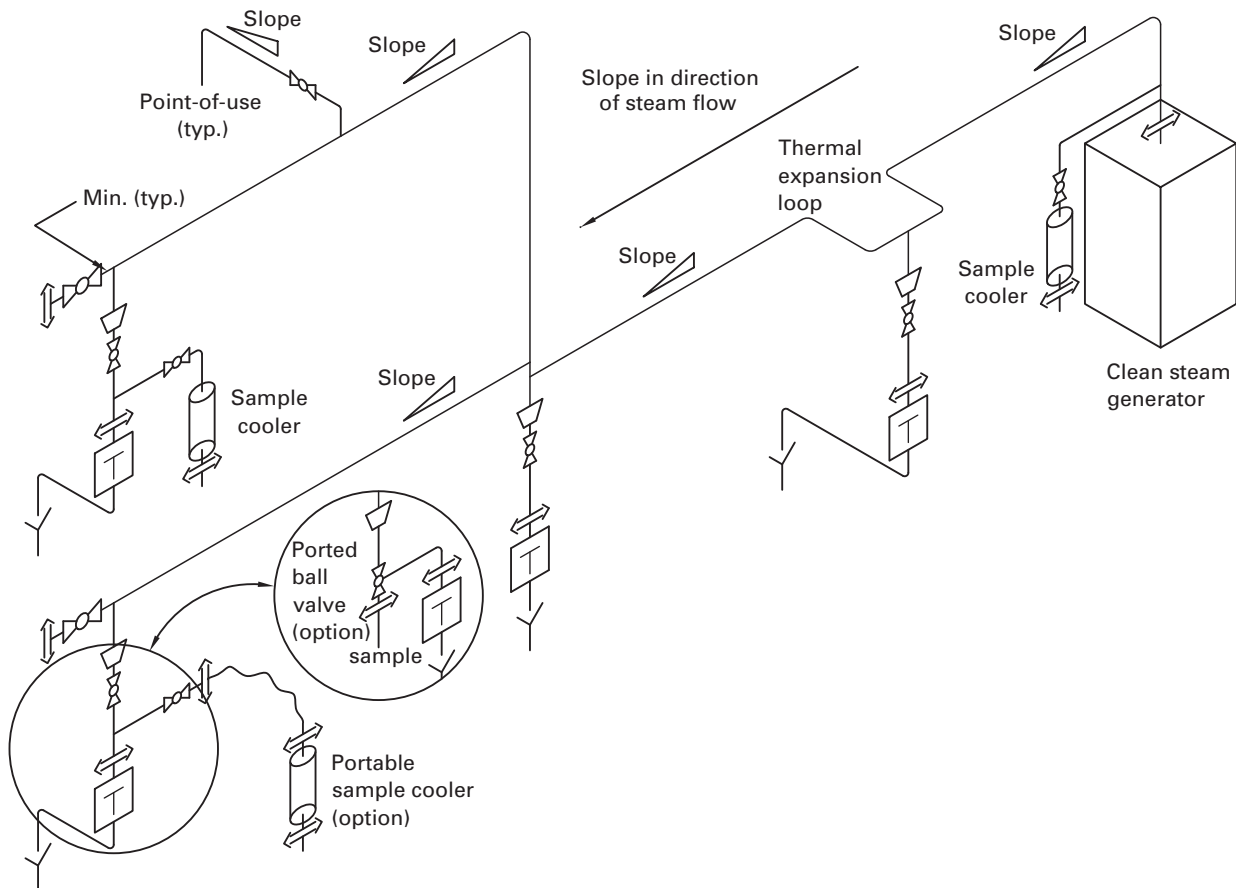
(d) Requirements for operation under CIP and SIP conditions [see SG-3.3.2.3(a)(11) and (a)(13)] can be relaxed when agreed to by the owner/user.

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

(f) Valves shall be accessible for maintenance.

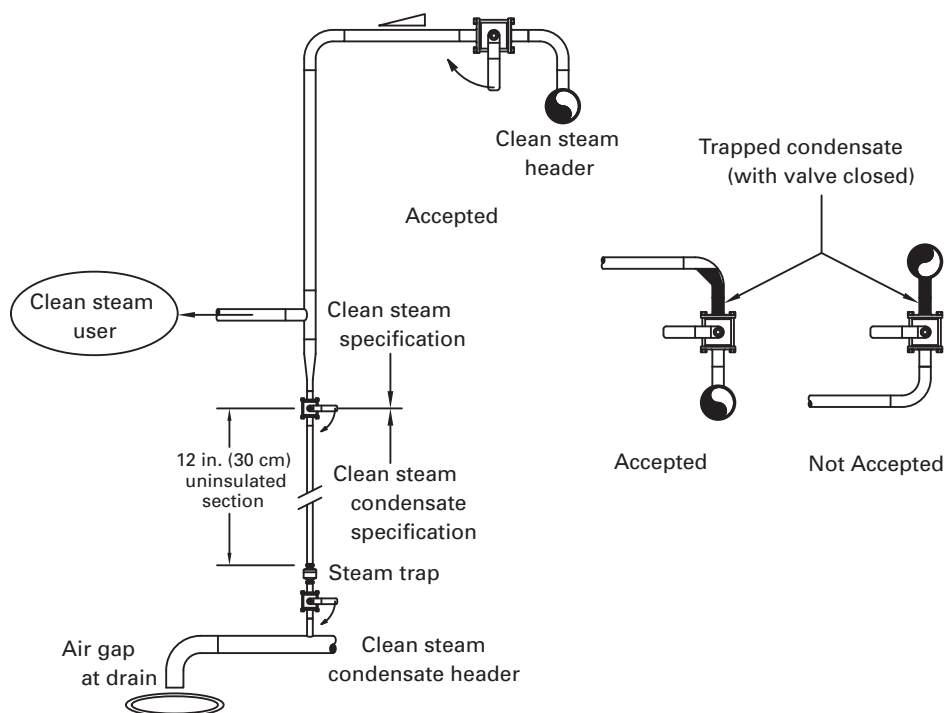
SD-4.3 Process Gases

SD-4.3.1 Process Gas Distribution Systems. For this section, a process gas distribution system is one that extends from the bulk supply source (including cylinders) to the points of use as defined by the owner/user. (16)

Fig. SD-4.2.2-1 Typical Clean Steam System Isometric

GENERAL NOTE: Provide steam traps

- (a) where line transitions from horizontal to vertical (at the bottom of the vertical riser)
- (b) at least every 100 ft (30 m)
- (c) at end of each header or branch
- (d) at thermal expansion loops or transitions
- (e) where steam is sampled

Fig. SD-4.2.2-2 Clean Steam Point-of-Use Design

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/user 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/user 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 304L-type or 316L-type alloys. Orbital welding is the recommended joining method. Inside clean rooms, the materials of choice are 304L-type or 316L-type stainless steel tubing and fittings. The owner/user 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 prefilters 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-4.4 Process Waste Systems

(16)

This section addresses process waste systems because the reliable function of the waste system can reduce the risk of contamination to the process. By designing systems that can be cleaned and rendered safe for access and preventive maintenance, reliable operation may be achieved.

SD-4.4.1 General. The manufacturing of biologics generates liquid waste in various quantities that may or may not contain viable microorganisms. The liquid waste comes directly from the process fluids and may include cleaning solutions mixed with product components, buffers, or media.

The performance of process waste treatment systems may benefit from the sanitary design requirements of Part SD. The design of the process waste transfer line(s)

shall prevent process waste backflow to the process system(s), reducing the risk of contamination.

The effectiveness and safety of process waste treatment systems have been shown to benefit from incorporating the design principles of Part SD. This is true of bio-inactivation systems where heat or chemical dosing is used, or where biosafety containment is required.

SD-4.4.2 Bio-Inactivation Systems. Depending on the type of waste, the treatment method is chosen based on effectiveness, efficiency, and jurisdictional requirements. The owner/user shall define the inactivation conditions and verify the effectiveness of the system with respect to these requirements. Bio-inactivation may be designed to be continuous or batch type and is achieved using one or more of the following methods:

- (a) thermal
- (b) chemical
- (c) radiation

The system design should minimize fouling and buildup of solids and films. Bio-inactivation systems should be cleanable to allow safe disassembly and maintenance. Where biosafety containment is a requirement, the system shall be sanitizable.

In bio-inactivation systems, piping design features specified in SD-2 and SD-3 may help in achieving proper and repeatable operation of these process waste systems.

SD-5 PROCESS SYSTEMS

SD-5.1 Upstream Systems

SD-5.1.1 Bioreactors and Fermentors

(16) SD-5.1.1.1 General

(a) *Scope.* For 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 or 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-5.1.1.1-1 and SD-5.1.1.1-2):

- (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 the 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. Process-contacting subassemblies require special design consideration for cleaning and bioburden control.

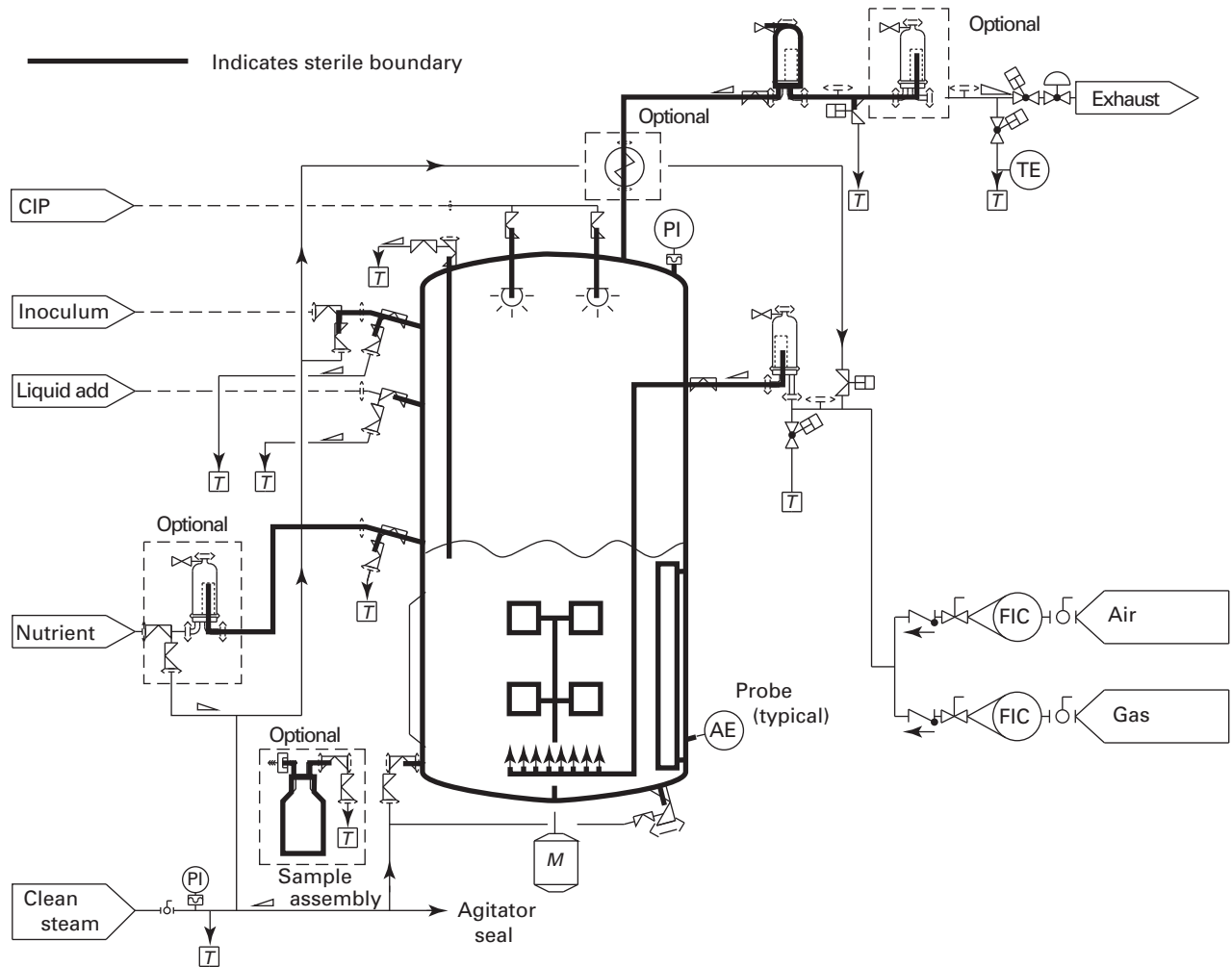
(d) The bioreactor design for cleanability and sterility shall take into consideration the biosafety level requirement for the system. A bioreactor shall be designed in accordance with a biosafety level requirement as defined by the National Institutes of Health or equivalent organization (e.g., BSL-1, 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 owner/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 the 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.

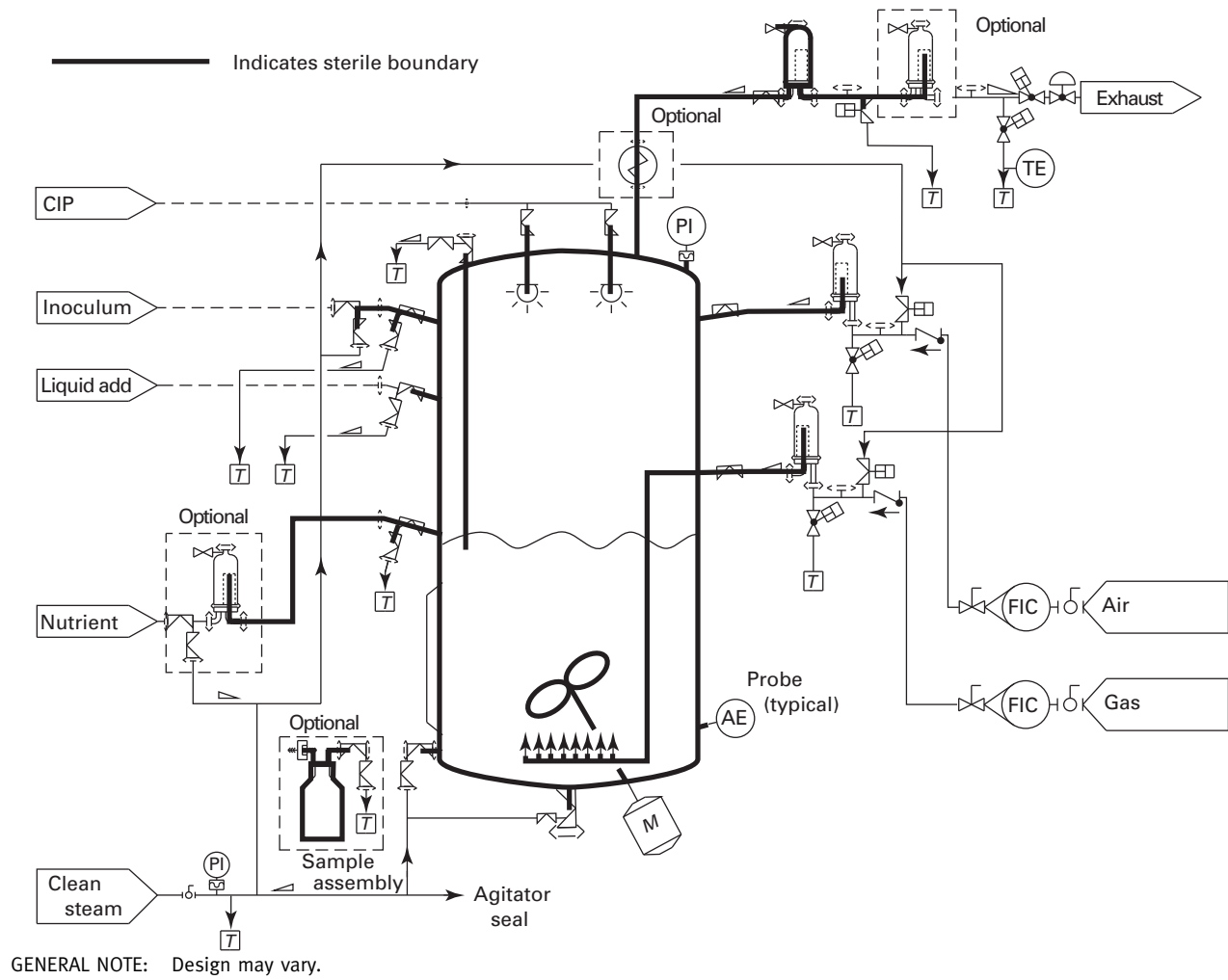
(f) The area within the sterile envelope should be designed for CIP. For components that cannot be CIP'd, the design shall allow removal for replacement or manual cleaning out of place.

(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-5.1.1.2 Inlet Gas Assembly. 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

Fig. SD-5.1.1.1-1 Fermentor Sterile Envelope

GENERAL NOTE: Design may vary.

Fig. SD-5.1.1.1-2 Bioreactor Sterile Envelope

is not limited to the items in SD-5.1.1.2.1 through SD-5.1.1.2.4.

SD-5.1.1.2.1 Flow Control Devices

(a) Flow control devices (e.g., rotameters, mass flow controllers, and 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.

SD-5.1.1.2.2 Inlet Filter Assembly

(a) For 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.

SD-5.1.1.2.3 Gas Sparging Assemblies

(a) 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-5.1.1.2.3-1 through SD-5.1.1.2.3-4) 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-3.4.2.

(b) Spargers shall be designed for SIP with the vessel.

(c) 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 replacement or cleaning out of place.

(d) The removable sparger shall be supplied with the means to ensure that the installation orientation is in compliance with design intent.

(e) If the bioreactor is sterilized with media in the vessel, the SIP operation shall direct steam flow through the sparge device.

(f) 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.

(g) All wetted surfaces shall be sloped to drain by gravity into the vessel.

(h) If a check valve is installed in the sparge line within the sterile envelope, it shall be designed for CIP and SIP.

SD-5.1.1.2.4 Inlet Gas 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-3.1.2.

(c) Inlet gas piping within the sterile envelope shall meet slope requirements as defined for GSD3 in Table SD-2.4.3.1-1.

SD-5.1.1.3 Exhaust Gas Assembly. 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 items in SD-5.1.1.3.1 through SD-5.1.1.3.3.

SD-5.1.1.3.1 Exhaust Filter

(a) For 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-5.1.1.3.1-1), exhaust heaters (Fig. SD-5.1.1.3.1-2), or steam jacketed or electrically heated traced filter housings (Fig. SD-5.1.1.3.1-3). These items shall be designed for SIP and CIP.

SD-5.1.1.3.2 Exhaust Gas Piping

(a) The exhaust gas assembly within the sterile envelope shall meet the requirements as defined in SD-3.1.2.

(b) Exhaust gas piping within the sterile envelope shall meet slope requirements as defined for GSD3 in Table SD-2.4.3.1-1.

Fig. SD-5.1.1.2.3-1 Gas Sparging Assembly — Lance

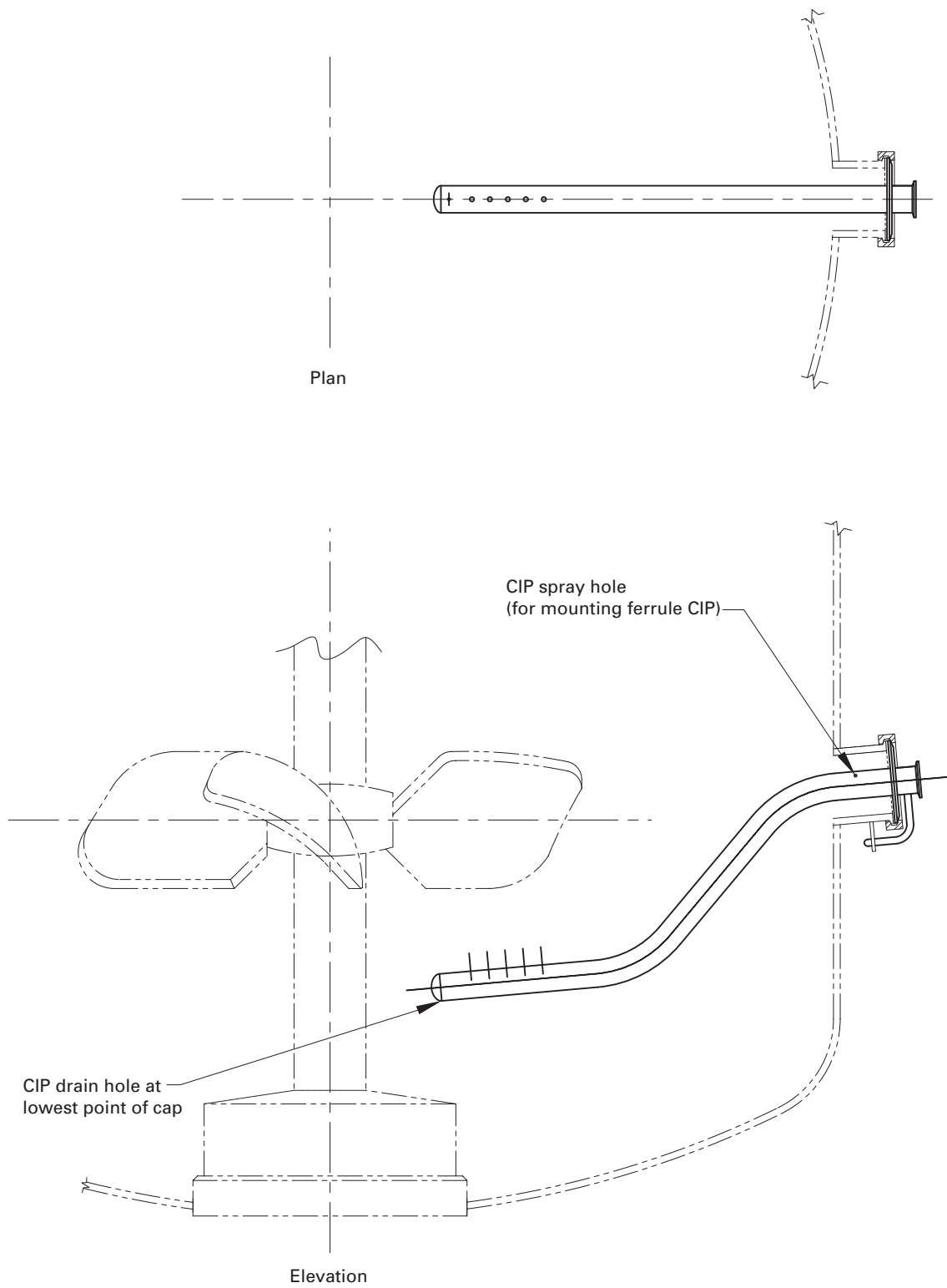


Fig. SD-5.1.1.2.3-2 Gas Sparging Assembly — Sintered

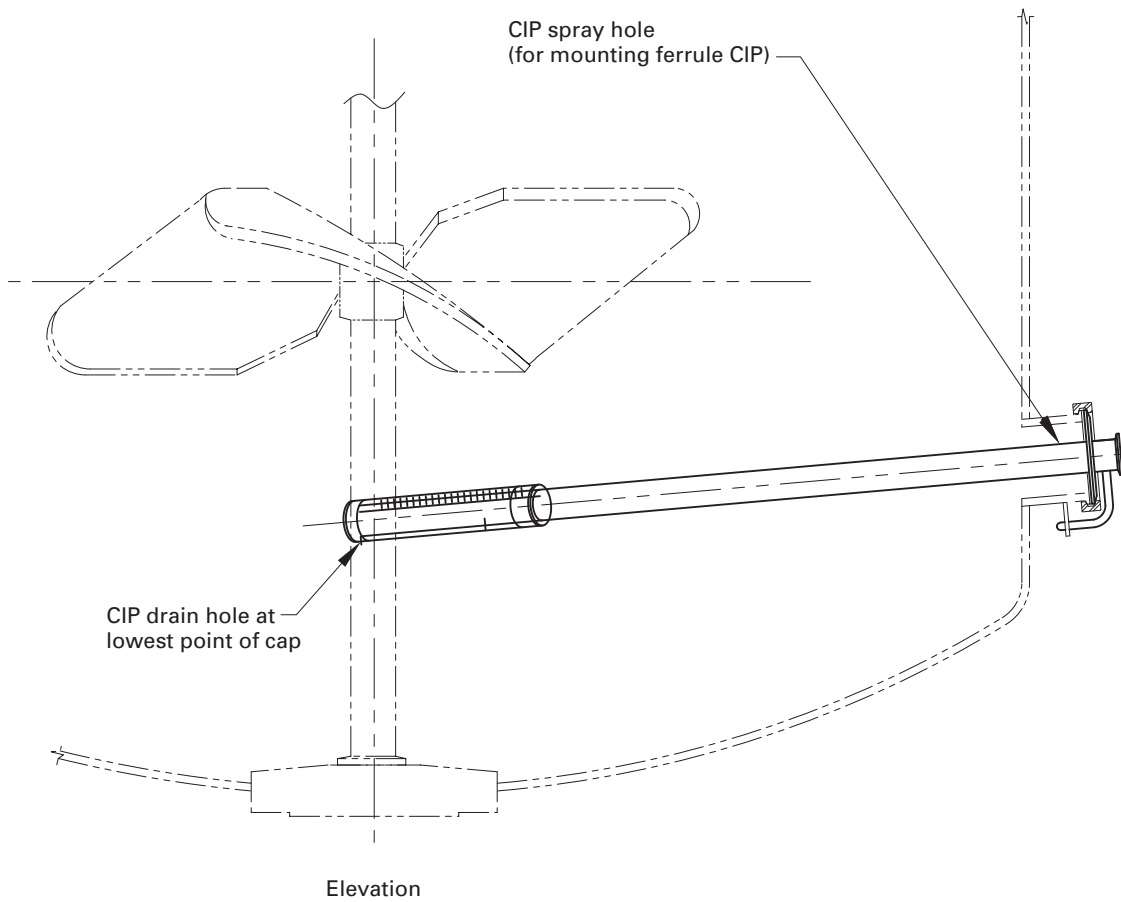
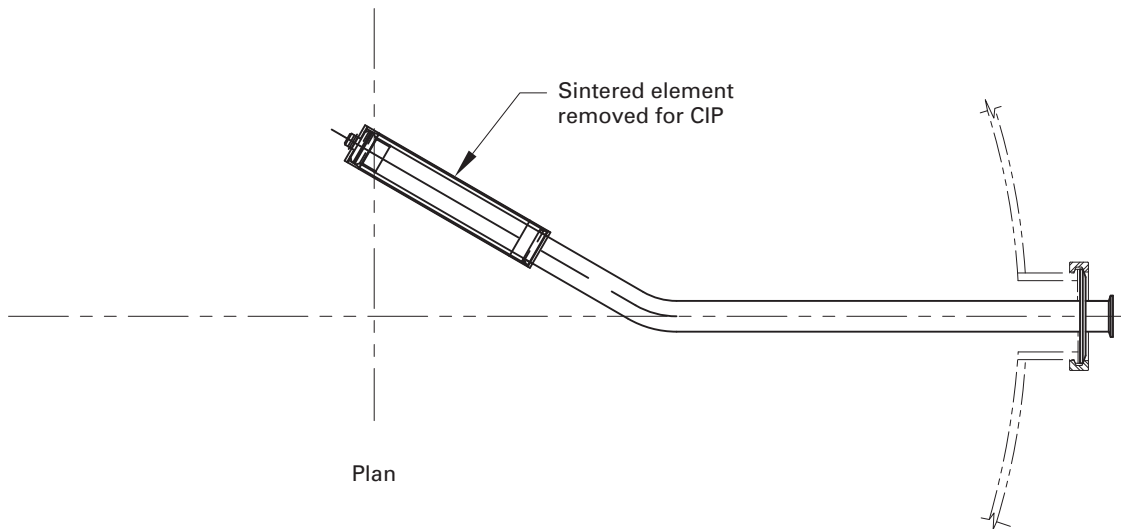


Fig. SD-5.1.1.2.3-3 Gas Sparging Assembly — Ring

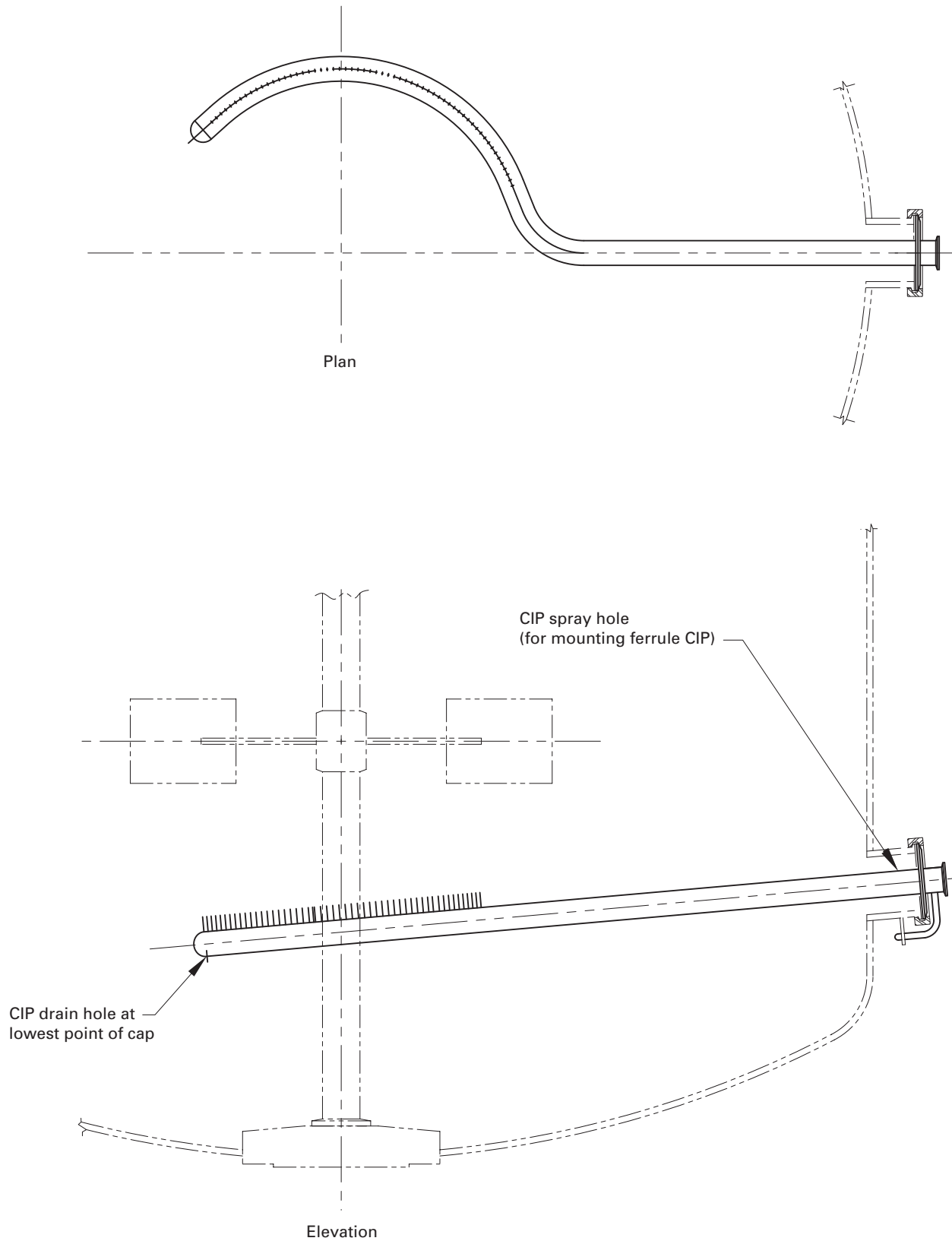


Fig. SD-5.1.1.2.3-4 Gas Sparging Assembly — Single Orifice

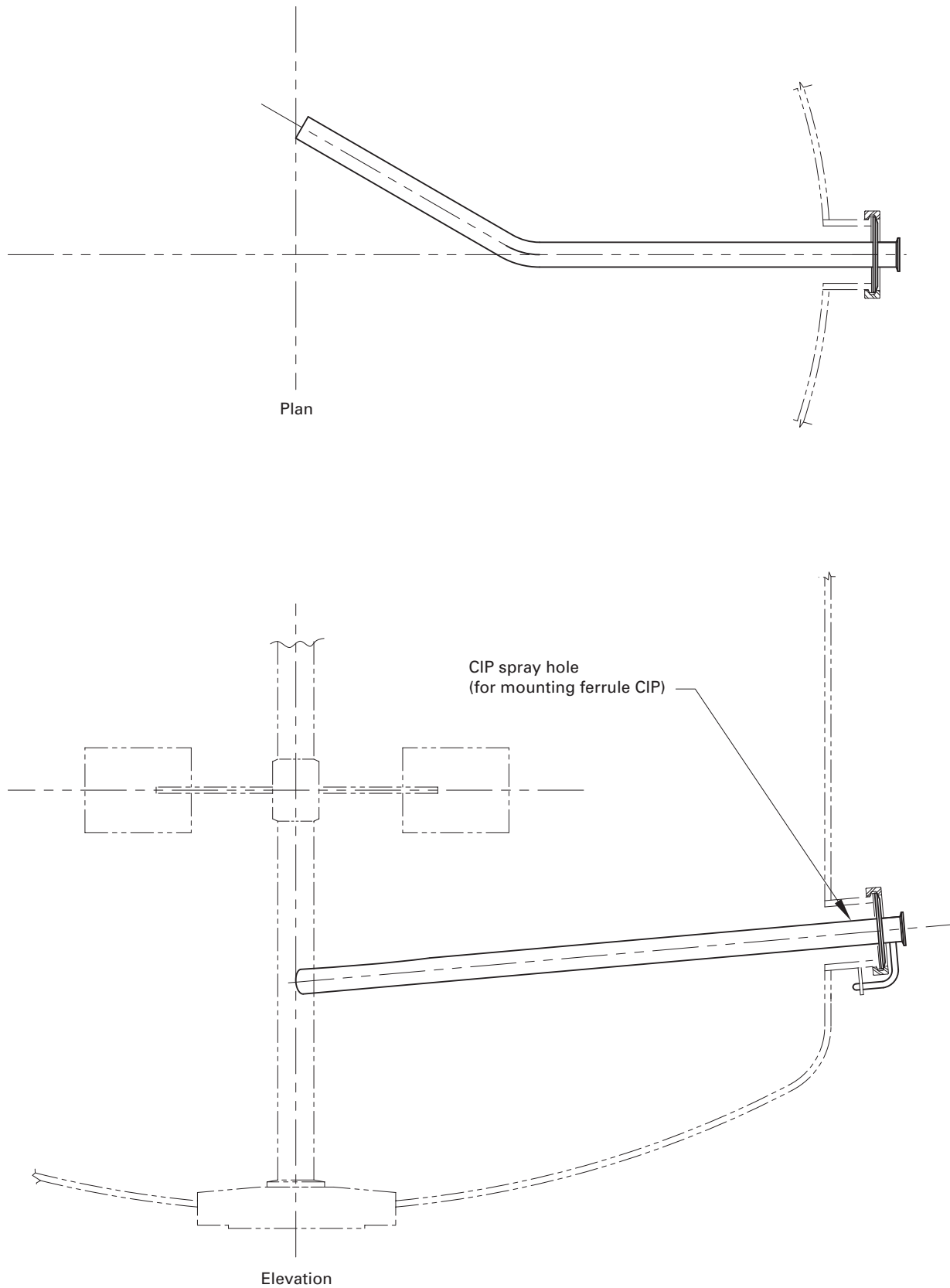


Fig. SD-5.1.1.3.1-1 Exhaust Gas Condenser

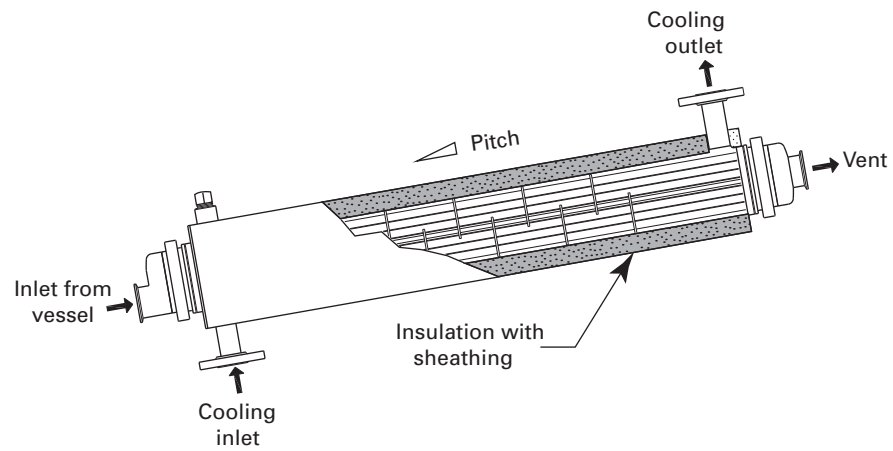


Fig. SD-5.1.1.3.1-2 Exhaust Gas Heater

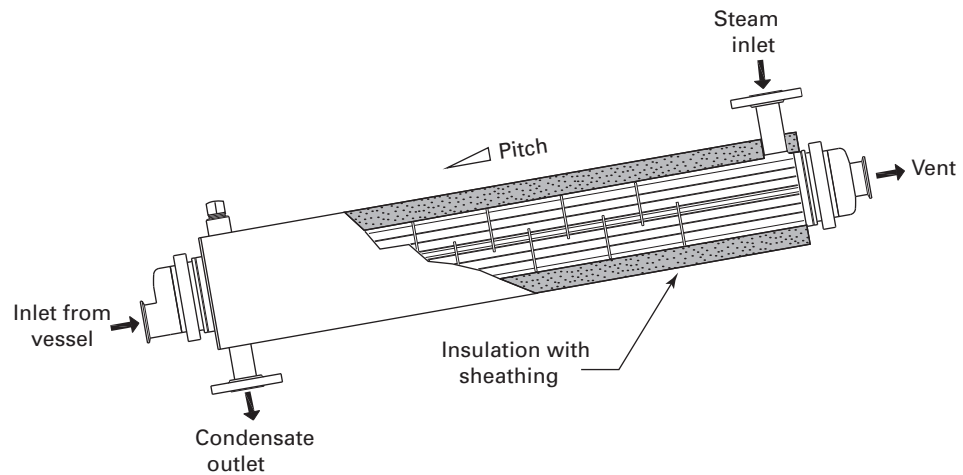
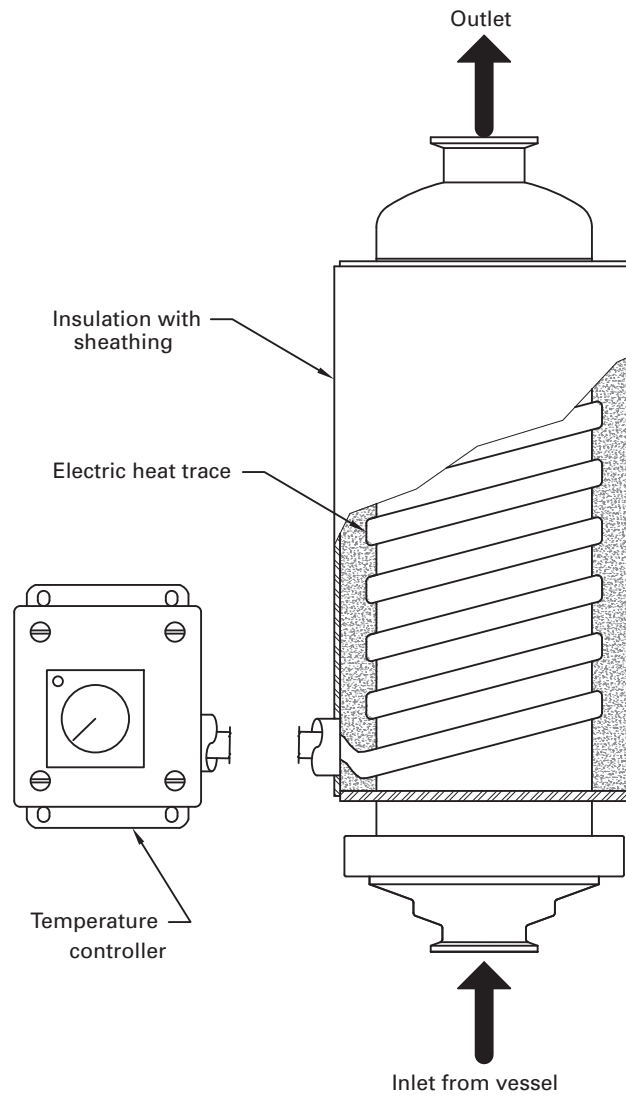


Fig. SD-5.1.1.3.1-3 Electrically Heat Traced Filter Housing



(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.

SD-5.1.1.3.3 Back Pressure Control Devices

(a) If required, back pressure control devices (e.g., modulating control valves or regulators) should be installed outside of the sterile boundary.

(b) Back pressure 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-5.1.1.4 Piping Systems

SD-5.1.1.4.1 Feed Lines. This section applies to bioreactor piping systems used to feed liquid ingredients (e.g., pH control reagents, antifoam reagents, media, nutrient, and inoculum).

(a) 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.

(b) 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.

(c) Valve and piping orientation shall be designed to provide complete drainage during CIP and SIP.

(16) **SD-5.1.1.4.2 Dip Tubes.** This section applies to all bioreactor port tube-extensions within the vessel.

(a) Bioreactor dip tubes shall meet the requirements of SD-3.4.2.

(b) Removable dip tubes (see Fig. SD-3.4.3-1) 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.

(c) All wetted surfaces shall be sloped to drain by gravity into the vessel.

(d) The SIP operation shall direct or balance steam distribution to establish and maintain sterilization temperature within the tube during the sterilization hold period.

(e) 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.

(f) Bioreactor dip tubes shall be designed for CIP or cleaning out of place (COP).

(g) If the dip tube is installed in the vessel during CIP, both the inside and outside of the dip tube shall be cleaned.

SD-5.1.1.4.3 Harvest Valves/Bottom Outlet Valve. This section applies to all valves installed in the vessel bottom head.

(a) Harvest valves shall meet the requirements of SG-3.3.2.3.

(b) Bottom outlet valves shall be drainable and installed in such a way as to ensure complete drainage of the bioreactor contents.

(c) Bioreactor harvest valves shall be designed for SIP and CIP or COP.

SD-5.1.1.5 Miscellaneous Internal Components

SD-5.1.1.5.1 Agitation Assemblies. This section applies to mechanical agitator assemblies mounted in the bioreactor for achieving one or more mixing-related unit operations (e.g., blending, mass transfer, heat transfer, and solids suspension).

(a) Agitators shall meet the requirements of SD-3.5.

(b) Agitators with double mechanical seals (see Fig. SG-2.3.2.3-2) or magnetic couplings (Fig. SD-3.5.5-2) are recommended to isolate bioreactor contents from the environment.

(c) Agitator seal or magnetic coupling components shall be designed for CIP and SIP.

(d) Provisions shall be included in the design to clean the product-contact surfaces of impellers. Additional spray elements may be required to achieve coverage.

(e) Bottom-mounted agitators shall not interfere with free and complete drainage of bioreactor contents.

SD-5.1.1.5.2 Mechanical Foam Breaker Assemblies. This section applies to mechanical foam breaker assemblies that may be mounted in the bioreactor for reducing or eliminating foam accumulation in the vapor space of the bioreactor.

(a) Foam breaker assemblies shall meet the requirements of SD-3.5.

(b) Foam breakers with either double mechanical seals (Fig. SG-2.3.2.3-2) or magnetic couplings (Fig. SD-3.5.5-2) are recommended to isolate bioreactor contents from the environment.

(c) Foam breaker seal or magnetic coupling components shall be designed for CIP and/or SIP as appropriate.

SD-5.1.1.5.3 Internal Coils

(a) Internal coils should be avoided where possible.

(b) Product-contact surfaces of internal coils require provisions for CIP and SIP.

SD-5.1.1.5.4 Baffles. Baffle assemblies shall meet the requirements of SD-3.5.

SD-5.1.1.5.5 Sprayballs/Devices/Wands. This section applies to sprayballs, wands, and other devices (see Fig. SD-3.9.2.1-1) that may be mounted in the

bioreactor vessel for distributing cleaning solution during CIP operations.

(a) Spray device assemblies shall meet the requirements of SD-3.4.2 and SD-3.9.

(b) If not removed during processing, spray device assemblies shall be designed for SIP.

(1) The SIP operation shall direct or balance steam distribution to establish and maintain sterilization temperature within the spray device during the sterilization hold period.

(2) With the exception of a combination sparger/spray device, internal spray devices should be located above the bioreactor operating liquid level.

(3) 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-5.1.1.6 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-5.1.2 Cell Disrupters

(a) Product contact material shall not affect product quality or integrity.

(b) The device shall be designed with the ability to optimize drainability.

(c) The design shall incorporate nonshedding components and parts.

(d) Safety rupture disks shall be oriented for drainability while maintaining system integrity and safety.

(e) The disrupter shall be designed for ease of disassembly to allow for COP.

(16) SD-5.1.3 Centrifuges

SD-5.1.3.1 General Description. Centrifugation is a process used to separate suspended materials of different densities using centrifugal force. Centrifuges may be used for collection of solids such as harvest of cells, inclusion bodies of precipitated protein, or clarification of bioprocess solutions. Different types of centrifuges include disk stack centrifuges, tubular bowl centrifuges, single-use centrifuges, and ultracentrifuges.

SD-5.1.3.2 Process Parameters. The owner/user should define the following process parameters:

(a) whether the centrifuge will be used for collection of solids, for clarification, or for both

(b) whether the centrifuge is intended for open, closed, or briefly exposed operation(s)

(c) the biosafety level containment and room classification requirements of the process and system

(d) product phase (e.g., supernatant or solids)

(e) cleaning requirements (e.g., CIP or manual cleaning)

(f) sanitization requirements (e.g., SIP)

(g) batch size

(h) process liquid feed flow rate

(i) solids cell type or particle size and distribution

(j) solid concentration [in packed cell volume (PCV)]

(k) feed pressure

(l) process temperature

(m) density difference between solvent and suspended solids

(n) viscosity and surface tension of liquid

For each parameter, the user may also define warning and alarm tolerances or limits. Additional process requirements may be defined by the owner/user.

SD-5.1.3.3 Performance Requirements. The owner/user shall define the following system performance requirements:

(a) maximum allowable processing and cleaning/sanitization times

(b) desired purity (e.g., PCV in supernatant or % solids)

For each parameter, the user may also define warning and alarm tolerances or limits. Additional performance requirements may be defined by the owner/user.

SD-5.1.3.4 Disk Stack Centrifuge. In bioprocessing, the disk stack centrifuge is typically used to separate cells from cell broth or cell debris or acid precipitates from liquid, or to recover inclusion bodies after homogenization of microbial cells. A disk stack centrifuge consists of a relatively shallow cylindrical bowl containing a number (stack) of closely spaced (e.g., U.S. equivalent 0.4 mm to 3.0 mm) metal disk plates or stacks that rotate.

SD-5.1.3.4.1 Operating Capabilities and System Function. The centrifuge shall be capable of the following functions:

(a) *Cleaning.* Centrifuges should be designed for cleaning in place. Different parts within the centrifuge may have different cleaning requirements or procedures. Centrifuges that will be CIP'd shall be constructed of materials compatible with the chemistry and conditions of the cleaning process (SD-2.4.1.2). Centrifuges designed for CIP shall comply with SD-2.4.2. Additional requirements for disk stack centrifuges subject to CIP include

(1) The vendor shall ensure that all product contact surfaces are cleanable with the CIP process. This includes adequate velocity of cleaning solutions in piping per SD-5.3.3.3. The use of instrument tees conforming with Tables DT-4.1.2-10 and DT-4.1.2-11 is

recommended for instruments. However, all product contact branches (e.g., instrument tee/ports, process branches) shall be exposed to cleaning fluids during CIP.

(2) The vendor should design the equipment to include sample collection points that allow for representative cleaning verification/validation of all product contact branches.

(3) Spray devices shall conform with SD-3.9.

(4) The vendor shall specify the recommended CIP solution supply rate and pressure requirements for effective cleaning.

(5) Due to fluctuations in flow (e.g., bowl discharge), use of recirculating CIP flow paths may require break-tanks, bypass flows, and pumps that can generate suction when run dry.

(6) The centrifuge manufacturer shall identify all areas of primary and incidental product contact that require manual cleaning in addition to CIP.

Centrifuges that are not designed for CIP shall be capable of disassembly and reassembly for cleaning and examination.

(b) *Sterilization/Sanitization.* The owner/user shall inform the manufacturer of the sterilization/sanitization and storage requirements (e.g., temperature, pressure, chemistry) and storage condition (e.g., flooded or dry). The vendor/owner shall agree to the defined sterile envelope or boundary.

Centrifuges that will be SIP'd shall be designed in accordance with SD-2.3.1.1. The vendor shall demonstrate saturated steam penetration across components that define the sterile boundary of the system.

Centrifuges that will be chemically sanitized shall be sanitized with an agent and process that have been proven to achieve the bioburden reduction requirements of the system.

The vendor should recommend the operating conditions (e.g., sanitizing agent supply flow rate, bowl speed, discharge rate) required to ensure effective chemical sanitization.

SD-5.2 Downstream Systems

SD-5.2.1 Filtration

(16) SD-5.2.1.1 General

(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-5.2.1.1-1).

(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 process fluid 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-5.2.1.1.1 Cleaning

(a) Filtration systems that are designed for cleaning in place shall be designed in accordance with SD-2.4.2 unless otherwise agreed to by the owner/user and manufacturer.

(b) Tangential flow filtration elements may be designed for repeated use and cleaned along with the system. When multiple-use elements are cleaned in place, system design shall ensure suitable conditions (e.g., flow rates) to properly clean the filtration elements.

(c) Direct flow filtration elements are typically not reused and are not installed during the cleaning process.

SD-5.2.1.1.2 Sanitization. The owner/user is responsible for defining the sanitization requirements based on the level of bioburden control required for the unit operation. All components and filter elements shall be either compatible with the selected sanitization agents and conditions or capable of being removed or isolated prior to the sanitization process while maintaining a flow path through the system.

(a) *Chemical Sanitization.* Equipment intended to be chemically sanitized shall be designed to ensure contact between process contact surfaces and the sanitization solution.

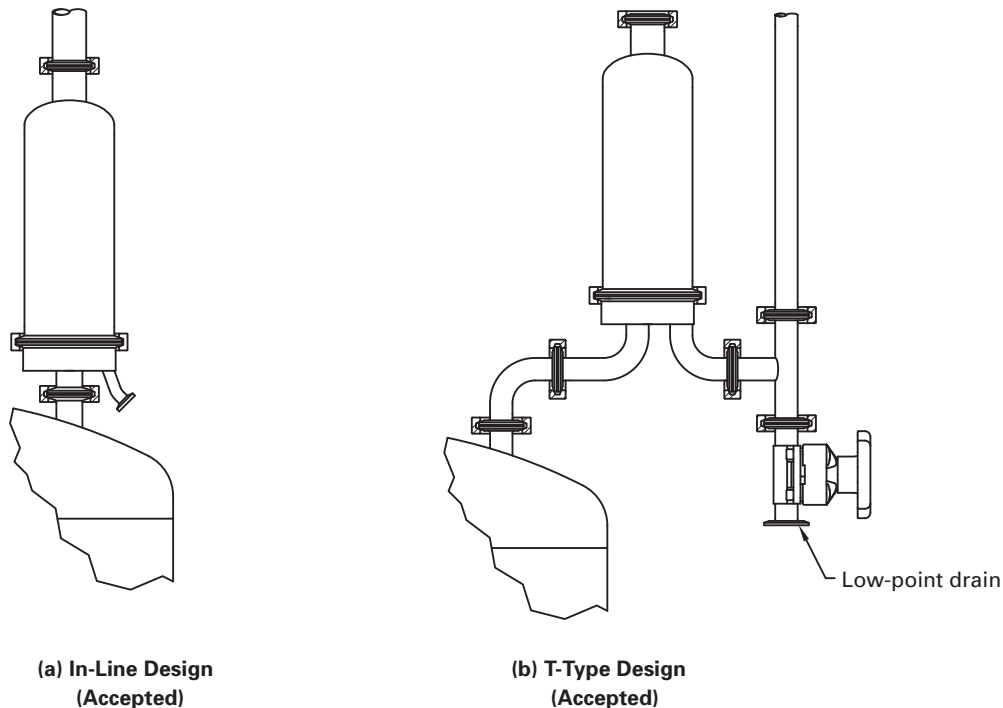
(b) *Thermal Sanitization or Sterilization.* Temperature, flow direction, and differential pressure of the thermal sanitization or sterilization process shall be defined by the owner/user. The properties of the filter elements shall be considered to confirm compatibility of the element with the exposure conditions of a thermal sanitization process.

SD-5.2.1.2 Micro/Ultrafiltration 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 holdup volume shall be minimized.

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

Fig. SD-5.2.1.1-1 Tank/Vessel Vent Filters

SD-5.2.1.3 Depth Filtration. [Reserved for future content]

SD-5.2.1.4 Tangential/Cross Flow Filtration. [Reserved for future content]

(16) **SD-5.2.2** [Reserved for future content]

SD-5.2.3 Chromatography. For this section, “system” is intended to cover the chromatography piping skid, not including the associated column.

SD-5.2.3.1 Cleaning. Chromatography systems shall be designed for cleaning in place. Systems should be designed in accordance with SD-3.1 unless otherwise agreed by the owner/user and manufacturer.

SD-5.2.3.2 Sanitization

SD-5.2.3.2.1 Chemical Sanitization. Chemical sanitization processes are used to reduce bioburden. All process contact surfaces of system components shall either be compatible with the selected sanitization agents or be capable of being removed or isolated prior to the sanitization process. Chromatography systems are typically stored flooded with a sanitizing solution to maintain bioburden control.

SD-5.2.3.2.2 Thermal Sanitization. Chromatography systems may be designed for thermal sanitization. However, because it is generally not possible to perform thermal sanitization of columns, the requirement is often waived for chromatography systems. If a system is

designed for thermal sanitization, components shall be designed for the specified conditions, or shall be removed or isolated prior to the sanitization process. Note that if items are removed for sanitization, they should be sanitized separately and reinstalled in a controlled environment to avoid contaminating the system.

SD-5.3 Process Support Systems

SD-5.3.1 Cabinet Washers

(16)

SD-5.3.1.1 General

(a) *Scope.* This section describes the requirements for washers that are designed to clean various materials and components such as glassware, drums, containers, hoses, pallets, and accessories (washable items) that are not cleaned in place. Requirements in this section are intended to be applied to cabinet washers, but may be applied to other types of washers as appropriate.

(b) Cabinet washers shall be fully automatic and should be capable of multiple cycle types for various load conditions. Cabinet washers may be designed with an integrated chemical addition system or receive cleaning solutions from a CIP system.

(c) All wetted process contact surfaces shall be of hygienic design per the applicable sections of this Standard.

(d) Cabinet washers shall include racks or holding systems designed to enable repeatable exposure of washable items to cleaning solutions.

SD-5.3.1.2 Cleaning Cycles

(a) Cabinet washers shall be capable of delivering cleaning solutions and of the subsequent rinsing of cleaning solutions from washed surfaces.

(b) Cabinet washers should have the ability to perform the following general phases during the cycle:

- (1) prewashing
- (2) washing
- (3) rinsing
- (4) final rinsing
- (5) drying with heated filtered air
- (6) cooling with filtered air

(c) The design should enable multiple chemical additions during the prewashing and washing processes.

(d) Cleaning solution temperature shall be controlled and monitored during washing and rinsing phases.

(e) The pressure and flow rates of cleaning solutions supplied to dynamic and static spray devices within the chamber and/or loading racks should be monitored.

(f) If cleaning solutions are recirculated during the cycle, the recirculation pump shall meet the requirements of SD-3.3.2.

(g) The design should provide final rinse water at an elevated temperature [e.g., > 149°F (65°C)] for sanitization and improved drying efficiency.

SD-5.3.1.3 Rinse Requirements

(a) The final rinse step may be performed using recirculated water integrated with drain steps or as a single-pass rinse (or series of single-pass rinses) to remove residual cleaning solutions. The final rinse water at the outlet of the washer shall meet the owner/user's acceptance criteria (e.g., conductivity, total organic carbon, cycle time).

(b) The ways of providing a single-pass rinse include

(1) direct connection supply from a utility water system with hygienic safeguards to prevent backflow. If a direct utility connection is used, the design should mitigate the effect of variation in supply pressure (e.g., due to draw by other users) and its impact on the flow rate.

(2) use of a water break-tank. The break-tank shall be self-drainable and vented. Rinse water from the break-tank shall not contribute to the soiling or bioburden load in the cabinet.

(c) The hydraulic conditions (i.e., pressure and flow rate) for the rinsing phases shall be consistent with those established for washing phases to ensure consistent rinsing of the washable items, the chamber interior, and the complete hydraulic circuit.

(d) The system shall be designed to provide analytical verification of final rinse water quality (e.g., conductivity and/or total organic carbon).

SD-5.3.1.4 Components**SD-5.3.1.4.1 General**

(a) *Materials of Construction*

(1) Process contact surfaces shall comply with the requirements of SD-2.4.1.

(2) All welded metallic process contact surfaces shall be passivated in accordance with SF-2.6.

(3) External surfaces of the washer cabinet shall be fabricated with material that is resistant to cleaning and sanitizing agents as specified by the owner/user.

(4) Process contact polymeric materials shall comply with Parts SG and PM.

(5) Process contact metallic materials shall comply with Part MM.

(b) *Surface Finish*. The surface finishes for the interior surfaces of the chamber, wetted process contact tubing, and exterior surfaces exposed to cleaning solutions shall be specified by the owner/user using designations provided in Table SF-2.4-1. Electropolishing is not required unless specified by the owner/user.

SD-5.3.1.4.2 Washer Chamber**SD-5.3.1.4.2.1 General**

(a) The interior surfaces of the chamber are considered process contact surfaces. These surfaces, which have the potential to drip onto washed items, shall have complete spray coverage (see SD-6.1).

(b) The interior of the chamber shall comply with SD-2.4.2. Internal surfaces that may be difficult to clean (e.g., wheels, cabling, external surfaces of exposed hygienic-clamp connections) should be minimized and assessed for the risk to product quality.

(c) All internal surfaces shall be sloped for drainability with a slope agreed on between the owner/user and fabricator. Where possible, a slope of not less than 1/8 in./ft (10 mm/m) is recommended.

(d) The chamber drainability should be verified during fabrication. Verification methods and acceptance criteria for drainability shall be agreed on in advance by all the parties.

(e) Where the chamber interfaces with the clean room, the external surfaces shall meet the owner/user's specified requirements.

(f) External surfaces should be insulated to minimize heat transmission and promote cleaning and drying.

(g) Breastplates, reinforcing pads, doubler plates, poison pads, etc., which are required for welding dissimilar material to the chamber, should be of the same material as the chamber.

(h) Lubricants shall not be used where they may come in contact with cleaning solutions or washable items.

SD-5.3.1.4.2.2 Chamber Openings

(a) Nozzles that are designed to be cleaned by a spray device should have the smallest L/D ratio practical.

For non-flow through nozzles, an L/D of less than 2 is recommended (see Fig. SD-3.4.2-1).

(b) Sidewalls and chamber-ceiling nozzles should be flush with the interior of the chamber (see Fig. SD-3.4.2-5).

(c) Instrument probes and sidewall penetrations (see Fig. SD-3.4.2-2) shall be sloped for drainability, unless the instruments used require horizontal mounting (see Fig. SD-3.4.2-3).

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

(e) Process valves shall meet the requirements of SG-3.3.2.3.

(f) Sample valves shall meet the requirements of SD-3.11.2.1.

(g) Sight glasses on the chamber shall meet the requirements of Fig. SD-3.4.6-1. Sight glasses should be designed with the smallest L/D practical and should incorporate cleanable seal designs.

SD-5.3.1.4.3 Washer Door and Door Seals

(a) Washer doors and door seals shall be designed to prevent wash fluid leakage during the entire wash cycle.

(b) For multiple-door systems, the doors shall be interlocked to allow the opening of only one door at a time for loading and unloading.

(c) Both sliding and swing door designs are acceptable.

(d) Doors that interface with classified clean rooms should not be retracted to an uncontrolled space.

(e) Construction of the door shall meet SD-2.4.1.

(f) The internal surface finish of the door shall be the same as specified for the chamber internal surfaces.

(g) Solid or inflatable door seals shall meet the requirements of SD-2.4.1.1 (e.g., conforming to FDA 21 CFR 177 and USP Section <88> Class VI).

(h) Refer to Part SG for specifications of seals.

SD-5.3.1.4.4 Internal Components

(a) Washer cabinet internal components include loading racks and supports, thermowells, spray manifolds, etc.

(b) Weld-in thermowells [see Fig. SD-3.4.3-2, illustrations (e) and (f)] shall have the same finish as the chamber internals.

(c) Loading Racks/Accessories

(1) The racks are designed to support the cleaning of specific washable items. The rack design should be verified to provide complete spray coverage for washable items defined by the owner/user in an arrangement for which the loading rack is designed.

(2) Loading racks shall secure the washable items during the wash cycle.

(3) Loading racks may be designed to distribute rinse and cleaning solutions to interior and exterior surfaces of the washable items.

(4) Loading racks should have a surface finish that meets the surface finish requirements of the chamber. Surface finish verification may not be possible for all components of the loading rack.

(5) The loading rack manifold fabrication shall comply with SD-3.1.2.3.

(6) Loading racks shall be self-drainable.

(7) Loading rack design considerations should include the disassembly required for inspection and maintenance.

SD-5.3.1.4.5 Air Drying, Intake, and Exhaust Systems. Where specified by the owner/user to dry washed items the following provisions are applicable:

(a) The air intake system shall be filtered. A prefilter and HEPA filter system are recommended to protect the washed items.

(b) The drying system shall provide heated, filtered air to the chamber, the hydraulic circuit, and in-line components.

(c) The filtered air used for drying may be supplied from a controlled or uncontrolled environment.

(d) Temperature and humidity variability of intake air should be considered in system design.

(e) The exhaust ducting should be designed to direct condensate to a drain.

SD-5.3.1.4.6 Spray Systems. Design of spray systems in cabinet washers requires the integration of manifolded spray devices in the chamber with those installed in loading racks. Spray systems in cabinet washers may use both static and dynamic spray devices that comply with SD-3.9.

(a) Loading-rack spray systems may have interchangeable spray devices to accommodate a variety of washable items in a single rack.

(b) Translational/reciprocating spray devices in the cabinet using mechanical devices (e.g., pulleys and PTFE sheathed cables) should be designed for ease of disassembly for inspection and maintenance.

(c) Mechanical devices used in the chamber shall be compatible with the process fluids and shall be cleanable.

SD-5.3.1.4.7 Chemical Addition Systems. When cleaning solutions are not provided by a CIP system, the following provisions are applicable:

(a) A number of chemicals that function as pH adjusters, emulsifying agents, and/or soil removers may be added during the cabinet washer cycles. The design considerations should include positive identification of each chemical delivery and connection.

(b) Concentrated chemicals may be delivered to the washer from bulk distribution systems or from local holding containers. The design of concentrated chemical delivery and storage systems should consider minimizing human contact.

(c) Design of concentrated chemical storage and distribution components should consider safety provisions enumerated in SD-5.3.3.2(h).

(d) The design should include monitoring of adequate bulk chemical supply (e.g., level) for the entire wash cycle.

SD-5.3.1.4.8 Recirculation Pumps

(a) The pump shall have sufficient capacity (flow rate and pressure) for all spray configurations used in the washer.

(b) Pumps shall comply with SD-3.3.2.

(c) Pump seals shall comply with Part SG.

(d) Pumps should be designed and configured to enable access for removal, inspection, and maintenance.

SD-5.3.1.4.9 Heat Exchangers

(a) Heat exchangers included in cabinet washers to heat cleaning solutions, rinse water, etc., shall comply with SD-3.6.

(b) Heat exchangers using steam or a thermal liquid may include shell-and-tube, coil, or tube types.

(c) Electric heat exchangers may be direct or indirect immersion type heaters.

SD-5.3.1.4.10 Instrumentation

(a) All process contact instruments should comply with the applicable sections of Part PI.

(b) The design should enable operators to monitor process parameters without having to pass through changes in room classifications.

SD-5.3.1.5 Branch Connections

(a) The provisions of SD-3.1.2.2 are applicable to liquid-service process contact piping leading to the chamber and delivering cleaning solutions to the spray manifolds.

(b) Liquid-service branch connections with an L/D greater than 2 shall be provided with low-point drains that are opened between each phase of the washing cycle to avoid cross-contamination.

SD-5.3.1.6 Fabrication

(a) Cabinet washers shall comply with the fabrication requirements of SD-2.4.1.

(b) Tubing within the process contact boundary should be orbital-welded tubing where possible and shall comply with Part MJ.

SD-5.3.1.7 Maintenance

(a) Cabinet washers should be designed to enable access for inspection and service of components that are subject to wear and to allow periodic calibration of instruments.

(b) Mechanical components and instruments that require maintenance may be located in an unclassified space where the maintenance can be performed.

(c) The washer design considerations should include integration with the space where maintenance is performed (e.g., minimizing moisture due to condensation).

SD-5.3.1.8 Testing. The test requirements shall be defined by the owner/user and agreed to by the manufacturer, and may include tests beyond those described in this section. These tests apply to newly installed systems and to modifications of existing systems (e.g., the addition of a loading rack to an existing system).

SD-5.3.1.8.1 Spray Device Coverage Test. Cabinet washers should be tested to confirm complete spray coverage of the specified washable items and the interior process contact surfaces of the washer chamber. The spray device coverage testing described in SD-6.1 is applicable to cabinet washers. The spray device coverage test procedure described in Nonmandatory Appendix L may be used for cabinet washers with the following additional considerations:

(a) Testing should include empty configurations (i.e., loading rack only).

(b) Testing should include racks loaded to capacity.

(c) It is acceptable to bypass the drying phase of the cycle to examine the wet conditions. If parts are dry when inspected, they should be gently rewetted with ambient or cold water to observe any residual riboflavin fluorescence.

(d) The sequence in which parts are examined should be documented to prevent false positive results due to transfer of residual riboflavin from one washable item to a clean washable item.

SD-5.3.1.8.2 Drainability Test. The proposed drainability test procedure in SD-6.4 for vessels may be applied to cabinet washers with the following exceptions/considerations:

(a) It is not necessary to fill the chamber with the outlet closed. The chamber should be wetted by liquid delivered through the spray system.

(b) The chamber drainability test should be performed without drain pump assistance.

SD-5.3.1.8.3 Cycle Performance Test. The performance test should demonstrate the ability to clean loaded items based on an initial list of washable items agreed to by the end-user and manufacturer. The test should verify removal of residue from surfaces and that the final rinse meets the specified water quality (e.g., an acceptable compendial water requirement) at the drain within a specified period of time. The test should verify that the process contact surfaces within the washer are also cleaned to the same specifications used for the washable items.

SD-5.3.1.9 Turnover Package Documentation. The documentation requirements of GR-5 are applicable to process contact components/instruments of cabinet washers.

SD-5.3.2 Steam Sterilizers/Autoclaves

SD-5.3.2.1 General. For 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 bioseals 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-5.3.2.2 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-5.3.2.2.1 through SD-5.3.2.2.3.

SD-5.3.2.2.1 Hard Goods Cycles. “Hard goods” refers 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-5.3.2.2.2 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 overpressure 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-5.3.2.2.3 Air Filter Sterilization. An independent air filter SIP sterilization 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-5.3.2.3 Components

SD-5.3.2.3.1 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 eliminate 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 (Table MJ-8.4-1) 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 35 R_a 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, SG-3.1.2, and SG-3.3. 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-4.2.

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

SD-5.3.2.3.2 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-5.3.2.3.3 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 of the vent filter elements should be provided.

SD-5.3.2.3.4 Steam Traps. Refer to SD-3.12 for requirements of steam traps.

SD-5.3.2.3.5 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-5.3.2.3.6 Valves. Valves and sealing materials located within the sterile boundary shall comply with SG-3.3.2.3. 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-5.3.2.3.7 Check Valves. Provisions to prevent back-siphoning into the service feed systems should be considered.

SD-5.3.2.3.8 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-5.3.2.4 Other Features

SD-5.3.2.4.1 Drain Temperature. Waste to drain temperature shall comply with owner/user specifications. The owner/user must specify discharge temperature requirements to the manufacturer.

SD-5.3.2.4.2 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 the following:

(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 $\pm 0.18^\circ\text{F}$ (0.1°C) 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-5.3.3 CIP Systems and Design

SD-5.3.3.1 General

SD-5.3.3.1.1 Scope and Definitions

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

(1) *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).

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

(3) *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.

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

(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-5.3.3.1.2 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 an owner/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-5.3.3.1.3 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

(4) fluid hydraulics

(c) A CIP system should include the capability to control directly or indirectly (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 air blow)

SD-5.3.3.2 CIP Skid Design

(a) For 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-3.4. The tank(s) shall be designed for cleanability per SD-5.3.3.4 and shall be equipped with a spray device(s) per SD-3.9.

(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-5.2.1.

(e) Heat exchange equipment shall be designed and fabricated per SD-3.6.1.

Table SD-5.3.3.3-1 Flow Rates to Achieve 5 ft/sec (1.52 m/s)

Sanitary Tube Size				Flow Rate	
O.D.		I.D.			
in.	mm	in.	mm	gal/min	L/min
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

(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-3.3.2. 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-5.3.3.3 CIP Flow Rate Guidelines for Process Lines (16)

(a) For effective cleaning, the CIP flow rate shall be sufficient to ensure that the cleaning agent and rinsing solutions wet all targeted surfaces within the CIP boundary. The CIP flow rate should be greater than the process flow rate.

(b) Table SD-5.3.3.3-1 details flow rates that ensure solution contact in straight horizontal and vertical lines for line sizes up to 2 in. (50 mm) without branches, fittings, and other in-line components. These flow rates correspond to a flow velocity of 5 ft/sec (1.5 m/s), which is well into the turbulent range and typical for CIP solutions that are within the scope of this section and all line sizes referenced in Part DT.

(c) CIP flow rate requirements should be considered in conjunction with other CIP process variables (e.g., temperature, chemical concentration, and time).

(d) Air trapped in branches may inhibit full contact of cleaning agent and rinsing solution to those process contact surfaces. The flow direction, line orientation, line size, and presence and orientation of branches, fittings, and other equipment can have a significant influence on the flow rate required to remove air. Adequate solution contact may be achieved at a flow velocity of 5 ft/sec (1.5 m/s) with 1.5 in. (38 mm) and larger short-outlet tees (Table DT-4.1.2-5). Smaller diameter short-outlet tees and tees with longer branches may require velocities greater than 5 ft/sec (1.5 m/s) for adequate solution contact. Solution contact in branches can be enhanced in the design by

(1) strategic use of zero-static valves

(2) flow through branch or bleeding air from branch

(3) orienting blocked branches in the horizontal position

(4) use of flush-mounted instrument fittings, short-outlet tees, gauge tees, or minimum L/D "instrument cups" for small lines

(5) orienting branches so the flow of the liquid entering the tee is directed toward the blocked branch

(e) Branches with risk of incomplete solution contact should be considered worst-case locations that may require local cleaning verification.

NOTE: Factors that may mitigate the risk of insufficient cleaning due to incomplete air removal from branches include

(a) CIP flow rates higher than process flow rates are likely to wet all surfaces that were soiled.

(b) Instruments or other devices protruding into the flow path may create additional local turbulence.

(c) Condensate generated during hot washes or hot rinses as part of a CIP cycle may provide some additional rinsing of surfaces.

(d) Dynamic flow conditions during route transitions and air blows may assist wetting.

SD-5.3.3.4 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-5.3.3.

(b) The use and application of a particular spray device design to satisfy these requirements shall be decided by the owner/user. Spray devices shall be designed and fabricated per SD-3.9 (also see Fig. SD-3.9.2.1-1 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) Figure SD-3.9.2.1-2 details ranges of flow recommendations for static sprayballs on vertical process vessels under typical cleaning loads. The recommendations in Fig. SD-3.9.2.1-2 ensure sufficient coverage.

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

(5) Sufficient exposure shall be confirmed by coverage testing per SD-6.1 at the 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-5.3.3.5 CIP Distribution Design

SD-5.3.3.5.1 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-5.3.3.5 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-2.4.3. Slope designation GSD2 is recommended.

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

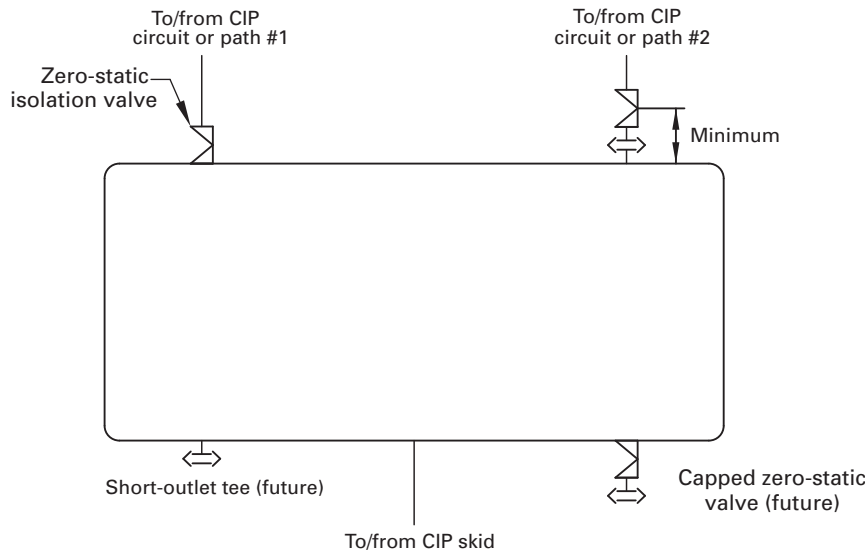
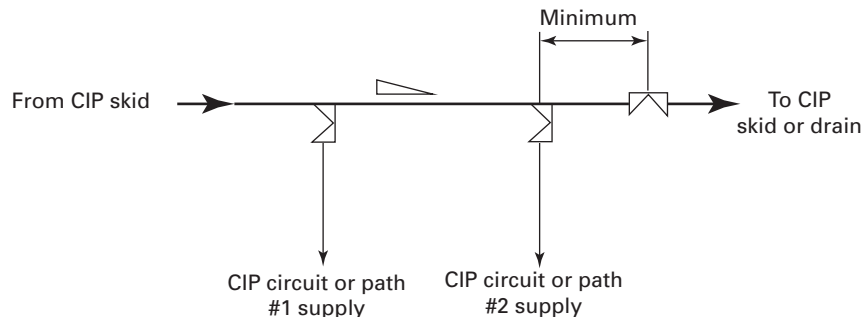
(b) Looped Headers (See Fig. SD-5.3.3.5.1-1)

(1) For 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-3.1.2.2 (see Fig. SD-3.1.2.2-1 for details). The use of short-outlet tees or zero-static valves is to be decided by the owner/user.

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

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

Fig. SD-5.3.3.5.1-1 CIP Looped Header (Supply or Return)**Fig. SD-5.3.3.5.1-2 Zero-Static Chain**

(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-3.7.1.

(d) *Multiport Valves.* For 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 SG-3.3.2.3(a) for details].

(e) *Zero-Static Chains* (See Fig. SD-5.3.3.5.1-2)

(1) For 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-5.3.3.5.1-3)

(1) For 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-5.3.3.5.2 CIP Distribution Piping

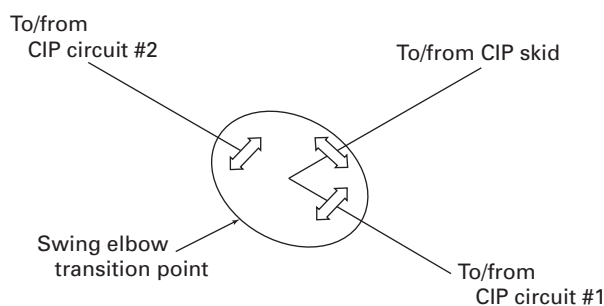
(a) The distribution piping and components in a recirculated CIP circuit shall be hygienic for design and fabrication as per SD-3.1.2 and SD-2.4.3.

(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-3.1.2 and SD-2.4.3 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-5.3.2.3 and SD-5.3.2.4.

(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.

Fig. SD-5.3.3.5.1-3 Swing Elbow Arrangement**SD-5.3.3.5.3 CIP Return Pumps**

(a) CIP return pumps (if required) shall be designed and fabricated per SD-3.3.2. 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-5.3.3.5.4 CIP Return Eductors. For 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).

(16) SD-5.3.4 Thermal Treatment Systems

SD-5.3.4.1 General. The thermal treatment systems described here reduce or eliminate viable microorganisms and viruses in a liquid under continuous flow conditions. Treatment of process liquids using high temperature for a short residence time may be desired to minimize degradation of the product or a product intermediate. Thermal systems may be designed to achieve goals that do not require sterilization of the process liquid, such as inactivation of viruses or a particular bacterial species. Bio-inactivation (waste treatment) systems (SD-4.4.2) and food pasteurization systems are not included in the scope of this section.

SD-5.3.4.1.1 Terminology. “High-temperature short time” (HTST) refers to processing at a combination of temperature and time that is designed to achieve a desired level of bioburden reduction or viral inactivation. Treatment conditions (i.e., exposure temperatures and residence times) for HTST systems range broadly, depending on the performance goal of the system.

“Ultra-high temperature” (UHT) refers to processing at temperatures above 275°F (135°C) with rapid heating and cooling and short exposure times to achieve what is generally accepted as a sterile condition.

SD-5.3.4.2 Performance Requirements. The owner/user shall define the following system performance requirements:

- (a) treatment temperature range
- (b) required residence time at treatment temperature
- (c) process liquid flow rate
- (d) discharge temperature range
- (e) maximum heating surface temperature, heat transfer fluid temperature, or process liquid heating rate (°F/sec, °C/s)

Additional performance requirements may be defined by the owner/user. Additional process parameters shall be specified by the owner/user, including specifying the process fluid’s incoming temperature and other properties.

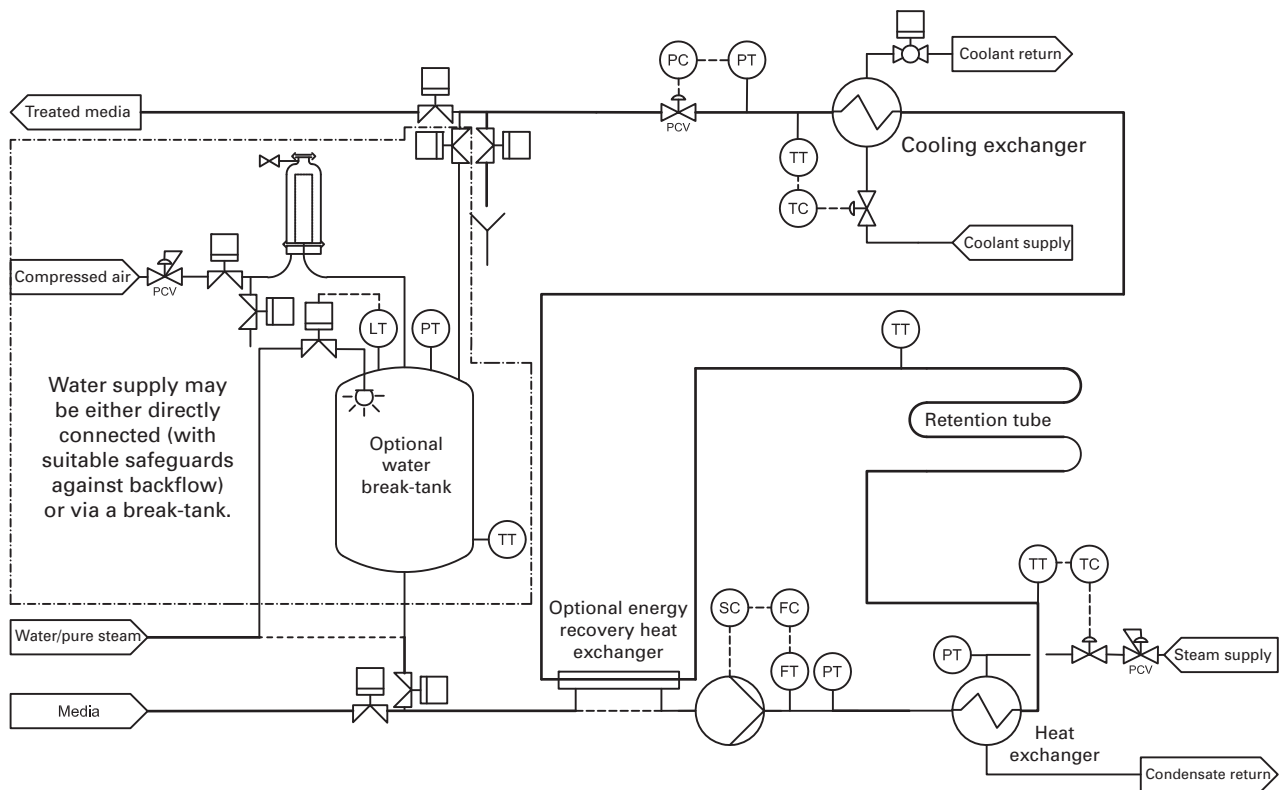
SD-5.3.4.3 Thermal Treatment System Design**SD-5.3.4.3.1 System Configuration**

(a) Thermal treatment system example configurations are shown in Figs. SD-5.3.4.3.1-1 and SD-5.3.4.3.1-2.

(b) HTST/UHT systems retain the process liquid at an elevated temperature in a retention tube.

(c) The upstream heat exchanger in HTST systems heats the process liquid, whereas the heating in UHT systems is achieved by heat exchanger or direct steam injection. Direct steam injection is performed with a steam injector valve (typical) or in an infusion chamber. These elements heat the process liquid to the required temperature.

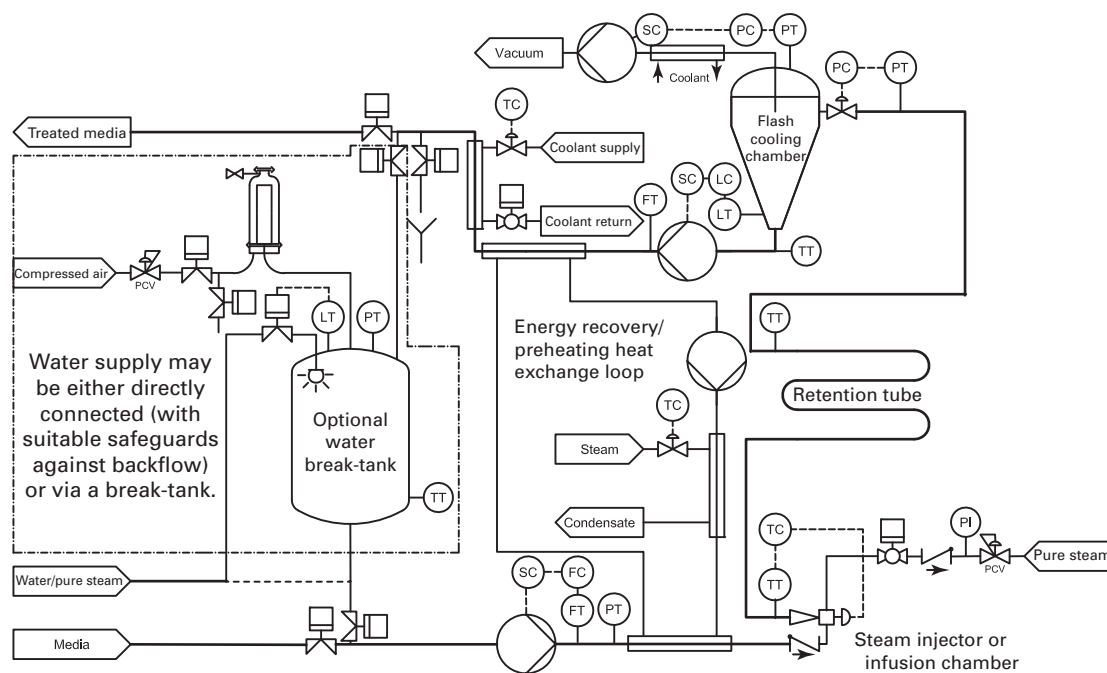
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Fig. SD-5.3.4.3.1-1 Example HTST Process Flow Schematic Diagram**GENERAL NOTES:**

- (a) Only major piping and instruments are shown.
- (b) Additional or alternative piping, valves, instruments, and equipment may be required for the following purposes:
 - (1) pressure safety
 - (2) media prefiltration with differential pressure monitoring
 - (3) CIP requirements
 - (4) SIP or hot water sanitization requirements
 - (5) alternative skid startup sanitization methods
 - (6) single-pass media startup sanitization methods
 - (7) low-pressure condensate return
 - (8) maintenance and calibration requirements
 - (9) energy recovery

Fig. SD-5.3.4.3.1-2 Example Direct Steam Injection UHT Process Flow Schematic Diagram

(16)

**GENERAL NOTES:**

- (a) Only major piping and instruments are shown.
- (b) Additional or alternative piping, valves, instruments, and equipment may be required for the following purposes:
 - (1) pressure safety
 - (2) media prefiltration with differential pressure monitoring
 - (3) CIP requirements
 - (4) SIP or hot-water sanitization requirements
 - (5) alternative skid startup sanitization methods
 - (6) single-pass media startup sanitization methods
 - (7) low-pressure condensate return
 - (8) maintenance and calibration requirements
 - (9) energy recovery
- (d) The downstream heat exchanger in HTST systems and/or the flash cooler in UHT systems cools the process liquid after the required residence time in the retention tube.
- (e) HTST/UHT systems may also be equipped with an energy recovery heat exchange system.
- (f) At a minimum, the following parameters shall be monitored and controlled by the system:
 - (1) heater outlet temperature
 - (2) cooler outlet temperature
 - (3) flow rate
 - (4) back pressure
- (g) The retention tube outlet temperature shall be continuously monitored by the system.
- (h) The system shall be configured to enable priming to purge any entrapped gases and residual liquids (e.g., storage solutions) to the drain and to heat the system during startup. The owner/user shall specify whether the system shall be primed using compendial water (from a break-tank or from a backflow-protected direct water system connection) or sanitized and primed using the process liquid.

SD-5.3.4.3.2 Heat Exchangers. Heat exchangers shall be designed to meet the performance requirements in SD-5.3.4.2 and the applicable design criteria of SD-3.6. The owner/user shall specify any additional parameters required by the manufacturer, such as utilities available and process liquid characteristics. Heat exchangers should be designed and operated at higher treated process liquid pressure than the utility side or untreated process liquid-side pressure during heat treatment to reduce the risk of process liquid contamination, unless the owner/user has assessed the risk of an alternate design. The owner/user should identify any requirements needed to minimize process fouling (e.g., minimum Reynolds number or velocity and/or maximum process contact surface temperature).

Energy recovery heat exchangers use either direct or indirect recovery of energy residing in heated process liquid flow by preheating incoming process liquids with

exiting treated liquid. Direct recovery uses one heat exchanger for this purpose, typically tube-in-tube, which shall be hygienic on both hot and cold sides. Indirect recovery uses two exchangers with a recirculated heat transfer fluid to prevent process liquid contamination.

Heat exchangers in HTST and UHT applications are typically more challenging to clean than heat exchangers in most other bioprocess applications. The following types of heat exchangers may be used in thermal treatment systems:

(a) *Shell and Tube*. Shell-and-tube heat exchangers may be straight tube or U-tube. The effect of bypass through the bonnet drain slots and slippage between the bonnet and tube sheet shall be considered in thermal design of the heat exchanger.

(b) *Coil*. Coil heat exchangers are defined as a coiled tube for process liquid flow, inside a shell designed for a heating/cooling medium. Coil heat exchangers shall be installed in a self-drainable vertical orientation.

(c) *Electric*. Electric heat exchangers shall be designed to provide uniform heating, for example, where electric current is applied directly to the process-contacting tube.

(d) *Tube-in-Tube*. Process liquid, typically in the inner tube, is enclosed in an outer tube containing counterflow heating or cooling fluid.

(e) *Plate-and-Frame*. See cautions in SD-3.6 regarding use of plate-and-frame heat exchangers before considering use in this application.

SD-5.3.4.3.3 Steam Injectors

(a) Steam injectors shall introduce pure steam directly into process liquids to provide precise, instantaneous heating in HTST or UHT systems.

(b) Steam injectors shall be installed such that single-phase flow is achieved at the desired outlet temperature. A sight glass installed downstream of the steam injector is recommended to confirm single-phase flow.

(c) Steam injectors shall be oriented to permit CIP, or designed for disassembly and cleaning out of place (COP), with agreement from the owner/user. Where the steam injection system is designed for CIP, it shall be drainable and exposed to CIP solution across the seat of the steam injection valve.

(d) Consideration should be given to how condensate introduced into the process liquid may dilute the media and alter the overall flow rate.

SD-5.3.4.3.4 Flash Chambers. [Reserved for future content]

SD-5.3.4.3.5 Pumps. Pumps used in HTST/UHT systems shall be hygienic and shall comply with SD-3.3.

SD-5.3.4.3.6 Retention Tube

(a) The owner/user shall specify the average residence time required to achieve the required residence

time in order to account for axial dispersion in the piping.

(b) The retention tube diameter should be no larger than the main system piping diameter in order to minimize the residence time range due to axial dispersion.

(c) The retention tube should be designed with consideration for axial mixing due to turbulence and velocity profiles in the tube. (For example, the average centerline velocity in turbulent flow in tubing is typically 20% to 25% greater than the overall average velocity.)

(1) The design shall take into account the owner-defined acceptable probability target that each process fluid particle meets the required residence time.

(2) The Taylor equation for axial dispersion in turbulent flow can be used to determine the required tube length. As an example, Fig. SD-5.3.4.3.6-1 shows the theoretical additional retention tube length that would be required for a water-like liquid treated at 216°F (102°C) for 10 sec in a 1-in. (25-mm) nominal retention tube to account for axial dispersion, assuming an insignificant number of bends. In the figure, to ensure that less than 1 particle out of 10^{12} has less than the 10-sec required residence time at 9.2 gal/min (35 L/min), the retention tube length would have to increase by 24%. Actual retention tube geometry, such as the number and radii of elbows, coils, or U-bends, may impact the results.

(d) The retention tube shall be designed to enable visual inspection at its inlet and outlet. The owner/user shall specify whether inspection is required for two-phase flow during operation and/or for cleaning effectiveness.

(e) The retention tube shall be designed to maintain a consistent temperature within the tube during heat treatment (e.g., the tube should be insulated and shall not have branches or tees that could result in low local temperatures).

(f) No device shall be permitted for short-circuiting a portion of the retention tube (e.g., bypass valves) to compensate for changes in rate of process liquid flow.

(g) The retention tube shall have a continuous upward slope toward the discharge complying with Table SD-2.4.3.1-1 category GSD3 to ensure that air is purged from the retention tube during operation. It shall be drainable during cleaning and/or sterilization operations.

(h) No portion of the retention tube between the inlet and the outlet temperature sensors shall be heated.

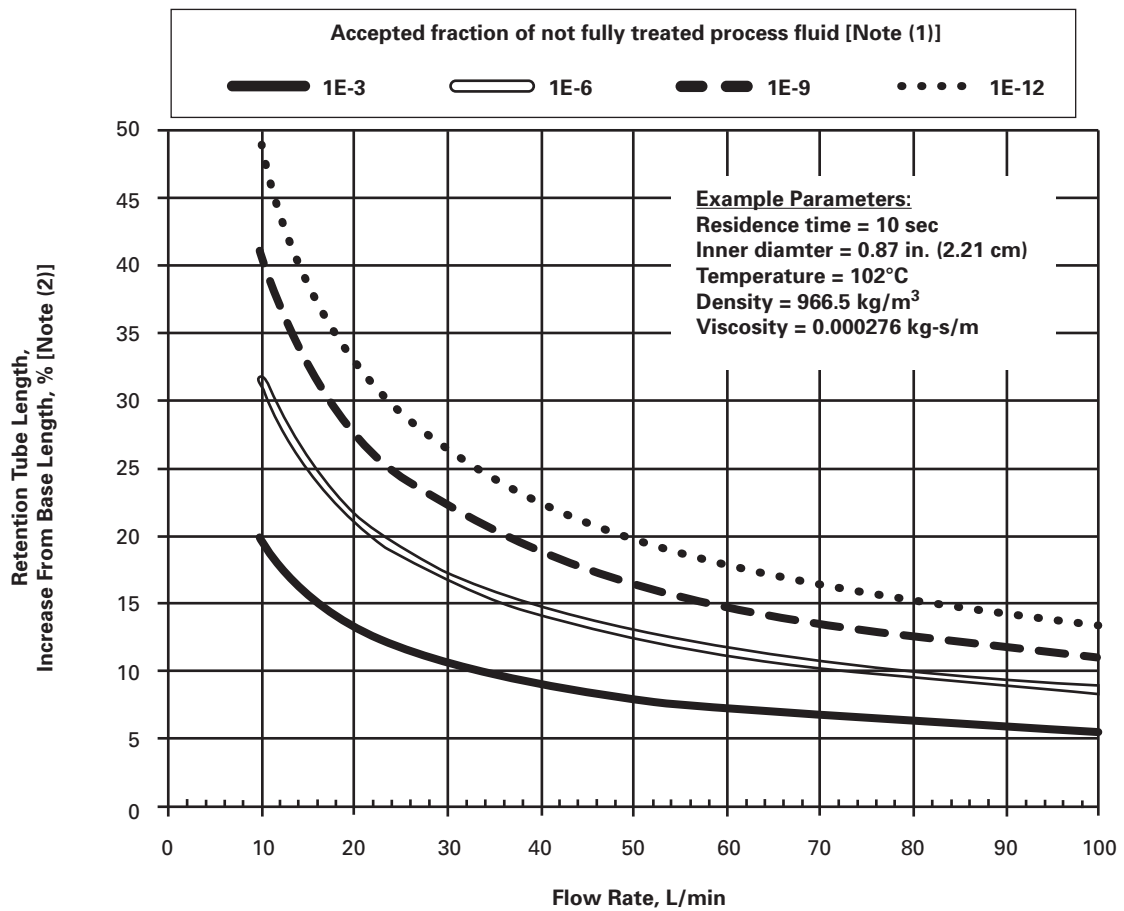
SD-5.3.4.3.7 Instrumentation. [Reserved for future content]

SD-5.3.4.3.8 Flow Control. The flow rate shall be controlled and monitored to ensure proper system operation.

SD-5.3.4.3.9 Back Pressure Control. The system shall be designed to ensure that pressure downstream of the heating exchanger or steam injector is above the

Fig. SD-5.3.4.3.6-1 Example of Additional Retention Tube Length Required to Account for Axial Mixing

(16)



NOTES:

- (1) "Not fully treated" fluid is defined as fluid whose retention time is less than the required retention time.
- (2) "Base length" is the average fluid velocity in the retention tube multiplied by the required retention time.

process fluid boiling pressure, until the treated fluid has been cooled or until it reaches a flash chamber for cooling. A pressure of at least 10 psi (0.7 bar) above the boiling pressure is recommended.

SD-5.3.4.3.10 Materials of Construction

(a) The following should be considered in selection of materials used in fabrication of HTST/UHT systems:

(1) Cyclic temperature and pressure conditions may shorten the life of materials.

(2) Solutions at high temperature may accelerate the rate of metal corrosion or elastomer/polymer degradation.

(3) High-temperature operating conditions used in UHT systems may exceed the temperature ratings of typical bioprocessing equipment or components.

(b) Although UHT processing conditions are outside the normal performance ranges specified in SD-2.3.1.1, process-contacting materials shall meet the requirements of Parts MM, PM, and SG.

SD-5.3.4.3.11 System Interfaces

(a) The owner/user shall specify the maximum allowable discharge temperature for connections to the system outlet and drains.

(b) The owner/user shall specify whether system sanitization/sterilization ends within the system boundary or extends beyond the system boundary to upstream or downstream equipment.

(c) To design appropriate interfaces with source and destination systems, the owner/user shall provide the stated purpose of the system and the functional location within the process (e.g., upstream or downstream of sterilizing filters). The owner/user shall specify whether the thermal treatment system is intended to be implemented as part of an open, functionally closed, or briefly exposed process.

SD-5.3.4.4 Operating Capabilities and System Function. Thermal treatment systems shall be capable of the following functions.

SD-5.3.4.4.1 Drainability. The process contact portions of the system shall be drainable per SD-2.4.3.

SD-5.3.4.4.2 Cleaning. Thermal treatment systems shall be designed for cleaning in place of process contact surfaces. Different elements within the system may have different cleaning requirements or procedures. Where fouling of heated surfaces may occur, cleaning and operational procedures should address potential fouling of those segments of the system. When compendial water from a break-tank is used in nonrecirculating mode to condition and flush the system, provision shall be made for the sanitization of the water tank and its piping at a minimum.

SD-5.3.4.4.3 Sterilization. If sterilization of the thermal treatment system is required, the area within

the sterile envelope or boundary shall be designed accordingly. Sterilization may be provided by conditioning the system with liquid at exposure temperature for the required duration, by chemical sterilization, or with a SIP cycle.

SD-5.3.4.4.4 Priming. The initial liquid passing through the thermal treatment system is not expected to meet the required treatment parameters. The system shall be capable of a priming operation to fill the system with liquid, remove air, and establish pressure and flow control. The thermal treatment system may be primed by the process liquid to be treated or by a priming liquid (e.g., WFI).

SD-5.3.4.4.5 Thermal Sanitization. The owner/user shall define the sanitization conditions (e.g., time and temperature). UHT systems shall be sanitized. HTST systems should be sanitized when needed to ensure that the treated process liquid is not compromised. An HTST system may not require sanitization in all cases. For example, if the system is cleaned and primed using WFI to achieve treatment temperatures, the WFI used for startup may not pose a risk of contamination of the downstream piping. For a functionally closed system, the owner/end-user shall define which components (e.g., the receiving vessel, cooling exchanger, flash chamber) must be thermally sanitized to meet the functional closure criteria.

SD-5.3.4.4.6 Temperature Stabilization. Thermal treatment systems shall be designed to stabilize the temperature of the liquid before diverting it to the destination. Heating, cooling, flow rate, and back pressure controls are enabled and allowed to stabilize.

If the system uses a priming liquid, such as WFI, the system shall stabilize the temperature using the priming liquid and then transition to and restabilize using the process liquid. Stabilization using the process liquid should continue until all the priming liquid has been cleared from the system, at which point the system shall divert the heat-treated process liquid to the destination.

SD-5.3.4.4.7 Heat Treatment. The system shall deliver heat-treated process liquid to the destination only if the performance requirements are met. If they are not met, the system shall divert the liquid to another destination (typically to a drain or a collection vessel). If the heat treatment conditions are not maintained, the owner/user shall specify whether the system resanitizes itself, continues diverting until the temperature and flow requirements are reestablished without resanitization, or performs a shutdown sequence.

The heat treatment continues until the desired amount of liquid is treated. At the conclusion of the process batch, the system may flush residual treated process liquid forward using a treated priming liquid to maximize recovery.

SD-5.3.4.4.8 Post-Use Sequence. At the end of the treatment process, the system shall turn off the heating and cooling equipment. The system may flush the HTST or UHT equipment with water to prepare for subsequent cleaning. The post-use sequence should finish by draining the system or promptly initiating the CIP sequence.

SD-5.3.4.5 Product Impact Considerations (Degradation, Fouling, Precipitation). [Reserved for future content]

SD-5.3.4.6 Testing. Process parameters (e.g., residence time at temperature) to be tested for HTST or UHT shall be defined by the owner/user. The system design should accommodate test instrumentation required to verify the process parameters and confirm the control/monitoring process performance.

(a) Temperature performance should be verified using temperature measurement devices independent of the system instruments at the inlet and outlet of the retention tube. The independent sensors should be positioned in a manner that allows measurement of the bulk fluid temperature.

(b) Average residence time should be determined. It may be determined by dividing the retention tube volume by the measured flow rate.

(c) Minimum residence time may be characterized at a given flow rate by measuring the time lag response between the inlet and outlet of the retention tube as a result of a step change in the supply fluid temperature.

(d) If a surface temperature limit has been specified by the owner/user, the heating surface temperature should be verified. For electrically heated tubing, the exterior surface temperature may be measured to provide an indirect, but conservative, measure of the interior surface temperature. For steam-liquid or liquid-liquid heat exchangers, the utility-side (e.g., steam or hot water) inlet temperature may be measured to provide an indirect, but conservative, measure of the tube surface temperature.

(e) Initial testing of new equipment should document the heat supplied to meet the process requirements. Changes in the heat required to meet the process requirements may indicate the onset of deleterious fouling. The heat supplied can be correlated to power input for electrically heated tubes, steam pressure for steam heat exchangers, and non-process liquid inlet and outlet temperatures for liquid-liquid heat exchangers.

(f) Initial testing of system performance should document the steady-state pump speed, pump differential pressure, flow rate, system back pressure, and back pressure control valve position. The pump speed, flow rate, and pump differential pressure may be compared to the manufacturer's pump curve as a benchmark. Changes to the relationship among pump speed, pump pressure differential, flow rate, and back pressure control valve

position over time may provide an indication of pump performance degradation, flow instrumentation drift, or fouling affecting system flow resistance.

SD-5.3.4.7 Maintenance. [Reserved for future content]

SD-5.3.5 Solution Preparation Systems. Solution preparation systems are used for the preparation, storage, and distribution of buffer solutions, media solutions, and other reagents used in bioprocessing, formulation, and filling operations. Systems may include components for transfer and mixing of solids and liquids (e.g., agitators, in-line mixers, vacuum transfer equipment, intermediate bulk containers). The systems may also include tanks/vessels for solution preparation and for solution storage. Systems may also include components designed specifically for bioburden reduction or solution conditioning. Examples of these include filtration systems and thermal conditioning systems such as UHT/HTST systems. (16)

Preparation tanks may be designed for operations that are briefly exposed to the room environment (e.g., addition of reagents through an open port) when appropriate measures are exercised for bioburden control and other particulate contamination (e.g., filtration to reduce bioburden after reagents are dissolved).

The owner/user shall define which process contact surfaces require cleaning and/or sanitization (e.g., vessel internals, solids transfer equipment, solution transfer lines, vent lines) and which cleaning methods (e.g., CIP, COP, water rinses) and/or sanitization methods (e.g., chemical sanitization, SIP, hot-water flush) are to be used.

When a solution sterilizing-grade filter is SIP'd with the system, the sterile envelope shall include the filter membrane. In practice, this requires a design that achieves sterilization conditions across the filter membrane.

SD-5.3.5.1 Contamination Control. Measures should be taken to contain powders that are added to mixing tanks and to contain aerosols that may be generated during solution preparation to mitigate the risk of cross-contamination between operations. The owner/user shall assess the risk of cross-contamination between operations. Controls to mitigate the risk of cross-contamination may include

- (a) physical separation (e.g., separate rooms, isolators)
- (b) airflow controls (e.g., dust collection systems, filtration of circulated air, flow direction)
- (c) use of closed-process systems
- (d) temporal separation
- (e) procedural separation

The owner/user shall specify requirements for mitigation of risks from environmental contamination and growth of adventitious agents such as bacteria, fungi,

and viruses in solutions during processing and hold times.

SD-5.3.5.1.1 For systems that require closure, controls to achieve and maintain a functionally closed system after mixing may include

(a) equipment to achieve required bioburden reduction in prepared solutions (e.g., sterilizing-grade filters, HTST, sterilization vessels)

(b) technologies that prepare equipment for use (e.g., CIP, SIP, use of gamma-irradiated single-use components)

(c) procedures and designs to maintain control during processing and holds after bioburden reduction (e.g., system closure after sanitization, drying equipment for holds, and hold and processing time limits)

SD-5.3.5.1.2 Systems used for aseptic processing shall have all surfaces that contact sterile process streams downstream of the bioburden control device capable of being sterilized. This includes interfaces between components that are sterilized separately.

SD-5.3.5.1.3 Systems used for buffer distribution may require a filter to reduce bioburden during transfers to downstream systems, particularly when the buffer is growth-promoting or is transferred to a holding system before use. Tanks used for long-term storage of solutions should be designed to be sterilized unless the intended solution is bactericidal or bacteriostatic.

(16) SD-5.4 Fill and Finish Systems

SD-5.4.1 Lyophilizers/Freeze Dryers

(16) **SD-5.4.1.1 General.** For the purpose of this section, the terms “lyophilizer” and “freeze dryer” may be used synonymously. This section describes the requirements for cleanability and bioburden control of lyophilizers that are used for biopharmaceutical processing. This section applies to lyophilizers in which product is loaded onto shelves. Other designs that use methods and components not described in this section should be evaluated and agreed upon by the owner/user. A lyophilizer comprises a number of interconnected components. Components with process contact surfaces and/or product contact surfaces shall be designed for cleanability and bioburden control.

Lyophilizer surfaces of components, piping, equipment, or systems that are isolated by design from both product and process fluids are not process contact surfaces nor required to be designed for cleanability or bioburden control. Examples of surfaces that are not process contact surfaces include the exterior surfaces of equipment, drain lines, vacuum lines, and systems containing hydronic or hydraulic fluids.

SD-5.4.1.2 Components. A lyophilizer is comprised of functional components/systems, as shown in

Fig. 5.4.1.2-1, which are designed for isolation, cleanability, and/or bioburden control. These components/systems have the potential to affect product quality and include the following:

- (a) lyophilizer chamber
- (b) condenser vessel
- (c) lyophilizer shelves
- (d) vacuum systems
- (e) isolation bellows
- (f) internal moving parts
- (g) spray devices
- (h) gas filter assemblies
- (i) doors and door seals
- (j) valves
- (k) instruments

SD-5.4.1.2.1 General

(a) All components shall be rated for the applicable pressure, vacuum, temperature range, thermal shock, and exposure to sanitizing agents [e.g., vaporized hydrogen peroxide (VHP)] when applicable.

(b) Process contact surfaces made from metallic material should comply with SD-2.4.1.1 through SD-2.4.1.3.

(c) Process contact surfaces made from nonmetallic material should comply with SD-2.4.1.1, SD-2.4.1.2, SD-2.4.1.4, and Part PM.

SD-5.4.1.2.2 Lyophilizer Chamber

(a) The interior surfaces of the lyophilizer chamber (chamber vessel) are considered process contact surfaces.

(b) The lyophilizer chamber includes all necessary fittings and closures (e.g., doors, bellows, isolation valves). The chamber floor shall be self-draining.

(c) The surface finishes of the chamber internal surfaces (i.e., door, walls, ceiling, and floor) shall be specified by the owner/user using the designations in Table SF-2.4-1.

(d) Where the chamber interfaces with the clean room or isolator, the surfaces shall meet the owner/user's specified requirements.

SD-5.4.1.2.3 Condenser Vessel

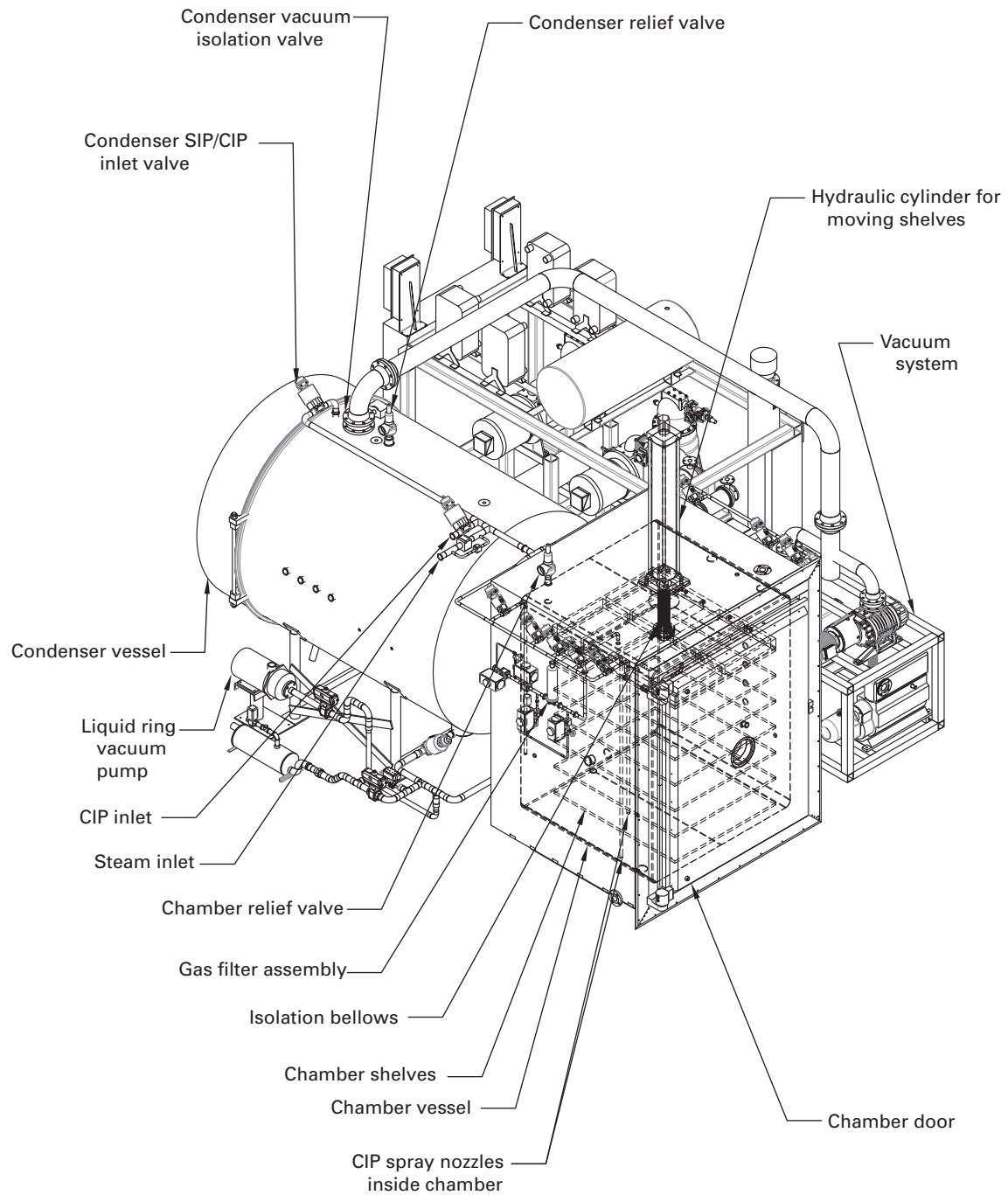
(a) The condenser vessel, used to contain the condenser heat exchanger, is connected to the chamber vessel and may be separated by a main isolation valve.

(b) All surfaces shall be self-draining.

(c) In systems designed with backstreaming prevention (i.e., prevention of reverse flow from the vacuum pumps), the condenser vessel is downstream of the chamber. The condenser vessel surfaces are not process contact surfaces and do not have surface finish requirements.

(d) In systems not designed with backstreaming prevention, the condenser vessel surfaces are process contact surfaces. The surface finishes of the condenser vessel

Fig. SD-5.4.1.2-1 Typical Lyophilizer Component Assembly



shall be specified by the owner/user using the designations in Table SF-2.4-1.

SD-5.4.1.2.4 Lyophilizer Shelves

(a) The flat surfaces of shelves supporting containers of product (e.g., vials containing product) are considered process contact surfaces.

(b) The flat surfaces of shelves are considered product contact surfaces if product without containers is placed directly on the shelves.

(c) Surfaces of the structural components of the shelves are considered process contact surfaces.

(d) The shelf heat transfer performance depends on shelf flatness. The loading/unloading and initial container closure performance require the shelves to be level. Therefore, shelves are not required to be sloped. Methods other than self-draining may be required to remove residual CIP liquid (e.g., collapsible shelves may be contracted to remove residual CIP liquid from shelf surfaces followed by a process that facilitates drying, such as SIP followed by a vacuum hold).

(e) The surface finishes of shelves shall be specified by the owner/user using the designations in Table SF-2.4-1. A rougher surface may be specified for the bottom side of the shelves by the owner/user to meet process requirements (e.g., stopper adhesion prevention).

SD-5.4.1.2.5 Vacuum Systems

(a) The lyophilizer vacuum pumps and condenser cooler establish a pressure gradient during lyophilization from the chamber vessel through the condenser vessel resulting in single-direction flow toward the lyophilizer vacuum pumps. To maintain an environment appropriate for aseptic processing in the chamber vessel, the vacuum system shall prevent reverse flow (backstreaming).

(b) The lyophilizer vacuum pumps are not hygienic components and should be designed to be outside the sterile boundary.

(c) Where vacuum pumps for wet service (e.g., liquid ring vacuum pumps) are used to evacuate air/vapor from the chamber and condenser vessels, they should be located outside the sterile boundary.

SD-5.4.1.2.6 Isolation Bellows

(a) Isolation bellows are employed to isolate nonhygienic moving components from the lyophilizer sterile boundary.

(b) The surfaces of the bellows and its mounting connections exposed to the inside of the lyophilizer are considered process contact surfaces and should be assessed for cleanability. The bellows shall be extended during the cleaning cycle to provide access to all exposed process contact surfaces.

(c) The bellows shall be sealed at each end to isolate the inside of the lyophilizer from external conditions. Bellows may be bolted or welded into place. A bellows

sealed by a bolted flange connection with an O-ring seal within the chamber vessel facilitates replacement and maintenance. The inside of the bellows may be evacuated, vented, or pressurized to facilitate retraction or extension of the bellows. The lyophilizer may be provided with a leak-test system to ensure the bellows are intact.

(d) When specified, the bellows shall be suitable for sterilization and shall allow for full penetration of the sterilizing agent at all surfaces inside the sterile boundary.

SD-5.4.1.2.7 Internal Moving Parts. The following should be considered in the design of moving parts (e.g., the raising and lowering of the shelves) within the chamber and/or condenser vessels:

(a) Nonmetallic material may be used for moving parts in order to reduce friction (e.g., PTFE, PEEK, UHMWPE). The selection of the material should consider minimizing particle generation.

(b) Contact surfaces between moving parts shall be exposed to solutions used for cleaning and bioburden control.

(c) A bellows may be used to isolate the chamber and/or condenser from moving parts that are not of hygienic design.

SD-5.4.1.2.8 Spray Devices

(a) Spray devices are used in lyophilizers to facilitate the cleaning of surfaces inside the chamber and condenser vessels. Spray devices in the condenser vessel may also be used for directing spray at the condenser cooler to facilitate defrosting of the condenser cooler.

(b) Spray devices designed for cleaning should provide sufficient flow and force to clean flat surfaces (e.g., shelves) by direct spray. Cleaning the internal surfaces of a lyophilizer by direct spray may require a supply pressure and flow rate that are substantially higher than are typical for cleaning an empty vessel. The supply pressure and flow rate should meet the manufacturer's recommendation for these spray devices.

(c) Both static and dynamic spray devices are acceptable for use in lyophilizers. The use and application of a particular spray device design should be agreed upon among the owner/user, lyophilizer manufacturer, and CIP system integrator. The number of spray devices may be reduced if the shelves are allowed to move during cleaning. Spraying of shelves should be designed to avoid the interference of spray streams of opposing directions.

(d) The use of threaded connections for spray devices shall be agreed upon by the owner/user.

(e) Spray devices shall meet the provisions of SD-3.9.2.

(f) Spray device design, location, and orientation shall ensure appurtenances (e.g., nozzles, bellows, shelf supports, and hoses) are exposed to complete spray coverage.

SD-5.4.1.2.9 Gas Filter Assemblies

(a) For the purpose of this paragraph, the gas filter assembly is defined as those filters installed for the purpose of filtering process gases supplied to the lyophilizer. The filter assembly includes the filter media, seals, housing, and connected tubing.

(b) The last filter in the path of the gas to the lyophilizer (proximal filter) shall be part of the sterile boundary and be designed for the chosen means of bioburden reduction (e.g., SIP or VHP). This filter shall be a sterilizing-grade filter. If a redundant sterilizing filter is used, both filters shall be included within the sterile boundary.

(c) Filter assemblies that are steamed in place shall be designed to

(1) limit the pressure drop across the filter to within the manufacturer's specifications in the specified flow direction

(2) permit temperature monitoring in a location representative of the coldest location

(3) accommodate the integrity testing of the proximal filter, either in situ or out of place

(d) If CIP of the gas filter assembly is specified, provisions shall be made in the design for removal of the filter element(s) prior to the CIP. Filter elements shall be reinstalled prior to sterilization of the filter assembly.

SD-5.4.1.2.10 Doors and Door Seals

(a) Lyophilizer doors and door seals shall be designed to withstand vacuum, cleaning, and sterilization conditions.

(b) Lyophilizer doors shall be accessible, cleanable, and replaceable and should be capable of undergoing inspection without dismantling.

(c) For multiple-door systems, the doors shall be interlocked to allow the opening of only one door at a time during normal operation.

(d) Doors and locking hardware that interface with the clean room should not be retracted to uncontrolled space.

(e) Both sliding and swing door designs are acceptable.

(f) Door seals can be made with either static or inflatable seals. Static seal grooves that hold the seal may be on either the door or the chamber.

(g) The seal groove may be set back from the chamber flange edge to keep the seal in position during vacuum conditions.

(h) Compression of a single static seal to achieve a metal-to-metal contact is preferred to avoid a gap between door and chamber vessel.

(i) The door static-seal design shall provide access for manual sanitization as the seal face under compression does not permit penetration of sterilizing agents.

(j) A combination (static and inflatable) seal design with the static seal circumscribing the inflatable seal provides for penetration of sterilizing agents across the sealing face of the inflatable seal.

(k) Door seal lubricants shall not be used in aseptic processing applications.

(l) Refer to Part SG for specifications of seals used in bioprocessing.

SD-5.4.1.2.11 Valves

(a) Valve design and selection for service shall follow SG-3.3.2.3(a) and Part SD as appropriate. The application of a specific valve type for a given service should be agreed on by the manufacturer and owner/user.

(b) Hygienic valves shall be used inside the sterile boundary.

(c) Diaphragm valves are acceptable for hygienic fluid service.

(d) Butterfly valves may be used as part of the sterile boundary when piping/tubing is larger than 2 in. in diameter.

(e) Ball valves may be used outside the sterile boundary to establish positive isolation.

(f) Pressure relief devices or rupture disks of hygienic design may be used as part of the sterile boundary.

(g) If the lyophilizer is designed for isolation between the chamber and condenser, the isolation valve may take the form of a mushroom valve, butterfly valve, or other proprietary valve design.

SD-5.4.1.2.12 Instruments

(a) All instruments within the sterile boundary should comply with all applicable sections of Part PI, including PI-2.1, PI-2.1.1(c) and (f), and PI-2.2.2.

(b) Instruments in process contact should be of hygienic design.

(c) Instrument probe surfaces and side port penetrations shall be oriented for self-drainage.

(d) Instruments installed within the sterile boundary should be designed for CIP and sterilization. Instruments not designed for CIP should be removed for cleaning and reinstalled for sterilization.

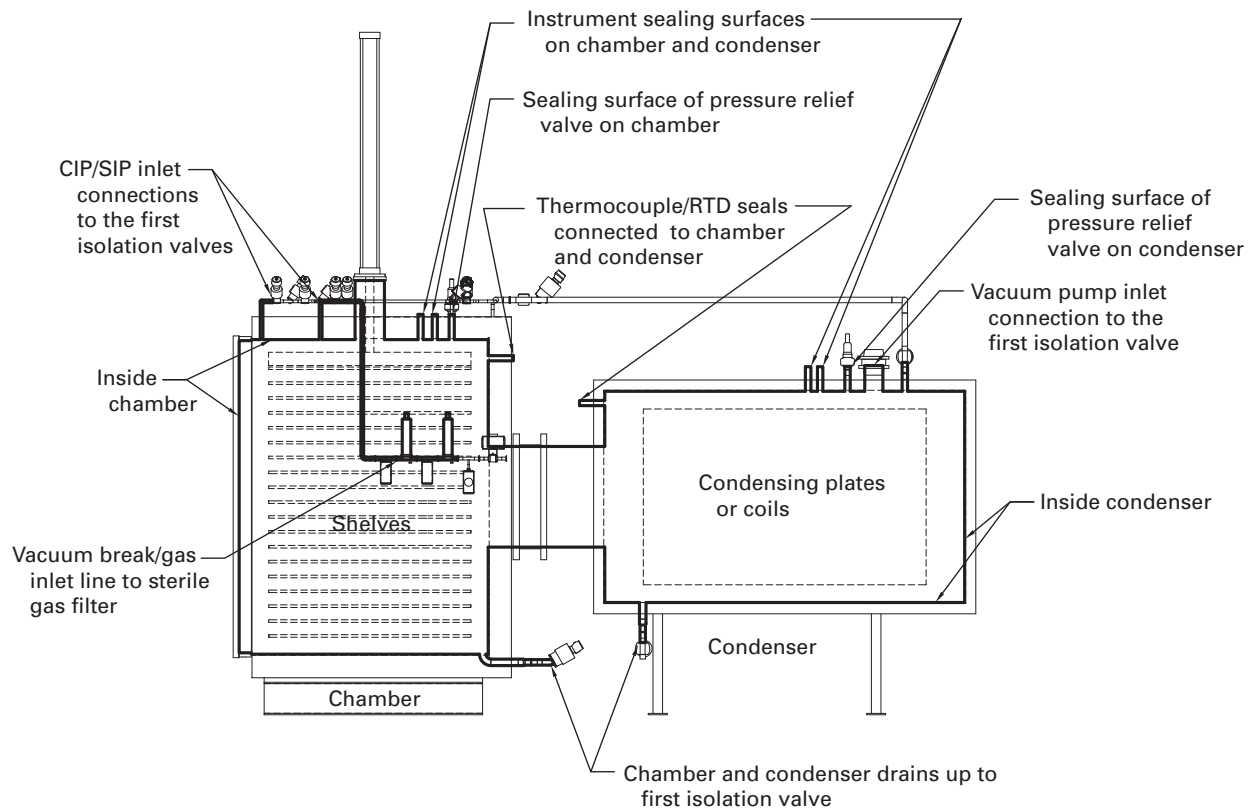
(e) Locations with product-sensing instruments (e.g., thermocouples and RTDs) and wire lead-throughs should be considered when designing for cleaning and sterilization.

(f) Instrumentation with integral seals or diaphragm seals is preferred within the sterile boundary. The risk of using instrumentation without integral seals or diaphragm seals (e.g., Pirani gauges) should be assessed based on the risk to product quality as determined by the owner/user.

SD-5.4.1.3 Sterile Boundary. For the purpose of identifying areas that should be exposed to sterilizing agents, the following areas within the chamber and condenser vessels define the sterile boundary as indicated in Fig. 5.4.1.3-1:

(a) the inside surfaces of the chamber vessel to the chamber door isolation seal.

(b) the inside surface of the condenser vessel to the condenser door isolation seal.

Fig. SD-5.4.1.3-1 Lyophilizer Sterile Boundary

(c) the chamber and condenser drains to the first isolation drain valve.

(d) the vacuum pump inlet connection in the condenser vessel to the first isolation vacuum valve closest to the condenser vessel.

(e) the vacuum break/gas inlet line to the sterile gas filter. If redundant sterilizing filters in series are used, the sterile boundary ends at the membrane of the filter farthest from the chamber vessel.

(f) the CIP/SIP inlet lines to the first CIP/SIP isolation valve that is closed during the lyophilization process.

(g) the sealing surface on all instruments connected to the chamber and condenser vessels.

(h) thermocouple/RTD seals connected directly to the chamber and condenser vessels.

(i) the exposed surface of the pressure relief valve or rupture disk.

SD-5.4.1.4 Internal Connections and Fasteners

(a) Threads sealed by an O-ring or hygienic gasket are acceptable. The use of exposed threads within the lyophilizer sterile boundary should be avoided. If other means of fastening are not practical, the use of exposed threads may be permitted with the agreement of the owner/user. The surfaces of exposed threads should be among those assessed for cleaning and penetration of sterilizing agents.

(b) For process contact surfaces, the use of pins, clevis rods, snap rings, and clips may be required to mount hardware inside the sterile boundary but should be minimized and agreed on by the owner/user. The surfaces of these fasteners should be among those assessed for cleaning and penetration of sterilizing agents.

(c) Socket head cap screws and counterbored holes inside the sterile boundary shall only be used with the agreement of the owner/user.

SD-5.4.1.5 CIP of Lyophilizers

(a) Systems used to clean lyophilizers shall comply with SD-5.3.3.1.2. Cleanability requirements of SD-2.4.2 are applicable to lyophilizers except for SD-2.4.2(b)(1), which does not apply to lyophilizer shelves.

(b) It is accepted practice to use water as the CIP fluid for cleaning water-soluble compounds. Water for injection shall be used for the final rinse in aseptic processing applications.

(c) The chamber vessel, which includes internal shelves, should be cleaned via internal spray devices designed to provide coverage of targeted surfaces. Risk to product quality should be considered when determining the required coverage. The acceptance criteria for coverage shall be agreed to by the manufacturer and owner/user. Nonmandatory Appendix L provides an acceptable procedure for spray device coverage testing.

(d) The process contact surfaces within the condenser vessel may be cleaned via internal spray devices to provide the coverage agreed on between the manufacturer and owner/user.

(e) Internal liquid distribution piping shall be sloped to meet the requirements of GSD2 to facilitate gravity draining.

(f) External liquid distribution piping shall be designed with valve actions that facilitate gravity draining. The pipe slope shall meet the requirements of GSD2.

(g) The liquid level in the chamber and condenser vessels should be minimized during once-through CIP by correct sizing of the drain and by providing slope to the respective drain. A CIP drain pump may be used to assist draining of the chamber and condenser vessels.

(h) When recirculated CIP is used, the following requirements apply:

(1) Recirculated systems shall be drainable including pump casing(s).

(2) Recirculated systems shall be capable of removing residual chemicals and debris during the final rinse.

(i) The chamber and condenser vessels shall be self-drainable.

(1) Process contact surfaces shall be sloped to meet the requirements of GSD3 for drainage of CIP fluids and to prevent the collection of condensate during the steaming processes.

(2) Interior surfaces of nozzles penetrating the vertical walls of the vessel shall be sloped to meet the requirements of GSD3.

(3) The floor of the vessel shall be sloped toward the drain connection to meet the requirements of GSD3, unless otherwise agreed to by the manufacturer and owner/user.

SD-5.4.1.6 Bioburden Reduction in Lyophilizers.

Lyophilizers designed for bioburden control should consider the following:

(a) pressure or vacuum hold testing in preparation for the bioburden reduction process. Refer to leak detection para. SD-5.4.1.7.

(b) evacuation of air from the chamber and condenser vessels to reduce the potential for air to be trapped during the bioburden reduction process. Effective air evacuation may be achieved through the use of a liquid ring vacuum pump or similar.

SD-5.4.1.6.1 Steam-in-Place. When designing lyophilizers for steam-in-place

(a) steam should enter the lyophilizer at only one point at a time to minimize the potential to trap air or condensate. If steam needs to enter through multiple locations simultaneously, the design should create flow paths that avoid air entrapment. The design should ensure that condensate will freely flow toward low-point drains.

(b) a dual control design may be used to deliver high steam flow rates that are often required during the heating phase and to maintain tight control of temperature and pressure during the exposure phase. For example, one regulator and/or control valve may be used for the heating phase and a separate regulator and/or control valve may be used for tight control during the exposure phase.

(c) a vacuum drying phase should be used to eliminate any condensate remaining within the sterile boundary following SIP.

(d) if cooling and drying are accomplished with the introduction of a process gas with open drains, a positive pressure differential shall be maintained to preserve the sterile boundary during this operation.

(e) temperature monitored throughout the SIP cycle should include coldest (worst-case) locations. If routine monitoring of worst-case locations is not practical, the temperature of locations that have been correlated to the actual worst-case locations may be monitored instead.

(f) to minimize cold locations during SIP, horizontal penetrations should be sloped to allow condensate to drain.

SD-5.4.1.6.2 Hydrogen Peroxide Sterilization.

When designing lyophilizers for sterilization with hydrogen peroxide gas under vacuum

(a) the system should be designed to be dried and have a surface temperature that meets the supplier's specification for the hydrogen peroxide supply system [typically 59°F (15°C) and 176°F (80°C)] prior to the start of the sterilization process.

(b) the system should be designed to verify that the residual hydrogen peroxide levels are below the established thresholds, after the sterilization process has been completed. Threshold levels should be agreed on by the owner/user for both operator's safety and the potential impact on the product quality.

SD-5.4.1.7 Leak Rate

(a) Lyophilizers designed for aseptic lyophilization processes shall be designed to meet leak-rate testing criteria as agreed to by the owner/user. The sterile boundary should be leak tested before aseptic operations begin. The leak rate is calculated as follows:

$$Q = \frac{\Delta PV}{\Delta t}$$

where

Q = leak rate, mbar-L/s

V = the lyophilizer system volume subject to the vacuum, adjusted to exclude the volume occupied by internal hardware, L

ΔP = the absolute pressure rise during the test, mbar

Δt = the test duration, sec

(b) Leak-rate testing should be performed on a clean, dry, and fully assembled and insulated system with the

condenser cooler in operation to capture residual vapor. Typically, leak rates less than 0.02 mbar-L/s are acceptable for new installations. Leak-rate testing is intended to confirm vacuum integrity of the system.

(c) Leak-rate tests are performed at high vacuum conditions with an absolute pressure typically on the order of 0.01 mbar.

(d) Sufficient stabilization time will avoid misinterpretation of the vacuum leak rate due to virtual leaks. Virtual leaks are identified by a leak rate that stabilizes over time.

(e) Individual component assemblies, which are subjected to vacuum conditions, should be helium leak tested prior to final installation.

SD-5.4.1.8 Branch Connections

(a) The provisions of SD-3.1.2.2 are applicable to liquid-service process contact piping leading to the lyophilizer.

(b) Nozzles within the sterile boundary should be designed to allow for full exposure to the sterilizing agent.

(c) Nozzles and other appurtenances that are cleaned by liquid spraying should allow complete coverage.

(d) Lyophilizer internals should be designed to avoid low points where fluid can be trapped.

SD-6 DESIGN CONFORMANCE TESTING

Design conformance testing shall not result in the formation of any surface anomalies or contamination. All design conformance tests and test results documentation shall have the date and time recorded. Each test document shall include a record of personnel who performed and confirmed the test results.

SD-6.1 Spray Device Coverage Test

An acceptable spray device coverage test procedure is provided in Nonmandatory Appendix L. The purpose of the spray device coverage test is to demonstrate and document liquid coverage of the process contact surfaces. The test provides information about liquid coverage and the conditions necessary to achieve this coverage as a prerequisite for cleaning of the process equipment. Effective coverage shall be visually determined using a fluorescent solution and an ultraviolet lamp or by other verification methods as agreed to by the owner/user and manufacturer. The minimum acceptable water quality is noncompensial purified water (e.g., reverse osmosis or deionized). Acceptance criteria and coverage test protocol should be agreed to by the owner/user and manufacturer.

Spray device coverage tests are not intended to demonstrate system cleanability. System cleanability is achieved through the equipment design, the spray design, knowledge of the soils, cleaning agent selection, and cleaning process parameters. Cleanability is verified

using a complete CIP per protocol during cleaning validation.

SD-6.2 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-6.3 Fluid Requirements for Leak Testing

Where leak testing is required, the following fluids shall be used:

(a) Hydrostatic testing shall use clean purified or deionized water filtered at 25 microns or better, unless otherwise agreed to by the owner/user.

(b) Pneumatic testing shall use oil-free clean dry air, nitrogen, or inert gas filtered at 25 microns or better, unless otherwise agreed to by the owner/user.

SD-6.4 Vessel Drainability Test

(16)

Specific steps or operations in a bioprocess may require vessels to be self-draining. A drainability test for such vessels shall be conducted as agreed to by all parties. As a proposed test procedure, the following should be considered:

(a) The vessel shall be in its intended operating orientation within a tolerance agreed to by the owner/user.

(b) The vessel shall be filled approximately to the weld seam that joins the shell to the bottom head.

(c) The outlet valve shall be opened, the vessel shall be vented to atmosphere, and the vessel shall be allowed to drain by gravity.

(d) There shall be no puddles of water left on the bottom of the vessel greater than as agreed to by the owner/user and manufacturer.

It is generally understood that residual water may be present in the form of droplets that typically do not exceed a diameter of 5 mm. Residual water droplets adhere to process surfaces due to surface tension and are not indicative of a vessel's drainability. Observed puddles that are displaced with a 1.0-in. (25-mm) rubber dowel applied perpendicular to the puddle and re-form at the point of displacement indicate a flat or unintended low point, and that area shall be repaired to the satisfaction of the owner/user. Puddles that are displaced with a 1.0-in. (25-mm) diameter rubber dowel applied perpendicular to the puddle and do not return to the point of displacement are considered to be large droplets and do not constitute a test failure.

NOTE: Filter housings are available in several designs. In some cases, flat-bottom filter housings are specified by the owner/user based on their risk-assessed process and equipment requirements. Flat-bottom cartridge-mount filter housings, including those that will be steamed in place, are exempt from this test, and the equipment shall be installed as agreed by the manufacturer and owner/user.

CHAPTER 3 MATERIALS

(16)

Part MM Metallic Materials

MM-1 PURPOSE AND SCOPE

The purpose of this Part is to identify metallic materials considered acceptable for use in hygienic service. It identifies material specifications, grades and alloys, matching filler metals, fabrication guidelines, and other attributes necessary for this service. It also specifies the data that must be submitted to the MM Subcommittee for any new or unlisted alloy that is proposed for inclusion in Part MM.

MM-2 ALLOY DESIGNATIONS

(16) MM-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 MM-2.1-1 through MM-2.1-4 are appropriate for the 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.

MM-3 USES OF SPECIFICATIONS

(16) MM-3.1 General

The documents listed in MM-4.2 through MM-4.7 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 MM-4.2 through MM-4.7 contain design rules that are in conflict with this Standard, the design rules of this Standard shall govern.

MM-3.2 Listed Specifications

(16)

Materials purchased to specifications listed in the appropriate sections of MM-4.2 through MM-4.7 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 SG-3.3.2.3. Materials used in applications governed by this Standard shall conform to a specification listed in the above paragraphs, except as provided in MM-3.3.

MM-3.3 Unlisted Specifications

(16)

Alloys in specifications not listed in MM-4.2 through MM-4.7 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 MM-4.2 through MM-4.7. Alloys not listed in Tables MM-2.1-1 through MM-2.1-4 may be used for applications governed by this Standard provided the following requirements are met:

- (a) The applicable requirements of MM-8 are met.
- (b) The specific written permission of the owner/user is obtained.

Materials listed in MM-5.2.6 are exempt from the requirements of MM-3.3.

MM-3.4 Unknown Materials

Materials of unknown origin or specification shall not be used in hygienic service.

MM-3.5 Reclaimed Materials

(16)

Reclaimed pipe/tube and other piping components may be used, provided they are properly identified as conforming to a published specification listed in MM-4.2, MM-4.3, MM-4.4, MM-4.5, or MM-4.6 or to a published specification not listed in those paragraphs and otherwise meeting the minimum requirements of MM-8. Sufficient cleaning and examination shall be done to determine minimum wall thickness and freedom from

(16) **Table MM-2.1-1 Wrought Stainless Steels: Nominal Compositions (wt. %)**

UNS Number [Note (1)]	EN Designation	C	Mn	N	Cr	Ni	Mo	Cu
Austenitic Stainless Steels								
S30400	...	0.07	2.00	0.10	17.5–19.5	8.0–10.5	...	...
...	1.4301	0.07	2.00	0.10	17.5–19.5	8.0–10.5	...	...
S30403	...	0.030	2.00	0.10	17.5–19.5	8.0–12.0	...	...
...	1.4307	0.030	2.00	0.10	17.5–19.5	8.0–10.5	...	...
...	1.4306	0.030	2.00	0.10	18.0–20.0	10.0–13.0	...	...
S31600	...	0.08	2.00	0.10	16.0–18.0	10.0–14.0	2.00–3.00	...
...	1.4401	0.07	2.00	0.10	16.5–18.5	10.0–13.0	2.00–2.50	...
S31603	...	0.030	2.00	0.10	16.0–18.0	10.0–14.0	2.00–3.00	...
...	1.4404	0.030	2.00	0.10	16.5–18.5	10.0–14.5	2.00–2.50	...
...	1.4435	0.030	2.00	0.10	17.0–19.0	12.5–15.0	2.50–3.00	...
Superaustenitic Stainless Steels								
S31703	...	0.030	2.00	0.10	18.0–20.0	11.0–15.0	3.0–4.0	...
...	1.4438	0.030	2.00	0.10	17.5–19.5	13.0–17.0	3.0–4.0	...
N08904	...	0.020	2.00	0.10	19.0–23.0	23.0–28.0	4.0–5.0	1.0–2.0
...	1.4539	0.020	2.00	0.15	19.0–21.0	24.0–26.0	4.0–5.0	1.20–2.00
N08367	...	0.030	2.00	0.18–0.25	20.0–22.0	23.5–25.5	6.0–7.0	0.75
S31254	...	0.020	1.00	0.18–0.25	19.5–20.5	17.5–18.5	6.0–6.5	0.50–1.00
...	1.4547	0.020	1.00	0.18–0.25	19.5–20.5	17.5–18.5	6.0–7.0	0.50–1.00
N08926	...	0.020	2.00	0.15–0.25	19.0–21.0	24.0–26.0	6.0–7.0	0.5–1.5
...	1.4529	0.020	1.00	0.15–0.25	19.0–21.0	24.0–26.0	6.0–7.0	0.50–1.50
Duplex Stainless Steels								
S32205	...	0.030	2.00	0.14–0.20	22.0–23.0	4.5–6.5	3.0–3.5	...
...	1.4462	0.030	2.00	0.10–0.22	21.0–23.0	4.5–6.5	2.50–3.5	...

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.
- (c) Alloys listed between horizontal lines are not equivalent, but comparable.

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 MM-2.1-2 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
...	2.4856	0.03–0.10	20.0–23.0	58.0 min	8.0–10.0	0.5	Fe: 5.0 max., (Nb + Ta): 3.15–4.15, Ti: 0.40 max.
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.
- (c) Alloys listed between horizontal lines are not equivalent, but comparable.

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 MM-2.1-3 Stainless Steel and Nickel Alloy Cast Designations

UNS Designation	ACI Designation	EN Designation	Approximate Wrought Equivalent	
			UNS Designation	EN Designation
Austenitic Stainless Steels				
J92600	CF8	...	S30400	...
...	...	1.4308	...	1.4301
J92500	CF3	...	S30403	...
...	...	1.4309	...	1.4307
...	...	...	...	1.4306
J92900	CF8M	...	S31600	...
...	...	1.4408	...	1.4401
J92800	CF3M	...	S31603	...
...	...	1.4409	...	1.4404
...	...	...	...	1.4435
Superaustenitic Stainless Steels				
J92999	CG3M	...	S31703	...
...	...	1.4412	...	1.4438
J94651	CN3MN	...	N08367	...
J93254	CK3MCuN	...	S31254	...
...	...	1.4557	...	1.4547
Duplex Stainless Steels				
J92205	CD3MN	...	S32205	...
...	...	1.4470	...	1.4462
Nickel-Based Alloys				
N26625	CW6MC	...	N06625	...
...	...	...	...	2.4856
N30002	CW12MW	...	N10276	...
...	...	...	...	2.4819
N26455	CW2M	...	N10276	...
...	...	...	...	2.4610
...	...	...	...	2.4819
N30107	CW6M	...	N10276	...
...	...	...	...	2.4819
N26002	CX2MW	...	N26022	...
...	...	...	...	2.4602

GENERAL NOTE: Alloys listed between horizontal lines are not equivalent, but comparable.

Table MM-2.1-4 Wrought Copper: Nominal Compositions (wt. %) (Cleaned for Oxygen Service) (16)

UNS Number	EN Designation	Cu + Ag	P	O
C10200	...	99.95	...	0.00010 max.
C12000	...	99.90	0.008–0.012	...
C12200	...	99.90	0.015–0.040	...
...	CW024A	99.90	0.015–0.040	...

GENERAL NOTES:

- (a) Minimum, unless range or maximum is indicated.
 (b) Copper grades listed between horizontal lines are not equivalent, but comparable.

imperfections that would be unacceptable in the intended service.

MM-3.6 Designation of Alloy and Fluid Service

The user is responsible for designating the specific alloy, from MM-2, to be used for each system having a process 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.

MM-4 REFERENCED SPECIFICATIONS

MM-4.1 General

(16)

Standards and specifications adopted by reference in this Standard are listed by product form 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. Sources for procuring any of the listed material specifications are found in Nonmandatory Appendix V.

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.

The ASME Boiler and Pressure Vessel Code (BPVC) has adopted many of the listed ASTM material specifications. Materials furnished to the latest edition of these ASME specifications are also considered to be in conformance with this Standard.

When preparing a Material Test Report (MTR), a material manufacturer may transcribe data produced by other organizations, provided he accepts responsibility for the accuracy and authenticity of the data.

MM-4.2 Tubing/Piping

Tubing and piping manufactured in accordance with the following specifications may be used:

ASTM A213/A213M, Specification for Seamless Ferritic and Austenitic Alloy — Steel Boiler, Superheater, and Heat-Exchanger Tubes

ASTM A249/A249M, Specification for Welded Austenitic Steel Boiler, Superheater, Heat-Exchanger, and Condenser Tubes

ASTM A269, Specification for Seamless and Welded Austenitic Stainless Steel Tubing for General Service

ASTM A270/A270M, Specification for Seamless and Welded Austenitic and Ferritic/Austenitic Stainless Steel Sanitary Tubing

ASTM A312/312M, Specification for Seamless, Welded, and Heavily Cold Worked Austenitic Stainless Steel Pipes

ASTM A511, Standard Specification for Seamless Stainless Steel Mechanical Tubing

ASTM A789/A789M, Standard Specification for Seamless and Welded Ferritic/Austenitic Stainless Steel Tubing for General Service

ASTM A790/A790M, Standard Specification for Seamless and Welded Ferritic/Austenitic Stainless Pipe

ASTM B619, Specification for Welded Nickel and Nickel-Cobalt Alloy Pipe

ASTM B622, Standard Specification for Seamless Nickel and Nickel-Cobalt Alloy Pipe and Tube

ASTM B626, Specification for Welded Nickel and Nickel-Cobalt Alloy Tube

ASTM B675, Specification for UNS N08367 Welded Pipe

ASTM B676, Specification for UNS N08367 Welded Tube

ASTM B690, Specification for Iron-Nickel-Chromium-Molybdenum Alloys (UNS N08366 and UNS N08367) Seamless Pipe and Tube

ASTM B819, Standard Specification for Seamless Copper Tube for Medical Gas Systems

DIN 17744, Wrought nickel alloys with molybdenum and chromium — Chemical composition

DIN 17751, Tubes of wrought nickel alloys — Properties

EN 10216-5, Seamless steel tubes for pressure purposes — Technical delivery conditions — Part 5: Stainless steel tubes

EN 10217-7, Welded steel tubes for pressure purposes — Technical delivery conditions — Part 7: Stainless steel tubes

EN 10312, Welded stainless steel tubes for the conveyance of water and other aqueous liquids — Technical delivery conditions

EN 13348, Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum

MM-4.3 Castings

Castings manufactured in accordance with the following specifications may be used:

ASTM A351/A351M, Specification for Castings, Austenitic, for Pressure-Containing Parts

ASTM A494/A494M, Standard Specification for Castings, Nickel and Nickel Alloy

ASTM A743/A743M, Specification for Castings, Iron-Chromium, Iron-Chromium-Nickel, Corrosion Resistant, for General Application

ASTM A744/A744M, Standard Specification for Castings, Iron-Chromium-Nickel, Corrosion Resistant, for Severe Service

ASTM A890/A890M, Specification for Castings, Iron-Chromium-Nickel-Molybdenum Corrosion-Resistant, Duplex (Austenitic/Ferritic) for General Application

ASTM A995/A995M, Standard Specification for Castings, Austenitic-Ferritic (Duplex) Stainless Steel, for Pressure-Containing Parts

EN 10213, Steel castings for pressure purposes

EN 10283, Corrosion resistant steel castings

MM-4.4 Forgings

Forgings manufactured in accordance with the following specifications may be used:

ASTM A182/A182M, Specification for Forged or Rolled Alloy and Stainless Steel Pipe Flanges, Forged Fittings, and Valves and Parts for High-Temperature Service

ASTM B462, 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 B564, Specification for Nickel Alloy Forgings

EN 10222-5, Steel forgings for pressure purposes — Part 5: Martensitic, austenitic, and austenitic-ferritic stainless steels

EN 10250-4, Open die steel forgings for general engineering purposes — Part 4: Stainless steels

MM-4.5 Plate, Sheet, and Strip

Plate, sheet, and strip manufactured in accordance with the following specifications may be used:

ASTM A240/A240M, Specification for Chromium and Chromium-Nickel Stainless Steel Plate, Sheet, and Strip for Pressure Vessels and for General Applications

ASTM A666, Specification for Annealed or Cold-Worked Austenitic Stainless Steel Sheet, Strip, Plate, and Flat Bar

ASTM B443, Specification for Nickel-Chromium-Molybdenum-Columbium Alloy (UNS N06625) and Nickel-Chromium-Molybdenum-Silicon Alloy (UNS N06219) Plate, Sheet, and Strip

ASTM B575, 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 B688, Specification for Chromium-Nickel-Molybdenum-Iron (UNS N08366 and UNS N08367) Plate, Sheet, and Strip

DIN 17744, Wrought nickel alloys with molybdenum and chromium — Chemical composition

DIN 17750, Strip and sheet of nickel and wrought nickel alloys — Properties

EN 10028-1, Flat products made of steels for pressure purposes — Part 1 — General requirements

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 10095, Heat resistant steels and nickel alloys

MM-4.6 Hollow Products, Rod, and Bar Stock

Hollow products, rod, and bar stock manufactured in accordance with the following specifications may be used:

ASTM A276, Standard Specification for Stainless Steel Bars and Shapes

ASTM A479/A479M, Specification for Stainless Steel Bars and Shapes for Use in Boilers and Other Pressure Vessels

ASTM B574, 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 B691, Specification for Iron-Nickel-Chromium-Molybdenum Alloys (UNS N08366 and UNS N08367) Rod, Bar, and Wire

DIN 17744, Wrought nickel alloys with molybdenum and chromium — Chemical composition

DIN 17752, Wrought nickel and nickel alloy rods and bars — Requirements and testing

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 10095, Heat resistant steels and nickel alloys

EN 10263-1, Steel rod, bars and wire for cold heading and cold extrusion — Part 1: General technical delivery conditions

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

For austenitic stainless steels, hollow products and bar stock are acceptable for nozzles and may be used where permitted by the owner/user.

MM-4.7 Copper Alloy Fittings

Fittings manufactured in accordance with the following specifications may be used where permitted by the owner/user:

ASME B16.22, Wrought Copper and Copper Alloy Solder-Joint Pressure Fittings

ASME B16.50, Wrought Copper and Copper Alloy Braze-Joint Pressure Fittings

MM-5 BASE METALS AND FILLER MATERIALS

(16)

MM-5.1 General

This section provides requirements and recommendations for the base metals listed in Tables MM-2.1-1 through MM-2.1-4. The use of base metals other than those listed in this section is permitted with the owner/user's written approval (see MM-3.3).

This section also recommends filler metals and consumable inserts for welding these alloys in order to produce weldments whose weld metal has corrosion resistance consistent with that of the base metal. Details necessary for welding are provided in Part MJ.

MM-5.2 Base Metals

MM-5.2.1 Austenitic Stainless Steels

MM-5.2.1.1 Weld Ends. Weld ends that are to be autogenously welded shall have a sulfur content between 0.005 wt. % and 0.017 wt. % [see also MJ-2.1.1(a)]. This requirement applies to the austenitic stainless steels listed in Tables MM-2.1-1 and MM-2.1-3. This requirement does not apply to materials used in the construction of process components, only to the weld ends of process components in their final form.

MM-5.2.1.2 Ferrite. If specific ferrite levels in austenitic stainless steels are deemed necessary to maintain certain properties, the owner/user shall specify required ferrite ranges separately for the base metal, for welds in the solution-annealed 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 MM-5.2.1.2-1 for predicted ferrite number ranges for various austenitic stainless steel product forms. These are not acceptance criteria. The listed ferrite numbers refer to as-solidified austenitic 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.

MM-5.2.2 Superaustenitic Stainless Steels. The superaustenitic stainless steels in Tables MM-2.1-1 and

(16) **Table MM-5.2.1.2-1 Predicted Ferrite Number (FN) Ranges for Various Austenitic Stainless Steel Product Forms and Welds**

Product Form	Expected FN
Wrought product forms with sulfur levels less than 0.005%	0.5 to 4
Wrought product forms with a sulfur range of 0.005% to 0.017%	1.0 to 6
GMAW/GTAW using E316L [Note (1)]	4 to 12 [Note (2)]
SMAW using ER316L [Notes (3), (4)]	4 to 10 [Note (5)]
CF8M and CF3M castings	5 to 15

GENERAL NOTE: FN ranges determined from D. J. Kotecki and T. A. Siewart, "WRC-1992 Constitution Diagram for Stainless Steel Weld Metals: A Modification of the WRC-1988 Diagram," *Welding Journal* 71(5), p. 171-s, 1992.

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 FN to 4 FN loss in the as-deposited weld metal.
- (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.

MM-2.1-3 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 to 1,900°F (540°C to 1 040°C). This is a concern during welding and other thermomechanical processes, including solution annealing. It is, therefore, desirable to keep exposure time within this temperature range to a minimum.

Owners/users are cautioned that any service temperature, heat treatment, or joining procedure that exposes these materials to these temperatures should be minimized. The material manufacturer should be consulted for specific instructions regarding heat treatment.

MM-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.

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 to 1,830°F (650°C to 1 000°C). Owners/users are cautioned that any service temperature, heat treatment, or joining

procedure that exposes this material to these temperatures should be minimized. The material manufacturer should be consulted for specific instructions regarding heat treatment.

MM-5.2.4 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/user.

MM-5.2.5 Copper Alloys. In applications allowed in Part SD and/or approved by the owner/user, copper tubing may be used for process gas distribution systems.

MM-5.2.6 Special Alloys. When specified by the owner/user, alloys listed in Table MM-5.2.6-1 may be used for process contact surfaces in unique applications, such as original equipment manufacturer (OEM) process instrumentation, pump internals, etc. These alloys, when serving as process contact surfaces, must meet all applicable surface finish requirements of this Standard.

MM-5.2.7 Unlisted Alloys. Alloys not listed in Part MM and having corrosion resistance less than that typical of UNS S30403 may be used for process contact surfaces in unique applications such as OEM instrumentation when the owner/user has determined that the proposed material is suitable for the intended service.

MM-5.3 Filler Materials

Filler material shall conform to a published specification. Table MM-5.3-1 lists the recommended filler metals for welding the listed austenitic, superaustenitic, and duplex stainless steels and nickel alloys.

Table MM-5.3-2 lists the recommended materials from which consumable inserts may be made for use in welding the listed superaustenitic and duplex stainless steels.

Filler materials other than those listed in Tables MM-5.3-1 and MM-5.3-2 may be used with the prior approval of the owner/user provided that

- (a) they produce weld metal having corrosion resistance equal to or greater than that of the base metal
- (b) the welding procedure is qualified in accordance with Part MJ

Proprietary filler materials may be used with the prior agreement of the owner/user, provided all procedure and performance qualification requirements of Part MJ of this Standard are met.

MM-5.3.1 Austenitic Stainless Steels. Only the low-carbon grades of stainless steel filler metals may be used to weld these alloys.

(16) **Table MM-5.2.6-1 Materials for OEM Equipment**

UNS Number	EN Designation	Common Name
...	...	Platinum (coating)
...	...	Gold (coating)
...	...	Silver (coating)
R50250	...	Ti — Grade 1
...	3.7025	...
R50400	...	Ti — Grade 2
...	3.7026	...
R56400	...	Ti — Grade 5
...	3.7164	...
R52400	...	Ti — Grade 7
R56320	...	Ti — Grade 9
R53400	...	Ti — Grade 12
N06200	...	Hastelloy C-2000 [Note (1)]
N06600	...	Inconel 600 [Note (2)]
S17400	...	17-4 PH [Note (3)]
...	1.4542	...

GENERAL NOTE: Alloys listed between horizontal lines are not equivalent, but comparable.

NOTES:

- (1) Hastelloy C-2000 is a registered trademark of Haynes International, Inc.
- (2) Inconel is a registered trademark of Special Metals Corp.
- (3) 17-4 PH is a registered trademark of AK Steel, Cincinnati, Ohio.

MM-5.3.2 Superaustenitic and Duplex Stainless Steels. If a filler metal or consumable insert is used during the manufacture of process components, it should be in accordance with the filler metals or consumable inserts listed in Table MM-5.3-1 or Table MM-5.3-2, respectively. Other nickel–chromium–molybdenum filler metals or consumable inserts may be used as long as the corrosion resistance of the final weld metal meets or exceeds that of the base metal. The manufacturer must also identify the filler metal or consumable insert as part of the documentation.

MM-5.3.3 Copper Alloys. Table MM-5.3.3-1 lists the filler metals to be used for brazing copper tubing.

MM-5.4 Heat Treatment

Heat treatment of process components made from the austenitic stainless steels in Table MM-2.1-1 is not addressed by this Standard.

For the listed superaustenitic and duplex stainless steels, if the filler metals or consumable inserts in

Table MM-5.3-1 or Table MM-5.3-2 are used, a postweld heat treatment is not required. If those alloys are welded autogenously, postweld heat treatment is required in accordance with Table MM-5.4-1.

MM-6 MECHANICAL PROPERTIES

MM-6.1 General

(16)

The specific service environment for which the alloys in Tables MM-2.1-1 through MM-2.1-4 may be used is not within the scope of this Standard. The possibility of material deterioration in service should be considered by the owner/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.

MM-6.2 Tubing/Piping

All tube or pipe used for process contact surfaces and non-process contact surfaces shall meet the mechanical property requirements of the specification to which they are manufactured.

MM-6.3 Fittings and Valves

(16)

Refer to DT-2 for strength requirements for fittings and valves.

When material is cold worked, its mechanical properties can be expected to change from those of the original heat of the raw material. MTRs for fittings are therefore 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.

MM-6.4 Toughness

(16)

Some of the materials listed in Tables MM-2.1-1 through MM-2.1-3, as well as Table MM-5.2.6-1, 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 (−7°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.

MM-6.5 Testing

Refer to DT-6 for the testing requirements for fittings and SG-4.3.1.1 for the testing requirements for valves.

MM-6.6 Positive Material Identification (PMI)

(16)

When PMI is performed, it is limited to alloy verification. Refer to Nonmandatory Appendix U for guidance regarding procedures and data interpretation.

Table MM-5.3-1 Filler Metals

Base Metal Alloy [Note (1)]		Filler Metal									
UNS Designation	EN Designation	SMAW					GTAW/GMAW/SAW/PAW				
		AWS Classification	SFA Specification	UNS Designation	ISO 14343-A Designation	EN Designation	AWS Classification	SFA Specification	UNS Designation	ISO 14343-A Designation	EN Designation
Austenitic Stainless Steels											
S30400	...	E308-15 E308-16 E308-17	5.4	W30810 W30810 W30810	...	...	ER308 ER308L ER308Si ER308LSi	5.9	S30880 S30883 S30881 S30888	...	...
...	1.4301	...	...	...	19 9 L 19 9 Nb	1.4316 1.4551	...	...	...	19 9 L Si 19 9 Nb Si	1.4316 1.4551
S30403	...	E308L-15 E308L-16 E308L-17	5.4	W30813 W30813 W30813	...	...	ER308L ER308LSi	5.9	S30883 S30888	...	...
...	1.4307	...	...	...	19 9 L 19 9 Nb	1.4316 1.4551	...	...	...	19 9 L Si 19 9 Nb Si	1.4316 1.4551
...	1.4306	...	...	...	19 9 L 19 9 Nb	1.4316 1.4551	...	...	...	19 9 L Si 19 9 Nb Si	1.4316 1.4551
S31600	...	E316-15 E316-16 E316-17	5.4	W31610 W31610 W31610	...	...	ER316L ER316LSi	5.9	S31683 S31688	...	...
...	1.4401	...	...	...	19 12 3 L 19 12 3 Nb 20 25 5 Cu N L	1.4430 1.4576 1.4519	...	...	...	19 12 3 L Si 19 12 3 Nb Si 20 25 5 Cu L	1.4430 1.4576 1.4519
S31603	...	E316L-15 E316L-16 E316L-17	5.4	W31613 W31613 W31613	...	...	ER316L ER316LSi	5.9	S31683 S31688	...	...
...	1.4404	...	...	...	19 12 3 L 19 12 3 Nb	1.4430 1.4576	...	...	...	19 12 3 L Si 19 12 3 Nb Si 20 25 5 Cu L	1.4430 1.4576 1.4519
...	1.4435	...	...	...	19 12 3 L 19 12 3 Nb 18 16 5 N L 20 16 3 Mn N L 20 25 5 Cu N L	1.4430 1.4576 1.4440 1.4455 1.4519	...	...	...	19 12 3 L Si 19 12 3 Nb Si 18 16 5 N L 20 16 3 Mn L 20 25 5 Cu L	1.4430 1.4576 1.4440 1.4455 1.4519
Superaustenitic Stainless Steels											
S31703	...	E317L-15 E317L-16 E317L-17	5.4	W31713 W31713 W31713	...	...	ER317L	5.9	S31783	...	...
...	1.4438	...	...	...	18 16 5 N L 20 25 5 Cu N L	1.4440 1.4519	...	...	...	18 16 5 N L 20 25 5 Cu L	1.4440 1.4519
N08904	...	ENiCrMo-3 ENiCrMo-4 ENiCrMo-10	5.11	W86112 W80276 W86022	...	...	ERNiCrMo-3 ERNiCrMo-4 ERNiCrMo-10	5.14	N06625 N10276 N06022	...	...
...	1.4539	...	...	...	20 25 5 Cu N L Ni 6625 [Note (2)]	1.4519 2.4621	...	...	...	20 25 5 Cu N L Ni 6625 [Note (3)]	1.4519 2.4831

Table MM-5.3-1 Filler Metals (Cont'd)

Base Metal Alloy [Note (1)]		Filler Metal									
UNS Designation	EN Designation	SMAW					GTAW/GMAW/SAW/PAW				
		AWS Classification	SFA Specification	UNS Designation	ISO 14172 Designation	EN Designation	AWS Classification	SFA Specification	UNS Designation	ISO 18274 Designation	EN Designation
S31254	...	ENiCrMo-3 ENiCrMo-4 ENiCrMo-10	5.11	W86112 W80276 W86022	...	...	ERNiCrMo-3 ERNiCrMo-4 ERNiCrMo-10	5.14	N06625 N10276 N06022	...	...
...	1.4547	...	...	...	Ni 6059 Ni 6625	2.4609 2.4621	...	...	...	Ni 6082 Ni 6625	2.4806 2.4831
N08367	...	ENiCrMo-3 ENiCrMo-4 ENiCrMo-10	5.11	W86112 W80276 W86022	...	...	ERNiCrMo-3 ERNiCrMo-4 ERNiCrMo-10	5.14	N06625 N10276 N06022	...	...
N08926	...	ENiCrMo-3 ENiCrMo-4 ENiCrMo-10	5.11	W86112 W80276 W86022	...	...	ERNiCrMo-3 ERNiCrMo-4 ERNiCrMo-10	5.14	N06625 N10276 N06022	...	...
...	1.4529	...	...	...	Ni 6059 Ni 6625	2.4609 2.4621	...	...	...	Ni 6059 Ni 6625	2.4607 2.4831
Duplex Stainless Steels [Note (4)]											
S32205	...	E2209	5.4	W39209	...	...	ER2209	5.9	S39209 [Note (5)]	...	...
		E2553 E2593 E2594 E2595		W39553 W39593 W39594 W39595			ER2553 ER2594		S39553 S32750		
...	1.4462	...	...	...	22 9 3 N L [Note (6)]	1.4462	...	...	...	22 9 3 N L [Notes (5), (6)]	1.4462
					22 9 4 N L [Note (6)]	14501				22 9 4 N L [Note (6)]	14501
Nickel Alloys											
N10276	...	ENiCrMo-3 ENiCrMo-4 ENiCrMo-10	5.11	W86112 W80276 W86022	...	...	ERNiCrMo-3 ERNiCrMo-4 ERNiCrMo-10	5.14	N06625 N10276 N06022	...	...
...	2.4819	...	...	...	Ni 6059	2.4609	...	...	...	Ni 6059	2.4607
N06022	...	ENiCrMo-3 ENiCrMo-4 ENiCrMo-10	5.11	W86112 W80276 W86022	...	...	ERNiCrMo-3 ERNiCrMo-4 ERNiCrMo-10	5.14	N06625 N10276 N06022	...	...
...	2.4602	...	...	...	Ni 6059	2.4609	...	...	...	Ni 6059	2.4607
N06625	...	ENiCrMo-3 ENiCrMo-4 ENiCrMo-10	5.11	W86112 W80276 W86022	...	...	ERNiCrMo-3 ERNiCrMo-4 ERNiCrMo-10	5.14	N06625 N10276 N06022	...	...
...	2.4856	...	...	...	Ni 6625	2.4621	...	...	...	Ni 6625	2.4831

GENERAL NOTE: The use of AWS/UNS filler metal is recommended for welding of UNS base metal; the use of EN filler metal is recommended for welding of EN base metal.

NOTES:

- (1) Alloys listed between horizontal lines are not equivalent, but comparable.
- (2) Filler metal designation as per ISO 14172.
- (3) Filler metal designation as per ISO 18274.
- (4) Any super duplex stainless steel filler metal can be used to weld any duplex stainless steel.
- (5) Addition of up to 5% of nitrogen to the shielding gas is recommended to aid in obtaining ferrite/austenite balance.
- (6) Filler metal designation as per ISO 14343-A.

Table MM-5.3-2 Consumable Inserts for Superaustenitic and Duplex Stainless Steels**(16)**

Base Metal Alloy [Note (1)]			Insert Alloy [Note (2)]	
UNS Designation	ACI Designation	EN Designation	UNS Designation	EN Designation
Superaustenitic Stainless Steels				
N08904	...	...	N06625 N06022 N10276	...
...	...	1.4539	...	2.4856 2.4602 2.4819
N08367	...	...	N06625 N06022 N10276	...
N08926	...	...	N06625 N06022 N10276	...
...	...	1.4529	...	2.4856 2.4602 2.4819
S31254	...	...	N06625 N06022 N10276	...
...	...	1.4547	...	2.4856 2.4602 2.4819
J94651	CN3MN	...	N06625 N06022 N10276	...
J93254	CK3MCuN	...	N06625 N06022 N10276	...
...	...	1.4557	...	2.4856 2.4602 2.4819
Duplex Stainless Steels				
S32205	...	...	N06022 N10276	...
...	...	1.4462	...	2.4602 2.4819
J92205	CD3MN	...	N06022 N10276	...
...	...	1.4470	...	2.4602 2.4819

GENERAL NOTE: The use of UNS consumable inserts is recommended for welding of UNS base metal; the use of EN consumable inserts is recommended for welding of EN base metal.

NOTES:

(1) Alloys listed between horizontal lines are not equivalent, but comparable.

(2) See MM-4 for listed rod, bar, or plate specifications from which these consumable inserts may be manufactured.

(16)

Table MM-5.3.3-1 Brazing Filler Metals for Copper

Base Metal [Note (1)]		Filler Metal			
UNS Number	EN Designation	AWS Classification	SFA Specification	UNS Designation	EN Designation
C10200	...	BCuP-3	5.8	C55281	...
		BCuP-4		C55283	...
		BCuP-5		C55284	...
		BCuP-6		C55280	...
		BCuP-7		C55282	...
C12000	...	BCuP-3	5.8	C55281	...
		BCuP-4		C55283	...
		BCuP-5		C55284	...
		BCuP-6		C55280	...
		BCuP-7		C55282	...
C12200	...	BCuP-3	5.8	C55281	...
		BCuP-4		C55283	...
		BCuP-5		C55284	...
		BCuP-6		C55280	...
		BCuP-7		C55282	...
...	CW024A	...	...	...	...

GENERAL NOTE: The use of AWS/UNS filler metal is recommended for brazing of UNS base metal; the use of EN filler metal is recommended for brazing of EN base metal.

NOTE:

(1) Copper grades listed between horizontal lines are not equivalent, but comparable.

(16) **Table MM-5.4-1 Solution Anneal Heat Treatment Requirements for Superaustenitic and Duplex Stainless Steels**

Base Metal Alloy [Note (1)]		Solution Anneal Temperature [Notes (2), (3), and (4)]
UNS Designation	EN Designation	
Superaustenitic Stainless Steels		
S31703 ...	... 1.4438	1,900°F (1 040°C)
N08904 ...	... 1.4539	
S31254 ...	... 1.4547	2,100°F (1 150°C)
N08367	...	
N08926 ...	... 1.4529	2,025°F (1 105°C)
Duplex Stainless Steels		
S32205 ...	... 1.4462	1,870–2,010°F (1 020–1 100°C)

NOTES:

- (1) Alloys listed between horizontal lines are not equivalent, but comparable.
- (2) Minimum solution anneal temperature unless range is specified.
- (3) No minimum anneal time is specified, however, very short anneal times can result in inadequate time at temperature to restore the corrosion resistance of autogenous welds.
- (4) Post solution anneal cooling shall be achieved by a water quench or rapid cooling by other means.

MM-7 CORROSION-RESISTANCE REQUIREMENTS**MM-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.

(16) MM-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
- (b) to determine the compatibility of an alloy in an owner/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.

MM-8 ADDITION OF NEW ALLOYS TO PART MM**MM-8.1 General****(16)**

Metallic materials of construction may be considered for use under the rules of this Standard by providing the following information to the ASME BPE Staff Secretary as follows:

(a) listing of the alloy in an industry-recognized specification or standard including tensile strength properties.

(b) evidence that the proposed material will have corrosion resistance equal to or greater than 304L stainless steel (UNS S30403) in a service environment within the scope of this Standard. See Nonmandatory Appendix F for additional information.

(c) evidence that the material can be mechanically polished, electropolished, and/or passivated to meet the applicable requirements of Part SF.

(d) a recommended welding process(es), filler metal(s), and evidence showing that the combination of base metal, filler metal(s), and recommended welding process(es) meets the applicable requirements of Parts MJ and SF. Special restrictions, exceptions, or guidance shall be noted.

Part PM

Polymeric and Other Nonmetallic Materials

(16) PM-1 PURPOSE AND SCOPE

The purpose of this Part is to provide the basis for selecting and using polymeric and other nonmetallic materials.

This Part describes the types of polymeric and other nonmetallic materials, identifies different ways to characterize materials, and describes various applications and their requirements. This Part includes requirements for both single-use and multiuse components.

(16) PM-2 MATERIALS

Polymeric and nonmetallic materials have found widespread use in bioprocessing equipment because of their broad range of physical and chemical properties, their ability to be formed into complex shapes, and their biocompatibility. Polymeric materials may be used in a range of applications including static and dynamic seals, hoses, pumps, tubing, barrier coatings, diaphragms, valves, filters, etc. The choice of material class depends on the design requirements and material performance, both as installed and during use.

For in-depth discussion and guidance on polymeric and nonmetallic materials, see Nonmandatory Appendix N.

(16) PM-2.1 Materials of Construction

Materials of construction shall be selected to maintain the purity and integrity of the product/process fluid. It is the owner/user's responsibility to select the appropriate materials of construction for the conditions of use. Materials should be compatible with the stated processing conditions, cleaning solutions (where appropriate), and sterilizing conditions (where appropriate), etc., as specified by the owner/user. The following sections outline the major classes of polymeric and nonmetallic materials and their requirements for use in bioprocessing equipment.

(16) PM-2.1.1 Thermoplastic Polymers. Thermoplastic polymers will melt and flow to form desired shapes when sufficiently heated. They can be melt-processed into a wide variety of shapes by molding, extruding, thermoforming, etc., and can be re-formed and shaped with heat and/or pressure.

Thermoplastic materials are often used for fittings, tubing, piping, diaphragms, seals, liners for vessels, column tubes, filter media and capsules, etc. Examples of thermoplastic polymers are shown in Table PM-2.1.1-1.

Some thermoplastics, such as thermoplastic elastomers, combine an elastomer such as ethylene propylene diene monomer (EPDM) with a plastic such as polypropylene, giving the resulting thermoplastic compound properties of flex endurance and sealability and can be used for tubing, seals, diaphragms, etc. Thermoplastic elastomers (TPE) combine the features of melt processability and flexibility.

Many polymeric materials are described in ASTM standards that detail their composition and mechanical properties. It is the owner/user's responsibility to select materials that are appropriate for their applications.

Filler materials may be used to enhance the properties of thermoplastic polymers. Fillers may be carbon based, inorganic, metallic, organometallic, etc., as needed for performance.

Additives for thermoplastic polymers may be used to aid in thermal stability, flexibility, gamma stability, extrudate performance, crystallization control, oxidative stability, mold release, plasticization, and adhesion. Additives may be used in the bulk of the polymer as well as the surface, as required.

PM-2.1.2 Thermoset Polymers. Thermosets are polymers that, in their final state after processing, are rendered substantially insoluble and infusible. Fully processed thermosets cannot be resoftened or re-formed by exposure to heat. Exposure to excessive heat will cause degradation. (16)

Thermoset polymers are processed from a liquid or malleable state and are converted to the solid state by irreversible curing with heat, catalysis, or other means. Chemical cross-links are formed between polymer chains during the curing process. This results in an interconnected polymer network with the cross-link junctions restricting flow of the polymer when exposed to thermal or mechanical stresses.

Thermoset polymers can be classified into either thermoset elastomers or thermoset resins, with the elastomers being more common. Thermoset elastomers are often elastic and soft materials and are used for seals, gaskets, tubing, diaphragms, hoses, etc. Examples of thermoset polymers are shown in Table PM-2.1.2-1.

Most thermoset polymeric materials contain reinforcing fillers and other additives to meet required use conditions. Fillers may be carbon based, inorganic, metallic, organometallic, etc., as needed for performance. Elastomer formulations typically contain 5% to 50% filler to achieve optimum properties.

Table PM-2.1.1-1 Common Thermoplastic Polymers and Applications

Type of Polymer	Example Polymers	Example Applications
General thermoplastics	Polyester (PET) Polyamide (nylon) Polycarbonate Polysulfones Polyether ether ketone (PEEK)	Fittings, connectors, filter housings, piping and rigid tubing, column tubes, filter media
Thermoplastic polyolefins	Polypropylene (PP) Ultra-low-density polyethylene (ULDPE) Low-density polyethylene (LDPE) High-density polyethylene (HDPE) Ultra-high-molecular-weight polyethylene (UHMW)	Fittings, connectors, piping and rigid tubing, filter media and capsules, bags
Thermoplastic fluoropolymers	Fluorinated ethylene propylene (FEP) Perfluoroalkoxy (PFA) Polytetrafluoroethylene (PTFE) Ethylene tetrafluoroethylene (ETFE) Polyvinylidene fluoride (PVDF)	Fittings, piping and tubing, flexible hose, filter media and capsules, diaphragms, pumps, vessel liners
Thermoplastic elastomers (TPE)	Blends with EPDM with polypropylene Styrene-isobutylene-styrene block polymers Copolymers of ethylene and octane Ethylene-vinyl acetate copolymer (EVA)	Tubing, bags

Table PM-2.1.2-1 Common Thermoset Polymers and Applications

Type of Polymer	Example Polymers	Example Applications
Thermoset elastomers	Ethylene propylene diene (EPDM) Ethylene propylene rubber (EPR) Silicone (VMQ) Fluoroelastomers (FKM) Perfluoroelastomer (FFKM)	Tubing, seals, gaskets, diaphragms, and hoses
Rigid thermosets	Fiber-reinforced polymer (FRP/GRP) composites	Tanks and pipes

- (16) **PM-2.1.3 Other Nonmetallic Materials.** Solid single-phase nonmetallic materials can be divided into amorphous nonmetallic materials (e.g., glass, amorphous carbon) and crystalline nonmetallic materials (e.g., sintered silicon carbide, graphite).

If manufactured by heating and subsequent cooling, these materials are often referred to as ceramics. Materials may consist of a mixture of an amorphous and a crystalline phase (e.g., glass-ceramics). To improve performance, nonmetallic materials may be combined with other materials such as metals or polymers to form multiphase mixtures. Examples of such materials are metal-matrix composites such as cemented tungsten carbide with an alloyed nickel binder matrix and resin-impregnated carbon-graphites. Some of the more commonly used nonmetallic materials are listed in Table PM-2.1.3-1.

PM-2.2 General Requirements

Materials shall be selected to not affect the purity or integrity of the drug product. The owner/user is responsible for the qualification of materials for the

intended use. The requirements for compliance are summarized in PM-2.2.1. The requirements relate to identification, traceability, biocompatibility, and marking. Methods for characterizing material performance are discussed in PM-3. Application-specific performance requirements are detailed within section PM-4.

Polymeric materials exposed to process fluids and/or that have a high probability of exposure shall comply to the USP directive with regard to USP <87> (or ISO 10993-5) and USP <88> Class VI (or ISO 10993-6, -10, and -11) on biological reactivity (see PM-3.1). Examples of materials that may come into direct contact with process fluids include tubing, pipe, fittings, filters, bags, gaskets, O-rings, diaphragms, pinch tubes, and valve stem seals.

PM-2.2.1 Certificate of Compliance. A Certificate of Compliance shall be issued by the manufacturer to certify compliance to this Standard when required by the end-user. Additional certification documentation may be required. The Certificate of Compliance shall contain the information summarized in Table PM-2.2.1-1.

Table PM-2.1.3-1 Examples of Nonmetallics

Examples of Nonmetallics	Types of Nonmetallic	Example Applications
Glass Borosilicate Soda-lime	Amorphous inorganic nonmetallic material	Sight glasses, vessel lights, optical sensors, glass electrodes
Sintered materials Aluminum oxide Silicon carbide Silicon nitride Tungsten carbide Zirconium dioxide	Crystalline inorganic nonmetallic material	Mechanical seals, bearings, process sensors
Reaction-bonded materials Silicon carbide Silicon nitride	Multiphase mixture of crystalline silicon carbide or nitride and silicon	Mechanical seals
Siliconized carbon-graphite	Multiphase mixture of crystalline silicon carbide, carbon, and graphite	Mechanical seals
Resin-impregnated carbon-graphite	Multiphase mixture of carbon, graphite, organic resin, and potential inorganic nonmetallic additives	Mechanical seals
Cemented materials Tungsten carbide with alloyed binder Tungsten carbide with nickel binder Tungsten carbide with cobalt binder	Crystalline inorganic nonmetallic in a metallic matrix	Mechanical seals, bearings

PM-2.2.2 Labeling and Marking. Manufacturers shall mark the package containing polymer components or assemblies with the manufacturer's name, part number, and lot number or unique identifier (see Table PM-2.2.1-1) to enable the manufacturer to trace back to the raw material(s) and processing conditions used to fabricate the component/assembly. Manufacturers should mark the component/assembly itself to avoid potential loss of traceability and to aid in positive identification of components/assemblies after use.

(16) PM-2.2.3 Change Management

PM-2.2.3.1 General. Change management requirements apply to polymeric or other nonmetallic process contact materials and components. These requirements apply to single-use and multiuse components.

PM-2.2.3.2 Change Classifications

(a) *Significant Changes.* A significant change is a change that may affect form, fit, or function of the materials/components. Significant changes require owner/user notification and may also require retesting. Examples of significant changes may include

- (1) formulation changes
- (2) manufacturing means, methods, or materials changes

- (3) changes to published or agreed specifications
- (4) discontinuance of a material or component
- (5) changes in regulatory or compliance status (e.g., USP)

(b) *Minor Changes.* A minor change is a change that is not expected to affect form, fit, or function.

PM-2.2.3.3 Owner/User Notification. The supplier shall notify the owner/user of a significant change. The owner/user should be notified of a planned significant change a minimum of 6 months prior to the change becoming effective or distribution of the modified material or component.

PM-2.2.3.4 Supplier Responsibilities. The supplier is responsible for effectively managing changes both internally and through the supply chain. The impact of the change may vary depending on the material or component supplied. The supplier shall document how change management will be executed for their materials or components.

PM-2.2.3.5 Owner/User Responsibilities. The owner/user should supply any specific requirements for change management, including point of contact. The owner/user should evaluate the change notification for impact to their process.

Table PM-2.2.1-1 Content Required on the Certificate of Compliance**(16)**

Requirements to Conform to ASME BPE	Applications									
	Polymeric Seals (Includes Diaphragms and Hygienic Union Seals) [Note (1)]		Filters		Chro- matography Columns	Connectors (Includes Steam to/ Through)	Polymeric Containers (Rigid and Flexible)	Other Polymeric Process Components	Nonmetallic Process Components	Single-Use Assemblies
	Hoses	Tubing	[Note (2)]							
Manufacturer's name	X	X	X	X	X	X	X	X	X	X
Manufacturer's contact information	X	X	X	X	X	X	X	X	X	X
Part number	X	X	X	X	X	X	X	X	X	X
Lot number or unique identifier or serial number	X	X	X	X	X	X	X	X	X	X
Material(s) of construction (process contact)	X	X	X	...	X	X	X	X	X	...
Compound number or unique identifier	X	...	X	...	...	...	...	X	X	...
Cure date or date of manufacture	X	...	X	X	X	...	X	X	...	X
USP <87> or ISO 10993-5	X	X	X	X	X	X	X	X	X	X
USP <88> Class VI or ISO 10993-6, -10, -11	X	X	X	X	X	X	X	X	...	X

GENERAL NOTE: For components subjected to operations such as gamma irradiation or steam, specific certification shall be provided. See PM-4.1.5.

NOTES:

- (1) For hygienic union seals, the intrusion category shall be provided (SG-4.2).
- (2) Specific lot release criteria may be required for different types of filtration elements depending on their type and application. These additional requirements should be decided by the owner/user and the supplier.

PM-3 PROPERTIES AND PERFORMANCE

Materials should be selected to retain their functional properties and to minimize their impact on the process fluid. Materials should be selected to not affect the purity and integrity of the drug product. This section outlines the requirements for biocompatibility, extractables/leachables, physical properties, and chemical compatibility. Each of the following sections should be considered for the application.

PM-3.1 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. Polymer materials shall be biocompatible with the system fluid to ensure that the system fluid is not adversely affected by the polymer material. The biocompatibility and the proper material selection shall be the responsibility of the system user.

Biocompatibility testing of candidate components 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> (or ISO 10993-6, -10, and -11) and involves intramuscular implantation, intracutaneous injection, and systemic toxicity testing. In vitro testing is described in the United States Pharmacopeia in Chapter <87> (or ISO 10993-5) and is used to place extract from candidate polymers in direct contact with living cells (typically mouse cells) for a prescribed period of time. The amount of cell lysing (death) shall be recorded and reported for the particular polymer material.

Material manufacturers shall provide, on customer request, documentation (test report) of the in vivo USP <88> Class VI and in vitro USP <87> testing on final manufactured parts. Failure of either test indicates unacceptable biocompatibility of candidate material. Such failures are often attributed to leachables from cured elastomeric seals extractables and may include

catalyst residues, cross-linking agents, process aids, plasticizers, etc.

(16) PM-3.2 Extractables and Leachables

PM-3.2.1 General. Testing of process equipment/components made of polymeric materials for extractables and leachables should be done to identify chemical substances that could migrate into the process fluid, potentially affecting the process or altering the final product. Some examples of chemical substances identified in this testing include oligomers, monomers, curing (cross-linking) agents, catalysts, antioxidants, initiators, dyes, pigments, plasticizers, and mold release agents. The data generated may be used to make risk-based decisions of the potential impact that any identified substances may have on the final drug product and may aid in the selection of equipment/components. Nonmandatory Appendix O-4 provides an overview of bioprocessing equipment/component evaluation related to extractables and leachables characterization.

PM-3.2.2 Extractables. Extractables are chemical substances that can be removed from polymeric materials using appropriate solvents (e.g., polar and nonpolar). Extraction studies are conducted under conditions that exceed typical bioprocess manufacturing or storage conditions (e.g., higher temperature, pH, or concentration or longer exposure time) and are used to generate an extractables profile for a given polymeric material. Manufacturers should provide extractables profile data for polymeric materials used in equipment/components on request by the owner/user. The extractables profile generated may vary depending on both the extraction conditions and the extraction fluids used in the study. Depending on the purpose of the study, one or more of the following types of extraction study should be done to generate an extractables profile.

PM-3.2.2.1 Polymeric Material Specific Extraction Study. This study is done to generate an extractables profile that characterizes the total content of soluble chemical substances contained in the polymeric material. The extraction solvent(s) and conditions shall be appropriate for the particular polymeric material being tested. Nonmandatory Appendix O-2 identifies recommended conditions for a polymeric material specific extraction study.

PM-3.2.2.2 Extraction Study in Bioprocess Model Solutions. This study is done to generate an extractables profile under conditions that exceed those typically found in bioprocessing applications. The model solutions and extraction conditions should be selected based on the intended use of the equipment/component. This study generates an extractables profile that may be used to predict potential leachables. Nonmandatory Appendix O-3 identifies recommended conditions for an extraction study in bioprocess model solutions.

PM-3.2.3 Leachables. Leachables, typically a subset of extractables, are chemical substances that migrate into the drug product from process equipment or its container under normal conditions of use and/or storage. Leachables may also be created as a result of chemical reactions with other leachables and/or ingredients in the process fluid or drug product. Leachables studies conducted in process and of the final product shall be the responsibility of the owner/user.

PM-3.2.4 Sample Preparation. Extraction studies shall include careful sample preparation appropriate to the test article and analytical techniques to be used.

The size of the sample should be determined in consideration of the material, test equipment, analytical test sensitivity, and the sample available for testing.

Any tool used for sample preparation shall not adulterate the sample.

Prior to extraction, test samples should be exposed to the same pretreatment process (under worst-case conditions) that the material would see when used as intended.

PM-3.2.5 Documentation. Documentation of results shall include the extraction method(s), analytical technique(s) protocol, sample surface area (or weight) to volume ratio, and extraction time and temperature. Relative limits of detection should be reported.

PM-3.2.6 Risk Assessment. The owner/user should consider supplier data, relevant standards, regulatory guidance, and industry recommendations as listed in Nonmandatory Appendix O, when performing a risk assessment.

The results of the risk assessment should determine the suitability of the equipment/component for its intended use.

PM-3.3 Physical and Mechanical Properties of Thermoplastic Polymers

The physical and mechanical properties of thermoplastics are important to better understand how fluid exposure could affect the polymer's strength, stiffness, inertness, durability, barrier properties, etc. Physical and mechanical properties can be characterized using many different standards (e.g., ASTM, ISO, DIN, and JIS). Typical properties include tensile strength, elongation to break, modulus, and, in some cases, seam strength, weld strength, coefficient of friction, compression set, tensile set, hardness, specific gravity, transparency, etc.

Common useful tests for evaluating thermoplastic performance are listed in Nonmandatory Appendix K.

The interpretation of immersion test results is dependent on the specific application. In such cases, a different material may be more suitable for the application. The overall life of the equipment may be shortened significantly if the correct polymer is not selected. The end-user must ultimately interpret the relevance of the test results for the applicable process.

PM-3.4 Chemical Compatibility of Thermoplastic Polymers

Chemical concentration, temperature, and duration of exposure can all affect the property retention of thermoplastic polymers. When selecting a thermoplastic polymer for chemical contact, the user should consult the supplier for case histories and test data, where available.

If further testing is required, specific fluids should be used to expose test samples for the necessary time and temperature.

PM-3.5 Physical and Mechanical Properties of Thermoset Polymers

Physical and mechanical properties can be characterized using many different standards (e.g., ASTM, ISO, DIN, and JIS). Typical properties include hardness, tensile strength, elongation to break, modulus, and tear strength. In some cases, abrasion resistance, compression set, specific gravity, transparency, etc., may be important. Properties may be affected by manufacturing and use conditions (e.g., temperature, pressure, physical stress). Common tests for evaluating physical and mechanical properties are listed in Nonmandatory Appendix K. Property requirements should be discussed between the owner/user and the supplier, and the owner/user shall be responsible for determining the suitability of the material for the application.

PM-3.6 Chemical Compatibility of Thermoset Elastomers

Chemical concentration, temperature, and duration of exposure can all affect the property retention of thermoset elastomers. When selecting a thermoset elastomer for chemical contact, the user should consult the supplier for case histories and test data, where available. If further testing is required, specific fluids should be used to expose test samples for the necessary time and temperature. Chemical compatibility is particularly important for materials that are reused. Chemical compatibility testing should be done to screen candidate materials for applications involving cleaning, storage, or exposure to potentially harsh chemicals.

PM-3.7 Physical and Mechanical Properties of Other Nonmetallic Materials

Physical and mechanical properties of other nonmetallic materials, such as those listed in Table PM-2.1.3-1, may be characterized using many different standards (e.g., ASTM, ISO, DIN, and JIS). Typical properties may include, but are not limited to, hardness, strength, self-lubrication, and transparency. In some cases, low friction between sliding surfaces may be important. Properties may be affected by use conditions. Material selection should be discussed between the owner/user and supplier, and the owner/user shall be responsible for

determining the suitability of the material for the application.

PM-3.8 Chemical Compatibility of Nonmetallic Materials

Chemical composition, temperature, and duration of exposure may all affect the properties of other nonmetallic materials. When selecting nonmetallic materials, such as those listed in Table PM-2.1.3-1, the user should consult the supplier for test data, where available. If further testing is required, specific fluids should be used to expose test samples for the necessary time and temperature.

PM-3.9 Polymeric Surface Finish

Polymeric material contact surface classifications are found in Part SF.

PM-4 APPLICATIONS

PM-4.1 Single-Use Components and Assemblies

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 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-4.1.1 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-4.1.1.1 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 on agreement between the manufacturer and end-user.

PM-4.1.1.2 Certificate of Compliance. The single-use component or assembly manufacturer shall issue a Certificate of Compliance that contains the following information:

- (a) manufacturer
- (b) part identifier
- (c) lot identifier
- (d) date of manufacture and/or expiration date
- (e) compliance information

Additional information can be included in the Certificate of Compliance on agreement between the manufacturer and end-user.

- (16) **PM-4.1.2 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 (see PM-4.1.7 and Nonmandatory Appendix N, section N-2). Inspection shall be performed to confirm the quality of the packaging and that the contents meet the specified criteria between the supplier and end-user.

PM-4.1.2.1 Inspection. Single-use components and assemblies shall be inspected for the presence of particulates or other contaminants before primary packaging as agreed on by the 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-4.1.2.2 Packaging. The purpose of packaging of single-use components and assemblies is to control the potential introduction of bioburden, particulates, or other contaminants. 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-4.1.1.1.

PM-4.1.3 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-4.1.4 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 process 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 process contact surface, but it is preferred to evaluate the complete component and assembly. At a minimum, the process 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 the end-user and manufacturer

Additionally, the user should consider protein adsorption, preservative absorption, leaching of low-molecular-weight compounds, endotoxins, and the presence of animal-derived compounds in single-use components and assemblies.

- PM-4.1.5 Sterilization (Bioburden Control).** Single-use assemblies and components shall be compatible with the intended sterilization method. Common sterilization methods include autoclaving and gamma irradiation. Autoclaving is generally performed by the owner/user. Gamma irradiation is generally contracted to a third party by the manufacturer. The owner/user shall determine the appropriate method and level of documentation required for the given application. (16)

PM-4.1.5.1 Gamma Irradiation. Single-use assemblies that will be gamma irradiated shall be manufactured in a controlled environment. The maximum recommended gamma irradiation dose should be specified by the manufacturer of the single-use assembly or component. When establishing a maximum dose, the manufacturer should consider the effects on physical and mechanical properties (e.g., appearance, tensile) and chemical characteristics of the materials used (e.g., leachable/extractable effects). The supplier shall provide lot-specific certification of processing to the owner/user. The degrees of validation are the following: (16)

(a) validated sterility assurance level per a recognized standard (e.g., ISO 11137).

(b) gamma irradiated to the specified dose range. No validation of the effectiveness is conducted.

- PM-4.1.6 Shelf Life, Storage, and Expiration Date.** The shelf life of a single-use component or assembly is the duration under specified storage conditions from the date of manufacture to the last date the product can be placed in service and remain suitable for its intended use. The expiration date is the date after which the shelf life has been exceeded. The manufacturer shall, on request, provide methodology used to determine shelf life or expiration date such as aging tests, stability tests, or other industry standards. (16)

(a) *Nonsterilized Components and Assemblies.* The manufacturer shall provide an expiration date (preferred) or the manufacturing date and shelf life, plus storage requirements and any special handling requirements. Shelf life shall be based on raw material, component, and/or assembly data.

(b) *Sterilized Components and Assemblies.* The manufacturer shall provide expiration dates, storage requirements, and any special handling requirements. Shelf life shall be based on raw material, component and/or assembly data, sterilization method, and package integrity. Package integrity testing shall be performed per a relevant standard (e.g., ISO 11607). See PM-4.1.2.2.

- (16) **PM-4.1.7 Particulates.** Single-use components and systems should be free of loose, nonembedded, and solid particulates as seen by direct visual observation, without magnification. Particulates greater than or equal to 100 μ are considered to be visible. The TAPPI Size Estimation Chart may be used for reference. Particulates smaller than 100 μ are considered to be subvisible and should be minimized.

PM-4.1.7.1 General. Particulates may unintentionally be present on surfaces of the single-use article and may impact the manufacturing process and/or product. Particulate sources include machines, materials, methods, environment, and people. More information and characteristics of particulates may be found in Nonmandatory Appendix N, section N-2.

PM-4.1.7.2 Mitigation Techniques. The materials, design, manufacturing operations, environment, and product use should be considered for their impact on particulate generation and control. A program should be established to characterize, quantify, control, and minimize particulates, as applicable. The level of observation and particulate control should be appropriate for the degree of risk for the particular application (e.g., fill/finish).

PM-4.1.7.2.1 Suppliers. Suppliers should implement controls to ensure their single-use product can meet their established particulate criteria. Some controls include the following:

- (a) proper use and maintenance of manufacturing equipment
- (b) use of controlled environments for the manufacturing and assembly process such as a classified clean room or clean zone
- (c) appropriate packaging; see PM-4.1.2
- (d) training of manufacturing personnel on particulate control practices
- (e) product inspection and documentation of batch records
- (f) establishment of a particulate investigation process to identify/quantify foreign particulates and determine their source, along with a corrective action plan

PM-4.1.7.2.2 Owner/User. Owners/users should implement controls to ensure their use of single-use products can meet their established particulate criteria. Some controls include the following:

- (a) procedures to determine risk associated with particulate matter
- (b) supplier quality agreements with agreed-on particulate acceptance criteria
- (c) required incoming inspection documentation
- (d) training of personnel in best practices for the handling and use of single-use products

- (e) establishment of a particulate investigation process to identify/quantify foreign particulates and determine their source, along with a corrective action plan

PM-4.2 Piping

The following shall be considered in the design of polymeric rigid piping and tubing.

PM-4.2.1 Sizing Comparisons. Thermoplastic piping systems are available in a variety of sizing standards. Tube/pipe (e.g., Schedule 40, Schedule 80), Standard Dimensional Ratio (SDR) 11, and SDR 21 are some of the most common standards used. Table PM-4.2.1-1 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, cleanability, and drainability. Tube inside dimensions are critical for alignment to stainless steel systems.

PM-4.2.2 Pressure Ratings. Polymer piping systems have varying pressure ratings depending on material and sizing standards. 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-4.2.3 Thermal Expansion. Polymeric materials will expand and contract with changing temperature conditions. The effect of thermal expansion must be considered and designed for in 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 is 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

Table PM-4.2.1-1 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
$\frac{1}{2}$	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
$\frac{3}{4}$	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
$1\frac{1}{4}$	...	...	...	...	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
$1\frac{1}{2}$	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
$2\frac{1}{2}$	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

α = coefficient of thermal expansion, mm/m/°C
material and temperature dependent

ΔL = change in length, mm

ΔT = temperature change, °C

Typical coefficients of thermal expansion at room temperature by material type are found below. Consult the 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-4.2.4 System Support Criteria

PM-4.2.4.1 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 increase 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-4.2.4.2 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 cleanliness.

PM-4.2.5 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-3.1.

PM-4.3 Hose Assemblies

PM-4.3.1 General. This section defines 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-4.3.2 Hose Construction

PM-4.3.2.1 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 braiding, and various elastomeric materials. The liner design shall allow for drainability and cleanability as required by the end-user.

PM-4.3.2.2 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-3.2.1-1, illustration (d)]. Band-style hose clamps are not recommended [see Fig. SD-3.2.1-1, 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-7-1.

PM-4.3.2.3 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-4.3.2.4 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 using 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-4.3.2.5 Hose Materials. Hose assembly materials shall conform to applicable sections of SD-2.4.1.2 and PM-2.1.

(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 <88> Class VI (or ISO 10993-6, -10, and -11) tests on all polymeric process contact materials. End-users may request similar testing on noncontact layers

that may come in contact with the process fluid if the inner liner fails. Hose assembly suppliers shall provide, on 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 process.

(d) *Extractables*. Hose assembly materials shall conform to the requirements of PM-3.2.

PM-4.3.3 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-4.3.3.1 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-4.3.3.2 Nonroutine Events. The complete procedure for nonroutine events such as passivation, derouging, and postconstruction 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-4.3.3.3 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-3.2).

(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-4.3.3.4 Sterilizing Systems. Hose assembly requirements shall be based on the sterilization method used. 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 cooldown stages.

PM-4.3.4 Hose Assembly Installation. Hose assemblies shall be installed per SD-3.2 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-4.3.5 Compliance Requirements

PM-4.3.5.1 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-4.3.5.2 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 <88> Class VI (or ISO 10993-6, -10, and -11)
- (f) packaging and storage recommendations (this may be in another document)

The 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-4.3.5.3 Test Requirements. Conformance testing is done on 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.

PM-4.4 Chromatography Columns

PM-4.4.1 General. This section defines typical design elements related to large-scale chromatography columns and includes columns that are intended for repeated use in processing. Although chromatography processes are not typically aseptic, design features for cleaning and/or sanitization should be considered. More information on chromatography columns can be found in Nonmandatory Appendix S.

PM-4.4.2 Pressure-Retaining Parts. The column tube is both a product contact surface and a pressure-retaining component. Chromatography columns are vessels operating under pressure and should meet the requirements of ASME BPVC, Section VIII, as referred to in GR-1, as applicable. If the column tube is acrylic, it shall comply with ASME PVHO-1, Case 14, Low UV.

The owner/user is responsible for informing the manufacturer of the normal and abnormal operating conditions to which the column may be exposed. The manufacturer is responsible for ensuring the column will operate safely under said conditions.

PM-4.4.3 Design for Cleaning and Sanitization

PM-4.4.3.1 Cleaning. Columns should be designed in accordance with SD-2.4.2 with the exception of the bed supports and flow distributor. Cleaning of chromatography columns is achieved by control of contact time and concentration of the appropriate cleaning agents.

PM-4.4.3.1.1 Seals. All seals shall conform to Part SG.

PM-4.4.3.1.2 Exterior Surfaces. Exterior surfaces of columns shall be nonabsorbent and compatible with cleaning agents. Columns shall be designed to allow effective removal of cleaning agents from surfaces.

PM-4.4.3.1.3 Hygienic Connections. Hygienic connections shall conform to other Parts of this Standard.

PM-4.4.3.2 Sanitization

PM-4.4.3.2.1 Chemical Sanitization. All product contact surfaces within the system shall be compatible with the sanitization agents selected.

PM-4.4.3.2.2 Thermal Sanitization. When thermal sanitization is used, all column product contact surfaces shall be designed to accommodate expansion and contraction during exposure and cooldown stages.

PM-4.4.4 Column Materials. Column materials for all product contact surface wetted parts shall conform to applicable sections of Parts SD, PM, and SF.

PM-4.4.5 Column Performance. The owner/user shall be responsible for informing the manufacturer of the conditions under which the column may be expected to operate. This shall include the methods, frequency, and duration of cleaning and sanitization procedures. In addition to the service temperature and pressure, any parameters that may affect the column performance shall be provided.

PM-4.4.5.1 Service Temperature and Pressure. Columns shall be capable of withstanding thermal and pressure cycling between the rated upper and lower temperature and pressure limits.

PM-4.4.5.2 Routine Maintenance. To ensure continued column performance, consideration must be made to the accessibility of all column components for routine maintenance.

PM-4.4.6 Compliance Requirements

PM-4.4.6.1 General Requirements. A unique identifier shall be indelibly marked on the column or the column's support structure. The unique identifier shall enable the owner/user to identify the supplier and the supplier to identify the raw material and processing conditions used to fabricate the article.

PM-4.4.6.2 Certificate of Compliance. A Certificate of Compliance shall be issued by the column manufacturer to certify compliance to this Standard when required by the owner/user.

The Certificate of Compliance shall contain the following information:

- (a) manufacturer's name
- (b) unique identifier of the column
- (c) material of construction of process contact items
- (d) compliance to USP <87> Class VI (or ISO 10993-5) and USP <88> (or ISO10993-6, -10, and -11)]

Also see Table PM-2.2.1-1.

PM-4.5 Filtration Elements and Components

(16)

PM-4.5.1 General. This section defines and recommends design elements related to hygienic filtration processes. This section includes aseptic and nonaseptic processes and includes the following filtration components: housings, holders, and elements. More information on filtration elements and components may be found in Nonmandatory Appendix S.

PM-4.5.2 Filtration Formats. There are two basic modes of filtration: direct flow and tangential flow. For multiuse filters, cleaning and/or sanitization should be considered. For single-use filters, sanitization requirements shall be determined by the owner/user.

PM-4.5.3 Housing and Encapsulation. Filter housings and encapsulated components are wetted and are vessels operating under pressure. Requirements for vessels operating under pressure are found in ASME BPVC, Section VIII, as referred to in GR-1. The owner/user shall be responsible for informing the manufacturer of all expected operating conditions to which the filter housings may be exposed. The manufacturer shall be responsible for ensuring the filter housings and encapsulated components will operate safely under said conditions.

PM-4.5.3.1 Housings. Housings shall be designed in accordance with Part SD. Materials used in the construction of filtration housings shall conform to Part MM for metallic materials or Part PM for polymeric materials.

PM-4.5.3.2 Encapsulation. Encapsulated filtration elements are designed for handling purposes or in place of metallic housings. Materials used in the encapsulation of filtration elements shall conform to Part PM for polymeric materials or Part MM for metallic materials.

PM-4.5.3.2.1 Holders. Materials used in the construction of holders shall conform to Part MM for metallic materials or Part PM for polymeric materials.

PM-4.5.4 Design for Cleaning and Sanitization

PM-4.5.4.1 Cleaning. Filtration elements shall be designed in accordance with SD-3.1 and shall be compatible with the cleaning agents (to be agreed by the manufacturer and owner/user).

PM-4.5.4.1.1 Seals. All seals shall conform to Part SG.

PM-4.5.4.1.2 Exterior Surfaces. All exterior surfaces shall conform to SD-2.4.4.2.

PM-4.5.4.2 Sanitization

PM-4.5.4.2.1 Chemical Sanitization. Chemical sanitization processes are used to reduce bioburden. All product contact surfaces shall be compatible with the sanitization agents selected (to be agreed by the manufacturer and owner/user).

PM-4.5.4.2.2 Thermal Sanitization. Thermal sanitization requirements should be considered during the design process. The components shall be designed to accommodate the elevated temperatures and the expansion and contraction during exposure and cool-down stages. Special consideration should be given when designing for potential vacuum situations. Filtration elements should be tested and verified for multiple steam cycles per vendor qualification methods. Filtration elements shall conform to SD-2.3.1.

PM-4.5.5 Filtration Performance. The owner/user shall be responsible for informing the manufacturer of all the conditions under which the filter elements may be expected to operate. This shall include the methods, frequency, and duration of cleaning and sanitization procedures. In addition to the service temperature and pressure, any parameters that may affect the filtration performance shall be provided.

PM-4.5.5.1 Service Temperature and Pressure. Filtration elements shall be capable of withstanding thermal and pressure cycling between the rated upper and lower temperature and pressure limits.

PM-4.5.5.2 Routine Maintenance. To ensure continued filtration performance, consideration shall be given to the accessibility of all filtration components for routine maintenance.

PM-4.5.5.2.1 Integrity Testing and Permeability

(a) *Integrity Testing.* Tests may be required to ensure that the filtration elements and components are integral and meet specific process requirements. Sterilizing-grade membranes should be tested to the specific bacterial retention protocol (refer to 2004 cGMP Filtration Guideline and ASTM F838).

The following are typical integrity test procedures that may be performed:

- (1) pressure decay test
- (2) bubble point test
- (3) diffusional flow test
- (4) water intrusion test

Other integrity testing methods should be agreed on between the manufacturer and owner/user. Integrity testing may be performed either pre- or postprocess.

(b) *Normalized Water Permeability.* During tangential flow applications, a normalized water permeability test (NWP; see Nonmandatory Appendix S-2.5) or clean water flux test may be performed.

PM-4.5.6 Installation. Installation shall be in accordance with the manufacturer's guidelines.

PM-4.5.7 Compliance Requirements

PM-4.5.7.1 General Requirements. A unique identifier shall be indelibly marked on the filtration element or support structure. The unique identifier shall enable the owner/user to identify the supplier and the supplier to identify the raw material and processing conditions used to fabricate the article. A Certificate of Compliance shall be issued by the filtration element manufacturer to certify compliance to this Standard when required by the owner/user.

PM-4.5.7.2 Certificate of Compliance. The Certificate of Compliance shall contain the following information:

- (a) manufacturer's name
- (b) date of manufacture of the element
- (c) unique identifier of the element
- (d) material of construction of process contact items
- (e) compliance to USP <87> (or ISO 10993-5) and USP <88> Class VI (or ISO 10993-6, -10, and -11)

Other certifications of compliance should be agreed on by the manufacturer and owner/user.

PM-4.6 Polymeric Hygienic Unions

When using polymeric hygienic unions, several application variables should be considered to ensure optimum performance. Some variables include fluid type, process temperature, system pressure, vibration, materials of construction, sterilization method (where appropriate), cleaning methods (where appropriate), and duration of use.

PM-4.6.1 Multiuse

PM-4.6.1.1 Installation. The manufacturer shall provide installation procedures.

PM-4.6.1.2 Performance. Ferrules and clamps should be designed and manufactured to maintain component alignment, ensure proper assembly, and avoid leakage. Ferrules should meet the nominal dimensions of Table DT-7-1, except for dimension A, which shall

achieve clearance as per DT-9.4(e). Pressure and temperature ratings of polymeric hygienic unions should be provided by the manufacturer.

PM-4.6.1.3 Cleaning. Ferrules and clamps should be cleanable as per SD-2.4.2 and SD-3.1.2.2.

PM-4.6.1.4 Bioburden Control. [Reserved for future content]

PM-4.6.1.5 Seals. [Reserved for future content]

PM-4.6.2 Single-Use. For general single-use requirements, see PM-4.1.

PM-4.6.2.1 Installation. See PM-4.6.1.1.

PM-4.6.2.2 Performance. See PM-4.6.1.2.

PM-4.6.2.3 Seals. See PM-4.6.1.5.

PM-4.7 Steam-Through and Steam-to Connections

PM-4.7.1 General Requirements. Steam-through and steam-to connectors are designed to connect single-use systems to multiuse (metallic) systems. Steam-through and steam-to connections shall

(a) form a hygienic clamp union, meeting the requirements of Parts DT and SG

(b) maintain a seal (section SG-4)

(c) be self-draining (Part SD)

(d) be sterilizable per PM-4.1.5

(e) be compatible with SIP, poststerilization (e.g., gamma irradiation) at 266°F (130°C) for 1 hr (exposed surfaces)

(f) meet the biocompatibility requirements of PM-3.1

(g) meet the Certificate of Compliance requirements of Table PM-2.2.1-1

Owners/users shall review the manufacturer's pressure/temperature ratings against the design conditions for all applicable processing conditions (e.g., SIP, product transfer, etc.).

(16)

CHAPTER 4 PROCESS COMPONENTS

Part DT Dimensions and Tolerances for Process Components

DT-1 PURPOSE AND SCOPE

The purpose of this Part is to provide requirements that ensure process component fit-up and compatibility.

This Part specifies dimensions, tolerances, and all supplementary conditions for process components.

(16) DT-2 PRESSURE RATING

Metallic fittings manufactured to this Part shall meet or exceed the pressure ratings shown in Table DT-2-1 and shall have an ambient temperature bursting strength of at least three times the 100°F (38°C) rated internal working pressure as shown in Table DT-2-1 (see also Fig. DT-2-1).

Fabricated components employing welds shall be rated at 100% of the above ratings.

Valves manufactured to this Part shall be rated per the manufacturer's marked pressure and temperature recommendations.

DT-3 WALL THICKNESS

The nominal wall thickness of the fittings and process components at the point of joining shall be the same as the tube to which they are welded. The thickness of the weld ends shall conform with the tolerances listed in Tables DT-3-1 and DT-3-2.

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-7, 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-8 and Fig. MJ-8.4-1.

DT-4 DIMENSIONS

Process components are designed for use with nominal outside diameter (O.D.) tubing for the sizes listed in Table DT-4-1. The dimensions are accompanied with soft metric conversions from the U.S. Customary units

and are listed for reference only (see GR-6). For nominal metric size tubing and fittings, refer to the appropriate international standards.

DT-4.1 Fitting Dimensions

Dimensions for fittings that are governed by this Standard are grouped and categorized into tables.

All sizes shown in these tables are nominal O.D. tube sizes.

All automatic weld end fittings shall have minimum tangent lengths per Table DT-4.1-1. The tangent length, *T*, is defined as the straight length measured from the welding end.

The categorized groups in DT-4.1.1 through DT-4.1.5 designate specific fitting dimensions.

DT-4.1.1 Elbows/Bends. Refer to Tables DT-4.1.1-1 through DT-4.1.1-8.

DT-4.1.2 Tees/Crosses. Refer to Tables DT-4.1.2-1 through DT-4.1.2-11.

DT-4.1.3 Reducers. Refer to Tables DT-4.1.3-1 through DT-4.1.3-3.

DT-4.1.4 Ferrules. Refer to Table DT-4.1.4-1. Hygienic clamp ferrule dimensions are specified in Table DT-7-1.

DT-4.1.5 Caps. Refer to Tables DT-4.1.5-1 and DT-4.1.5-2.

DT-4.2 Nonstandard Fitting Dimensions

Fittings not specifically described in Tables DT-4.1.1-1 through DT-4.1.5-2 may be constructed using combinations of centerline-to-end dimensions from the tables.

For tees and crosses, use Tables DT-4.1.2-4 and DT-4.1.2-8 for standard clamp leg lengths; Tables DT-4.1.2-2 and DT-4.1.2-7 for short-outlet branch clamp lengths; Table DT-4.1.2-3 for short-outlet run clamp lengths; and Table DT-4.1.2-1 for weld end lengths. Consideration shall be made for clamp clearances when fabricating fittings not depicted in Tables DT-4.1.1-1 through DT-4.1.5-2.

DT-4.3 Special Angle Fittings Dimensions

Special angle fittings can be offered if in accordance with all DT tables, with the exception of "O" (off angle) in Table DT-3-1. Fittings furnished to this Standard shall not be mitered.

(16) DT-4.4 Valve Dimensions

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 hygienic clamp connections covered by this Standard are given in Table DT-4.4.1-1. All sizes shown are nominal O.D. tube sizes.

The categorized group in DT-4.4.1 designates specific valve dimensions.

DT-4.4.1 Diaphragm Valves. Refer to Table DT-4.4.1-1.

(16) DT-4.5 Filter Dimensions

Standard dimensions for filter components covered by this Standard are referenced in SD-3.8 and are given in Tables DT-4.5.1-1 and DT-4.5.2-1.

DT-4.5.1 Code 7 Tapered Locking Tab Retainer: Recessed. Refer to Table DT-4.5.1-1.

DT-4.5.2 Code 7 Tapered Locking Tab Retainer: External. Refer to Table DT-4.5.2-1.

DT-5 MATERIALS

Materials used in the manufacture of fittings and other process components shall conform to one of the material specifications listed in Part MM.

DT-6 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-2-1 at 100°F (38°C).

(16) DT-7 TOLERANCES

Tables DT-3-1, DT-3-2, DT-4-1, and DT-7-1 list the required tolerances for fabricated fittings and process components depicted by this Standard. Table DT-7-1 lists the required tolerances for machined hygienic clamp ferrule profiles. When ferrules are welded to a process component and polished, then the tolerance in Tables DT-3-1, DT-3-2, and DT-4-1 shall apply. For tubing tolerances, refer to ASTM A270, Supplement 2. Table DT-7-2 lists the required tolerances for transfer panel nozzles and jumpers.

These tolerances shall apply after heat and surface treatment.

The control portion of the fitting or process components (refer to C in the Table DT-3-1 illustration) is 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-4.1.4-1 for ferrule lengths and Table DT-4.1.5-1 for automatic tube weld caps.

DT-8 WELD ENDS

(16)

Where a 316L-type alloy is specified, the material of the automatic weld end shall conform to the requirements for chemical composition as prescribed in MM-5.2.1.1. For nonautomatic weld ends, the chemical composition shall meet the requirements of the applicable ASTM specification.

Automatic weld ends furnished to this Standard shall be furnished with square-cut ends, free from burrs and breaks. All weld end connections for valves shall have a minimum unobstructed weld end length equal to or greater than the minimum control portion as per DT-7.

DT-9 HYGIENIC CLAMP UNIONS

DT-9.1 Typical Hygienic Clamp Unions

Typical hygienic clamp unions are described in SG-2.2.2.

DT-9.2 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-2-1 and Part SG. Gasket seal performance in the clamp union shall be based on the principles of SG-4 and shall comply with the dimensional requirements of Fig. SG-4.2-1 when the union assembly is tightened to an amount recommended by the manufacturer. Gasket seal width as shown in Fig. SG-4.2-1 shall be a maximum of 0.085 in. in the uncompressed condition prior to installation.

DT-9.3 Connections

(16)

Connections meeting all dimensions of Table DT-7-1 are considered interchangeable. Alternative sealing designs are acceptable, provided the following are met:

- (a) dimensions A, B, C, and D of Table DT-7-1
- (b) dimensions A and B of Table DT-9.3-1

In the case of non flow-through connections, dimension B of Table DT-7-1 shall not apply. All connections shall meet the applicable requirements of paras. SD-3.1, SG-3.3.2.1, and SG-3.3.2.2.

(16) DT-9.4 Hygienic Clamps

Hygienic clamps shall be designed and manufactured through the entire range of all union component dimensional tolerances to accomplish the following:

- (a) completely retain all components in a fully sealed state to meet the requirements of DT-2
- (b) maintain proper component alignment during installation and operation per SG-3.3.2.1
- (c) cause the ferrules to be aligned to meet a uniform nominal gap per Fig. SG-4.2-1 when installed and tightened to the proper design specifications
- (d) 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-9.3-1 when installed and tightened to achieve the nominal gap per Fig. SG-4.2-1

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.

- (e) avoid any interference with any clamp union components or itself that would prevent proper assembly when assembled with all components (see Fig. DT-2-1)

DT-10 MINIMUM EXAMINATION REQUIREMENTS**DT-10.1 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) process contact surface finish designation [only one surface finish (SF) designation allowed]
- (f) reference to ASME BPE
 - (1) ASME BPE Certificate of Authorization holders shall mark the reference to this Standard by applying their ASME Certification Mark with BPE Designator. Refer to Fig. CR-1-1.
 - (2) Non-ASME BPE Certificate of Authorization holders shall only mark "BPE."
- (g) pressure rating for valves
- (h) no damage or other noncompliances

DT-10.2 Documentation Verification

Refer to Part GR for documentation verification requirements.

DT-10.3 Physical Examination

For this paragraph, 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 (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 defect(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 used.

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).

DT-11 MARKING**DT-11.1 Fitting Marking Information**

Except as specified in DT-11.1.1, each fitting and process component shall be permanently marked by any suitable method not injurious to the process contact surface to show the following:

- (a) heat number/code traceable to Material Test Report for each process contact surface component
- (b) material type
- (c) manufacturer's name, logo, or trademark
- (d) reference to this Standard (BPE)

(1) ASME BPE Certificate of Authorization holders shall mark the reference to this Standard by applying their ASME Mark with BPE Designator. Refer to Fig. CR-1-1.

(2) Non-ASME BPE Certificate of Authorization holders shall only mark "BPE."

- (e) process contact surface designation for the appropriate BPE specification [only one surface finish (SF) designation allowed]

NOTE: All marking of a process component should be made outside of the control portion to optimize welding fit-up and identification.

DT-11.1.1 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-11.2 Valve Marking Information

Except as specified in DT-11.2.1, each valve shall be permanently marked by any suitable method not injurious to the process 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 (BPE)

(1) ASME BPE Certificate of Authorization holders shall mark the reference to this Standard by applying their ASME Mark with BPE Designator. Refer to Fig. CR-1-1.

(2) Non-ASME BPE Certificate of Authorization holders shall only mark "BPE."

(f) process contact surface designation for the appropriate BPE specification [only one surface finish (SF) designation allowed]

NOTE: All marking of a process component should be made outside of the control portion to optimize welding fit-up and identification.

DT-11.2.1 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.

DT-11.3 Modified Surfaces

When the surface finish of a process component is modified, the surface finish designation marking shall be changed to match the final surface finish designation according to Table SF-2.4-1. Only the final finish designation shall be indicated.

After removal of the original markings, all dimensions and tolerances must comply with Table DT-3-1 and, as applicable, Table DT-3-2.

DT-12 PACKAGING

All end connections of fittings or process components shall be protected with end caps. Additionally, fittings 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.

(16) **Table DT-2-1 Metallic Hygienic Unions: Rated Internal Working Pressure**

Temperature		< 3 in. Clamp		3 in. Clamp		4 in. Clamp		6 in. Clamp	
°F	°C	psig	kPa	psig	kPa	psig	kPa	psig	kPa
100	38	200	1 379	200	1 379	200	1 379	150	1 034
250	121	165	1 138	150	1 034	125	862	75	517

GENERAL NOTES:

- (a) These pressure ratings apply to the hygienic clamp and gasket. For information on pressure ratings, see the manufacturer's guidelines for the components.
- (b) For installation practices, refer to Fig. DT-2-1.

Fig. DT-2-1 Clamp Conditions at Installation

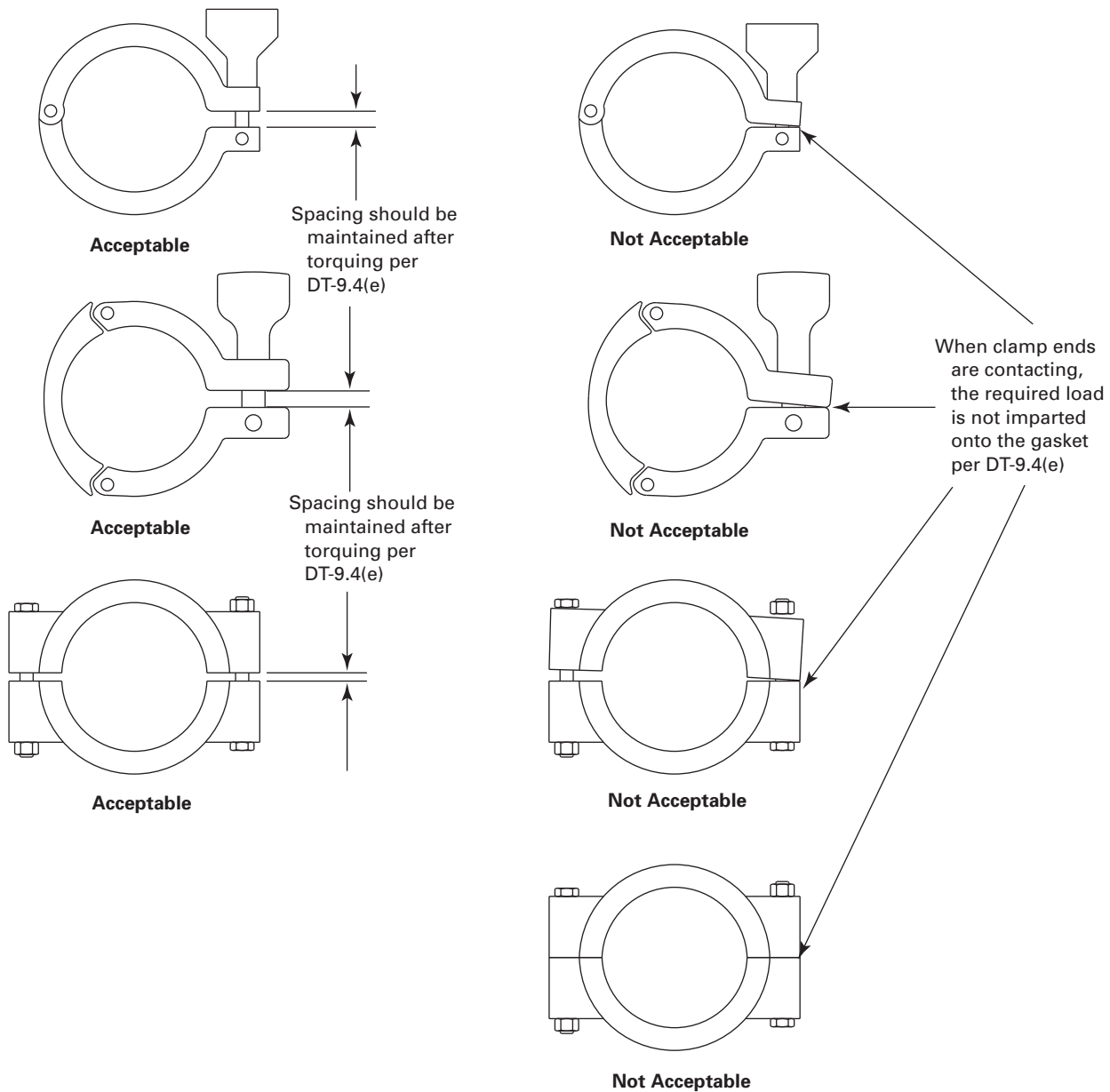
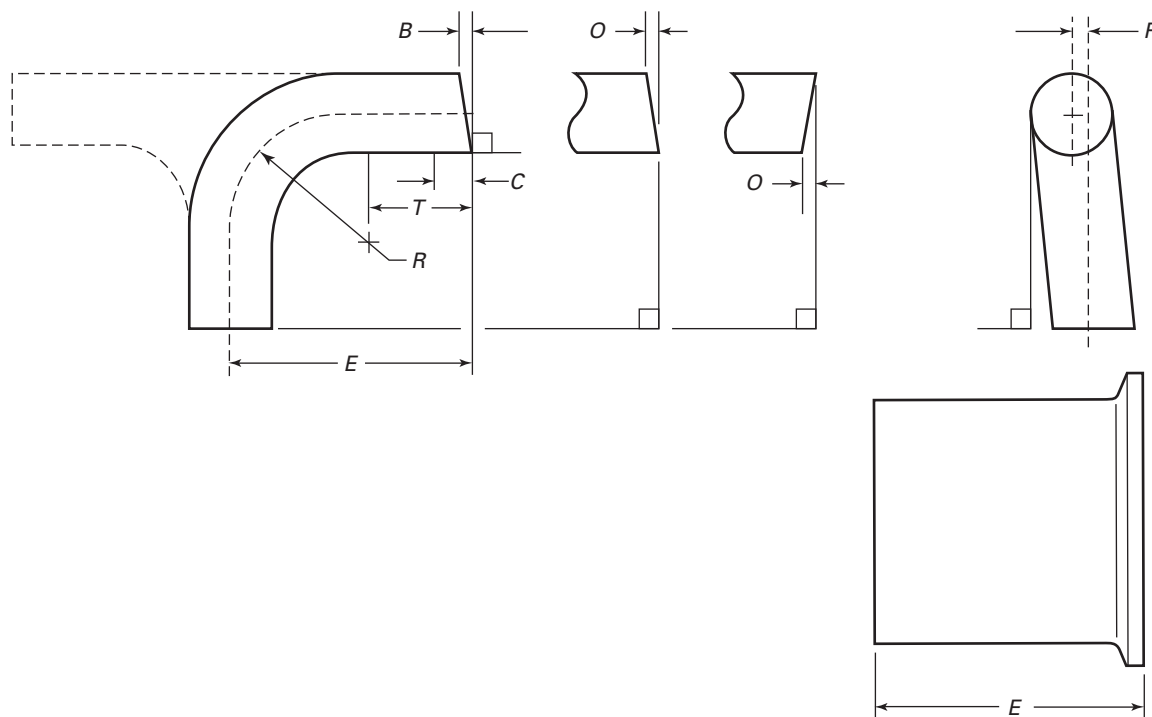


Table DT-3-1 Final Tolerances for Mechanically Polished Fittings and Process Components

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 NOTES:

- 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-3-2 for electropolished wall thickness tolerances.
- See DT-7 (Tolerances) for *C* control portion lengths.
- See Table DT-4.1-1 for *T* tangent length dimensions.
- Tolerance for centerline radius (CLR) is ±10% of the nominal dimension (*R*).

Table DT-3-2 Final Tolerances for Electropolished Fittings and Process Components

Nominal Size, in.	Wall Thickness	
	in.	mm
$\frac{1}{4}$	+0.003/−0.006	+0.08/−0.15
$\frac{3}{8}$	+0.003/−0.006	+0.08/−0.15
$\frac{1}{2}$	+0.005/−0.010	+0.13/−0.25
$\frac{3}{4}$	+0.005/−0.010	+0.13/−0.25
1	+0.005/−0.010	+0.13/−0.25
$1\frac{1}{2}$	+0.005/−0.010	+0.13/−0.25
2	+0.005/−0.010	+0.13/−0.25
$2\frac{1}{2}$	+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-4-1 Nominal O.D. Tubing Sizes

Nominal Size, in.	Tube O.D.		Tube Wall Thickness	
	in.	mm	in.	mm
$\frac{1}{4}$	0.250	6.35	0.035	0.89
$\frac{3}{8}$	0.375	9.53	0.035	0.89
$\frac{1}{2}$	0.500	12.70	0.065	1.65
$\frac{3}{4}$	0.750	19.05	0.065	1.65
1	1.000	25.40	0.065	1.65
$1\frac{1}{2}$	1.500	38.10	0.065	1.65
2	2.000	50.80	0.065	1.65
$2\frac{1}{2}$	2.500	63.50	0.065	1.65
3	3.000	76.20	0.065	1.65
4	4.000	101.60	0.083	2.11
6	6.000	152.40	0.109	2.77

GENERAL NOTE: Refer to ASTM A270, Supplement 2 for tubing tolerances.

Table DT-4.1-1 Tangent Lengths

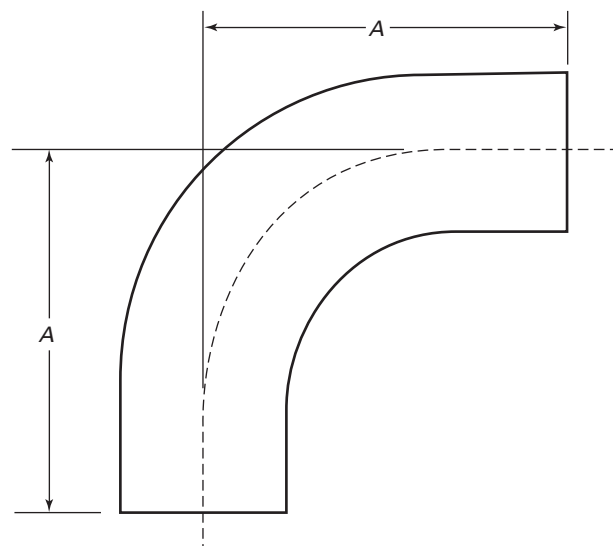
(16)

Nominal O.D. Tube Size, in.	Tangent, <i>T</i>	
	in.	mm
$\frac{1}{4}$	1.500	38.10
$\frac{3}{8}$	1.500	38.10
$\frac{1}{2}$	1.500	38.10
$\frac{3}{4}$	1.500	38.10
1	1.500	38.10
$1\frac{1}{2}$	1.500	38.10
2	1.500	38.10
$2\frac{1}{2}$	1.500	38.10
3	1.750	44.45
4	2.000	50.80
6	2.500	63.50

GENERAL NOTES:

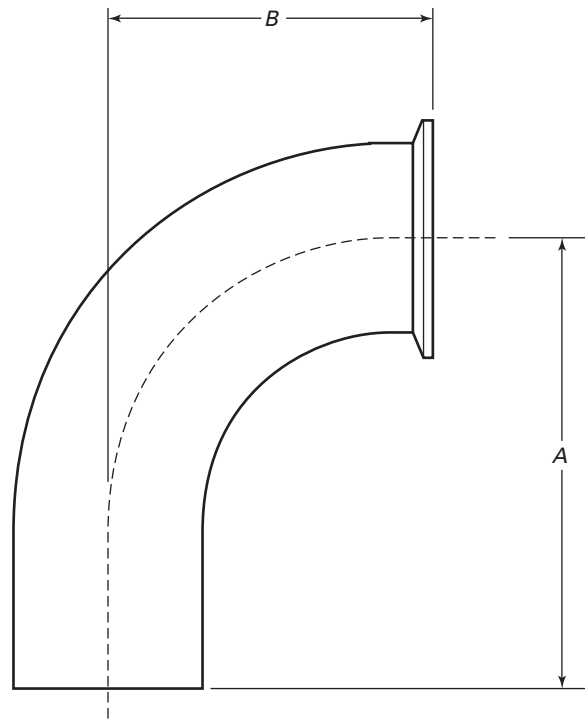
- Minimum tangent lengths for ferrules do not apply. See Table DT-4.1.4-1, dimensions *B* and *C*, for available length options.
- Minimum tangent length for $\frac{1}{4}$ in. to $\frac{3}{4}$ in. size automatic tube weld: 180 deg return bend does not conform (see Table DT-4.1.1-7, dimension *B*).
- Minimum tangent lengths for Tables DT-4.1.2-2, DT-4.1.2-3, DT-4.1.2-7, DT-4.1.3-1, and DT-4.1.3-2 do not apply.

(16) Table DT-4.1.1-1 Automatic Tube Weld: 90-deg Elbow

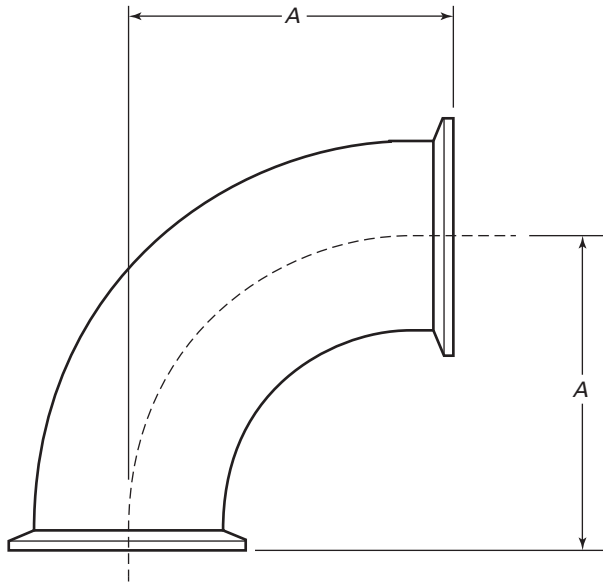


Nominal Size, in.	A	
	in.	mm
1/4	2.625	66.68
3/8	2.625	66.68
1/2	3.000	76.20
3/4	3.000	76.20
1	3.000	76.20
1 1/2	3.750	95.25
2	4.750	120.65
2 1/2	5.500	139.70
3	6.250	158.75
4	8.000	203.20
6	11.500	292.10

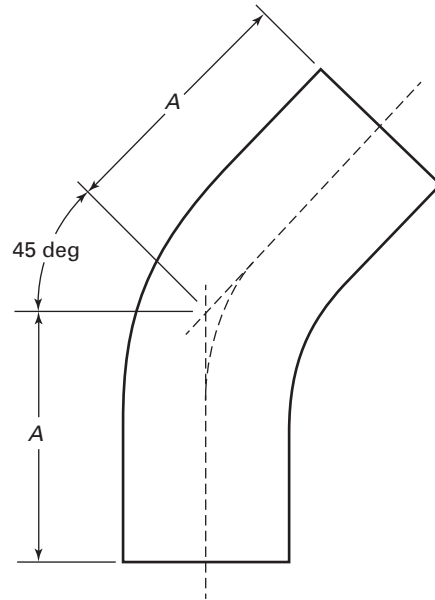
Table DT-4.1.1-2 Automatic Tube Weld: Hygienic Clamp Joint, 90-deg Elbow (16)



Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/4	2.625	66.68	1.625	41.28
3/8	2.625	66.68	1.625	41.26
1/2	3.000	76.20	1.625	41.28
3/4	3.000	76.20	1.625	41.28
1	3.000	76.20	2.000	50.80
1 1/2	3.750	95.25	2.750	69.85
2	4.750	120.65	3.500	88.90
2 1/2	5.500	139.70	4.250	107.95
3	6.250	158.75	5.000	127.00
4	8.000	203.20	6.625	168.28
6	11.500	292.10	10.500	266.70

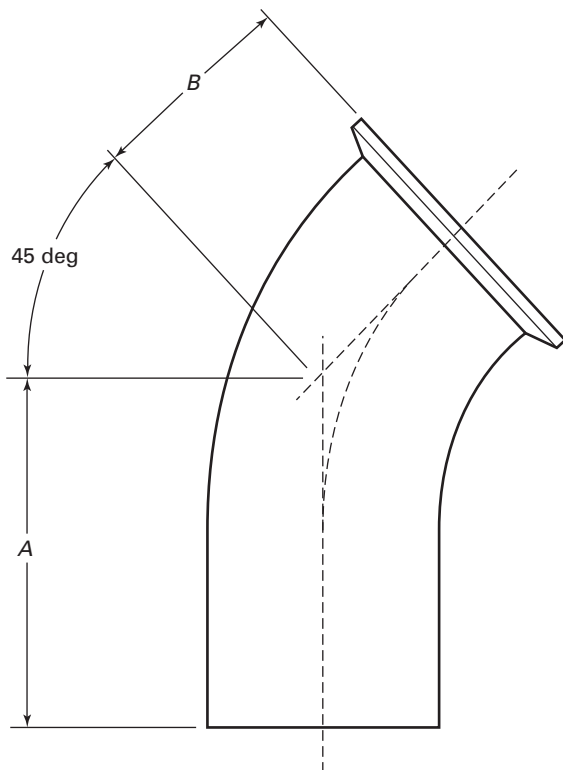
(16) **Table DT-4.1.1-3 Hygienic Clamp Joint: 90-deg Elbow**

Nominal Size, in.	A	
	in.	mm
$\frac{1}{4}$	1.625	41.28
$\frac{3}{8}$	1.625	41.28
$\frac{1}{2}$	1.625	41.28
$\frac{3}{4}$	1.625	41.28
1	2.000	50.80
$1\frac{1}{2}$	2.750	69.85
2	3.500	88.90
$2\frac{1}{2}$	4.250	107.95
3	5.000	127.00
4	6.625	168.28
6	10.500	266.70

Table DT-4.1.1-4 Automatic Tube Weld: 45-deg Elbow (16)

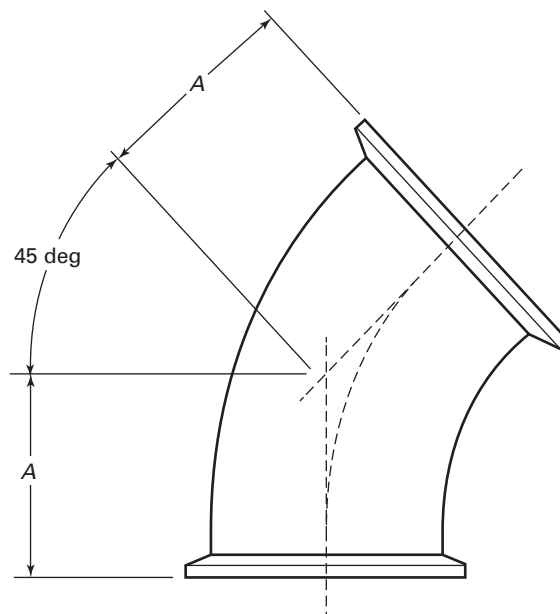
Nominal Size, in.	A	
	in.	mm
$\frac{1}{4}$	2.000	50.80
$\frac{3}{8}$	2.000	50.80
$\frac{1}{2}$	2.250	57.15
$\frac{3}{4}$	2.250	57.15
1	2.250	57.15
$1\frac{1}{2}$	2.500	63.50
2	3.000	76.20
$2\frac{1}{2}$	3.375	85.73
3	3.625	92.08
4	4.500	114.30
6	6.250	158.75

(16) Table DT-4.1.1-5 Automatic Tube Weld: Hygienic Clamp Joint, 45-deg Elbow

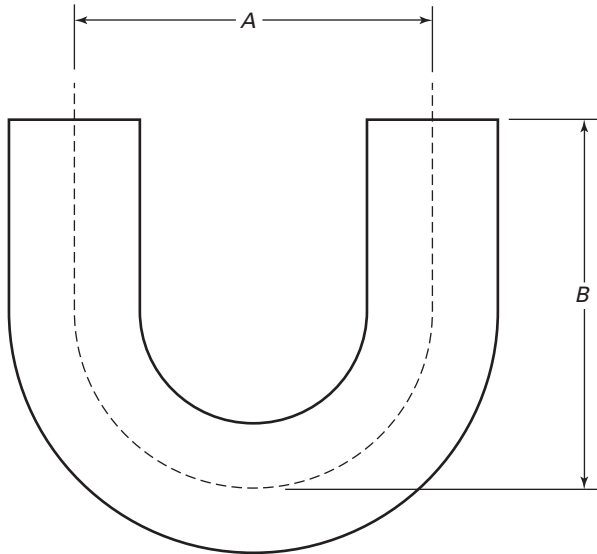


Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/4	2.000	50.80	1.000	25.40
3/8	2.000	50.80	1.000	25.40
1/2	2.250	57.15	1.000	25.40
3/4	2.250	57.15	1.000	25.40
1	2.250	57.15	1.125	28.58
1 1/2	2.500	63.50	1.438	36.53
2	3.000	76.20	1.750	44.45
2 1/2	3.375	85.73	2.063	52.40
3	3.625	92.08	2.375	60.33
4	4.500	114.30	3.125	79.38
6	6.250	158.75	5.250	133.35

Table DT-4.1.1-6 Hygienic Clamp Joint: 45-deg Elbow (16)



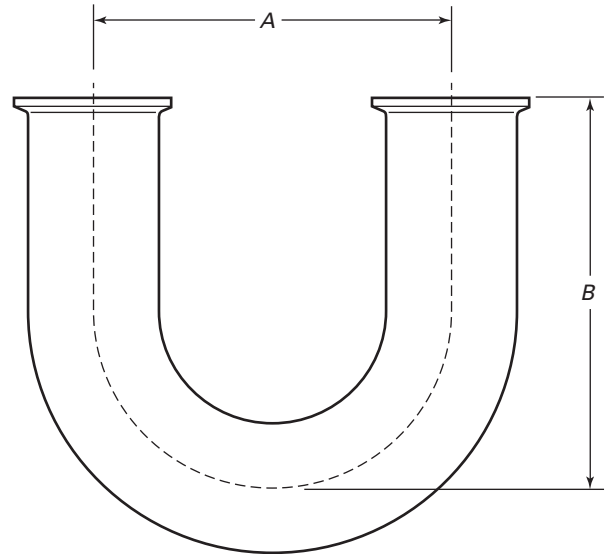
Nominal Size, in.	A	
	in.	mm
1/4	1.000	25.40
3/8	1.000	25.40
1/2	1.000	25.40
3/4	1.000	25.40
1	1.125	28.58
1 1/2	1.438	36.53
2	1.750	44.45
2 1/2	2.063	52.40
3	2.375	60.33
4	3.125	79.38
6	5.250	133.35

(16) **Table DT-4.1.1-7 Automatic Tube Weld: 180-deg Return Bend**

Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/4	4.500	114.30	2.625	66.68
3/8	4.500	114.30	2.625	66.68
1/2	4.500	114.30	3.000	76.20
3/4	4.500	114.30	3.000	76.20
1	3.000	76.20	3.000	76.20
1 1/2	4.500	114.30	4.500	114.30
2	6.000	152.40	5.000	127.00
2 1/2	7.500	190.50	5.750	146.05
3	9.000	228.60	6.500	165.10
4	12.000	304.80	8.500	215.90
6	18.000	457.20	11.500	292.10

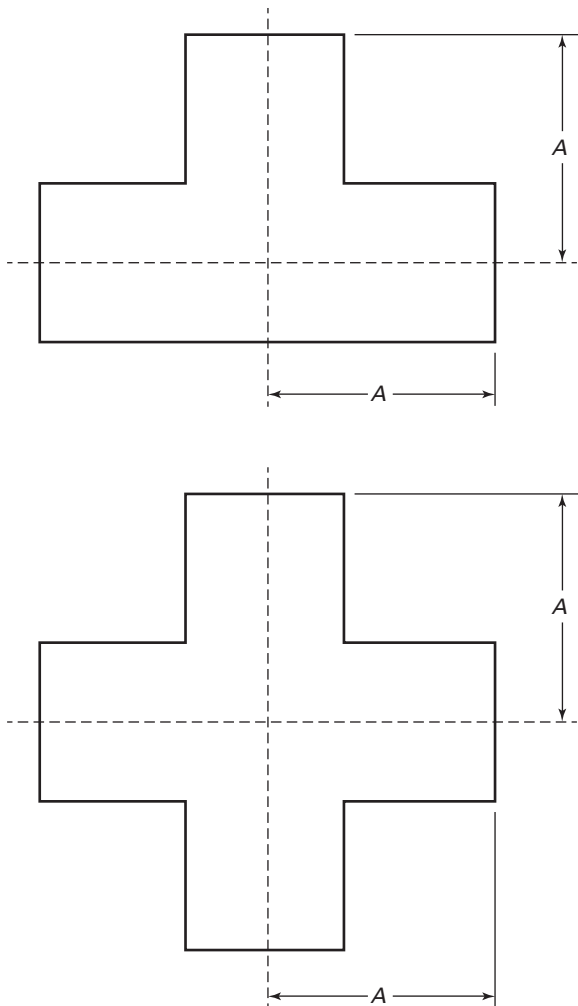
Table DT-4.1.1-8 Hygienic Clamp Joint: 180-deg Return Bend

(16)



Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/4	4.500	114.30	3.125	79.38
3/8	4.500	114.30	3.125	79.38
1/2	4.500	114.30	3.500	88.90
3/4	4.500	114.30	3.500	88.90
1	3.000	76.20	3.500	88.90
1 1/2	4.500	114.30	5.000	127.00
2	6.000	152.40	5.500	139.70
2 1/2	7.500	190.50	6.250	165.10
3	9.000	228.60	7.000	177.80
4	12.000	304.80	9.125	231.78
6	18.000	457.20	13.000	330.20

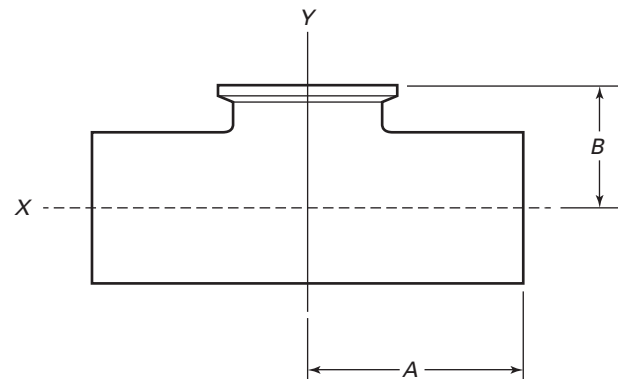
GENERAL NOTE: 1/4 in.–3/4 in. sizes do not conform to Table DT-4.1-1.

(16) **Table DT-4.1.2-1 Automatic Tube Weld: Straight Tee and Cross**

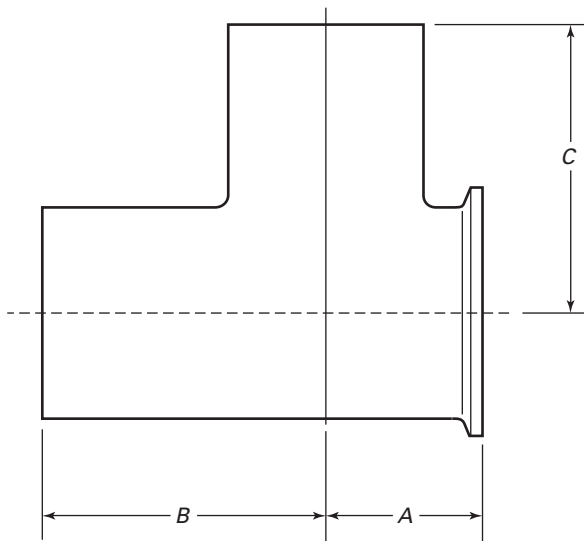
Nominal Size, in.	A	
	in.	mm
$\frac{1}{4}$	1.750	44.45
$\frac{3}{8}$	1.750	44.45
$\frac{1}{2}$	1.875	47.63
$\frac{3}{4}$	2.000	50.80
1	2.125	53.98
$1\frac{1}{2}$	2.375	60.33
2	2.875	73.03
$2\frac{1}{2}$	3.125	79.38
3	3.375	85.73
4	4.125	104.78
6	5.625	142.88

Table DT-4.1.2-2 Automatic Tube Weld: Short-Outlet Hygienic Clamp Joint Tee

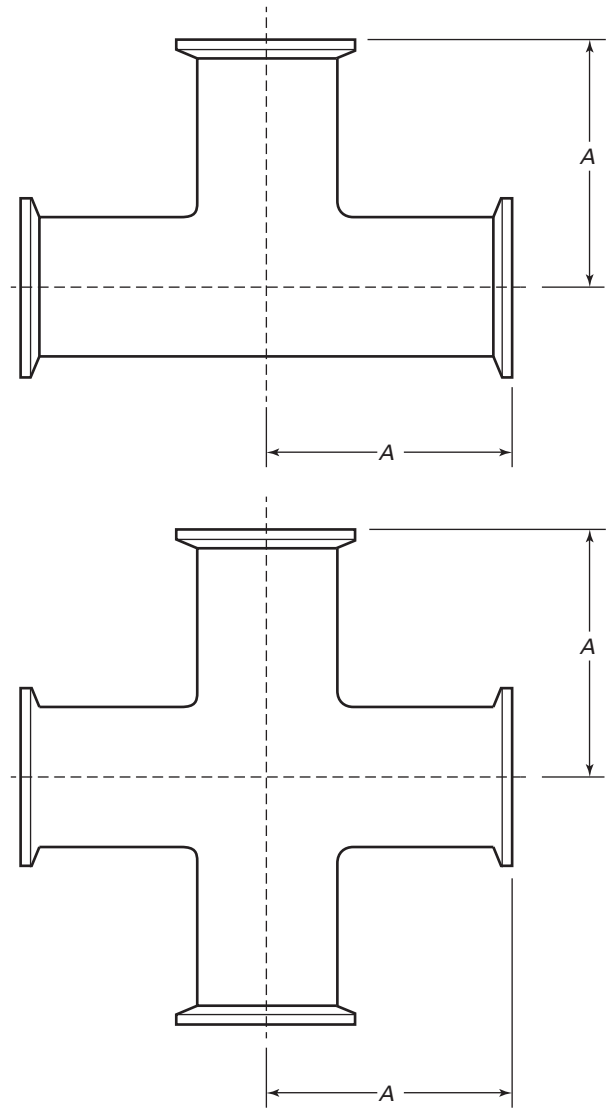
(16)



Nominal Size, in.	A		B	
	in.	mm	in.	mm
$\frac{1}{4}$	1.750	44.45	1.000	25.40
$\frac{3}{8}$	1.750	44.45	1.000	25.40
$\frac{1}{2}$	1.875	47.63	1.000	25.40
$\frac{3}{4}$	2.000	50.80	1.125	28.58
1	2.125	53.98	1.125	28.58
$1\frac{1}{2}$	2.375	60.33	1.375	34.93
2	2.875	73.03	1.625	41.28
$2\frac{1}{2}$	3.125	79.38	1.875	47.63
3	3.375	85.73	2.125	53.98
4	4.125	104.78	2.750	69.85
6	5.625	142.88	4.625	117.48

(16) **Table DT-4.1.2-3 Hygienic Mechanical Joint:
Short-Outlet Run Tee**

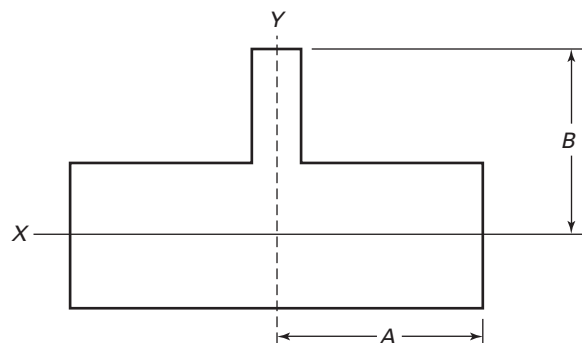
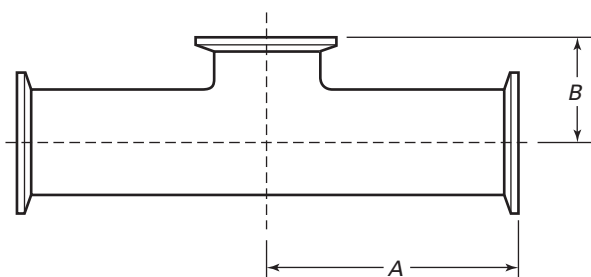
Nominal Size, in.	A		B		C	
	in.	mm	in.	mm	in.	mm
1/4	0.875	22.23	1.750	44.45	1.750	44.45
3/8	0.875	22.23	1.750	44.45	1.750	44.45
1/2	0.875	22.23	1.875	47.63	1.875	47.63
3/4	1.000	25.40	2.000	50.80	2.000	50.80
1	1.125	28.58	2.125	53.98	2.125	53.98
1 1/2	1.375	34.93	2.375	60.33	2.375	60.33
2	1.625	41.28	2.875	73.03	2.875	73.03
2 1/2	1.875	47.63	3.125	79.38	3.125	79.38
3	2.125	53.98	3.375	85.73	3.375	85.73
4	2.750	69.85	4.125	104.78	4.125	104.78
6	4.625	117.48	5.625	142.88	5.625	142.88

**Table DT-4.1.2-4 Hygienic Clamp Joint: Straight
Tee and Cross** (16)

Nominal Size, in.	A	
	in.	mm
1/4	2.250	57.15
3/8	2.250	57.15
1/2	2.250	57.15
3/4	2.375	60.33
1	2.625	66.68
1 1/2	2.875	73.03
2	3.375	85.73
2 1/2	3.625	92.08
3	3.875	98.43
4	4.750	120.65
6	7.125	180.98

**Table DT-4.1.2-6 Automatic Tube Weld:
Reducing Tee**

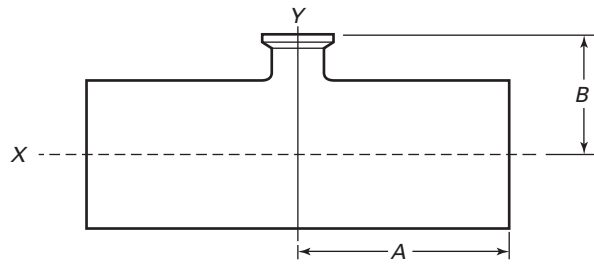
(16)

**Table DT-4.1.2-5 Hygienic Clamp Joint:
Short-Outlet Tee**

Nominal Size, in.	A		B	
	in.	mm	in.	mm
1/2	2.250	57.15	1.000	25.40
3/4	2.375	60.33	1.125	28.58
1	2.625	66.68	1.125	28.58
1 1/2	2.875	73.03	1.375	34.93
2	3.375	85.73	1.625	41.28
2 1/2	3.625	92.08	1.875	47.63
3	3.875	98.43	2.125	53.98
4	4.750	120.65	2.750	69.85
6	7.125	180.98	4.625	117.48

Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
3/8	1/4	1.750	44.45	1.750	44.45
1/2	1/4	1.875	47.63	1.875	47.63
1/2	3/8	1.875	47.63	1.875	47.63
3/4	1/4	2.000	50.80	2.000	50.80
3/4	3/8	2.000	50.80	2.000	50.80
3/4	1/2	2.000	50.80	2.000	50.80
1	1/4	2.125	53.98	2.125	53.98
1	3/8	2.125	53.98	2.125	53.98
1	1/2	2.125	53.98	2.125	53.98
1	3/4	2.125	53.98	2.125	53.98
1 1/2	1/2	2.375	60.33	2.375	60.33
1 1/2	3/4	2.375	60.33	2.375	60.33
1 1/2	1	2.375	60.33	2.375	60.33
2	1/2	2.875	73.03	2.625	66.68
2	3/4	2.875	73.03	2.625	66.68
2	1	2.875	73.03	2.625	66.68
2	1 1/2	2.875	73.03	2.625	66.68
2 1/2	1/2	3.125	79.38	2.875	73.03
2 1/2	3/4	3.125	79.38	2.875	73.03
2 1/2	1	3.125	79.38	2.875	73.03
2 1/2	1 1/2	3.125	79.38	2.875	73.03
2 1/2	2	3.125	79.38	2.875	73.03
3	1/2	3.375	85.73	3.125	79.38
3	3/4	3.375	85.73	3.125	79.38
3	1	3.375	85.73	3.125	79.38
3	1 1/2	3.375	85.73	3.125	79.38
3	2	3.375	85.73	3.125	79.38
3	2 1/2	3.375	85.73	3.125	79.38
4	1/2	4.125	104.78	3.625	92.08
4	3/4	4.125	104.78	3.625	92.08
4	1	4.125	104.78	3.625	92.08
4	1 1/2	4.125	104.78	3.625	92.08
4	2	4.125	104.78	3.875	98.43
4	2 1/2	4.125	104.78	3.875	98.43
4	3	4.125	104.78	3.875	98.43
6	3	5.625	142.88	4.875	123.83
6	4	5.625	142.88	5.125	130.18

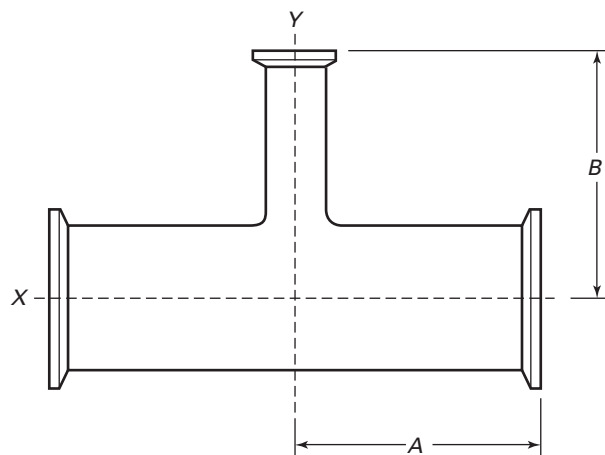
(16)

Table DT-4.1.2-7 Automatic Tube Weld: Short-Outlet Hygienic Clamp, Joint Reducing Tee

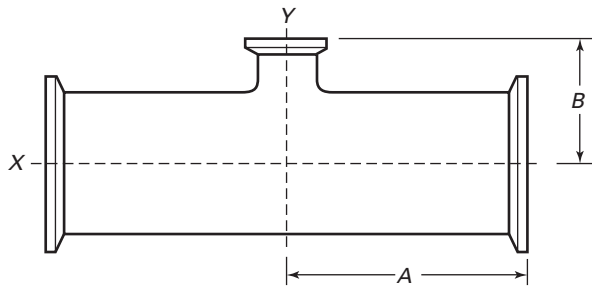
Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
3/8	1/4	1.750	44.45	1.000	25.40
1/2	1/4	1.875	47.63	1.000	25.40
1/2	3/8	1.875	47.63	1.000	25.40
3/4	1/4	2.000	50.80	1.000	25.40
3/4	3/8	2.000	50.80	1.000	25.40
3/4	1/2	2.000	50.80	1.000	25.40
1	1/4	2.125	53.98	1.125	28.58
1	3/8	2.125	53.98	1.125	28.58
1	1/2	2.125	53.98	1.125	28.58
1	3/4	2.125	53.98	1.125	28.58
1 1/2	1/2	2.375	60.33	1.375	34.93
1 1/2	3/4	2.375	60.33	1.375	34.93
1 1/2	1	2.375	60.33	1.375	34.93
2	1/2	2.875	73.03	1.625	41.28
2	3/4	2.875	73.03	1.625	41.28
2	1	2.875	73.03	1.625	41.28
2	1 1/2	2.875	73.03	1.625	41.28
2 1/2	1/2	3.125	79.38	1.875	47.63
2 1/2	3/4	3.125	79.38	1.875	47.63
2 1/2	1	3.125	79.38	1.875	47.63
2 1/2	1 1/2	3.125	79.38	1.875	47.63
2 1/2	2	3.125	79.38	1.875	47.63
3	1/2	3.375	85.73	2.125	53.98
3	3/4	3.375	85.73	2.125	53.98
3	1	3.375	85.73	2.125	53.98
3	1 1/2	3.375	85.73	2.125	53.98
3	2	3.375	85.73	2.125	53.98
3	2 1/2	3.375	85.73	2.125	53.98
4	1/2	4.125	104.78	2.625	66.68
4	3/4	4.125	104.78	2.625	66.68
4	1	4.125	104.78	2.625	66.68
4	1 1/2	4.125	104.78	2.625	66.68
4	2	4.125	104.78	2.625	66.68
4	2 1/2	4.125	104.78	2.625	66.68
4	3	4.125	104.78	2.625	66.68
6	1/2	5.625	142.88	3.625	92.08
6	3/4	5.625	142.88	3.625	92.08
6	1	5.625	142.88	3.625	92.08
6	1 1/2	5.625	142.88	3.625	92.08
6	2	5.625	142.88	3.625	92.08
6	2 1/2	5.625	142.88	3.625	92.08
6	3	5.625	142.88	3.625	92.08
6	4	5.625	142.88	3.750	95.25

Table DT-4.1.2-8 Hygienic Clamp Joint: Reducing Tee

(16)



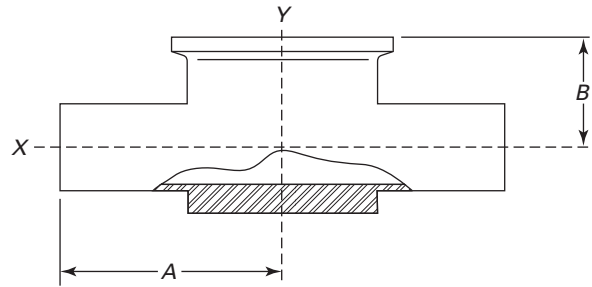
Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
3/8	1/4	2.250	57.15	2.250	57.15
1/2	1/4	2.375	60.33	2.375	60.33
1/2	3/8	2.375	60.33	2.375	60.33
3/4	1/4	2.500	63.50	2.500	63.50
3/4	3/8	2.500	63.50	2.500	63.50
3/4	1/2	2.500	63.50	2.500	63.50
1	1/4	2.625	66.68	2.625	66.68
1	3/8	2.625	66.68	2.625	66.68
1	1/2	2.625	66.68	2.625	66.68
1	3/4	2.625	66.68	2.625	66.68
1 1/2	1/2	2.875	73.03	2.875	73.03
1 1/2	3/4	2.875	73.03	2.875	73.03
1 1/2	1	2.875	73.03	2.875	73.03
2	1/2	3.375	85.73	3.125	79.38
2	3/4	3.375	85.73	3.125	79.38
2	1	3.375	85.73	3.125	79.38
2	1 1/2	3.375	85.73	3.125	79.38
2 1/2	1/2	3.625	92.08	3.375	85.73
2 1/2	3/4	3.625	92.08	3.375	85.73
2 1/2	1	3.625	92.08	3.375	85.73
2 1/2	1 1/2	3.625	92.08	3.375	85.73
2 1/2	2	3.625	92.08	3.375	85.73
3	1/2	3.875	98.43	3.625	92.08
3	3/4	3.875	98.43	3.625	92.08
3	1	3.875	98.43	3.625	92.08
3	1 1/2	3.875	98.43	3.625	92.08
3	2	3.875	98.43	3.625	98.43
3	2 1/2	3.875	98.43	3.625	98.43
4	1/2	4.750	120.65	4.125	104.78
4	3/4	4.750	120.65	4.125	104.78
4	1	4.750	120.65	4.125	104.78
4	1 1/2	4.750	120.65	4.125	104.78
4	2	4.750	120.65	4.375	111.13
4	2 1/2	4.750	120.65	4.375	111.13
4	3	4.750	120.65	4.375	111.13
6	3	7.125	180.98	5.375	136.53
6	4	7.125	180.98	5.750	146.05

(16) **Table DT-4.1.2-9 Hygienic Clamp Joint: Short-Outlet Reducing Tee**

Nominal Size, in.		A		B	
X	Y	in.	mm	in.	mm
3/8	1/4	2.250	57.15	1.000	25.40
1/2	1/4	2.375	60.33	1.000	25.40
1/2	3/8	2.375	60.33	1.000	25.40
3/4	1/4	2.500	63.50	1.000	25.40
3/4	3/8	2.500	63.50	1.000	25.40
3/4	1/2	2.500	63.50	1.000	25.40
1	1/4	2.625	66.68	1.125	28.58
1	3/8	2.625	66.68	1.125	28.58
1	1/2	2.625	66.68	1.125	28.58
1	3/4	2.625	66.68	1.125	28.58
1 1/2	1/2	2.875	73.03	1.375	34.93
1 1/2	3/4	2.875	73.03	1.375	34.93
1 1/2	1	2.875	73.03	1.375	34.93
2	1/2	3.375	85.73	1.625	41.28
2	3/4	3.375	85.73	1.625	41.28
2	1	3.375	85.73	1.625	41.28
2	1 1/2	3.375	85.73	1.625	41.28
2 1/2	1/2	3.625	92.08	1.875	47.63
2 1/2	3/4	3.625	92.08	1.875	47.63
2 1/2	1	3.625	92.08	1.875	47.63
2 1/2	1 1/2	3.625	92.08	1.875	47.63
2 1/2	2	3.625	92.08	1.875	47.63
3	1/2	3.875	98.43	2.125	53.98
3	3/4	3.875	98.43	2.125	53.98
3	1	3.875	98.43	2.125	53.98
3	1 1/2	3.875	98.43	2.125	53.98
3	2	3.875	98.43	2.125	53.98
3	2 1/2	3.875	98.43	2.125	53.98
4	1/2	4.750	120.65	2.625	66.68
4	3/4	4.750	120.65	2.625	66.68
4	1	4.750	120.65	2.625	66.68
4	1 1/2	4.750	120.65	2.625	66.68
4	2	4.750	120.65	2.625	66.68
4	2 1/2	4.750	120.65	2.625	66.68
4	3	4.750	120.65	2.625	66.68
6	1/2	7.125	180.98	3.625	92.08
6	3/4	7.125	180.98	3.625	92.08
6	1	7.125	180.98	3.625	92.08
6	1 1/2	7.125	180.98	3.625	92.08
6	2	7.125	180.98	3.625	92.08
6	2 1/2	7.125	180.98	3.625	92.08
6	3	7.125	180.98	3.625	92.08
6	4	7.125	180.98	3.750	95.25

Table DT-4.1.2-10 Automatic Tube Weld: Instrument Tee

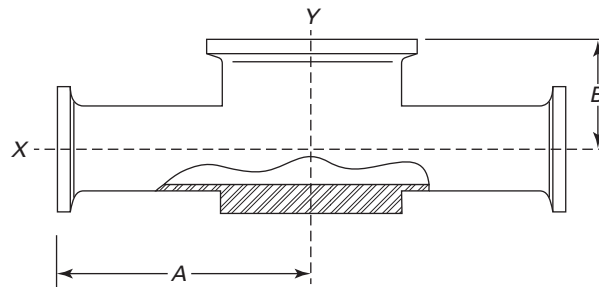
(16)



Nominal Size, in.			A		B	
X	Y		in.	mm	in.	mm
1/2	×	1 1/2	2.500	63.50	0.875	22.23
3/4	×	1 1/2	2.500	63.50	1.000	25.40
1	×	1 1/2	2.500	63.50	1.125	28.58
1/2	×	2	2.750	69.85	1.000	25.40
3/4	×	2	2.750	69.85	1.125	28.58
1	×	2	2.750	69.85	1.250	31.75
1 1/2	×	2	2.750	69.85	1.500	38.10

Table DT-4.1.2-11 Hygienic Clamp Joint: Instrument Tee

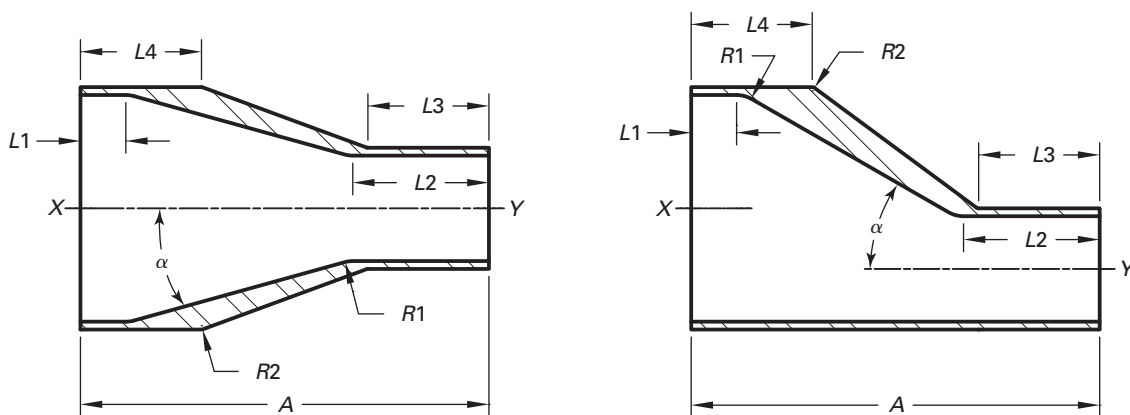
(16)



Nominal Size, in.			A		B	
X	Y		in.	mm	in.	mm
1/2	×	1 1/2	3.000	76.20	0.875	22.23
3/4	×	1 1/2	3.000	76.20	1.000	25.40
1	×	1 1/2	3.000	76.20	1.125	28.58
1/2	×	2	3.250	82.55	1.000	25.40
3/4	×	2	3.250	82.55	1.125	28.58
1	×	2	3.250	82.55	1.250	31.75
1 1/2	×	2	3.250	82.55	1.500	38.10

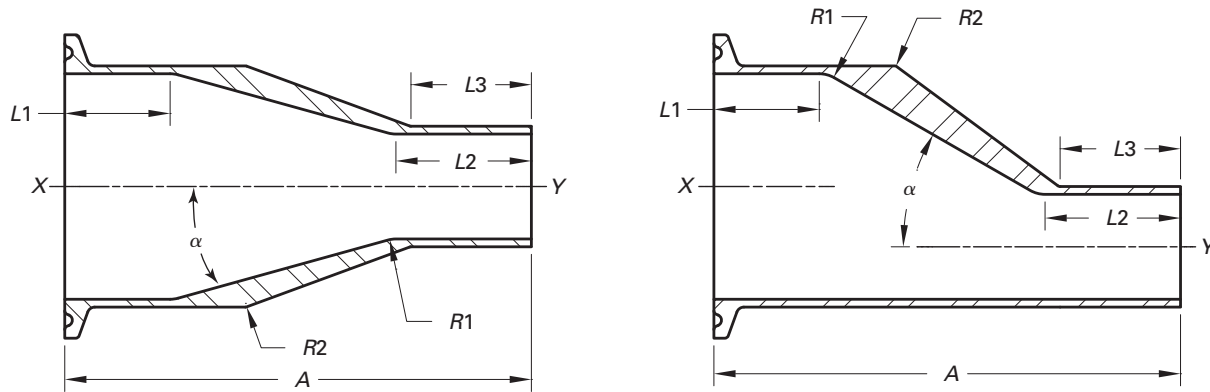
Table DT-4.1.3-1 Automatic Tube Weld: Concentric and Eccentric Reducer

(16)



Nominal Size, in.		Overall Length, A,		I.D. Tangent, Large End, L1, min.		I.D. Tangent, Small End, L2, min.		O.D. Tangent, Small End, L3, min.		O.D. Tangent, Large End, L4, min.		Internal Taper, α , max., deg	Internal Radius, R1, min.		External Radius, R2, min.	
X	Y	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm		in.	mm	in.	mm
3/8	1/4	1.625	41.28	0.375	9.53	0.875	22.23	0.750	19.05	0.750	19.05	30	0.250	6.35	0.031	0.79
1/2	1/4	1.875	47.63	0.375	9.53	0.875	22.23	0.750	19.05	1.000	25.40	30	0.250	6.35	0.031	0.79
1/2	3/8	1.875	47.63	0.375	9.53	0.875	22.23	0.750	19.05	1.000	25.40	30	0.250	6.35	0.031	0.79
3/4	3/8	2.000	50.80	0.375	9.53	0.875	22.23	0.750	19.05	1.000	25.40	30	0.250	6.35	0.031	0.79
3/4	1/2	2.125	53.98	0.375	9.53	1.125	28.58	1.000	25.40	1.000	25.40	30	0.250	6.35	0.031	0.79
1	1/2	2.500	63.50	0.375	9.53	1.125	28.58	1.000	25.40	1.000	25.40	30	0.250	6.35	0.031	0.79
1	3/4	2.125	53.98	0.375	9.53	1.125	28.58	1.000	25.40	1.000	25.40	30	0.250	6.35	0.031	0.79
1 1/2	3/4	3.000	76.20	0.375	9.53	1.125	28.58	1.000	25.40	1.000	25.40	30	0.250	6.35	0.031	0.79
1 1/2	1	2.500	63.50	0.375	9.53	1.125	28.58	1.000	25.40	1.000	25.40	30	0.250	6.35	0.031	0.79
2	1	3.375	85.73	0.375	9.53	1.125	28.58	1.000	25.40	1.000	25.40	30	0.250	6.35	0.031	0.79
2	1 1/2	2.500	63.50	0.375	9.53	1.125	28.58	1.000	25.40	1.000	25.40	30	0.250	6.35	0.031	0.79
2 1/2	1 1/2	3.375	85.73	0.375	9.53	1.125	28.58	1.000	25.40	1.000	25.40	30	0.250	6.35	0.031	0.79
2 1/2	2	2.500	63.50	0.375	9.53	1.125	28.58	1.000	25.40	1.000	25.40	30	0.250	6.35	0.031	0.79
3	1 1/2	4.250	107.95	0.375	9.53	1.125	28.58	1.000	25.40	1.500	38.10	30	0.250	6.35	0.031	0.79
3	2	3.375	85.73	0.375	9.53	1.125	28.58	1.000	25.40	1.500	38.10	30	0.250	6.35	0.031	0.79
3	2 1/2	2.625	66.68	0.375	9.53	1.125	28.58	1.000	25.40	1.500	38.10	30	0.250	6.35	0.031	0.79
4	2	5.125	130.18	0.375	9.53	1.125	28.58	1.000	25.40	1.500	38.10	30	0.250	6.35	0.031	0.79
4	2 1/2	4.250	107.95	0.375	9.53	1.125	28.58	1.000	25.40	1.500	38.10	30	0.250	6.35	0.031	0.79
4	3	3.875	98.43	0.375	9.53	1.625	41.28	1.500	38.10	1.500	38.10	30	0.250	6.35	0.031	0.79
6	3	7.250	184.15	0.375	9.53	1.625	41.28	1.500	38.10	2.000	50.80	44	0.250	6.35	0.031	0.79
6	4	5.625	142.88	0.375	9.53	1.625	41.28	1.500	38.10	2.000	50.80	44	0.250	6.35	0.031	0.79

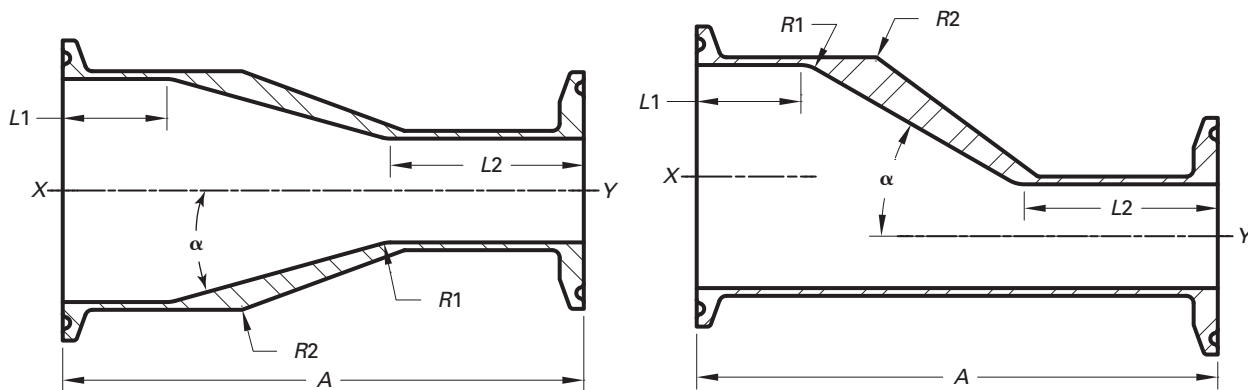
(16) Table DT-4.1.3-2 Hygienic Clamp Joint: Tube Weld Concentric and Eccentric Reducer



Nominal Size, in.		Overall Length, A,		I.D. Tangent, Large End, L1, min.		I.D. Tangent, Small End, L2, min.		O.D. Tangent, Small End, L3, min.		Internal Taper, α , max., deg	Internal Radius, R1, min.		External Radius, R2, min.	
X	Y	in.	mm	in.	mm	in.	mm	in.	mm		in.	mm	in.	mm
$\frac{3}{8}$	$\frac{1}{4}$	2.125	53.98	0.375	9.53	0.875	22.23	0.750	19.05	30	0.250	6.35	0.031	0.79
$\frac{1}{2}$	$\frac{1}{4}$	2.375	60.33	0.375	9.53	0.875	22.23	0.750	19.05	30	0.250	6.35	0.031	0.79
$\frac{1}{2}$	$\frac{3}{8}$	2.375	60.33	0.375	9.53	0.875	22.23	0.750	19.05	30	0.250	6.35	0.031	0.79
$\frac{3}{4}$	$\frac{3}{8}$	2.500	63.50	0.375	9.53	0.875	22.23	0.750	19.05	30	0.250	6.35	0.031	0.79
$\frac{3}{4}$	$\frac{1}{2}$	2.625	66.68	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
1	$\frac{1}{2}$	3.000	76.20	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
1	$\frac{3}{4}$	2.625	66.68	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
$1\frac{1}{2}$	$\frac{3}{4}$	3.500	88.90	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
$1\frac{1}{2}$	1	3.000	76.20	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
2	1	3.875	98.43	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
2	$1\frac{1}{2}$	3.000	76.20	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
$2\frac{1}{2}$	$1\frac{1}{2}$	3.875	98.43	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
$2\frac{1}{2}$	2	3.000	76.20	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
3	$1\frac{1}{2}$	4.750	120.65	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
3	2	3.875	98.43	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
3	$2\frac{1}{2}$	3.125	79.38	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
4	2	5.750	146.05	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
4	$2\frac{1}{2}$	4.875	123.83	0.375	9.53	1.125	28.58	1.000	25.40	30	0.250	6.35	0.031	0.79
4	3	4.500	114.30	0.375	9.53	1.625	41.28	1.500	38.10	30	0.250	6.35	0.031	0.79
6	3	8.000	203.20	0.375	9.53	1.625	41.28	1.500	38.10	44	0.250	6.35	0.031	0.79
6	4	6.375	161.93	0.375	9.53	1.625	41.28	1.500	38.10	44	0.250	6.35	0.031	0.79

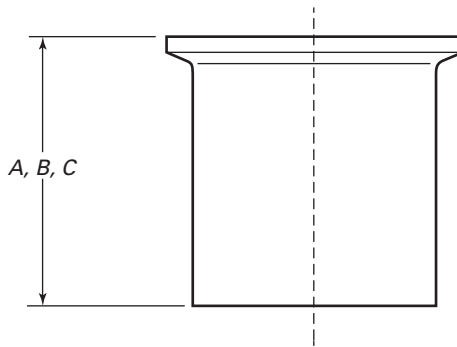
Table DT-4.1.3-3 Hygienic Clamp Joint: Concentric and Eccentric Reducer

(16)



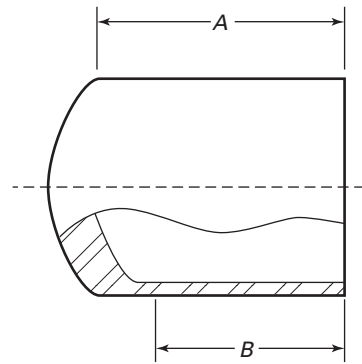
Nominal Size, in.		Overall Length, A,		I.D. Tangent, Large End, L1, min.		I.D. Tangent, Small End, L2, min.		Internal Taper, α , max., deg	Internal Radius, R1, min.		External Radius, R2, min.	
X	Y	in.	mm	in.	mm	in.	mm		in.	mm	in.	mm
$\frac{3}{8}$	$\frac{1}{4}$	2.625	66.68	0.375	9.53	0.875	22.23	30	0.250	6.35	0.031	0.79
$\frac{1}{2}$	$\frac{1}{4}$	2.875	73.03	0.375	9.53	0.875	22.23	30	0.250	6.35	0.031	0.79
$\frac{1}{2}$	$\frac{3}{8}$	2.875	73.03	0.375	9.53	0.875	22.23	30	0.250	6.35	0.031	0.79
$\frac{3}{4}$	$\frac{3}{8}$	3.000	76.20	0.375	9.53	0.875	22.23	30	0.250	6.35	0.031	0.79
$\frac{3}{4}$	$\frac{1}{2}$	3.125	79.38	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
1	$\frac{1}{2}$	3.500	88.90	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
1	$\frac{3}{4}$	3.125	79.38	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
$1\frac{1}{2}$	$\frac{3}{4}$	4.000	101.60	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
$1\frac{1}{2}$	1	3.500	88.90	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
2	1	4.375	111.13	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
2	$1\frac{1}{2}$	3.500	88.90	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
$2\frac{1}{2}$	$1\frac{1}{2}$	4.375	111.13	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
$2\frac{1}{2}$	2	3.500	88.90	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
3	$1\frac{1}{2}$	5.250	133.35	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
3	2	4.375	111.13	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
3	$2\frac{1}{2}$	3.625	92.08	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
4	2	6.250	158.75	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
4	$2\frac{1}{2}$	5.375	136.53	0.375	9.53	1.125	28.58	30	0.250	6.35	0.031	0.79
4	3	5.000	127.00	0.375	9.53	1.625	41.28	30	0.250	6.35	0.031	0.79
6	3	8.500	215.90	0.375	9.53	1.625	41.28	44	0.250	6.35	0.031	0.79
6	4	7.000	177.80	0.375	9.53	1.625	41.28	44	0.250	6.35	0.031	0.79

(16) Table DT-4.1.4-1 Automatic Tube Weld: Ferrule



Nominal Size, in.	A		B		C	
	in.	mm	in.	mm	in.	mm
$\frac{1}{4}$	1.750	44.45	1.125	28.58	0.500	12.70
$\frac{3}{8}$	1.750	44.45	1.125	28.58	0.500	12.70
$\frac{1}{2}$	1.750	44.45	1.125	28.58	0.500	12.70
$\frac{3}{4}$	1.750	44.45	1.125	28.58	0.500	12.70
1	1.750	44.45	1.125	28.58	0.500	12.70
$1\frac{1}{2}$	1.750	44.45	1.125	28.58	0.500	12.70
2	2.250	57.15	1.125	28.58	0.500	12.70
$2\frac{1}{2}$	2.250	57.15	1.125	28.58	0.500	12.70
3	2.250	57.15	1.125	28.58	0.500	12.70
4	2.250	57.15	1.125	28.58	0.625	15.88
6	3.000	76.20	1.500	38.10	0.750	19.05

Table DT-4.1.5-1 Automatic Tube Weld: Cap (16)



Nominal Size, in.	A	
	in.	mm
$\frac{1}{2}$	1.500	38.10
$\frac{3}{4}$	1.500	38.10
1	1.500	38.10
$1\frac{1}{2}$	1.500	38.10
2	1.500	38.10
$2\frac{1}{2}$	1.500	38.10
3	1.750	44.45
4	2.000	50.80
6	2.500	63.50

GENERAL NOTE: Minimum I.D. control portion length, B, is 0.375 in. (9.53 mm) for all sizes.

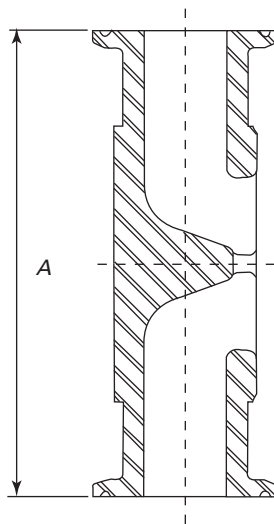
Table DT-4.1.5-2 Hygienic Clamp Joint: Solid End Cap

(16)



Nominal Size, in.	Type	A, min.	
		in.	mm
$\frac{1}{4}$	A	0.187	4.75
$\frac{3}{8}$	A	0.187	4.75
$\frac{1}{2}$	A	0.187	4.75
$\frac{3}{4}$	A	0.187	4.75
1	A	0.250	6.35
1	B	0.250	6.35
$1\frac{1}{2}$	B	0.250	6.35
2	B	0.250	6.35
$2\frac{1}{2}$	B	0.250	6.35
3	B	0.250	6.35
4	B	0.312	7.92
6	B	0.437	11.10

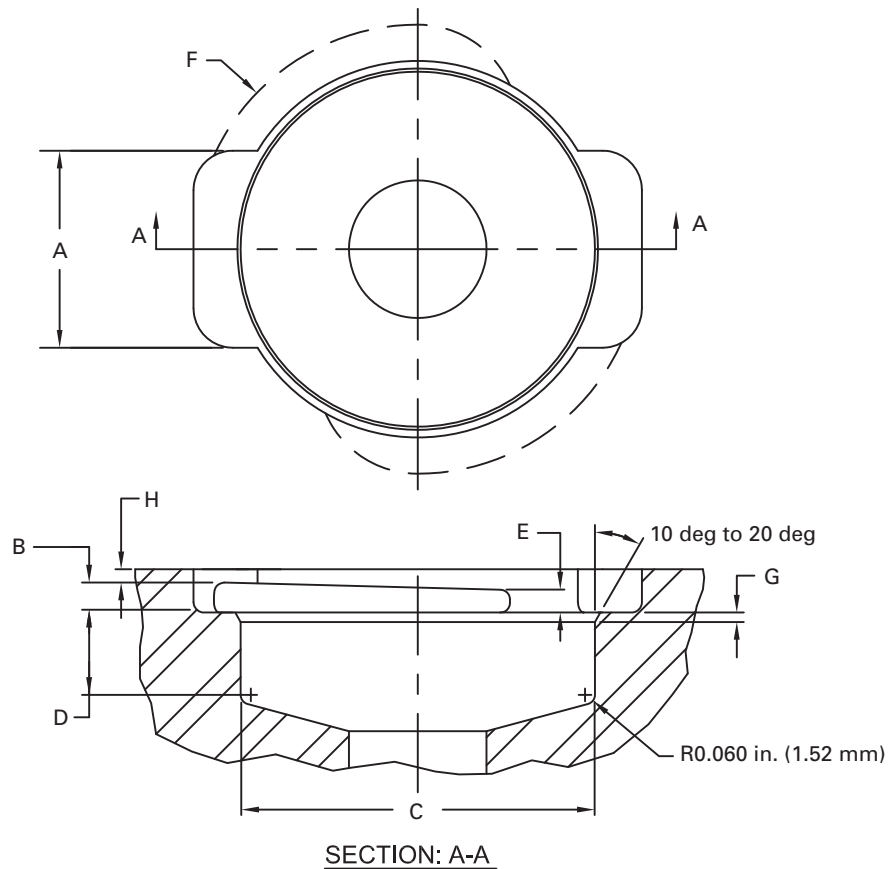
(16)

Table DT-4.4.1-1 Hygienic Clamp Joint: Weir-Style Diaphragm Valve

Nominal Size, in.	A	
	in.	mm
$\frac{1}{4}$ fractional	2.500	63.50
$\frac{3}{8}$ fractional	2.500	63.50
$\frac{1}{2}$ fractional	2.500	63.50
$\frac{1}{2}$	3.500	88.90
$\frac{3}{4}$	4.000	101.60
1	4.500	114.30
$1\frac{1}{2}$	5.500	139.70
2	6.250	158.75
$2\frac{1}{2}$	7.630	193.80
3	8.750	222.25
4	11.500	292.10

Table DT-4.5.1-1 Tapered Locking Tab Retainer: Recessed

(16)



	Dimension		Tolerance		
	in.	mm	in.	mm	
A	1.250 (min.) 1.400 (max.)	31.75 (min.) 35.56 (max.)	...	...	Note (1)
B	0.173	4.39	±0.004	±0.10	...
C	2.250	57.15	+0.003/-0.000	+0.08/-0.00	...
D	0.550 (min.)	13.97 (min.)	...	...	...
E	0.134	3.40	±0.004	±0.10	...
F	R1.430	R36.32	±0.010	±0.25	Note (1)
G	0.060 (max.)	1.52 (max.)	...	...	Note (2)
H	0.125 (max.)	3.18 (max.)	...	...	...

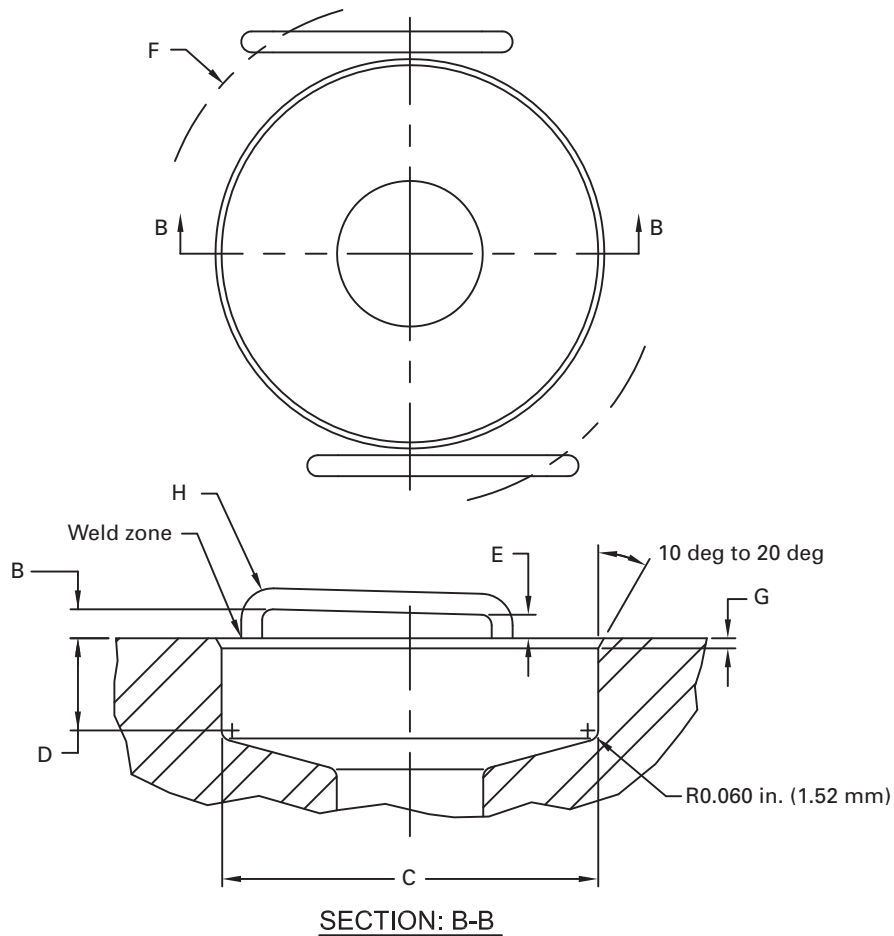
GENERAL NOTES:

- (a) Locking tab retainer options are shown as possible options and do not represent all possible designs.
 (b) All surfaces shall meet the specified finish of wetted surfaces, excluding the weld zones.

NOTES:

- (1) Clearance for locking tabs.
 (2) O-ring lead-in chamfer.

(16)

Table DT-4.5.2-1 Tapered Locking Tab Retainer: External

	Dimension		Tolerance		
	in.	mm	in.	mm	
B	0.173	4.39	±0.004	±0.10	...
C	2.250	57.15	+0.003/-0.000	+0.08/-0.00	...
D	0.550 (min.)	13.97 (min.)	...	...	...
E	0.134	3.40	±0.004	±0.10	...
F	R1.430	R36.32	±0.010	±0.25	Note (1)
G	0.060 (max.)	1.52 (max.)	...	...	Note (2)
H	0.125 (max.)	3.18 (max.)	...	...	...

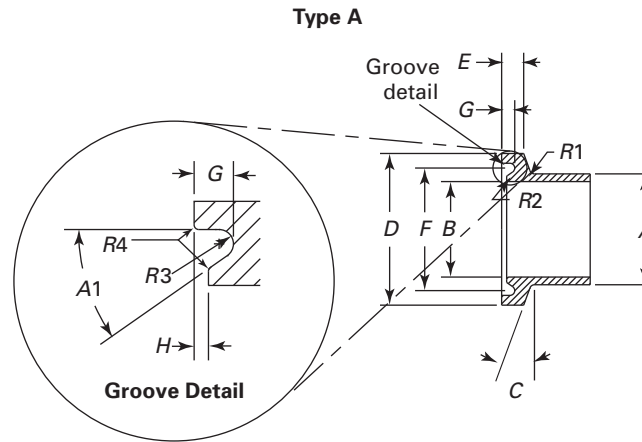
GENERAL NOTES:

- (a) Locking tab retainer options are shown as possible options and do not represent all possible designs.
 (b) All surfaces shall meet the specified finish of wetted surfaces, excluding the weld zones.

NOTES:

- (1) Clearance for locking tabs.
 (2) O-ring lead-in chamfer.

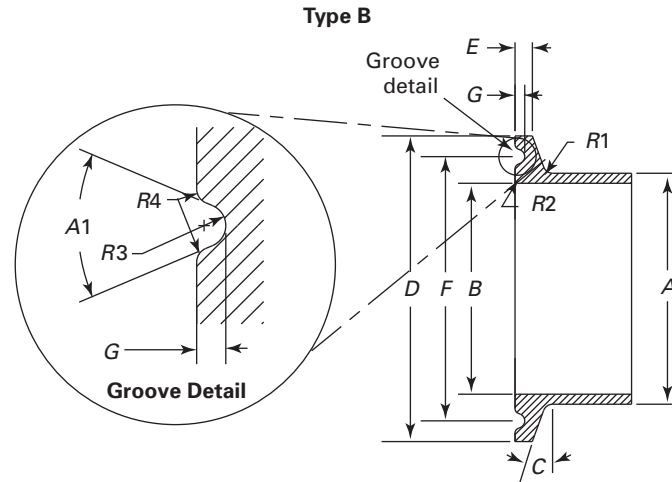
Table DT-7-1 Hygienic Clamp Ferrule Standard Dimensions and Tolerances



Nominal Size, in.	Type	Tube Diameter, A				I.D. Bore, B				Flange Angle, C, deg		Flange Diameter, D						Flange Thickness, E, ref.		Groove Diameter, F					
		Dimension		Tolerance, ±		Dimension		Tolerance, ±		Dimension	Tolerance, ±	Dimension		Tolerance, +		Tolerance, -		Dimension		Dimension		Tolerance, +		Tolerance, -	
		in.	mm	in.	mm	in.	mm	in.	mm			in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm
1/4	A	0.250	6.35	0.005	0.13	0.180	4.57	0.005	0.13	20	0.5	0.984	25.0	0.005	0.13	0.005	0.13	0.143	3.63	0.800	20.32	0.005	0.13	0.005	0.13
3/8	A	0.375	9.53	0.005	0.13	0.305	7.75	0.005	0.13	20	0.5	0.984	25.0	0.005	0.13	0.005	0.13	0.143	3.63	0.800	20.32	0.005	0.13	0.005	0.13
1/2	A	0.500	12.70	0.005	0.13	0.370	9.40	0.005	0.13	20	0.5	0.984	25.0	0.005	0.13	0.005	0.13	0.143	3.63	0.800	20.32	0.005	0.13	0.005	0.13
3/4	A	0.750	19.05	0.005	0.13	0.620	15.75	0.005	0.13	20	0.5	0.984	25.0	0.005	0.13	0.005	0.13	0.143	3.63	0.800	20.32	0.005	0.13	0.005	0.13
1	A	1.000	25.40	0.005	0.13	0.870	22.10	0.005	0.13	20	1.0	1.339	34.0	0.005	0.13	0.005	0.13	0.143	3.63	1.160	29.46	0.005	0.13	0.005	0.13

Nominal Size, in.	Type	Groove Depth, G				Face Offset, H				Groove Detail, R3				Groove Detail, R4				Groove Detail, A1, deg		Radius, R1, max.		Radius, R2			
		Dimension		Tolerance, ±		Dimension		Tolerance, ±		Dimension		Tolerance, ±		Dimension		Tolerance, ±		Dimension	Tolerance, ±	in.	mm	Maximum		Minimum	
		in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm					in.	mm	in.	mm
1/4	A	0.085	2.16	0.005	0.13	0.031	0.79	0.005	0.13	0.031	0.79	0.005	0.13	0.020	0.51	0.005	0.13	35	1	0.031	0.79	0.031	0.79	0.005	0.13
3/8	A	0.085	2.16	0.005	0.13	0.031	0.79	0.005	0.13	0.031	0.79	0.005	0.13	0.020	0.51	0.005	0.13	35	1	0.031	0.79	0.031	0.79	0.005	0.13
1/2	A	0.085	2.16	0.005	0.13	0.031	0.79	0.005	0.13	0.031	0.79	0.005	0.13	0.020	0.51	0.005	0.13	35	1	0.031	0.79	0.031	0.79	0.005	0.13
3/4	A	0.085	2.16	0.005	0.13	0.031	0.79	0.005	0.13	0.031	0.79	0.005	0.13	0.020	0.51	0.005	0.13	35	1	0.031	0.79	0.031	0.79	0.005	0.13
1	A	0.085	2.16	0.005	0.13	0.031	0.79	0.005	0.13	0.031	0.79	0.005	0.13	0.020	0.51	0.005	0.13	35	1	0.031	0.79	0.031	0.79	0.005	0.13

Table DT-7-1 Hygienic Clamp Ferrule Standard Dimensions and Tolerances (Cont'd)



Nominal Size, in.	Type	Tube Diameter, <i>A</i>				I.D. Bore, <i>B</i>				Flange Angle, <i>C</i> , deg		Flange Diameter, <i>D</i>						Flange Thickness, <i>E</i> , ref.		Groove Diameter, <i>F</i>							
		Dimension		Tolerance, ±		Dimension		Tolerance, ±				Dimension		Tolerance, +		Tolerance, −				Dimension		Dimension		Tolerance, +		Tolerance, −	
		in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm		
1	B	1.000	25.40	0.005	0.13	0.870	22.10	0.005	0.13	20	1.0	1.984	50.39	0.008	0.20	0.005	0.13	0.112	2.84	1.718	43.64	0.005	0.13	0.005	0.13		
1½	B	1.500	38.10	0.008	0.20	1.370	34.80	0.005	0.13	20	1.0	1.984	50.39	0.008	0.20	0.005	0.13	0.112	2.84	1.718	43.64	0.005	0.13	0.005	0.13		
2	B	2.000	50.80	0.008	0.20	1.870	47.50	0.005	0.13	20	1.0	2.516	63.91	0.008	0.20	0.008	0.20	0.112	2.84	2.218	56.34	0.005	0.13	0.005	0.13		
2½	B	2.500	63.50	0.010	0.25	2.370	60.20	0.005	0.13	20	1.0	3.047	77.39	0.008	0.20	0.008	0.20	0.112	2.84	2.781	70.64	0.005	0.13	0.005	0.13		
3	B	3.000	76.20	0.010	0.25	2.870	72.90	0.005	0.13	20	1.0	3.579	90.91	0.010	0.25	0.010	0.25	0.112	2.84	3.281	83.34	0.005	0.13	0.005	0.13		
4	B	4.000	101.60	0.015	0.38	3.834	97.38	0.005	0.13	20	1.0	4.682	118.92	0.015	0.38	0.015	0.38	0.112	2.84	4.344	110.34	0.005	0.13	0.005	0.13		
6	B	6.000	152.40	0.030	0.76	5.782	146.86	0.005	0.13	20	1.0	6.570	166.88	0.030	0.76	0.030	0.76	0.220	5.59	6.176	156.87	0.005	0.13	0.005	0.13		
Nominal Size, in.	Type	Groove Depth, <i>G</i>				Face Offset, <i>H</i>		Groove Detail, <i>R3</i>				Groove Detail, <i>R4</i>				Groove Detail, <i>A1</i> , deg		Radius, <i>R1</i> , max.		Radius, <i>R2</i>							
		Dimension		Tolerance, ±				Dimension		Tolerance, ±		Dimension		Tolerance, ±						Maximum		Minimum					
		in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm				
1	B	0.063	1.60	0.005	0.13	N/A	N/A	0.047	1.19	0.005	0.13	0.020	0.51	0.005	0.13	46	1	0.063	1.60	0.031	0.79	0.005	0.13				
1½	B	0.063	1.60	0.005	0.13	N/A	N/A	0.047	1.19	0.005	0.13	0.020	0.51	0.005	0.13	46	1	0.063	1.60	0.031	0.79	0.005	0.13				
2	B	0.063	1.60	0.005	0.13	N/A	N/A	0.047	1.19	0.005	0.13	0.020	0.51	0.005	0.13	46	1	0.063	1.60	0.031	0.79	0.005	0.13				
2½	B	0.063	1.60	0.005	0.13	N/A	N/A	0.047	1.19	0.005	0.13	0.020	0.51	0.005	0.13	46	1	0.063	1.60	0.031	0.79	0.005	0.13				
3	B	0.063	1.60	0.005	0.13	N/A	N/A	0.047	1.19	0.005	0.13	0.020	0.51	0.005	0.13	46	1	0.063	1.60	0.031	0.79	0.005	0.13				
4	B	0.063	1.60	0.005	0.13	N/A	N/A	0.047	1.19	0.005	0.13	0.020	0.51	0.005	0.13	46	1	0.063	1.60	0.031	0.79	0.005	0.13				
6	B	0.063	1.60	0.005	0.13	N/A	N/A	0.047	1.19	0.005	0.13	0.020	0.51	0.005	0.13	46	1	0.063	1.60	0.031	0.79	0.005	0.13				

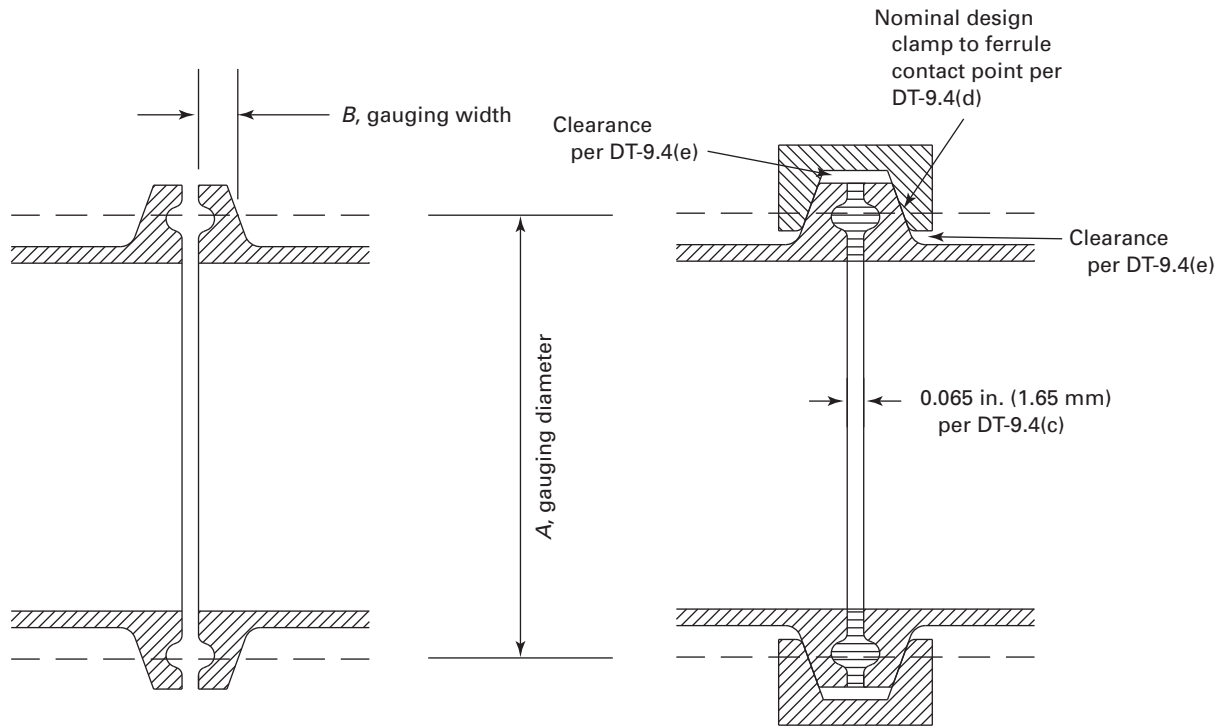
GENERAL NOTES:

- (a) Dimensions and tolerances apply to machined finishes only.
 (b) I.D. bore dimension B should be measured on the ferrule face side only.

Table DT-7-2 Transfer Panel and Jumper Tolerances**(16)**

Connection Nominal Size, in.	Flatness Tolerance Maximum Gap Allowed		Center-to-Center Dimensional Tolerance, ±	
	in.	mm	in.	mm
1/2	0.010	0.25	0.015	0.38
3/4	0.010	0.25	0.015	0.38
1	0.020	0.51	0.015	0.38
1 1/2	0.020	0.51	0.015	0.38
2	0.025	0.64	0.015	0.38
2 1/2	0.025	0.64	0.015	0.38
3	0.030	0.76	0.015	0.38
4	0.040	1.02	0.015	0.38

(16)

Table DT-9.3-1 Hygienic Clamp Ferrule: Design Criteria

Nominal Size, in.	Type	Basic Gauging and Contact Diameter, <i>A</i> (ref.)		Gauging Width, <i>B</i>				Hygienic Clamp Size, in.
		Dimension		Dimension		Tolerance, ±		
		in.	mm	in.	mm	in.	mm	
1/4	A	0.867	22.02	0.164	4.17	0.004	0.10	3/4
3/8	A	0.867	22.02	0.164	4.17	0.004	0.10	3/4
1/2	A	0.867	22.02	0.164	4.17	0.004	0.10	3/4
3/4	A	0.867	22.02	0.164	4.17	0.004	0.10	3/4
1	A	1.222	31.04	0.164	4.17	0.004	0.10	ISO DN15
1	B	1.748	44.39	0.155	3.94	0.005	0.13	1 1/2
1 1/2	B	1.748	44.39	0.155	3.94	0.005	0.13	1 1/2
2	B	2.280	57.91	0.155	3.94	0.005	0.13	2
2 1/2	B	2.811	71.39	0.155	3.94	0.005	0.13	2 1/2
3	B	3.264	82.91	0.169	4.30	0.005	0.13	3
4	B	4.288	108.92	0.184	4.66	0.005	0.13	4
6	B	6.255	158.88	0.277	7.04	0.005	0.13	6

Part PI

Process Instrumentation

(16) PI-1 PURPOSE AND SCOPE

The purpose of this Part is to provide requirements for process instrumentation. This Part defines the minimum requirements for the application of process contact instrumentation in hygienic systems. This Part applies to instrument components that are in contact with the process.

(16) PI-2 PROCESS INSTRUMENTATION GENERAL REQUIREMENTS

Process instrumentation includes sensors, transmitters, analyzers, controllers, recorders, transducers, final control elements, signal converting or conditioning devices, and supporting components (e.g., light sources and sight glasses).

Final control elements such as control valves or variable-speed pumps are covered in other Parts of this Standard.

PI-2.1 General Considerations

PI-2.1.1 Installation. All process instrumentation should be installed per the manufacturer's instructions for proper operation.

Indicating devices shall be oriented and located such that they can be easily viewed for maintenance and operation purposes. Instruments shall be located and oriented so connections can be easily made and adequate space is provided for calibration, maintenance, and replacement.

Instruments, connecting tubing, and systems shall be supported by mounting brackets as necessary to prevent potential stresses on the instrument and tubing system, and to allow for ease of removal without disturbing the adjacent components.

Remote-mounted devices (transmitters, etc.) shall be mounted with appropriate supports to a permanent structure. Ladders, handrails, guardrails, etc., shall not be acceptable mounting supports. If necessary, dedicated instrument supports shall be provided.

PI-2.1.2 Internal Design and Process Connections

(a) Sensors shall be designed in such a way that a failure will not cause contamination hazards to the process and environment.

(b) Liquid-filled elements in measuring devices should not contain materials that can potentially impact product quality.

(c) The internal volume of the liquid-filled elements should be minimized.

(d) Instruments should have integral hygienic fittings. Threaded ferrules are not acceptable to convert standard instrumentation to hygienic standards. Process connections shall be of hygienic design, per the requirements of Parts SD and SG, in order to ensure cleanability of the system.

(e) Gauge siphons (pigtales) shall not be used. Isolation valves should be used if required by the owner/user for routine maintenance or calibration.

(f) Where required for proper operation, all instruments, valves, and in-line devices shall be permanently marked for proper installation (flow direction or orientation).

PI-2.1.3 Exterior Design. Material selection shall consider all intended uses, ambient conditions, and cleaning agents as specified by the owner/user. Sensors and transmitters shall be housed in an enclosure with an appropriate protection rating as specified by the owner/user and shall comply with Parts SD and SG.

PI-2.2 Instrumentation Categories

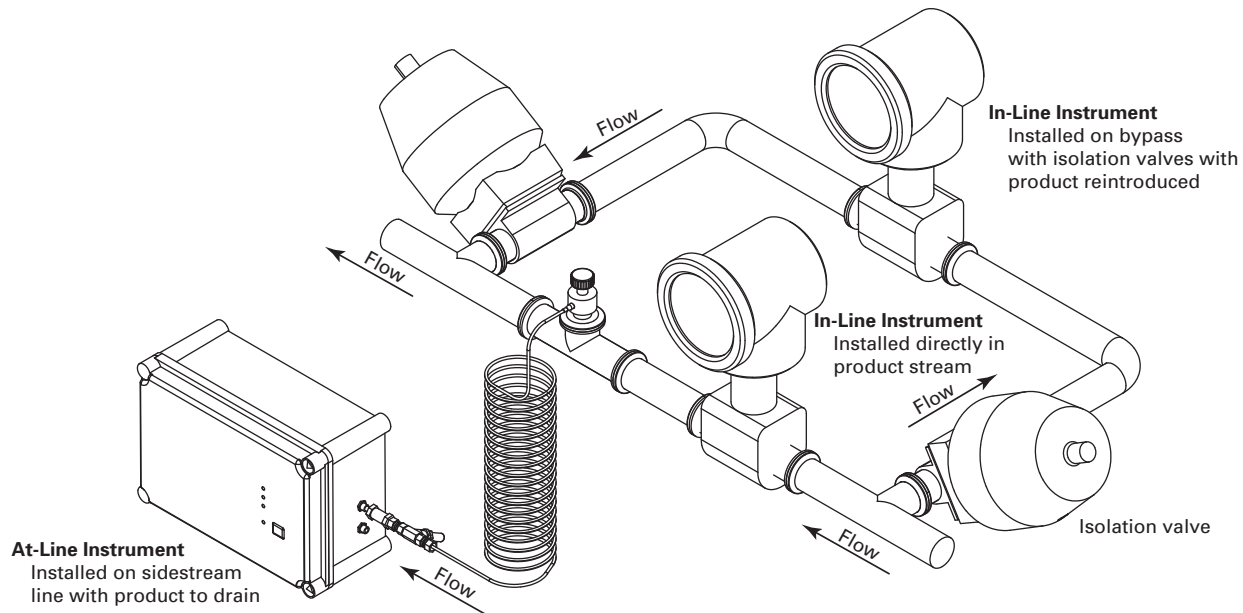
Process instrumentation may be broadly categorized by process installation type as in-line, insertion, at-line, and off-line devices. Process instruments within these categories share some basic installation recommendations for hygienic design and in-process performance.

PI-2.2.1 In-Line Devices. In-line process instruments are self-contained devices installed directly into the process tubing system similar to a standard fitting. Basic installation requirements for hygienic operation as found in Part SD pertain to in-line process instrumentation.

In-line devices may be installed directly in the process stream or in a bypass line to facilitate periodic services (see Fig. PI-2.2.1-1). Device-specific recommendations are defined later in this Part.

PI-2.2.2 Insertion Devices. Insertion devices are instruments that are inserted directly into the process tubing system or process vessel to measure a parameter.

Insertion devices generally require proper immersion in the process fluid for optimal performance. Installation

Fig. PI-2.2.1-1 In-Line and At-Line Instrument Installation Examples

of insertion devices must balance performance requirements and hygienic design. Refer to later sections of this Part and/or the manufacturer's recommended guidelines for specific recommendations (see Fig. PI-2.2.2-1).

PI-2.2.3 At-Line Devices. At-line devices are instruments that measure various parameters by the means of a sidestream sampling loop, which is generally not reintroduced back into the process. Connection of the sampling stream shall be compliant with Part SD and designed to ensure continuous sampling flow to maintain hygienic operation for optimal measurement (see Fig. PI-2.2.1-1).

PI-2.2.4 Off-Line Devices. Off-line devices are instruments located away from the main process and are not covered in this Part.

PI-3 INSTRUMENT RECEIVING, HANDLING, AND STORAGE

PI-3.1 Introduction

Material compatibility and environmental storage conditions shall be considered when receiving, handling, and storing process instrumentation. All instruments shall have markings such as labels, tags, barcodes, or radio-frequency identification (RFID) to ease identification.

PI-3.2 Instrument Receiving

The instrument(s) shall be identified by part/model numbers.

PI-3.2.1 Original Packaging. The integrity of the original packaging of any component, with cleaning certifications such as passivated, cleaned for oxygen service, or hydrocarbon free, shall be maintained during inspection and storage.

PI-3.3 Instrument Handling: Protection of Process Connections and Surface Finish

Care shall be taken to protect the process connection(s) and surface finish of the instrument during receiving, handling, calibration, and storage.

PI-3.4 Instrument Storage

PI-3.4.1 Special Considerations. Special considerations for storage shall be made for certain instrumentation, such as analytical instruments, according to the manufacturer's recommendations.

PI-3.4.2 Instrument Shelf Life and Environmental Requirements. Instruments with limited shelf lives or environmental requirements (temperature, humidity, etc.) shall be identified.

Additional information regarding instrument receiving, handling, and storage is contained in Nonmandatory Appendix Q.

PI-4 FLOWMETERS

PI-4.1 Coriolis Flowmeter

PI-4.1.1 General Considerations. This section provides the requirements for installation and operation of

Fig. PI-2.2.2-1 Accepted Insertion Device Installation Examples

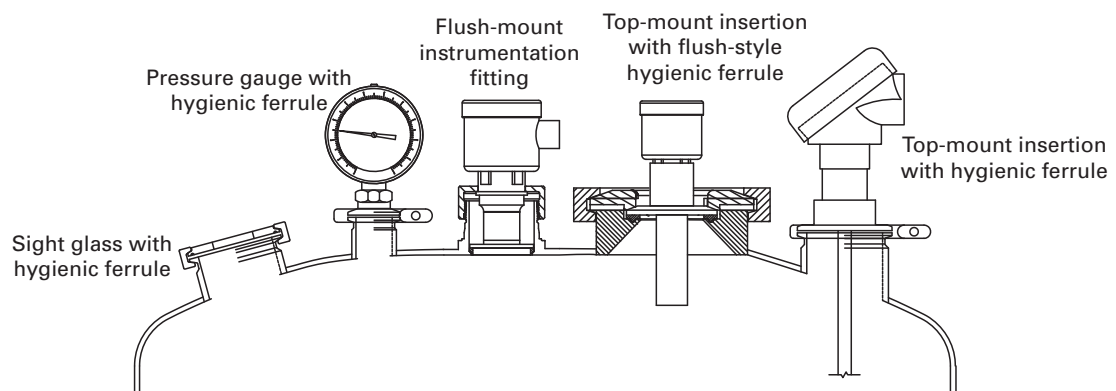
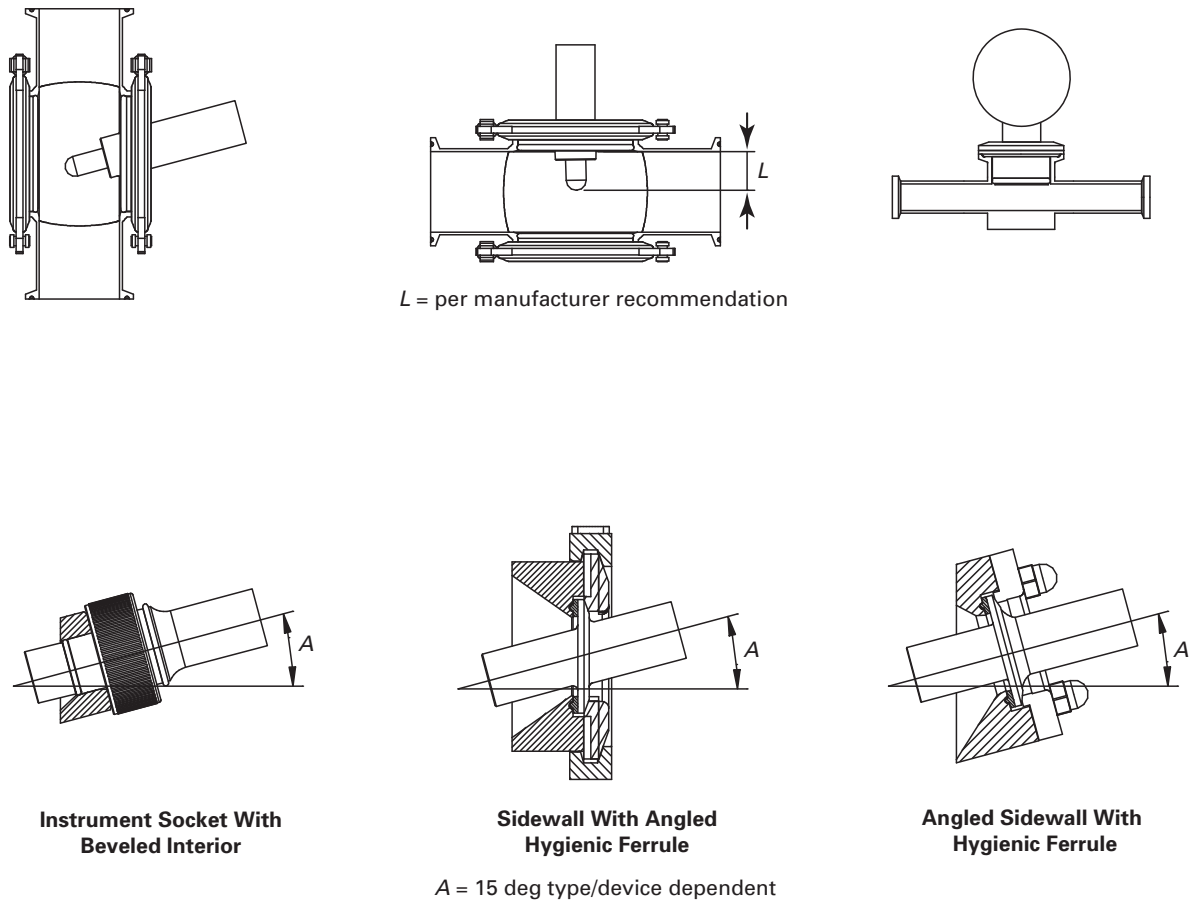
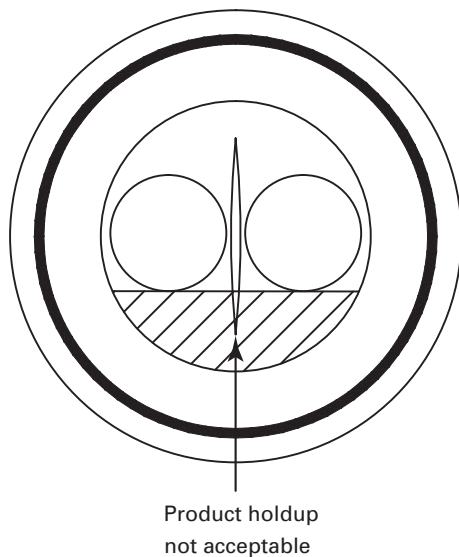


Fig. PI-4.1.3.2-1 Manifold or Flow Splitter for Dual-Tube Construction Flowmeters and Potential for Product Holdup



Coriolis flowmeters specific to bioprocessing and pharmaceutical industries as well as other applications with hygienic requirements.

The design, construction, and fabrication of Coriolis flowmeters are governed by other Parts of this Standard. PI-4.1.2 and PI-4.1.3 may be used as a general reference.

PI-4.1.2 Essential Components. Improper design and/or installation of a flowmeter can affect the drainability and cleanability of the system to which it is attached. Three components of Coriolis flowmeters affect drainability and cleanability: the flow tube(s), the manifold or flow splitter, and the process connections in combination with the installation angle.

The Coriolis flowmeter shall meet the process contact surface requirements as specified in Part SF for all the process-wetted components including flow tube(s), manifold/flow splitter, and process connection.

PI-4.1.3 Components

PI-4.1.3.1 Flow Tube(s). Coriolis flowmeters are either of single-tube or dual-tube construction. The tube(s) can be either straight or bent. The geometry of tube bends shall be considered when assessing drainability and determining installation requirements.

PI-4.1.3.2 Manifold or Flow Splitter. The manifolds or flow splitters for dual-tube construction flowmeters are the interface between the sensor process connections and the sensor measuring tubes and they can create product holdup as shown in Fig. PI-4.1.3.2-1. The geometry of manifolds or flow splitters shall be considered when assessing drainability and determining installation requirements.

PI-4.1.3.3 Process Connections. The interface between the process connections and the sensor tube(s) may result in product holdup, even with single straight tube flowmeters. This is shown for concentrically reducing process connections in Fig. PI-4.1.3.3-1. Eccentrically reducing process connections may allow a single-tube construction flowmeter, with a tube inside diameter differing from the process line inside diameter, to be mounted in horizontal piping. The geometry of process connections, including reductions in flow area, shall be considered when assessing drainability and determining installation requirements. The Coriolis flowmeter shall use acceptable hygienic connections and fittings as per Part SG.

PI-4.1.4 Installation. The manufacturer shall provide the owner/user with the mounting and cleanability requirements necessary to maintain, operate, and properly drain the flowmeter.

PI-4.1.4.1 Drainability. The flow tube or tubes, the manifold or flow splitter, and the process connections shall be considered a system. If a design can be supplied with different types of process connections, then the orientation shall consider the worst case for drainability, or each type of process connection shall be considered individually.

Coriolis flowmeters should be drainable with gravity. Coriolis flowmeters that are not drainable with gravity shall be indicated by the manufacturer and should be of single-tube or other system design to minimize product holdup. An additional motive force (e.g., air purge) may be required to ensure complete drainability.

Drainability requirements should be determined by process requirement and shall be defined by the owner/user.

PI-4.1.4.2 Cleanability. Coriolis flowmeters using a dual-tube construction with small-diameter tubes have a potential for plugging and can adversely affect the cleanability of the flowmeter. It is the responsibility of the owner/user to assess the risk of plugging and the effectiveness of cleaning processes, based on their process and the information provided by the manufacturer.

Requirements relating to cleanability, sterility, and drainability are addressed in Part SD.

PI-4.1.4.3 Mounting Location. It is recommended to install the Coriolis flowmeter vertically with the process fluid flowing upward through the flowmeter (refer to Fig. PI-4.1.4.3-1). If the Coriolis flowmeter is to be installed horizontally, then drainability shall be considered (e.g., by gravity or air purge).

PI-4.1.4.4 Orientation. The Coriolis flowmeter will operate in any orientation as long as the flow tube(s) remain full of process fluid.

For Coriolis flowmeters that are drainable with gravity, the manufacturer shall provide the owner/user with

Fig. PI-4.1.3.3-1 Concentrically Reducing Process Connection

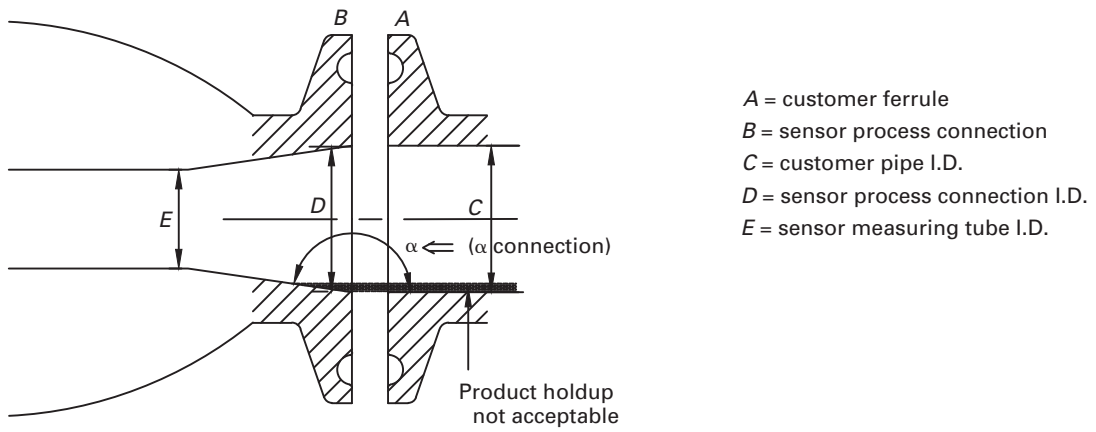


Fig. PI-4.1.4.3-1 Vertical Installation

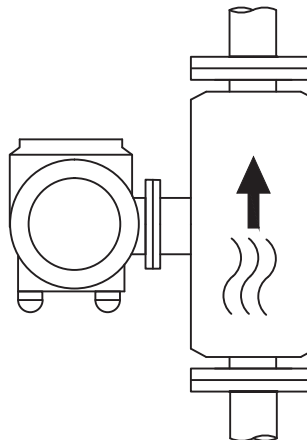
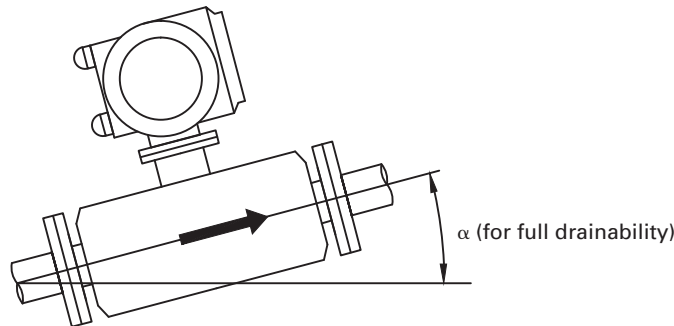


Fig. PI-4.1.4.4-1 Minimum Angle of Inclination, α 

information on how the flowmeter is to be installed to ensure effective drainability.

For flowmeters that are mounted in-plane with the process line, the information should include the minimum angle of inclination, α , and how to orient the flowmeter in that plane (refer to Fig. PI-4.1.4.4-1 for definition of angle of inclination, α). It is recommended that the information be provided in pictorial format.

The manufacturer's recommendation for installation and support of Coriolis flowmeters should be followed.

PI-4.1.4.5 Special Considerations for Passivation of Coriolis Flowmeters. Coriolis flowmeter materials of construction vary significantly between manufacturers. Certain passivation procedures may damage Coriolis flowmeter materials. If the Coriolis flowmeter is to be passivated, the complete passivation procedure should be provided by the owner/user to the manufacturer for review and approval.

If the owner/user and the manufacturer cannot agree on an acceptable passivation procedure, the owner/user shall remove the flowmeter during passivation.

PI-4.1.5 Performance. The Coriolis flowmeter performance varies depending on the parameter to which it applies (e.g., mass, volume, density, temperature, or viscosity).

Guidelines and common terminology for selection, installation, calibration, and operation of Coriolis flowmeters are identified in ASME MFC-11 and ISO 10790.

PI-4.1.5.1 Accuracy. For Coriolis flowmeters, the accuracy specification usually includes the combined effects of linearity, repeatability, hysteresis, and zero stability.

PI-4.1.5.2 Process Influences. Coriolis flowmeters deliver their best performance when completely filled with a uniformly distributed process fluid. Entrained gas should be eliminated or minimized. Multiphase applications involving nonhomogeneous mixtures can cause measurement errors. The use of filters, air and/or vapor eliminators, or other protective devices to reduce errors in measurement should be placed upstream from the Coriolis flowmeter.

PI-4.1.5.3 Ambient Influences. Large differences in the temperature between the measuring tube(s) and the ambient temperature can cause errors in the temperature compensation (e.g., CIP/SIP). The use of insulation materials can reduce these effects.

PI-4.1.6 Selection. The major consideration when selecting and sizing a Coriolis flowmeter is the trade-off between pressure drop and flowmeter performance (accuracy).

The necessary engineering data shall be supplied by the owner/user to ensure correct sizing of the Coriolis flowmeter. The manufacturer shall use this information to provide all necessary calculations for minimum and maximum velocities, accuracy, and pressure drop. This will optimize the flowmeter performance over the flow rate range with a pressure drop that is acceptable for both CIP/SIP and normal operating conditions.

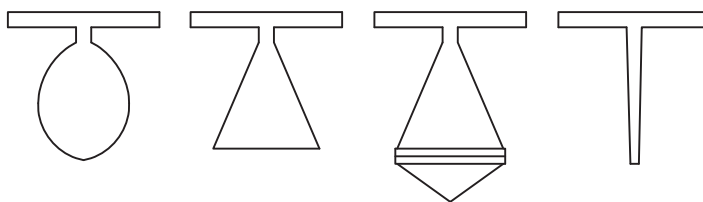
Chemical compatibility should be established between process-wetted materials [i.e., the flow tube(s), the manifold or flow splitter, the process connections] and the process fluid and the cleaning fluid (e.g., process, CIP, SIP, and passivation).

PI-4.1.7 Maintenance. There are no specific maintenance requirements for a Coriolis mass flowmeter.

PI-4.1.7.1 Seals/Gaskets. The manufacturer shall advise the owner/user if the process connections are not fully welded to the sensor body and if use of a seal/gasket assembly that requires periodic inspection is needed.

PI-4.1.7.2 Recalibration/Verification Schedule. A Coriolis flowmeter properly installed and operated within the manufacturer's guidelines on clean, noncorrosive, and nonabrasive fluids is stable. The frequency of recalibration or verification of the flowmeter is governed by the criticality of the measurement and the nature of the operating conditions. The frequency of calibration verification shall be determined by the owner/user.

As the Coriolis mass flowmeter is a mass flow device, it is preferable to perform the calibration verification against a mass traceable reference. Calibration against

Fig. PI-5.1.2.1-1 Bulb, Horn, Isolated Horn, and Rod-Style Antenna

a volume traceable reference combined with a density traceable reference may be used where applicable. Master flowmeters may be used to verify calibration of Coriolis flowmeters.

Calibration of the mass reference or a master flowmeter shall be traceable to nationally recognized standards or other standard as agreed to by the owner/user and manufacturer.

Calibration procedures can be found in ASME MFC-11.

PI-5 LEVEL INSTRUMENTS

PI-5.1 Radar Level Instruments

PI-5.1.1 General. Radar level instruments are also referred to as noncontact radar, free space radar, and through-air radar level instruments.

These instruments use high-frequency electromagnetic signals to measure the distance between the instrument and the upper surface of the targeted process fluid directly below the instrument.

These instruments should be configured for the specific combination of vessel and process fluid to ensure measurement performance.

PI-5.1.2 Essential Components. A radar level instrument is comprised of an antenna, a process connection, and supporting electronics.

The process contact components of a radar level instrument shall meet the surface requirements as specified in Part SF and material of construction requirements as specified in Part MM or Part PM. Requirements of process contact welds are specified in Part MJ.

PI-5.1.2.1 Antenna. The antenna of a radar level instrument is available in bulb, horn, or rod construction (see Fig. PI-5.1.2.1-1). The antenna is either isolated by or encapsulated in polymeric or other nonmetallic material.

PI-5.1.2.2 Process Connection. The radar level instruments and isolating seals shall use hygienic connections as per Parts SD, DT, and SG.

PI-5.1.3 Installation. The mounting location and orientation of the antenna should be in accordance with the manufacturer's recommendations. This is important

in order to achieve the specified performance, as well as to ensure cleanability.

PI-5.1.3.1 Drainability. To prevent any liquid holdup on the sensor's process contact surfaces, the radar level instrument should be mounted perpendicular to the surface of the process fluid.

PI-5.1.3.2 Cleanability. Cleanability is determined by the combination of antenna design and geometry and the location of the process connection. For effective cleanability, shadowing effects, recessed areas, and annular spaces created by the installed antenna should be taken into consideration.

PI-5.1.3.3 Mounting Location. The process connection should be located on top of the vessel. For the most accurate results, the mounting location should be selected to minimize or avoid obstructions within the space below the antenna.

To ensure a reliable level measurement, the mounting location should be $\frac{1}{3}$ to $\frac{2}{3}$ of the vessel radius, as measured from the vessel centerline (see Fig. PI-5.1.3.3-1).

The minimum detectable vessel level is given by the mounting location. To determine if the vessel is completely empty, the sensor should be pointed to the lowest section of the vessel.

PI-5.1.3.4 Orientation. The sensor should be mounted perpendicular to the surface of the process fluid.

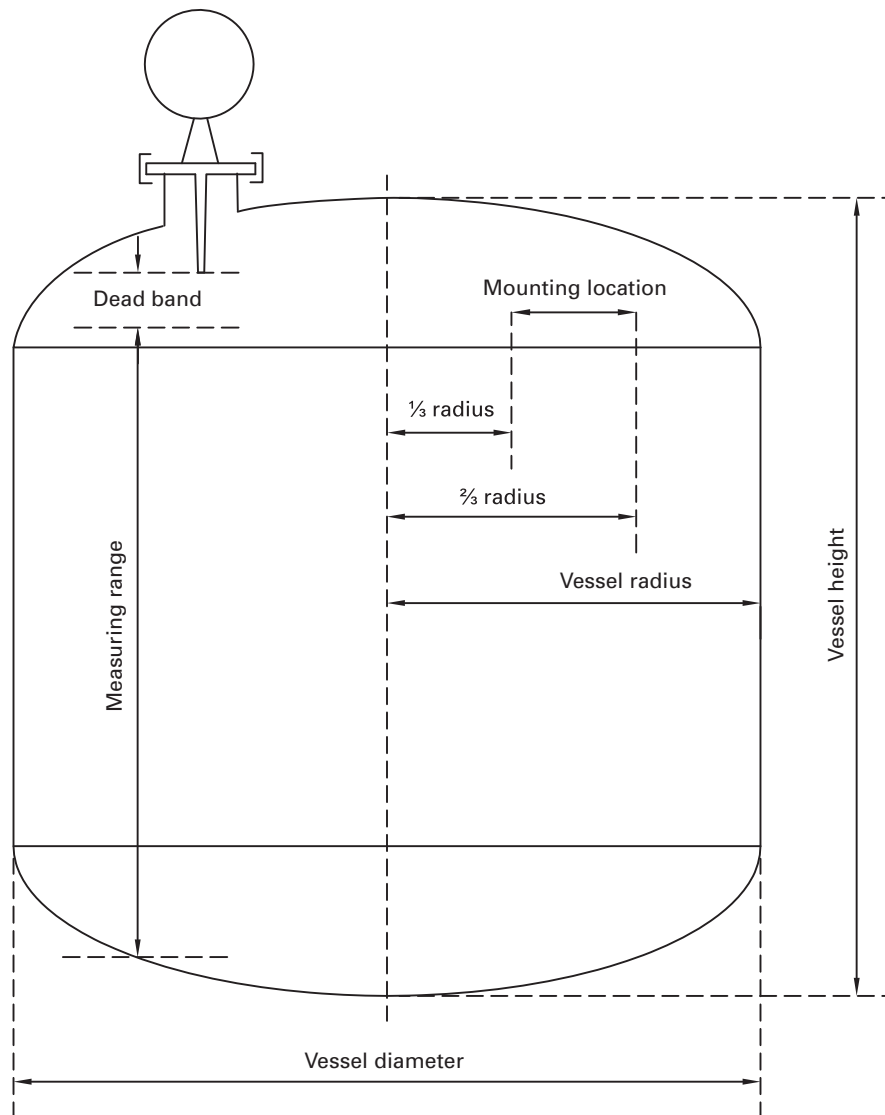
PI-5.1.3.5 Insertion Length/Depth. A vessel's maximum working level shall be below the insertion depth of the radar level instrument.

PI-5.1.3.6 Special Considerations. Each instrument has a specific minimum measuring distance (also referred to as blocking distance or dead band) (see Fig. PI-5.1.3.3-1) immediately in front of the antenna, in which measurements are not possible.

When radar level instruments are installed in nonmetallic vessels, the signal may detect objects outside the vessel. The owner/user should consult with the manufacturer for additional requirements.

The owner/user should consult the manufacturer regarding energy emitted by the radar level instrument to evaluate potential impact on the process fluid.

Fig. PI-5.1.3.3-1 Dead Band, Measuring Range, and Mounting Location



PI-5.1.4 Performance. Performance is determined primarily by the reflective properties of the process fluid, mounting location, and orientation within the vessel.

PI-5.1.4.1 Accuracy. The accuracy shall include the combined effects of linearity, repeatability, and hysteresis.

PI-5.1.4.2 Process Influences. The following process conditions may reduce the radar signal strength returned to the antenna, which may impact on the measuring performance:

- (a) a wavy or rippled surface
- (b) vortices in the process fluid
- (c) large changes of the reflective properties of the process fluid
- (d) foam, steam, or mist on top of the process fluid
- (e) buildup on the antenna

PI-5.1.4.3 Ambient Influences. Ambient influences do not affect the measuring performance if they are within the manufacturer's specifications.

PI-5.1.5 Selection. The main consideration when selecting a radar level instrument is the required performance for the specific application as described in PI-5.1.4.

PI-6 PRESSURE INSTRUMENTS

[Reserved for future content]

PI-7 TEMPERATURE SENSORS AND ASSOCIATED COMPONENTS

PI-7.1 General

This section presents requirements for commonly used temperature-sensing instruments. Additional information on temperature sensors and influences on sensor performance can be found in Nonmandatory Appendix P.

PI-7.2 Components

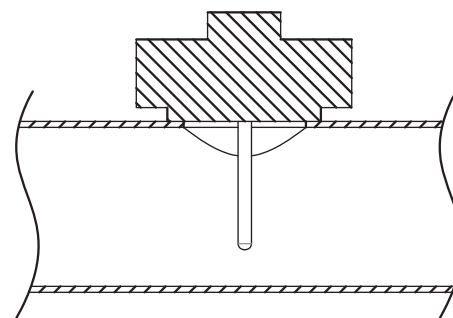
PI-7.2.1 Sensors. Temperature sensors addressed in this section include resistance temperature detectors (RTDs) and thermocouples. RTDs are the preferred sensing technology. Thermocouples are acceptable with owner/user approval.

PI-7.2.2 Thermowells. Thermowells are used to protect the sensor and enable calibration or replacement without stopping the process or breaching the system boundary. Common thermowell styles are straight thermowells and elbow thermowells.

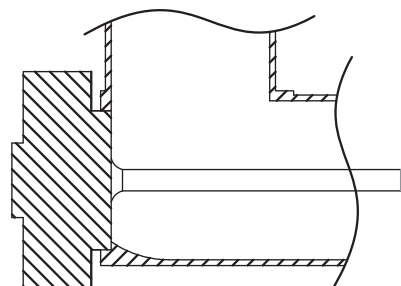
PI-7.3 Installation

Installation methods include tee style, elbow style, or nonintrusive (see Fig. PI-7.3-1). Tee- and elbow-style

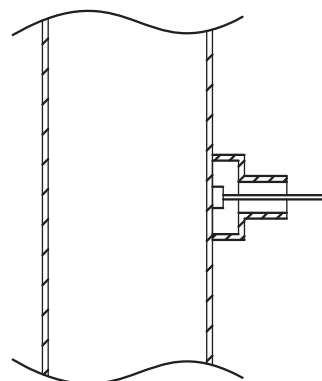
Fig. PI-7.3-1 Typical Installation Styles



(a) Direct or Indirect Insertion in Tee



(b) Direct or Indirect Insertion in an Elbow



(c) Nonintrusive

GENERAL NOTE: Shown with nonspecific hygienic connections.

installations can be direct insertion (sensor is in direct contact with the process fluid) or indirect insertion (sensor is isolated from the process by an installed thermowell). Nonintrusive sensors covered in this section are integral sensors with a section of process tubing. Clamp-on-style nonintrusive sensors are not addressed in this section.

(a) *Tee-Style Installations.* When tee-style installations are used for direct or indirect insertion, a hygienic process connection or weld end shall be used.

(b) *Elbow-Style Installations.* When elbow installations are used, the process connections shall be hygienic connections or weld ends. When using a direct insertion sensor in an elbow, the instrument connection shall be a hygienic connection.

(c) *Nonintrusive-Style Installations.* The process connections for nonintrusive sensors shall be hygienic connections or weld ends.

PI-7.3.1 Drainability. The installed sensor shall meet the drainability requirements of Part SD.

PI-7.3.2 Cleanability. The installed sensor shall meet the cleanability requirements of Part SD.

PI-7.3.3 Mounting Location. The sensor mounting location shall be specified by the owner/user to ensure the measurement meets the process system requirements. Locations near process influences per PI-7.4.3 and ambient influences per PI-7.4.4 should be avoided whenever possible as they can affect the accuracy of the measurement.

When selecting mounting locations in vessels, the minimum working volume of the vessel shall be considered. The inserted sensor shall not interfere with operations, such as filling and draining of the vessel. In vessels with agitators, consideration should be given to the effect of the sensor location on the mixing pattern.

PI-7.3.4 Orientation

(a) *All Insertion-Style Sensors.* The installation orientation shall ensure that the insertion length (see para. PI-7.3.5) is in contact with the process fluid under all operating conditions.

(b) *Elbow Thermowells.* For process systems with tubing size less than 2.5 in. (64 mm), the flow shall be toward the sensor tip [see Fig. PI-7.3.4-1, illustration (a)].

For systems with tubing size of 2.5 in. (64 mm) or greater, flow toward the sensor tip or perpendicular to the sensor is acceptable as long as the full insertion length is covered by the process fluid under all operating conditions [see Fig. PI-7.3.4-1, illustration (b)].

(c) *Nonintrusive Sensors.* Nonintrusive sensors shall be mounted such that the process fluid is always in contact with the instrument wall/tube where the sensing element is located. The preferred orientation is vertical, in a vertical section of the process tubing where the flow direction is upward. For alternate orientations, the

sensor manufacturer's installation recommendations shall be followed (see Fig. PI-7.3.4-2).

PI-7.3.5 Insertion Length/Depth

(a) *Insertion and Sensitive Lengths.* "Insertion length" is the length of the sensor or thermowell in contact with the process fluid. "Sensitive length" is the length of the measuring element, internal to the sensor.

NOTE: These terms are not applicable for nonintrusive-type sensors.

(b) *Tee Installations.* The insertion length should be 10 times the diameter of the sensor tip or thermowell tip, plus the element sensitive length (see Fig. PI-7.3.5-1).

Alternate insertion lengths are acceptable with proper consideration of the installation details and sensor design (consult the manufacturer) and with owner/user approval.

The minimum insertion shall locate the midpoint of the sensitive length at the centerline of the process tube.

The maximum insertion shall maintain a minimum of one sensor tip diameter or thermowell tip diameter spacing between the instrument tip and tube wall opposite the installation point.

(c) *Insertion Length in Elbow Thermowells.* The insertion length should be 10 times the diameter of the sensor tip or thermowell tip, plus the measuring element sensitive length (see Fig. PI-7.3.5-2). Alternate insertion lengths are acceptable with owner/user approval.

PI-7.3.6 Special Considerations

(16)

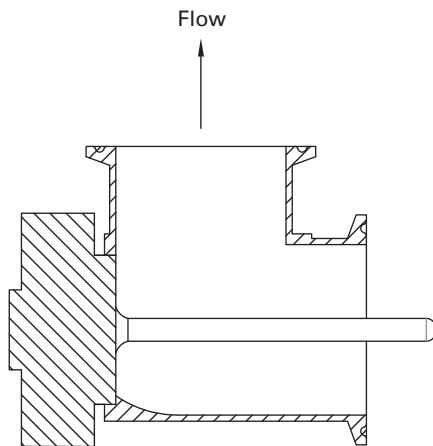
(a) Thermowells

(1) *Response Time.* When the temperature measurement response time (see PI-7.4.2) is critical to the process system operation, thermowells can be constructed using thin walls and smaller diameters. The owner/user shall consult with the sensor/thermowell manufacturer regarding design and material selection to ensure proper operation under the required system operating conditions.

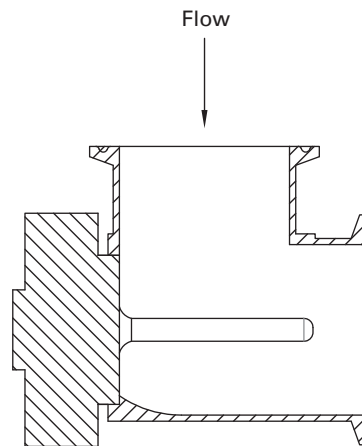
(2) *Measurement Accuracy.* Proper thermal contact between the sensor and thermowell is important to ensure measurement accuracy. The thermowell bore diameter should be designed to be 0.01 in. (0.25 mm) greater than the sensor diameter. A spring-loaded sensor design should be used to ensure sensor tip contact with the inside end of the thermowell. Use of thermally conductive compound between the outer sensor wall and internal surface of the thermowell and/or metal-to-metal contact is recommended. Consult with the sensor manufacturer regarding the application of thermal compound.

(b) *Nonintrusive Sensors.* Nonintrusive-style sensors will typically provide a slower response time than most insertion-style sensors.

Fig. PI-7.3.4-1 Accepted Elbow Orientations and Flow Directions



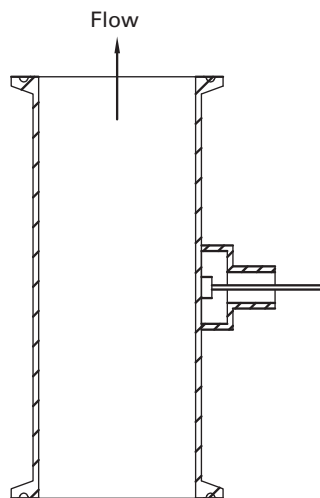
(a) For All Tube Sizes



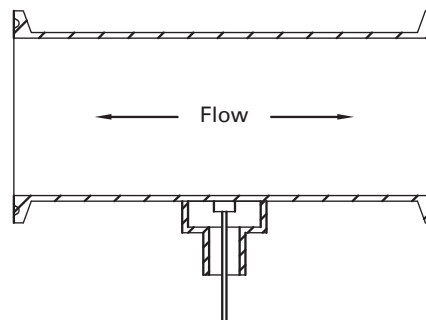
(b) For Tube Sizes 2.5 in. (64 mm) and Larger

GENERAL NOTE: Shown with nonspecific hygienic connections.

Fig. PI-7.3.4-2 Accepted Nonintrusive Orientations and Flow Directions

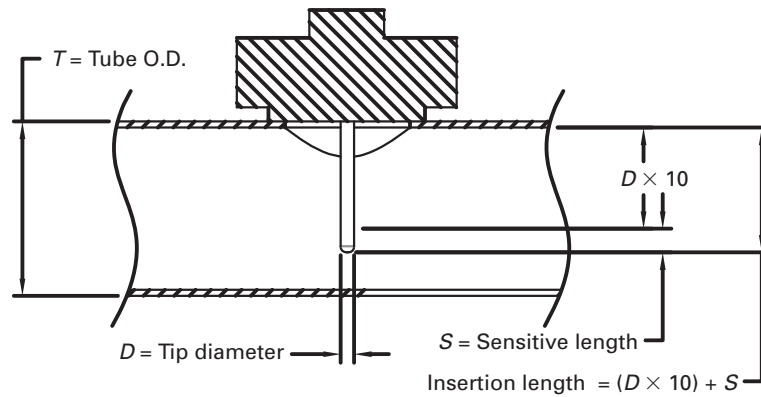
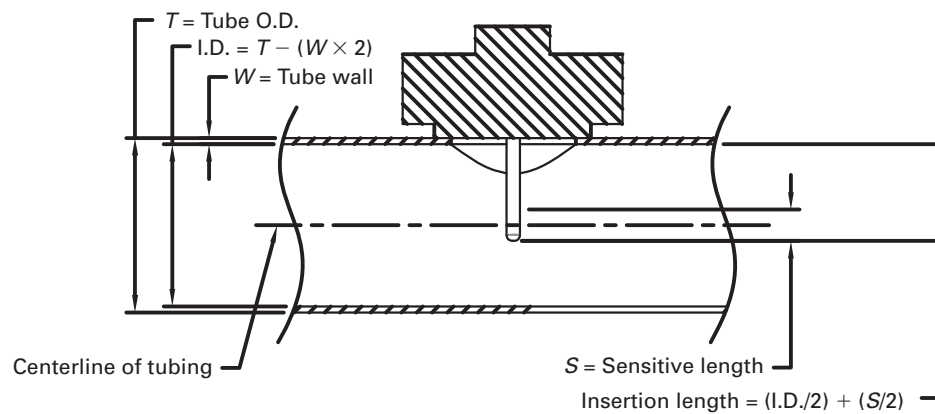
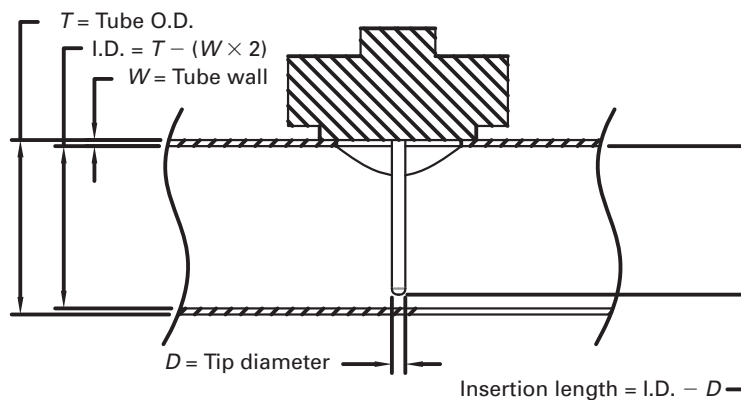


(a) Vertical Orientation With Flow Upward

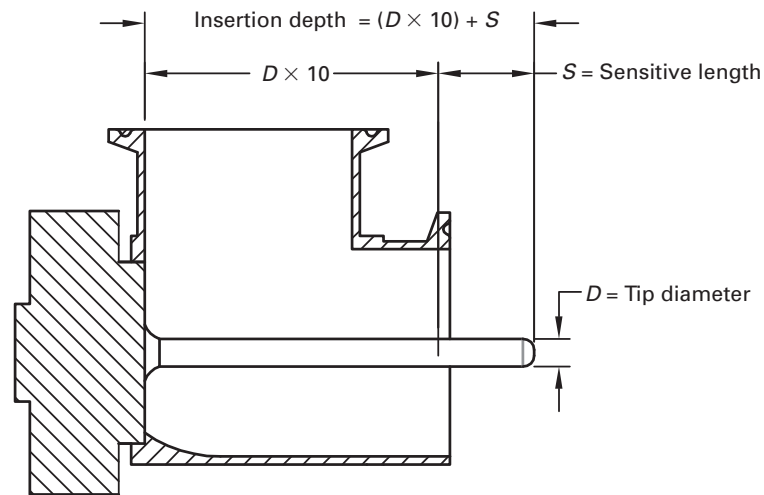
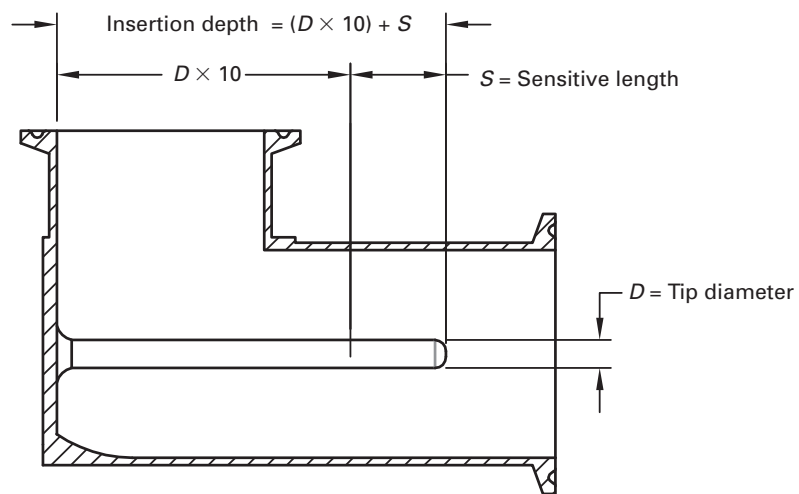


(b) Horizontal Orientation With Sensor Located on Bottom Side of Installation

GENERAL NOTE: Shown with nonspecific hygienic connections.

Fig. PI-7.3.5-1 Sensor Insertion Lengths for Tee Installations**(a) Optimum Insertion Length****(b) Minimum Insertion Length****(c) Maximum Insertion Length**

GENERAL NOTE: Shown with nonspecific hygienic connections.

Fig. PI-7.3.5-2 Sensor Insertion Lengths for Elbow Installations**(a) Direct Insertion Elbow****(b) Indirect Insertion Elbow Thermowell**

GENERAL NOTE: Shown with nonspecific hygienic connections.

PI-7.4 Performance

PI-7.4.1 Accuracy. The measurement accuracy will be influenced by the characteristics of the selected sensor, sensor insertion depth, ambient temperature, installation location, flow condition, and wiring.

(a) *Sensor Accuracy.* ASTM E1137 and IEC 60751 define the nominal resistance vs. temperature relationship and standard sensor interchangeability criteria for RTD-type sensors.

ASTM E230 defines the nominal millivolts vs. temperature relationship and accuracy for various thermocouple-type sensors.

(b) *Wiring and Cabling.* Sensor wiring lengths and configuration shall be considered when assessing measurement accuracy.

PI-7.4.2 Response Time. When temperature transients are important to monitor or control, the response time specification for the selected sensor (or sensor with a thermowell) shall be less than one-half the desired or anticipated process system response time.

PI-7.4.3 Process Influences. Entrained gas bubbles shall be minimized near the fluid temperature measurement location as gas can cause a delay in sensor response due to variations in thermal conductivity and/or instability in the temperature measurement.

PI-7.4.4 Ambient Influences. The insertion criteria should be followed to reduce the stem conduction effects caused by the temperature differences between the process and ambient area. When the recommended insertion length per PI-7.3.5 is not feasible, insulating the exterior portion of the sensing instrument is recommended.

Nonintrusive-style sensor accuracy can be affected by the temperature difference between the process and ambient area. Insulating the exterior portion of the sensor can reduce this effect.

PI-7.5 Selection

PI-7.5.1 Sensor Selection. Sensor type, materials, construction methods, and performance criteria (stability, repeatability, hysteresis, and self-heating) shall be considered when choosing a sensor.

(a) Insertion-style sensors are preferred as they provide the best measurement accuracy and responsiveness.

(b) Nonintrusive sensors are acceptable when insertion-type sensors are not feasible due to potential flow restrictions or small-diameter process tubing.

PI-7.5.2 Thermowell Selection. A thermowell shall be used for insertion-type temperature sensors that require sensor removal without breaching the process system boundary.

(a) Thermowells installed within the process system boundary shall be fabricated with hygienic connections or be welded to the process tubing.

(b) ASME PTC 19.3 TW, where applicable, shall be considered to ensure sufficient thermowell strength under all process conditions.

(c) Thermowell design and style (straight or elbow type) shall be specified based on line size, process conditions, and installation location. Elbow thermowells are preferred for line sizes that are 0.5 in. (13 mm) in diameter or less. Straight thermowells are acceptable when the insertion length criteria can be achieved.

(d) Thermowell installations may cause a pressure drop, which shall be considered in the system design.

PI-7.6 Sensor Calibration Verification

(16)

Calibration methods for temperature sensors are described in ASTM E644 and ASTM E220.

PI-8 ANALYTICAL INSTRUMENTS

PI-8.1 Conductivity

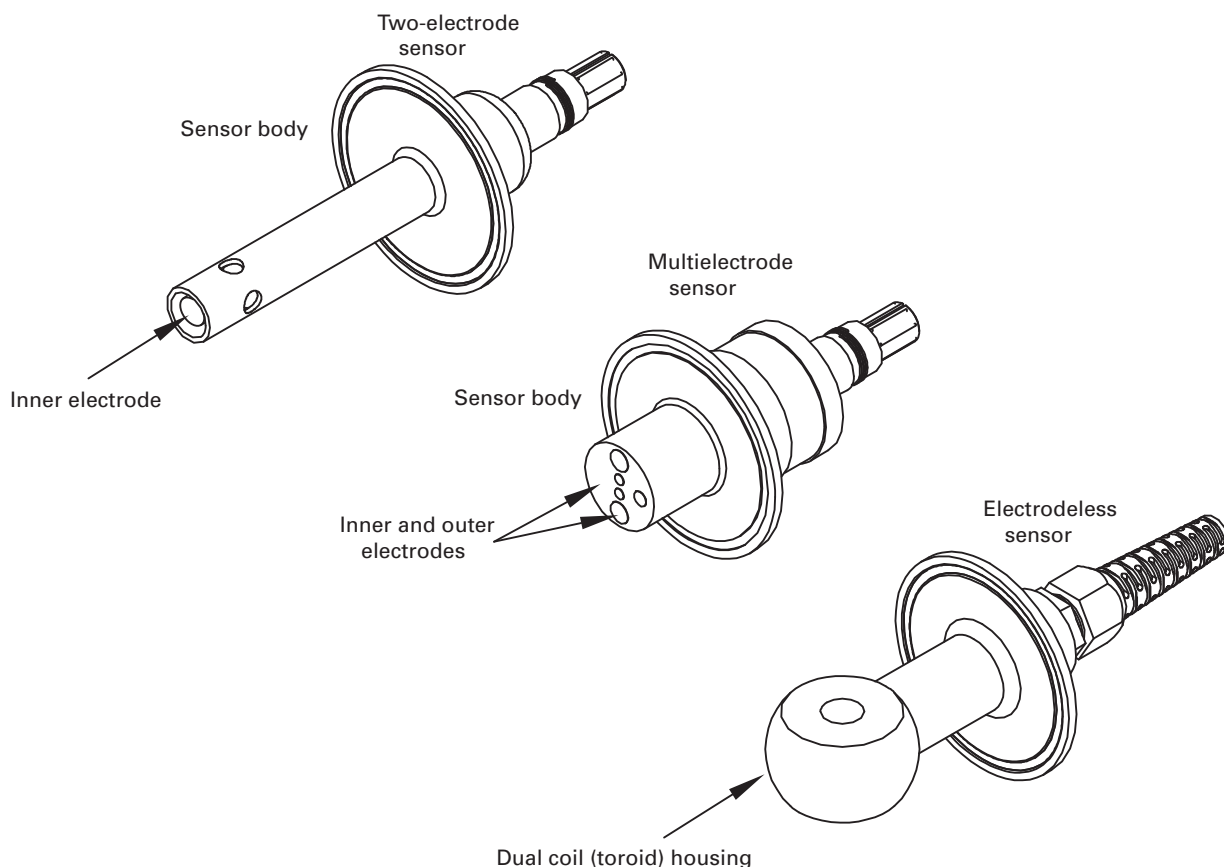
PI-8.1.1 General. Conductivity measurements are used to determine the level of ionic activity within an aqueous media. They are used in hygienic applications for in-line monitoring of process and water systems. Compensated water, in part, requires conductivity measurements of water for injection (WFI) and purified water (PW) as an integral component of validated systems.

There are three basic types of conductivity sensors designed for specific measurement ranges: two-electrode, multielectrode, and electrodeless. Sensor-type selection is dependent on intended measurement and installation requirements. The owner/user should consult the manufacturer for final selection suitability based on the design criteria and may use PI-8.1.5 as a general reference.

Temperature impacts conductivity measurements by increasing conductivity as temperature increases. All conductivity sensors shall use either an internal or external temperature sensor for compensation to express the conductivity of the solution at a standard temperature.

PI-8.1.2 Essential Components. An electrode-type sensor has wetted electrodes, between which an AC voltage is applied and the amperage measured is expressed as conductivity (see Fig. PI-8.1.2-1).

An electrodeless sensor consists of a nonconductive body material encapsulating two nonwetted coils/toroids. Measurements are made of the induced current from the powered coil to the measurement coil by having the process fluid pass through the center and around the outside of the nonwetted coils (see Fig. PI-8.1.2-1).

Fig. PI-8.1.2-1 Conductivity-Type Examples

PI-8.1.2.1 Sensor Types. There are three typical designs of conductivity sensors.

(a) *Two-Electrode.* A two-electrode-type conductivity sensor generally consists of an outer shaft/body and inner electrode. Conductivity measurements are made in this interstitial space and require this area to be fully wetted.

(b) *Multielectrode.* A multielectrode-type conductivity sensor consists of a wetted body with inner and outer electrodes generally arranged on the same plane. Conductivity measurements are made immediately in front of and in between the electrodes and require this area to be fully wetted. A nonconductive material of construction is required between the electrodes with the sensor body generally used as the insulator.

(c) *Electrodeless.* An electrodeless-type conductivity sensor consists of two encapsulated coils. One coil generates a current and the second coil detects changes proportionate to the conductivity of the process fluid. An electrodeless sensor requires process fluid through and around the coils for proper measurements.

PI-8.1.3 Installation. All conductivity sensors require full immersion of their measurement electrodes or coils into the process fluid for proper functionality.

Most conductivity sensors are offered as insertion devices, with some manufacturers offering in-line options.

Electrode conductivity sensors should be installed with flow into the sensor while maintaining drainability. Figure PI-8.1.3-1 provides examples of acceptable installations.

PI-8.1.3.1 Drainability. Conductivity sensors shall be installed in accordance with Part SD to ensure drainability.

PI-8.1.3.2 Cleanability. Conductivity sensors shall be cleanable as required in Part SD.

PI-8.1.3.3 Mounting Location. Insertion electrode sensors perform best with process fluid flow into the sensor's electrode(s) as shown in Fig. PI-8.1.3-1.

Electrodeless sensors shall be mounted with coils fully immersed in the process.

In-line installations shall ensure continuous process fluid flow around sensor electrodes or coils to maximize measurement accuracy.

PI-8.1.3.4 Orientation. Conductivity sensors shall be oriented to ensure electrodes or coils are fully wetted.

Fig. PI-8.1.3-1 Accepted Installations for Conductivity Sensors

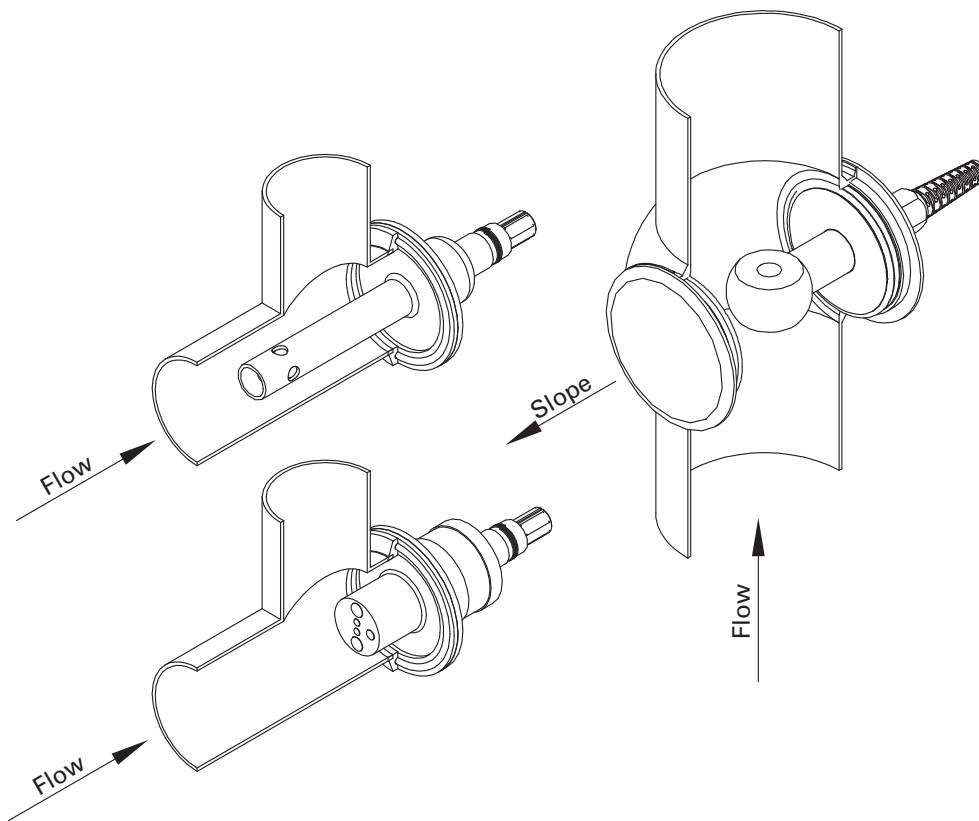
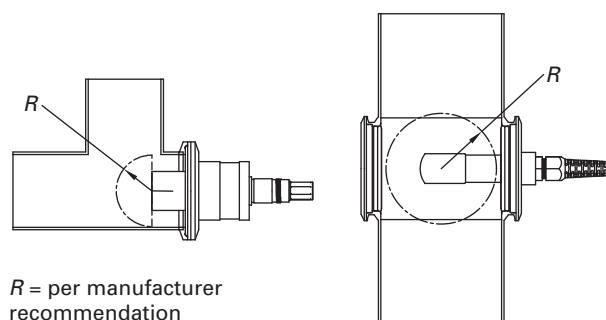


Fig. PI-8.1.3.6-1 Installation Clearance Requirements

Horizontal installations should not be top-mounted insertions to avoid air pockets or bubbles interfering with the measurement.

PI-8.1.3.5 Immersion Length/Depth. The owner/user shall follow the manufacturer's recommendations regarding immersion length/depth to allow for sufficient clearance of electrodes or coil fields.

PI-8.1.3.6 Special Consideration. Sensor electrodes mounted too close to tube or vessel walls may cause conductivity field distortions resulting in measurement inaccuracies. The owner/user shall consult the manufacturer's clearance requirements and recommendations (see Fig. PI-8.1.3.6-1).

Conductivity sensors for purified water of WFI systems shall be installed in such a manner as to allow periodic calibration in accordance with compendial water requirements.

PI-8.1.4 Performance. Conductivity devices are generally required to be full of process liquid and free of air pockets. Consult the manufacturer for details.

PI-8.1.4.1 Accuracy. Compendial water guidelines establish a standard for the quality assessment of water based on measurements of the electrolytic conductivity. Sensors used for WFI or PW systems shall comply with this accuracy requirement.

PI-8.1.4.2 Response Time. Conductivity sensor response times are impacted predominately by the response time of the temperature-sensing element. All sensor types are responsive to changing conductivity levels without changes in temperature. Electrodeless sensors are slower to respond in processes with changing temperatures due to the nonconductive nature of the coils' encapsulating material.

PI-8.1.4.3 Process Influences. Temperature changes impact conductivity measurements of a process fluid. All conductivity sensors shall use either an internal or external temperature sensor for compensation as required.

PI-8.1.4.4 Ambient Influences. Not applicable.

PI-8.1.5 Selection. Sensor selection shall be based on the anticipated conductivity range of the process. The following may be used as a general selection reference:

(a) Two-electrode sensors should be selected for WFI systems, PW systems, or other process fluids that have low conductivity ranges. These sensors are most suitable for systems from 0.02 $\mu\text{S}/\text{cm}$ to 10 000 $\mu\text{S}/\text{cm}$.

(b) Multielectrode (more than two) sensors should be selected for process fluids that have medium to high conductivities, such as those found on CIP or chromatography systems. These sensors are most suitable for systems ranging from 0.01 $\mu\text{S}/\text{cm}$ to 800 $\mu\text{S}/\text{cm}$.

(c) Electrodeless (inductive or toroidal) sensors should be selected for process fluids that have the highest conductivity. These sensors are most suitable for systems ranging from 0.1 mS/cm to 2 000 mS/cm.

PI-8.1.6 Maintenance

PI-8.1.6.1 Calibration/Verification Schedule. Sensors used in WFI or PW systems shall be calibrated in accordance with compendial water requirements.

PI-8.2 pH — Glass Measuring Electrode

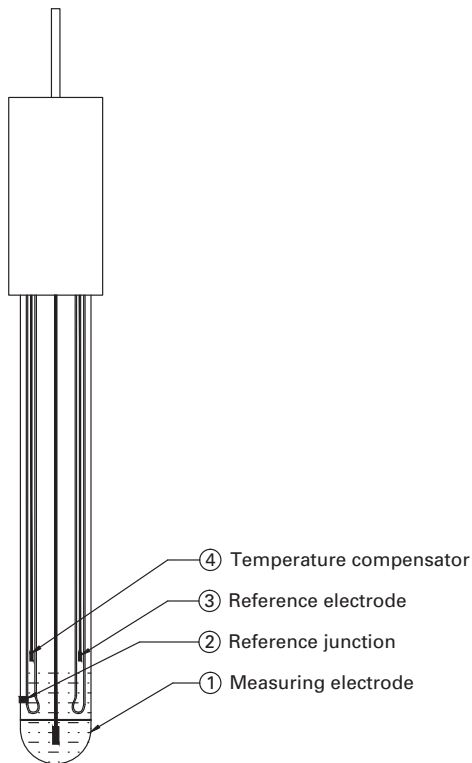
PI-8.2.1 General. This section provides the requirements for installation and operation of ion-selective pH sensors specific to bioprocessing and pharmaceutical industries as well as other applications with hygienic requirements.

The design, construction, and fabrication of pH sensors are governed by other parts of this Standard.

PI-8.2.2 Components. Commonly used pH sensor technologies incorporate four major components

- (a) an ion-selective electrode (measuring electrode)
- (b) an electrolyte-filled reference electrode
- (c) a liquid interface (reference junction)
- (d) an internal or external temperature sensor (temperature compensator)

Typical pH sensor construction combines all four of these components into one body, referred to as a combination pH sensor (see Fig. PI-8.2.2-1).

Fig. PI-8.2.2-1 pH Sensor Components

Other components that compose a complete sensor assembly may include elastomeric seals and gaskets, polymeric- and/or metallic-based components, holders, and hygienic clamp connections.

PI-8.2.3 Installation. All pH sensors require insertion of the measuring electrode and reference junction into the process fluid for proper functionality. Most pH sensors are offered as insertion devices. Figure PI-8.2.3-1 provides examples of acceptable installations. The owner/user should consult with the sensor manufacturer to determine other installation options.

PI-8.2.3.1 Drainability. When installed, pH sensor assemblies shall be drainable in accordance with Part SD.

PI-8.2.3.2 Cleanability. The owner/user should consult with the sensor manufacturer regarding suitability of the sensor for the intended use and sterilization/sanitization methods.

PI-8.2.3.3 Mounting Location. Sensor mounting location affects sensor performance. The following process-specific issues should be considered when specifying the location and use of a pH sensor:

(a) The point of addition of acid and/or base to the process solution should be considered when locating a pH sensor. Sufficient distance and/or time is required to ensure complete liquid mixing and reaction.

(b) Locating sensors in areas prone to flashing, cavitation, or siphoning or where the sensor may not be in constant contact with liquid should be avoided.

(c) Maintenance of pH sensors should be considered when selecting sensor location.

The owner/user should consult with the sensor manufacturer for mounting recommendations.

PI-8.2.3.4 Orientation. pH sensors should be installed in horizontal tubing, up-flow tubing, appropriately designed flow cells, and vessels. Most pH sensor technologies exhibit optimal performance when installed at 15 deg or more from the horizontal (see Fig. PI-8.2.3.4-1).

pH sensors can be sensitive to flow profile. Orientation should be kept consistent in order to produce repeatable results.

The owner/user should follow the sensor manufacturer's installation orientation recommendations for optimal measurement reliability.

PI-8.2.3.5 Insertion Length/Depth. The sensor shall be inserted far enough into the tube or vessel so that the sensor measuring electrode and reference junction are always in contact with the process fluid. Unprotected sensor exposure should be limited to help prevent inadvertent breakage. Maximum recommended insertion of an unprotected sensor from the holder is less than or equal to 0.25 in. (6.3 mm) as measured from the reference junction (see Fig. PI-8.2.3.5-1).

The owner/user should consult with the sensor manufacturer for appropriate sensor design and sensor holder selection.

PI-8.2.3.6 Special Considerations. The measuring electrode and reference junction should be kept wet at all times whether in service or in storage. Extended periods without liquid contact will permanently affect sensor performance.

pH sensors are consumable devices and require periodic replacement. The owner/user should consider sensor accessibility during installation planning.

The owner/user should consult with the sensor manufacturer for specific storage, handling, and rewetting recommendations.

PI-8.2.4 Performance. pH sensor performance will degrade over time. The rate of degradation is application, maintenance, and installation dependent. Critical factors that affect performance and the frequency of replacement are

(a) changes in span and response (measuring electrode function)

(b) changes in offset and stability (reference electrode function)

(c) temperature compensator response

(d) installation (insertion length, location, and orientation)

Fig. PI-8.2.3-1 Accepted pH Sensor Installations

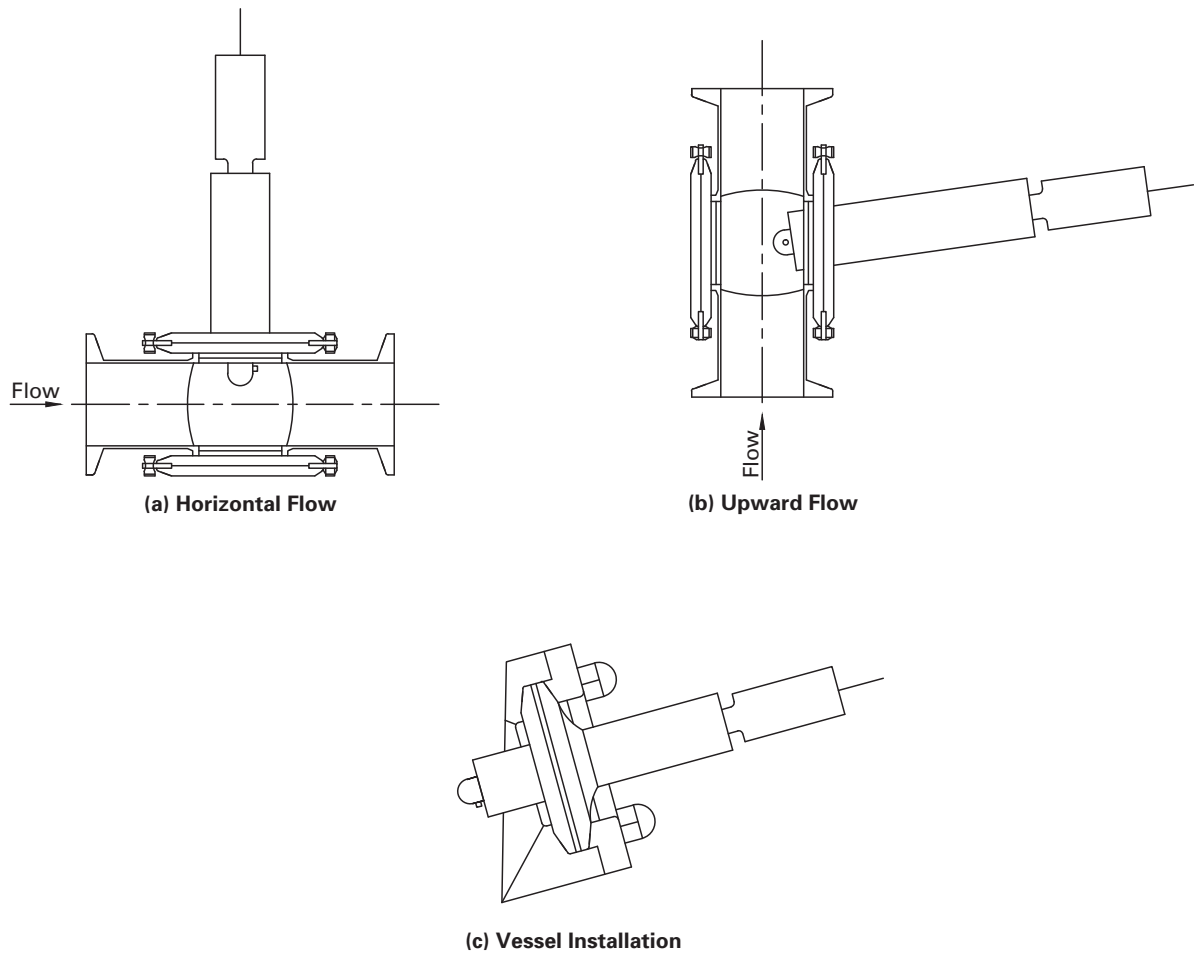
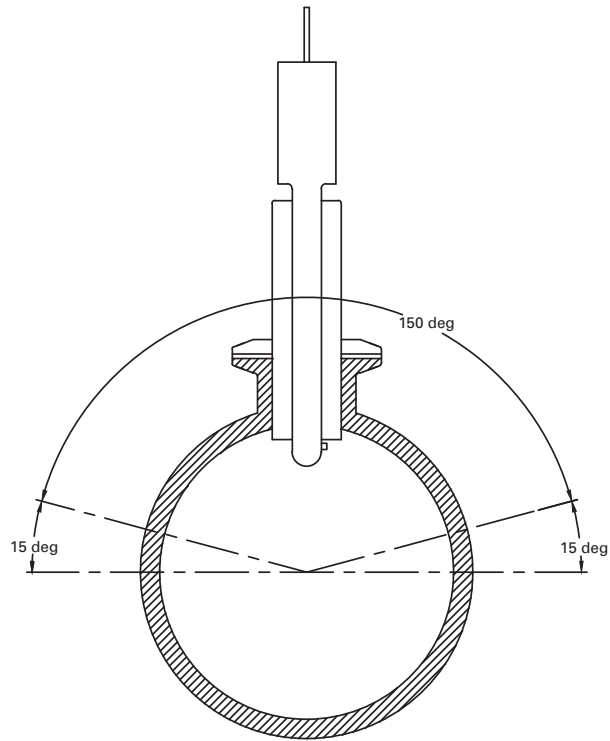
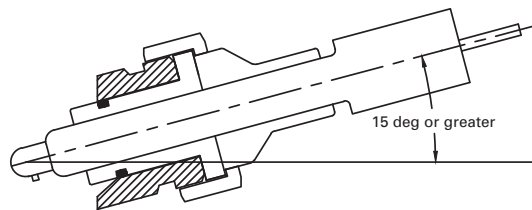


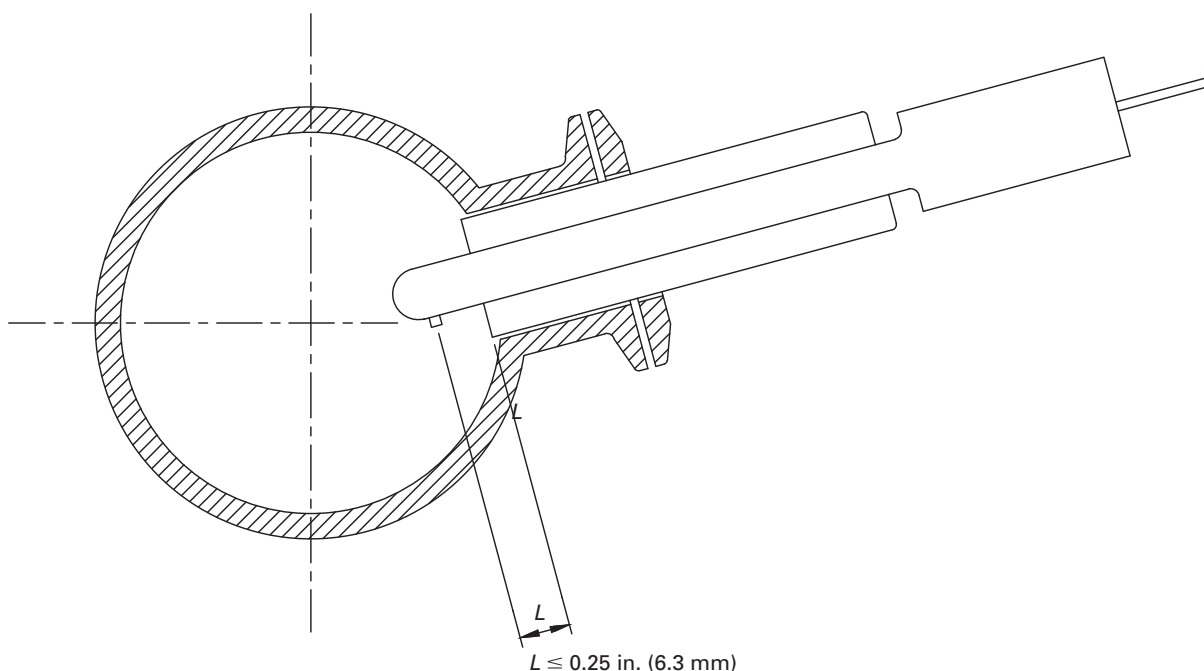
Fig. PI-8.2.3.4-1 Accepted Mounting Orientations



(a) Horizontal Flow Orientation



(b) Upward Flow or Vessel Orientation

Fig. PI-8.2.3.5-1 Insertion Length or Depth

(e) maintenance schedules and methods
 (f) postmaintenance sensor recovery time
 pH sensors are sensitive to coating and/or plugging of the measuring electrode and reference junction. After cleaning, sensors should be calibrated.

The owner/user should contact the sensor manufacturer for recommendations based on documented owner/user performance requirements.

PI-8.2.4.1 Accuracy. Published pH sensor accuracy can be affected by calibration (standardization) methods, maintenance procedures and frequencies, cleaning methods, process conditions, sensor design, installation, and sensor age and condition, as well as the ambient conditions.

PI-8.2.4.2 Response Time. pH sensor response time is affected by sensor design, sensor age and condition, and process temperature. As a sensor ages or process fluid temperature decreases, sensor response time will become slower.

PI-8.2.4.3 Process Influences. pH sensors are sensitive to process influences that include, but are not limited to, process fluid velocity, process fluid temperature, high pH, and high ionic strength.

Process fluid velocity in excess of 8 ft/sec (2.4 m/s) can cause excessive signal noise and physical damage.

As process fluid temperature increases, response time becomes faster but sensor life may be adversely affected.

High pH (over 12 pH) will tend to decrease sensor life.

High ionic strength chemicals such as those used in CIP systems can decrease sensor life.

The owner/user should discuss process conditions with the sensor manufacturer to minimize potentially negative process influences.

PI-8.2.4.4 Ambient Influences. pH sensors, in combination with other loop components (electronics and cables), can be affected by electrical noise, electromagnetic/radio-frequency interference (EMI/RFI), ground loops, close coupling of sensors with other instruments or equipment, and external washdown environments.

The owner/user should consult with the sensor manufacturer to match the complete loop with ambient conditions.

PI-8.2.5 Selection. The owner/user should consult with the manufacturer to determine sensor applicability and loop component (mounting hardware, cable, and electronics) compatibility.

PI-8.2.6 Maintenance. Maintenance schedules and methods shall be established by the owner/user based on owner/user historical experience and sensor manufacturer recommendations.

PI-8.2.6.1 Calibration/Verification Schedule. pH sensors should be calibrated using multipoint and/or single-point methods.

A multipoint calibration adjusts both the sensor span (measuring electrode) and sensor offset (reference electrode). A single-point calibration, often referred to as standardization, only adjusts the sensor offset.

pH sensor span, offset, response time, and stability can be affected by coating and/or plugging of the measuring

electrode and reference junction. Operators should perform a calibration or standardization after each cleaning or sterilization cycle.

The owner/user should consult with the sensor manufacturer to establish procedures based on sensor design, owner/user expectations, instrument historical performance, and process design.

PI-9 OPTICAL

PI-9.1 Optical Devices

- (16) **PI-9.1.1 General.** Optical devices are used to measure various process characteristics parameters including color, turbidity, concentration, percent suspended solids, optical density, particle and cell size/shape, cell density, and cell viability. Applications include filtration, chromatography, cell culture fermentation, and water systems.

PI-9.1.2 Components

- (16) **PI-9.1.2.1 Light Source(s).** Optical devices include a light source(s) such as visible (VIS), ultraviolet (UV), near infrared (NIR), or infrared (IR), which is transmitted into the process fluid.
- (16) **PI-9.1.2.2 Sensor.** Sensor types include photo detectors, photomultipliers, and CCD (charge-coupled device) imaging chips. The system can involve various optical components to focus, filter, and enhance the light beam either one-dimensionally or multidimensionally.
- (16) **PI-9.1.2.3 Sight Glass.** Sight glasses are one of the key components of an optical device. Process fluid-contacting components of the sight glass assembly shall comply with Parts MM and PM.
- (a) When glass is used as a sight glass for viewing (viewport), a glass fused to metal hermetic compression seal shall be used. 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. Bubbles shall not be present on the glass surface.
- (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 defects such as crevices and pits.
- (d) Cracked glass shall not be used.
- (e) Sight glasses shall be marked with the glass type, maximum pressure, and temperature rating as per Part DT.
- (f) Typical sight glass mountings are shown in Fig. SD-3.4.6-1.

- (16) **PI-9.1.3 Installation.** The measuring probe should be installed past the boundary layer. Seals used for installation of viewport sight glass shall meet the requirements of Part SG.

PI-9.1.3.1 Drainability. Optical devices shall be installed in accordance with Part SD to ensure drainability. (16)

PI-9.1.3.2 Cleanability. Process fluid-contacting surfaces of optical devices shall be cleanable as required per Part SD. (16)

PI-9.1.3.3 Mounting Location. Optical devices shall be mounted in a pipe or vessel where a representative measurement can be made.

A light or combined light and sight glass for viewing shall be mounted as shown in Fig. PI-9.1.3.3-1.

PI-9.1.3.4 Orientation. The preferred mounting of in-line optical devices is in the vertical section of tubing to avoid particle segregation. The probe should be in constant contact with the process fluid.

PI-9.1.3.5 Insertion Length. For tube diameters less than 1 in. (25 mm), experimental test data should be used to assess performance. (16)

For in-line installation of tube diameters ranging from 1 in. (25 mm) to 4 in. (100 mm), optical probes should be mounted a minimum ($L_{\min}$) of 0.3 in. (8 mm) away from any interior tube wall (reference Fig. PI-9.1.3.5-1).

For vessels and tubing in excess of 4 in. (100 mm) diameter, optical probes should be mounted where the glass measurement surface is a minimum ($L_{\min}$) of 1.5 in. (38 mm) from any interior tube wall (reference Fig. PI-9.1.3.5-2).

PI-9.1.3.6 Special Considerations. Special care should be taken for process fluids that are adversely impacted by temperature to avoid high temperatures on the process side of the sight glass or optical window caused by the optical devices. Testing of the optical device at the maximum operating wattage of the probe or probes should not result in still water within 0.5 in. (13 mm) of the probe rising more than 2°F (1°C) in 1 hr. (16)

For light sources used for viewing only, a thermal switch, timer, momentary switch, IR filter, or some other suitable means should be considered to control overheating.

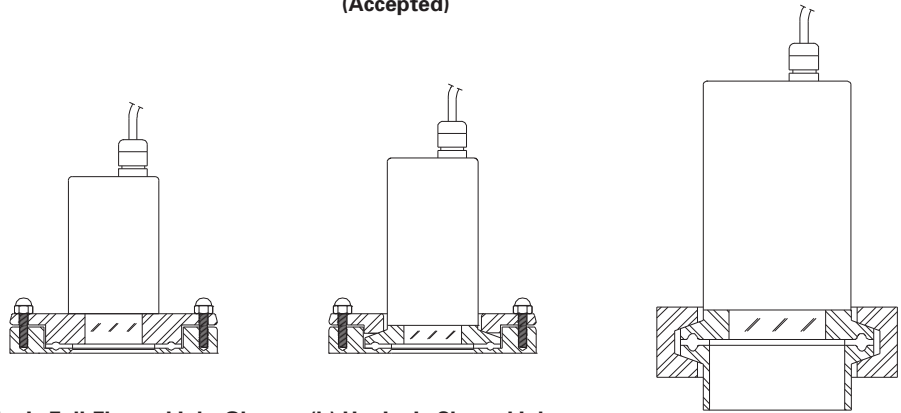
PI-9.1.4 Performance. In-line optical devices generally require the tube to be full of liquid and free of excess air pockets. Certain optical devices can tolerate the presence of some air bubbles. The owner/user should consult with the optical device manufacturer for guidance.

PI-9.1.4.1 Accuracy. Optical devices are inherently accurate and repeatable but dependent on device-specific calibration. (16)

PI-9.1.4.2 Response Time. Optical sensing elements provide instantaneous readings with no delays due to process conditions such as temperature or flow. The owner/user should consult the manufacturer if a specific response time is required. (16)

Fig. PI-9.1.3.3-1 Vessel Light Glass Design and Mounting

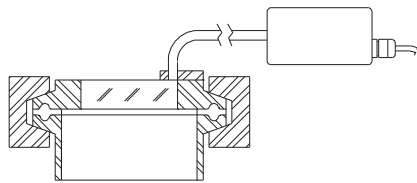
(Accepted)



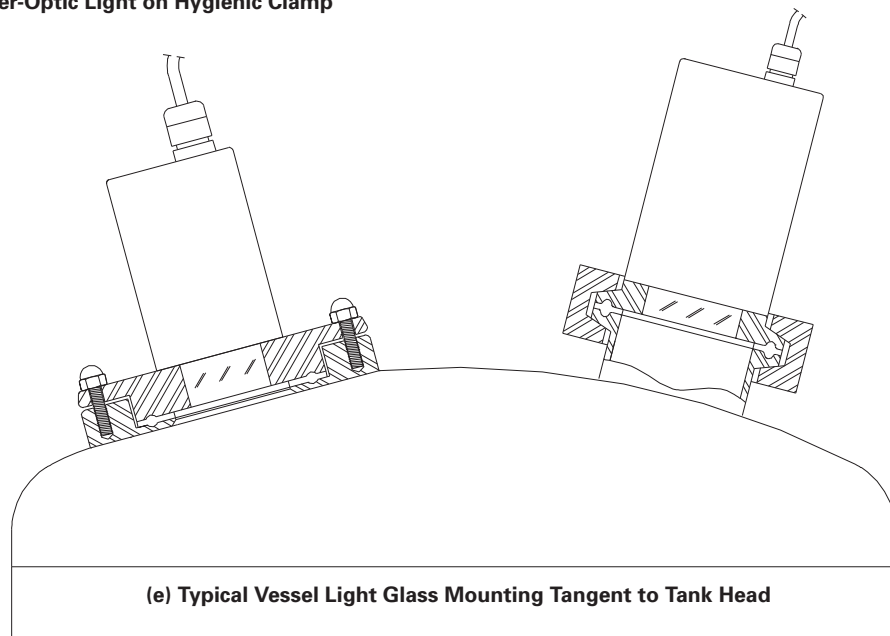
(a) Hygienic Full-Flange Light Glass on Hygienic Clamp Pad

(b) Hygienic Clamp Light on Hygienic Clamp Pad

(c) Hygienic Clamp Light



(d) Fiber-Optic Light on Hygienic Clamp



(e) Typical Vessel Light Glass Mounting Tangent to Tank Head

Fig. PI-9.1.3.5-1 In-Line Insertion Length

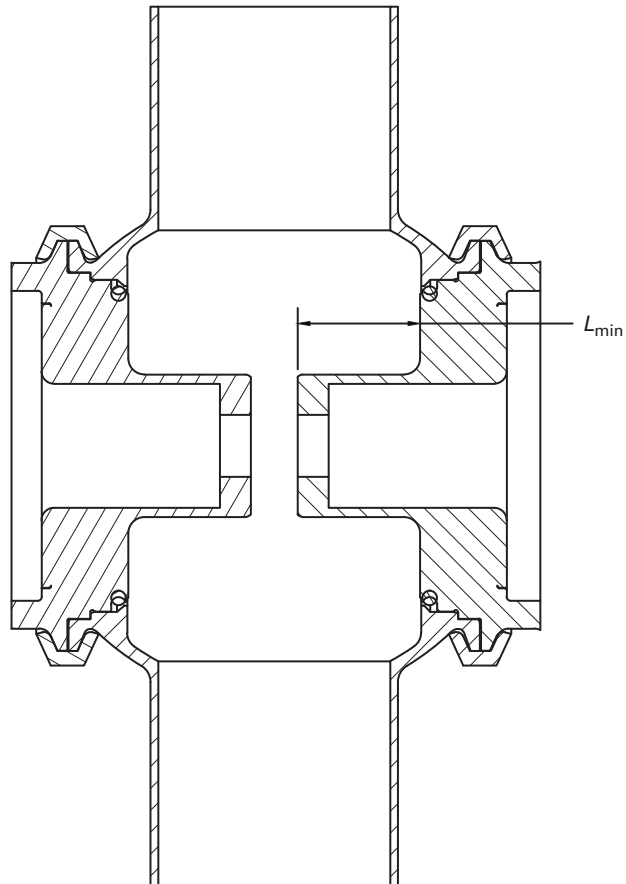
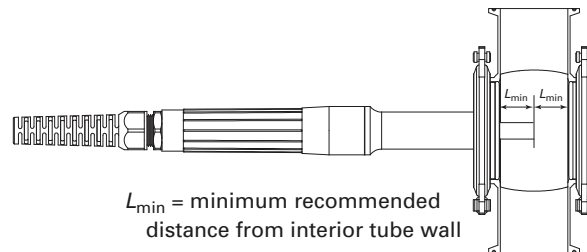


Fig. PI-9.1.3.5-2 Insertion Probe Length



PI-9.1.4.3 Process Influences. Velocity and particulate content in the process fluid may impact the cleaning frequency requirement of the optical device.

- (16) **PI-9.1.4.4 Ambient Influences.** Some optical sensing electronics have limited process and ambient temperature ranges. The owner/user should consult the manufacturer to ensure the selection is compatible with the temperature conditions.

PI-9.1.5 Selection. Optical device sensing technologies vary based on the intended application and suitable measurement ranges. The owner/user shall determine the desired measurement range and unit of measurement before selecting the optical device and associated technology. (16)

Part SG

Sealing Components

SG-1 PURPOSE AND SCOPE

The purpose of this Part is to provide the requirements for the sealing components of seals, valves, and fittings used in the bioprocessing industry. These sealing components create or maintain process boundaries between system components and/or subassemblies to ensure process system integrity. This Part defines the design of seals, valves, and fittings. This Part also enables equipment manufacturers, system designers, and owners/users to specify the required seal, valve, and fitting type and performance for specific applications. It is not the intent of this Part to inhibit the development or use of new technologies.

SG-2 SEALING COMPONENT TYPES

SG-2.1 General

Sealing components used in bioprocessing equipment take a variety of forms based on their function within the system and the process boundaries to the atmosphere and other systems, which they must maintain. The following sections define the main types of sealing components and their acceptability for use in the bioprocessing industry. For this section, seals are divided into static and dynamic seals. All acceptable seals shall meet the design criteria, materials, and performance characteristics contained in this Standard.

SG-2.2 Static Seals

SG-2.2.1 General. A static seal is characterized by the absence of relative motion between sealing surfaces, or between the sealing surface and a mating surface, after initial installation. Small amounts of movement that might be caused by thermal expansion, vibration, bolt stretch, or seal response to fluid pressure do not alter the static definition.

SG-2.2.2 Hygienic Unions. Hygienic unions provide connections between process components (e.g., pipe fittings, tank fittings, instruments, and hoses) to ensure the process integrity is maintained. They include seals between two ferrules.

The geometry of the most common hygienic union is governed by Table DT-7-1 and is shown in Figs. SG-2.2.2-1 and SG-2.2.2-2. Other geometries for the opposing ferrules are also used in the industry and are controlled by relevant industry standards [e.g., ISO 2852,

DIN 11864 (-1, -2, -3, O-rings)]. (See Figs. SG-2.2.2-3 and SG-2.2.2-4.)

Other hygienic unions and cross-sectional geometries shall meet all of the requirements of this Standard, except for the ferrule dimensions.

Nonhygienic connections shown in Fig. SG-2.2.2-5 are not recommended (e.g., threaded fittings exposed to process fluid).

SG-2.2.3 O-Ring Seals. An O-ring is a ring seal with a circular cross section (a toroid), designed to be seated in a groove and compressed during assembly. O-rings are most often used as static seals. These are used extensively in hygienic applications and can seal both radially and axially opposed faces. Common static O-ring applications include sealing fasteners, shaft couplings, and pump and filtration components.

Other ring seal geometries of varying cross sections (e.g., manway gaskets) may be used in hygienic applications. However, significant differences may exist in their performance (e.g., pressure and cleanability), and they should be evaluated accordingly.

Examples of O-ring industry standards include SAE AS568, Aerospace Size Standard for O-Rings, and ISO 3601, Fluid Power Systems — O-Rings.

For use in bioprocessing applications, O-rings and their mating surfaces shall meet the requirements of this Standard.

SG-2.2.4 Other Static Seals. Other static seals used in bioprocessing applications shall meet the requirements of this Standard (e.g., flat gaskets, L-cups, U-cups, stoppers, septums, and bioseals).

Inflatable static seals are static seals where gas is supplied to the inner part of the seal, providing a pillow barrier between the process and the atmosphere. They are commonly used in large process components, and in connections, to support structures.

SG-2.3 Dynamic Seals

A dynamic seal is characterized by the movement of the seal surface and a mating surface after initial installation.

SG-2.3.1 Valves

SG-2.3.1.1 General. Valves are process components that provide dynamic seals within the process. They also provide seals between the process and the atmosphere.

Fig. SG-2.2.2-1 Hygienic Union per Table DT-7-1

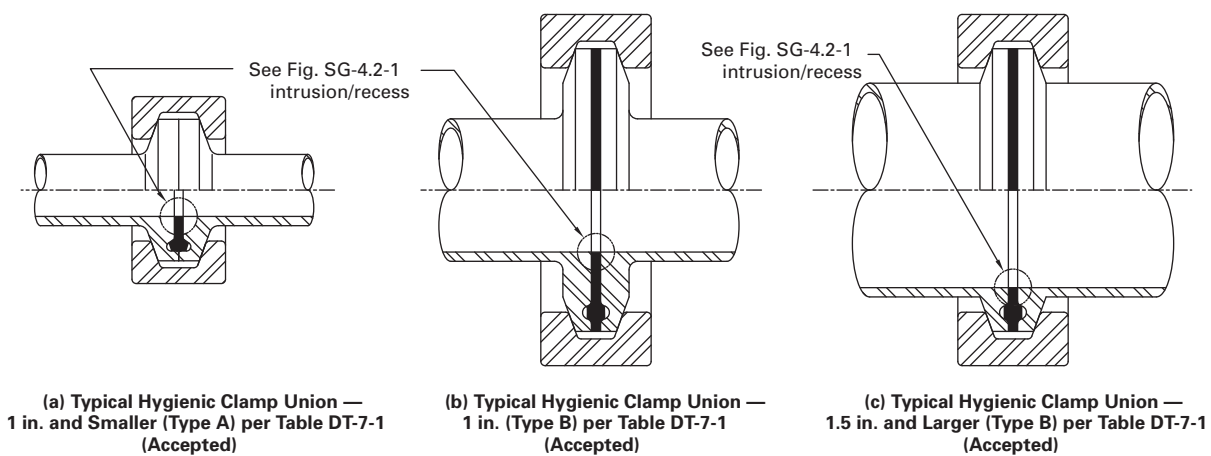


Fig. SG-2.2.2-2 Hygienic Clamp Union per Table DT-7-1

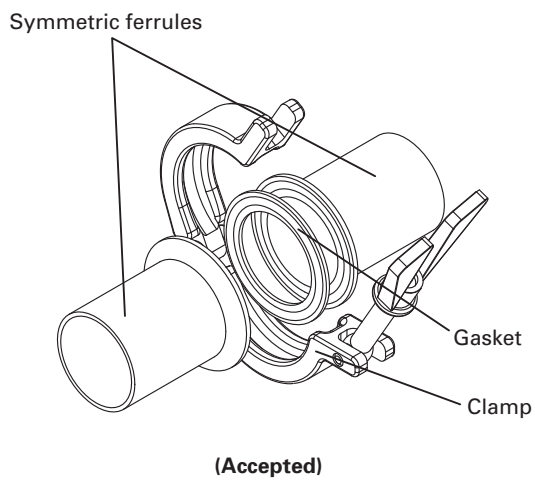


Fig. SG-2.2.2-3 Hygienic Union per DIN 11864

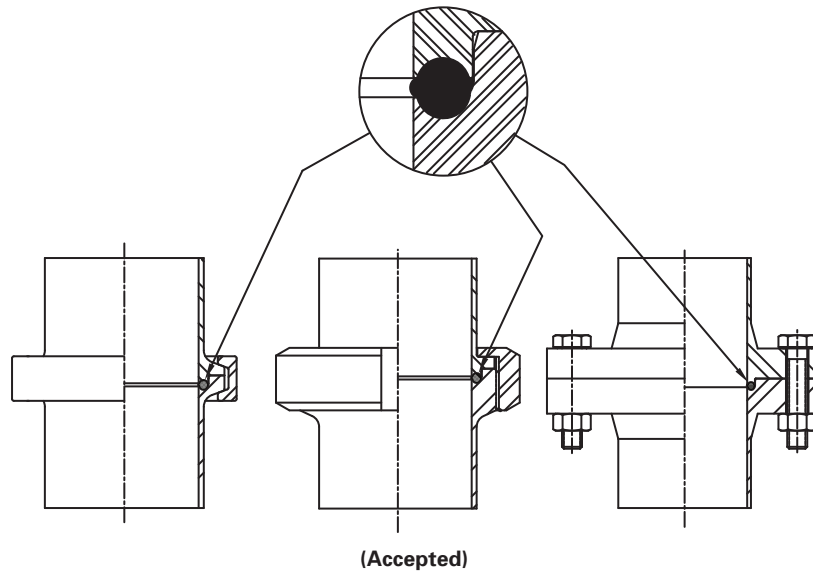


Fig. SG-2.2.2-4 Hygienic Clamp Union per DIN 11864

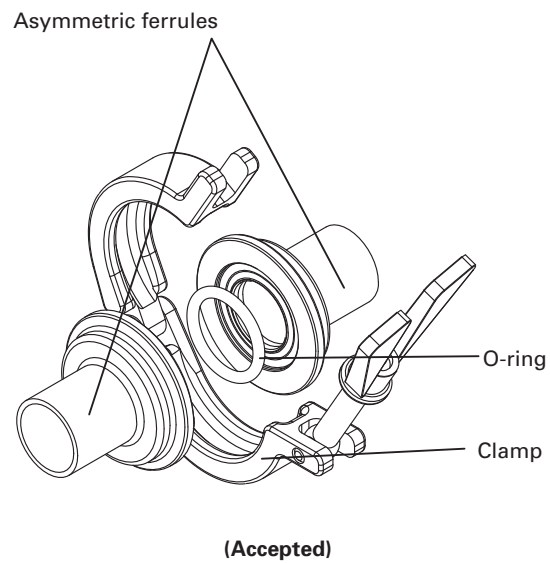


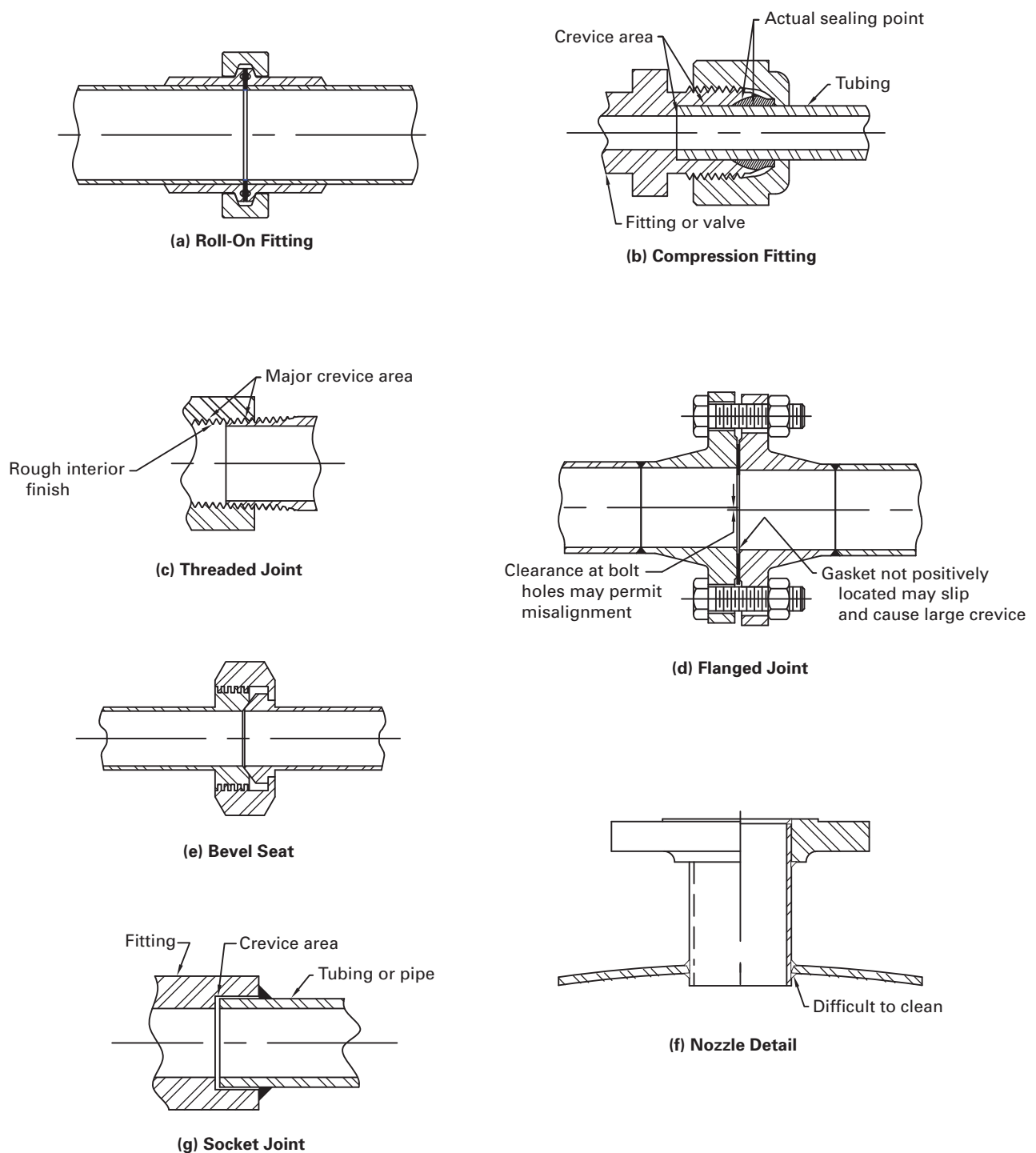
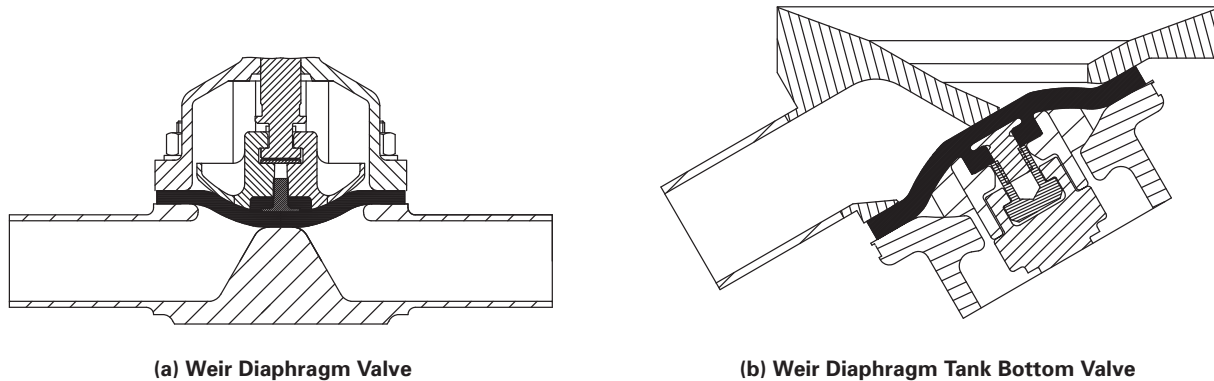
Fig. SG-2.2.2-5 Nonhygienic Connections**(Not Accepted for Hygienic Service)**

Fig. SG-2.3.1.2-1 Weir Valves



SG-2.3.1.2 Diaphragm Valves

(a) *Weir Diaphragm Valve, Weir Diaphragm Tank Bottom Valve.* The diaphragm seal is a flexible membrane that forms positive closure when compressed against the weir (see Fig. SG-2.3.1.2-1). The diaphragm is a product/process contact seal creating both static (atmospheric) and dynamic (differential) seals.

(b) *Radial Diaphragm Valve, Radial Diaphragm Tank Bottom Valve.* The diaphragm seal is a flexible membrane that forms positive closure when compressed against a radial seat (see Fig. SG-2.3.1.2-2). The diaphragm is typically a product/process contact seal creating both static (atmospheric) and dynamic (differential) seals. However, in some designs static seals may be used between body components.

(c) *Weirless Diaphragm Valve.* The diaphragm seal is a flexible membrane that modulates flow across a weirless valve body and also forms positive closure when compressed against the weirless valve body (see Fig. SG-2.3.1.2-3). The diaphragm is a product contact seal creating both atmospheric and differential seals.

(d) *Linear Control Valve.* A sliding seal (such as an O-ring) or nonsliding seal (such as a diaphragm) is used to seal a linear stem (see Fig. SG-2.3.1.2-4). For closure, the linear control valve may use a soft seal such as an O-ring or diaphragm or a metal-to-metal seal/seat.

(e) *Regulator Valve.* A control diaphragm is a flexible membrane that typically is used as a pressure barrier and also forms a static seal to the atmosphere. A plug-type dynamic seal may be used for closure. Static seals are used between body components. To regulate the flow, the operating diaphragm responds to pressure to control the regulating plug and functions as a static seal around its perimeter (see Fig. SG-2.3.1.2-5).

SG-2.3.1.3 Ball Valve and Ball Tank Bottom Valve.

The seat/seal functions as a dynamic seal against the

rotating ball. Static seals are used between body components. A dynamic seal is used on a rotary stem (see Fig. SG-2.3.1.3-1).

SG-2.3.1.4 Rising Stem Single, Double-Seat Mix-Proof, and Needle Valves. Plug(s) are used to close flow against seat(s). Dynamic seal(s) are used on linear stem(s). Static seals are used between body components (see Fig. SG-2.3.1.4-1).

SG-2.3.1.5 Butterfly Valves. The seat/seal creates a dynamic seal when the disk is rotated into the closed position (see Fig. SG-2.3.1.5-1). The seat/seal also forms the primary stem seal to prevent leakage through the stem journal.

SG-2.3.1.6 Thermostatic Steam Trap. The valve seat is closed by a plug attached to a dynamic bellows seal. The body cavity for a serviceable steam trap is typically sealed by a static seal (see Fig. SD-3.1.2.2-1). (16)

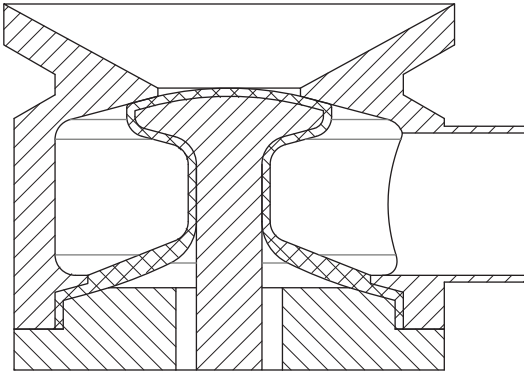
SG-2.3.1.7 Back Pressure Control Valve. A non-sliding seal (such as a diaphragm) is used to seal a linear stem. For closure, the valve may use a soft seal, such as an O-ring or diaphragm, or a metal-to-metal seal/seat (see Fig. SG-2.3.1.7-1). To regulate the flow, the operating diaphragm responds to pressure to control the regulating plug and functions as a static seal around its perimeter.

SG-2.3.1.8 Pinch Valve. Pinch valves use a flexible tube or sleeve that forms a differential seal when closed (see Fig. SG-2.3.1.8-1).

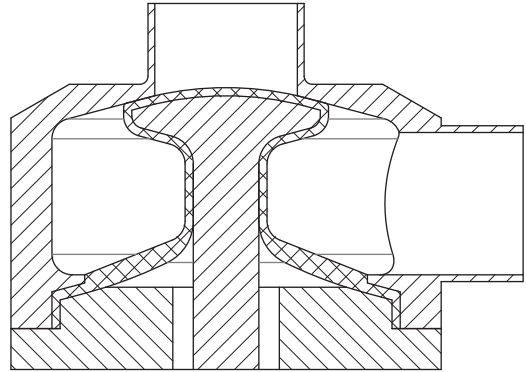
SG-2.3.1.9 Check, Pressure Relief, and Safety Pressure Relief Valves

(a) A check valve is a unidirectional flow device (see Fig. SG-2.3.1.9-1). When the application requires drainability, a check valve may include provisions for drainage, such as flats, drain holes, or a drain port.

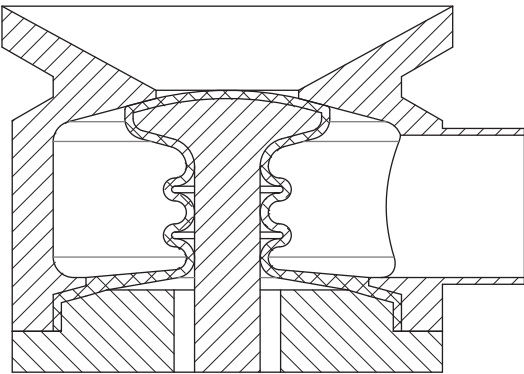
Fig. SG-2.3.1.2-2 Radial Valves



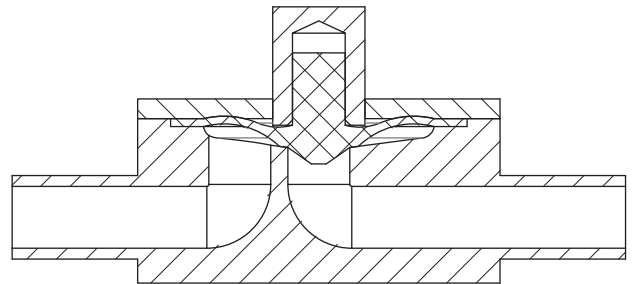
(a) Radial Diaphragm Tank Bottom Valve



(b) Radial Diaphragm Valve



(c) Bellows Radial Diaphragm Tank Bottom Valve



(d) In-Line Radial Diaphragm Valve

Fig. SG-2.3.1.2-3 Weirless Diaphragm Valve

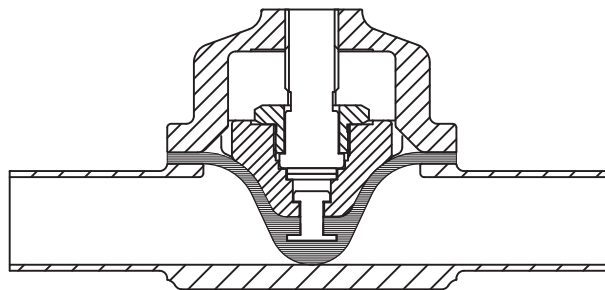
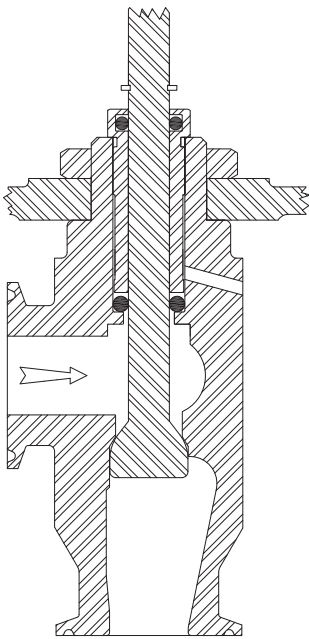
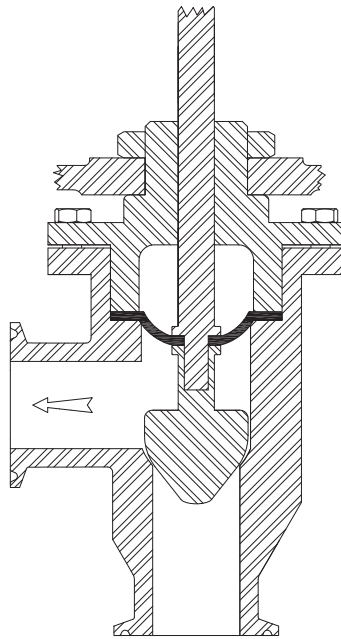


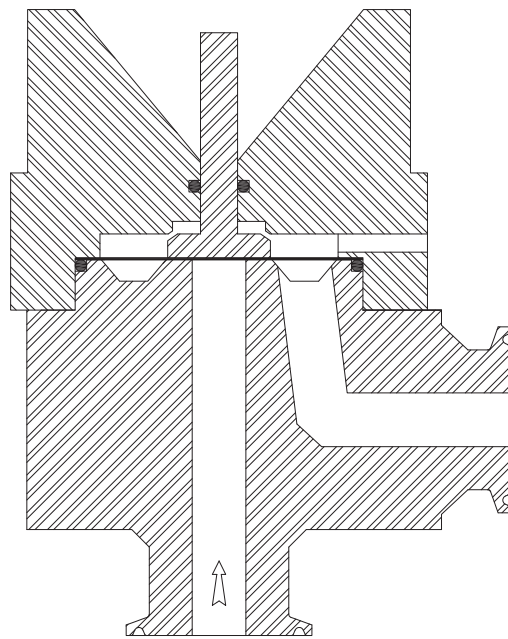
Fig. SG-2.3.1.2-4 Linear Control Valves



**(a) Linear Control Valve
With O-Ring Seal**



**(b) Linear Control Valve
With Elastomer Diaphragm Seal**



**(c) Linear Control Valve
With Metallic Diaphragm Seal**

Fig. SG-2.3.1.2-5 Regulator Valve

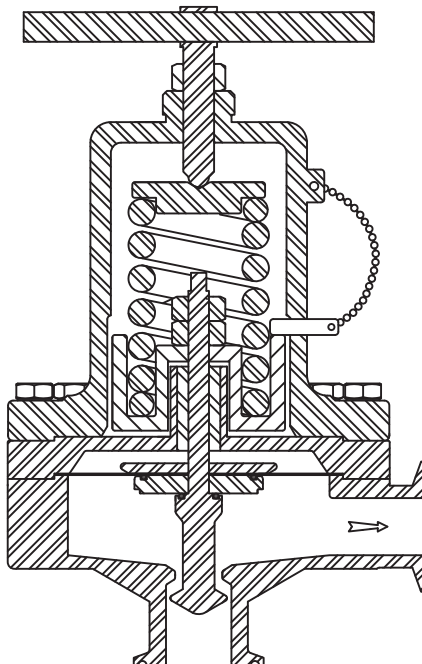


Fig. SG-2.3.1.3-1 Ball Valves

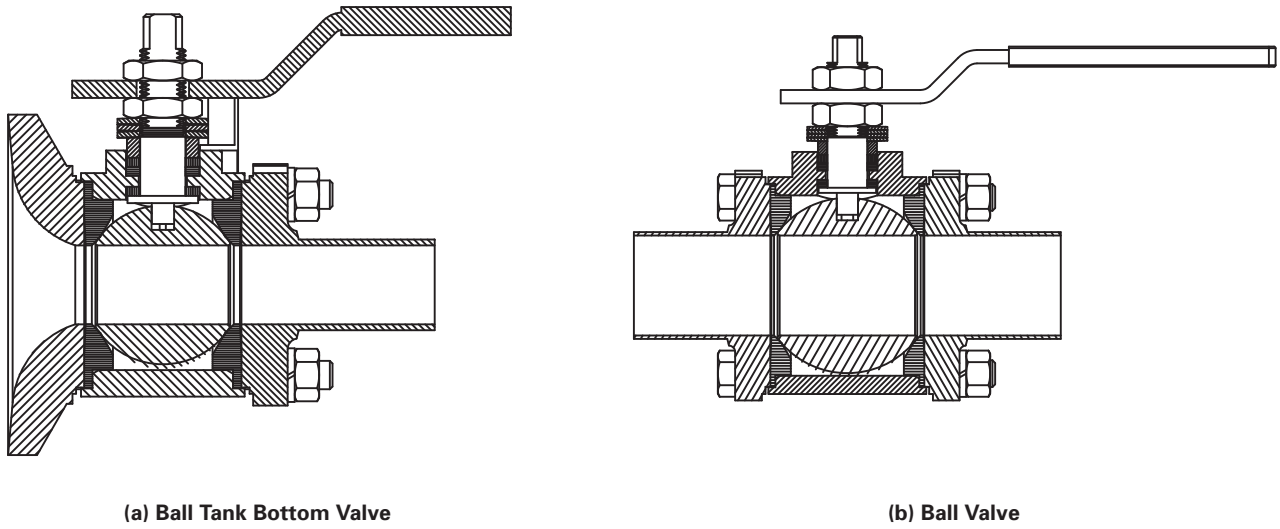


Fig. SG-2.3.1.4-1 Rising Stem Single, Double-Seat Mix-Proof, and Needle Valves

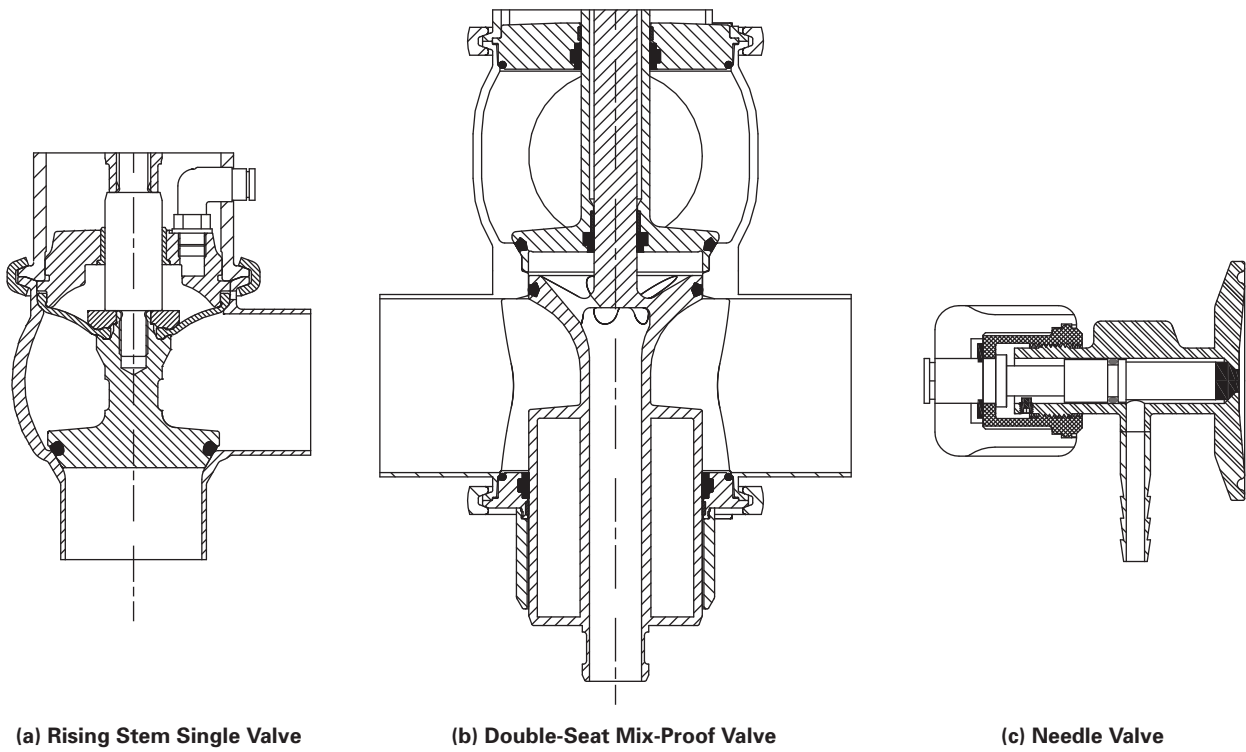


Fig. SG-2.3.1.5-1 Butterfly Valve

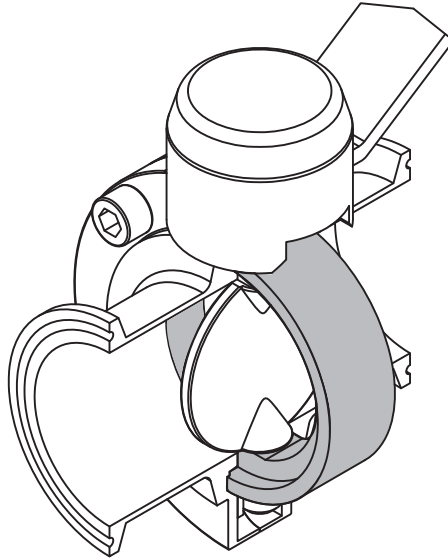


Fig. SG-2.3.1.7-1 Back Pressure Control Valve

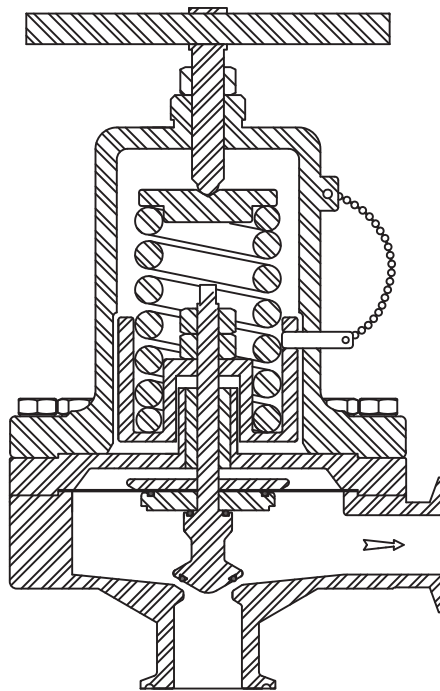


Fig. SG-2.3.1.8-1 Pinch Valve

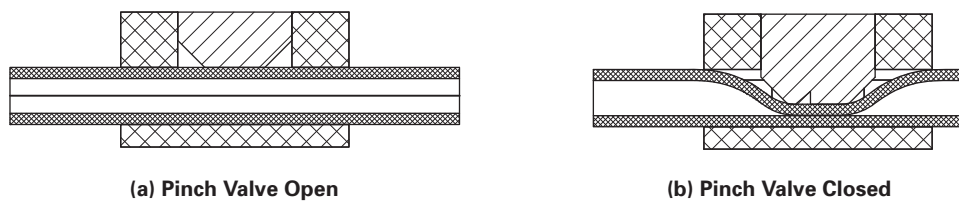
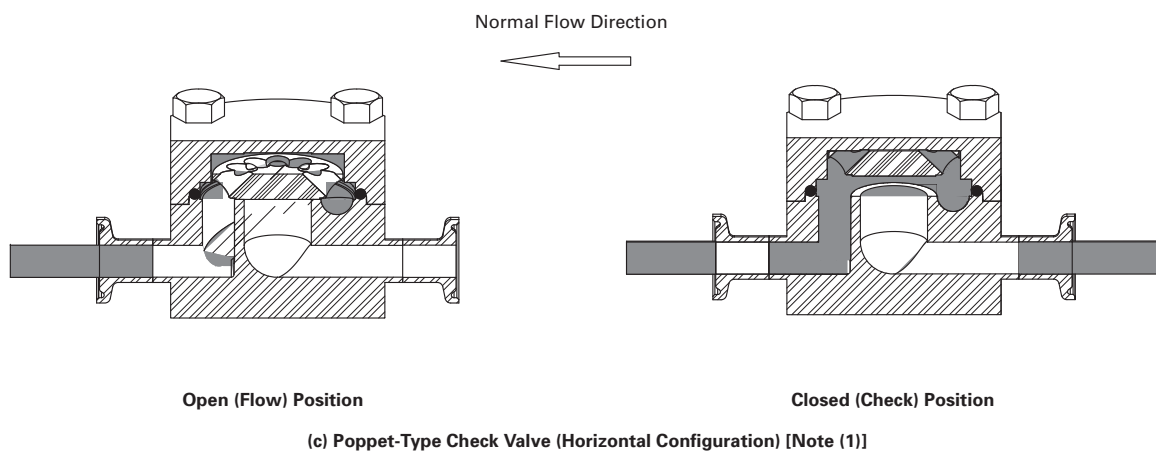
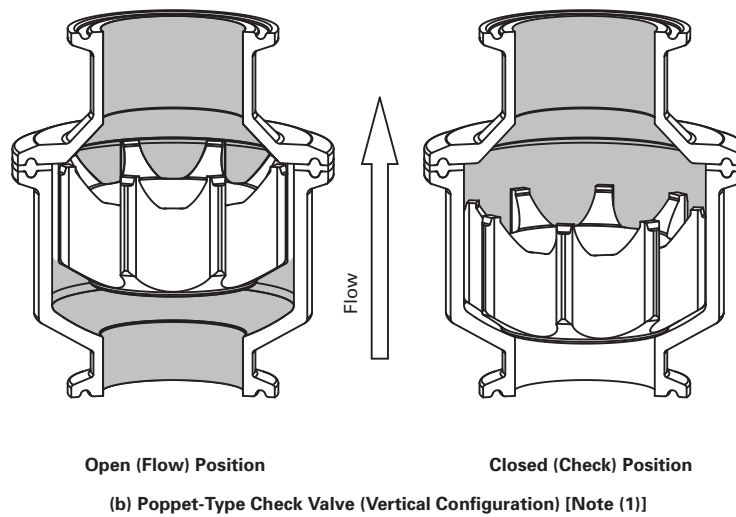
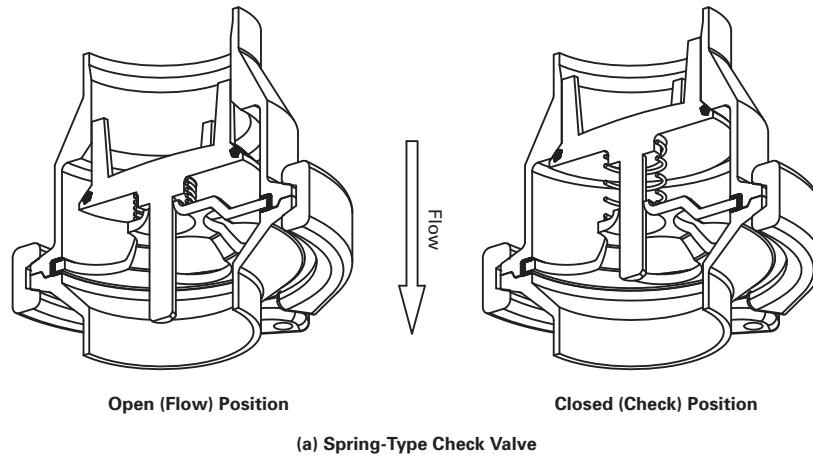
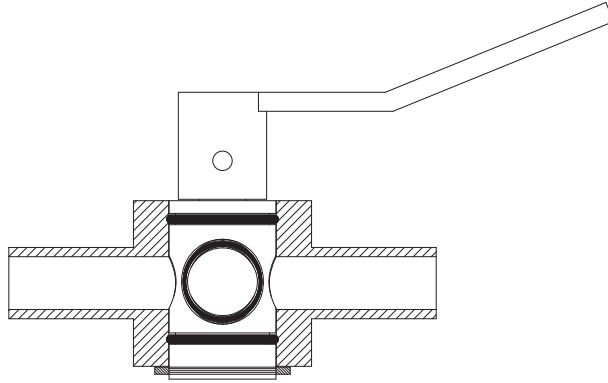


Fig. SG-2.3.1.9-1 Pressure Relief and Check Valves



NOTE:

(1) Gray color represents backflow blocked by the poppet.

Fig. SG-2.3.1.10-1 Plug Valve

(b) A pressure relief valve is a type of valve that relieves pressure in a system in order to protect against mechanical damage of equipment. An override device may be used to allow flow through the valve for the purpose of cleaning. Pressure relief valves allow bypassing of the overpressured fluid back into the process line or a safe location (e.g., from a pump discharge back to the pump suction).

(c) A safety pressure relief valve is a type of valve used to relieve the pressure in a system or vessel, caused by a process upset, instrument or equipment failure, or fire. Its purpose is to protect people and equipment from a potential explosion or leak. The flow is one-directional. In case of overpressure, the fluid is discharged to a safe location outside the pressurized system.

SG-2.3.1.10 Plug Valves. The plug-body valve or plug-seal valve functions as a dynamic seal against the rotating plug (see Fig. SG-2.3.1.10-1).

SG-2.3.2 Mechanical Seals

SG-2.3.2.1 General

(a) An end face mechanical seal is a device that controls leakage of fluids along rotating shafts. Sealing is accomplished by a stationary face bearing against the face of a rotating ring mounted to the shaft. The sealing faces are perpendicular to the shaft axis. Axial mechanical force and fluid pressure maintain the contact between the wearing seal faces.

(b) Selection of the proper seal for the specific equipment and application is the responsibility of the owner/user. The owner/user shall consult the equipment supplier/manufacturer.

SG-2.3.2.2 Single Mechanical Seals

(a) Single mechanical seals are seal arrangements in which there is only one mechanical seal per seal chamber.

(b) Single mechanical seals offer simplicity and an observable leakage path to the atmosphere.

(c) Single mechanical seals weep fluid across the face in the direction from high pressure to low pressure.

(d) Single Mechanical Seals for Pumps

(1) The process fluid provides lubrication and cooling for the faces. A single seal operating in dry or vacuum conditions will result in seal failure.

(2) Not all process fluids will provide adequate lubrication and cooling. In this case an alternative seal design or flush plan shall be considered.

(3) A typical single seal for pumps is illustrated in Fig. SG-2.3.2.2-1.

(e) Single Mechanical Seals for Top-Mounted Agitators

(1) Single mechanical seals for top-mounted agitators operate in the head space of the vessel typically exposed to the gas phase of the process fluid.

(2) Top-mounted agitator single seals may contain a debris well to catch wear material from dry contacting faces.

(3) A typical single-seal design for top-mounted agitators is illustrated in Fig. SG-2.3.2.2-2.

SG-2.3.2.3 Dual Mechanical Seals

(16)

(a) Dual Pressurized Mechanical Seals

(1) Dual pressurized mechanical seals consist of an inboard mechanical seal and an outboard mechanical seal. Pressurized barrier fluid is injected between these two seals. The inboard mechanical seal has process contact, and the outboard mechanical seal has atmospheric contact.

(2) Pressurized barrier fluid means the barrier fluid pressure is higher than the process pressure acting on the inboard mechanical seal.

(3) Dual pressurized mechanical seals offer absolute separation of process and atmosphere.

(4) The pressurized barrier fluid will weep into the process and will weep into the atmosphere.

(5) The owner/user shall arrange for a pressurized barrier fluid to be introduced between the inboard seal and the outboard seal to ensure a positive barrier exists

between the process and the atmosphere. A liquid barrier fluid such as water also cools and lubricates the dual mechanical seal. Gas barrier fluid such as air provides a barrier between the atmosphere and process only and does not provide cooling or lubrication to the seal faces.

(6) Providing barrier fluid flow and pressure at an appropriate temperature is the responsibility of the owner/user and shall be based on the recommendation of the equipment manufacturer.

(7) A typical dual pressurized mechanical seal is illustrated in Fig. SG-2.3.2.3-1 for pumps and Fig. SG-2.3.2.3-2 for top-entry agitators.

(b) Dual Unpressurized Mechanical Seals

(1) Dual unpressurized mechanical seals consist of an inboard mechanical seal and an outboard mechanical seal. Buffer fluid is injected between these two seals. The inboard mechanical seal has process contact, and the outboard mechanical seal has atmospheric contact.

(2) Unpressurized buffer fluid means the buffer fluid pressure is lower than the process pressure acting on the inboard mechanical seal. The highest pressure in the sealing system is the process pressure on the inboard side of the inboard seal. The lowest pressure of the system is the atmosphere pressure on the outboard seal.

(3) Dual unpressurized mechanical seals offer absolute separation of the atmosphere from the process but do not provide absolute separation of the process from the atmosphere.

(4) Process fluid will weep into the unpressurized buffer fluid, and the buffer fluid will in turn weep into the atmosphere along with dilute process fluid.

(5) The owner/user shall arrange for an unpressurized buffer fluid to be introduced between the inboard seal and the outboard seal to ensure a buffer between the process and the atmosphere. The process fluid will penetrate between the inboard seal faces. The buffer fluid with traces of process fluid will penetrate the outboard seal faces.

(6) Providing buffer fluid flow and pressure at an appropriate temperature is the responsibility of the owner/user and shall be based on the recommendation of the equipment manufacturer.

(7) A typical dual unpressurized mechanical seal is illustrated in Fig. SG-2.3.2.3-3.

- (16) **SG-2.3.2.4 Flush Plans.** A flush plan describes how the end face mechanical seal is lubricated and cooled. The flush plan numbers directly reflect plans that were developed by The American Petroleum Institute (API 682), were subsequently approved by the American National Standards Institute (ASME B73 series), and are global standard shorthand for seal support systems. If properly implemented to the requirements of this Standard, all of the following flush plans are acceptable for use in the bioprocessing industry. The numbering system used below is also recognized and used by The Fluid Sealing Association (FSA) and the

Fig. SG-2.3.2.2-1 Single Mechanical Seal

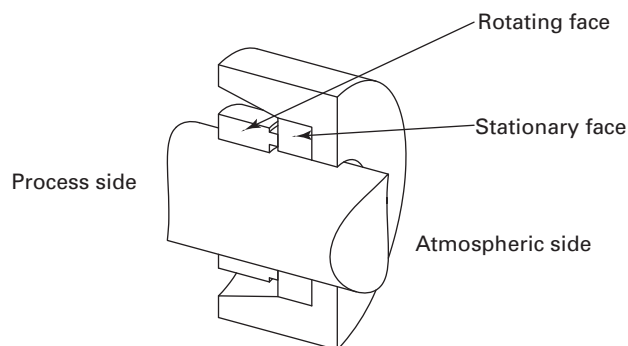


Fig. SG-2.3.2.2-2 Single Seal for Top-Entry Agitator

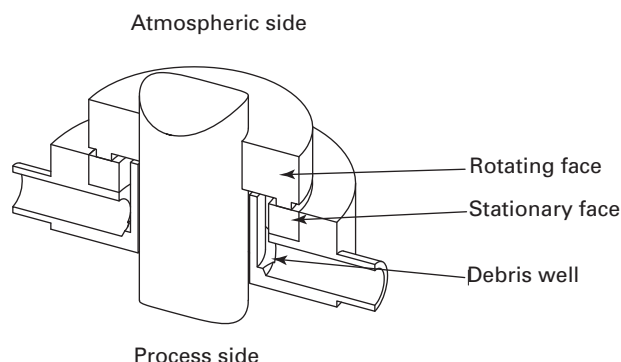


Fig. SG-2.3.2.3-1 Dual Pressurized Mechanical Seal for Pumps

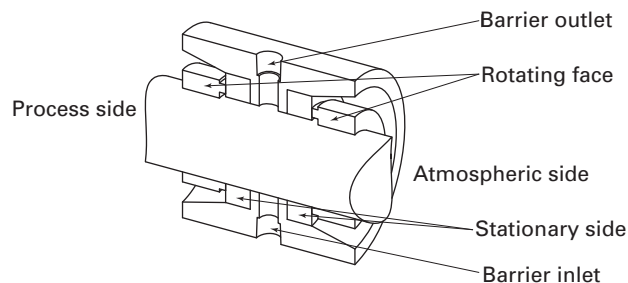


Fig. SG-2.3.2.3-2 Dual Pressurized Mechanical Seal for Top-Entry Agitator

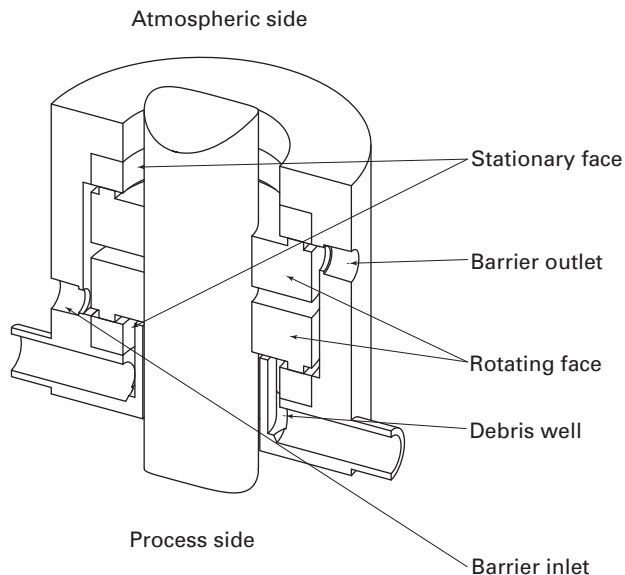
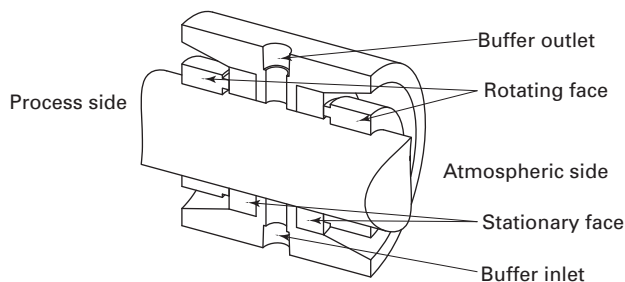


Fig. SG-2.3.2.3-3 Dual Unpressurized Mechanical Seal for Pumps



European Sealing Association (ESA as a group associated with FSA). ISO 21049, API 682, and ISO 13709 also contain important information about support systems for mechanical seals.

(a) *Flush Plan 01*. Internal seal chamber circulation for single seal from pump discharge. A high-pressure discharge of the process fluid flows to the low-pressure seal chamber. The flow of process fluid cools and lubricates the seal faces. See Fig. SG-2.3.2.4-1.

(b) *Flush Plan 02*. Dead-ended seal chamber with no other sources of flush for single seal. The ambient conditions of the seal chamber are satisfactory for the process fluid to remain a coolant and lubricant for the seal faces. See Fig. SG-2.3.2.4-2.

(c) *Flush Plan 03*. Dead-ended seal chamber with circulation between the seal chamber and the pump created by the design of the sealing chamber. The flow of process fluid cools and lubricates the seal faces and may prevent

the accumulation of solids in the seal chamber. See Fig. SG-2.3.2.4-3.

(d) *Flush Plan 11*. Seal flush from pump discharge for single seal. Often uses an orifice, but the flush line itself may be considered an orifice. A high-pressure discharge of the process fluid flows to the low-pressure seal chamber. The flow of process fluid cools and lubricates the seal faces. See Fig. SG-2.3.2.4-4.

(e) *Flush Plan 32*. Seal flush from external source. This plan is used for single seals. A fluid that is compatible with the process is injected into the seal cavity to cool and lubricate the seal. Plan 32 flush fluid will go into the process. See Fig. SG-2.3.2.4-5.

(f) *Flush Plan 52*. This plan is for unpressurized dual seals only. Unpressurized buffer fluid circulates through a reservoir. The buffer fluid is at a pressure less than the process side of the inboard seal. This plan offers protection from product entering the atmosphere and, when used under vacuum conditions, from the atmosphere entering the seal chamber. See Figs. SG-2.3.2.4-6 and SG-2.3.2.4-7.

(g) *Flush Plan BPE52*. Flow and pressure are taken from the pump discharge and injected between the dual seals. The seal cavity is vented to a low-pressure point. This flush plan is used exclusively for dual unpressurized seals. See Fig. SG-2.3.2.4-8.

(h) *Flush Plan 53*. This plan is for pressurized dual seals only. Pressurized barrier fluid is circulated through a reservoir where the barrier fluid is cooled then returned to the seal cavity. Circulation must be provided by a pumping device located in the dual-seal design. This arrangement ensures that the atmosphere and pumped process fluid cannot cross-contaminate. The barrier fluid shall be compatible with the product. See Figs. SG-2.3.2.4-9 and SG-2.3.2.4-10.

(i) *Flush Plan 54*. This plan is for dual pressurized seals only. Pressurized barrier fluid is circulated through the dual-seal cavity from an external source. The source of flow and pressure is undefined in this flush plan. The barrier fluid pressure between the inboard and outboard seals shall be higher than the process pressure acting on the inboard seal. The barrier fluid shall be compatible with the process fluid. See Figs. SG-2.3.2.4-11 and SG-2.3.2.4-12.

(j) *Flush Plan 55*. This plan is for unpressurized dual seals only. Unpressurized buffer fluid is circulated through the dual-seal cavity from an external source. The source of flow and pressure is undefined in this flush plan. The buffer fluid is at a pressure less than the process side of the inboard seal. This plan offers protection from the process fluid entering the atmosphere and, when used under vacuum conditions, from the atmosphere entering the seal chamber. See Figs. SG-2.3.2.4-13 and SG-2.3.2.4-14.

(k) *Flush Plan 74*. This plan is for gas-pressurized dual seals only. The barrier fluid pressure between the

Fig. SG-2.3.2.4-1 Flush Plan 01

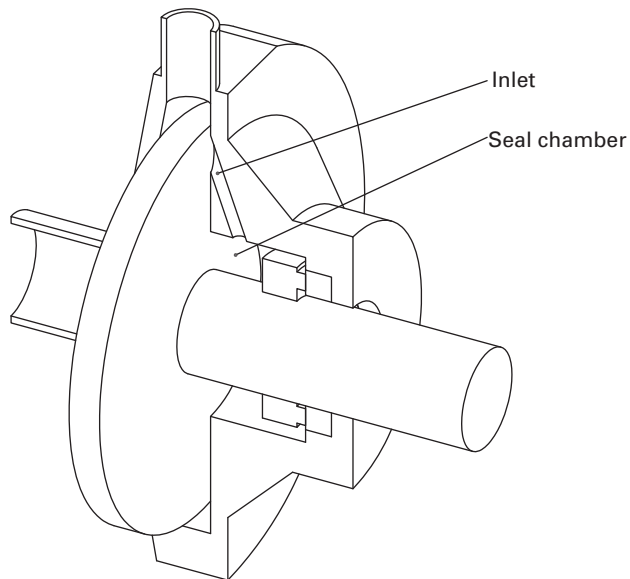


Fig. SG-2.3.2.4-4 Flush Plan 11

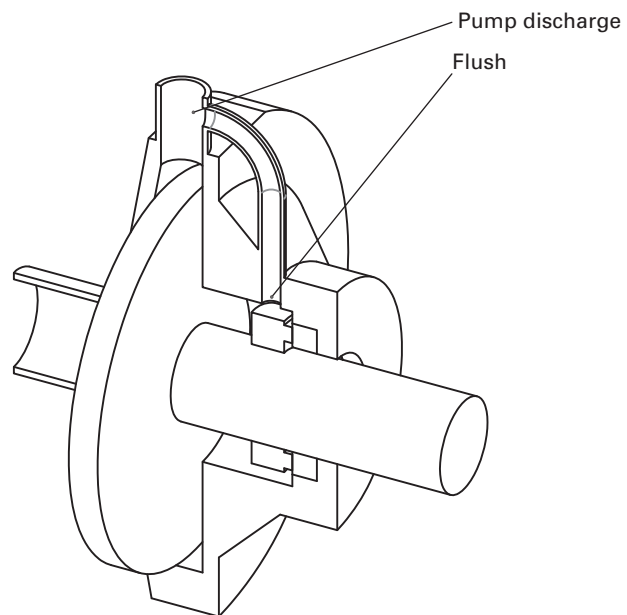


Fig. SG-2.3.2.4-2 Flush Plan 02

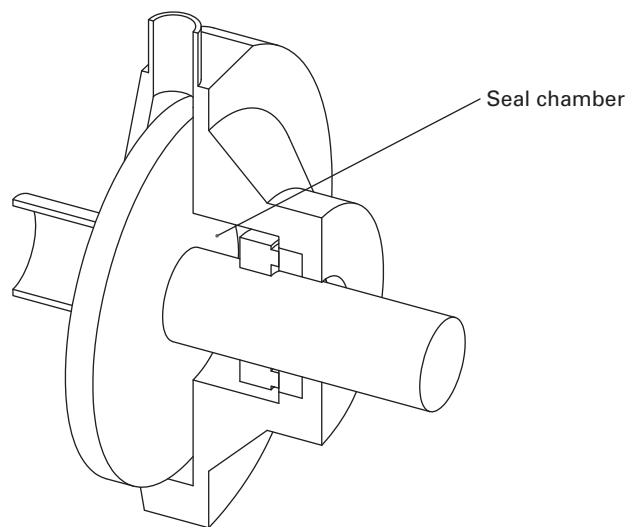


Fig. SG-2.3.2.4-5 Flush Plan 32

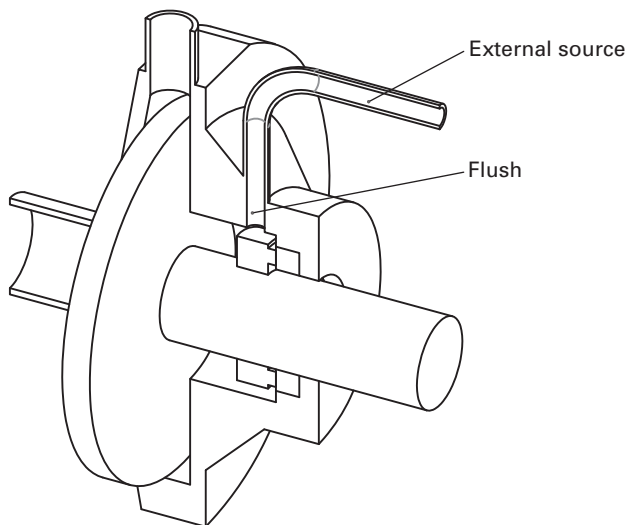


Fig. SG-2.3.2.4-3 Flush Plan 03

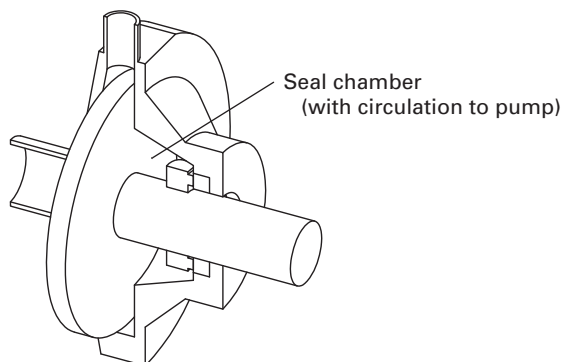


Fig. SG-2.3.2.4-6 Flush Plan 52 for Pump

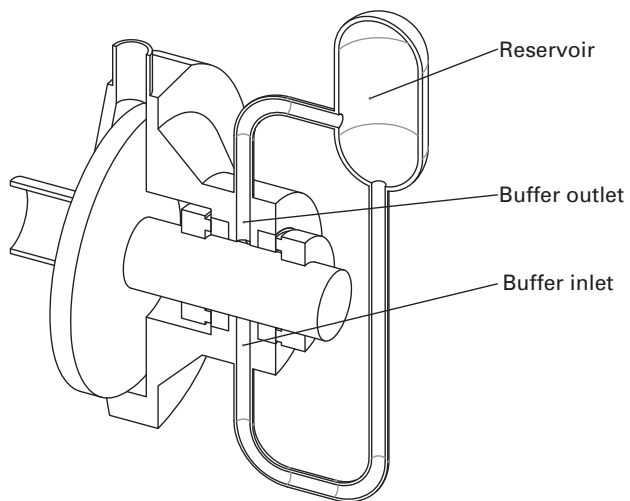


Fig. SG-2.3.2.4-8 Flush Plan BPE52 for Pump

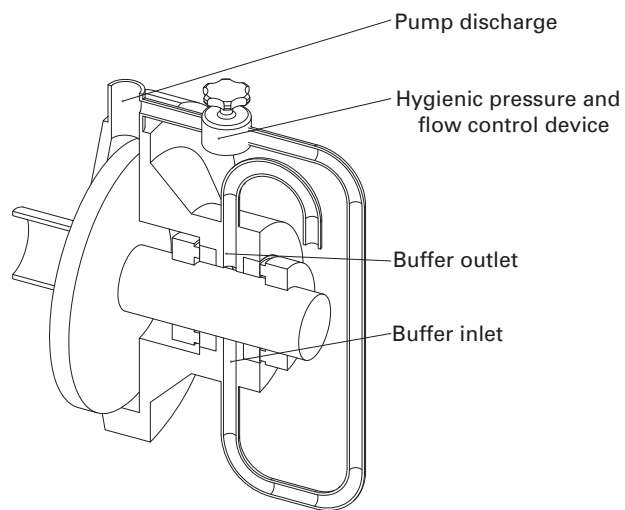


Fig. SG-2.3.2.4-7 Flush Plan 52 for Top-Entry Agitator

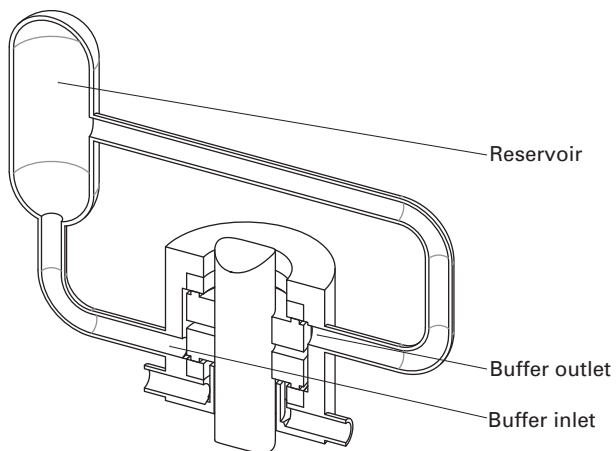


Fig. SG-2.3.2.4-9 Flush Plan 53 for Pump

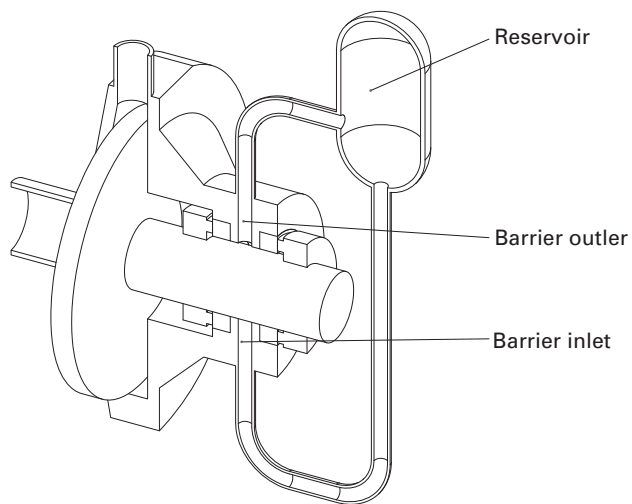


Fig. SG-2.3.2.4-10 Flush Plan 53 for Top-Entry Agitator

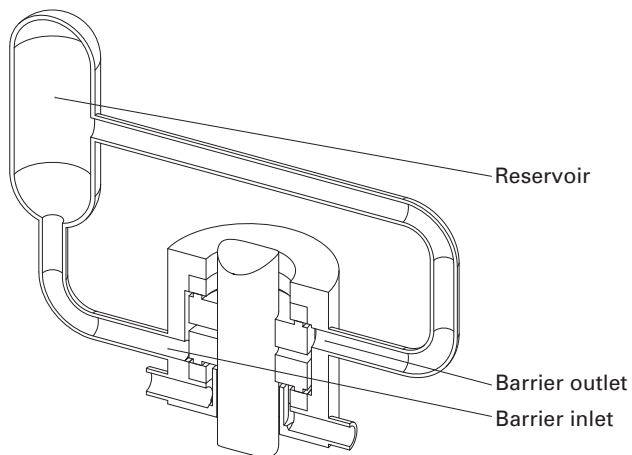


Fig. SG-2.3.2.4-11 Flush Plan 54 for Pump

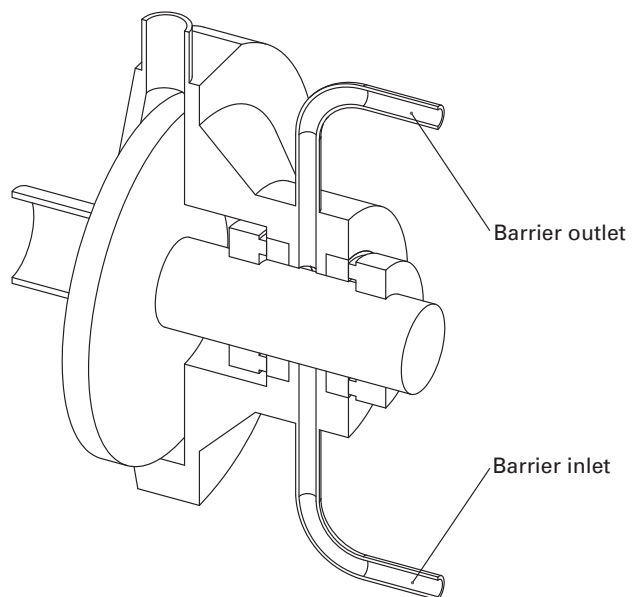


Fig. SG-2.3.2.4-12 Flush Plan 54 for Top-Entry Agitator

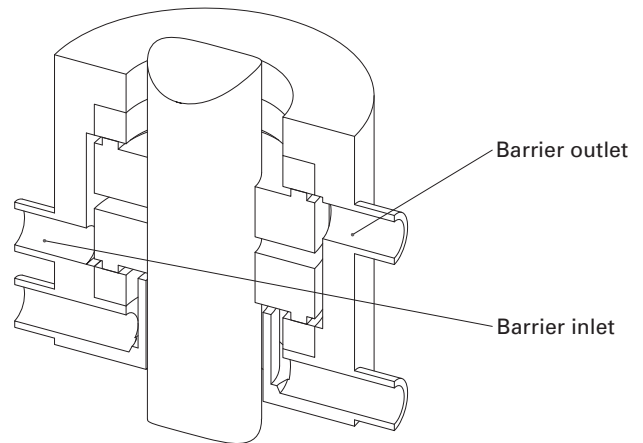


Fig. SG-2.3.2.4-13 Flush Plan 55 for Pump

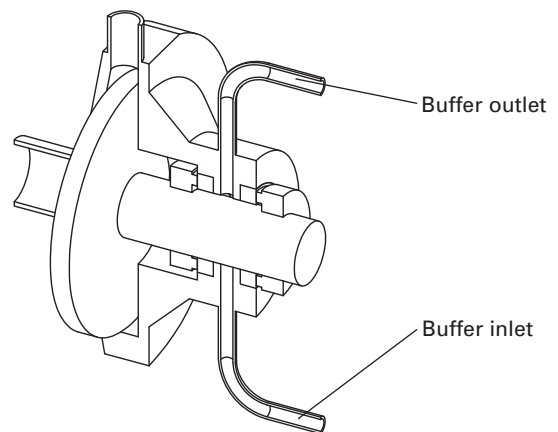


Fig. SG-2.3.2.4-14 Flush Plan 55 for Top-Entry Agitator

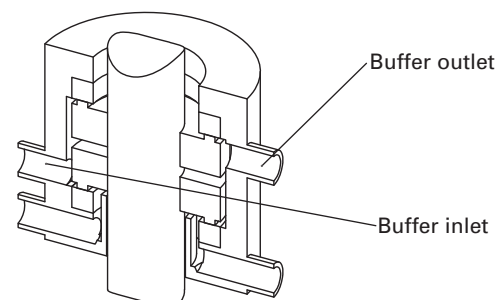
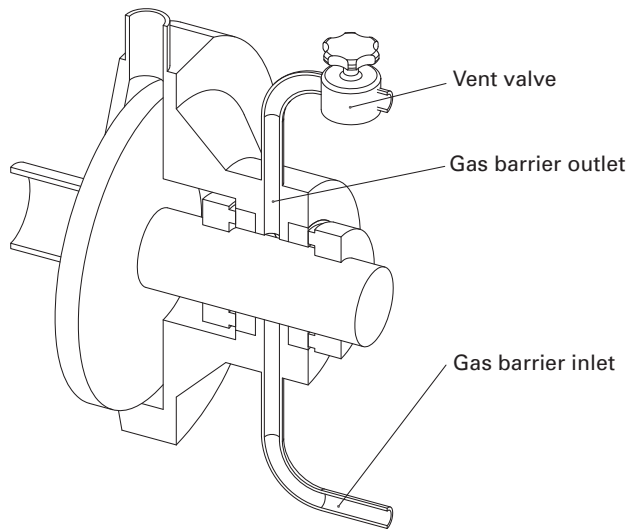
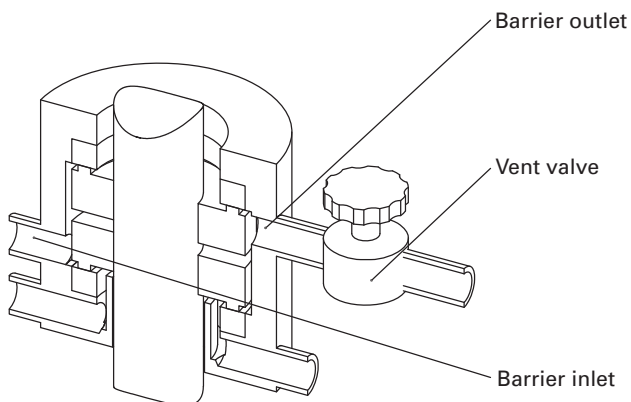


Fig. SG-2.3.2.4-15 Flush Plan 74 for Pump**Fig. SG-2.3.2.4-16 Flush Plan 74 for Top-Entry Agitator**

inboard and outboard seals shall be higher than the process pressure acting on the inboard seal. The barrier fluid must be compatible with the process fluid. See Figs. SG-2.3.2.4-15 and SG-2.3.2.4-16.

SG-2.3.3 Other Dynamic Seals

SG-2.3.3.1 Reciprocating Seals. Reciprocating seals have axial movement between the inner and outer elements, as in a plunger or a piston and a cylinder. The seal, usually an O-ring, slides along the sealing surface.

SG-2.3.3.2 Oscillating Seals. Oscillating seals have angular movement around an arc, as in a valve handle. The seal, usually an O-ring, slides between the inner and outer elements and has limited or no longitudinal movement.

SG-3 SEALING COMPONENTS GENERAL DESIGN REQUIREMENTS (GENERAL PROVISIONS)

SG-3.1 Seal Design Conditions

The equipment supplier/manufacturer 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 (reference Form R-1, Application Data Sheet). It is up to the equipment supplier/manufacturer to inform the owner/user of the service life expectancy and the methods that will ensure that the seal operates within its design specification.

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/manufacturer.

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 owner/user. This shall include the methods, frequency, and length of operation.

SG-3.1.6 Cleaning. The complete cleaning procedure shall be supplied by the owner/user to the supplier/manufacturer for evaluation and selection of compatible material. This shall include the methods, frequency, and length of operation.

SG-3.1.7 Passivation. The complete passivation procedure shall be supplied by the owner/user. The equipment supplier/manufacturer shall inform the owner/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.

SG-3.2 System Requirements

All systems require cleaning and sterilization of seals on a regular basis. This is necessary to ensure elimination of any bacterial growth, which could harm the seal, 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 process contact surface(s) 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 used. All process contact 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 stages. Seal materials that are corrosion resistant to saturated steam and pure steam shall be used. 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-2.3.1.1.

(b) Chemical sterilization.

(c) Hot air sterilization at 320°F (160°C).

(d) Irradiation.

SG-3.2.3 Passivation Systems. The following are typical passivation and derouging systems:

(a) acid treatments

(b) proprietary trade formulations

Full information shall be provided by the supplier/manufacturer as to the corrosive or erosive effect on the seal. See Nonmandatory Appendix D, Rouge and Stainless Steel, and Nonmandatory Appendix E, Passivation Procedure Qualification.

SG-3.3 Seal Construction

(16) SG-3.3.1 Materials

(a) *Biocompatibility*. Biocompatibility testing shall be performed per PM-3.1. Qualification testing of final manufactured seals can be performed on any given size seal (or combination thereof) within a seal 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 on initial qualification of the material and process by the seal supplier/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 temperature. Material selection shall be governed by Part PM and reference Form R-1, Application Data Sheet. It is unlikely that any single seal material can withstand all conditions present

in the facility. Material selection should be done in concert with the seal supplier/manufacturer to ensure that seal performance is maximized for each location within a process. However, material selection remains the responsibility of the owner/user.

(c) *Permeation Resistance*. Seal permeation shall be included in seal leakage criteria and is 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 the seal supplier/manufacturer based on performance and the requirements in Part SF.

(4) Molded seals and components shall have molding flash removed to prevent contact with the process stream.

(e) *Particle Generation*. Seal designs should minimize wear that generates particles that could enter the process stream.

(f) *Lubrication*. When required to facilitate installation, seals may be lubricated with an acceptable lubricant that is compatible with the seal material and process. The supplier/manufacturer shall advise the owner/user of special lubrication requirements. The selection of accepted lubricant is the responsibility of the owner/user.

SG-3.3.2 Design

SG-3.3.2.1 General

(a) *Crevices*. A smooth, contoured, pocketless interior surface shall be created when seals are placed between the seal contact surfaces. All recessed seal contact surfaces shall avoid sharp corners and be easily cleanable with the seal removed. All seal and seal contact surfaces shall be designed to minimize cracks or crevices that might harbor system media.

(b) *Dead Spaces*. Dead spaces are defined here as a void in the process contact surface(s) portion of the structure not completely occupied by a seal and are 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-3.3.2.2 Static Seals

(a) *Static Seal General Design Requirements*. SG-2.2 lists some standards describing the design of hygienic unions, O-rings, and other static seals. Figures SG-2.2.2-1 through SG-2.2.2-4 illustrate typical static hygienic and

O-ring connections. Figure SG-2.2.2-5 illustrates unacceptable connections. In addition, the following general requirements apply to all hygienic static seals:

(1) Gaskets and O-ring seals shall seal and meet the cleanability and bioburden control requirements of the application. Fittings should be selected or designed to consider the gasket or O-ring geometry, materials of construction, and seal performance under operating conditions.

(2) Static seals should be self-aligning and self-positioning.

(b) *Hygienic Unions*. Most common hygienic union geometries used in bioprocessing are listed in SG-2.2.2. All hygienic unions shall comply with the general design requirements in this Part, the material requirements of Parts MM and PM, and the surface finish requirements of Part SF. Intrusion categories of hygienic seals are defined in SG-4.2 and illustrated in Fig. SG-4.2-1.

(c) *O-Ring Seals*

(1) *General O-Ring and Gland Design Criteria*. An O-ring is a seal with a circular cross section (a toroid), designed to be seated in a groove and compressed during assembly. These are most often used in static seals. O-rings are used extensively in hygienic applications and can seal by applying compression (squeeze) on the radially and/or axially opposed faces. In addition to sealing performance during bioprocessing production, performance during other processes, typically CIP and bioburden control processes, shall be considered in the design of a hygienic O-ring seal. The following design criteria should be evaluated:

(-a) seal performance under all process conditions

(-b) proximity of the sealing point to the bulk fluid flow for CIP and bioburden control processes

(-c) consistent location of the sealing point and exposed surfaces under all relevant process conditions

(-d) ability to handle the effects of thermal expansion and chemical swell

(-e) drainability

Often designs that target specific criteria sacrifice others. For example, installation of O-rings in tight grooves to improve cleanability often causes problems due to the thermal expansion of elastomers being significantly greater than the thermal expansion of stainless steel or other nonmetallic materials.

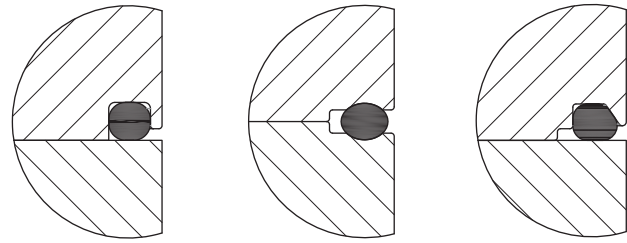
The end-user/owner should consult with the seal designer to optimize the design for an application. The end-user/owner should determine whether an O-ring seal provides adequate overall performance for a specific application.

Some examples of O-ring groove designs are shown in Fig. SG-3.3.2.2-1.

(2) *O-Ring/Gland Sizing (Fill)*. Proper gland design and appropriate O-ring selection are critical for proper sealing. O-ring selection includes the proper sizing and

Fig. SG-3.3.2.2-1 Examples of Static O-Ring Grooves

(16)



proper material selection for the process environment. An O-ring gland shall include sufficient room for thermal expansion and chemical swell to prevent seal material extrusion and damage. Seal designs that compress in multiple directions require extra caution.

(3) *O-Ring Stretch (Elastomeric O-Rings)*. It is suggested that O-ring stretch during installation be limited. The designer should consider the maximum amount of allowable stretch to prevent O-ring breakage during part assembly. When located in position for use, the O-ring stretch should not exceed 5%. Similarly, the O-ring diameter should not be too large for a groove, which would cause the ring to buckle. Overstretching or oversizing an O-ring can lead to premature seal failure.

(4) *O-Ring Compression (Squeeze)*. Proper O-ring compression is critical to proper sealing. At ambient temperature, O-ring compression is frequently in the range of 10% to 25%; however, this can vary greatly depending on materials, conditions, and applications (e.g., static vs. dynamic). O-ring compressions over 30% should generally be avoided. Relative O-ring compression can increase during heating due to thermal expansion. Factors to consider for O-ring compression include chemical swell, temperature change, elastomer hardness, etc. Caution should be taken when substituting elastomeric seals for nonelastomeric seals or vice versa. A nonelastomeric seal may require a crush groove, and direct substitution of an elastomer into such a groove may result in premature seal failure.

(5) *O-Ring Thermal Expansion*. O-ring thermal expansion is dependent on the particular material and formulation. The O-ring supplier/manufacturer can provide information on the material's coefficient of thermal expansion (CTE) characteristics.

(6) Hygienic O-ring connections are available (see Figs. SG-2.2.2-3 and SG-2.2.2-4) in threaded, flanged, or clamped styles. The O-ring connections shall be manufactured to a hygienic standard (e.g., DIN 11864 parts 1 to 3) or shall be accepted as a hygienic connection by a recognized independent organization [e.g., the European Hygienic Engineering and Design Group (EHEDG)]. O-ring connections shall comply with SG-3.3.2.2(c)(6) and SD-3.1.1. The construction of the fitting shall be such that excessive deformation of the

seal will not be caused as a result of overtightening the connection.

(7) O-Rings Fabricated From Molded or Extruded Section Using Vulcanized Molded Joints

(-a) O-Rings. Fully molded O-rings should be used, wherever possible.

(-b) 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:

(-1) Materials. All bonded joint seal materials shall be compliant with SG-3.3.1 and any additional requirements specified by the owner/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.

(-2) Joint Integrity. The joint integrity shall meet the strength requirements of the application. A vulcanized O-ring should contain only one joint. Where tooling availability limits seal diameter, extra joints can be included by prior arrangement with the owner/user.

(-3) Excessive Material and Tool Marks. 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.

(-c) Adhesive-Bonded Joints. Adhesive-bonded joints should be avoided and their use must be agreed to between the supplier/manufacturer and the owner/user.

(d) Other Static Seals

(1) Flat Gaskets. All flat gaskets shall comply with the general design requirements in this Part, the material requirements of Part PM, and the surface finish requirements of Parts SD and SF.

(2) Inflatable Seals. Inflatable seals shall comply with the general design requirements of this document.

(16) SG-3.3.2.3 Valves

(a) General

(1) Process flow valves should optimize drainability and prevent pooling when installed in their proper drain orientation.

(2) When possible, welding valves into the process line is the preferred method of installation to minimize the use of seals.

(3) All process contact surfaces of components designed for CIP/SIP shall be easily accessible by CIP fluids and SIP steam.

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

(5) Cavity fillers shall not be used.

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

(7) Cluster, block, and multiport valves should be designed and installed to minimize dead legs and optimize drainability.

(8) The internal volume of the valve should be kept to a minimum while meeting other requirements of the process design.

(9) Any crevices (e.g., between mating parts of a valve) should be minimized in areas in contact with the process.

(10) Any guiding of valve trim and operating mechanisms should be minimized in areas in contact with the process.

(11) Valves intended for CIP/SIP/sanitization shall be capable of opening as required during those processes.

(12) Valves not capable of CIP shall be able to be disassembled for cleaning/steaming.

(13) The valve design should enable immediate leakage detection between the process side and environment at any seal when possible. The area between a primary and secondary stem seal should be fitted with a leakage detection port to indicate primary seal leakage.

(14) Pneumatically controlled valves shall be designed to prevent air transfer from the actuator to the process.

(15) All seats and seals shall comply with the requirements of this Standard, or as agreed on between the supplier/manufacturer and owner/user.

(16) The owner/user should refer to Form R-1, Application Data Sheet, when communicating process conditions to the supplier/manufacturer. The valve supplier/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 owner/user.

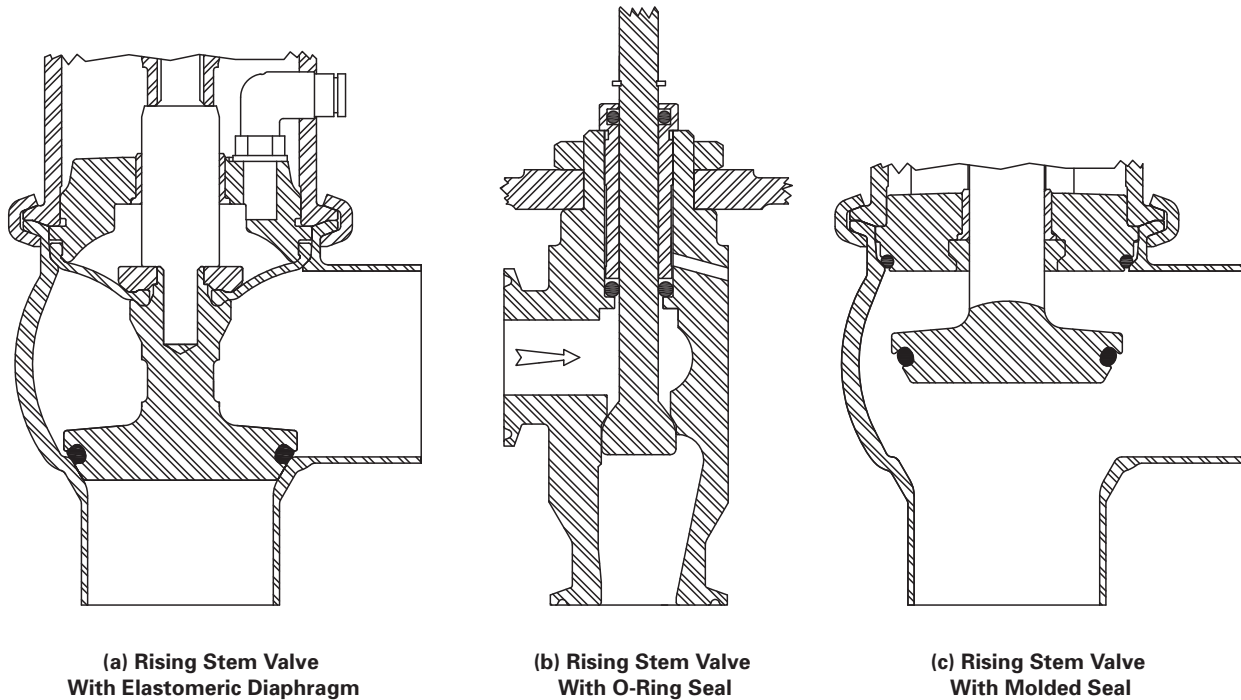
(b) Diaphragm Valves

(1) Diaphragm valves use nonsliding seals and are the preferred valve for bioprocessing fluid applications.

(2) Two-way, weir-style diaphragm valve bodies shall be permanently marked on both sides of the body to show optimum drain position. Orientation of welded and machined multiple-port bodies shall be included on submittal drawings. Other types of diaphragm valves should be installed to the manufacturer's recommendations.

(3) Point-of-use (POU) valves should be designed with the seal at or below the lowest point in the tube to facilitate draining.

(4) Diaphragms should be marked in accordance with Section 12.3 of MSS-SP-88.

Fig. SG-3.3.2.3-1 Seals for Rising Stem Valves

(5) Weirless diaphragm valves use nonsliding seals. The installation angle is not critical due to the elimination of the weir in the body design; however, the valve should be installed to the manufacturer's recommendations.

(c) *Rising Stem Seal Valves.* Rising stem seal valves use sliding and nonsliding seals (see Fig. SG-3.3.2.3-1). Suitable designs are available for fluid utility applications such as clean steam and CIP as well as for product. The owner/user shall define the degree of suitability of the design for the application.

(1) Seals for rising stem valves are classified as follows:

(-a) *Primary Rising Stem Seals.* Primary rising stem seals serve as pressure barriers for process fluids. Such seals shall be exposed for cleaning and shall meet the pressure and temperature requirements of the specified materials as outlined in this Standard and the aseptic and bioburden control requirements specified by the owner/user. In addition, they shall meet all of the general requirements for seals outlined in this section. Primary sealing can be provided in different ways.

(-1) Nonsliding seals such as bellows and diaphragms eliminate contamination risk by preventing the product/process contact surface(s) portion of the stem from contacting the atmosphere. When the primary stem seal is a nonsliding seal, a secondary stem seal is not required.

(-2) Sliding seals such as lip-seals and O-rings can be used for the reciprocating stem between process

fluid and atmosphere. Single sliding stem seals can be used for fluid utility applications such as clean steam and CIP. If sliding seals are to be used as the primary seal for product contact applications, there should be a secondary stem seal to facilitate cleaning and sanitization behind the primary sliding seal.

(-b) *Secondary Rising Stem Seals.* Secondary seals serve as the sealing between atmosphere and a stem disinfection chamber (e.g., steam barrier or disinfection means barrier). These seals shall be designed to serve as pressure barriers for sanitizing fluid. Such seals shall meet the pressure and temperature requirements of the specified material outlined in Part SG of this Standard. Secondary stem seals are typically sliding seals (e.g., O-rings or lip-seals).

(2) 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, if the surface can become exposed to the system fluid under the normal course of system operation.

(3) Primary stem O-ring seals shall be fitted in grooves located as close to the valve body cavity as possible to meet bioburden control requirements.

(4) When made from metal, static seals shall meet the surface finish requirements for the valve housing interior on the side facing the process fluid.

(d) *Regulator Valves*. When using regulator valves, a means of override is normally required to allow cleanability and drainability of the valve.

(e) *Ball Valves*. Ball valves (Fig. SG-2.3.1.3-1) are not recommended for product contact streams. The owner/user should determine whether a ball valve is acceptable for other process contact applications. Applications where ball valves are typically acceptable include liquid and gas utility and process support applications, such as clean steam. The valve bore I.D., including ball and body, shall match the I.D. of the connecting tubing to allow self-draining. Cavity fillers shall not be used.

(f) *Butterfly Valves*. Butterfly valves use sliding seals. Butterfly valves are commonly used for powder and vacuum applications. The valve should be installed per the manufacturer's recommendations to allow self-draining.

(g) *Steam Traps (Thermostatic)*. A thermostatic steam trap shall be designed to minimize the risk of soil attachment to the process fluid surfaces. The bellows should have a low subcool to prevent the backup of condensate into the process equipment and clean steam system. Steam traps shall be installed with an uninsulated section upstream of the trap to facilitate proper steam trap function (see Fig. SD-3.12-1).

(h) *Back Pressure Control Valves*. Back pressure control valves shall be designed to allow free draining through the outlet or inlet port. Crevices created by a pierced diaphragm or soft seat plug shall be minimized.

(i) *Pinch Valves*. When using pinch valves, care must be taken to prevent permanent deformation of the flexible tube or sleeve that restricts the flow or affects drainability.

(j) *Check Valves*. Check valves may use sliding and/or nonsliding seals. A check valve, clack valve, nonreturn valve, or one-way valve is a valve that allows fluid flow in one direction. Check valves using an exposed coil spring shall be of a design to prevent the coil spring from full compression creating an enclosure.

(k) *Plug Valves*. Rotating plug valves use sliding seals and are not preferred in product contact applications. Plug valves are suitable for liquid and gas utility applications such as clean steam and CIP. The plug valve uses a 1/4-turn cylindrical plug with O-ring seals to provide straight-through flow. The plug I.D. does not always match the I.D. of the tubing; therefore, self-drainability of the valve is limited.

SG-3.3.2.4 End Face Mechanical Seal General Design Requirements

(a) General

(1) Mechanical seal hardware used to mount the mechanical seal to equipment shall be consistent with nonpooling and drainability requirements of Part SD.

(2) Springs and drive mechanisms (e.g., pins) shall not be located in the process fluid.

(3) When applicable, the seal should be designed in accordance with this Standard for CIP and/or SIP.

(4) Surface requirements for the process side of the mechanical seal shall be consistent with the requirements of Part SF.

(5) Process-side hardware radii shall meet the requirements of SD-2.4.2(g).

(6) Secondary seals are used in static and dynamic positions. The dynamic position in a typical mechanical seal is where the secondary seal is in contact with the spring-loaded seal face. The dynamic secondary seal accommodates motion during operation and face movement as the primary faces wear. Secondary seal cavities shall be located and designed so that the process side is accessible to fluid flow and is drainable consistent with the requirements of Part SD.

(7) Secondary seal material should be selected to minimize compression set on all phases of operation, which may include CIP and/or SIP.

(8) Materials of construction shall meet Part PM for polymers or other nonmetallics and Part MM for metal components. The owner/user is responsible for selection of appropriate materials in consultation with the equipment supplier/manufacturer.

(9) Form R-1, Application Data Sheet, should be filled out with appropriate information to make a correct seal selection.

(10) Assembly lubrication will be specified by the owner/user in consultation with the equipment manufacturer. The owner/user will determine compatibility of the lubricant with the process. The equipment supplier/manufacturer will determine the compatibility of the lubricant with the seal components.

(b) Single Mechanical Seal

(1) Single mechanical seals are applied for their simplicity, observable leakage path to the atmosphere, and no requirement for a seal support system.

(2) Single mechanical seals protect the process boundary at the seal's secondary seals and at the seal's primary face.

(3) When operating in pressurized process fluid, single mechanical seals will weep process fluid to atmosphere. If a process upset occurs that creates a temporary vacuum in the equipment, the seal will weep atmosphere into the process fluid.

(4) Single liquid mechanical seals are applied when the process fluid has desirable lubricating characteristics to support the rubbing of the primary seal faces.

(-a) Fluids that have desirable lubricating characteristics do not include fluids that change state, are in gaseous phase, precipitate solids, and cause thin film bonding, congealing, solidification, or crystallization between the seal faces.

(-b) An example of a possible desirable lubricant is pure steam condensate at 100°F (38°C).

(5) Single dry contacting gas seals will operate in a gaseous phase environment.

(c) Dual Pressurized Mechanical Seal

(1) Dual pressurized mechanical seals are preferred to prevent process fluid from weeping to atmosphere and to prevent atmosphere from weeping into the process.

(2) Dual pressurized mechanical seals protect the process boundary with a pressurized barrier fluid.

(3) Dual pressurized seals are used when the process fluid does not have desirable lubricating characteristics.

(4) Dual pressurized seals shall be designed for liquid or gas barrier fluid. Dual pressurized seals cannot be designed for gas and liquid lubrication.

(5) Dual pressurized gas barrier seals can be contacting or noncontacting face design.

(6) A barrier fluid compatible with the process fluid and atmosphere shall be specified by the owner/user. The owner/user should consult with the equipment supplier/manufacturer to determine suitability of the barrier fluid for the dual pressurized mechanical seal.

(7) The owner/user should provide Form R-1, Application Data Sheet, so the supplier/manufacturer can recommend pressure, flow rate, and temperature of the barrier fluid.

(d) Dual Unpressurized Mechanical Seal

(1) Dual unpressurized mechanical seals are preferred to prevent dilution of the process fluid by the buffer fluid weeping across the inboard faces. The buffer fluid will prevent atmosphere from entering the process fluid. The process fluid will weep into the buffer fluid that may weep to the atmosphere.

(2) Dual unpressurized mechanical seals protect the process boundary with an unpressurized buffer fluid.

(3) Dual unpressurized seals are used when the process fluid has desirable lubricating characteristics.

(4) Dual unpressurized seals shall be designed for liquid or gas buffer fluid. Dual unpressurized seals cannot be designed for gas and liquid lubrication.

(5) Dual unpressurized gas buffer seals can be contacting or noncontacting face design.

(6) A buffer fluid compatible with the process fluid and atmosphere should be specified by the owner/user. The owner/user should consult with the equipment vendor to determine suitability of the buffer fluid for the dual unpressurized mechanical seal.

(7) The owner/user should provide Form R-1, Application Data Sheet, so the supplier/manufacturer can recommend pressure, flow rate, and temperature of the buffer fluid.

SG-3.4 Compliance Requirements for Sealing Elements

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 owner/user. Additional agreements may be required; refer to SD-2.4.1. At a minimum, seals exposed to process contact fluids and/or that have a high probability of exposure will comply with the United States Pharmacopeia (USP) directive with regard to USP <87> (or ISO 10993-5) and USP <88> Class VI (or ISO 10993-6, -10, and -11) on biological reactivity (see Part PM for additional details). 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. See PM-2.2.1.

SG-3.4.3 Test Requirements. Conformance testing is done on 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, on request of the owner/user, a certificate of design conformance that the sealed union meets the intrusion requirements of SG-4.2. 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 (e.g., 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-3.4.4 Additional Requirements. [Reserved for future content]

SG-3.5 Seal Identification

Marking on the seal package should include all items listed in SG-3.4.2.

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. When marking diaphragms, any marking shall be done on those portions of the diaphragm that are not exposed beyond the sealing portion of the housing.

SG-3.6 Other Seal Requirements

[Reserved for future content]

SG-4 SEAL PERFORMANCE REQUIREMENTS

SG-4.1 General Requirements

Seals form an integral part of process systems and maintain static and/or dynamic system boundaries

while being exposed to chemical, thermal, and mechanical (hydraulic and pneumatic) conditions in both cyclic and continuous modes of operation. On exposure to operating conditions, the seal shall not swell, shed, crack, erode, or otherwise deteriorate to an extent that it impacts the product or process during its expected lifetime. The seal shall not add to nor remove from the process or product to which it is exposed beyond an acceptable level (see section PM-3). Following exposure to the process conditions, the seal shall be capable of being inspected, serviced, and/or replaced. Specific seal performance criteria shall be established by the owner/user in consultation with the seal supplier/manufacturer. Form R-1, Application Data Sheet, may be used to communicate expected process conditions.

Any given seal is not designed to perform in all possible operating conditions.

Parameters for evaluating the performance of a seal include leak rate, sealing location, dimensional stability, material stability (including shedding), and serviceability. The requirements for each of the parameters depend on the seal type and application. To predict how a seal will perform in service it shall be evaluated (e.g., testing, past performance). Standardized performance test conditions and methods permit a consistent approach to gathering data used to evaluate seal performance. When evaluating performance test data, the owner/user should consider if the test parameters are relevant to the conditions expected in the application. Performance data should be considered when determining the appropriate service interval for the desired application.

SG-4.2 Static Seal Performance

Static seals shall meet the general performance requirements of SG-4.1.

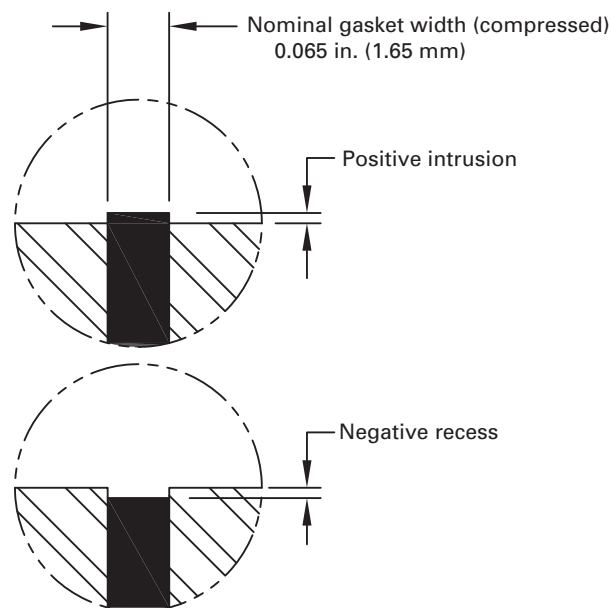
On initial installation, a hygienic static seal shall provide a substantially flush interface with the hygienic clamp ferrules. Hygienic seals shall meet and be designated by one of the following intrusion categories when tested by the seal manufacturers:

(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 purpose of a flush interface is to minimize the entrapment of material in a dead space that can lead to microbial growth and contamination (see Fig. SG-4.2-1). Excessive intrusion into the process stream may lead to erosion of elastomeric seals, thereby contaminating the process stream. The amount of intrusion depends on the dimensional control of the seal, the hygienic clamp ferrule dimensions [see Table DT-7-1 and Fig. SG-2.2.2-1, 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.

Fig. SG-4.2-1 Typical Hygienic Clamp Union: Allowable Gasket Intrusion



Testing parameters used to identify the desired performance should be based on the intended operating conditions. Nonmandatory Appendix J identifies standard process test conditions (SPTC) and a method for performing testing to gather data used to evaluate the appropriate level (e.g., 10, 100, or 500) of the seal for the given service life. Performance data are collected at 10-, 100-, and/or 500-cycle intervals. The 10-cycle interval is intended to provide data for short durations (e.g., single-use or inspect-between-use applications). The 100- and 500-cycle intervals are intended to provide data on the service life of the seals (e.g., multiple-use applications) that are not routinely inspected.

SG-4.3 Dynamic Seal Performance

SG-4.3.1 Valve Seal Performance. Valve seal performance is acceptable when the seal maintains the system boundaries and design flow characteristics for which it was intended (e.g., static and/or dynamic). A valve seal shall operate through the desired range of motion against differential pressure. It shall be hygienic and meet the cleanability requirements stated in SG-3.3.2.3. A valve seal shall meet these performance conditions following exposure to operating conditions in both cyclic and continuous modes of operation.

Performance data shall be collected at intervals that reflect the use mode (e.g., discrete/open/closed or modulating), operation (e.g., continuous or cyclic), and intended service life (e.g., continuous hours of exposure or number of cycles) of the valve seal.

Testing parameters shall be based on the operating conditions of the intended application. Nonmandatory

Appendix J identifies standard process test conditions and a method for conducting performance tests of seals in simulated process conditions. For valve seal testing, the method identified in Nonmandatory Appendix J requires modification to reflect a specific use mode and intended operation of a valve seal. Form R-1, Application Data Sheet, identifies a number of operational conditions (e.g., chemistry, temperature, pressure) to consider when developing nonstandard performance tests.

- (16) **SG-4.3.1.1 New Valve Seal Performance.** 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.

For diaphragm valves, the following requirements shall apply:

- (a) seat leakage rates per MSS-SP-88, EN 12266-1, or ANSI/FCI Standard 70-2, Class VI
- (b) shell leakage rates per MSS-SP-88 category C or EN 12266-1

SG-4.3.2 Mechanical Seal Performance. Mechanical seal performance may be characterized by leakage rate, service life, cleanability, particle shedding, suitability for application, and heat generation. Acceptable values for each of these characteristics may vary widely, so it is strongly advised that the mechanical seal's various characteristics and the ramifications of each to the service are understood.

Nonmandatory Appendix J-2.1 provides important information about mechanical seal performance. It provides exceptions to normal seal performance that are commonly found in the industry. Familiarity with these items will help the reader understand the impact that design, installation, and operation can have on mechanical seal performance. Also included in Nonmandatory Appendix J-2.1 are outlines for various methods of testing seal integrity.

SG-4.3.2.1 New Mechanical Seal Performance.

There are four key points between procurement and operation of a new mechanical seal where the seal might be evaluated for performance. The four key points are manufacturing, installation, assembly, and use.

(a) *Point of Manufacture.* Mechanical seal manufacturers have performance requirements for new seals. The manufacturer's tests should be accepted. If special performance requirements are necessary, those special requirements shall be specified.

If the mechanical seal manufacturer alters the design, material, or manufacturing technique of a mechanical seal in service, it is the responsibility of the mechanical seal manufacturer to inform all relevant parties that changes have occurred. Specific information may be requested from the seal manufacturer to support the premise that seal performance has not been altered.

(b) *Point of Seal Installation.* The mechanical seal will be installed in a piece of equipment. An original equipment manufacturer (OEM) will typically have its own test to verify the performance of the mechanical seal. The test of the OEM should be accepted. A review of the OEM test procedure may be requested. The OEM should consult with their seal supplier/manufacturer for seal performance issues and questions.

Contractors may install a new seal in a piece of equipment. The seal performance test may be reviewed with the installation contractor.

If unique conditions exist where special performance requirements are necessary, it is the customer's responsibility to specify the additional requirements. An acceptable performance test may be developed.

If the OEM alters the design, material, or manufacturing technique of a mechanical seal in service, or is informed by the seal manufacturer that the design, material, or manufacturing technique has been altered, it is the responsibility of the OEM to inform all relevant parties that changes have occurred.

(c) *Point of Systems Assembly.* The equipment that contains the seal is installed in a system. The systems supplier/manufacturer will have standard test procedures for testing the system integrity. The test procedures of the system's supplier/manufacturer should be accepted. A review of the test procedure may be requested. The system assembler should consult with their OEM supplier/manufacturer for seal performance issues and questions.

If the system assembler alters the design, material, or manufacturing technique of a mechanical seal in service, or is informed by the OEM that the design, material, or manufacturing technique has been altered, it is the responsibility of the system assembler to inform all relevant parties that changes have occurred.

(d) *Point of Use.* Once the system is delivered to the owner/user, it is the owner/user's responsibility to determine if the mechanical seals meet performance requirements. The owner/user should consult with their system designer/manufacturer/vendor for seal performance issues and questions.

SG-4.3.2.2 Installed Seals. Original point-of-use performance requirements shall be used to determine if the seal is suitable for continued use. Refurbished seals shall be held to the original point-of-use performance requirements. It is the owner/user's responsibility to monitor equipment for failure.

SG-5 SEAL APPLICATIONS

SG-5.1 General Considerations

This section provides guidance for selecting sealing components for common applications. Each component is recommended for its suitability for the particular

(16)

application, and the selection reflects current common industry practice.

Every component has its own limited process capabilities and service life for each application in which it is used. Application characteristics such as size, speed, pressure, temperature, cycles, and cycle time help define an application envelope and will determine the suitability of a particular component. Appropriate component selection requires understanding of the application requirements and component capabilities.

In order to use the component selection guidance in this section

(a) The owner/user shall collect the required application data (e.g., Form R-1, Application Data Sheet).

(b) If the owner/user's application data fall inside the component's application envelope, then the guidance provided is valid.

(c) If the owner/user's application data fall outside the component's application envelope, then the owner/user should consult with the vendor to find the appropriate component.

SG-5.2 Process Systems

[Reserved for future content]

(16) SG-5.3 Compensial Ambient/Hot-Water Distribution Systems

The application and selection of sealing components are based on compensial water at temperatures between 68°F and 185°F (20°C and 85°C) and pressures greater than 0 psig (0 barg) up to 87 psig (6 barg). Systems may be exposed to hot-water sanitization and/or intermittent steam at up to 266°F (130°C).

These systems are typically constructed of metallic materials.

The section describing each seal type may list additional characteristics of the system and equipment necessary to ensure proper application of that component.

(a) Materials used for seals in compensial water systems shall meet the requirements of Part PM and should be appropriate for use within the general performance envelope, unless otherwise agreed to by the seal/equipment supplier and owner/user.

(b) Sealing components used in compensial water systems should be selected based on requirements for long-term seal reliability in a continuous-duty cycle.

SG-5.3.1 Static Seal Recommendations for Compensial Water Static seals used in compensial water systems shall meet the specific design requirements of SG-3.3.2.2.

(a) Specific materials (e.g., EPDM, FKM, PTFE) and material compositions within a given type used for static seals vary in performance. The owner/user should consult with the seal/equipment supplier to determine which material(s) have the best balance of properties

for their specific static application and expectations for service life.

(b) Hygienic union fitting details (e.g., torque settings, choice of clamping mechanism, alignment; see ASME B31.3, Part 335.1) significantly affect the performance and longevity of static sealing components and should be considered. For example, two-bolt high-pressure clamps are often used to secure low-pressure seals in compensial water systems. Overtightening of these clamps may damage seals and/or cause excessive intrusion (see SG-4.2).

SG-5.3.1.1 Additional Considerations

(a) Most compensial water systems are sanitized with hot water (self-sanitizing). When systems are steam-sanitized, the owner/user should consult with the static seal manufacturer to determine the appropriate materials/fittings based on operational requirements.

(b) Seals used in systems that are periodically heated for sanitization should be selected to accommodate thermal cycling.

SG-5.3.2 Valves for Compensial Water

SG-5.3.2.1 Seals for Compensial Water. A polymer seal material is acceptable provided that the manufacturer rates the seal material for the pressure and temperature limits and the material is compatible with the service stated in SG-5.3.

SG-5.3.2.2 Valve Types for Compensial Water

(a) Valves must meet the general design requirements of SG-3.3.2.3(a).

(b) Diaphragm valves, which have nonsliding seals, as designated in SG-2.3.1.2(a), (b), and (c), are preferred.

(c) Other valve types with nonsliding seals are acceptable [e.g., pinch valves designated in SG-2.3.1.8; bellows seals like those shown in Fig. SG-2.3.1.2-2, illustration (c); membrane or diaphragm seals like those shown in Fig. SG-2.3.1.2-4, illustrations (b) and (c), Fig. SG-2.3.1.2-5, or Fig. SG-2.3.1.4-1, illustration (a)].

(d) Valves with sliding seals in process contact are not acceptable (e.g., ball, butterfly, or plug valves) unless the design enables maintaining both sides of the sliding seal in a clean and sanitized condition.

(e) Valves with nonsliding and sliding seals are acceptable if only the nonsliding seal is in process contact (e.g., needle, control, or rising stem valves with O-ring seals).

SG-5.3.3 Single Mechanical Seals for Compensial Water per Paras. SG-3.3.2.4(a) and (b)

SG-5.3.3.1 Additional Application Conditions Relevant to Mechanical Seals. The fluid in contact with the mechanical seal is process compensial water during operation. The corrosive component is compensial water.

SG-5.3.3.2 Additional Equipment Characteristics Relevant to Mechanical Seals. The selections shown in SG-5.3.3.3 and SG-5.3.3.4 apply only for equipment with

- (a) shaft sizes: ≤ 2 in. (50 mm)
- (b) shaft speed: 0 RPM to 3,600 RPM
- (c) radial runout: < 0.002 in. (0.05 mm) total indicator reading (TIR)
- (d) perpendicularity of mounting flange: < 0.002 in. (0.05 mm) TIR to shaft
- (e) axial movement: < 0.005 in. (0.13 mm)

SG-5.3.3.3 Materials of Construction. Materials of construction shall comply with Part MM and/or Part PM, as appropriate.

There are two sets of conditions that should be considered for material selection in compendial water due to the tribological characteristics of the seal face pair

- (a) operating 68°F to 160°F (20°C to 71°C), steam at 266°F (130°C) and 0 RPM, and 0 psig to 87 psig (0 barg to 6 barg)

- (b) operating 68°F to 185°F (20°C to 85°C), steam at 266°F (130°C) and 0 RPM, and 0 psig to 87 psig (0 barg to 6 barg)

SG-5.3.3.4 Flush Plans. Flush Plan numbers 01, 02, 03, and 11, as defined in SG-2.3.2.4, are recommended. Compendial water is the seal face lubricant.

SG-5.4 Clean/USP Pure Steam

[Reserved for future content]

SG-5.5 CIP

[Reserved for future content]

CHAPTER 5 FABRICATION, ASSEMBLY, AND ERECTION

(16)

Part MJ Materials Joining

MJ-1 PURPOSE AND SCOPE

The purpose of this Part is to provide requirements for the joining of metallic and polymeric materials. This includes joining methods, welding procedure and performance qualifications, examination, inspection, testing, and acceptance criteria.

MJ-2 MATERIALS

MJ-2.1 Base Metals

(16) MJ-2.1.1 Stainless Steels

(a) *Austenitic Stainless Steels.* Only the austenitic stainless steel grades listed in Table MM-2.1-1 or Table MM-2.1-3 may be used for welded components, except as permitted in MM-5.1.

Weld ends that are to be autogenously welded (without filler metal or consumable inserts) shall meet the requirements of MM-5.2.1.1.

However, a process component or tube of one of the above alloys with a sulfur content either below the lower limit or above the upper limit for sulfur in MM-5.2.1.1 may be used in a welded connection, provided all of the following conditions are met:

(1) Use of the process component or tube is agreed to by the owner/user.

(2) All welds on the component or tube are internally inspected and meet the requirements of MJ-8.4.

(b) *Superaustenitic Stainless Steels.* Only the superaustenitic stainless steel grades listed in Table MM-2.1-1 or Table MM-2.1-3 may be used for welded components, except as permitted in MM-5.1.

The superaustenitic stainless steels are prone to the precipitation of undesirable secondary intermetallic phases such as sigma and chi. The cautions of MM-5.2.3 must be considered when welding superaustenitic stainless steels.

(c) *Duplex Stainless Steels.* Only the duplex stainless steel grades listed in Table MM-2.1-1 or Table MM-2.1-3

may be used for welded components, except as permitted in MM-5.1. The cautions of MM-5.2.3 must be considered when welding duplex stainless steels.

MJ-2.1.2 Nickel Alloys. Only the nickel alloys listed in Table MM-2.1-2 or Table MM-2.1-3 may be used for welded components, except as permitted in MM-5.1.

MJ-2.1.3 Copper Alloys. Only the copper alloys listed in Table MM-2.1-4 may be used for brazed systems.

MJ-2.1.4 Other Metals. Other metals (e.g., titanium, tantalum, palladium, or gold, as used in instrumentation) may be joined, when specified by the owner/user.

MJ-2.2 Filler Metals

MJ-2.2.1 Stainless Steels. When filler metals are used, the matching filler metals listed in Tables MM-5.3-1 and MM-5.3-2 shall be used, except that higher alloy filler metals may be used when specified by the owner/user. (16)

Austenitic stainless steel grades may be welded with or without filler metals. See MM-5.3 and MM-5.3.1 for further instructions.

Superaustenitic stainless steels may be welded with or without filler metals or consumable inserts. When welded autogenously (without filler metal or consumable inserts), postweld heat treatment in accordance with MM-5.4 is required. See MM-5.2.2, MM-5.3, and MM-5.3.2 for further instructions.

Duplex stainless steels may be welded with or without filler metals or consumable inserts. When welded autogenously, postweld heat treatment in accordance with MM-5.4 is required. 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. 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. See MM-5.2.3, MM-5.3, and MM-5.3.2 for further instructions.

- (16) **MJ-2.2.2 Nickel Alloys.** When filler metals are used, the matching filler metals listed in Tables MM-5.3-1 and MM-5.3-2 shall be used, except that higher alloy filler metals may be used when specified by the owner/user.

Nickel alloys may be welded with or without filler metals. Postweld solution heat treatment is not required. See MM-5.3 for further instructions.

- (16) **MJ-2.2.3 Copper Alloys.** Brazing joint filler metals shall comply with Table MM-5.3.3-1. Copper-to-copper joints shall be brazed using copper-phosphorus or copper-phosphorus-silver brazing filler metal (BCuP series) without flux.

(16) **MJ-2.3 Nonmetallics**

Joining of polymeric materials shall be performed in accordance with MJ-9. 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 JOINT DESIGN AND PREPARATION

(16) **MJ-3.1 General**

All butt joints in which one or both weld faces are process contact surfaces shall have continuous complete weld joint penetration. This requirement exists for welds made from either one side or both sides of the weld joint. All weld joints must have the process contact surfaces properly purged or protected for the prevention of discoloration or contamination. External attachments (e.g., lift lugs, dimple jackets, or ladder clips) must have any discoloration of the process 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 process contact surface, shall either be joined with a full penetration groove weld with a reinforcing fillet weld [similar to Fig. SD-3.4.2-2, illustration (a)], or have at least one telltale hole provided if double fillet welded only [similar to Fig. SD-3.4.2-2, illustration (b)]. A telltale hole is required on all lap, tee, corner, or edge joints that have one or both welds as a process contact surface and are not attached by full penetration welds. The telltale hole shall provide a path for process fluid or test media flow if the inner weld containment fails. Telltale holes are not required when all welds are on process contact surfaces [e.g., Fig. SD-3.4.3-1, illustration (c) detail or similar]. The telltale hole shall be no larger than NPS $\frac{1}{4}$ in. (6 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-3.2 Pressure Vessels and Tanks (16)

Weld joint designs shall be those permitted by ASME BPVC, Section VIII and shall comply with MJ-3.1.

MJ-3.3 Piping (16)

Weld joint designs shall be those permitted by ASME B31.3 and shall comply with MJ-3.1.

MJ-3.4 Tubing (16)

Weld 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-3-1 and DT-3-2. The butt weld joints shall be properly cleaned within $\frac{1}{2}$ 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 it must be agreed to by the owner/user and contractor.

MJ-3.5 Tube-Attachment Welds (16)

(a) Tube-attachment welds are those that

- (1) make branch connections other than those used to fabricate the fittings described in Part DT
 - (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 section include

- (1) those governed by MJ-8.4
- (2) tube-to-tubesheet welds that are governed by ASME BPVC, Section VIII, in addition to the visual inspection requirements of Part SF and MJ-8.2

These welds may be performed manually, by machine, or by an automatic welding process. Joint designs shall comply with MJ-3.1. The weld joints for complete penetration welds shall be prepared by means compatible with hygienic service. The weld joints shall be properly cleaned within $\frac{1}{2}$ in. (13 mm) on the inside and outside surfaces, where accessible, prior to welding. Fillet welds, groove welds, or a combination of both may be used.

MJ-3.6 Brazed Joints

Joint design shall comply with the latest edition of NFPA 99.

MJ-4 JOINING PROCESSES AND PROCEDURES (16)

MJ-4.1 Introduction

All welds, including tack welds, shall be made in accordance with a welding procedure qualified in accordance with MJ-5. All welders and welding operators,

including those who make tack welds, shall be qualified per MJ-6.

MJ-4.2 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 AWS A3.0. The owner/user and contractor shall agree that the welding process selected will provide the desired results.

MJ-4.3 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 AWS A3.0. Every effort shall be made to use an automatic or machine welding process. Autogenous welds, welds with filler wire, or welds with consumable inserts are acceptable 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-4.4 Brazing

Joining of copper and copper alloy materials by brazing shall be in accordance with NFPA 99. All brazing procedures shall be qualified per MJ-5. All brazers shall be qualified per MJ-6.

MJ-5 PROCEDURE QUALIFICATIONS

MJ-5.1 Pressure Vessels and Tanks

Welding procedures for pressure vessels and tanks shall be qualified in accordance with ASME BPVC, Section VIII.

MJ-5.2 Piping

Welding procedures for piping systems shall be qualified in accordance with ASME B31.3.

MJ-5.3 Tubing

Welding procedures for hygienic tubing systems shall be qualified in accordance with ASME B31.3, with the following additions:

- A change in the type or nominal composition of the backing (purge) gas shall require requalification.
- 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.

Table MJ-6.3-1 Metallic Tube/Pipe Diameter Limits for Orbital GTAW Performance Qualification (16)

Outside Diameter of Test Coupon		Outside Diameter Qualified			
		Minimum		Maximum	
in.	mm	in.	mm	in.	mm
$\leq \frac{1}{2}$	≤ 13	None	None	$\frac{1}{2}$	13
$> \frac{1}{2}$ to $3\frac{1}{2}$	> 13 to 89	$> \frac{1}{2}$	> 13	$3\frac{1}{2}$	89
$> 3\frac{1}{2}$	> 89	$> 3\frac{1}{2}$	> 89	Unlimited	Unlimited

This includes qualification of procedures for welding of components to Part DT but does not apply to longitudinal welds on tubes made in accordance with a recognized standard.

MJ-5.4 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 meet the requirements of ASTM A923 Methods A and/or C.

MJ-5.5 Brazing

Brazing procedures for piping systems shall be qualified in accordance with NFPA 99.

MJ-6 PERFORMANCE QUALIFICATIONS

MJ-6.1 Pressure Vessels and Tanks

Welder and welding operator performance qualifications for pressure vessels and tanks shall be in accordance with ASME BPVC, Section VIII.

MJ-6.2 Piping

Welder and welding operator performance qualifications for piping systems shall be in accordance with ASME B31.3. When the piping is to be used for hygienic systems, the essential variables for welding operators in MJ-6.3 shall also apply.

MJ-6.3 Tubing

Welder and welding operator performance qualifications for hygienic tubing systems shall be in accordance with ASME B31.3. This includes qualification of welders and welding operators who fabricate components in accordance with Part DT but not those who manufacture tubes in accordance with a recognized standard.

For the qualification of welding operators, the following essential variables also apply:

- welding of a joint using an edge preparation other than a square groove.
- the addition or deletion of solid backing.
- a change in the fit-up gap from that qualified.
- a change in pipe/tube diameter. See Table MJ-6.3-1.

(16) Table MJ-6.3-2 Metallic Weld Thickness Limits for Orbital GTAW Performance Qualification

Thickness of Test Coupon, <i>t</i>		Deposited Weld Thickness Qualified		
		Minimum		Maximum
in.	mm	in.	mm	
$< \frac{1}{16}$	< 1.5	t	t	$2t$
$\frac{1}{16} \leq t \leq \frac{3}{8}$	$1.5 \leq t \leq 10$	$\frac{1}{16}$	1.5	$2t$
$> \frac{3}{8}$	> 10	$\frac{3}{16}$	5	Unlimited

(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-6.3-2.

(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, either the original ASME BPVC, Section IX qualification coupon or another tube-to-tube weld coupon made by that same welding operator shall be visually examined and shall meet all the requirements of Table MJ-8.4-1.

Any change in the variables listed in MJ-6.3 requires welding of a new test coupon, for which only visual inspection in accordance with Table MJ-8.4-1 is required. Compliance with the variables in MJ-6.3 shall be documented.

MJ-6.4 Brazing

Brazer performance qualifications, for piping systems, shall be in accordance with NFPA 99 and shall be made under an internal purge and exhibit full joint penetration.

MJ-7 EXAMINATION, INSPECTION, AND TESTING

Owner/user, inspection contractor, and/or engineer shall agree to the types of examinations, inspections, and testing unless otherwise specified in the applicable code.

MJ-7.1 Examination Procedures

MJ-7.1.1 Pressure Vessels and Tanks. Examination procedures for pressure vessels and tanks shall be in accordance with ASME BPVC, Section VIII.

MJ-7.1.2 Piping. Examination procedures for piping systems shall be in accordance with ASME B31.3.

MJ-7.1.3 Tubing. Examination procedures for tubing systems shall be in accordance with ASME B31.3.

MJ-7.1.4 Tube Attachments. Examination procedures for tubing systems shall be performed in accordance with ASME B31.3.

MJ-7.1.5 Brazing. Examination procedures for brazed systems shall be in accordance with NFPA 99.

MJ-7.2 Personnel Requirements

MJ-7.2.1 Pressure Vessels and Tanks. Personnel performing examinations of pressure vessels and tanks designed to ASME BPVC, Section VIII shall meet the requirements of the appropriate section of that Code.

All inspectors shall be qualified in accordance with GR-4.1.

All Inspectors' Delegates shall meet the requirements of GR-4.2.

MJ-7.2.2 Piping. All examiners, inspectors, and Inspectors' Delegates shall be qualified in accordance with GR-4.

MJ-7.2.3 Tubing. All examiners, inspectors, and Inspectors' Delegates shall be qualified in accordance with GR-4.

MJ-7.2.4 Tube Attachments. All examiners, inspectors, and Inspectors' Delegates shall be qualified in accordance with GR-4.

MJ-7.2.5 Copper Tubing/Piping. All examiners, inspectors, and Inspectors' Delegates shall be qualified in accordance with GR-4.

MJ-7.2.6 Examination Personnel Eye Examination Requirements. Personnel performing examinations shall have eye examinations as follows:

(a) *Near Vision Acuity.* The individual shall have natural or corrected near distance acuity in at least one eye such that the individual is capable of reading a minimum of a Jaeger Number 2 or equivalent type and size letter at a distance designated on the chart but no less than 12 in. (305 mm). This test shall be administered initially and at least annually thereafter.

(b) *Color Contrast.* The individual shall demonstrate the capability of distinguishing and differentiating contrast among colors. This test shall be administered initially and, thereafter, at intervals not exceeding 3 yr.

These examinations shall be administered by an ophthalmologist, optometrist, medical doctor, registered nurse or nurse practitioner, certified physician assistant, or other ophthalmic medical personnel and shall include the state or province (or applicable jurisdictional) license number.

MJ-7.3 Examination, Inspection, and Testing Requirements

MJ-7.3.1 Pressure Vessels and Tanks

(a) *Examination.* Examinations shall be performed in accordance with the provisions of ASME BPVC,

Section VIII. In addition, all welds having a process contact surface shall be visually examined by the fabricator.

(b) *Inspection.* In addition to the inspection required by ASME BPVC, Section VIII, the owner/user or inspection contractor shall perform inspection(s) necessary to ensure compliance with this Standard as well as any additional requirements of the owner/user's specification.

(c) *Testing.* In addition to the testing required by ASME BPVC, Section VIII, the owner/user or inspection contractor shall perform testing necessary to ensure compliance with this Standard as well as any additional requirements of the owner/user's specification.

MJ-7.3.2 Piping

(a) *Examination.* Examinations shall be performed in accordance with the provisions of the specified fluid service in ASME B31.3.

(b) *Inspection.* The owner/user, inspection contractor, and/or engineer shall agree to the minimum percentage of process contact welds to be selected for borescopic or direct visual inspection, and they shall inform the installation contractor. The inspection 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 process contact surfaces on at least 20% of the welds in each system installed. A representative sample of each welder's and/or welding operator's work (as applicable) must be included.

The examination required for compliance with ASME B31.3 may be included in the minimum inspection percentage, provided those examinations were direct visual or borescopic and of the process contact surface.

(c) *Testing.* Leak testing of piping systems shall be performed in accordance with the specified fluid service requirements in ASME B31.3.

(16) MJ-7.3.3 Tubing

(a) *Examination.* Examinations shall be performed in accordance with the provisions of the specified fluid service in ASME B31.3. The external surfaces of all welds shall be visually examined.

If ASME B31.3, High Purity Fluid Service (Chapter X), is specified, radiographic, ultrasonic, or in-process examination is not required unless specified by the owner/user.

(b) *Inspection.* The owner/user, inspection contractor, and/or engineer shall agree to the minimum percentage of process contact welds to be selected for borescopic or direct visual inspection, and they shall inform the installation contractor. The inspection 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 process contact surfaces on at least 20% of the welds in each system installed. A representative sample of each welder's and/or welding operator's (as applicable) work must be included. There shall also be a plan for inspecting a representative sample of each welder's and/or welding operator's (as applicable) first shift of production. A procedure shall be submitted for inspecting blind welds. The random selection of accessible welds to be inspected shall be up to the owner/user's inspector's discretion.

The examination required for compliance with ASME B31.3 may be included in the minimum inspection percentage, provided those examinations were direct visual or borescopic and of the process contact surface.

(c) *Testing.* Leak testing of tubing systems shall be performed in accordance with the specified fluid service requirements in ASME B31.3.

MJ-7.3.4 Tube Attachments

(a) *Examination.* Examinations shall be performed in accordance with the provisions of the specified fluid service in ASME B31.3. The external surfaces of all welds shall be visually examined.

(b) *Inspection.* Visual inspection shall be performed on all process contact surfaces affected by the attachment welding.

(c) *Testing.* Testing shall be performed in conjunction with the system test.

MJ-7.3.5 Brazing

(a) *Examination.* Examinations shall be performed in accordance with NFPA 99.

(b) *Inspection.* The owner/user, inspection contractor, and/or engineer shall agree to the minimum percentage of brazed joints to be selected for direct visual inspection, and they shall inform the installation contractor. The inspection contractor shall submit an inspection plan to ensure that joints meet the acceptance criteria of this Part. A representative sample of each brazer's work must be included.

(c) *Testing.* Leak testing of copper systems shall be performed in accordance with the specified fluid service requirements in ASME B31.3.

MJ-7.4 Records

See GR-5.

MJ-8 ACCEPTANCE CRITERIA

MJ-8.1 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 process fluid. The weld shall not have any discontinuities such as cracks, voids, porosity, or joint misalignment

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that will promote contamination of the process fluid. All welding procedures shall be qualified to MJ-5.

MJ-8.2 Pressure Vessel and Tank Welds

Weld acceptance criteria for pressure vessels and tanks shall be in accordance with ASME BPVC, Section VIII, with the additional requirements of Table MJ-8.2-1.

MJ-8.3 Piping Welds

Weld acceptance criteria for piping shall be in accordance with the specified fluid service of ASME B31.3. The additional requirements of Table MJ-8.3-1 shall apply. See SD-3.1.1 for cautionary information if using pipe instead of tube for hygienic systems.

MJ-8.4 Tubing Welds

Weld acceptance criteria (including borescopic acceptance criteria) for tubing and components shall be in accordance with Table MJ-8.4-1 (see also Figs. MJ-8.4-1 through MJ-8.4-4). This includes welds on components but not longitudinal welds on tubes manufactured in accordance with a recognized standard.

Preproduction sample welds, when required, shall be submitted by the contractor to the owner/user to establish weld quality. The 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 on by the owner/user and contractor. The 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 the 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-8.4.1 Sample Welds. Sample welds for tubing shall meet all the acceptance criteria of Table MJ-8.4-1. An internal bead width of 1.0 to 2.5 times the nominal wall thickness is required.

MJ-8.4.2 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 process contact side

All rewelds shall either totally consume the original weld or overlap the original weld with no base metal between the welds.

MJ-8.5 Tube-Attachment Welds

The acceptance criteria for tube-attachment welds shall be in accordance with Table MJ-8.5-1 (see also Fig. MJ-8.5-1).

MJ-8.5.1 Sample Welds. Sample welds are not required for tube-attachment welds or seal welds.

MJ-8.5.2 Rewelding. Rewelding is allowed, except for welds that are process contact surfaces, for which the rewelding restrictions of MJ-8.4.2 apply.

MJ-8.6 Brazed Joints

Brazed joint acceptance criteria shall be in accordance with NFPA 99.

MJ-9 JOINING OF POLYMERIC MATERIALS

MJ-9.1 General

Polymeric materials are described in Part PM. All joining techniques may not be available for all polymeric materials, nor are all methods acceptable for all processes. The selection of materials of construction and joining techniques is based on application requirements.

MJ-9.2 Weld Joint Design and Preparation

The weld surfaces to be joined shall be properly aligned. This may include planing or facing of the components. The weld surfaces shall be protected against adverse environmental influences, including excessive moisture, extreme temperature conditions, excessive drafts, and contamination sources (e.g., dirt, dust, oil, foreign material shavings).

MJ-9.2.1 Tubing and Piping. Joint designs for tubing, piping, 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 for the applicable welding procedure specification (WPS).

MJ-9.3 Joining Processes and Procedures

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Tube and pipe systems composed of polymeric materials are joined by a variety of heat fusion welding methods, including beadless fusion, noncontact infrared (IR) fusion, contact butt fusion, and socket fusion. Fusion does not require solvents or glue to join material, and nothing is added or changed chemically between the two components being joined. Other joining methods may be used when agreed on by the owner/user. Joining of polymeric materials shall be performed in accordance with a documented WPS that is qualified in accordance

Table MJ-8.2-1 Visual Examination Acceptance Criteria for Welds on Metallic Pressure Vessels and Tanks (16)

Discontinuities	Welds on Process Contact Surfaces			Welds on Non-Process Contact Surfaces	
	Welds Left in the As-Welded Condition	Prior to Postweld Finishing	After Postweld Finishing	Welds Left in the As-Welded Condition	After Postweld Finishing
Cracks	None	None	None	None	None
Lack of fusion	None	None	None	None	None
Incomplete penetration	None on process contact side; otherwise, see Note (1)	None on process contact side; otherwise, see Note (1)	None on process contact side; otherwise, see Note (1)	See Notes (1) and (2)	See Notes (1) and (2)
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 (e.g., tungsten) or non-metallic]	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)
Groove weld concavity	See Note (1)	See Note (1)	Maximum of 10% of the nominal wall thickness of thinner member	See Note (1)	See Note (1)
Fillet weld convexity	$\frac{1}{16}$ in. (1.5 mm) max.	Per applicable design and fabrication code	$\frac{1}{32}$ in. (0.8 mm) max.	See Note (1)	See Note (1)
Discoloration (heat-affected zone)	Heat-affected zone (HAZ) may be permitted to have light straw to light blue color (see Figs. MJ-8.4-2 and MJ-8.4-3). 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 (3).	N/A	HAZ may be permitted to have light straw to light blue color (see Figs. MJ-8.4-2 and MJ-8.4-3). 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 (3).	Per customer specification	Per customer specification
Discoloration (weld bead)	None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (3).	N/A	None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (3).	Per customer specification	Per customer specification
Oxide island	Oxide islands are permitted as long as they are adherent to the surface. Reflective color of oxide island is not cause for rejection. Alloy types are identified in Tables MM-2.1-1, MM-2.1-2, and MM-2.1-3.	N/A	None allowed	Oxide islands permitted	Oxide islands permitted

Table MJ-8.2-1 Visual Examination Acceptance Criteria for Welds on Metallic Pressure Vessels and Tanks (Cont'd)

Discontinuities	Welds on Process Contact Surfaces			Welds on Non-Process Contact Surfaces	
	Welds Left in the As-Welded Condition	Prior to Postweld Finishing	After Postweld Finishing	Welds Left in the As-Welded Condition	After Postweld Finishing
Reinforcement	See Note (1)	See Note (1)	$\frac{1}{32}$ in. (0.8 mm) max.	See Note (1)	See Note (1)
Tack welds	See Note (1)	N/A	N/A	See Note (1)	N/A
Arc strikes	None	N/A	None	None	None
Overlap	None	None	None	None	None
Weld bead width	N/A	N/A	N/A	N/A	N/A
Minimum fillet weld size	See Note (1)	See Note (1)	See Note (1)	See Note (1)	See Note (1)
Misalignment (mismatch)	See Note (1)	See Note (1)	See Note (1)	See Note (1)	See Note (1)

NOTES:

- (1) The limits of ASME BPVC, Section VIII shall apply.
(2) Does not apply to insulation sheathing and similar welds.
(3) Welds on pressure vessels or tanks that have been in service may require unique criteria.

(16) Table MJ-8.3-1 Visual Examination Acceptance Criteria for Welds on Metallic Pipe

Discontinuities	Welds on Process Contact Surfaces			Welds on Non-Process Contact Surfaces	
	Welds Left in the As-Welded Condition	Prior to Postweld Finishing	After Postweld Finishing	Welds Left in the As-Welded Condition	After Postweld Finishing
Cracks	None	None	None	None	None
Lack of fusion	None	None	None	None	None
Incomplete penetration	None	None on process contact side; otherwise, see Note (1)	None on process contact side; otherwise, see Note (1)	See Notes (1) and (2)	See Notes (1) and (2)
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 (e.g., tungsten) 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 (1)	See Note (1)	See Note (1)	See Note (1)	See Note (1)
Fillet weld convexity	$\frac{1}{16}$ in. (1.5 mm) max.	See Note (1)	$\frac{1}{32}$ in. (0.8 mm) max.	See Note (1)	See Note (1)

Table MJ-8.3-1 Visual Examination Acceptance Criteria for Welds on Metallic Pipe (Cont'd)

Discontinuities	Welds on Process Contact Surfaces			Welds on Non-Process Contact Surfaces	
	Welds Left in the As-Welded Condition	Prior to Postweld Finishing	After Postweld Finishing	Welds Left in the As-Welded Condition	After Postweld Finishing
Discoloration (heat-affected zone)	Heat-affected zone (HAZ) may be permitted to have light straw to light blue color (see Figs. MJ-8.4-2 and MJ-8.4-3). 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 (3).	N/A [see Note (3)]	HAZ may be permitted to have light straw to light blue color (see Figs. MJ-8.4-2 and MJ-8.4-3). 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 (3).	Per customer specification	Per customer specification
Discoloration (weld bead)	None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (3).	N/A [see Note (3)]	None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (3).	Per customer specification	Per customer specification
Oxide island	Oxide islands are permitted as long as they are adherent to the surface. Reflective color of oxide island is not cause for rejection. Alloy types are identified in Tables MM-2.1-1, MM-2.1-2, and MM-2.1-3.	N/A	None allowed	Oxide islands permitted	Oxide islands permitted
Reinforcement	See Note (1)	See Note (1)	$\frac{1}{32}$ in. (0.8 mm) max.	See Note (1)	See Note (1)
Tack welds	Must be fully consumed by final weld bead	Must be fully consumed by final weld bead	Must be fully consumed by final weld bead	Per customer specification	Per customer specification
Arc strikes	None	None	None	None	None
Overlap	None	None	None	None	None
Weld bead width	N/A	N/A	N/A	N/A	N/A
Minimum fillet weld size	See Note (1)	See Note (1)	See Note (1)	See Note (1)	See Note (1)
Misalignment (mismatch)	See Notes (1) and (4)	See Notes (1) and (4)	See Notes (1) and (4)	See Notes (1) and (4)	See Notes (1) and (4)

NOTES:

- (1) The limits of ASME B31.3 shall apply.
- (2) Does not apply to insulation sheathing and similar welds.
- (3) Special surface preparation may be needed to meet the criteria. Welds on piping that has been in service may require unique criteria.
- (4) It is recognized that the I.D. misalignment is more relevant to hygienic design than O.D. misalignment. However, not all connections facilitate ready measurement of I.D. misalignment. For situations where compliance with O.D. misalignment criteria results in an I.D. misalignment that could affect drainability or cleanability, see Nonmandatory Appendix C for further details.

(16) **Table MJ-8.4-1 Visual Examination Acceptance Criteria for Groove Welds on Metallic Tube-to-Tube Butt Joints**

Discontinuities	Welds on Process Contact Surfaces	Welds on Non-Process Contact Surfaces
Cracks	None	None
Lack of fusion	None	None
Incomplete penetration	None [see Fig. MJ-8.4-1, illustration (g)]	None [see Fig. MJ-8.4-1, illustration (g)]
Porosity	None open to the surface; otherwise, see Note (1)	None open to the surface; otherwise, see Note (1)
Inclusions [metallic (e.g., tungsten) or nonmetallic]	None open to the surface; otherwise, see Note (1)	See Note (1)
Undercut	None	See Note (1)
Concavity	10% T_w max. [see Fig. MJ-8.4-1, illustration (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-3 [see Note (2)].	10% T_w max. [see Fig. MJ-8.4-1, illustration (c)] over entire circumference with up to 15% T_w permitted over a maximum of 25% of the circumference [see Note (2)]
Convexity	10% T_w max. [see Fig. MJ-8.4-1, illustration (f)] [see Note (2)]	0.015 in. (0.38 mm) max. [see Fig. MJ-8.4-1, illustration (e)] [see Note (2)]
Discoloration (heat-affected zone)	Heat-affected zone (HAZ) may be permitted to have light straw to light blue color (see Figs. MJ-8.4-2 and MJ-8.4-3). 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 (3)	Discoloration level shall be agreed on between the owner/user and contractor. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user. See Note (3)
Discoloration (weld bead)	None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (3)	Discoloration level shall be agreed on between the owner/user and contractor. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user. See Note (3)
Reinforcement	See convexity	See convexity
Tack welds	Must be fully consumed by final weld bead [see Note (4)]	Same as process contact side
Arc strikes	None	See Note (5)
Overlap	None	None
Weld bead width	No limit provided that complete joint penetration is achieved	If process contact surface cannot be inspected (such as I.D. of a tube beyond the reach of remote vision equipment), then the non-process contact surface weld bead shall be straight and uniform around the entire weld circumference [see Fig. MJ-8.4-4, illustration (a)]. The minimum weld bead width shall not be less than 50% of the maximum weld bead width [see Fig. MJ-8.4-4, illustration (b)]. The maximum weld bead mean-der shall be 25% of the weld bead width, measured as a deviation from the weld centerline, as defined in Fig. MJ-8.4-4, illustration (c).
Minimum throat	N/A	N/A
Misalignment (mis-match) [Notes (6) and (7)]	N/A [see Note (6)]	15% T_w max. [see Fig. MJ-8.4-1, 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-8.4-1, illustration (b) does not apply to 4-in. and 6-in. tube [see Notes (2) and (6)].
Oxide island	Oxide islands are permitted as long as they are adherent to the surface. Reflective color of oxide island is not cause for rejection. Alloy types are identified in Tables MM-2.1-1, MM-2.1-2, and MM-2.1-3.	Oxide islands permitted

Table MJ-8.4-1 Visual Examination Acceptance Criteria for Groove Welds on Metallic Tube-to-Tube Butt Joints (Cont'd)

GENERAL NOTE: Includes all product forms (e.g., tube, fittings, castings, forgings, and bar) whose final dimensions meet Part DT requirements.

NOTES:

- (1) The limits of ASME B31.3 shall apply.
- (2) T_w is the nominal wall thickness of the thinner of the two members being joined. Weld metal shall blend smoothly into base metal.
- (3) Welds on tubing that has been in service may require unique criteria.
- (4) Any weld that shows unconsumed tack welds on the non-process contact surface shall be inspected on the process contact surface; otherwise it is rejected. If the weld cannot be inspected on the process contact surface, rewelding per MJ-8.4.2 is not allowed. Rewelding per MJ-8.4.2 is allowed if the weld can be inspected on the process contact surface after rewelding.
- (5) Arc strikes on the non-process contact surface may be removed by mechanical polishing as long as the minimum design wall thickness is not compromised.
- (6) Note that misalignment is controlled on the O.D. and is based on allowable O.D. dimensions and tolerances of fittings and tubing. The owner/user is cautioned that this can result in greater I.D. misalignment because this also takes into consideration the wall thickness dimensions and tolerances of fittings and tubing. However, there are no specified I.D. misalignment acceptance criteria.
- (7) It is recognized that the I.D. misalignment is more relevant to hygienic design than O.D. misalignment. However, not all connections facilitate ready measurement of I.D. misalignment. For situations where compliance with O.D. misalignment criteria results in an I.D. misalignment that could affect drainability or cleanability, see Nonmandatory Appendix C for further details.

(16) **Fig. MJ-8.4-1 Acceptable and Unacceptable Weld Profiles for Groove Welds on Metallic Tube-to-Tube Butt Joints**

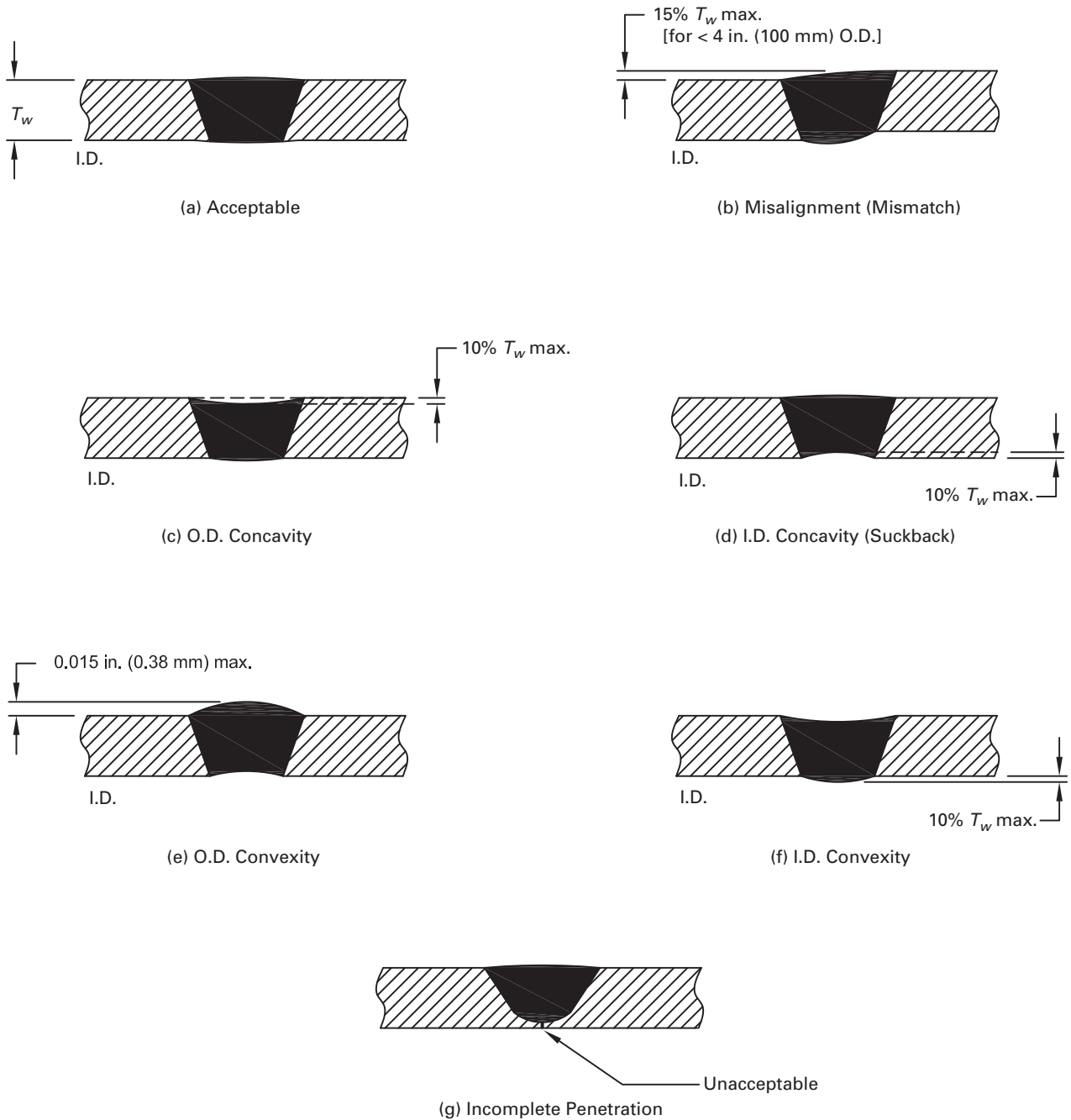
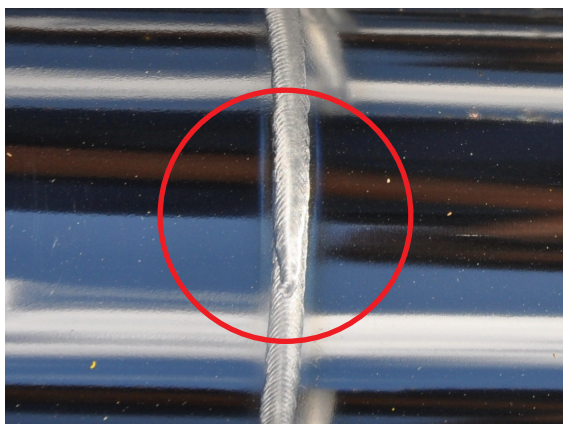
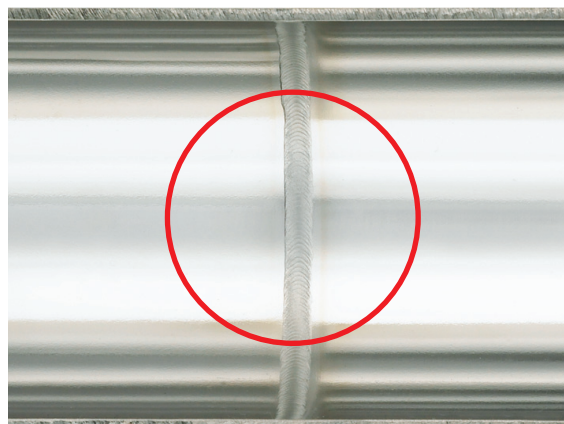


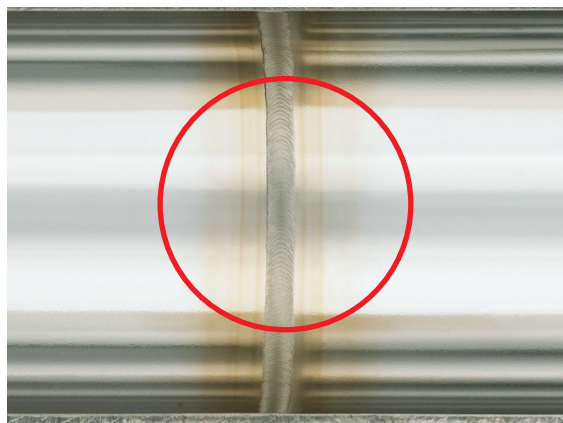
Fig. MJ-8.4-2 Discoloration Acceptance Criteria for Welds and Heat-Affected Zones on Electropolished UNS S31603 Tubing (16)



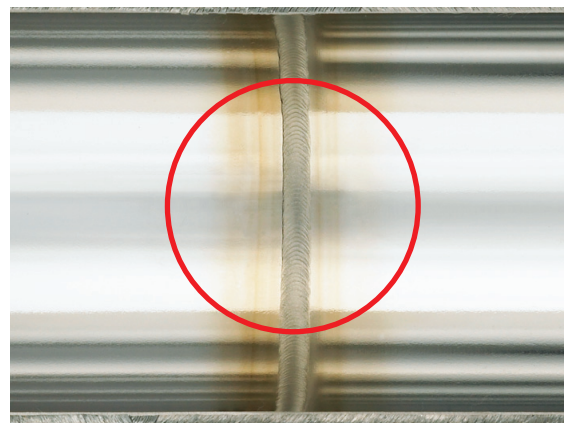
Sample #1a



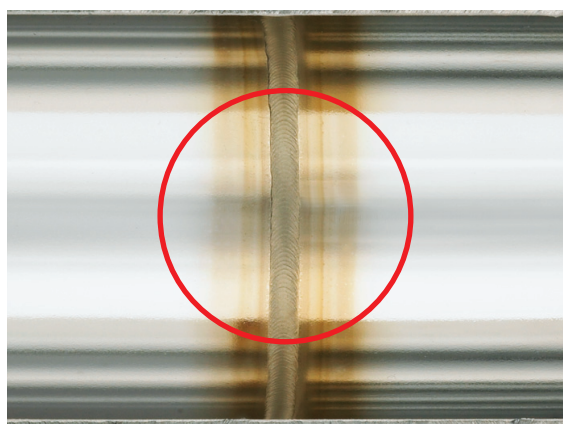
Sample #1b



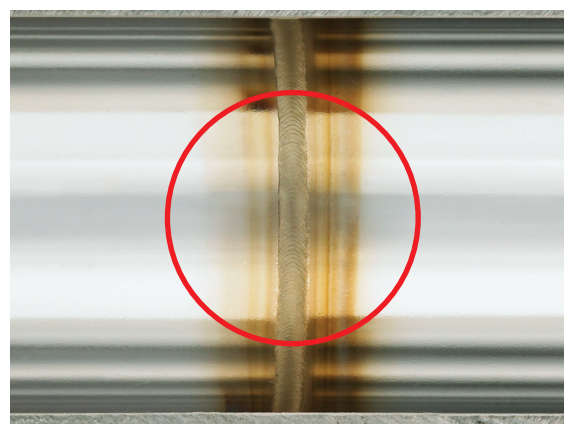
Sample #2



Sample #3



Sample #4



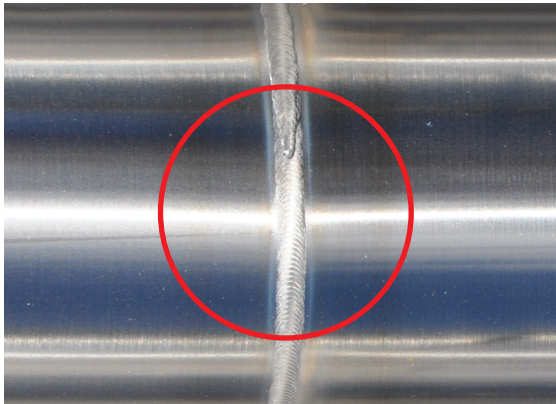
Sample #5

The weld beads shown in the above photographs are the weld beads on the I.D. of the tubing. The area for comparison in each photograph is the area inside the red circle. The weld bead shall have no discoloration. Weld heat-affected zones on electropolished UNS S31603 tubing with discoloration levels no worse than Samples #1 through #4 in the as-welded condition are acceptable. Heat-affected zone discoloration levels more severe than that shown in Sample #4 are unacceptable. Sample #5 shows unacceptable weld and heat-affected zone discoloration levels for comparison. The user is cautioned that the colors observed during direct visual examination or borescope examination will be different viewing directly down (90 deg) at the surface compared with viewing at a lower angle along the edges.

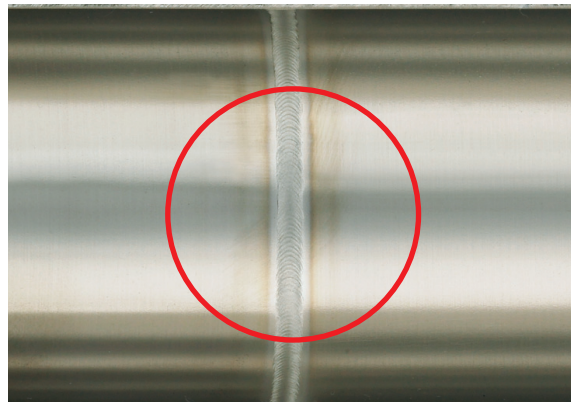
GENERAL NOTE: The user is cautioned that electronic versions or photocopies of these acceptance criteria shall not be used for evaluation of sample or production welds since subtle differences in color can influence weld acceptability. Nonmandatory Appendix M explains the technique by which these acceptance criteria were determined.

This figure is also available as a stand-alone document from ASME as ASME BPE-EP.

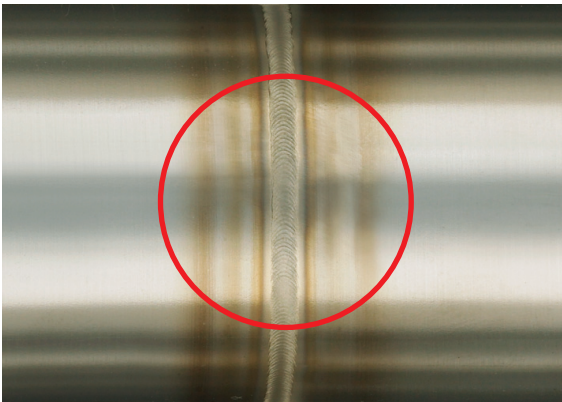
(16) **Fig. MJ-8.4-3 Discoloration Acceptance Criteria for Welds and Heat-Affected Zones on Mechanically Polished UNS S31603 Tubing**



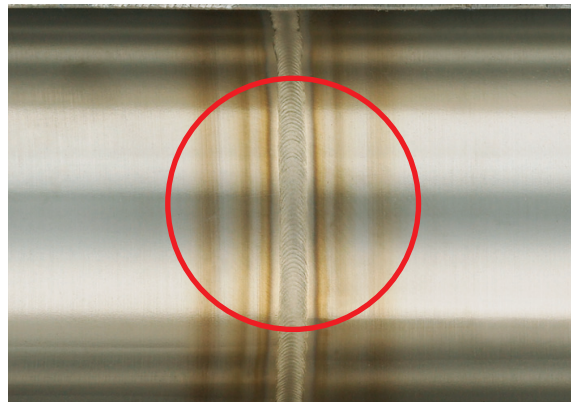
Sample #1a



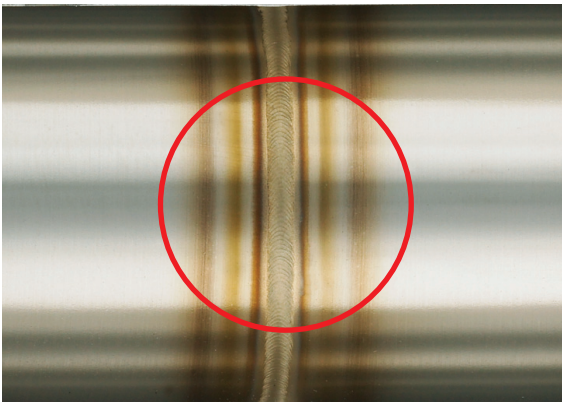
Sample #1b



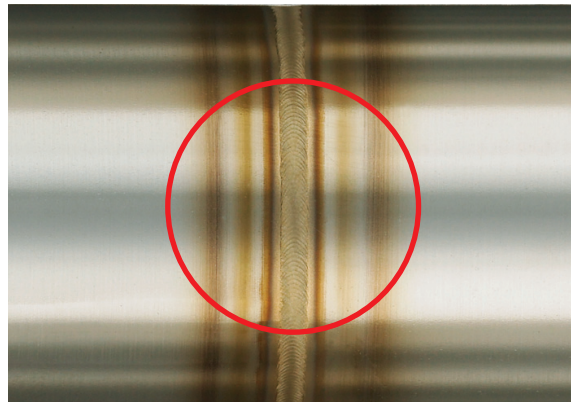
Sample #2



Sample #3



Sample #4



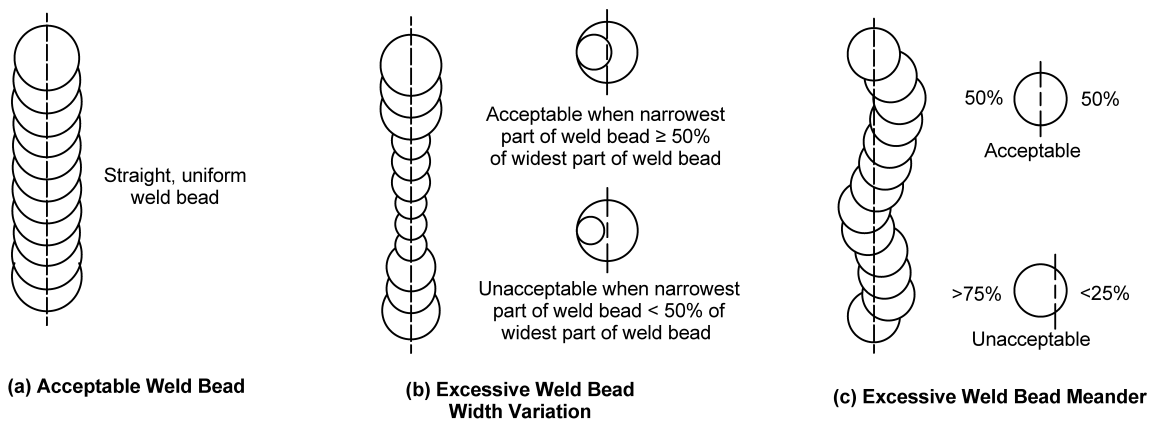
Sample #5

The weld beads shown in the above photographs are the weld beads on the I.D. of the tubing. The area for comparison in each photograph is the area inside the red circle. The weld bead shall have no discoloration. Weld heat-affected zones on mechanically polished UNS S31603 tubing with discoloration levels no worse than Samples #1 through #3 in the as-welded condition are acceptable. Heat-affected zone discoloration levels more severe than that shown in Sample #3 are unacceptable. Samples #4 and #5 show unacceptable weld and heat-affected zone discoloration levels for comparison. The user is cautioned that the colors observed during direct visual examination or borescope examination will be different viewing directly down (90 deg) at the surface compared with viewing at a lower angle along the edges.

GENERAL NOTE: The user is cautioned that electronic versions or photocopies of these acceptance criteria shall not be used for evaluation of sample or production welds since subtle differences in color can influence weld acceptability. Nonmandatory Appendix M explains the technique by which these acceptance criteria were determined.

This figure is also available as a stand-alone document from ASME as ASME BPE-MP.

Fig. MJ-8.4-4 Acceptable and Unacceptable Metallic Weld Bead Width and Meander on Non-Process Contact Surfaces of Groove Welds on Tube-to-Tube Butt Joints (16)



GENERAL NOTE: Applies only to non-process contact surfaces and only if weld on process contact surface cannot be inspected.

(16) **Table MJ-8.5-1 Visual Examination Acceptance Criteria for Metallic Tube-Attachment Welds**

Discontinuities	Groove Welds [Note (1)]		Fillet Welds	
	Welds on Process Contact Surfaces	Welds on Non-Process Contact Surfaces	Welds on Process Contact Surfaces	Welds on Non-Process Contact Surfaces
Cracks	None	None	None	None
Lack of fusion	None	None	None	None
Incomplete penetration	None	None	N/A	N/A [see Note (2)]
Porosity	None open to the surface; otherwise, see Note (3)	None open to the surface; otherwise, see Note (3)	None open to the surface; otherwise, see Note (3)	None open to the surface; otherwise, see Note (3)
Inclusions [metallic (e.g., tungsten) or nonmetallic]	None open to the surface	None open to the surface	None open to the surface	None open to the surface
Undercut	None	See Note (3)	None, see Note (4). [For autogenous fillet welds see Fig. MJ-8.5-1, illustration (c)]	See Notes (3) and (5). [For autogenous fillet welds see Fig. MJ-8.5-1, illustration (c)]
Concavity	10% T_w max. [see Fig. MJ-8.4-1, 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-3 [see Note (6)].	10% T_w [see Fig. MJ-8.4-1, illustrations (c) and (d)] over entire circumference with up to 15% T_w permitted over a maximum of 25% of the circumference [see Note (6)]	N/A [see Fig. MJ-8.5-1, illustrations (a) and (c), and Note (4)]	N/A [see Fig. MJ-8.5-1, illustrations (a) and (c), and Note (5)]
Convexity	10% T_w max.	0.015 in. (0.38 mm) max. and Note (3)	10% T_w max. [see Fig. MJ-8.5-1, illustration (b) and Note (6)]	N/A
Discoloration (heat-affected zone)	Heat-affected zone (HAZ) may be permitted to have light straw to light blue color (see Figs. MJ-8.4-2 and MJ-8.4-3). 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 (7)	Discoloration level shall be agreed on between the owner/user and contractor. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user. See Note (7)	HAZ may be permitted to have light straw to light blue color (see Figs. MJ-8.4-2 and MJ-8.4-3). 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 (7)	Discoloration level shall be agreed on between the owner/user and contractor. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user. See Note (7)
Discoloration (weld bead)	None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (7)	Discoloration level shall be agreed on between the owner/user and contractor. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user. This criterion does not apply to oxide islands visible on weld bead. See Note (7)	None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (7)	Discoloration level shall be agreed on between the owner/user and contractor. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user. This criterion does not apply to oxide islands visible on weld bead. See Note (7)

Table MJ-8.5-1 Visual Examination Acceptance Criteria for Metallic Tube-Attachment Welds (Cont'd)

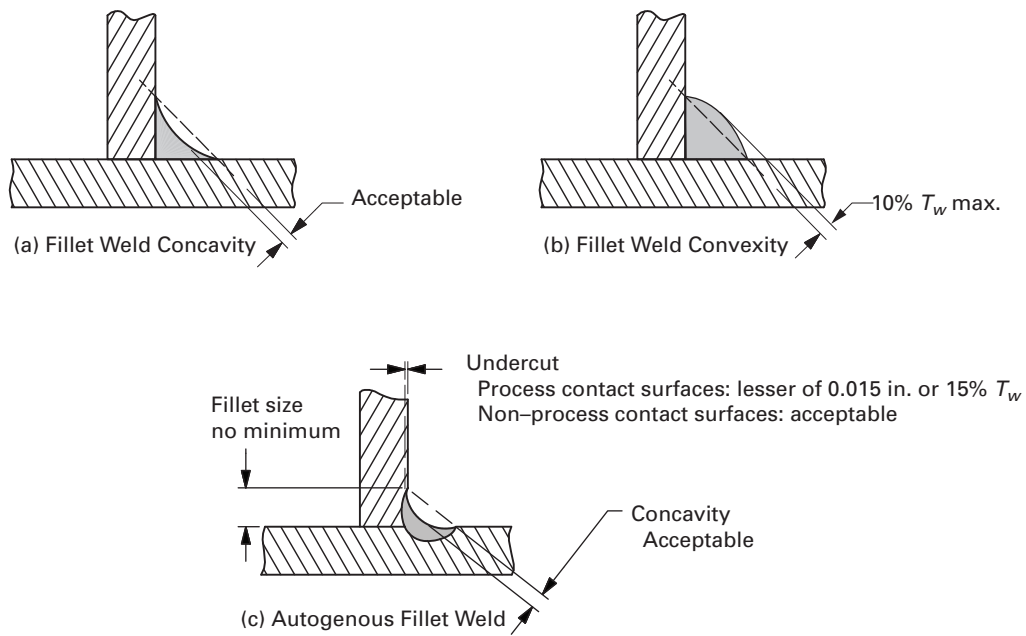
Groove Welds [Note (1)]			Fillet Welds	
Discontinuities	Welds on Process Contact Surfaces	Welds on Non-Process Contact Surfaces	Welds on Process Contact Surfaces	Welds on Non-Process Contact Surfaces
Oxide island	Oxide islands are permitted as long as they are adherent to the surface. Reflective color of oxide island is not cause for rejection. Alloy types are identified in Tables MM-2.1-1, MM-2.1-2, and MM-2.1-3.	Oxide islands permitted	Oxide islands are permitted as long as they are adherent to the surface. Reflective color of oxide island is not cause for rejection. Alloy types are identified in Tables MM-2.1-1, MM-2.1-2, and MM-2.1-3.	Oxide islands permitted
Reinforcement	See convexity	See convexity	N/A	N/A
Tack welds	Must be fully consumed by final weld bead; see Note (8)	Must be fully consumed by final weld bead; see Note (9)	Must be fully consumed by final weld bead; see Note (8)	Must be fully consumed by final weld bead; see Note (9)
Arc strikes	None	See Note (10)	None	See Note (10)
Overlap	None	None	None	None
Weld bead width	N/A	N/A	N/A	N/A
Minimum fillet weld size	N/A	N/A	Per client specification and Note (4). [For autogenous fillet welds see Fig. MJ-8.5-1, illustration (c)]	Per client specification and Note (5). [For autogenous fillet welds see Fig. MJ-8.5-1, illustration (c)]
Misalignment (mismatch)	N/A as long as other conditions are met	N/A as long as other conditions are met	N/A	N/A

GENERAL NOTE: Tube attachment welds include groove welds and fillet welds in various joint configurations, such as proximity stems on jumpers on transfer panels, transfer panel nozzles, and locator pins on sprayballs.

NOTES:

- (1) Any weld where penetration is required into the joint.
- (2) Penetration to the process contact surfaces is neither required nor prohibited. Welds that penetrate through to the process contact surface may exhibit intermittent penetration. Weld penetration through to the process contact surface must meet all other process contact surface requirements of this table.
- (3) The limits of ASME B31.3 shall apply.
- (4) For welds designated by the owner/user as autogenous fillet welds (seal welds), there is no minimum fillet weld size or throat. Concavity requirements are not applicable. Undercut in process contact surfaces shall not exceed the lesser of 0.015 in. or 15% T_w and shall have a smooth transition between weld and base metal.
- (5) For welds designated by the owner/user as autogenous fillet welds (seal welds), there is no minimum fillet weld size or throat. Concavity and undercut requirements are not applicable.
- (6) T_w is the nominal thickness of the thinner of the two members being joined. Weld metal must blend smoothly into base metal.
- (7) Welds on tube attachments that have been in service may require unique criteria.
- (8) Rewelding per MJ-8.5-2 is allowed.
- (9) Any weld showing unconsumed tack weld(s) on the non-process contact surface can be rewelded per MJ-8.5-2 if the process contact surface can be reinspected. Otherwise, it is rejected.
- (10) Arc strikes on the non-process contact surface may be removed by mechanical polishing as long as the minimum design wall thickness is not compromised.

(16) **Fig. MJ-8.5-1 Acceptable Weld Profiles for Metallic Tube-Attachment Fillet Welds**



with MJ-9.4. The owner/user, contractor, and manufacturer shall agree that the welding process selected will provide the desired results.

- (16) **MJ-9.3.1 Beadless Welding.** Beadless welding (a material-dependent process) shall be used where drainability is required (see Fig. MJ-9.7.1-1) (reference SD-2.4.3).

MJ-9.3.1.1 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.

- (16) **MJ-9.3.2 Noncontact IR and Contact Butt Fusion Welding.** Noncontact infrared and contact butt fusion are not suitable joining processes for systems requiring drainability. Either may be acceptable for single-use applications. Refer to the WPS or manufacturer's written procedures.

- (16) **MJ-9.3.3 Socket Fusion Welding.** Socket fusion is not suitable for systems requiring drainability. Socket fusion may be acceptable for single-use applications where approved by the owner/user for the intended service. Refer to the WPS or manufacturer's written procedures.

- (16) **MJ-9.4 Procedure Qualifications**

Welding procedures shall be qualified in accordance with AWS B2.4. A WPS shall be provided for each polymeric material and process being used. Environmental condition recommendations shall be included in the WPS.

MJ-9.5 Performance Qualifications

Welder and welding operator performance qualifications shall be in accordance with AWS B2.4. The quality of polymeric weld joints depends on the qualification of the welders and welding operators, the suitability of the equipment used, environmental influences, and adherence to the applicable WPS. Welders and welding operators shall be trained and possess a valid qualification certificate from the manufacturer for the process and material being welded.

MJ-9.6 Examination, Inspection, and Testing

Examination, inspection, and testing criteria and methods are dictated by material type and joining method. The owner/user, inspection contractor, and/or engineer shall agree to the types of examinations, inspections, and testing unless otherwise specified in the applicable code.

MJ-9.6.1 Examination Procedures. Written visual examination procedures shall be used.

MJ-9.6.2 Personnel Requirements

MJ-9.6.2.1 Personnel Qualifications. All examiners, inspectors, and Inspectors' Delegates shall be qualified in accordance with GR-4 and shall be trained and possess a valid qualification certificate from the manufacturer for the process and material being welded.

MJ-9.6.2.2 Examination Personnel Eye Examination Requirements. Personnel performing examinations shall have eye examinations as follows:

(a) *Near Vision Acuity.* The individual shall have natural or corrected near distance acuity in at least one eye such that the individual is capable of reading a minimum of a Jaeger Number 2 or equivalent type and size letter at a distance designated on the chart but no less than 12 in. (305 mm). This test shall be administered initially and at least annually thereafter.

(b) *Color Contrast.* The individual shall demonstrate the capability of distinguishing and differentiating contrast among colors. This test shall be administered initially and, thereafter, at intervals not exceeding 3 yr.

These examinations shall be administered by an ophthalmologist, optometrist, medical doctor, registered nurse or nurse practitioner, certified physician assistant, or other ophthalmic medical personnel and shall include the state or province (or applicable jurisdictional) license number.

MJ-9.6.3 Examination, Inspection, and Testing Requirements

MJ-9.6.3.1 Examination. Examinations shall be performed in accordance with the provisions of the specified fluid service in ASME B31.3.

The external surfaces of all welds shall be visually examined. If ASME B31.3, High Purity Fluid Service (Chapter X), is specified, radiographic, ultrasonic, or in-process examination is not required unless specified by the owner/user.

Preproduction sample welds, when required, shall be submitted by the contractor to the owner/user to establish weld quality. The 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 on by the owner/user and contractor. The 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 welder and/or welding operator (as applicable) and welding equipment.

The sample welds described in the preceding paragraphs, and any associated welding machine printed records (e.g., welding parameter printouts directly from the 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.

- (16) **MJ-9.6.3.2 Inspection.** The owner/user, inspection contractor, and/or engineer shall agree to the minimum percentage of process contact welds to be selected for borescopic or direct visual inspection, and they shall inform the installation contractor. The inspection 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 process contact surfaces or visual inspection with light illumination of the weld cross sections on at least 20% of the welds in each system installed. A representative sample of each welder's and/or welding operator's (as applicable) work shall be included. There shall also be a plan for inspecting a representative sample of each welder's and/or welding operator's (as applicable) first shift of production. A procedure shall be submitted for inspecting blind welds. The random selection of accessible welds to be inspected shall be up to the owner/user's inspector's discretion.

The examination required for compliance with ASME B31.3 may be included in the minimum inspection percentage, provided those examinations were direct visual or borescopic and of the process contact surface.

MJ-9.6.3.3 Testing. Hydrostatic leak testing shall be performed in accordance with the specified fluid service requirements in ASME B31.3. Hydrostatic leak testing shall never exceed the manufacturer's rating of the system installed.

The use of pneumatic testing is not recommended on these systems.

MJ-9.6.4 Records. See GR-5.

MJ-9.7 Weld Acceptance Criteria

Common visual acceptance criteria include complete bonding of joining surface, straight and aligned joints, and exclusion of dirt and foreign substances in the weld zone.

- (16) **MJ-9.7.1 Acceptance Criteria for Beadless Welds.**

An acceptable beadless weld is shown in Fig. MJ-9.7.1-1, illustration (a). Weld acceptance criteria shall be in accordance with the following:

(a) *Cracks and Crevices.* Any crack or crevice would generally indicate lack of full penetration welds. Internal or external cracks or crevices shall not be permitted in the weld zone [see Fig. MJ-9.7.1-1, illustration (b)].

(b) *Pits and Pores.* Pits and pores shall not be present in the weld zone on the interior surface [see Fig. MJ-9.7.1-1, illustration (c)].

(c) *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.

(1) The maximum single void diameter shall be 10% of nominal wall thickness.

(2) The maximum total for all void diameters in a given cross-sectional examination shall be 10% of nominal wall thickness [see Fig. MJ-9.7.1-1, illustration (d)].

(d) *Fit-Up and Mismatch.* Components shall be aligned so as to prevent holdup that would contribute to contamination of the process fluid. The maximum misalignment is 10% of nominal wall thickness [see Fig. MJ-9.7.1-1, illustration (e)]. It is not recommended to join components of different wall thicknesses.

(e) *Inclusions.* Any dark, visible inclusion(s) or speck(s) on the process contact surface of the weld zone are considered foreign materials and are not acceptable [see Fig. MJ-9.7.1-1, illustration (f)].

(f) *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 on the surface or at the weld interface could indicate improper cleaning or joint preparation and is rejectable [see Fig. MJ-9.7.1-1, illustration (g)].

(g) *Concavity.* Maximum inside diameter (I.D.) concavity shall be limited to 10% of the nominal wall thickness [see Fig. MJ-9.7.1-1, illustration (h)].

MJ-9.7.2 Acceptance Criteria for Nonbeadless Welds. Acceptance criteria for nonbeadless welds in piping shall be in accordance with AWS G1.10M or DVS 2202-1.

MJ-9.7.3 Acceptance Criteria for Sample Welds.

Sample welds shall meet all the acceptance criteria of MJ-9.7.1.

MJ-9.7.4 Rewelding. Rewelding is not allowed.

MJ-9.8 Documentation Requirements

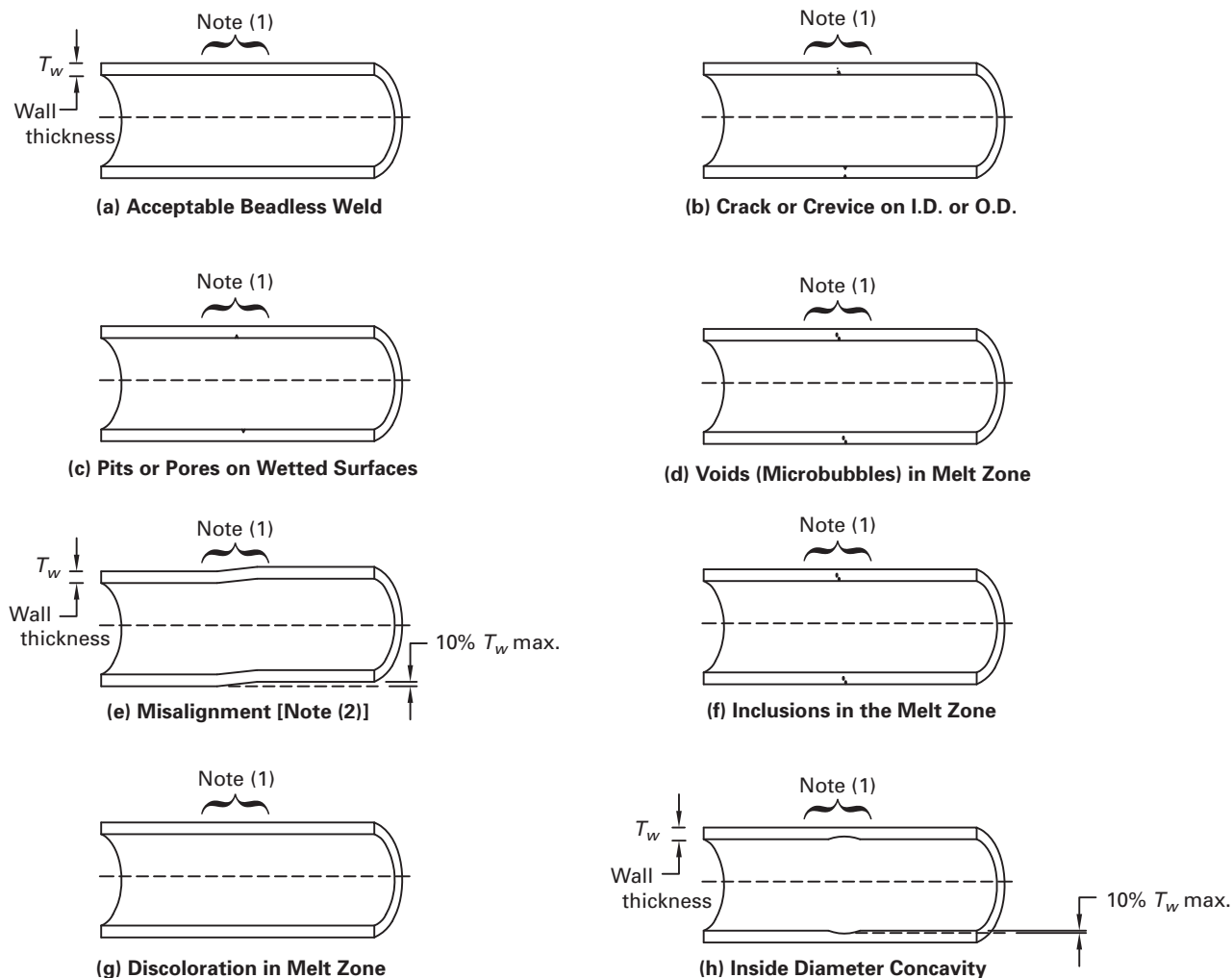
(16)

The following documentation shall be presented to the owner/user or their designee, as a minimum:

(a) *Welding Documentation.* Welding procedure specifications (WPSs) used, their procedure qualification records (PQRs), and welder performance qualifications (WPQs)/performance qualification test records (PQTRs) and/or welding operator performance qualifications (WOPQs).

(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 and/or welding operator identification of each weld shall be provided either on the weld map or on the inspection log.

Fusion equipment that electronically stores welding histories and serializes welds should be used. Welding history shall be turned over, in printed or electronic

Fig. MJ-9.7.1-1 Acceptable and Unacceptable Weld Profiles for Polymeric Beadless Welds**NOTES:**

- (1) Weld examination area: melt zone (area that was supported during fusion).
- (2) Note that misalignment is controlled on the O.D. and is based on allowable O.D. dimensions and tolerances of fittings and piping. The owner/user is cautioned that this can result in greater I.D. misalignment because this also takes into consideration the wall thickness dimensions and tolerances of fittings and piping. However, there are no specified I.D. misalignment acceptance criteria.

format, to the owner/user on completion of work and as part of the installation qualification (IQ) process.

(c) *Materials.* All molded fittings, molded valves, and extruded piping shall be intrinsically identified to provide, as a minimum, material of construction, lot number, and date of production to ensure traceability. Certificates of Compliance shall be provided for molded/extruded components not individually labeled.

(d) *Testing Records.* Other records (e.g., pressure test, surface finish) shall be provided as required by the owner/user.

MJ-10 DOCUMENTATION REQUIREMENTS

The requirements for metallic materials and weld documentation are listed in GR-5. For polymeric materials, see MJ-9.8.

MJ-11 PASSIVATION

Refer to SD-3.1.2.3(i).

Part SF

Process Contact Surface Finishes

SF-1 PURPOSE AND SCOPE

The purpose of this Part is to provide process contact surface finish acceptance criteria for metallic and polymeric materials.

SF-2 METALLIC APPLICATIONS

SF-2.1 Applicable Systems

This Part shall be applicable to all systems designated by the owner/user or representative thereof.

Process 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-2.2 Acceptance Criteria

Acceptance criteria, for common austenitic stainless steels as per Table MM-2.1-1, are listed in Tables SF-2.2-1 and SF-2.2-2. Acceptance criteria for other alloys as described in Part MM may differ and should be mutually agreed on by both the owner/user and supplier prior to ordering material. Visual comparison charts or samples may be used to define acceptable and/or unacceptable process contact surfaces.

SF-2.3 Examination Techniques Employed in the Classification of Process Contact Surface Finishes

Process contact surface finish examinations shall be made by one or more of the following methods:

- (a) visual examination
 - (1) direct visual examination
 - (2) indirect visual examination (e.g., borescopes, mirrors)
- (b) liquid penetrant testing
- (c) surface roughness measurement device (profilometer)

Acceptance criteria for metallic process contact surface finishes are shown in Table SF-2.2-1.

Acceptance criteria for electropolished metallic process contact surface finishes shall meet requirements

shown in Table SF-2.2-2 in addition to those shown in Table SF-2.2-1.

Visual examination shall be performed in accordance with examination requirements in BPVC, Section V, Article 9, Visual Examination. The same techniques shall be used for both examinations and inspections.

SF-2.4 Surface Condition

(16)

Process contact surfaces shall be finished using mechanical polishing, cold working, machining, passivation, or electropolishing processes in conformance with applicable sections of this Part. When required by the owner/user, the electropolishing or passivation contractors shall qualify their procedures in accordance with the appropriate appendices as referenced in this Part. All surfaces shall be clean. Some finishing methods may result in a variance in luster that is acceptable if the surface roughness values meet the requirements in Table SF-2.4-1. Buffing to produce a high gloss or mirror finish is unacceptable as a final surface finish on any process contact surface. Cleanliness applies to finished components/equipment as produced and packaged by the manufacturer. Subsequent shipping, storage, handling, and/or installation may affect the cleanliness, and it will become a contractual issue between owner/user and manufacturer/service provider.

SF-2.5 Electropolishing Procedure Qualification

Electropolishing service providers shall maintain and implement a quality assurance/control program for 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 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.

SF-2.6 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

Table SF-2.2-1 Acceptance Criteria for Metallic Process Contact Surface Finishes**(16)**

Anomaly or Indication	Acceptance Criteria
Pits	If diameter <0.020 in. (0.51 mm) and bottom is shiny [Notes (1) and (2)]. Pits <0.003 in. (0.08 mm) diameter are irrelevant and acceptable.
Cluster of pits	No more than 4 pits per 0.5 in. (13 mm) × 0.5 in. (13 mm) inspection window. The cumulative total diameter of all relevant pits shall not exceed 0.040 in. (1.02 mm).
Dents	None accepted [Note (3)]
Finishing marks	If R_a max. is met
Welds	Welds used in the as-welded condition shall meet the requirements of MJ-8. Welds finished after welding shall be flush with the base metal, and concavity and convexity shall meet the requirements of MJ-8. Such finishing shall meet the R_a requirements of Table SF-2.4-1.
Nicks	None accepted
Scratches	For tubing, if cumulative length is <12.0 in. (305 mm) per 20 ft (6.1 m) tube length or prorated and if depth is <0.003 in. (0.08 mm) For fittings, valves, and other process components, if cumulative length is <0.25 in. (6.4 mm), depth <0.003 in. (0.08 mm), and R_a max. is met For vessels, if length <0.50 in. (13 mm) at 0.003 in. (0.08 mm) depth and if <3 per inspection window [Note (4)]
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-2.4-1
Weld slag	For tubing, up to 3 per 20 ft (6.1 m) 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-8 and Table MJ-8.4-1)
Porosity	None open to the surface

GENERAL NOTE: This table covers surface finishes that are mechanically polished or any other finishing method that meets the R_a max.

NOTES:

- (1) Black bottom pit of any depth is not acceptable.
- (2) Pits in superaustenitic and nickel alloys may exceed this value. Acceptance criteria for pit size shall be established by agreement between owner/user and supplier. All other pit criteria remain the same.
- (3) For vessels, dents in the area covered by and resulting from welding dimple heat transfer jackets are acceptable.
- (4) An inspection window is defined as an area 4 in. × 4 in. (100 mm × 100 mm).

(16) **Table SF-2.2-2 Additional Acceptance Criteria for Electropolished Metallic Process Contact Surface Finishes**

Anomaly or Indication	Acceptance Criteria
Blistering	None accepted
Cloudiness	Acceptable if R_a is met
End grain effect	Acceptable if R_a max. is met
Fixture marks	Acceptable if electropolished
Haze	Acceptable if R_a is met
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
Variance in luster	Acceptable if R_a max. is met

Table SF-2.4-1 R_a Readings for Metallic Process Contact Surfaces

Surface Designation	Mechanically Polished [Note (1)]	
	R_a Max.	
	$\mu\text{in.}$	μm
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.	
	$\mu\text{in.}$	μm
SF4	15	0.38
SF5	20	0.51
SF6	25	0.64

GENERAL NOTES:

- (a) All R_a readings are to be in accordance with ASME B46.1.
- (b) All R_a readings are taken across the lay, wherever possible.
- (c) No single R_a reading shall exceed the R_a max. value in this table.
- (d) Other R_a readings are available if agreed on between the owner/user and supplier, not to exceed values in this table.

NOTE:

- (1) Or any other finishing method that meets the R_a max.

Table SF-2.6-1 Acceptance Criteria for Metallic Passivated Process Contact Surface Finishes

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-8.2-1 through MJ-8.5-1)
Visible construction debris	None accepted
Visible oils or organic compounds	None accepted

GENERAL NOTES:

- (a) Surface condition must meet Tables SF-2.2-1 and/or SF-2.2-2, as applicable.
 (b) Additional tests/acceptance criteria may be selected from Table E-5-1 in Nonmandatory Appendix E.

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 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 process contact surfaces, the acceptance criteria in Table SF-2.6-1 apply in addition to Table SF-2.2-1 and/or Table SF-2.2-2, as applicable. Tests to ensure the presence of a passive layer shall be agreed to between the owner/user and contractor.

SF-2.7 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.

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

Publisher: The American Society of Mechanical Engineers (ASME), Two Park Avenue, New York, NY 10016-5990 (www.asme.org)

ISO 3274, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Nominal characteristics of contact (stylus) instruments

ISO 4287, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters

ISO 4288, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture

ISO 11562, Geometrical Product Specifications (GPS) — Surface texture: Profile method — Metrological characteristics of phase correct filters

Publisher: International Organization for Standardization (ISO), Central Secretariat, Chemin de Blandonnet 8, Case Postale 401, 1214 Vernier, Geneva, Switzerland (www.iso.org)

SF-2.8 Rouge and Stainless Steel

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 on

(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 conditions the system is exposed to (e.g., water purity, process chemicals, temperatures, pressures, mechanical stresses, flow velocities, and concentration of dissolved gases, such as oxygen or carbon dioxide)

(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 provides the methods to measure rouge in a system both in the process solution and on the actual process contact surface. It also suggests various fabrication and operation practices to minimize rouge formation and methods/techniques for its remediation. See the definition of rouge in GR-8.

For more information, refer to the ISPE Water and Steam Systems Baseline® Pharmaceutical Engineering Guide.

Table SF-3.3-1 Acceptance Criteria for Polymeric Process Contact Surface Finishes

Anomaly or Indication	Acceptance Criteria
Scratches	For rigid tubing/piping, if cumulative length is <12.0 in. (305 mm) per 20 ft (6.1 m) tube/pipe length or prorated and if depth <0.003 in. (0.08 mm) For other process components, surface finish must be agreed on by supplier and owner/user
Surface cracks	None accepted
Surface inclusions	None accepted
Surface roughness, R_a	See Table SF-3.4-1

GENERAL NOTE: All process contact surface finishes shall be defined by the owner/user and supplier using the criteria described in SF-1.

SF-3 POLYMERIC APPLICATIONS

SF-3.1 Applicable Systems

This section shall be applicable to all systems designated by the owner/user or representative thereof.

Process 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-3.2 Materials

The preferred materials of construction for these systems shall be as described in PM-2.

SF-3.3 Examination Techniques Employed in the Classification of Process Contact Surface Finishes

Process contact surface finish inspections shall be made by one or more of the following methods:

(a) visual inspection

(1) direct visual examination (e.g., illumination through pipe/tube wall)

(2) indirect visual examination (e.g., borescopes, mirrors)

(b) surface roughness measurement device: profilometer or other surface measurement devices

Acceptance criteria of polymeric process contact surface finishes are shown in Table SF-3.3-1.

Visual examination 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.

The same techniques shall be used for both examinations and inspections.

SF-3.4 Surface Condition

The following surface finishes of polymeric 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 used terms and may not be applicable in all cases. The final criteria shall be determined by the R_a values shown in Table SF-3.4-1.

Table SF-3.4-1 R_a Readings for Polymeric Process Contact Surfaces

Surface Designation	R_a max.	
	μ in.	μ m
SFP0	No finish requirement	No finish requirement
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:

(a) No single R_a reading shall exceed the R_a max. value in this table.

(b) Other R_a readings are available if agreed on between owner/user and supplier, not to exceed values in this table.

CHAPTER 6 CERTIFICATION

(16)

Part CR Certification Requirements

(16)

CR-1 PURPOSE AND SCOPE

Part CR and ASME CA-1, Conformity Assessment Requirements, together establish requirements for organizations providing components in accordance with the BPE Standard to obtain a Certificate of Authorization and the ASME Certification Mark (see Fig. CR-1-1). This is a voluntary certification program.

NOTE: Administrative requirements pertaining to the obtainment of an ASME Certificate of Authorization for the application of the ASME Certification Mark on BPE components in Part CR have been relocated to ASME CA-1.

In Part CR, the term “components” shall be limited to tubing and fittings.

CR-2 GENERAL

(a) An organization providing components meeting the requirements of this Standard is issued a Certificate of Authorization and the ASME Certification Mark on successful completion of a survey and approval by ASME. Certificate Holders maintain certification through audits and renew certification of an existing certificate number through a renewal survey. All surveys and audits are performed by ASME to determine the

adequacy of the quality management system and to verify the organization’s knowledge, understanding, and capabilities of providing a component in conformance with the BPE Standard under the organization’s Quality Management System (QMS).

(b) Figure CR-2-1 provides a graphic of several acceptable certification methodologies for companies with one or more facilities. A corporate QMS manual may be used at various facilities that operate under the same company name, or each facility may operate under its own QMS manual. Should a corporate program be developed and used at various facilities, a Corporate Certificate of Authorization will be issued to the location where the corporate QMS is controlled, established, maintained, and approved for issuance and use. For each facility where the corporate QMS is being implemented, surveys and audits will be conducted, and a Certificate of Authorization will be issued at each facility. The Corporate Certificate of Authorization will be issued a certificate number. The Certificate of Authorization will have the same certificate number as the Corporate Certificate of Authorization; however, it will be followed by a dash number. Each Certificate of Authorization will be issued in sequential numerical order.

EXAMPLE:

Corporate Certificate of Authorization number: BPE-100
Certificate of Authorization, Facility #1: BPE-100-1
Certificate of Authorization, Facility #2: BPE-100-2
Certificate of Authorization, Facility #3: BPE-100-3

A Certificate of Authorization authorizes the use of the ASME Certification Mark. A Corporate Certificate of Authorization does not authorize the use of the Certification Mark; therefore, the ASME Certification Mark will not be issued with a Corporate Certificate of Authorization.

(c) 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 the products stamped with the ASME Certification Mark and

Fig. CR-1-1 ASME Certification Mark With BPE Designator

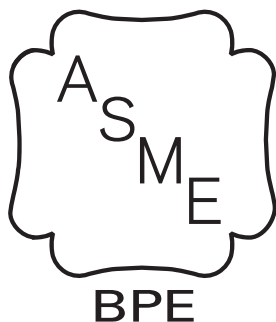
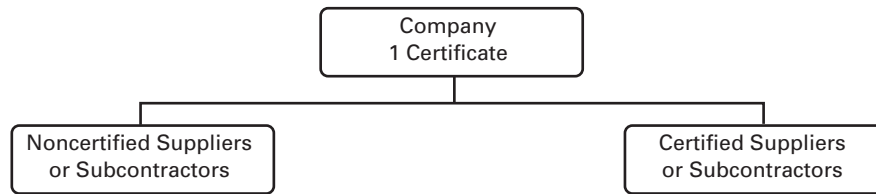


Fig. CR-2-1 Options for Certification of Organizations

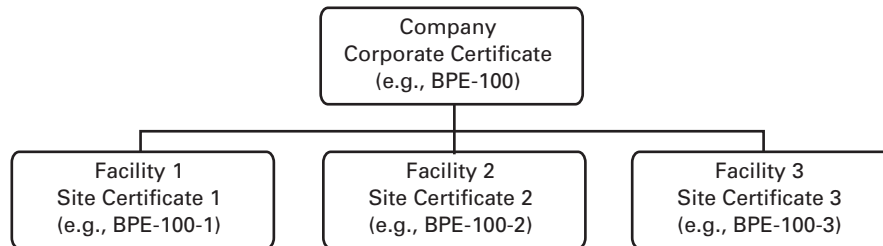
1. One company that purchases raw materials or products from either certified suppliers or subcontractors or noncertified subcontractors (where only the final company is certified).



2. One company with only one facility.



3. One company with numerous facilities — one certificate covering all facilities.



BPE Designator meet the requirements on which the certification is based.

CR-2.1 ASME BPE Certificate Holders

(a) An ASME BPE Certificate Holder has a Quality Management System that has been reviewed and accepted by ASME and has demonstrated its capability to fulfill the requirements of this Standard for the scope of work identified on the Certificate of Authorization. The Certificate Holder is authorized under a valid Certificate of Authorization to mark components, and/or documentation traceable to the components, in conformity with this Standard with the ASME Certification Mark.

(b) Certificate Holders are issued a certificate number to be used to attest to the validity of their certification on data reports and/or certificates of conformance.

(c) Written references indicating that an organization is a Certificate Holder are not valid without reference to the certificate number.

CR-2.2 ASME BPE Certificate Holder's Responsibilities

The responsibilities of the Certificate Holder include the following:

- (a) obtaining a BPE Certificate of Authorization.

(b) compliance with the latest edition of ASME CA-1 as applicable to the BPE Certification Program.

(c) compliance with all requirements of this Standard, as applicable, for the scope of work identified on the BPE Certificate of Authorization.

(d) establishing and maintaining a Quality Management System under Part CR of this Standard.

(e) documenting a Quality Management System.

(f) filing a control copy of the Quality Management System manual with ASME. The QMS manual shall provide a detailed description of the items and services that are being provided under the company's ASME BPE Certificate of Authorization.

(g) preparing procedures, work instructions, forms, and other implementing documents used under the Quality Management System.

(h) ensuring that the BPE Designator is used in conjunction with the ASME Certification Mark.

(i) qualifying suppliers of subcontracted work.

(j) qualifying and certifying a Certified Individual.

CR-2.3 Certification Designator

The BPE Certification Designator shall be the responsibility of the Certificate Holder. The Certification Designator shall consist of the uppercase letters "BPE" and shall be of a design having similar proportions to

that shown in Fig. CR-1-1. The Certification Designator shall be legible and located immediately underneath the ASME Certification Mark.

CR-2.4 Subcontracting

The ASME BPE Certificate Holder providing any component with the proper ASME Certification Mark and BPE Designator 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-2-1 provides a graphic of several acceptable certification methodologies for subcontracting.

Work provided by others who are not in possession of a valid BPE Certificate of Authorization shall be verified as meeting the requirements of the Standard by the Certificate Holder through surveys and audits. The experience and knowledge requirements of auditors shall be documented in the Quality Management System manual. The BPE Certificate Holder shall have objective evidence that qualified auditors meet the experience and knowledge requirements as specified in their program. The BPE Certificate Holder shall have objective evidence of the surveys and audits performed. As a minimum, the frequency of surveys and audits shall be commensurate with surveys and audits performed by ASME.

A Certificate Holder is not required to conduct surveys or audits of subcontractors holding a valid ASME BPE Certificate of Authorization.

CR-2.5 Quality Management System

The applicant shall establish and maintain an effective 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-2.5.1 Quality Management System Control. A Quality Management System is a formalized set of quality assurance guidelines, procedures, forms, and other discretionary documentation specific to each applicant, compiled into a manual providing guidance, structure, and authority to an applicant's Quality Assurance Program.

CR-2.5.1.1 In complying with the ASME BPE Standard the QMS shall include, but not be limited to, the following:

- (a) a means to verify proper documentation and traceability of finished product and raw material.
- (b) a means to verify compliance of outsourced goods and services such as electropolishing or passivation.

- (c) the control of quality during manufacture or fabrication including that of testing, examination, repair, and handling of the product.

- (d) evaluation, auditing, qualification, and monitoring of suppliers of raw material, finished goods, and unfinished goods. This is not required of those suppliers and service providers holding a valid ASME BPE Certificate of Authorization.

- (e) the control and proper segregation of outsourced product from receipt through final integration of finished product.

- (f) company organization chart identifying the chain of management with regard to internal audit and quality control personnel.

- (g) the further requirements of CR-2.5.

CR-2.5.1.2 The QMS shall include provisions to ensure compliance of the product with

- (a) the general and design requirements of Parts GR and SD

- (b) the physical attributes requirements of Parts MM, PM, DT, PI, SG, and SF as appropriate to the product

- (c) materials requirements of Part MM for metals, Part PM for polymeric materials, and Part SG for seals and gaskets

- (d) materials joining requirements of Part MJ for metals and for polymeric materials in both component manufacture and assembly/installation

Unless otherwise specified in this Standard, examination/testing shall be conducted at the frequencies specified in the applicable referenced product specification(s), or else at a minimum of 10%. Such examination/testing may be performed by the Certificate Holder's quality department or by a qualified third party.

CR-2.5.2 Requirements for Designated Oversight.

The use of the ASME Certification Mark and BPE Designator 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., a Certified Individual). The data reports or certificates of conformance, or both, shall be retained for a period of not less than 5 yr.

CR-2.5.2.1 Duties of the Certified Individual. The Certified Individual shall

- (a) verify that each item, or lot of items, to which the ASME Certification Mark and BPE Designator 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-2.5.2.2 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 ASME Certification Mark

(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-2.5.3 Evaluation of the Quality Management System. The QMS manual shall include provisions for a system performance review and evaluation by management at least annually. This review may be conducted by internal personnel or by a qualified third party (e.g., an ANAB- or CEOC-recognized organization) with evaluation by and improvements/corrections implemented by management.

CR-2.5.4 Applicant's Facilities and Equipment. 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 the final product with this Standard.

CR-2.5.5 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*

CR-2.5.6 Monitoring of Quality Control Measuring and Testing Devices

(a) Procedures shall be in effect to ensure that tools, gauges, instruments, and other measuring and testing devices used to verify compliance with the appropriate requirements are calibrated and properly adjusted at specific periods or use intervals to maintain accuracy within necessary limits. Periodic checks on these devices shall be performed to determine that calibration is maintained.

(b) Calibration shall be made against certified samples having known valid relationships and documented traceability to nationally recognized standards, where such standards exist. If no known nationally recognized standard exists, the basis for calibration shall be documented.

(c) Control measures shall include provisions for measuring and testing equipment identification and for determining calibration status by equipment marking or on records traceable to the equipment.

CR-2.5.7 Discrepancies With Measuring and Testing Devices

(a) When discrepancies beyond an acceptable tolerance range for measuring and testing devices are found during calibration, appropriate corrective action shall be taken, and material measured or tested since the previous calibration shall be reviewed to determine that all applicable requirements have been met.

(b) When periodic checks on equipment are performed to determine that calibration is maintained, potential product or source material discrepancies need only be resolved to the previous check, provided

(1) the methods used and frequency of periodic checking are described in calibration procedures

(2) the calibration discrepancy was found by periodic check

CR-2.5.8 Internal Audits. Internal audits shall be performed in accordance with the following requirements:

(a) Audits shall be performed at least annually in accordance with written procedures or checklists by personnel not having direct responsibility in the areas being audited.

(b) Audit results shall be documented by auditing personnel for review by management having responsibility in the area being audited.

(c) Procedures shall include provisions for documentation of corrective action taken in response to deficiencies. Follow-up action, including re-audit of deficient areas where indicated, shall be taken to verify implementation of such corrective actions.

In addition to ASME audits of the applicant or Certificate Holder, a comprehensive system of planned and periodic internal audits shall be carried out to ensure

ongoing compliance with all aspects of the QMS and to reaffirm the effectiveness of the program.

CR-2.5.9 Corrective Action. Measures shall be established to ensure that conditions not meeting quality requirements, such as failures, malfunctions, deviations, defective material and equipment, nonconformances, and quality system deficiencies, are promptly identified and reported to appropriate levels of management. These measures shall also ensure that the cause of conditions adverse to established quality levels is determined and corrected.

The identification of significant or recurring conditions not meeting quality requirements, the cause of these conditions, and the corrective action taken shall be documented and reported to appropriate levels of management.

These requirements shall also extend to the performance of the approved supplier's corrective action measures.

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MANDATORY APPENDIX I

SUBMITTAL OF TECHNICAL INQUIRIES TO THE BIOPROCESSING EQUIPMENT (BPE) COMMITTEE

I-1 INTRODUCTION

(a) This Mandatory Appendix provides guidance to BPE Standard users for submitting technical inquiries to the Committee. Technical inquiries include requests for revisions or additions to the rules of the Standard, requests for Code Cases, and requests for interpretations of the Standard, as described in the following:

(1) *Revisions*. Revisions are considered to accommodate technological developments, address administrative requirements, incorporate Code Cases, or clarify the intent of the Standard.

(2) *Code Cases*. Code Cases represent alternatives or additions to existing rules. Code Cases are written as a question and reply, and are usually intended to be incorporated into the Standard at a later date. When used, Code Cases prescribe mandatory requirements in the same sense as the text of the Standard. However, users are cautioned that not all jurisdictions or owners automatically accept Code Cases. The most common applications for Code Cases are

(-a) to permit early implementation of an approved revision based on an urgent need

(-b) to permit the use of a new material for construction

(-c) to gain experience with new materials or alternative rules prior to incorporation directly into the Standard

(3) *Interpretations*. Interpretations provide clarification of the meaning of existing rules and are also presented in question and reply format. Interpretations do not introduce new requirements. In cases where existing text does not fully convey the meaning that was intended, and revision of the rules is required to support an interpretation, an Intent Interpretation will be issued and the Standard will be revised.

(b) The rules, Code Cases, and Interpretations established by the Committee are not to be considered as approving, recommending, certifying, or endorsing any proprietary or specific design, or as limiting in any way the freedom of manufacturers, constructors, or owners to choose any method of design or any form of construction that conforms to the rules of the Standard.

(c) Inquiries that do not comply with the provisions of this Mandatory Appendix or that do not provide

sufficient information for the Committee's full understanding may result in the request being returned to the inquirer with no action.

I-2 INQUIRY FORMAT

Submittals to the Committee shall include

(a) *Purpose*. Specify one of the following:

(1) revision of present rules

(2) new or additional rules

(3) Code Case

(4) Interpretation

(b) *Background*. Provide the information needed for the Committee's understanding of the inquiry, being sure to include reference to the applicable Edition, Addenda, paragraphs, figures, and tables. Preferably, provide a copy of the specific referenced portions of the Standard.

(c) *Presentations*. The inquirer may desire or be asked to attend a meeting of the Committee to make a formal presentation or to answer questions from the Committee members with regard to the inquiry. Attendance at a Committee meeting shall be at the expense of the inquirer. The inquirer's attendance or lack of attendance at a meeting shall not be a basis for acceptance or rejection of the inquiry by the Committee.

I-3 REVISIONS OR ADDITIONS

Requests for revisions or additions shall provide the following:

(a) *Proposed Revisions or Additions*. For revisions, identify the rules of the Standard that require revision and submit a copy of the appropriate rules as they appear in the Standard, marked up with the proposed revision. For additions, provide the recommended wording referenced to the existing rules.

(b) *Statement of Need*. Provide a brief explanation of the need for the revision or addition.

(c) *Background Information*. Provide background information to support the revision or addition, including any data or changes in technology that form the basis for the request that will allow the Committee to adequately evaluate the proposed revision or addition. Sketches, tables, figures, and graphs should be submitted as appropriate. When applicable, identify any pertinent paragraph in the Standard that would be affected

by the revision or addition and identify paragraphs in the Standard that reference the paragraphs that are to be revised or added.

I-4 CODE CASES

Requests for Code Cases shall provide a Statement of Need and Background Information similar to that defined in I-3(b) and (c), respectively, for revisions or additions. The urgency of the Code Case (e.g., project underway or imminent, new procedure, etc.) must be defined and it must be confirmed that the request is in connection with equipment that will be governed by the ASME BPE Standard. The proposed Code Case should identify the part, paragraph, table, and/or figure and be written as a Question and a Reply in the same format as existing Code Cases. Requests for Code Cases should also indicate the applicable Editions and Addenda to which the proposed Code Case applies.

I-5 INTERPRETATIONS

(a) Requests for Interpretations shall provide the following:

(1) *Inquiry*. Provide a condensed and precise question, omitting superfluous background information and, when possible, composed in such a way that a “yes” or “no” *Reply*, with brief provisos if needed, is acceptable. The question should be technically and editorially correct.

(2) *Reply*. Provide a proposed *Reply* that will clearly and concisely answer the *Inquiry* question. Preferably, the *Reply* should be “yes” or “no,” with brief provisos if needed.

(3) *Background Information*. Provide any background information that will assist the Committee in understanding the proposed *Inquiry* and *Reply*.

(b) Requests for Interpretations must be limited to an interpretation of a particular requirement in the Standard or a Code Case. The Committee cannot consider consulting-type requests such as the following:

(1) a review of calculations, design drawings, welding qualifications, or descriptions of equipment or parts to determine compliance with requirements in the Standard

(2) a request for assistance in performing any Standard-prescribed functions relating to, but not limited to, material selection, designs, calculations, fabrication, inspection, pressure testing, or installation

(3) a request seeking the rationale for requirements in the Standard

I-6 SUBMITTALS

Submittals to and responses from the Committee shall meet the following:

(a) *Submittal*. Inquiries from BPE Standard users shall be in English and preferably be submitted in typewritten form. However, legible handwritten inquiries will also be considered. They shall include the name, address, telephone number, fax number, and e-mail address, if available, of the inquirer and be mailed to the following address:

Secretary
ASME BPE Committee
The American Society of Mechanical Engineers
Two Park Avenue
New York, NY 10016-5990

(b) *Response*. The Secretary of the ASME BPE Committee or of the appropriate Subcommittee shall acknowledge receipt of each properly prepared inquiry and shall provide a written response to the inquirer on completion of the requested action by the Standards Committee.

MANDATORY APPENDIX II

STANDARD UNITS

See Table II-1.

Table II-1 Standard Units

Quantity	U.S. Customary	SI Units
Length	inches (in.)	millimeters (mm)
Length	feet (ft)	meters (m)
Area	square inches (in. ²)	square centimeters (cm ²)
Volume	cubic inches (in. ³)	cubic centimeters (cm ³)
Volume	gallons (gal)	liters (L)
Pressure, gauge	pounds per in. ² (psi _g)	kilopascal (kPa _g)
Pressure, absolute	pounds per in. ² (psi _a)	kilopascal (kPa _a)
Vacuum	pounds per in. ² (psi)	kilopascal (kPa)
Temperature	degrees Fahrenheit (°F)	degrees Celsius (°C)
Angle (plane angle)	degrees or radians	degrees or radians
Surface finish	microinch (μin.)	micron or micrometer (μm)
Slope	inches per foot (in./ft)	millimeters/meter (mm/m)
Flow rate, liquid	gallons per minute (gal/min)	liters per minute (L/min)
Flow rate, gas	std. cubic feet per hour (std. ft ³ /hr)	std. liters per minute (std. L/min)
Speed/velocity	feet per second (ft/sec)	meters per second (m/s)
Coefficient of thermal expansion	inch per inch per degree [in./(in./°F)]	millimeters per millimeter per degree [mm/(mm/°C)]

NONMANDATORY APPENDIX A

COMMENTARY: SLAG AND OXIDE ISLANDS

(a) Inert-gas shielded welding processes do not produce slag. See GR-8 and AWS A3.0 for definition of slag.

(b) Welds on stainless steel tubing can produce a thin film that appears as localized islands on the surface of the weld. In welds on nickel alloys, stainless steels, or welds alloyed with nickel filler metals, these films have been identified as high-melting-point nonmetallic oxides, typically referred to as oxide islands.

(c) Oxide islands encountered on welds in stainless steels and nickel alloys identified in Tables MM-2.1-1, MM-2.1-2, and MM-2.1-3 are commonly found in one of the following forms:

(1) On stainless steels, a small, round, black spot at the termination of the weld bead, on the outside or inside surface, or both. This spot is generally unavoidable.

(2) On products made from cast or wrought stainless steels and nickel alloys, a thin film, gray or the same

color as the weld surface, may be evident because it covers the weld ripples.

(3) On nickel alloys or stainless steels welded with nickel alloy fillers, a thin film, having varying color with tints from gray to dark brown, may be evident because it covers the weld ripples.

(d) Slag in or on welds may be the result of faulty weld preparation, such as contamination, poor cleaning, or faulty tack welding procedures.

(e) 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.

(f) 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.

NONMANDATORY APPENDIX B MATERIAL AND WELD EXAMINATION/INSPECTION DOCUMENTATION

See Forms beginning on next page.

Form MEL-1 Material Examination Log

From (Supplier or Manufacturer): _____

Date Received: _____

Person Receiving Material (Printed): _____

Person Receiving Material (Signature): _____

[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.

(2) Markings verified to be in accordance with DT-11.

Copies: ☐ Owner ☐ A/E ☐ Contractors ☐ Consultants ☐ _____ ☐ _____ ☐ _____ ☐ _____ ☐ _____ ☐ File

BPE**Form MER-1 Material Examination Record**

Project Number/Name: _____ A/E Project Number: _____
 Record Number: _____ Received by: _____ Date Received: _____
 End-User/Owner: _____ Name and Date of Approval: _____

Customer Company Name: _____
(Enter the name of the company receiving the material.)

Address: _____
(Enter the address of the company receiving the material.)

Contact Names and Numbers: _____
(Enter the name(s) and contact information of personnel receiving the material.)

Supplier/Manufacturer Name: _____
(If receiving a product or material, enter the name of the company supplying the material.)

Address: _____
(If receiving a product or material, enter the address of the company supplying the material.)

Contact Information: _____
(If receiving material, enter the name(s) and contact information of personnel supplying the material.)

Project Information: _____ NCR Number: _____
(Related Specifications, Codes, and Standards) (NCR report number if needed)

Heat Number/Heat Code: _____ Material Specification: _____
(Record heat number(s) for the sample.) (ASTM spec., customer spec.)

P.O. Number: _____
(Enter associated purchase order number here.)

Packing List Number: _____
(Enter packing list and/or tracking number here.)

Lot Number: _____
(For multiple lot shipments, enter associated lot number here.)

Examiner's Information: _____
(The name of the examiner, company of examiner, etc.)

Material/Alloy Type: _____
(Type or grade of material (UNS S31603, N08367, etc.))

Material Description: _____
(Size, material product form (tubing, 90, 45, TEE, ferrule, valve, etc.))

DT-11 Compliant: _____
(Record Accept or Reject after markings verification.)

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 R_a : _____
(Record Accept or Reject after physical examination of the lot (if required).)

Visual Examination: _____
(Record Accept or Reject after physical examination.)

MTR(s) Verified: _____
(Record Accept or Reject for MTR compliance with specifications.)

Quantity Received: _____ Quantity Accepted: _____ Quantity Rejected: _____ Date Examined: _____

Comments: _____
(Record any notes for examination, and attach additional sheets if needed.)

Copies: ☐ Owner ☐ A/E ☐ Contractors ☐ Consultants ☐ _____ ☐ _____ ☐ File

Name and Date of Approval: _____

[illegible]

- (a) Welds must be uniquely identified per applicable drawings.
- (b) Rejected welds that can be rewelded shall use the same number with an "R" after it.
- (c) Rejected welds that must be cut out and replaced with a new weld shall be assigned the same identifier followed by an "A" for the first, "B" for the second, etc. in consecutive order.
- (d) If a weld is cut out for a reason other than a rejected weld, it shall be recorded as a "Deleted" weld in the Comments section. The replacement weld shall be assigned the next available identifier.
- (e) Coupon welds may be listed with production welds or listed separately. Either way, the coupon weld should be identified with the symbol "CPN" as either a prefix or a suffix to the user's weld numbering format.

(1) VO = Visual O.D. only; VI = Visual O.D. and I.D.; B = 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.

Form WEL-1

NONMANDATORY APPENDIX C

SLOPE MEASUREMENT AND JOINT MISALIGNMENT

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
- (e) Slope should be measured only on runs that are approximately horizontal.
- (f) Slope measurements may be made on either the top or bottom of the tubing/piping.

(g) 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.

(h) Slope shall be verified after the fabricator has completed, or corrected, the piping installation and set the slope.

C-2 JOINT MISALIGNMENT

In order to meet O.D. misalignment criteria in this Standard, the accumulated tolerances in piping, tubing, and fittings may result in a welded joint with an I.D. misalignment. Should this occur, the owner/user, installation contractor, and inspection contractor shall apply good engineering judgment to determine the best solution for the application considering flow, orientation, and drainability.

The orientation of the piping, tubing, or fittings should be considered prior to final disposition of the weld joint prior to welding.

(a) Vertical Orientation

(1) Misalignment should be uniformly distributed around the circumference.

(2) Direction of flow should be considered when assembling the components.

(b) Horizontal Orientation. Misalignment should be oriented to maximize drainability, normally accomplished by minimizing the I.D. misalignment at the bottom.

NONMANDATORY APPENDIX D

ROUGE AND STAINLESS STEEL

D-1 GENERAL

This Nonmandatory Appendix provides the methods to measure rouge in a system both in 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, see GR-8.

D-2 CONSIDERATIONS FOR REDUCING ROUGE FORMATION

Tables D-2-1 and D-2-2 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-2-1 and D-2-2.

(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-2-1 for a discussion of fabrication variables that affect the amount of rouge formation.

D-2.2 System Operation

See Table D-2-2 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 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-3.1-1 provides descriptions, 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-3.2-1 provides descriptions, 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 are 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 (i.e., sodium dithionite) is also fast and effective at removal of Class I rouge.

These chemistries are processed at elevated temperatures from 104°F to 176°F (40°C to 80°C) for between 2 hr and 12 hr. The process time and temperatures may depend on the severity of rouge accumulation, the system component's material of construction, and the concentration of chemistries. The concentration of each chemistry is based on 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-4.1-1.

(16) **D-4.2 Class II Rouge Remediation**

Class II rouge consists mostly of hematite or ferric iron oxide with some amount of chromium and nickel oxides as well as small carbon content. It is removed with chemistries that are very similar to the above processes with the addition of oxalic acid, which improves the effectiveness in removal of this type of rouge. 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-4.1-1.

D-4.3 Class III Rouge Remediation

Class III rouge is much more difficult to remove compared to Class I and Class II rouge, due to both 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 Class III 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, they 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 on 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 in both 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 to 176°F (60°C to 80°C)] and require longer contact time (8 hr to 48-plus hr); 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-4.1-1.

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-2-1 Considerations That Affect the Amount of Rouge Formation During the Fabrication of a System

Variables	Considerations
Category 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 than 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 lapping 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 and stress corrosion cracking. Surface occlusions from passivation fluids are minimized by the smooth, more even finish.
Passivation	Impedes or retards corrosive developments of stainless steel surfaces. The effectiveness of passivation methods in terms of depth and enhancement of surface alloy ratios (i.e., chrome to iron) determines 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 corrosion. 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 corrosion initiation site.
Welding, welding conditions, purging, etc.	Improper welds can result in chromium-depleted heat-affected zones (HAZs) and other conditions that reduce corrosion resistance. Weld discontinuities create opportunities to trap fluid-borne impurities. Cracks resulting from poor welds will create breaches in the 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 sulfur content will enhance the potential for successful welding.
Category 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 liquids, 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 systems and initially generate migratory Class I rouge. Where oxide films exist in established systems, 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-2-2 Considerations That Affect the Amount of Rouge Formation During the Operation of a System

Variables	Considerations
Category 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 and CO ₂)	For monographed fluids (PW, WFI, and pure steam), the constituency of dissolved gases is generally believed to have an 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-3.1-1 and D-3.2-1.)
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 affects 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-2-2 Considerations That Affect the Amount of Rouge Formation During the Operation of a System (Cont'd)

Variables	Considerations
Category 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 gaskets, 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 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-3.1-1 Process Fluid Analyses for the Identification of Mobile Constituents of Rouge

Type of Test	Test Description	Test Criteria	
		Pros	Cons
Ultra trace inorganic analysis (by 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 on 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-3.2-1 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 subsurface (or base metal)	Highly accurate method for positive identification and qualification of the surface metal composition. Used 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. Used 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 using 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 the 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-4.1-1 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 (i.e., sodium dithionite)	Effective at removing iron oxides without etching the surface but may generate sulfide fumes	Up 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 85% 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 85% phosphoric acid	Limited to accessible parts of systems, primarily vessels. Process times are approximately 1 min/ft ² .
	Sodium hydrosulfite (i.e., sodium dithionite)	Effective at removing iron oxides without etching the surface but may generate sulfide fumes	Up to 10% sodium hydrosulfite	2 hr to 12 hr at 40°C to 80°C

Table D-4.1-1 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 metallic surfaces	10% to 20% oxalic acid	8 hr to 48+ hr at 60°C to 80°C
	Citric acid with organic acids	May etch metallic 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 metallic 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 or nitric/ammonium bifluoride	Will etch metallic surfaces	15% to 40% nitric acid with 1% to 5% HF or 1% to 5% NH_4HF_2	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 85% 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 buildup may be present on the product contact surfaces after derouging and may 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 deionized water rinse shall immediately follow each of the above chemical treatments.

NONMANDATORY APPENDIX E

PASSIVATION PROCEDURE QUALIFICATION

E-1 GENERAL

This Nonmandatory Appendix 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 Nonmandatory Appendix 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 UNS S30400, S30403, S31600, and S31503 stainless steels. Superaustenitic stainless steels and nickel alloys may require a modified procedure.

This Nonmandatory Appendix defines a method for qualifying the passivation process used for system and process component surfaces.

This Nonmandatory 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 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 allow the chemical passivation to be most effective. The purpose of the final chemical passivation process is to enhance the passive layer and provide an alloy surface free of free 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., UNS S31603), the passivation treatment is most beneficial and important. With the superaustenitic stainless steels and nickel alloys, passivation is less critical, provided the surfaces are clean and free of contaminants. At the owner/user's option, passivation may be performed to remove any free iron on process contact surfaces and to facilitate the formation of the passive layer.

In a discussion on passivation, it should be realized that 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.

Discoloration and contamination (especially free iron) introduced during fabrication may also compromise corrosion resistance unless removed. Passivation after welding, by removing free iron, helps to restore the passive layer. It does not remove discoloration. Removal of 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 discoloration are specified (see Part MJ of this Standard).

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
- (b) after welding of new components into a system

E-3 PASSIVATION PROCEDURE (SEE SF-2.6)

E-3.1 Procedure Description

The passivation provider shall obtain welded and nonwelded sample component(s) or coupons from each

Table E-3.2-1 Minimum Surface Requirements for Process Qualification Samples

Material	Test Method	Cr/Fe Ratio	Oxide Depth
UNS S31600 or UNS S31603	AES	1.0 or greater	15 Å, min.
UNS S31600 or UNS S31603	GD-OES	1.0 or greater	15 Å, min.
UNS S31600 or UNS S31603	XPS/ESCA	1.3 or greater	15 Å, min.

GENERAL NOTES:

(a) XPS/ESCA readings of metal oxides typically obtain higher values than readings of metals.

(b) Additional alternative testing methods for cleanliness and passivation are shown in Table E-5-1.

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-3.2-1. Procedure qualification, as a minimum, shall include the following:

(a) *Process Description*. The following steps shall be described as a minimum (Table E-3.2-2 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) AES (auger electron spectroscopy) testing at the weld, including the worst discoloration area in the weld and heat-affected zone, and on the base metal to meet the requirements of Table E-3.2-1

(2) GD-OES (glow discharge–optical electron spectroscopy) testing at the weld, including the worst discoloration area in the weld and heat-affected zone, and on the base metal to meet the requirements of Table E-3.2-1

(3) XPS (X-ray photoelectron spectroscopy), also known as ESCA (electron spectroscopy for chemical analysis), testing at the weld, including the worst discoloration area in the weld and heat-affected zone, and on the base metal to meet the requirements of Table E-3.2-1

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, the ionic contaminants, process chemicals, and by-products 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.

Table E-3.2-2 Passivation Processes

Process Type	Process Description [Notes (1), (2)]	Comments [Note (3)]	Conditions of Process [Notes (4), (5)]	Chemistry [Note (6)]
Precleaning				
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-3.2-2 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 A380/A967. 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 A967		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 A967		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 a way as to meet or exceed ASTM B912.	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-3.2-2 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 deionized water rinse shall immediately follow each of the above chemical treatments.
- (6) Chemical percentages are based on weight percent.

(b) Final rinse shall meet pre-established conductivity (quality) requirements.

E-4.2 Certificate of Passivation Compliance

The passivation provider shall supply a Certificate of Compliance 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) postpassivation 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 provide assurance that the components or system have received the specified treatment. As a guide to owner/users and others, to help determine whether an acceptable surface has been achieved following a particular cleaning or chemical passivation procedure, Table E-5-1 has been developed.

E-5.1 Acceptance Criteria for Cleaned and/or Passivated Process Contact Surfaces (See Table SF-2.6-1)

Table E-5-1 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 A380/A967 (Pass/Fail)
- (b) precision inspection of cleaned and passivated parts under ASTM A380/A967 (Pass/Fail)
- (c) electrochemical field and bench tests
- (d) surface chemical analysis tests

Groups 1 and 2 of Table E-5-1 reflect the two main divisions in ASTM A380 and ASTM A967. The most obvious type of 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 A967, 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 A380 and ASTM A967 apply.

Groups 3 and 4 of Table E-5-1 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 in Table E-5-1, with the exception of cyclic polarization, are suitable for field tests such as those used for postpassivation testing of installed piping systems and passivated welded surfaces.

Passivation 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. 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-3.2-1); because of variability in accuracy, identical results obtained with the different test methods are not expected. The surface chemical analysis tests in Group 4 in Table E-5-1 include methods for evaluation of the thickness and chemical state of the passive layer on stainless steel. Cyclic polarization measurements (Group 3 in Table E-5-1) may also be used to provide a quantitative evaluation of the level of passivation. Cyclic polarization as well as the methodologies in Group 4 in Table E-5-1 might be applied to sacrificial coupons placed in systems subject to the complete passivation process.

Table E-5-1 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 A380/A967 (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 A380 (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 A380 (CT)	Bench or field test. After finish-cleaning, dry the cleaned surface per ASTM A380. 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 F22	The water-break test is performed by withdrawing the surface to be tested, in a vertical position, from a container overflowing with water. The interpretation of the test is based on the pattern of wetting.	General cleanliness of surface is easily determined. Useful in detecting hydrophobic contamination	Not quantitative. This test identifies the presence of retained oils and greases. The test is not applicable on all surfaces including, but not limited to, electropolished surfaces.
ASTM A380 water-wetting and drying; ASTM A967 water immersion practice A [PT (test for passivation)]	Bench or field test. Immersed in, or flushed with distilled water then air dried. 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 embedded iron	Not quantitative
High-humidity test ASTM A380 and ASTM A967 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 A967 Practice C (PT)	Bench or field test. This test is conducted in accordance with ASTM B117 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 embedded in the surface will become noticeable on 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-5-1 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 A380/A967 (Pass/Fail)			
Solvent ring test ASTM A380 (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 A380 (CT)	Bench test. This test requires the absence of white light and a flood-type ultraviolet 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 A380 (CT)	Bench test. This test is conducted in accordance with ASTM F21 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 A380/potassium ferricyanide-nitric acid ASTM A967 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 A380 or ASTM A967. Test nonsystem coupons only.	Identification of free iron contamination on surface. Very sensitive test	Not quantitative. This test will only identify free iron on the surface and will not directly measure the improvements of the passive oxide layer. 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 A380/ASTM A967 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. Embedded iron is detected, but difficult to detect small discrete iron particles

Table E-5-1 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 G61 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 G150 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 preset 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 repassivated after testing.
Koslow test kit 2026/3036 (PT)	Similar to the ec-pen, in that it measures the corrosion potential of the metal surface, the Koslow 2026/3036 consists of a meter, a probe, and an interconnecting 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-5-1 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

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-1-1. 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 G31, 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 G61, Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements for Localized Corrosion, and ASTM G150, 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-1-1.

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-3-1. Notice that although different equations are used to calculate the PRE number for the two different alloy systems [see Table F-3-1, 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-3-1 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-3-1 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-1-1 ASTM Corrosion Tests

ASTM Standard		Purpose of Test	Data Obtained	Typical Alloys Tested
ASTM A262	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-type alloys. 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-type alloys. 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 A923	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. Pretest 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 G48	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
	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 as surface finish of final product.	Report critical temperature	Ni-based and Cr-bearing alloys

Table F-1-1 ASTM Corrosion Tests (Cont'd)

ASTM Standard		Purpose of Test	Data Obtained	Typical Alloys Tested
ASTM G48 (cont'd)	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 as surface finish of final product.	Report critical temperature	Stainless steels
	Method A	Tests the susceptibility to intergranular attack associated with composition and processing	Report weight loss only	Ni-based alloys
ASTM G28	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-3-1 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 Superaustenitic 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 formulas. Other formulas may be used at the owner's discretion.

NOTES:

- (1) For stainless steels: $\text{PRE Number} = \%Cr + 3.3 [\%Mo + 0.5(\%W)] + 16(\%N)$.
- (2) For nickel alloys: $\text{PRE Number} = \%Cr + 1.5 (\%Mo + \%W + \%Nb)$.

NONMANDATORY APPENDIX G

FERRITE

(16) 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 austenitic 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 austenitic stainless steel base metal strongly depends on heat analysis, primarily the chromium to nickel ratio, product form, and final heat treatment. Whereas wrought 316L-type stainless steel materials in the solution annealed condition typically show very low ferrite levels of 0–3 vol.%, CF8M and CF3M stainless steel castings may contain 10–20 vol.% of ferritic phase in the austenitic matrix.

As-solidified austenitic 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 austenitic 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.

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), p. 171-s, 1992.

It should be recognized that many austenitic stainless steels with high nickel content and nickel alloys do not contain any ferrite in as-solidified welds.

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 on 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 have been no reported system failures related to delta ferrite content in welds.

G-3 CONTROL OF FERRITE CONTENT IN WELDS OF AUSTENITIC STAINLESS STEELS (16)

Ferrite in welds of austenitic 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 MM-2.1-1) with a restricted $Cr(eq)$ to $Ni(eq)$ ratio³ as per BN2⁴

² R. Morach and P. Ginter, "Influence of Low δ -Ferrite Content on the Corrosion Behaviour 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

H-1 SCOPE

This Nonmandatory 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 Nonmandatory Appendix is intended to provide general guidelines for qualification of the electropolish methods used to achieve required surface improvements. Electropolishing is used 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 processes
- (d) optimizes corrosion resistance

H-3 ELECTROPOLISH PROCEDURE QUALIFICATION

H-3.1 Method Procedure

This Nonmandatory Appendix is intended to provide general guidelines for qualifying the electropolish process used 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 used 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) scanning electron microscope (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-3.3-1.
- (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-3.3-1 Minimum Surface Requirements for Process Qualification Samples

Material	Cr/Fe Ratio	Depth [Note (1)]	Surface Photo [Note (2)]
UNS S31600 (316 SS), UNS S31603 (316L SS)	1 to 1 or greater	15 Å minimum	150X

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

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 (see Table I-1.1-1).

I-1.2 Section 2: Instrument Types and Required Documents

This section identifies the major instrument types and the required documentation, by VDR number (see Table I-1.2-1).

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.

(16) **Table I-1.1-1 Vendor Documentation Requirements for New Instruments: Section 1, VDR Definitions**

VDR #	Documentation	Definitions
1	Certified Arrangements/ 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 the 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 startup, 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 is 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 subsupplier who performed the test. Typically this testing is a destructive test, and the instrumentation being purchased was produced by 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-on 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 used in the calibration process. NOTE: All calibration certificates or reports must contain the instrument serial number.
9	Sizing calculations	Given two or three of the following parameters, 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-1.1-1 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 process contact metallic materials shall comply with the requirements listed in Part GR. REQUIRED ONLY FOR HYGIENIC APPLICATIONS
11	Certificate of Compliance for elastomers	The Certificate of Compliance for process contact elastomer materials shall comply with the requirements listed in Part GR. 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 R_a or BPE designation per Part SF; and whether any polishing compounds were used to meet the 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 process contact polymer-based materials shall comply with the requirements listed in Part GR. REQUIRED ONLY FOR HYGIENIC APPLICATIONS

**Table I-1.2-1 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: flow/level	2, 3, 4, 5, 10, 11, 12, 13
Indicator: humidity/pressure/temperature	2, 4, 8, 10, 12
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 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

J-1 SEALING COMPONENT PERFORMANCE EVALUATION

(16) J-1.1 Material and Component Testing

Standard process test conditions are presented here in order to assess hygienic union seal materials and diaphragm valve component seals. Typical steam operating parameters are presented in J-1.2.1. A simulated clean-in-place (CIP) and steam-in-place (SIP) test cycle is presented in J-1.2.2. Other considerations are presented in J-1.2.3. Any specific process conditions that fall outside the design of this standard test should be evaluated separately.

The specific material composition(s) used in the test article shall be evaluated against the process conditions to which it may be exposed, including routine sterilization and cleaning. For diaphragm valve testing, the test article should reflect the specific valve configuration to be used in the anticipated application. Other conditions or process parameters/chemicals, such as allowable extreme process upset conditions and nonroutine treatments (e.g., passivation, derouging), should also be considered. Form R-1, Application Data Sheet, defines a number of operational conditions (e.g., chemistry, temperature, pressure) to consider when developing non-standard performance tests.

Before testing

(a) verify that the material/component's service temperature and pressure rating meet the desired process conditions, including sterilization and cleaning.

(b) verify that the material/component is compatible with the intended process and cleaning chemicals at the routine concentrations used, including consideration for extreme allowable process conditions, per Part PM.

J-1.1.1 Test Article Requirements

(a) The following information, at a minimum, shall be included in test reports:

- (1) seal type
- (2) seal size
- (3) sample size
- (4) maximum rated pressure of valve or seal
- (5) for valves only
 - (-a) actuator model number and spring pressure
 - (-b) air pressure supplied to actuator
 - (-c) valve type

(-d) valve size

(-e) valve model number

(b) Test samples shall be representative of a certain model or product range of seals and shall be chosen randomly from those fabricated with the standard manufacturing process. Any modifications that may impact performance shall be included in the test report, e.g., travel stops. Knowledge of factors that impact material performance may help determine the minimum selection criteria of samples. Appropriate study design or supporting data are required to support all conclusions. Any differences or factors that impact material performance across the commercial product range shall be addressed. This includes, but is not limited to, seal materials of construction, size, shape, and manufacturing process.

J-1.2 Exposure Testing

(16)

Sections J-1.2.1 and J-1.2.2 present two example test cycles that can be performed on test articles. Simulated SIP testing in J-1.2.1 incorporates a typical steam sanitization cycle. J-1.2.2 provides simulated CIP and SIP testing and additional information for valve cycling. Components can be evaluated with either or both of these tests based on application requirements. Actuation requirements in J-1.2.1 and J-1.2.2 apply to valve testing only.

J-1.2.1 Simulated Steam-in-Place Testing. Expose (16) the material to multiple SIP cycles to establish a life expectancy for the application and configuration. The testing cycles should occur without intervention (e.g., retorquing of clamps or fasteners), beyond initial installation procedures. All deviations identified during the test program should be documented and analyzed, including their impact on the test results and conclusions.

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 valve clamps and fasteners, etc., per manufacturer's procedures.

(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.* Constant, ambient, as close to 77°F (25°C) as possible.

(2) *System Pressure.* Minimum 45 psig (3.1 bar).

(3) *Test System Volume.* A fixed volume of less than 2.6 gal (10 L).

(4) *Test Exposure Time.* At least 1 hr.

(5) *Equilibration Time.* System dependent.

(6) *Passing Criteria.* Less than 0.5 psig (0.0345 bar) pressure drop in 1 hr or conformance to SG-4.3.1.1(a) and (b).

(c) *Steam-in-Place.* Expose the system to a simulated SIP with saturated USP pure steam or equivalent (e.g., steam generated from DI/RO water or equivalent).

(1) *System Temperature.* Above 266°F (130°C).

(2) *System Pressure.* Saturated steam pressure.

(3) *Test System Volume.* A fixed volume of less than 2.6 gal (10 L) is recommended.

(4) *Test Exposure Time.* Minimum of one continuous hour greater than 266°F (130°C).

(5) *Actuations.* Minimum of ten actuations per cycle (at SIP temperature).

(d) *Cool Down.* Cool the system with ambient clean dry air.

(1) *System Temperature.* Ambient, as close to 77°F (25°C) as possible.

(2) *System Pressure.* 0 psig to 45 psig (0 bar to 3.1 bar).

(3) *Cool-Down Target.* Until the system reaches 77°F (25°C).

(e) *Repeat Steps.* Repeat steps in paras. J-1.2.1(c) and (d) until 10, 100, and 500 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 77°F (25°C) as possible.

(2) *System Pressure.* Minimum of 45 psig (3.1 bar).

(3) *Test System Volume.* A fixed volume of less than 2.6 gal (10 L) is recommended.

(4) *Test Exposure Time.* Minimum of 1 hr.

(5) *Passing Criteria.* Less than 0.5 psig (0.0345 bar) pressure drop in 1 hr or conformance to SG-4.3.1.1(a) and (b).

(16) J-1.2.2 Simulated Combined CIP and SIP Testing.

Expose the component to multiple CIP and SIP cycles to determine relative performance. Because this cycle is designed to assess material degradation, actual performance in service may differ. The testing cycles should occur without intervention (e.g., retorquing of clamps or fasteners) beyond initial installation procedures. All deviations identified during the test program should be documented and analyzed, including their impact on the test results and conclusions.

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 valve clamps and fasteners, etc., per manufacturer's procedures.

(b) *DI/RO Water Rinse — 5 min*

(1) *System Temperature.* ≤104°F (≤40°C)

(2) *System Pressure.* 72.5 psig ± 7.3 psig (5 bar ± 0.5 bar)

(3) *Actuations.* 15 (10 sec open, 10 sec closed)

(c) *Chemical Wash 1 — 30 min*

(1) *System Temperature.* 176°F ± 9°F (80°C ± 5°C)

(2) *System Pressure.* 72.5 psig ± 7.3 psig (5 bar ± 0.5 bar)

(3) *Actuations.* 30 (5 sec closed, 55 sec open)

(4) *Chemical.* Sodium hydroxide (0.5N, 0.5M, 2% w/w)

(d) *DI/RO Water Rinse — 5 min*

(1) *System Temperature.* ≤104°F (≤40°C)

(2) *System Pressure.* 72.5 psig ± 7.3 psig (5 bar ± 0.5 bar)

(3) *Actuations.* 15 (10 sec open, 10 sec closed)

(e) *Chemical Wash 2 — 30 min*

(1) *System Temperature.* 176°F ± 9°F (80°C ± 5°C)

(2) *System Pressure.* 72.5 psig ± 7.3 psig (5 bar ± 0.5 bar)

(3) *Actuations.* 30 (5 sec closed, 55 sec open)

(4) *Chemical.* Phosphoric acid (0.36N, 0.12M, 1.2% w/w)

(f) *DI/RO Water Rinse — 5 min*

(1) *System Temperature.* ≤104°F (≤40°C)

(2) *System Pressure.* 72.5 psig ± 7.3 psig (5 bar ± 0.5 bar)

(3) *Actuations.* 15 (10 sec open, 10 sec closed)

(g) *SIP — 30 min*

(1) *System Temperature.* Saturated USP pure steam or equivalent (e.g., steam generated from DI/RO water or equivalent) ≥266°F (≥130°C)

(2) *System Stabilization Time.* 5 min

(3) *Actuations.* 150 (5 sec open, 5 sec closed)

(h) *Cool Down.* Cool system to <194°F (<90°C).

(i) Repeat steps in paras. J-1.2.2(b) through (h) and assess performance at appropriate intervals (e.g., 10, 100, 500 cycles).

J-1.2.3 Other Process Testing Considerations

J-1.2.3.1 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 lyophilizers, shall require the addition of a vacuum hold test requirement.

- (16) **J-1.2.3.2 Additional Cleaning Chemicals.** Additional integrated CIP test exposures should also be considered as part of 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. In addition to those listed in J-1.2.2, other cleaning agents such as sodium hypochlorite (0.67N, 0.67M, 0.5% w/w) should be assessed as required.

J-1.3 Test Acceptance Criteria

J-1.3.1 Hygienic Fittings. 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 (10, 100, or 500) of SIP exposure/cool-down cycles:

- (a) Pressure hold test shall be passed after the 10th, 100th, and/or 500th SIP exposure cycle.
- (b) Compliance with SG-4.2 shall be established after the 10th, 100th, and/or 500th SIP exposure cycle (Intrusion Category I or II) for gaskets.
- (c) The condition of the seal shall be examined after the 10th, 100th, and/or 500th SIP exposure cycle, and any direct visible changes (e.g., surface defects, compression marks, discoloration, or erosion) shall be recorded. Cracks, tears, or holes will be considered failures.
- (d) Inspection at 0 (initial), 10 (through outlet), 100 (through outlet), and 500 (through disassembly of fittings) cycles.

J-1.3.2 Valve Diaphragms. The purpose of this section is to establish recommendations for evaluating diaphragm service life under specified process conditions in order to

- (a) provide acceptance criteria for hygienic performance of diaphragms when conducting the performance evaluation test per this Nonmandatory Appendix.
- (b) provide additional observations that may be recorded after performing the test or when evaluating valve diaphragms that are in service.

J-1.3.2.1 General Requirements for Performance Evaluation Test for Valve Diaphragms, per This Nonmandatory Appendix. Prior to testing, ensure that

- (a) the manufacturer's installation and operational procedures are followed.
- (b) a new diaphragm and new backing (if applicable) are used.
- (c) the valve mating surfaces are dry and free of scratches and any residual material.
- (d) the manual bonnet or actuator compressor is undamaged.

Figures J-1.3.2.1-1 through J-1.3.2.1-5 provide visual reference to the terminology used in this section.

J-1.3.2.2 Test Acceptance Criteria — Required Criteria for Hygienic Performance of Diaphragms

(a) After conducting performance evaluation testing per this Nonmandatory Appendix, the following criteria will determine if the diaphragm has passed or failed the test:

- (1) Valve passes pressure test criteria per this Nonmandatory Appendix.
- (2) Diaphragm stud is attached.
- (3) Product contact surface is free of surface splits, tears, cracks, or blisters.
- (4) Diaphragm flexes and inverts without displaying any cracks or tears to product contact surface.
- (5) Reinforcement fabric, if present, does not penetrate into product contact surface.
- (6) No visually apparent adherence of diaphragm material to valve seat.
- (b) The following checks can also be recorded as observations after performing the test, where applicable. These are also useful when evaluating valve diaphragms that are in service.

(1) Check that the marking on the diaphragm, according to SG-3.3.2.3(b)(4), is present and legible.

(2) Check that the diaphragm stud is firmly attached, not rotated, and undamaged. The bayonet pin should be centered to the stud.

(3) Check for creases or marks that traverse the sealing bead. Some flattening of the bead is a normal occurrence from compression during assembly and/or operation. Uneven compression indicates improper assembly.

(4) Check that deformation into valve cavities aligns with the center bead and is not excessive.

(5) Check that compressor deformation marks on the backing align with the center bead and are not excessive. Extreme deformation is an indication of overclosure.

(6) Check that the backing is free of splits and cracks.

(7) Check that bolt holes are round and not elongated. Elongated bolt holes indicate overclosure and/or improper assembly or excessive service life.

(8) Check for any diaphragm discoloration. Discoloration of diaphragms may be unrelated to diaphragm performance (e.g., rouging) or an indication that the diaphragm is not suitable for the application (e.g., unsuitable diaphragm material selection).

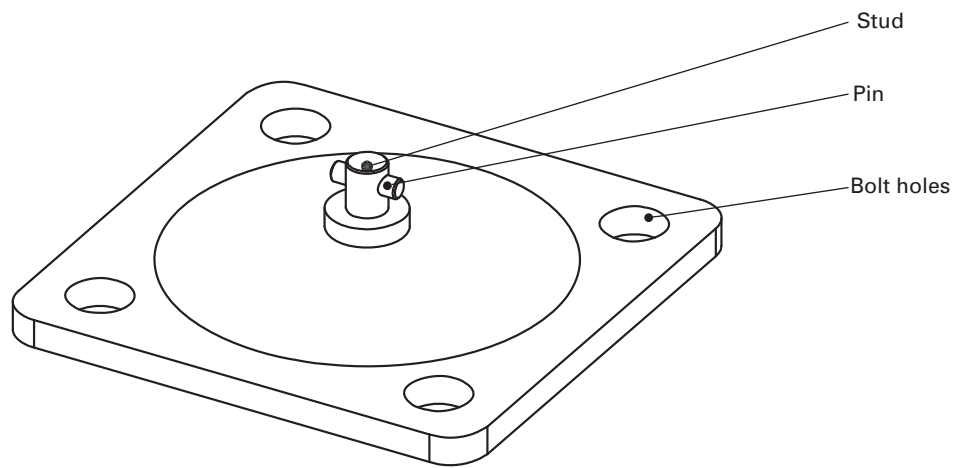
(9) Check that there is no evidence of adherence of diaphragm material to the body/bonnet flange.

J-2 MECHANICAL SEAL PERFORMANCE EVALUATION

J-2.1 Mechanical Seal Performance Evaluation

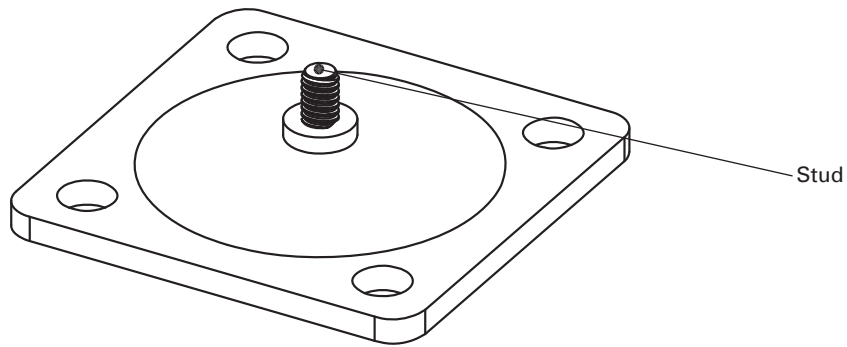
SG-4.3.2 of this Standard enumerates the various points, from manufacture to owner/user, that seal performance may be tested. This Standard recommends

Fig. J-1.3.2.1-1 Weir-Style Diaphragm

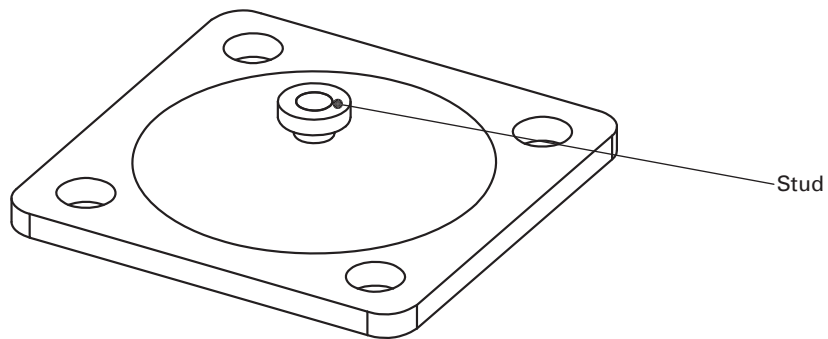


(a) Bayonet Style

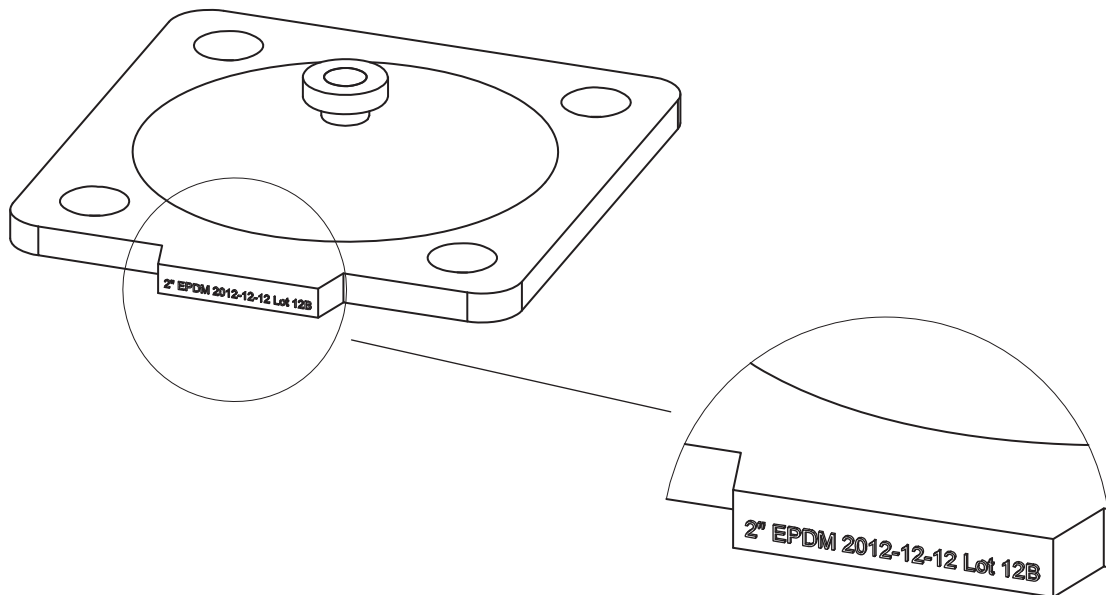
Fig. J-1.3.2.1-1 Weir-Style Diaphragm (Cont'd)



(b) Threaded Style

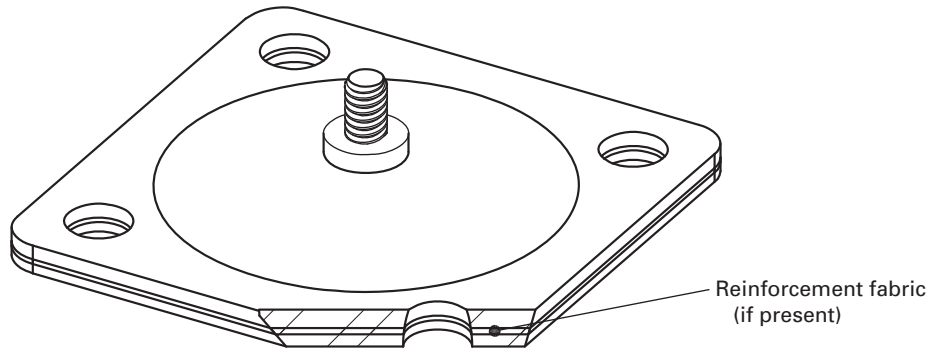


(c) Button Style

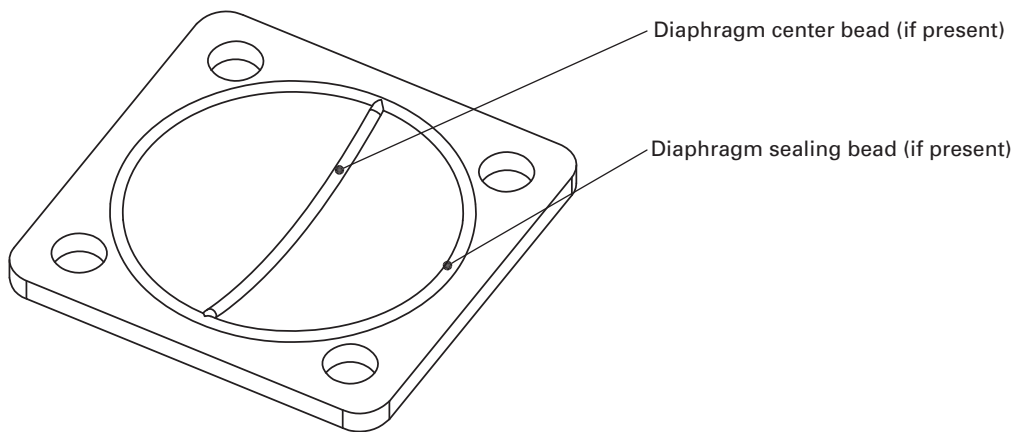


(d) Example of Diaphragm Marking

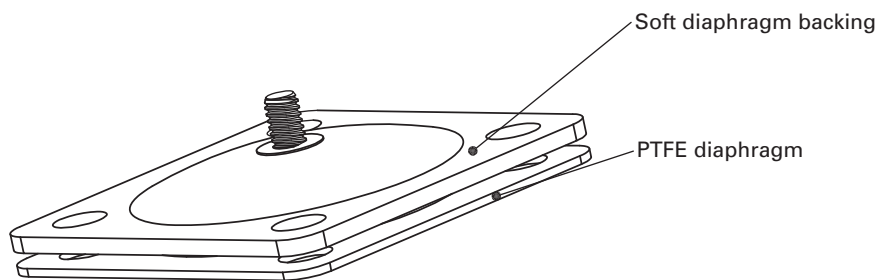
Fig. J-1.3.2.1-1 Weir-Style Diaphragm (Cont'd)



(e)



(f)



(g)

Fig. J-1.3.2.1-2 Weir-Style Body

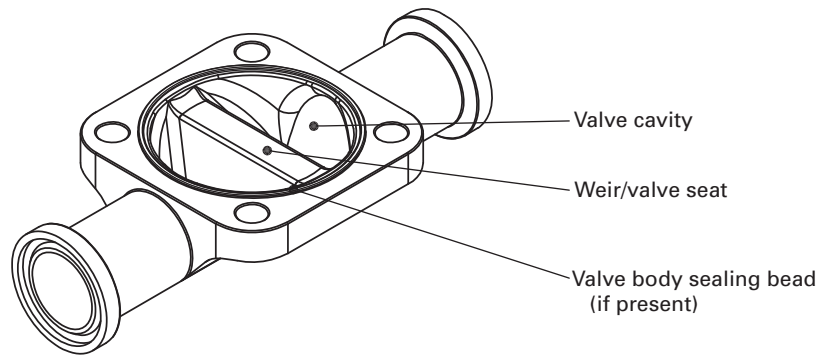


Fig. J-1.3.2.1-3 Radial-Style Body

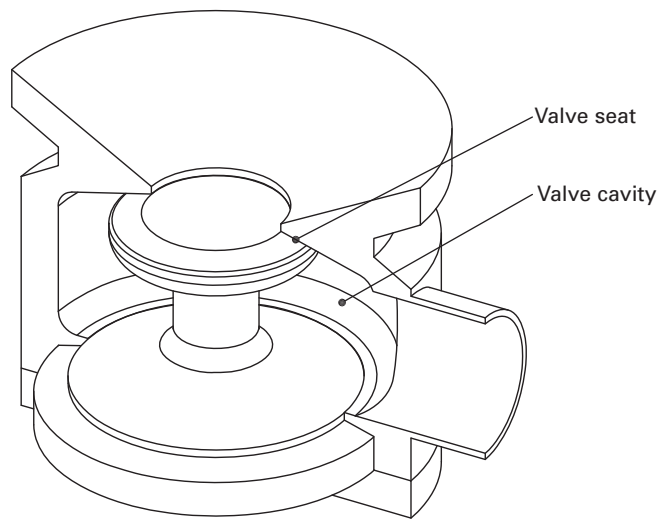


Fig. J-1.3.2.1-4 Manual Bonnet

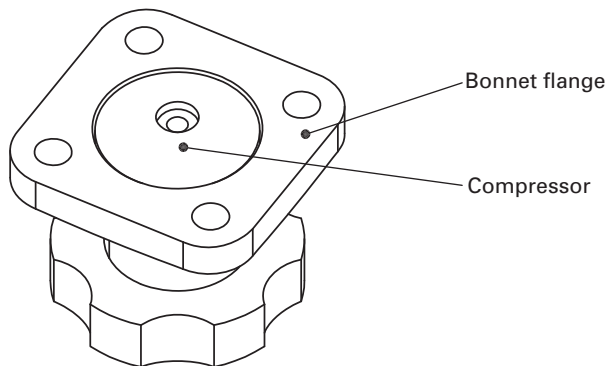
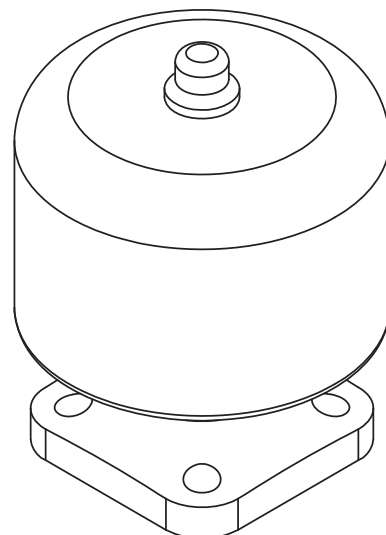


Fig. J-1.3.2.1-5 Pneumatic



that the performance test of the supplier/manufacturer be accepted at each point. The reason for this is twofold, as follows:

(a) A mechanical seal is a complex piece of equipment, and seal designs have proven to be very reliable directly from the supplier/manufacturer.

(b) A performance test conducted in an environment other than the process operating conditions and the specific piece of equipment provides little more than generalized results.

J-2.1.1 Factors Affecting Seal Performance. Seal performance may vary significantly depending on the environment in which the seal will operate. Mechanical seal designers must take into account many factors such as the following:

- (a) shaft speed (revolutions per time)
- (b) shaft size
- (c) process pressure
- (d) process temperature
- (e) tribological characteristics of the lubricating fluid
- (f) weepage expectation
- (g) equipment on which the seal operates
- (h) start-stop operation
- (i) barrier or buffer fluid availability
- (j) multiprocess characteristics like CIP and SIP

J-2.1.2 Design Parameters. Once all process information is understood, the seal designer must determine the following:

- (a) seal face material(s)
- (b) secondary seal material(s)
- (c) type of lubrication such as boundary lubrication or full fluid film lubrication
- (d) seal balance
- (e) color of wearing materials
- (f) flush (piping) plan

All of these factors affect operating life and weepage of the mechanical seal.

Seal performance is dictated by many factors. A properly designed, installed, and operated seal can exceed operational expectations. Many mechanical seals do not meet their operational life because of a variety of errors. Exceptions to normal seal wear that lead to failure are listed, in part, in J-2.2.

J-2.2 Exceptions to Normal Seal Performance

It is rare that end face mechanical seals “wear out.” For a seal to be “worn out” implies that one or both of the primary seal faces have worn away due to normal rubbing friction. Three groups of examples to the exceptions to normal seal performance are listed in J-2.2.1 through J-2.2.3.

J-2.2.1 Event-Based Operational Failures. Examples of event-based operational failures are

- (a) pressure reversals

- (b) dead-heading pump
- (c) process upset conditions
- (d) tampering with seal support system or support system upset
- (e) lubricating fluid becomes contaminated
- (f) dry seal runs wet or liquid seal runs dry
- (g) faces glue together during shut-off
- (h) shock-induced failure — shaft

J-2.2.2 Design- and Application-Based Failures.

Examples of design- and application-based failures are

- (a) running seal dry when a liquid seal was designed or running seal wet when a dry seal was designed
- (b) operation outside of seal design parameters
- (c) improper selection of materials
- (d) insufficient cooling
- (e) dynamic secondary seal hang-up

J-2.2.3 Equipment-Based Failures. Examples of equipment-based failures are

- (a) excessive run-out/deflection
- (b) bolting distortion/equipment mounting flange flatness
- (c) equipment alignment
- (d) pipe strain and pipe support issues
- (e) vibration
- (f) bearing failure

J-2.3 Mechanical Seal Integrity Tests

(16)

Performance of mechanical seals may be tested several different ways. Test methods may vary between companies, and sometimes within a company. The following section provides a framework from which a test procedure may be drawn followed by a reasonable assessment of the test results. Unless otherwise specified, the test fluid is water for the liquid seals and oil-free compressed air or nitrogen for the gas seals. These tests will only verify the integrity of the seal faces and secondary seals. These tests do NOT reveal any information about the validity of the seal selection, expected seal life, or dynamic seal performance. The following tests describe examples of effective methods to verify seal integrity. The owner/user may modify the test or pass/fail criteria.

J-2.3.1 Single Mechanical Seals: Liquid Lubricated by Process

(a) *Wet Test.* A single-cartridge seal or noncartridge seal must be installed in equipment for a performance test. A liquid seal is tested dynamically with liquid lubrication. Visible leakage is a typical quantifier to verify integrity of a seal.

(1) *Dynamic Wet Test for Liquid-Lubricated Single Mechanical Seal*

Step 1: Follow all safety rules and regulations during assembly and testing of the seal.

Step 2: After the seal has been installed, flood the equipment with the test liquid, paying special

- attention that the seal chamber has been completely flooded.
- Step 3:* Confirm that the equipment is capable of withstanding the test pressure.
- Step 4:* Operate and pressurize the equipment.
- Step 5:* Observe the seal. If the test criteria have been met the seal passes the test.
- Step 6:* If the seal fails the test criteria initially, consider operating the equipment longer to see if the seal wears in and passes the test.
- Step 7:* Document the results.
- Step 8:* If the seal does not pass the test, follow the procedure for resolution.

(2) Static Wet Test for Liquid-Lubricated Single Mechanical Seal

- Step 1:* Follow all safety rules and regulations during assembly and testing of the seal.
- Step 2:* After the seal has been installed, flood the equipment with the test liquid, paying special attention that the seal chamber has been completely flooded.
- Step 3:* Confirm that the equipment is capable of withstanding the test pressure.
- Step 4:* Pressurize the equipment.
- Step 5:* Observe the seal. If the test criteria are met the seal passes the test.
- Step 6:* If the seal fails the test criteria initially, consider rotating the shaft manually a few turns.
- Step 7:* Document the results.
- Step 8:* If the seal does not pass the test, follow the procedure for resolution.

(b) Dry Test. A single-cartridge liquid mechanical seal or noncartridge liquid mechanical seal must be installed in equipment for a performance test. A liquid seal tested dry with gas pressure, typically air or nitrogen, is tested statically. Gas flow across the seal is the typical quantifier to test the integrity of the seal. If the flow rate of gas across the seal is greater than 1 std. ft³/hr/in. (1.1 L/hr/mm) shaft diameter at 30 psi (2 bar) the seal may be considered failed. Other pass/fail criteria may be applied if required.

(1) Static Dry Test for Liquid-Lubricated Single Mechanical Seal

- Step 1:* Follow all safety rules and regulations during assembly and testing of the seal.
- Step 2:* Confirm that the equipment is capable of safely withstanding the test pressure.
- Step 3:* Install an appropriately sized flowmeter and pressure regulator to the equipment.
- Step 4:* Seal all other openings in the equipment.
- Step 5:* Pressurize the equipment to 30 psi (2 bar). Do not block off the source of pressure. Hold the pressure constant.
- Step 6:* Let the pressure stabilize in the equipment and read the flowmeter.

Step 7: If the flowmeter reads less than 1 std. ft³/hr/in. (1.1 L/hr/mm) of shaft diameter, the seal passes the test.

Step 8: If the seal does not meet the test criteria, consider turning the shaft slowly BY HAND to see if the flow rate is reduced.

Step 9: Document the results.

Step 10: If the seal does not pass the test, follow procedures for resolution.

(2) Static Dry Test for Liquid-Lubricated Single Mechanical Seal

Step 1: Follow all safety rules and regulations during assembly and testing of the seal.

Step 2: Confirm that the equipment is capable of safely withstanding the test pressure.

Step 3: Attach a pressure source and a pressure regulator to the equipment.

Step 4: Seal all other openings in the equipment.

Step 5: Pressurize the equipment to 30 psi (2 bar).

Step 6: Note time, pressure, volume, and temperature of the equipment.

Step 7: Block off the source of pressure.

Step 8: Wait for a designated time.

Step 9: Note the ending time, pressure, volume, and temperature of the equipment.

Step 10: Use the ideal gas law and the measured time to calculate the volume flow of gas over the seal per hour.

Step 11: If the calculations reveal less than 1 std. ft³/hr/in. (1.1 L/hr/mm) of shaft diameter, the seal passes the test.

Step 12: If the seal does not meet the test criteria, consider turning the shaft slowly BY HAND to see if the flow rate is reduced.

Step 13: Document the results.

Step 14: If the seal does not pass the test, follow standard procedures for resolution.

J-2.3.2 Dual Mechanical Seals: Liquid Lubricated by Barrier Fluid (Dual Pressurized) or by Process and Buffer Fluid (Dual Unpressurized)

(a) Wet Test. Dynamic and static barrier and buffer fluid tests may be used to check the integrity of a dual mechanical seal. A dual-cartridge mechanical seal may be capable of being bench tested. A dual-component seal must be installed in equipment for a performance test. However, it is not possible to view the inboard seal and in many cases it is not possible to view the outboard seal. This means that a static or dynamic liquid test will only reveal if secondary seals are installed properly and if proper face contact is occurring.

(1) Static Wet Bench Test for Liquid-Lubricated Dual-Cartridge Mechanical Seals

Step 1: Follow all safety rules and regulations during assembly and testing of the seals.

- Step 2: Confirm that the equipment and seal cartridge are capable of safely handling the test pressure.
- Step 3: Find and plug appropriate ports in the seal cartridge.
- Step 4: Connect the pressure line to the appropriate port in the seal cartridge.
- Step 5: Important: Double check that bolting in the seal cartridge is adequate to hold the test pressure.
- Step 6: Fill the seal cavity with test liquid, usually water, taking special care to purge the cavity of all air.
- Step 7: Pressurize the seal to 30 psi (2 bar).
- Step 8: Observe both ends of the seal cartridge. If no visible leakage occurs the seal passes the test.
- Step 9: Document the results.
- Step 10: If the seal does not pass the test, follow the procedure for resolution.

(2) *Static and Dynamic Wet Test for Dual Liquid Mechanical Seal Installed in Equipment.* In this test it will not be possible to view the inboard seal of the dual seal. Therefore the inboard seal will not be observed for visible leakage. It MIGHT be possible to view the outboard seal. Therefore these tests will ONLY reveal if inboard secondary seals have been installed properly and are undamaged AND IF the inboard seal faces are in proper rubbing contact.

- Step 1: Follow all safety rules and regulations during assembly and testing of the seals.
- Step 2: Confirm that the equipment and seal are capable of safely handling the test pressure.
- Step 3: For the dynamic test, confirm that the pressure, temperature, and flow rate of the barrier fluid or the buffer fluid are appropriate for the test.
- Step 4: Connect the pressure line and pressure gauge to the appropriate port in the seal cavity.
- Step 5: Fill the seal cavity with test liquid, usually water, taking special care to purge the cavity of all air.
- Step 6: Pressurize the seal to 30 psi (2 bar).
- Step 7: Shut "IN" and "OUT" valves to the seal to isolate the pressure for no more than 5 sec to avoid seal damage.
- Step 8: Observe the pressure drop. If the pressure does not immediately drop, the seal parts are in place and operating and pass the test.
- Step 9: Document the results.
- Step 10: If the seal does not pass the test, follow the procedure for resolution.

(b) *Dry Test for Liquid Mechanical Seal, Static Test Only.* This is a bench test of a dual-cartridge seal or an

installed-in-equipment test for a cartridge or component seal.

- Step 1: Follow all safety rules and regulations during assembly and testing of the seal.
- Step 2: Confirm that the equipment is capable of safely withstanding the test pressure.
- Step 3: Attach a source of gas pressure, a pressure regulator, and a flowmeter to the seal.
- Step 4: Plug all other openings in the equipment.
- Step 5: Pressurize the seal to 30 psig (2 bar).
- Step 6: Let the pressure equalize.
- Step 7: Note the gas flow rate on the flowmeter.
- Step 8: If the flowmeter reveals less than 1 std. ft³/hr/in. (1.1 L/hr/mm) of shaft diameter, the seal passes the test.
- Step 9: If the seal does not meet the test criteria and is installed in the equipment, consider turning the shaft slowly BY HAND to see if the flow rate is reduced.
- Step 10: Document the results.
- Step 11: If the seal does not pass the test, follow standard procedures for resolution.

(c) *Dry Test for Gas Mechanical Seal Designed, Static, or Dynamic Test.* This is a bench test of a dual-cartridge mechanical seal or an installed-in-equipment test for a cartridge or component mechanical seal.

- Step 1: Follow all safety rules and regulations during assembly and testing of the seal.
- Step 2: Confirm that the equipment is capable of safely withstanding the test pressure.
- Step 3: Attach a source of gas pressure, a pressure regulator, and a flowmeter to the seal.
- Step 4: Plug all other openings in the equipment.
- Step 5: Pressurize the seal to 30 psi (2 bar) [for lift-off seals 50 psi to 60 psi (4 bar)].
- Step 6: Let the pressure equalize.
- Step 7: If it is a dynamic test, and it is safe to do so, operate the equipment.
- Step 8: Note the gas flow rate on the flowmeter.
- Step 9: If the flowmeter reveals less than 1 std. ft³/hr/in. (1.1 L/hr/mm) (for lift-off seals 2 std. ft³/hr/in.) of shaft diameter, the seal passes the test.
- Step 10: If the test is performed statically and does not meet the test criteria and is installed in the equipment, consider turning the shaft slowly BY HAND to see if the flow rate is reduced.
- Step 11: Document the results.
- Step 12: If the seal does not pass the test, follow standard procedures for resolution.

J-2.4 Mechanical Seal Testing Notes

(a) *Safety Precaution.* If testing dual-cartridge mechanical seals that are not installed in the equipment, then it is necessary to review the seal design. The seal cartridge must be capable of containing the pressure

injected into the seal chamber. Using compressible fluids can be a very dangerous method for bench testing dual seals.

(b) When gas is used as a test fluid, the volume of gas passing across the mechanical seal determines the seal integrity. Determining the volume of gas passing across seal faces is the preferred method when using a compressible fluid as a test fluid.

(c) Pressure drop of compressible fluid tests are acceptable when used consistently AND checked against operational sealing success. Equipment

manufacturers and assemblers use pressure drop tests that have been proven repeatable in the field. Experience of the OEM and assembler allows for accurate and repeatable interpretation of the results.

(d) Volume flow across a seal MAY be calculated using the ideal gas law if all the following information is known in the test system:

- (1) initial pressure and final pressure
- (2) initial temperature and final temperature
- (3) volume of the system; constant and known
- (4) the system is dry

NONMANDATORY APPENDIX K

STANDARD TEST METHODS FOR POLYMERS

K-1 STANDARD TEST METHODS FOR THERMOPLASTIC POLYMERS

ASTM C177, Standard Test Method for Steady-State Heat Flux Measurements and Thermal Transmission Properties by Means of the Guarded-Hot-Plate Apparatus

ASTM D256, Standard Test Method for Determining the Izod Pendulum Impact Resistance of Plastics

ASTM D543, Standard Practices for Evaluating the Resistance of Plastics to Chemical Reagents

ASTM D570, Standard Test Method for Water Absorption of Plastics

ASTM D638, Standard Test Method for Tensile Properties of Plastics

ASTM D648, Standard Test Method for Deflection Temperature of Plastics Under Flexural Load in the Edgewise Position

ASTM D785, Standard Test Method for Rockwell Hardness of Plastics and Electric Insulating Materials

ASTM D789, Standard Test Methods for Determination of Solution Viscosities of Polyamide (PA)

ASTM D790, Standard Test Method for Flexural Properties of Unreinforced and Reinforced Plastics and Electric Insulating Materials

ASTM D2240 or ISO 48, Standard Test Method for Rubber Property—International Hardness or Durometer Hardness

ASTM D3418, Standard Test Method for Transition Temperatures and Enthalpies of Fusion and Crystallization of Polymers by Differential Scanning Calorimetry

Publisher: American Society of Testing and Materials (ASTM International), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959 (www.astm.org)

K-2 STANDARD TEST METHODS FOR THERMOSET POLYMERS

ASTM D395 or ISO 815, Standard Test Methods for Rubber Property — Compression Set

ASTM D412 or ISO 37 — Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension

ASTM D471 or ISO 1817, Standard Test Method for Rubber Property — Effect of Liquids

ASTM D624, ISO 34, or ISO 816, Tear Strength

ASTM D2240 or ISO 48, Standard Test Method for Rubber Property — International Hardness or Durometer Hardness

Publisher: American Society of Testing and Materials (ASTM International), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959 (www.astm.org)

K-3 THERMOSET POLYMER TEST PROPERTIES

Refer to Table K-3-1.

K-4 INTERPRETATION OF THERMOSET MATERIAL PROPERTY CHANGES

Refer to Table K-4-1.

K-5 TESTING PROTOCOLS FOR THERMOSET POLYMERS

K-5.1 Samples

Sample parts shall be prepared according to ASTM D412 (ISO 37). Samples tested per this specification shall be from the same formulation as finished parts.

K-5.2 Immersion Fluids

(16)

Test fluids and test temperatures for fluid immersions are as follows:

(a) sodium hydroxide — (0.5N, 0.5M, 2% w/w) at 176°F (80°C)

(b) phosphoric acid — (0.36N, 0.12M, 1.2% w/w) at 176°F (80°C)

(c) sodium hypochlorite — (0.67N, 0.67M, 0.5% w/w) at 176°F (80°C)

(d) saturated clean steam at 266°F (130°C)

Rinse samples with water to a neutral pH, or minimum conductivity, and dry before testing.

Additional test fluids and conditions may be specified.

K-5.3 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 K-2, as applicable.

K-5.4 Elastomer Testing: Property Retention

Elastomer material testing requirements are listed in Table K-3-1. 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.

Table K-3-1 Thermoset Polymer Test Properties**(16)**

Property Change (From Original Value)	Test Designation	Description and Application (Reference Table K-4-1)
Fluid immersion (70 hr, 166 hr, and 502 hr at specified temperature) [Note (1)]	...	...
Compression set	ASTM D395B or ISO 815	Measure of recovery after deformation
Volume and/or weight	ASTM D471 or ISO 1817	Absorption of solvent or extraction of soluble constituents from elastomer
Hardness, IRHD, or Shore	ASTM D1415, D2240, or ISO 48	Changes related to solvent and/or temperature; higher numbers indicate harder material
100% modulus	ASTM D412 or ISO 37	Measure of force required to extend sample by 100%
Tensile strength at break	ASTM D412 or ISO 37	Force needed to stretch part to breaking point
Elongation at break	ASTM D412 or ISO 37	Percent elongation at break
Tear strength	ASTM D624 or ISO 34	Elastomer resistance to tear

NOTE:

(1) Test duration times are 0/+2 hr.

Table K-4-1 Interpretation of Thermoset 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 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 and may be the 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

NONMANDATORY APPENDIX L

SPRAY DEVICE COVERAGE TESTING

L-1 SCOPE

This Nonmandatory Appendix defines an acceptable method for performing spray device coverage testing for bioprocessing equipment.

L-2 PURPOSE

The purpose of a spray device coverage test is to document fluid coverage of the process contact surfaces of bioprocessing equipment. The test provides information about fluid coverage and the conditions necessary to achieve this coverage as a prerequisite for cleaning of the process equipment. The coverage test is not intended to demonstrate cleanability, but rather the ability to deliver cleaning solutions to the target surfaces. Cleanability is verified using a full CIP protocol during cleaning validation.

L-3 MATERIALS

(a) A concentration of 0.08 g/L to 0.22 g/L riboflavin (vitamin B2) aqueous solution provides visible fluorescence under ultraviolet light. The riboflavin should be free of animal-derived ingredients (ADI). Riboflavin is water soluble, noncorrosive, and nonreactive on materials commonly used to manufacture bioprocessing equipment (e.g., stainless steel, polymers, and ceramics). Riboflavin fluoresces with exposure to long-wavelength ultraviolet (UV) light with peak intensity at 365 nm. Note that if other fluorescent materials are used, the UV wavelength for optimum visibility may be different.

(b) UV lamps are available with different wavelengths and intensities. A lamp with a peak wavelength of 365 nm and an intensity of 4 000 $\mu\text{W}/\text{cm}^2$ at a distance of approximately 15 in. (38 cm) is optimal to observe riboflavin fluorescence. Ultraviolet lamp intensity is inversely proportional to the square of the distance from the source. Ultraviolet lamps of this intensity may present a safety hazard to the eyes and skin. Personal protective equipment (PPE) is recommended. UV lamps of other wavelengths can be used, but stronger concentrations of riboflavin may be required for detection.

(c) An extension mirror or borescope camera can be useful for visual inspection of hard-to-reach areas.

(d) The quality of water used for the formulation of the riboflavin solution and for coverage testing shall be agreed to by the owner/user and manufacturer. The

minimum acceptable water quality is noncompensial purified water (e.g., reverse osmosis or deionized).

L-4 PROCEDURE

L-4.1 Equipment Preparation

(a) All internal appurtenances should be installed (e.g., agitators, level probes, and dip tubes) during the spray device coverage testing. If conducting the test with all interior appurtenances in place is not practical, alternative means to simulate shadowing should be agreed on with the owner/user (e.g., dummy shafts and dip tubes may be used). If the agitator is installed, it should be rotated at the same rate as planned for CIP.

(b) All internal surfaces and appurtenances shall be clean prior to the coverage test. Contaminated surfaces (e.g., with grease or oil) may produce inconclusive results.

(c) Verify that the spray device(s) is installed in the designed location and orientation (where applicable).

L-4.2 Application of Fluorescent Solution

(a) The test shall be performed by spraying the fluorescent solution as a mist on all targeted surfaces of the bioprocess equipment including walls, nozzles, baffles, and other appurtenances. The solution application should minimize droplet formation and runoff. Care should be taken to avoid applying the fluorescent agent to areas that are outside of the process boundary (e.g., the side of the manway gasket that is not exposed to the process). Note that the inside of dip tubes or similar hollow members not targeted by the spray device may require a separate rinse path during the test.

(b) Using an ultraviolet light permits visual verification that the targeted surfaces have been wetted with the fluorescent solution. Fluorescent agents such as riboflavin typically fluoresce only when they are wet.

(c) The riboflavin application inspection methods shall be consistent with the postrinse inspection methods.

L-4.3 Execute Rinse

(a) The rinse should be performed with ambient (or colder) temperature water to allow for immediate inspection of wet surfaces. The use of other temperatures shall be agreed on with the owner/user.

(b) The rinse should be performed before the riboflavin solution has dried, as the test is designed to confirm coverage and not cleaning.

(c) The rinse shall be performed in a once-through mode.

(d) Conditions such as flow rate, pressure, and time shall be recorded during the coverage test as described in L-6.

L-4.4 Inspection

(a) Inspection should be performed before the surfaces dry. Surfaces must be wet to detect riboflavin fluorescence.

(b) If surfaces are dry at the time of inspection, the surfaces shall be gently rewetted from bottom and up with ambient or cold water to observe any residual riboflavin fluorescence. Rewetting and inspecting lower surfaces first and higher surfaces next will reduce the likelihood of misidentification of the location of residual riboflavin.

(c) Ambient light should be minimized to improve the visibility of riboflavin fluorescence.

(d) The postrinse inspection methods shall be consistent with the riboflavin application inspection methods.

(e) For large enclosures (e.g., vessels with manways) confined space entry may be necessary to conduct a thorough inspection.

(f) The inspection sequence should be designed to avoid false results due to transfer of residual riboflavin from internal or external sources.

L-5 ACCEPTANCE CRITERIA

(a) Acceptance criteria and coverage test protocol shall be agreed on with the owner/user before the coverage test.

(b) A typical acceptance criterion is removal, to the limit of visual detection, of the riboflavin solution from all targeted areas or as otherwise agreed on with the owner/user.

(c) If areas of residual riboflavin are present, they should be documented, and a corrective action plan should be established with the owner/user.

L-6 RECOMMENDED DOCUMENTATION

(a) Test configuration sketch (reference the OEM drawing) and description (with, e.g., line size, instrument locations, elevation)

(b) *Spray Device Data*

(1) Model, make, serial number, and tag number.

(2) Verify correct installation, orientation, down pipe, and down pipe length.

(3) Recommended pressure and flow conditions (data sheet).

(c) *Instrument Data*

(1) Data sheets (instrument ranges)

(2) Calibration certificates for instruments

(d) *Riboflavin Solution Data*

(1) Riboflavin catalog number and lot number

(2) Expiration date

(3) Amount of riboflavin

(4) Amount of water and quality

(5) Time and date of preparation

(6) Time and date of application and preinspection

(7) Time and date of rinse and postinspection

(e) *UV Lamp Data*. Model number and data sheet

(f) *Temperature of Rinse Water*

(g) For initial flow path and each subsequent transition to a different flow path, document

(1) Flow rate

(2) Time (burst/delay sequence, if applicable)

(3) Pressure (measured as close to the spray device as practical)

(4) For dual-axis dynamic spray devices, time, flow, and pressure to complete a pattern

(h) *Test Results*

(1) Pass/fail

(2) If applicable, residual riboflavin location(s) and descriptions

(3) If applicable, corrective actions taken

NONMANDATORY APPENDIX M

COMMENTARY: UNS S31603 WELD HEAT-AFFECTED ZONE DISCOLORATION ACCEPTANCE CRITERIA

(a) The acceptance criteria for discoloration on weld heat-affected zones were developed by making autogenous square groove welds on 2-in.-diameter UNS S31603 stainless steel tube-to-tube butt joints whose inside diameters were purged with argon containing controlled amounts of oxygen. The oxygen levels reported were measured on the downstream side of the welds. For the sample numbers listed in Figs. MJ-8.4-2 and MJ-8.4-3, the oxygen contents were as follows:

- (1) #1a and #1b — 10 parts per million (ppm)
- (2) #2 — 25 ppm
- (3) #3 — 35 ppm
- (4) #4 — 50 ppm
- (5) #5 — 80 ppm

(b) All welds were made with the gas-tungsten arc welding (GTAW) process using 95% argon — 5% hydrogen shielding gas.

(c) The electropolished tubing used for the test welds had an SF4 surface finish (15 μ in. R_a max.) and the mechanically polished tubing had an SF1 surface finish (20 μ in. R_a max.).

(d) The photos shown in Figs. MJ-8.4-2 and MJ-8.4-3 were taken using a camera having direct visual access to the weld surfaces.

(e) The corrosion resistance of the welded samples was determined by both ASTM G150, Critical Pitting Temperature Test, and the modified ASTM G61, Potentiodynamic Polarization Corrosion Test.

(f) ASTM G150 determines the voltage-independent critical pitting temperature (CPT) by way of a potentiostatic technique that determines the temperature above which pitting corrosion proceeds on its own under standardized test conditions. Higher CPTs indicate increased resistance to pitting corrosion.

The modified ASTM G61 determines the voltage (potential) at which the anodic current increases rapidly during a standardized cyclic polarization test at room temperature. The voltage determined, referred to as the E_{PIT} , is a measure of resistance to pitting corrosion. Higher, or more noble, values of E_{PIT} indicate increased resistance to pitting corrosion.

Neither the CPT nor the E_{PIT} values determined are material properties per se; rather, they are the result of standardized tests designed to rank different materials or different surface finishes of the same material in their resistance to the stable propagation of pits in a standard test environment.

(g) The acceptable levels of discoloration identified in Figs. MJ-8.4-2 and MJ-8.4-3 are based on corrosion resistance, not on the oxygen levels of the internal purge gas used during welding. As a result, the photographs in Figs. MJ-8.4-2 and MJ-8.4-3 should be used to identify the degree of discoloration by number, but not to specify the amount of oxygen in the backing gas.

(h) All welds were tested in the as-welded condition, with no postweld conditioning.

(i) For the electropolished tubing in Fig. MJ-8.4-2, acceptable levels of heat-affected zone discoloration were those that exhibited corrosion resistance similar to unwelded, electropolished UNS S31603 base metal in the ASTM G150 test.

(j) For the mechanically polished tubing in Fig. MJ-8.4-3, acceptable levels of heat-affected zone discoloration were those that exhibited corrosion resistance similar to that of a cold-rolled, mill-finished, UNS S31603 base metal.

(k) It is generally accepted that as-welded heat-affected zones on mechanically polished tubing having the same level of discoloration as weld heat-affected zones on electropolished tubing will exhibit lower resistance to pitting than the heat-affected zone on electropolished tubing.

(l) The user is cautioned that the amount of discoloration and its appearance can be influenced by factors other than oxygen, as listed below:

(1) High levels of moisture in the backing gas can increase the degree of discoloration.

(2) Other contaminants, such as hydrocarbons, moisture, and some types of particulates on the surface prior to welding, can all affect discoloration levels.

(3) Hydrogen in the argon backing gas can significantly reduce the amount of discoloration.

(4) The metal's surface finish can also affect the appearance of the discoloration.

NONMANDATORY APPENDIX N

GUIDANCE WHEN CHOOSING POLYMERIC AND NONMETALLIC MATERIALS

N-1 GENERAL

Polymer materials can be divided into two general classes: thermoplastics and thermosets. The composition, form, and construction of these materials determine their suitability for use in their various applications, and the systems designer should be aware of their strengths and limitations.

Polymer materials may be manufactured from a single monomer (homopolymer) or multiple monomers (copolymers). They may be filled or unfilled. They may be elastomeric or rigid. They may exist in an amorphous, crystalline, or semicrystalline state. They may consist of either single or multiple microphases, be manufactured as composites, and include adhesive materials.

Nonmetallic materials may be rigid or flexible, amorphous or crystalline, exist in single or multiple microphases, and formed into complex mixtures and composites. These materials can offer a range of unique properties (e.g., extreme hardness, chemical inertness, self-lubrication, or transparency). The system designer and owner/user should be aware of the broad range of physical and chemical properties of these materials.

N-2 PARTICULATES

(16)

N-2.1 Characterization

Particulates are characterized by several attributes including, but not limited to, size, morphology/shape, hardness, and chemical composition. These attributes may affect the ability to detect, measure, capture, identify, and control the particulates.

(a) *Physical Form*. Particulates may be of varying shapes. Some may be long and thin while others may be short and round. A majority of the particulates are irregular shapes with complex geometries.

(b) *Material Makeup*. Intrinsic particulates are native to the single-use system and include materials of construction or ingredients in the process formulation. Extrinsic particulates are foreign to the single-use system and come from the manufacturing environment or process personnel.

(c) *Hardness*. Particulates may be rigid or soft.

(d) *Chemical Composition*

N-2.2 Levels of Acceptance

Acceptable levels of particulate quantity and size distribution in single-use components and assemblies should be determined by their intended use. Owners/users should use established industry standards for the end product to quantify acceptable particulate criteria. Some of the industry standards available as acceptance criteria for drug products include USP <1>, USP <787>, USP <788>, USP <790>, EP 2.9.19, EP 2.9.20, JP 6.06, and JP 6.07.

(16) N-1.1 Gamma Irradiation

Gamma irradiation of polymers may change the physical properties of the polymeric material [see PM-4.1.6(b)]. Other effects may include discoloration and generation of low-molecular-weight compounds. Antioxidants or stabilizers may have been added to the polymeric material to minimize changes in physical properties.

NONMANDATORY APPENDIX O

GENERAL BACKGROUND/USEFUL INFORMATION FOR EXTRACTABLES AND LEACHABLES

(16) O-1 REFERENCES

- 21 CFR 211.94, Code of Federal Regulations, Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals
- Guidance for Industry-Container Closure Systems for Packaging Human Drugs and Biologics, FDA/CDER/CBER
- ICH Q3A, Guidance for Industry, FDA, "Impurities in New Drug Substances"
- ICH Q9, Guidance for Industry, FDA, "Quality Risk Management"
- Publisher: U.S. Food and Drug Administration (FDA), 10903 New Hampshire Avenue, Silver Spring, MD 20993 (www.fda.gov)
- "Accumulation of Organic Compounds Leached From Plastic Materials Used in Biopharmaceutical Process Containers"
- Publisher: Parenteral Drug Association, 4350 East West Highway, Suite 150, Bethesda, MD 20814 (<http://journal.pda.org/>)
- "BPSA Recommendations for Testing and Evaluation of Extractables From Single-Use Process Equipment," Bio-Process Systems Alliance, 2010
- Publisher: Bio-Process Systems Alliance, 1850 M Street, NW, Suite 700, Washington, DC 20036 (www.bpsalliance.org)
- EP 3.1.5, Polyethylene With Additives for Containers for Parenteral Preparations and for Ophthalmic Preparations
- EP 3.1.9, Silicone Elastomers for Closures and Tubing
- EP 3.1.13, Plastic Additives
- Publisher: European Directorate for the Quality of Medicines & Healthcare (EDQM Council of Europe), 7 alle Kastner, CS 30026, F-67081 Strasbourg, France (www.edqm.eu)
- "Extractables and Leachables: Challenges and Strategies in Biopharmaceutical Development"
- "Recommendations for Extractables and Leachables Testing, Part 1: Introduction, Regulatory Issues, and Risk Assessment"; Part 2: "Executing a Program"
- "Toward Industry Standardization of Extractables Testing for Single-Use Systems: A Collective BPSA Perspective"
- Publisher: BioProcess International, One Research Drive, Suite 400A, Westborough, MA 01581 (www.bioprocessintl.com)
- ISO 10993-18:2005(E), "Biological Evaluation of Medical Devices," Part 5: "Tests for In Vitro Cytotoxicity"; Part 13: "Identification and Quantification of Degradation Products from Polymeric Medical Devices"; Part 16: "Toxicokinetic Study Design for Degradation Products and Leachables"; Part 17: "Establishment of Allowable Limits for Leachable Substances"; Part 18: "Chemical Characterization of Materials"
- Publisher: International Organization for Standardization (ISO), Central Secretariat, Chemin de Blandonnet 8, Case Postale 401, 1214 Vernier, Geneva, Switzerland (www.iso.org)
- Jenke, D., Compatibility of Pharmaceutical Solutions and Contact Materials Safety Assessments of Extractables and Leachables for Pharmaceutical Products
- Publisher: John Wiley & Sons, 111 River Street, Hoboken, NJ 07030-5774 (<http://www.wiley.com>)
- PQRI — Safety Thresholds and Best Practices for Extractables and Leachables in OINDP
- Publisher: Product Quality Research Institute (PQRI), 2107 Wilson Blvd., Suite 700, Arlington, VA 22201-3042 (www.pqri.org)
- "Standardization of Single Use Components' Extractable Studies for Industry"
- "Standardized Extractables Testing Protocol for Single-Use Systems in Biomanufacturing"
- Publisher: International Society for Pharmaceutical Engineering (ISPE), 3109 W. Dr. Martin Luther King, Jr. Blvd, Tampa, FL 33607 (www.ispe.org)
- USP <88>, Biological Reactivity Tests, In Vivo
- USP <232>, Elemental Impurities Limits
- USP <661.1>, Plastic Materials of Construction
- Publisher: U.S. Pharmacopeial Convention (USP), 12601 Twinbrook Parkway, Rockville, MD 20852-1790 (www.usp.org/usp-nf)

O-2 RECOMMENDED CONDITIONS FOR A POLYMERIC MATERIAL-SPECIFIC EXTRACTION

(16)

(a) *Surface Preparation.* Materials of construction with a high likelihood for contact.

(b) *Sample Size.* 60 cm²/20 mL of extract fluid or 0.2 g/1 mL of extract fluid.

(c) *Test Temperature.* When a soxhlet extractor is used, fluid temperature is controlled by the condenser, near room temperature. For other methods of solvent extraction, the temperature may be elevated compared with the anticipated actual use conditions.

(d) *Test Solvents.* Use of one compatible polar solvent (e.g., ethanol, DI water) and one nonpolar solvent (e.g., hexane or toluene) to maximize extraction.

(e) *Test Time.* 24 hr.

(16) **O-3 RECOMMENDED CONDITIONS FOR AN EXTRACTION STUDY IN BIOPROCESS MODEL SOLUTIONS**

(a) *Surface Preparation.* Final article and contact surface should be used.

(b) *Sample Size.* 60 cm²/20 mL of fluid or 0.2 g/1 mL of fluid.

(c) *Test Temperature.* 40°C.

(d) *Test Fluids.* 20% ethanol (v/v), 0.1 M phosphoric acid (H₃PO₄), 0.1 M sodium hydroxide (NaOH), 5.0 M salt solution (NaCl), and/or purified water (meets USP requirements, at a minimum).

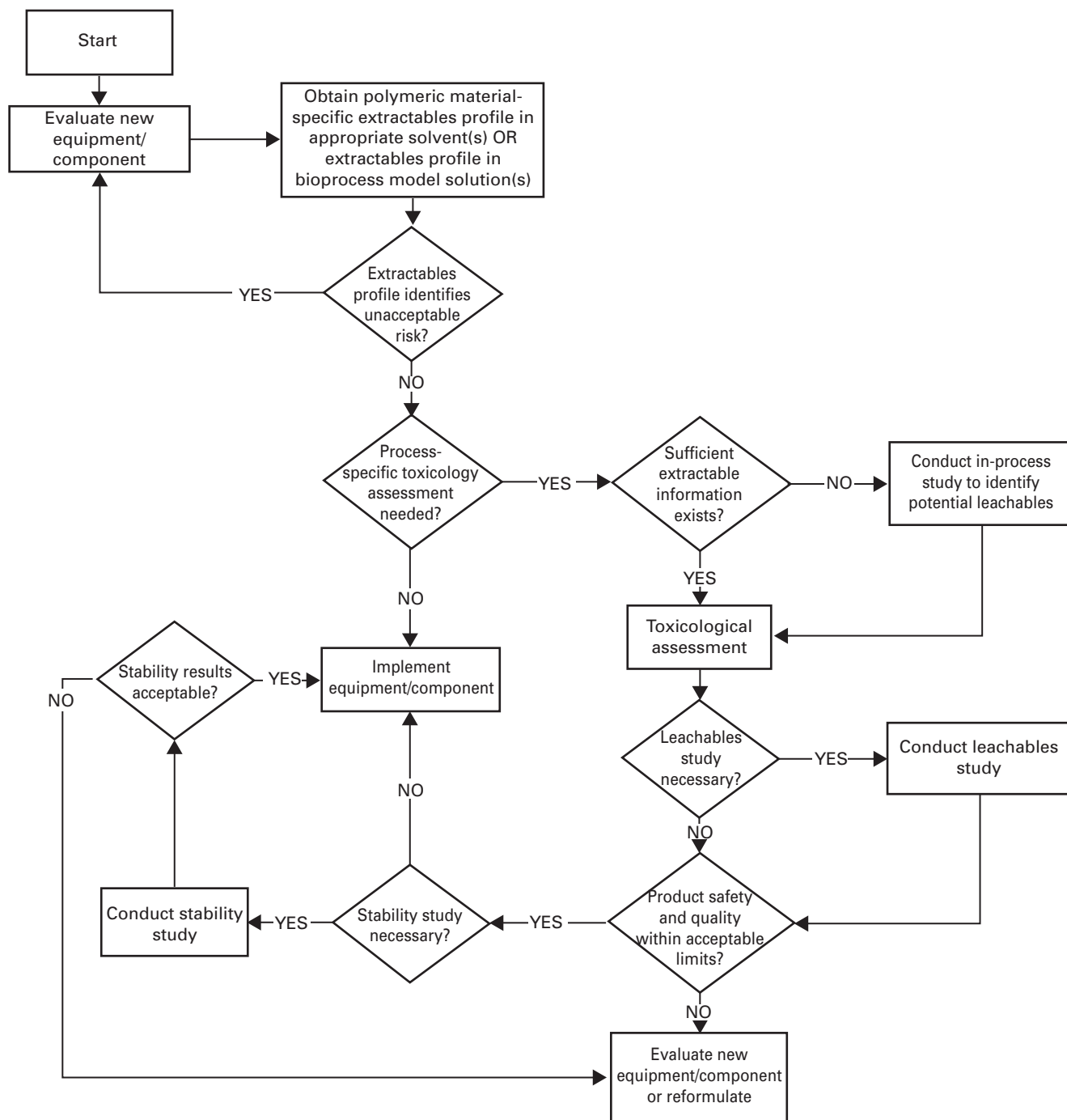
(e) *Test Time.* 30 days, unagitated.

O-4 OVERVIEW OF BIOPROCESSING EQUIPMENT/ COMPONENT EVALUATION RELATED TO EXTRACTABLES AND LEACHABLES CHARACTERIZATION (16)

See Fig. O-4-1.

Fig. O-4-1 Flowchart of Bioprocessing Equipment/Component Evaluation Related to Extractables and Leachables Characterization

(16)



NONMANDATORY APPENDIX P

TEMPERATURE SENSORS AND ASSOCIATED COMPONENTS

P-1 GENERAL

This Nonmandatory Appendix presents additional information not addressed in PI-7 on temperature sensors and various influences on sensor performance.

P-1.1 General Considerations

Platinum-based resistance temperature detectors (RTDs) are the most commonly used temperature-sensing technology. Alternative temperature measurement technologies are available that may be selected based on system design and owner/user preference. Manufacturers of the temperature sensors can confirm that the selected instrument meets the specified performance requirements in the environmental conditions at the installation location.

P-2 EXTERNAL SUPPORT COMPONENTS

Temperature sensor assemblies may include components external to the sensor that will influence the measurement accuracy. Assemblies typically may include enclosures, wire and cables, and transmitters. The instrument manufacturer can provide guidance on appropriate external components needed to meet the required measurement accuracy of the system.

P-3 MEASUREMENT ACCURACY

Total measurement accuracy includes, but is not limited to, sensor accuracy, installation effects on accuracy, wiring and cabling influences, electronics accuracy, process influences, and ambient influences.

P-3.1 Sensor Accuracy

The sensor manufacturer's stated accuracy represents the sensor performance as verified by the manufacturer's calibration laboratory. The sensor can be expected to meet the interchangeability criteria based on the tolerance class stated by the manufacturer and defined by the industry standards per PI-7.4.1.

A multipoint calibration can be performed to define the actual resistance vs. temperature relationship of the specific RTD. This calibration data can be used to improve the measurement accuracy.

P-3.2 Wiring and Cabling

Sensor wiring configuration and wire length will influence the measurement accuracy due to resistance

variation between lead wires and the lead wire compensation technique used.

(a) For RTDs, accuracy is influenced by lead wire compensation, specifically when long cable lengths are used. Four-wire designs provide the most effective compensation. Three-wire designs are effective for shorter cable lengths. Two-wire designs are generally not recommended by sensor manufacturers unless a closely mounted transmitter is incorporated into the instrument assembly.

(b) RTDs with long cable runs typically use shielded cable to minimize the influence of electrical noise along the cable run.

(c) For commonly used thermocouples, it is best to match the extension wire type with the thermocouple type. For thermocouple types R, S, and B (platinum based), alternate extension wire is commonly used. The manufacturer can provide guidance regarding extension wire choices, including when to use shielded wire.

P-3.3 Electronics

The accuracy and stability of electronic devices and control systems should be included in the assessment of the total measurement accuracy.

Matching electronics to sensor calibration data is an effective way to improve measurement accuracy and is preferred for process measurements where process system accuracy better than $\pm 3^\circ\text{F}$ (1.5°C) is required.

Electronics have an input resistance limitation that limits sensor cable lengths. Input resistance should not exceed the capability of the electronics. Refer to the manufacturer's specifications.

P-3.4 Process Influences

Stagnant flow, heating/cooling sources, valves, tubing construction, and other instruments near the fluid temperature measurement location can also influence the measurement accuracy.

P-3.5 Ambient Influences

(a) *Environmental Influences.* Moisture and other environmental conditions near the measurement location can influence the measurement and/or damage the sensor. Sensor installation should incorporate wire/cable connector and/or an enclosure (connection head). The enclosure rating should meet or exceed the NEMA rating (or international equivalent) for the installation location as defined by the owner/user. Selection of an

appropriate enclosure should be based on ambient conditions during system operation and cleaning/sterilization cycles.

(b) *Ambient Temperature Effects.* For sensor assemblies with an internal transmitter, the maximum operating temperature of the transmitter should be considered when insulating the assembly to minimize the influence of the ambient temperature (see PI-7.4.4).

P-4 SELECTION

P-4.1 Sensor Selection

(a) Consider the cable/wire length necessary to support removal for calibration or other maintenance activities.

(b) RTD-based sensors will generally provide the most accurate temperature measurement.

(c) A thermocouple-based sensor may be an effective choice where the accuracy requirements can be achieved and the control system accepts a millivolt (mV) input.

(d) Bimetallic, mechanical temperature sensors are typically used only for local indication due to the limited measurement range and accuracy.

(e) Liquid-in-glass (LiG) temperature sensors are not an effective choice due to various performance, capability, and environmental concerns.

P-4.2 Transmitter Selection

When a transmitter is required, a sensor/transmitter combined calibration is preferred to achieve the best accuracy.

P-5 MAINTENANCE

Sensor maintenance should include calibration verification and general sensor inspection.

P-5.1 Sensor Calibration Verification

(a) *Methods.* Specific calibration verification approaches should be according to the manufacturer's recommendations and specific process system performance requirements.

Sensor/transmitter combined calibration should be verified as a system. The association between sensor/transmitter system components should be maintained through tagging and/or serialization.

When verifying sensor or sensor/transmitter system accuracy, the typical verification temperature is the midpoint of the process operating temperature. At a minimum, sensors should be verified at 32°F (0°C).

Bimetallic sensors should be calibrated in the orientation of final use.

(b) *Frequency.* Sensor calibration should be verified annually. Alternate verification frequency may be specified based on criticality of the measurement and historical sensor verification data.

P-5.2 Sensor Inspection

An insulation resistance test (sensor lead wire to sensor body) on all RTDs and ungrounded thermocouples should be performed during periodic verification. Insulation resistance should be tested per the manufacturer's specification.

Physical inspection should be performed at each periodic verification event per the manufacturer's specification for the specific sensor, including an examination of overall condition and cleanliness of the sensor. The manufacturer's recommendations should be followed regarding cleaning, repair, or replacement if the sensor or thermowell exhibits indications of wear, damage, or other conditions that may affect performance or the useful life of the instrument.

NONMANDATORY APPENDIX Q

INSTRUMENT RECEIVING, HANDLING, AND STORAGE

Q-1 INTRODUCTION

This Nonmandatory Appendix is a supplement to PI-3.

Q-2 INSTRUMENT RECEIVING

The instrument(s) shall be verified against the packing slip prior to items leaving quarantine for release to inspection and/or storage.

Q-2.1 Warnings and Documentation

Refer to the product manual for any warnings and/or notices (e.g., ANSI Z535.6) regarding the instrument and comply accordingly. Documentation, such as calibration reports, material traceability, etc., should be kept with the instrument or handled per the owner/user's document control procedures.

Q-2.2 Incoming Inspection

Incoming inspection shall be performed to check for manufacturing defects per Parts DT and SF and/or other standards and internal quality criteria.

Q-3 INSTRUMENT HANDLING

Many instruments are assemblies of components. If it is necessary to disassemble the instrument to component level, component control is required.

Q-3.1 Instrument Assembly Segregation

When disassembling an instrument, each instrument assembly shall be segregated or kitted from other instrument assemblies to avoid mixing of components.

Q-3.2 Component Labels

Each component should, when possible, have a printed, individual, waterproof component label that includes information such as the instrument name, component part description, serial number, P & ID location, or barcode. Each component should have a unique part number. The preferred method for doing this is to use the serial number followed by (A) — first component; (B) — second component; etc.

Q-4 STORAGE

After receiving and inspections, instruments shall be packaged for storage to protect them from environmental conditions and contamination. The outside of the packaging shall be labeled to clearly identify the stored instrument.

NONMANDATORY APPENDIX R APPLICATION DATA SHEET

See Form R-1 beginning on the next page.

Form R-1 Application Data Sheet

Identification # _____
Tag # _____
P & ID # _____

Client: _____
Project: _____
Location: _____
Date: _____

Application/ Operation	Service	Application Details		Normal Operating Temperature, °F or °C [Note (1)]	Operating Low Temperature, °F or °C	(High) Design Temperature, °F or °C	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/wk/yr	Duration, hr/day
	Size										
	Rupture disk set pressure	Pressure _____ psi (bar)									
		Service Descriptions	Concentration, %								
	Process Fluid										
Steam	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		Concentration, % _____								
	Nitric acid ☐ Yes ☐ No		Concentration, % _____								
	Phosphoric acid ☐ Yes ☐ No		Concentration, % _____								
	Other ☐ Yes ☐ No		Concentration, % _____								
Solids	☐ Yes ☐ No		Concentration, % _____								
Valve Operation											
Mode of Operation: Valves	Manual ☐ Yes ☐ No										
	Automated ☐ Yes ☐ No		Minimum air pressure _____ psi or bar Maximum air pressure _____ psi or bar								
Diaphragm material currently using? (please state in the space below)											

Form R-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 sides; 100% ΔP is when closing against pressure on the upstream side only.

NONMANDATORY APPENDIX S

GUIDANCE ON POLYMER APPLICATIONS: CHROMATOGRAPHY COLUMNS AND FILTRATION

(16)

(16) S-1 CHROMATOGRAPHY COLUMNS

S-1.1 General

Chromatography columns are used in processes to purify products or isolate substances of interest from other components contained within process solutions. Typical examples include large-scale purification of biopharmaceuticals and fine chemicals.

S-1.2 Column Construction

A typical chromatography column is comprised of a cylindrical shell (the “tube”) closed at each end. The space between the ends of the column is filled with a medium (referred to as the “stationary phase” or “bed”) in which the chromatography separation takes place. The liquid that travels axially through the column is referred to as the “mobile phase.”

At each end of the column, a “bed support” retains the medium within the tube. This device is a porous disk typically constructed of a rigid, finely woven mesh or a semipermeable material. Behind each bed support is a “flow distributor.” The flow distributor ensures uniform distribution of the mobile phase. The distributor is typically attached to a “rigid support plate,” which is a pressure-retaining component that includes hygienic connections.

Usually, one end of the column is designed in such a way that it can be inserted into the column tube rather than fixing it to the end (much like a piston in a syringe), thereby allowing adjustment of the bed height. This assembly is referred to as the “adapter.” A column is typically installed with its axis oriented vertically and the adapter positioned at the top.

Chromatography columns may include additional mechanical features, such as the ability to add and remove the medium without opening the column and the ability to mechanically compress the bed.

S-1.3 Cleaning

The purpose of cleaning a chromatography column is to prevent environmental contamination, product-to-product carryover, or cross-contamination.

S-1.4 Sanitization

Chemical sanitization processes are used to reduce bioburden.

S-2 FILTRATION

(16)

S-2.1 General

Liquid or gas filtration is used to isolate processes, to purify substances of interest, to concentrate, to exchange buffer/diafilter, for viral removal, and for sterilization/bioburden reduction.

S-2.2 Filtration Formats

Typical examples include large-scale filtration and separation of biopharmaceuticals and fine chemicals using direct flow filtration (DFF) and tangential flow filtration (TFF). The filter elements used in both modes may be hydrophobic or hydrophilic. The principal difference between DFF and TFF is the direction of flow with respect to the filter surface. In TFF, the process fluid flow is tangential to the filter media with only a portion of the process fluid passing through it. This results in one inlet stream and two outlet streams. In DFF, the process fluid flow is perpendicular to the filter media with all of the process fluid passing through the filter media. This results in one inlet and one outlet.

S-2.2.1 Direct Flow Filtration. In DFF, the process fluid passes through the filtration media in a single pass. These filters are typically used for clarification, gas and vent filtration, virus reduction, and process fluid sterilization. This mode of filtration is also known as dead-end filtration, depth filtration, and normal flow filtration.

S-2.2.1.1 Filtration Elements. A typical DFF element may be one of the following acceptable designs:

(a) *Pleated or Wrapped Design.* Comprised of a cylindrical shell, which can have the media either pleated or wrapped. The flow path is typically from the outside of the cartridge through the wrap or pleat pack to the core. One end of the cylindrical shell can be either sealed (capped) or left open (referred to as “double open end”). Housing connections are typically flat gasket or various O-ring configurations. For submicron filtration, single-open-end designs are preferred with a secured double O-ring connection.

(b) *Lenticular Design.* Comprised of two sheets of filtration media cut in a circular design sandwiched and supported by a flow channel. These formats are usually stacked on top of each other. One end is closed for flow while the other end is connected either by a flat gasket

seal or by an O-ring connection. Sealing between the stacked formats is accomplished by either compression or welding.

(c) *Hollow Fiber Design.* Comprised of small-diameter permeable tubular membranes that are sealed on opposite ends by “potting.” The flow path can be from either direction (from inside to outside or vice versa) of the tubes to either end of the potting. The end of the potting is capped or sealed and the other end has single-open-end designs with Code 7 connection being preferred for submicron filtration.

S-2.2.2 Tangential Flow Filtration. In TFF, also known as cross-flow filtration, the bulk of the process fluid flow is tangential to the filter media surface and is typically referred to as “feed” or “retentate.” The portion of the process fluid that flows through the filter media is typically referred to as “permeate” or “filtrate” and is captured as a separate flow stream. TFF filter media are usually classified as microfiltration, ultrafiltration, or reverse osmosis based on the filter media pore size. TFF is typically used for clarification, diafiltration (buffer exchange), and/or concentration of a substance of interest.

S-2.2.2.1 Filtration Elements. A typical TFF element may be one of the following acceptable designs:

(a) *Hollow Fiber.* Comprised of one or more permeable membrane tubes, which are typically sealed into a housing on both ends by potting in a shell-and-tube design. The “shell” side of the membranes and the inside of the tubes are generally the two distinct different portions of the device as they can communicate only through the membrane of the tube. Hollow fiber elements are typically 0.079 in. (2 mm) or less in inner diameter. The two typical operation arrangements are inside-out and outside-in. In the inside-out arrangement, the process fluid is pumped into the inside of the tubes; in this case, the retentate will emerge out the other end of the tube, and permeate will be collected on the shell side of the device. In the outside-in arrangement, the process fluid is pumped into one end of the shell, and the retentate emerges out the other end; in this case, permeate is collected from the inside of the tubes.

(b) *Tubular.* A tubular membrane is characterized by its discrete tubes and large lumen sizes, which are typically 0.5 in. (12 mm) or greater inner diameter. These lumens are usually metallic or polymeric and provide strong structural support for the membranes. Tubular membranes flow from inside out, with turbulent flow in the retentate stream keeping the membrane surface clean. Permeate flows through the walls of the tubes and is collected outside the modules. Modules are constructed of metallic or polymeric materials, to accommodate user needs. Solids levels of up to 5% by weight are commonly handled by tubular membranes.

(c) *Plate and Frame.* Plate-and-frame or flat-sheet filters are characterized by an envelope-type structure formed out of two pieces of membrane. In this type of device, process fluid is passed over the outside of the envelope and passes through the membrane into the inside of the envelope; the remaining material that did not pass through the membrane is the retentate. In a plate-and-frame arrangement, there is usually a rigid or semirigid frame that supports the membrane so that there is always a flowpath on the inside and outside of the envelopes. This frame may be a rigid metallic or polymeric frame or something as simple as a screen or straps.

(d) *Spiral Wound.* Spiral-wound membrane devices are constructed from an envelope of membrane that is wound around a hollow core. The inside of the envelope is connected to the hollow core in such a way as to allow fluid from inside the envelope to pass through the center of the hollow core. The feed material is passed into one end of the device and passes over the outside of the envelope. The permeate passes through the membrane into the inside of the envelope and eventually outside the hollow core. The retentate passes out the opposite end of the spiral device from the feed.

(e) *Monolith.* A monolith membrane is characterized by a porous rigid body with long flow paths (lumens) that pass through the middle. These lumens are coated on the inside diameter with a highly controlled porous surface or membrane. Typically, these devices are made of ceramic material, which withstands high temperatures or aggressive chemicals. The process fluid is fed into one end of the device and the retentate passes out the other end; the permeate passes through the membrane surface and porous body and is collected on the outside of the device.

S-2.3 Housings and Encapsulation

Housings are designed with different options, such as the capacity for handling multiple elements, and various inlet and outlet options. Encapsulated filtration elements are designed for handling purposes or in place of metallic housings.

S-2.3.1 Holders. Holders are used to stack or hold in place the filter elements and to manage or direct the process fluid. The holders are designed to ensure proper sealing between the inlet and outlet connections, as well as between the encapsulated elements.

S-2.4 Design for Cleaning

S-2.4.1 Cleaning. The purpose of cleaning a DFF system is to prevent environmental contamination, product-to-product carryover, or cross-contamination. For TFF, flow rates are also an important design parameter for effective cleaning.

S-2.5 Normalized Water Permeability (NWP) Testing

S-2-5.1 To conduct an NWP test, the TFF system is controlled at one or more operating points with respect to feed flow and transmembrane pressure (TMP) using pyrogen-free purified water and/or a buffer or cleaning agent of suitable quality. The permeate pressure should be as close as possible to 0 psig (atm) to allow the permeate flow rate to reach its maximum. During the test, the permeate rate (flux) is measured, along with the temperature of the solution.

The water permeability is calculated using the following equation:

water permeability = permeate flux(l/m²-h)/TMP (psi or bar)

The resulting flow rates are normalized to a standard temperature by applying a temperature correction factor that accounts for the change in density. A baseline measurement of the membrane's permeability must be obtained when the membrane is new. For all subsequent measurements, the NWP test is performed following the cleaning of the membrane at operating conditions as close as possible to the original test.

NONMANDATORY APPENDIX T

GUIDANCE FOR THE USE OF U.S. CUSTOMARY AND SI UNITS

T-1 USE OF UNITS IN THE STANDARD

The units used within this Standard shall comply with Mandatory Appendix II. It is the responsibility of the individual and organization using the data from this Standard to ensure that appropriate units are used. Either U.S. Customary or SI units may be used as a consistent set. When SI units are selected, U.S. Customary values in referenced specifications may be converted to SI values to at least three significant figures for use in calculations and other aspects of design/construction.

(16) T-2 GUIDELINES USED TO DEVELOP SI EQUIVALENTS

The following guidelines were used to develop SI equivalents:

(a) SI units are placed in parentheses after the U.S. Customary units in the text.

(b) The table designation (e.g., table number) is the same for both the U.S. Customary and SI tables, with the addition of suffix "M" to the designator for the SI table, if a separate table is provided. In the text, references to a table use only the primary table number (i.e., without the "M"). For most tables, where interpolation is not required, SI units are placed in parentheses after the U.S. Customary unit.

(c) Separate SI versions of graphical information (charts) may be provided as necessary, except that if both axes are dimensionless, a single figure (chart) is used.

(d) In most cases, conversions of units in text were done using hard SI (approximate) conversion practices, with some soft conversions (exact) on a case-by-case basis, as appropriate. This was implemented by rounding the SI values to the number of significant figures of implied precision in the existing U.S. Customary units. For example, 8 in. has an implied precision of one significant figure. Therefore, the conversion to SI units would typically be 200 mm. This is a difference of about 1.6% from the "exact" or soft conversion of 203.2 mm. However, the precision of the conversion was determined by the Committee on a case-by-case basis. More significant digits were included in the SI equivalent if there was any question.

(e) Minimum thickness and radius values that are expressed in fractions of an inch were generally converted according to the following table:

Fraction, in.	Proposed SI	
	Conversion, mm	Difference, %
$\frac{1}{32}$	0.8	-0.8
$\frac{3}{64}$	1.2	-0.8
$\frac{1}{16}$	1.5	5.5
$\frac{3}{32}$	2.5	-5.0
$\frac{1}{8}$	3	5.5
$\frac{5}{32}$	4	-0.8
$\frac{3}{16}$	5	-5.0
$\frac{7}{32}$	5.5	1.0
$\frac{1}{4}$	6	5.5
$\frac{5}{16}$	8	-0.8
$\frac{3}{8}$	10	-5.0
$\frac{7}{16}$	11	1.0
$\frac{1}{2}$	13	-2.4
$\frac{9}{16}$	14	2.0
$\frac{5}{8}$	16	-0.8
$\frac{11}{16}$	17	2.6
$\frac{3}{4}$	19	0.3
$\frac{7}{8}$	22	1.0
1	25	1.6

(f) For nominal sizes that are in even increments of inches, even multiples of 25 mm were generally used. Intermediate values were interpolated rather than converted and rounded to the nearest millimeter. See examples in the following table:

Size, in.	Size, mm
$\frac{1}{4}$	6
$\frac{3}{8}$	10
$\frac{1}{2}$	13
$\frac{3}{4}$	19
1	25
$1\frac{1}{2}$	38
2	50
$2\frac{1}{2}$	64
3	75
4	100
6	150

(g) For all pressures, the SI units are in kPa (even when it is 1 000 kPa). Rounding was to one significant figure (two at the most) in most cases. See examples in

the following table. (Note that 14.7 psi converts to 101 kPa, while 15 psi converts to 100 kPa. While this may seem at first glance to be an anomaly, it is consistent with the rounding philosophy.)

Pressure, psi	Pressure, kPa
0.5	3
2	15
3	20
10	70
14.7	101
15	100
30	200
50	350
100	700
150	1 000
200	1 500
250	1 700

(h) In most cases, temperatures (e.g., for PWHT) were rounded to the nearest 5°C. Depending on the implied precision of the temperature, some were rounded to the nearest 0.1°C or 10°C or even 25°C. Temperatures colder than 0°F (negative values) were generally rounded to the nearest 0.1°C. The examples in the following table were created by rounding to the nearest 5°C, with one exception.

Temperature, °F	Temperature, °C
70	20
100	38
120	50
150	65
200	95
250	120
300	150
350	175
400	205
450	230
500	260
550	290
600	315
650	345
700	370
750	400
800	425
850	455
900	480
925	495
950	510
1,000	540
1,050	565
1,100	595
1,150	620
1,200	650
1,250	675
1,800	980
1,900	1 040
2,000	1 095
2,050	1 120

T-3 CHECKING EQUATIONS

When a single equation is provided, it has been checked using dimensional analysis to verify that the results obtained by using either the U.S. Customary or SI units provided are equivalent. When constants used in these equations are not dimensionless, different constants are provided for each system of units. Otherwise, a U.S. Customary and an SI version of the equation are provided. However, in all cases, the Standard user should check the equation for dimensional consistency.

T-4 SOFT CONVERSION FACTORS

The following table of “soft” conversion factors is provided for convenience. Multiply the U.S. Customary value by the factor given to obtain the SI value; similarly, divide the SI value by the factor given to obtain the U.S. Customary value. In most cases, it is appropriate to round the answer to three significant figures.

U.S. Customary	SI	Factor	Notes
in.	mm	25.4	...
ft	m	0.3048	...
in. ²	mm ²	645.16	...
ft ²	m ²	0.09290304	...
in. ³	mm ³	16,387.064	...
ft ³	m ³	0.02831685	...
U.S. gal	m ³	0.003785412	...
U.S. gal	L	3.785412	...
psi	kPa	6.89475729	...
°F	°C	5/9 × (°F–32)	Not for temperature difference
°F	°C	5/9 × °F	For temperature differences only
lbm	kg	0.4535924	...
lbf	N	4.448222	...
psi	P	6 894.75729	...
μin.	m	0.0254	...
gal/min	L/min	3.785	...
ft/sec	m/s	0.3048	...
in./in./°F	mm/mm/°C	1.8	...

NONMANDATORY APPENDIX U

POSITIVE MATERIAL IDENTIFICATION

(16)

U-1 POSITIVE MATERIAL IDENTIFICATION

Positive material identification (PMI) is a form of product (check) analysis in which a partial chemical composition is determined and used to verify material identification.

As discussed in this Standard, the scope of PMI is limited to alloy verification using portable, handheld X-ray fluorescence (XRF) equipment. Typically, this equipment cannot detect or measure elements having an atomic number less than 22 (titanium). For this reason, elements such as carbon, sulfur, and phosphorous cannot be detected. This makes it impossible to use this equipment in lieu of a complete chemical compositional analysis or to prove that a specific alloy conforms to a material specification. This equipment, therefore, is not suitable for material acceptance as a stand-alone analysis. Without the support of a referee analysis or a Material Test Report (MTR), PMI should not be used to accept materials, except for forensic situations in which unknown materials are being analyzed.

PMI results should not be the sole reason for material rejection either. When PMI results indicate that a material may be other than that specified, a referee analysis, suitable to the owner/user, purchaser (as appropriate), and organization performing the PMI should be performed, unless the owner/user permits rejection of material based solely on PMI results. Rather, PMI should be used in conjunction with MTRs or Certificates of Compliance from the material manufacturer.

U-2 GENERAL REQUIREMENTS

PMI shall be performed in accordance with a written procedure as described in U-4. The alloying elements to be tested shall be either those necessary to identify the alloy in question or those having a significant effect on the performance characteristics of the material. Unless otherwise specified in the contract, the elements to be analyzed shall be at the discretion of the organization performing the PMI. The instrument employed shall be capable of detecting the alloying elements of interest. Records of PMI tests shall be documented and provided to the owner/user on request.

The analytical technique to be used shall be mutually agreed on by the purchaser (as appropriate) and owner/user and shall be in accordance with ASTM E1476,

Standard Guide for Metals Identification, Grade Verification and Sorting, or another recognized industry standard method. The technique should also comply with this Appendix.

XRF analysis may be performed using either the analysis mode or the alloy identification (alloy matching) mode.

In the analysis mode, the PMI instrument will produce chemical composition data, including an accuracy tolerance, for each alloying element. This will result in a range of values for each alloying element. For a reading to be considered acceptable, one of the following two conditions must be met:

(a) The displayed data ranges, including the accuracy tolerance, shall overlap the corresponding chemical composition ranges in the applicable material specification.

(b) The nominal values displayed on the PMI instrument shall fall within the chemical composition ranges in the applicable material specification as modified by the product (check) analysis tolerances in the material specification incorporated by reference.

When used in the alloy identification mode, the instrument will display a specific alloy type, based on a comparison between the chemical composition data obtained during testing and the data ranges in the instrument's internal library. When using this mode, the user is cautioned that any alloy identified by the PMI instrument is defined by a single material specification in the unit's internal library whose chemical composition ranges may not coincide with those in the applicable material specification or contract requirement. As a result, the user of the PMI instrument must take into consideration potential differences between the material specification ranges loaded into the PMI unit's internal library and those specified for the material, component, or surface.

Since the material specifications loaded into the PMI unit's internal library may not coincide with those specified for the part being analyzed, the recommended mode of operation is the analysis mode.

U-3 CALIBRATION

Periodic calibrations shall be performed at frequencies recommended by the equipment manufacturer. These calibration tests shall be documented, although the specific data does not need to be recorded.

In addition, at the beginning of each shift, or prior to use, the instrument shall be checked at least three times against a known standard for each alloy category to be inspected during the shift, using the technique to be used during the shift. This check shall be performed under environmental conditions similar to those of the test location. All such standards shall be clearly identified as to nominal alloy composition. A certified reference material (CRM) that is an Analytical Reference Materials International (ARMI) or National Institute of Standards and Technology (NIST) traceable standard is recommended. As an alternative, the known sample could be provided with an MTR and a chemical composition analysis performed by an independent test laboratory.

U-4 PROCEDURE

A written procedure shall be used, and it shall include the following elements:

- (a) the instrument to be used
- (b) the analytical technique to be used
- (c) sampling plans for each material, component, or surface
- (d) material, component, or surface to be inspected
- (e) documentation requirements
- (f) material identification requirements
- (g) requirements for instrument calibration and instrument calibration checks
- (h) personnel qualification requirements
- (i) control of rejected materials

The procedure may also include segregation procedures for the tested material, marking, and small-percentage random sampling.

U-5 PERSONNEL TRAINING AND QUALIFICATION

Individuals performing PMI shall be trained and qualified. The training shall address the following as a minimum:

- (a) requirements for surface preparation prior to testing
- (b) minimum exposure times for adequate data collection
- (c) proper activation of the analyzer window shutter to ensure that it opens completely during exposure and data collection
- (d) assurance that the surface to be analyzed completely covers the analyzer window
- (e) precautions to take when using the alloy analyzer on curved or contoured surfaces
- (f) special instructions or ancillary equipment needed for analyzing welds

(g) demonstration of capabilities, if required by the owner/user

Records of training shall be maintained by the employer.

U-6 ACCEPTANCE/REJECTION

When an MTR is available, material may be accepted based on PMI results, if the PMI results for the required elements are acceptable and the data for all other required elements on the MTR are acceptable as well.

Gross deviations that are clearly outside the material specification limits, as modified by the product analysis tolerance (e.g., UNS S31603 for which PMI testing shows 1.50% molybdenum), shall be cause for immediate quarantine of the material. Referee analysis, agreeable to all parties, should be conducted to verify this unless the owner/user elects to permit rejection based solely on PMI results. When the referee analysis shows similar gross deviations, the material shall be rejected.

When no MTR is available, acceptance can be based solely on the results of alloy identification analysis when permitted by the owner/user.

U-7 PMI REFEREE METHODS

PMI is not meant to replace an MTR. If PMI testing produces unacceptable results, the material shall be quarantined, but it should not be immediately rejected. A quantitative referee method, acceptable to all parties, should be used, unless the owner/user decides otherwise. Examples of such methods may be found in ASTM E1476. Any remaining disputes shall be resolved with a third party that is accredited by the American Association for Laboratory Accreditation (A2LA) or an equivalent, if available.

U-8 PMI SPECIAL CONDITIONS

Generally, PMI of bare welding filler wire or inserts can be achieved with proper procedures.

The users of PMI are cautioned that most equipment is not typically suitable for analysis of small areas or small volumes of material, such as welds, and are not capable of accounting for dilution factors in welds. Special equipment adaptations, such as reduced-size detection windows, or special methods may be required to perform analysis on small areas. The equipment manufacturer should be consulted for such applications.

Analysis of welds, with or without filler metal, for weld acceptance is not recommended.

Analysis of coatings may require special analytical methods and is outside the scope of this Appendix.

NONMANDATORY APPENDIX V PROCUREMENT SOURCES

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To procure ASTM specifications, contact ASTM at www.astm.org.

To procure ASME specifications, contact ASME at www.asme.org.

DIN specifications may only be obtained from the following:

Beuth Verlag GmbH
Am DIN-Platz
Burggrafenstraße 6
10787 Berlin, Germany
phone +49 30 2601-2260
fax +49 30 2601-1260
E-mail: kundenservicebeuth.de
Website: www.din.de

EN specifications may be obtained from any of the following member organizations:

Country	Country Standards Development Organization	Website
Austria	Austrian Standards Institute (ASI)	www.austrian-standards.at
Belgium	Bureau de Normalisation/Bureau voor Normalisatie (NBN)	www.nbn.be
Bulgaria	Bulgarian Institute for Standardization (BDS)	www.bds-bg.org
Croatia	Croatian Standards Institute (HZN)	www.hzn.hr
Cyprus	Cyprus Organization for Standardisation (CYS)	www.cys.org.cy
Czech Republic	Czech Office for Standards, Metrology and Testing (UNMZ)	www.unmz.cz
Denmark	Dansk Standard (DS)	www.ds.dk
Estonia	Estonian Centre for Standardisation (EVS)	www.evs.ee
Finland	Suomen Standardisoimisliitto r.y. (SFS)	www.sfs.fi
Former Yugoslav Republic of Macedonia	Standardization Institute of the Republic of Macedonia (ISRM)	www.isrm.gov.mk
France	Association Française de Normalisation (AFNOR)	www.afnor.org
Germany	Deutsches Institut für Normung (DIN)	www.din.de
Greece	National Quality Infrastructure System (NQIS/ELOT)	www.elot.gr
Hungary	Hungarian Standards Institution (MSZT)	www.mszt.hu
Iceland	Icelandic Standards (IST)	www.stadlar.is
Ireland	National Standards Authority of Ireland (NSAI)	www.nsai.ie
Italy	Ente Nazionale Italiano di Unificazione (UNI)	www.uni.com
Latvia	Latvian Standard Ltd. (LVS)	www.lvs.lv
Lithuania	Lithuanian Standards Board (LSD)	www.lsd.lt
Luxembourg	Organisme Luxembourgeois de Normalisation (ILNAS)	www.portail-qualite.lu
Malta	The Malta Competition and Consumer Affairs Authority (MCCAA)	www.mccaa.org.mt
Netherlands	Nederlands Normalisatie-instituut (NEN)	www.nen.nl
Norway	Standards Norway (SN)	www.standard.no/
Poland	Polish Committee for Standardization (PKN)	www.pkn.pl
Portugal	Instituto Português da Qualidade (IPQ)	www.ipq.pt
Romania	Romanian Standards Association (ASRO)	www.asro.ro
Slovakia	Slovak Office of Standards Metrology and Testing (UNMS)	www.unms.sk
Slovenia	Slovenian Institute for Standardization (SIST)	www.sist.si
Spain	Asociación Española de Normalización y Certificación (AENOR)	www.aenor.es
Sweden	Swedish Standards Institute (SIS)	www.sis.se
Switzerland	Schweizerische Normen-Vereinigung (SNV)	www.snv.ch
Turkey	Turkish Standards Institution (TSE)	www.tse.org.tr
United Kingdom	British Standards Institution (BSI)	www.bsigroup.com

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