ASME BPE-2026

(Revision of ASME BPE-2024)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD

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FOREWORD

At the 1988 American Society of Mechanical Engineers (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 components, equipment, and systems 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 Committee for Standardization (CEN), the American Society for Testing and Materials (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 strove to reference existing standards that are applicable to biopharmaceutical equipment design and fabrication.

(d) This Standard represents the work of the BPE Standards Committee, and this edition includes the following:

Chapter 1, Introduction, Scope, and General Requirements
    Part GR, General Requirements
Chapter 2, Certification
    Part CR, Certification Requirements
Chapter 3, Materials
    Part MM, Metallic Materials
    Part PM, Polymeric and Other Nonmetallic Materials
Chapter 4, Design for Multiuse
    Part SD, Systems Design for Multiuse
Chapter 5, Process Components for Multiuse
    Part DT, Dimensions and Tolerances for Process Components
    Part PI, Process Instrumentation for Multiuse
    Part MC, Components for Multiuse

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Chapter 6, Fabrication, Assembly, and Erection for Multiuse
Part MJ, Materials Joining for Multiuse
Part SF, Process Contact Surface Finishes for Multiuse
Chapter 7, Design for Single-Use
Part SU, Systems Design for Single-Use
Chapter 8, Process Components for Single-Use
Part SC, Components for Single-Use
Part SI, Single-Use Process Instrumentation
Chapter 9, Fabrication, Assembly, and Erection for Single-Use
Part SJ, Joining Methods for Single-Use

The first edition of this Standard was approved as an American National Standard on May 20, 1997. This edition was approved by the American National Standards Institute (ANSI) on April 3, 2026.

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Revisions and Errata. The committee processes revisions to this Standard on a continuous basis to incorporate changes that appear necessary or desirable as demonstrated by the experience gained from the application of the Standard. Approved revisions will be published in the next edition of the Standard.

In addition, the committee may post errata on the committee web page. Errata become effective on the date posted. Users can register on the committee web page to receive email notifications of posted errata.

This Standard is always open for comment, and the committee welcomes proposals for revisions. Such proposals should be as specific as possible, citing the paragraph number, the proposed wording, and a detailed description of the reasons for the proposal, including any pertinent background information and supporting documentation.

Cases

(a) The most common applications for cases are

(1) to permit early implementation of a revision based on an urgent need

(2) to provide alternative requirements

(3) to allow users to gain experience with alternative or potential additional requirements prior to incorporation directly into the Standard

(4) to permit the use of a new material or process

(b) Users are cautioned that not all jurisdictions or owners automatically accept cases. Cases 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 Standard.

(c) A proposed case shall be written as a question and reply in the same format as existing cases. The proposal shall also include the following information:

(1) a statement of need and background information

(2) the urgency of the case (e.g., the case concerns a project that is underway or imminent)

(3) the Standard and the paragraph, figure, or table number

(4) the editions of the Standard to which the proposed case applies

(d) A case is effective for use when the public review process has been completed and it is approved by the cognizant supervisory board. Approved cases are posted on the committee web page.

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Committee Meetings. The BPE Standards Committee regularly holds meetings that are open to the public. Persons wishing to attend any meeting should contact the secretary of the committee. Information on future committee meetings can be found on the committee web page at https://go.asme.org/BPEcommittee.

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ASME BPE-2026
SUMMARY OF CHANGES

Following approval by the ASME BPE Standards Committee and ASME, and after public review, ASME BPE-2026 was approved by the American National Standards Institute on April 3, 2026.

ASME BPE-2026 includes the following changes identified by a margin note, **(26)**.

Page	*Location*	*Change*
2	GR-4	First sentence of second paragraph revised
2	GR-4.1	Subparagraph (b) revised
8	GR-5.4.1	First paragraph revised
8	GR-5.4.2	Subparagraph (b) revised and subpara. (c) added
8	GR-5.5.1	First sentence revised
8	GR-5.6	Added
9	GR-6.2	First sentence revised
9	GR-7.2	Revised
9	GR-10	Updated
12	GR-11	Revised
22	CR-1	(1) Revised (2) Figure CR-1-1 deleted
22	Table CR-1-1	Revised
22	CR-2	Revised
23	CR-2.1	Subparagraph (d) revised
23	CR-2.2.2	First paragraph and subpara. (a) revised
23	CR-2.2.3	Revised
24	CR-2.3	Second paragraph added
24	CR-2.3.2	Revised
25	MM-1	Revised
25	MM-3.2	Second paragraph deleted
26	Table MM-2.1-1	(1) Data for SUS890L and SUS312L added (2) General Note (a) revised
27	Table MM-2.1-2	General Note (a) revised
29	Table MM-2.1-4	O for C10200 and General Note (a) revised
29	MM-4	Updated
31	MM-5.2.1.1	Subparagraph (a) revised
32	MM-5.2.1.3	Last paragraph added
36	Table MM-5.3-2	(1) JIS Designation and JIS Z 3224 Designation columns and data for SUS890L and SUS312L added (2) General Note revised
39	Table MM-5.3-5	(1) JIS Designation columns and data for SUS890L and SUS312L added (2) General Note revised

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Page	*Location*	*Change*
42	Table MM-5.4-1	JIS Designation column and data for SUS890L and SUS312L added
41	MM-8.1	Penultimate sentence revised
41	MM-8.2	(1) MM-8.2.1 designation and title added, paragraph following subpara. (b) revised, and last paragraph deleted (2) MM-8.2.2 added
42	MM-9.1.1	Revised
44	PM-2.1.2	Updated
44	PM-2.1.2.1	Subparagraphs (a) and (b) revised
45	PM-2.2	Revised
45	PM-2.2.1	Revised
46	Table PM-2.2.1-1	(1) Penultimate row, General Note, and Note (1) revised (2) Last row deleted
48	PM-3	(1) PM-3 and PM-3.1 revised in their entirety (2) PM-3.1.1 added
50	PM-4.2.1	Revised
53	SD-2.3.1.1	First sentence revised
54	SD-2.4.1.1	Revised
56	SD-3.1.1	Subparagraph (i) revised
62	SD-3.1.2.3	Subparagraphs (g) and (h) revised
68	SD-3.4.1	First sentence revised
76	Figure SD-3.4.6-1	Caption for illustration (e) revised
77	SD-3.4.8	Revised in its entirety
77	SD-3.4.9	Revised in its entirety
77	SD-3.5.1	Subparagraph (j) revised
77	SD-3.5.2	“Tank” revised to “vessel” throughout
82	SD-3.5.5	Subparagraphs (a) and (b) revised
83	Figure SD-3.5.5-1	Illustration (a) revised
84	Figure SD-3.5.5-2	Revised
86	SD-3.7.1	Subparagraph (b) revised
89	SD-3.8.3	Revised
92	SD-3.8.8.2	Subparagraph (e) revised
92	SD-3.9.1	(1)Subparagraphs (a), (b), and (f)(2) revised (2) Subparagraph (h) added and subsequent subparagraph redesignated and editorially revised
93	SD-3.9.2.1	Subparagraph (b) revised
93	SD-3.9.2.2	Subparagraph (b) deleted and subsequent subparagraphs redesignated
96	SD-3.9.2.3	(1) Subparagraph (a) revised (2) Subparagraph (c) deleted and subsequent subparagraphs redesignated
100	SD-3.18.2	Revised
100	SD-3.18.6.2	Subparagraph (d) revised
101	SD-3.19.1	First sentence revised
101	SD-3.19.5	Added

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101	SD-3.20	(1) Added (2) Former Figure SD-6.3.4.2-4 redesignated as Figure SD-3.20.3-1
109	SD-5.1.1	(1) Revised (2) Former Figures SD-5.1.5-1 and SD-5.1.5-2 redesignated as Figures SD-5.1.1-1 and SD-5.1.1-2 and revised
118	SD-5.1.4.11	In title, spelling of “Fermentors” corrected
118	SD-5.1.5	Revised
119	SD-5.1.5.1	Revised
119	SD-5.1.5.2	Subparagraph (a) revised
119	SD-5.1.5.3	Added
119	SD-5.1.5.4	Subparagraphs (a), (f)(1), and (f)(2) revised
119	SD-5.1.5.5	Added
119	SD-5.1.6	Added
120	SD-5.2.3.2	Subparagraph (a) revised
122	SD-5.3.4	Revised in its entirety
123	SD-5.3.5.1	Second paragraph revised
123	SD-5.3.7	Revised in its entirety
124	SD-5.4.4.6	(1) Subparagraph (a) added and subsequent subparagraphs redesignated (2) Subparagraph (g) revised
125	Figure SD-5.4.5.1-1	Title revised
125	SD-5.4.5.2	Last sentence in first paragraph revised
126	SD-5.5.4.1	Revised
127	SD-5.5.4.3	Revised
127	SD-5.5.5.2	Revised
134	SD-5.7	Revised in its entirety
135	SD-6.1	Revised in its entirety
139	SD-6.3.1	Subparagraph (f) deleted
140	SD-6.3.4.1.1	Subparagraph (f) revised
140	Figure SD-6.3.4.1.1-1	Title revised
141	SD-6.3.4.2	Subparagraph (f) revised in its entirety
145	Figure SD-6.4.1.1-1	Revised
146	Figure SD-6.4.1.1-2	Revised
147	SD-6.4.4	Subparagraph (c) revised
148	SD-6.4.5.2	Last sentence revised
150	SD-6.5	Revised in its entirety
155	SD-6.6.4.7	Penultimate paragraph revised
156	SD-6.6.4.11	First sentence revised
157	SD-7.1	Last paragraph revised
157	SD-7.4	(1) Revised in its entirety (2) Figures SD-7.4-1 and SD-7.4-2 added
161	DT-10.1	Subparagraph (f)(1) revised
161	DT-11.1	Subparagraph (e)(1) revised
178	Table DT-4.1.2-10	Revised in its entirety
178	Table DT-4.1.2-11	Revised in its entirety

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200	PI-2.1.2	(1) Subparagraph (d) revised (2) Subparagraph (e) added and subsequent subparagraphs redesignated
208	PI-4.3	Added
210	PI-4.4	Added
211	PI-5.2	Added
214	PI-5.3	Added
216	PI-5.4	Added
220	Figure PI-6.1.2-1	Title and illustration (d) revised
219	PI-7.1	Revised
219	PI-7.2	Revised in its entirety
219	PI-7.3	(1) First paragraph and subpara. (b) revised (2) PI-7.3.1 and PI-7.3.2 deleted and subsequent paragraphs redesignated and revised
222	Figure PI-7.3.2-1	Former Figure PI-7.3.4-1 redesignated and revised
222	Figure PI-7.3.2-2	Former Figure PI-7.3.4-2 redesignated
223	Figure PI-7.3.4-1	Former Figure PI-7.3.5-1 redesignated and revised
224	Figure PI-7.3.4-2	Former Figure PI-7.3.5-2 redesignated and revised
225	PI-7.4	(1) PI-7.4.1, PI-7.4.2, and PI-7.4.4 revised (2) PI-7.4.5 added
225	PI-7.5	Revised in its entirety
225	PI-7.6	Deleted
230	PI-8.3	Added
235	Figure PI-9.1.3.2-1	Caption for illustration (e) revised
237	MC-1	Revised in its entirety
237	MC-2.2.2	First paragraph revised
241	MC-2.3.1.4	Revised in its entirety
241	MC-2.3.1.5	(1) Revised in its entirety (2) Figure MC-2.3.1.5-2 added
241	MC-2.3.1.7	Title revised
247	Figure MC-2.3.1.7-1	Title and image revised
256	MC-3.3.1	Subparagraphs (a) and (d) revised
257	MC-3.3.2.2	Subparagraph (b) revised
258	MC-3.3.2.3	Subparagraph (f) revised in its entirety
261	MC-3.4.1	Revised
262	MC-4.2	Revised
263	MC-4.3.1.1	Subparagraph (d) revised
264	MC-5.2.5	First sentence of subpara. (a) revised
265	MC-5.5.1	Subparagraph (e) revised
267	MJ-3.5	(1) Subparagraphs (b) and (b)(1) revised (2) Subparagraph (b)(3) added
272	MJ-6.3	Last paragraph added
273	MJ-7.3.3	In subpara. (a), second paragraph revised
275	Table MJ-8.2-1	Note (3) added and subsequent Note redesignated
277	Table MJ-8.3-1	Note (3) added and subsequent Notes redesignated
279	Table MJ-8.4-1	Note (3) added and subsequent Notes redesignated

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288	Figure MJ-8.5-1	In illustration (c), metric equivalent added
289	MJ-9.6.3.1	Second paragraph revised
290	MJ-11	Revised
293	Table SF-2.2-1	Revised
294	SF-2.4	Last sentence revised
294	Table SF-2.4.1-1	(1) Data for surface designations SF0 and SF3 revised (2) General Notes (c) and (d) deleted (3) Notes (2) and (3) added
294	SF-2.5	(1) Former SF-2.6 redesignated and revised (2) Former Table SF-2.6-1 redesignated as Table SF-2.5-1
294	SF-2.6	(1) Added (2) Former SF-2.5 redesignated as SF-2.6.2
294	SF-2.7	Added and subsequent paragraphs redesignated
295	SF-3.1	Second paragraph revised
296	SF-3.4	Subparagraph (c) added
298	SU-3.3	In last sentence, spelling of “specific” corrected
299	SU-4	Revised
301	SU-11.2	Last sentence added
301	SU-11.3.2	First paragraph revised
301	Table SU-12-1	Applicable section for “Animal-derived ingredients” revised
302	SC-3	(1) Title, first paragraph, and SC-3.2.1 revised (2) The term “bag” revised to “container” throughout
308	Part SI	(1) Relocated from Chapter 9 to Chapter 8 (2) Title of SI-2 revised (3) SI-2.1 through SI-3.3 and Table SI-2.4-1 added
310	SJ-2.3	First paragraph and subpara. (b)(3) revised
310	SJ-3.2	First sentence revised
311	SJ-3.3	Added
311	SJ-3.4	(1) Former SJ-3.3 redesignated and revised (2) Table SJ-3.4-1 added
313	Mandatory Appendix IV	Revised
317	Nonmandatory Appendix B	Form WOPQ-1 added
332	E-3	Revised
333	E-5.1	Title revised
343	Table F-3-1	Data for SUS890L and SUS312L added
344	G-1	Third and last paragraphs revised
353	K-1.3.1	Subparagraph (b) revised
353	K-1.3.2	Added and subsequent paragraphs redesignated
354	K-1.3.3.1	(1) Former K-1.3.2.1 redesignated (2) Former Figures K-1.3.2.1-1 through K-1.3.2.1-5 redesignated as Figures K-1.3.3.1-1 through K-1.3.3.1-5
354	K-1.3.3.2	(1) Former K-1.3.2.2 revised in its entirety (2) Tables K-1.3.3.2-1 through K-1.3.3.2-3 and Form K-1 added
368	Nonmandatory Appendix L	L-1 and L-2 editorially revised
374	O-1.1	Last paragraph revised
375	Table O-1.1-1	Revised

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Page	*Location*	*Change*
375	O-1.4	Title and first sentence revised
377	P-1	Updated
393	Nonmandatory Appendix Y	Procurement information for the Official Journal of the European Union added
394	Z-1	Revised
394	Z-3	Revised
394	Z-3.1	Subparagraph (b) revised
395	Z-3.2	Subparagraph (c)(8) revised
395	Z-3.4	Subparagraph (b) revised
395	Z-3.5	Fourth and last two paragraphs added
396	Z-3.6	Subparagraph (b) revised
396	Z-3.8	Subparagraphs (b)(2)(-c) through (b)(2)(-e) revised
397	Z-3.11	Revised
397	Z-3.12	Subparagraphs (a) and (b) revised
399	Nonmandatory Appendix AA	Title revised
399	AA-1	Revised
399	AA-1.2.3	(1) Added (2) Figure AA-1.2.3-1 added
400	AA-2.2	Penultimate sentence revised
400	AA-3.2.2	First paragraph revised
401	AA-4.2.2	First paragraph revised
411	EE-3.1	First paragraph revised
411	EE-3.2	Last paragraph revised
424	Table FF-1-2	Test description for immersion leak location revised
433	Table JJ-1	Columns for SDR 33 added
434	Nonmandatory Appendix KK	Added
440	Nonmandatory Appendix LL	Added
451	Index	Updated

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CHAPTER 1
INTRODUCTION, SCOPE, AND GENERAL REQUIREMENTS

PART GR
GENERAL REQUIREMENTS

GR-1 INTRODUCTION

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

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

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 conform to those 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.

New editions of the ASME BPE Standard may be used beginning with the date of issuance and become effective 6 months after the date of issuance.

GR-2 SCOPE OF THE ASME BPE STANDARD

The ASME BPE Standard provides requirements for components, equipment, and systems when there is contact with the product, raw materials, or product intermediates during clinical or commercial manufacturing of molecules intended for human or animal medicinal applications. It also applies to supporting systems that could directly or indirectly affect the clinical or commercial process [e.g., water-for-injection (WFI), clean steam, filtration, and intermediate product storage].

The Standard is intended for clinical and commercial manufacturing of pharmaceutical and biopharmaceutical products used for human and animal medicinal applications. However, some of the principles, practices, and guidance may be used for research and development, scale-up operations, or other products where the control and reduction of microbial, particulate, and endotoxin or pyrogen contamination is considered important.

This Standard provides requirements for components, equipment, and systems designed for multiuse processes that are subject to cleaning [e.g., clean-in-place (CIP), clean-out-of-place (COP)], sanitization and/or sterilization [e.g., steam-in-place (SIP)], and other operations used in the manufacturing of pharmaceuticals and biopharmaceuticals. This Standard also provides requirements for single-use systems and components that are discarded after use in one manufacturing campaign.

This Standard may be used, in whole or in part, for other applications in which 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

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(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, this Standard applies to the new construction. The system boundaries and requirements shall be specified by the owner/user.

The owner/user determines which requirements of the Standard are applicable to individual components, equipment, or systems based on intended service. However, for a component, equipment, or system to be BPE-conforming, adherence to all applicable requirements of this Standard is mandatory.

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.

Nonmandatory Appendix Z provides guidance on quality assurance programs. This is only required for organizations that are ASME BPE Certificate Holders or applicants (see Part CR). However, it may be used by any organization that implements this Standard.

(26) GR-4 EXAMINATION, INSPECTION, AND TESTING

The examination, inspection, and testing 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.

As it relates to vessels, process piping and tubing, and process contact equipment, this Standard uses the terms "examination," "inspection," and "testing" and other forms of these terms in a manner consistent with the uses in ASME BPVC, Section VIII, and ASME B31.3. References for examination, inspection, and testing per this Standard are listed in Nonmandatory Appendix CC. These requirements are in addition to the requirements of ASME BPVC, Section VIII, and ASME B31.3. This Standard also uses the common language meaning of these terms. Be aware of the differences between the usage as defined in GR-11 versus common usage.

(26) 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 Tanks. Owner's Inspector, as defined in ASME B31.3, paras. 340.4(a) and 340.4(b). Quality Inspector's Delegate, as defined in GR-11, 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 and standards, the inspector in this Standard is defined as one who is acceptable to the relevant regulatory authority.

GR-4.2 Quality Inspector's Delegate

Quality Inspector's Delegate qualifications shall be in accordance with the requirements listed herein. The employer of the Quality 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 Quality 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's Delegate and shall not independently conduct any tests or write a report of test results.

(b) Quality Inspector's 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's 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 being performed 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.

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Table GR-4.2-1
Quality 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 (MTRs)	...	X	...	...
(2) Certificates of Conformance	...	X	...	...
(3) Instrument calibration records	...	X	...	...
(4) Elastomers	...	X	...	...
(f) Evaluate to acceptance criteria	...	X	...	...
(g) Verify material conformance to specification	...	X	...	...
(h) Verify material storage/handling conformance	...	...	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	...	...

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Table GR-4.2-1
Quality Inspector's Delegate Capabilities (Cont'd)

Capability	Trainee	QID-1	QID-2	QID-3
Knowledge and Skills (Cont'd)				
(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	...
(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 conformance	...	...	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) Conformance with ASME BPVC (U-1)	...	...	...	X
(f) Documentation review	...	...	X	...
Welding Procedure Qualification				
Verify Welding Procedure Specification/Procedure Qualification Record (WPS/PQR) conformance	...	...	...	X
Welder and/or Welding Operator Performance Qualification				
Verify welder and/or welding operator performance qualification conformance	...	...	X	...

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Table GR-4.2-1
Quality Inspector's Delegate Capabilities (Cont'd)

Capability	Trainee	QID-1	QID-2	QID-3
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

(d) Quality Inspector's 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 months of documented relevant industry experience. Alternate methods for meeting the work experience requirement are at least one of the following:

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

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

(-c) possess an AWS CWI certificate[1] or ACCP Level II VT certificate[2] 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 months 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 certificate[1] or ACCP Level II VT certificate[2] 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

[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.

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(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 months 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 (minimum total = 80 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

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

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.

GR-5.2 General List of Documents

GR-5.2.1 Turnover Package Documentation for Multiuse Systems. Documentation required for current Good Manufacturing Practices (cGMP)-validated distribution systems, including the vessels, tubing systems on modules, super skids, skids, and the shop or field fabrication of tubing, includes the following:

(a) Materials Documentation

(1) Material Test Reports (MTRs)

(2) Certificates of Conformance

(3) Material Examination Logs

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(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 (1) through (5) by the owner/user's representative prior to welding

(7) Inspector qualifications

(8) documentation of the approval of (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 Certificates of Conformance

(12) nondestructive examination (NDE) 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-5.2.2 Technical Support Information. Documentation 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 Document Requirements for Metallic Materials

MTRs for metallic process components shall be verified to be in conformance to the applicable specification. In addition, the following documentation shall be provided to the owner/user or their designee.

GR-5.3.1 MTRs/Certificates of Conformance. The combination of documents, including Certificates of Conformance 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

(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. MTRs for tubing shall also state the year edition of the ASME BPE Standard.

GR-5.3.2 Electropolishing. The electropolishing service provider shall provide documentation for each type of component or process equipment (e.g., vessel, filter housing), including, but not limited to, the following information:

(a) service provider company name

(b) description of component or components or process equipment

(c) identification of component or components or process equipment

(d) identification of the qualified electropolishing procedure used

(e) final surface finish report (R_a if required by the owner/user)

GR-5.3.3 Passivation. The passivation service provider shall provide documentation for each type of component, type of process equipment (e.g., vessel, filter housing), or process system, including, but not limited to, the following information:

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(a) service provider company name
(b) description of component or components, process equipment, or process system
(c) identification of component or components, process equipment, or process system
(d) identification of the qualified passivation procedure used

GR-5.3.4 Weld and Examination/Inspection Log. 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-5.4 Records Retention

(26) **GR-5.4.1 Vessel Documentation.** For all bioprocessing ASME BPVC-stamped pressure 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-5.4.2 Welding Documentation (26)

(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. Records and retention of records for ASME pressure vessels shall be in accordance with ASME BPVC, Section VIII.

(c) Tanks. Records and retention of records for tanks shall be in accordance with the standard of construction.

GR-5.5 Document Requirements for Polymeric and Other Nonmetallic Materials

The manufacturer of polymeric and other nonmetallic components shall issue a Certificate of Conformance that the components meet requirements as shown in Table PM-2.2.1-1. In addition, the following documentation shall be provided to the owner/user or their designee.

GR-5.5.1 Seal Documentation. Seal manufacturers (26) shall provide, upon owner/user request, documentation (test report) of the biocompatibility testing requirements of PM-3.1 on final manufactured seals. A Certificate of Conformance shall be issued by the seal manufacturer to certify conformance to this Standard when required by the owner/user. The Certificate of Conformance shall contain the information listed in Table PM-2.2.1-1. Additional agreements may be required.

GR-5.5.2 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 MC-4.2.

GR-5.6 ASME BPE Certificate of Conformance for Vessels (26)

A Certificate of Conformance (C of C) shall be created for vessels that are marked with the ASME Single Certification Mark and the BPE certification designator. This C of C shall include the following information:

(a) serial number or unique identifier that provides traceability to the vessel marking, applicable MTRs, surface test report, or other certifications
(b) year built
(c) manufacturer's name, logo, or trademark
(d) ASME BPE Certificate Number
(e) edition of the ASME BPE Standard used
(f) the following statement: "This vessel conforms to the requirements of the ASME BPE Standard, with specific exclusions to the ASME BPE Standard listed."
(g) list of specific exclusions to the ASME BPE Standard

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(h) signature of the Certified Individual (CI) responsible for maintaining the ASME Single Certification Mark with the BPE certification designator as outlined in CR-2.3

(i) date of signature

The C of C shall be included in turnover package documentation per GR-5.2.

GR-6 PRODUCT IDENTIFICATION AND PACKAGING

Manufacturers shall use a combination of marking, labeling, and primary packaging for identification and protection of components, equipment, and assemblies.

GR-6.1 Marking and Labeling

Marking and labeling shall provide traceability for process contact components, equipment, and assemblies. Specific marking and labeling requirements are addressed in the applicable Parts of this Standard.

(26) GR-6.2 Packaging

Components and single-use assemblies shall be packaged by the manufacturer to protect against damage and contamination that may result from routine shipping and subsequent handling and storage to maintain the as-manufactured condition. Additional packaging that may be necessary for shipping and subsequent handling and storage is not addressed in this Standard except when necessary to maintain sterility or integrity. Specific packaging requirements are addressed in the applicable Parts of this Standard.

GR-7 PROCESS COMPATIBILITY

GR-7.1 Materials

Process contact surfaces of components shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the product given the following requirements:

(a) Materials shall be capable of withstanding process, cleaning, and sanitization conditions (e.g., temperature, pressure) and shall be chemically compatible with those conditions.

(b) For a metallic material to be acceptable for hygienic service, it shall meet the requirements in Part MM. For a polymeric or other nonmetallic material to be acceptable for hygienic service, it shall meet the requirements in Part PM.

(26) GR-7.2 Animal-Derived Ingredients

Process contact surfaces of components, equipment, and systems shall be constructed from and processed with materials that are free from animal-derived ingredients/products (ADI/ADP) or shall be manufactured with materials that meet the conditions of EMA/410/01 rev. 3.

GR-8 CONTAMINATION CONTROL

GR-8.1 Closed Systems

Components, equipment, and systems of closed processes shall be designed to mitigate the risk of contamination within the process zone, including the risk of ingress of contaminants during bioprocessing. Functionally closing a system is a two-step process:

(a) removal of latent viable and nonviable contaminants within the process zone prior to process or product contact (e.g., CIP, SIP, ionizing irradiation)

(b) prevention of ingress of viable and nonviable particulates during product contact

GR-8.2 Open Systems

Components, equipment, and systems of open processes shall be designed to mitigate the risk of bioburden proliferation within the process zone.

GR-9 U.S. CUSTOMARY AND SI UNITS

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

GR-10 REFERENCES (26)

Material specifications for metallic materials are listed by product form in Part MM and for polymeric materials in Part PM. Testing standards for polymeric materials are listed in the appropriate appendices. For this Standard, the most recent approved version of the following referenced standards shall apply:

3-A Sanitary Standards. 3-A Sanitary Standards.

ANSI/FCI Standard 70-2. Standard for Control Valve Seat Leakage. Fluid Controls Institute.

ASME B31.3. Process Piping. The American Society of Mechanical Engineers.

ASME B46.1. Surface Texture (Surface Roughness, Waviness, and Lay). The American Society of Mechanical Engineers.

ASME Boiler and Pressure Vessel Code, Section V. Nondestructive Examination. The American Society of Mechanical Engineers.

ASME Boiler and Pressure Vessel Code, Section VIII. Rules for Construction of Pressure Vessels. The American Society of Mechanical Engineers.

ASME Boiler and Pressure Vessel Code, Section IX. Welding, Brazing, and Fusing Qualifications. The American Society of Mechanical Engineers.

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ASME CA-1. Conformity Assessment Requirements. The American Society of Mechanical Engineers.
ASME MFC-6. Measurement of Fluid Flow in Pipes Using Vortex Flowmeters. The American Society of Mechanical Engineers.
ASME MFC-22. Measurement of Liquid by Turbine Flowmeters. The American Society of Mechanical Engineers.
ASME NM 3.3. Nonmetallic Materials, Part 3 — Properties. The American Society of Mechanical Engineers.
ASME PTC 19.3 TW. Thermowells. The American Society of Mechanical Engineers.
ASME PVHO-1. Safety Standard for Pressure Vessels for Human Occupancy. The American Society of Mechanical Engineers.
ASME QAI-1. Qualifications for Authorized Inspection. The American Society of Mechanical Engineers.
ASQ/ANSI Z1.4. Sampling Procedures and Tables for Inspection by Attributes. American Society for Quality.
ASTM A262. Standard Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels. ASTM International.
ASTM A380. Practice for Cleaning, Descaling, and Passivation of Stainless Steel Parts, Equipment, and Systems. ASTM International.
ASTM A923. Standard Test Methods for Detecting Detrimental Intermetallic Phase in Duplex Austenitic/Ferritic Stainless Steels. ASTM International.
ASTM A967. Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts. ASTM International.
ASTM A1015. Standard Guide for Videoborescoping of Tubular Products for Sanitary Applications. ASTM International.
ASTM A1084. Standard Test Method for Detecting Detrimental Phases in Lean Duplex Austenitic/Ferritic Stainless Steels. ASTM International.
ASTM B912. Standard Specification for Passivation of Stainless Steels Using Electropolishing. ASTM International.
ASTM D395. Standard Test Methods for Rubber Property — Compression Set. ASTM International.
ASTM D412. Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension. ASTM International.
ASTM D471. Standard Test Method for Rubber Property — Effect of Liquids. ASTM International.
ASTM D624. Standard Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers. ASTM International.
ASTM D1599. Standard Test Method for Resistance to Short-Time Hydraulic Pressure of Plastic Pipe, Tubing, and Fittings. ASTM International.
ASTM D2240. Standard Test Method for Rubber Property — Durometer Hardness. ASTM International.
ASTM D2657. Standard Practice for Heat Fusion Joining of Polyolefin Pipe and Fittings. ASTM International.
ASTM D4991. Standard Test Method for Leakage Testing of Empty Rigid Containers by Vacuum Method. ASTM International.
ASTM E112. Standard Test Methods for Determining Average Grain Size. ASTM International.
ASTM E220. Standard Test Method for Calibration of Thermocouples by Comparison Techniques. ASTM International.
ASTM E230/E230M. Standard Specification for Temperature-Electromotive Force (emf) Tables for Standardized Thermocouples. ASTM International.
ASTM E499. Standard Practice for Leaks Using the Mass Spectrometer Leak Detector in the Detector Probe Mode. ASTM International.
ASTM E515. Standard Practice for Leaks Using Bubble Emission Techniques. ASTM International.
ASTM E644. Standard Test Methods for Testing Industrial Resistance Thermometers. ASTM International.
ASTM E1003. Standard Practice for Hydrostatic Leak Testing. ASTM International.
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(26) GR-11 TERMS AND DEFINITIONS

animal-derived ingredients (ADI): products or ingredients derived from tissues or secretions of animals susceptible to transmissible spongiform encephalopathies (TSEs), primarily cattle's bovine spongiform encephalopathy (BSE).

animal-derived products (ADP): products made from animal-derived ingredients (ADI).

annealing, metallic: heating and cooling to produce softening.

annealing, polymeric: heating of a polymeric part to a temperature below its glass transition temperature in order to relieve internal stresses.

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 ASME Certificate Holder's documented evaluation of a supplier performed to verify, by examination of objective evidence, that those selected elements of a previously approved quality management system have been developed, documented, and implemented in accordance with specified requirements. A surveillance is not an audit.

audit (as performed by ASME or their designee on ASME BPE Certificate Holders and Applicants): see ASME CA-1.

Authorized Inspector (AI): an individual who meets the requirements specified in ASME QAI-1.

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.

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.

barrier fluid (mechanical seals): a fluid used as a lubricant between dual mechanical seals to isolate process and atmosphere. The pressure of the fluid is higher than that of the process.

beadless welding (polymeric): an autogenous butt fusion process in which a flexible, inflatable bladder is used to prevent the formation or intrusion of weld material on the process contact surface.

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

biocompatibility: the ability of a material or component to be in contact with living matter such as bacteria or mammalian cells without interfering in any way with the living matter's metabolism or ability to live and procreate.

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.

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blind weld: a weld joint whose internal surfaces are not accessible for either direct or remote visual examination.

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: generic term for a group of optical instruments for visual examinations. This includes rigid borescopes and flexible borescopes (fiberscopes). Often a camera chip is mounted to the borescope. (See also *videsoscope*.)

break: a discontinuity in the face of a fitting.

buffer fluid (mechanical seals): a fluid used as a lubricant between dual mechanical seals to control and minimize leakage from process to atmosphere. The pressure of the fluid is lower than that of the process.

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

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 or Quality System Certificate issued by ASME.

Certificate Holder: an organization holding a Certificate of Authorization or a Quality System Certificate issued by the Society upon satisfactory completion of evaluation of its capability to conform to the requirements of this Standard.

Certificate of Authorization: a document issued by ASME that authorizes the application of the ASME Single Certification Mark with the BPE certification designator 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.

certified individual (CI): an individual who meets the requirements specified in ASME QAI-1.

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: see *pure steam*.

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: a localized array of porosity having a random geometric distribution.

compendial water: purported to conform to USP and/or any other acknowledged body of work related to the quality, manufacture, or distribution of high-purity water.

compliance: performing a function or operation in a recognized way to abide by a law or legislative requirement such as complying with the Code of Federal Regulations (CFR). Compliance is externally imposed. Noncompliance is the failure to adhere to an act or law or regulation.

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 adjacent 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. This is a nonstandard term for underfill of a root surface or weld face (see AWS A3.0).

conformance: see *conformity*.

conformity: the state of meeting, acting, or behaving in accordance with a specification, procedure, method, stated rule, or standard such as the ASME BPE Standard. Nonconformity is the state when a process or action or system does not conform to a stated quality requirement, specification requirement, procedure, or standard such as the ASME BPE Standard.

consumable insert: a ring of metal placed between the two members to be welded that provides filler for the joint, when performed with fusion welding equipment.

convexity: a condition in which the surface of a welded joint is extended relative to the surface of the adjacent tube or pipe. Convexity is measured as a maximum

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distance from the outside or inside diameter surface of a welded joint along a line perpendicular to a line joining the weld toes. This is a nonstandard term for root surface or weld face reinforcement (see AWS A3.0).

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.

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.

Cr/Fe ratio: see *total Cr/Fe ratio*.

dead leg: a space where system design and operating conditions result in insufficient process fluid flow, presenting a risk for particulate, chemical, or biological contamination.

defects: discontinuities that by nature or accumulated effect (e.g., total crack length) render a part or product unable to meet requirements.

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.

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.

direct visual examination: a visual examination where there is an uninterrupted optical path from the observer's eye to the area to be examined. This can be either unaided or aided via mirrors, lenses, etc.

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 material, 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. (See also *defects*.)

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.

drainable: a designed characteristic of a component, equipment, or system that enables the removal of water by means of gravity except for that which remains due to surface adherence. Drain paths that become blocked due to surface-adhered water are not considered drainable.

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, direct 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 selectively removing material from a surface using a chemical and/or electrolytic process.

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

examination: as it relates to pressure vessels, tanks, process piping, and process contact equipment, the quality control functions carried out by the manufacturer, fabricator, or erector.

excessive penetration: weld penetration whose extent is greater than that required. (See also *convexity*.)

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

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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: a vessel for carrying out fermentation. Also called *fermenter*.

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 Nonmandatory Appendix H, Table H-4.3-1.

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

flushing: the flowing of water over the process contact surfaces of system components for the removal of particulates or water-soluble contaminants. Also called *rinsing*.

full penetration: a weld joint in which weld material extends all the way through the joint thickness.

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 metal is fused together either with or without the addition of filler material.

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 referred to by the nonstandard term "TIG," which means "tungsten inert gas.") GTAW may be performed either with or without filler metal.

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.

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 variations of the essential variables 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 joining or cutting.

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

High Efficiency Particulate Air (HEPA) filter: a type of air filter that removes 99.97% of particles 0.3 μ and larger in diameter.

higher alloy: a metal containing various alloying elements formulated to provide enhanced corrosion resistance beyond those that are typically observed in 316L-type stainless steel. Alloys with a pitting resistance equivalent number (PREN) ≥ 30 in the following families are considered higher alloys: duplex stainless steel, superaustenitic stainless steel, and nickel-based alloys.

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 specified pressure.

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.

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

incomplete fusion (metallic and rigid polymeric, multiuse pipe and tube): a weld discontinuity in which fusion does not occur between weld material and fusion 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. Also called *lack of fusion*.

incomplete fusion (polymeric single-use, flexible tubing): a weld discontinuity in which fusion does not occur between fusion faces, creating a gap that is open to the surface, in all or some portion of the weld circumference. Also called *lack of fusion*.

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incomplete penetration (metallic and rigid polymeric multiuse pipe and tube): a groove weld in which the weld material does not extend completely through the joint thickness. Also called *lack of penetration*.

incomplete penetration (polymeric single-use, flexible tubing): a weld that does not extend completely through from the outer surface to the inner surface of the polymeric tube wall. Also called *lack of penetration*.

indication: evidence obtained from a nondestructive examination method.

inspection:

as it relates to pressure vessels: functions or actions carried out by an ASME-accredited Authorized Inspector; normally a regular employee of an ASME-accredited Authorized Inspection Agency (or equivalent for other applicable codes or standards) in accordance with ASME BPVC, Section VIII.

as it relates to process piping, tubing, and process contact surfaces: functions performed by the owner's Inspector to verify that all required examinations and testing have been completed and to evaluate the physical attributes of the piping to the extent necessary to be satisfied that it conforms to all applicable requirements.

integrity test (single-use): a test used to confirm the defined barrier properties of a single-use system, in accordance with ASTM E3336.

interrupted electropolish: a break in the continuity of the electropolished surface appearance, due to a change of electropolishing conditions at the overlapping boundaries, which may occur when surfaces are electropolished by zones. It may be visible as haze, cloudiness, or variance in luster across these overlapping boundaries.

ISO class 1–9: clean room classifications based on air particulate concentration as defined by the International Organization for Standardization in ISO 14644-1.

joint penetration: the depth that a weld extends from the lower of the two adjacent base metal surfaces being joined into a joint, exclusive of reinforcement.

lack of fusion after reflow: a discontinuity in autogenous 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.

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

leak test (single-use): a test used to identify leaks not correlated to the defined barrier properties of a single-use system, in accordance with ASTM E3336.

looped header: a piping ring with multiple branches for inlet or outlet. The branches on the ring can be closed by valves, caps, or other means of flow isolation.

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.

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 Conformance as a single document.

material type: a commercial designation for a given alloy or chemical composition.

maximum allowable leakage limit (MALL) (single-use): the greatest leakage rate (or leak size) tolerable for a given single-use system to maintain its barrier properties under its use-case conditions (e.g., prevent any risk to product safety, product quality, or operator and environmental safety), in accordance with ASTM E3336.

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 is capable of operating for a sustained period of time. The maximum working temperature should relate to the maximum working pressure and the fluids involved.

meandering: alternating side-to-side deviation of a weld bead from the center of the joint. See Figure MJ-8.4-4, illustration (c).

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): one-millionth of a meter. Also called *micrometer* (1 μm).

misalignment: in welding, offset of the surfaces of two members to be joined or that have been joined. Also called *mismatch*.

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.

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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.

multiuse: a term describing process contact components, equipment, and systems that are designed to be cleaned, sanitized, or sterilized and used multiple times (also referred to as repeated use).

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.

noncontact IR fusion welding (polymeric): an autogenous butt fusion process in which a contact-free application of infrared heat is used to create the weldment.

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

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 with the electrode rotating (or orbiting) around the work. Orbital welding can be done with or without the addition of filler metal.

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.

owner/user: the body on 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.

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

particulates (single-use): small, solid, and mobile matter.

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 (metallic)[3]*:* is specified by nominal pipe size (NPS), or nominal diameter (DN) and wall thickness. Wall thickness is defined by schedule.

pipe (rigid polymeric)[3]*:* is specified by nominal pipe size (NPS) and wall thickness or by standard dimensional ratio (SDR), where SDR is the nominal outside diameter (O.D.) divided by the nominal wall thickness.

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. Polymers can be synthesized either through chain reactions or by templating. Some examples of polymers are plastics, proteins, DNA, and dendrimers.

[3] See SD-3.1.1(i) for ASME BPE pipe and tube application considerations.

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polymeric material: 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.

pressure vessel: a vessel that is designed to operate under pressure conditions and is designed and manufactured in accordance with a local, national, or international pressure vessel code or standard.

process component: a constituent part of equipment or a system that contacts the product or process fluid. Examples of process components include, but are not limited to, tube, fittings, gaskets, valves, 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.

process equipment: an assembly of components that, when combined, provides the platform for one or more process operations including, but not limited to, storage, momentum transfer, heat transfer, mass transfer, and separation. Examples of process equipment include, but are not limited to, pumps, vessels, heat exchangers, chromatography columns, centrifuges, and filter housings.

process system: an assembly of components, equipment, and subsystems that, when integrated, provides a platform for one or more process operations to produce an output within predefined specifications. Examples of process systems include, but are not limited to, bioreactor, chromatography, CIP, and purified water systems.

process zone: area to which the product is potentially exposed during manufacturing (e.g., interior of bioreactor after SIP). The manufacturing suite environment is not in the process zone unless the system is open.

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: also known as *clean 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.

Quality 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).

Quality System Certificate: a document issued by ASME that authorizes the use of an ASME Certificate number on Certificates of Conformance for a specified time and for a specified scope of activity.

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

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

reflow: in autogenous welding, a second pass used to repair specific defects.

reinforcement: see *convexity*.

remote visual examination: a visual examination where there is an interrupted optical path from the observer's eye to the area to be examined. This covers the use of photography, video systems, videoscopes, and borescopes.

repeated use: see *multiuse*.

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

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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*.

schedule: dimensional standard for pipe as defined by ASTM.

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

seal chamber: see *stuffing box*.

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

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

seal weld: a weld intended primarily to provide joint tightness against leakage in metallic piping for which strength or size requirements are optional. (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.

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.

single-use: a term describing process contact components, assemblies, and systems that are designed to be used once, and not to be cleaned or sterilized for reuse.

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.

solution annealing: heating a metal object to a suitable temperature, holding it at that temperature long enough to cause one or more constituents to enter into a solid solution, and then cooling it rapidly enough to hold such constituents in solution. (See ASTM A941.)

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.

special process: a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

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 Nonmandatory Appendix H, Table H-4.3-1.

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

strainer: a component that mechanically separates and retains suspended solid particulates from a process fluid. (See also *strainer body* and *strainer element*.)

strainer body: the subcomponent of a strainer that holds or houses the strainer element. A strainer body can be part of the process piping in which the strainer is installed (e.g., gasket strainer).

strainer element: the subcomponent of a strainer with openings (e.g., perforations, slots). This subcomponent provides the straining of suspended solid particulates.

stringer indication: a linear discontinuity containing 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

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