

ASME BPE-2022
(Revision of ASME BPE-2019)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD



**The American Society of
Mechanical Engineers**

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FOREWORD

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

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

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

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

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

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

(c) Throughout the development of the Standard, close liaison was made with the European CEN, ASTM, and the 3-A Dairy Standards. The purpose was to develop an ASME standard that would be distinctive, germane, and not in conflict with other industry standards. Wherever possible, the Committee strived to reference existing standards that are applicable to biopharmaceutical equipment design and fabrication.

(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

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
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 ANSI on March 21, 2022.

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R. Cosentino, Soleri do Brasil, Ltda.
J. W. Defeo, Hoffer Flow Controls, Inc.
J. M. Featherston, KROHNE INOR
D. Fennell, TQ Constructors, Inc.
J. Gleeson, Hamilton Co.
A. Kalantari, Mettler-Toledo
S. J. Kannengieszer, Brooks Instrument
D. T. Klees, Consultant

D. Kresge, CRB Consulting Engineers
D. Kwilosz, Eli Lilly and Co.
R. Large, Gannett Fleming
M. Muth, WIKA Instruments, LP
J. R. Nerstad, Pure Supply, Inc.
V. Pai, Advent Engineering Services, Inc.
C. Perelman, CRB Consulting Engineers
P. A. Petrillo, Millennium Facilities Resources, Inc.
R. Shankar, RSE
G. Tischler, Vega Americas
G. Woods, CrossPoint Engineering
J. Wynn, Paul Mueller Co.
J. Zipp, WIKA Alexander Wiegand SE and Co. KG
J. Ankers, *Contributing Member*, Ocean Alloys, LLC
K. Renger, *Contributing Member*, Jacobs

CORRESPONDENCE WITH THE BPE COMMITTEE

General. ASME Standards are developed and maintained with the intent to represent the consensus of concerned interests. As such, users of this Standard may interact with the Committee by requesting interpretations, proposing revisions or a case, and attending Committee meetings. Correspondence should be addressed to:

Secretary, BPE Standards Committee
The American Society of Mechanical Engineers
Two Park Avenue
New York, NY 10016-5990
<http://go.asme.org/Inquiry>

Proposing Revisions. Revisions are made periodically to the Standard 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 periodically.

The Committee welcomes proposals for revisions to this Standard. Such proposals should be as specific as possible, citing the paragraph number(s), the proposed wording, and a detailed description of the reasons for the proposal, including any pertinent documentation.

Proposing a Case. Cases may be issued to provide alternative rules when justified, to permit early implementation of an approved revision when the need is urgent, or to provide rules not covered by existing provisions. Cases are effective immediately upon ASME approval and shall be posted on the ASME Committee web page.

Requests for Cases shall provide a Statement of Need and Background Information. The request should identify the Standard and the paragraph, figure, or table number(s), and be written as a Question and Reply in the same format as existing Cases. Requests for Cases should also indicate the applicable edition(s) of the Standard to which the proposed Case applies.

Interpretations. Upon request, the BPE Standards Committee will render an interpretation of any requirement of the Standard. Interpretations can only be rendered in response to a written request sent to the Secretary of the BPE Standards Committee.

Requests for interpretation should preferably be submitted through the online Interpretation Submittal Form. The form is accessible at <http://go.asme.org/InterpretationRequest>. Upon submittal of the form, the Inquirer will receive an automatic e-mail confirming receipt.

If the Inquirer is unable to use the online form, he/she may mail the request to the Secretary of the BPE Standards Committee at the above address. The request for an interpretation should be clear and unambiguous. It is further recommended that the Inquirer submit his/her request in the following format:

- Subject: Cite the applicable paragraph number(s) and the topic of the inquiry in one or two words.
- Edition: Cite the applicable edition of the Standard for which the interpretation is being requested.
- Question: Phrase the question as a request for an interpretation of a specific requirement suitable for general understanding and use, not as a request for an approval of a proprietary design or situation. Please provide a condensed and precise question, composed in such a way that a “yes” or “no” reply is acceptable.
- Proposed Reply(ies): Provide a proposed reply(ies) in the form of “Yes” or “No,” with explanation as needed. If entering replies to more than one question, please number the questions and replies.
- Background Information: Provide the Committee with any background information that will assist the Committee in understanding the inquiry. The Inquirer may also include any plans or drawings that are necessary to explain the question; however, they should not contain proprietary names or information.

Requests that are not in the format described above may be rewritten in the appropriate format by the Committee prior to being answered, which may inadvertently change the intent of the original request.

Moreover, ASME does not act as a consultant for specific engineering problems or for the general application or understanding of the Standard requirements. If, based on the inquiry information submitted, it is the opinion of the Committee that the Inquirer should seek assistance, the inquiry will be returned with the recommendation that such assistance be obtained.

ASME procedures provide for reconsideration of any interpretation when or if additional information that might affect an interpretation is available. Further, persons aggrieved by an interpretation may appeal to the cognizant ASME Committee or Subcommittee. ASME does not “approve,” “certify,” “rate,” or “endorse” any item, construction, proprietary device, or activity.

Attending Committee Meetings. The BPE Standards Committee regularly holds meetings and/or telephone conferences that are open to the public. Persons wishing to attend any meeting and/or telephone conference should contact the Secretary of the BPE Standards Committee.

ASME BPE-2022

SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2022 was approved by the American National Standards Institute on March 21, 2022.

In ASME BPE-2022, Part SG has been redesignated as Part MC, its title has been revised, and all related cross-references have been updated throughout. In addition, ASME BPE-2022 includes the following changes identified by a margin note, (22).

<i>Page</i>	<i>Location</i>	<i>Change</i>
1	Chapter 1	Title revised
1	GR-2	First and last paragraphs revised
2	GR-4.1	Subparagraph (b) revised
2	GR-4.2	Revised
2	GR-4.2.1	First sentence revised
3	Table GR-4.2-1	Title revised
6	GR-4.2.3	Subparagraph (d) revised
7	GR-5.3	Title revised
7	GR-5.3.1	Last sentence added
7	GR-5.3.2	Revised
7	GR-5.3.3	Revised
8	GR-5.3.4	Revised
8	GR-7	(1) First paragraph revised (2) AWS D182, ASQ/ANSI Z1.4, ASTM D199, ASTM D4991, ASTM E499, ASTM E515, ASTM E1003, ISO 1402, ISO 2859-1, and PFI Standard ES-50 added
10	GR-8	(1) Definitions of <i>animal-derived ingredients (ADI)</i> , <i>animal-derived products (ADP)</i> , <i>audit</i> , <i>audit (as performed by ASME or their designee on ASME BPE Certificate Holders and Applicants)</i> , <i>compliance</i> , <i>conformance</i> , <i>conformity</i> , <i>drainable</i> , <i>looped header</i> , <i>multiuse</i> , <i>process equipment</i> , <i>process system</i> , <i>repeated use</i> , <i>single-use</i> , <i>special process</i> , <i>strainer</i> , <i>strainer body</i> , <i>strainer element</i> , <i>surveillance</i> , <i>survey</i> , <i>survey (as performed by ASME or their designee on ASME BPE Certificate Holders and Applicants)</i> , and <i>swing elbow</i> added (2) Definitions of <i>blind weld</i> , <i>clean steam</i> , <i>Quality Inspector's Delegate</i> , <i>Material Test Report (mill report or MTR)</i> , <i>process component</i> , <i>pure steam</i> , <i>testing (as it relates to pressure vessels)</i> , <i>testing (as it relates to process equipment)</i> , <i>testing (as it relates to process piping)</i> , and <i>testing (as it relates to vessels not rated for pressure service)</i> revised (3) Definition of <i>self-draining</i> deleted
20	Chapter 2	Former Chapter 6 redesignated and revised in its entirety
23	MM-2.1	Revised
23	MM-3.1	Revised

<i>Page</i>	<i>Location</i>	<i>Change</i>
23	MM-3.2	(1) First paragraph revised (2) Third and fourth paragraphs deleted
23	MM-3.3	Revised
24	Table MM-2.1-1	"JIS Designation" column and data added
25	Table MM-2.1-2	(1) "UNS Number" and "EN Designation" column heads revised (2) "JIS Designation" column and data added (3) For N10276 and N06022, "Other" data revised
26	Table MM-2.1-3	"JIS Designation" columns and data added
27	MM-3.5	Revised
27	MM-3.6	Deleted
27	MM-4.1	First paragraph revised
27	MM-4.2	(1) Title revised (2) ASTM A213/A213M, ASTM A249/A249M, ASTM A269/A269M, ASTM A270/A270M, ASTM A312/A312M, ASTM A511/A511M, ASTM B619/B619M, and ASTM B690/B690M revised (3) JIS G 3447, JIS G 3459, and JIS G 4903 added
28	MM-4.3	(1) ASTM A351/A351M, ASTM A743/A743M, and ASTM A890/A890M revised (2) JIS G 5121 added
28	MM-4.4	(1) ASTM A182/A182M, ASTM B462, and ASTM B564 revised (2) JIS G 3214 and JIS G 4319 added
28	MM-4.5	(1) ASTM A240/A240M, ASTM A666, ASTM B443, ASTM B575, and ASTM B688 revised (2) JIS G 4304, JIS G 4305, JIS G 4312, and JIS G 4902 added
28	MM-4.6	(1) Title, first paragraph, ASTM A276/A276M, ASTM B574, and ASTM B691 revised (2) EN 10263-1, EN 10263-5, and last paragraph deleted (3) JIS G 4303, JIS G 4308, JIS G 4311, JIS G 4901, JIS H 4553, and JIS H 4554 added
29	MM-4.7	Deleted
29	MM-5.2.1	(1) Title revised (2) MM-5.2.1.1 added (3) Former M-5.2.1.1 revised and redesignated as MM-5.2.1.1(a) (4) Former MM-5.2.1.2 revised and redesignated as MM-5.2.1.1(b) (5) Former MM-5.2.2 revised and redesignated as MM-5.2.1.2 (6) Former MM-5.2.3 revised and redesignated as MM-5.2.1.3
29	Table MM-5.2.1.1-1	Former Table MM-5.2.1.2-1 redesignated
30	MM-5.2.2	Added
30	MM-5.2.3	Former MM-5.2.4 redesignated
30	MM-5.2.4	Former MM-5.2.5 revised and redesignated
30	MM-5.2.5	Former MM-5.2.6 revised and redesignated
30	Table MM-5.2.5-1	(1) Former Table MM-5.2.6-1 redesignated (2) Note (3) revised
30	MM-5.2.6	Former MM-5.2.7 revised and redesignated
30	MM-5.3	(1) Cross-references to tables updated (2) Paragraph following subpara. (b) revised (3) Last paragraph added

<i>Page</i>	<i>Location</i>	<i>Change</i>
31	Table MM-5.3-1	(1) Title revised (2) “JIS Designation,” “JIS Z 3221 Designation,” and “JIS Z 3321 Designation” columns and data added (3) Under SMAW, “ISO 14343-A” revised to “ISO 3581-A”
33	Table MM-5.3-2	Added
34	Table MM-5.3-3	Added
35	Table MM-5.3-4	Added
36	Table MM-5.3-5	Former Table MM-5.3-2 redesignated
37	MM-5.3.1	Last sentence added
37	MM-5.3.2	Revised
37	MM-5.3.3	Added and subsequent paragraph redesignated
37	MM-5.3.4	Former MM-5.3.3 revised
38	Table MM-5.3.4-1	Former Table MM-5.3.3-1 redesignated
37	MM-5.4	Last paragraph revised
39	Table MM-5.4-1	Revised
37	MM-6	(1) Title revised (2) MM-6.1 deleted and subsequent paragraphs redesignated (3) In MM-6.2 (former MM-6.3), first paragraph revised (4) In MM-6.3 (former MM-6.4), cross-reference updated (5) In MM-6.4 (former MM-6.5), cross-reference updated
37	MM-8.1	First paragraph added
39	MM-9.1	First paragraph revised
39	MM-9.1.1	Subparagraph (d) revised
39	MM-9.1.2	Subparagraph (c) revised
42	Table PM-2.1.1-1	Revised
43	PM-2.2	First paragraph revised
43	PM-2.2.1	“Compliance” revised to “conformance” throughout
44	Table PM-2.2.1-1	Title and General Note revised
44	PM-2.2.3.1	Revised
48	PM-4.1	Revised in its entirety
48	PM-4.2.1	Penultimate sentence revised
50	PM-4.2.5	Last sentence revised
50	PM-4.3.2.5	Subparagraph (b) revised
50	PM-4.3.3.3	In subpara. (a), last sentence revised
51	PM-4.3.5	Title revised
51	PM-4.3.5.1	“Compliance” revised to “conformance” throughout
51	PM-4.3.5.2	Title and first sentence revised
51	PM-4.4	(1) Sections PM-4.4 and PM-4.5 deleted and former section PM-4.6 redesignated (2) Cross-references in current PM-4.4.2, PM-4.4.2.1, and PM-4.4.2.2 revised
52	Chapter 4	(1) Former Chapter 2 redesignated (2) Title revised
52	Part SD	Title revised
52	SD-1	Last sentence revised
52	SD-2	Revised

<i>Page</i>	<i>Location</i>	<i>Change</i>
52	SD-2.2	Revised in its entirety
52	SD-2.3	Revised in its entirety
53	SD-2.3.1	Revised
53	SD-2.3.1.1	Revised
53	SD-2.3.1.1.1	Subparagraph (b) revised
53	SD-2.3.1.1.2	Subparagraphs (f) through (h) added
54	SD-2.4.1.1	Last paragraph revised
54	SD-2.4.2	Subparagraph (b)(2) revised
54	SD-2.4.3.1	Revised
55	SD-2.4.3.2	Subparagraphs (b) and (c) and the last paragraph revised
55	SD-2.4.3.3	Revised
55	Table SD-2.4.3.1-1	Title revised
55	SD-2.4.3.4	Revised
55	SD-2.4.4.2	Subparagraph (e) revised
56	SD-2.6	Added
56	SD-3	Title revised
56	SD-3.1.1	Subparagraph (e) revised
63	SD-3.1.2.4	Subparagraph (a) revised
63	SD-3.1.2.4.1	Revised
63	SD-3.1.2.4.2	Subparagraph (a) revised
63	SD-3.2.1	Subparagraphs (a) and (d) revised
63	SD-3.2.2	Subparagraph (c) revised
64	SD-3.3.1	Subparagraphs (a), (c), (d), and (f) revised
65	SD-3.3.2.2	Subparagraph (f) revised
65	SD-3.3.2.4	Subparagraph (e) revised
69	SD-3.4	Revised in its entirety
70	Figure SD-3.4.2-1	Illustration (a) revised
72	Figure SD-3.4.2-3	(1) Title, illustrations, and Note (1) revised (2) Notes (2) through (4) added
76	Figure SD-3.4.3-2	Title and illustration (d) revised
77	Figure SD-3.4.6-1	(1) Illustration (b) revised (2) Note (1) added
78	SD-3.5.1	(1) Subparagraphs (a), (b), and (e) revised (2) Subparagraphs (g) and (k) added and former subparas. (g) through (i) redesignated
82	SD-3.5.3	Subparagraphs (f) and (g) revised
82	SD-3.5.4	Subparagraph (d) revised
82	SD-3.5.5	Subparagraphs (b) through (d), (f), and (g) revised
82	SD-3.5.6	Subparagraph (e) added
85	SD-3.6	Revised in its entirety
86	Figure SD-3.6.2-1	Former Figure SD-3.6.1-1 redesignated
87	SD-3.7.1	Subparagraph (c) revised
87	SD-3.7.2	Subparagraphs (c) and (g) revised
89	Figure SD-3.7.2-1	Title, illustration, and Notes revised
90	SD-3.7.3	Revised

<i>Page</i>	<i>Location</i>	<i>Change</i>
90	SD-3.7.4	Subparagraphs (b) through (d) revised
90	SD-3.7.5	Subparagraph (c) revised
90	SD-3.7.6	Subparagraphs (b) and (e) revised
90	SD-3.8	Revised in its entirety
93	SD-3.9.1	First sentence and subpara. (f)(2)(-a) editorially revised
94	SD-3.9.2	Subparagraphs (a), (b), (e), and (j) revised
94	SD-3.9.2.1	Subparagraphs (b) and (f) revised
95	SD-3.9.2.2	Subparagraphs (a) and (e) revised
97	SD-3.9.2.3	Subparagraphs (a) and (f) revised
98	SD-3.13	Subparagraphs (b) and (e) revised
99	SD-3.15	Subparagraphs (c), (f) through (h), and (j) revised
99	SD-3.16	Subparagraphs (a) and (c) revised
100	SD-3.17	Added
100	Figure SD-3.17.1-1	Added
101	SD-3.18	(1) Former PM-4.4 relocated and redesignated (2) SD-3.18.6 title revised (3) SD-3.18.6.2 revised
102	SD-4	Title revised
102	SD-4.1.1	Subparagraph (c) revised
102	SD-4.1.2.1	First sentence and sentence following subpara. (b) revised
102	SD-4.1.2.2	Subparagraphs (a), (b), (j), (l), and (n) revised
102	SD-4.2.1	Subparagraph (c) revised
104	SD-4.2.2	Subparagraphs (c), (g), and (h) revised
104	SD-4.2.3	Subparagraphs (a) and (d) revised
104	SD-4.3.1	Subparagraphs (a), (c), and (f) revised
107	SD-5.1.4.3	Subparagraph (e) editorially revised
107	SD-5.1.4.4	Subparagraph (d) revised
107	SD-5.1.4.7	Subparagraph (f) editorially revised
112	SD-5.1.4.11	Subparagraph (b) revised
112	SD-5.1.4.13	Subparagraph (b) revised
112	SD-5.1.4.14	Subparagraphs (b) and (c) revised
114	SD-5.1.5	Subparagraph (c) revised
114	SD-5.1.5.1	Subparagraphs (c) through (g) revised
117	SD-5.1.5.2	Subparagraphs (d) and (f) revised
117	SD-5.1.5.4	(1) Subparagraph (c) editorially revised (2) Subparagraph (f) added
117	SD-5.2	Revised in its entirety
119	SD-5.3	Revised in its entirety
121	SD-5.4	Revised in its entirety
123	Figure SD-5.4.5.1-1	Former Figure SD-5.4.4-1 redesignated
123	SD-5.5	Revised
123	SD-5.5.1	Added
123	SD-5.5.3	Added
124	SD-5.5.5.2	Revised
124	SD-5.6	Revised in its entirety

<i>Page</i>	<i>Location</i>	<i>Change</i>
125	Figure SD-5.6.4-1	Former Figure SD-5.6.2-1 redesignated
129	Figure SD-5.6.5-1	Former Figure SD-5.6.3-1 redesignated
130	SD-5.7.1	First sentence revised
131	SD-6.1.3.1	Subparagraph (b)(2) revised
131	SD-6.1.4	Subparagraphs (a)(1), (a)(4), (a)(5), and (b) revised
131	SD-6.1.4.1	Subparagraph (b) revised
132	SD-6.1.4.4	Subparagraph (c)(5) revised
132	SD-6.1.4.6	First paragraph revised
132	SD-6.1.4.7	Subparagraphs (a) and (c) revised
133	SD-6.1.4.8	Subparagraphs (b) and (c) revised
133	SD-6.1.4.9	Subparagraph (a) revised
133	SD-6.1.4.10	Subparagraph (a) revised
133	SD-6.1.5	Subparagraph (b) revised
133	SD-6.1.5.2	Subparagraph (c) revised
133	SD-6.1.5.3	Subparagraphs (c) and (f) revised
134	SD-6.1.7.3	First sentence revised
134	SD-6.2.4	Revised
135	SD-6.2.4.1	Last sentence revised
135	SD-6.2.4.6	Revised
135	SD-6.2.4.10	Subparagraph (a) revised
135	SD-6.3	Revised in its entirety
137	Figure SD-6.3.4.1.1-1	Added
138	Figure SD-6.3.4.2-1	Former Figure SD-6.3.4.6-1 redesignated
139	Figure SD-6.3.4.2-2	Former Figure SD-6.3.4.6-2 redesignated
139	Figure SD-6.3.4.2-3	Former Figure SD-6.3.4.6-3 redesignated
140	Table SD-6.3.4.2-4	Added
141	Table SD-6.3.5.2.1-1	Former Table SD-6.3.5.2-1 redesignated and revised in its entirety
142	SD-6.4.1.1	Definitions of <i>cooling equipment</i> and <i>heating equipment</i> revised
142	SD-6.4.3.2	Revised
145	SD-6.4.4.1	First paragraph and subpara. (b) revised
145	SD-6.4.4.4	Revised
145	SD-6.4.4.5	Subparagraphs (c) and (f) revised
147	SD-6.5.1	Definition of <i>general load immersion basket/rack</i> revised
148	SD-6.5.3	Subparagraphs (c) and (g) revised
148	SD-6.5.4	Subparagraph (a) revised
148	SD-6.5.4.1	Subparagraph (c) revised
148	SD-6.5.4.2	Subparagraph (g) revised
149	SD-6.5.4.3	Subparagraphs (a) and (b) revised
149	SD-6.5.5.1	Subparagraph (b) revised
149	SD-6.5.5.2	First sentence and last paragraph revised
150	SD-6.5.7.1	Subparagraphs (b) and (d) revised
151	SD-6.6.4	Subparagraph (b) revised
152	SD-6.6.4.7	Last paragraph revised
153	SD-6.6.4.9	First sentence revised

<i>Page</i>	<i>Location</i>	<i>Change</i>
153	SD-6.6.4.11	First paragraph revised
153	SD-6.6.5.1	Revised
155	SD-7.4	Revised in its entirety
156	Chapter 5	(1) Former Chapter 4 redesignated (2) Title revised
156	DT-2	Revised in its entirety
156	DT-3	Second paragraph revised
156	DT-4	First sentence revised
156	DT-4.1.1	Revised
156	DT-4.1.2	Revised
156	DT-4.1.4	Revised
157	DT-4.4	Second paragraph deleted
157	DT-4.4.1	(1) Title revised (2) Last sentence added
157	DT-4.6	Added
157	DT-7	Revised in its entirety
157	DT-8	First paragraph revised
158	DT-9.2	Revised
158	DT-9.3	Revised
158	DT-9.4	Subparagraph (e) revised
158	DT-10.3	Second and fourth paragraphs revised
159	DT-11.1	(1) Title, first paragraph, and subpara. (a) revised (2) Subparagraph (c) added and subsequent subparagraphs redesignated
159	DT-11.1.1	(1) Subparagraph (a) revised (2) Subparagraph (c) added
159	DT-11.2	Section DT-11.2 deleted and former section DT-11.3 redesignated
159	Table DT-2-1	Revised in its entirety
160	Table DT-3-1	(1) Title revised (2) General Note (f) added
192	Figure DT-9.4-1	Former Figure DT-2-1 redesignated
161	Table DT-3-2	(1) Title revised (2) General Note added
161	Table DT-4-1	General Note revised
166	Table DT-4.1.1-9	Added
167	Table DT-4.1.1-10	Added
170	Table DT-4.1.2-6	Revised
172	Table DT-4.1.2-8	Revised
174	Table DT-4.1.2-12	Added
175	Table DT-4.1.2-13	Added
181	Table DT-4.4.1-1	Title revised
184	Table DT-7.1-1	Table DT-7-1 redesignated
187	Table DT-7.1-2	(1) Former Table DT-7-2 redesignated (2) Illustrations and data in “Face Offset, <i>H</i> ” columns revised
190	Table DT-7.3-1	Table DT-7-3 revised and redesignated
193	Table DT-11.1.1-1	Added

<i>Page</i>	<i>Location</i>	<i>Change</i>
194	Part PI	Title revised
194	PI-2	First two paragraphs deleted
194	PI-2.1.1	First paragraph revised
194	PI-2.1.3	First sentence revised
197	PI-2.2.3	Revised
200	PI-4.2.2.1	(1) Subparagraph (e) and last paragraph deleted (2) Former subpara. (f) redesignated as (e)
201	Figure PI-4.2.2-1	Revised
202	PI-4.2.3.1	Former PI-4.2.3.1 and PI-4.2.3.2 deleted and PI-4.2.3.3 redesignated
202	PI-4.2.4	Former PI-4.2.4 deleted and PI-4.2.5 redesignated
202	PI-4.2.5	Former PI-4.2.6 revised and redesignated
211	PI-8.1	Revised in its entirety (including figures)
214	PI-8.2	Revised in its entirety (including figures)
215	PI-9.1.3	Former PI-9.1.3.1 deleted and subsequent paragraphs redesignated
217	Figure PI-9.1.3.2-1	Former Figure PI-9.1.3.3-1 redesignated
218	Figure PI-9.1.3.4-1	Former Figure PI-9.1.3.5-1 redesignated
218	Figure PI-9.1.3.4-2	Former Figure PI-9.1.3.5-2 redesignated
220	Figure MC-2.2.2-1	Cross-reference in title revised
220	Figure MC-2.2.2-2	Cross-reference in title revised
223	MC-2.3.1.9	Subparagraph (a) revised
230	MC-2.3.2.1	(1) Subparagraph (a) reformatted as first paragraph (2) Subparagraph (b) deleted
230	MC-2.3.2.3	Subparagraphs (a), (a)(1), (a)(3), (a)(5) through (a)(7), (b), (b)(1), (b)(3), (b)(6), and (b)(7) revised
231	Figure MC-2.3.2.3-1	Title revised
231	Figure MC-2.3.2.3-2	Title revised
232	Figure MC-2.3.2.3-3	Title revised
232	MC-2.3.2.4	Subparagraphs (f) through (k) revised
237	MC-3.1	Revised in its entirety
237	MC-3.2	Revised in its entirety
237	MC-3.3.1	Subparagraphs (a) and (f) revised
238	MC-3.3.2.1	Subparagraph (b) revised
238	MC-3.3.2.2	Subparagraphs (c)(7)(-b)(-2) and (c)(7)(-c) revised
239	MC-3.3.2.3	(1) Subparagraphs (a)(1), (a)(3), (a)(6), (b)(2), (b)(3), (c), (c)(3), (e), (f), (h), and (k) revised (2) Subparagraphs (a)(5), (a)(15), and (a)(16) deleted and subsequent subparagraphs redesignated (3) Subparagraph (a)(14) added
241	MC-3.3.2.4	Subparagraphs (a)(8), (a)(10), (c), (c)(1) through (c)(7), (d), and (d)(1) through (d)(7) revised
242	MC-3.4.1	Revised
243	MC-3.4.3	Revised
243	MC-4.1	First paragraph revised
244	MC-4.3.1	First paragraph revised

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244	MC-4.3.1.1	Second paragraph revised
244	MC-4.3.2.1	Subparagraph (d) revised
245	MC-5.1.1	Revised
246	MC-5.3	Subparagraph (a) revised
248	Chapter 6	(1) Former Chapter 5 redesignated (2) Title revised
248	Part MJ	Title revised
249	MJ-3.1	Revised
249	MJ-3.2	Added
250	Figure MJ-3.2-1	Added
251	Figure MJ-3.2-2	Added
249	MJ-3.2.1	(1) Former MJ-3.2 redesignated (2) Title revised
249	MJ-3.2.2	Added
253	MJ-7.2.2	Revised
253	MJ-7.2.3	Revised
253	MJ-7.2.4	Revised
253	MJ-7.2.5	Revised
253	MJ-7.2.6	(1) First paragraph revised (2) Subparagraphs (a) and (b) and last paragraph deleted
255	MJ-8.3	(1) First paragraph revised (2) Second paragraph added
255	MJ-8.4.2	Subparagraph (d) added
256	Table MJ-8.2-1	Revised
258	Table MJ-8.3-1	Revised
260	Table MJ-8.4-1	Revised
262	Figure MJ-8.4-1	Labels revised
263	Figure MJ-8.4-2	Text underneath figure revised
264	Figure MJ-8.4-3	Text underneath figure revised
265	Figure MJ-8.4-4	Labels for illustrations (b) and (c) revised
266	Table MJ-8.5-1	Revised
268	Figure MJ-8.5-1	Labels revised
269	MJ-9.6.2.1	Revised
269	MJ-9.6.2.2	(1) First paragraph revised (2) Subparagraphs (a) and (b) and last paragraph deleted
269	MJ-9.7.1	Revised in its entirety
270	Table MJ-9.7.1-1	Added
271	Figure MJ-9.7.1-1	Labels and illustration (d) revised
272	Part SF	Title revised
272	SF-2.2	Revised
273	Table SF-2.2-1	Revised
272	SF-2.3.2	Cross-reference updated
273	SF-2.4.1	Last sentence revised
274	Table SF-2.4.1-1	General Note (d) revised
274	SF-2.6	Revised

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275	Table SF-2.6-1	General Note (a) revised
274	SF-2.8	Second paragraph revised
276	Table SF-3.3-1	Revised
276	Table SF-3.4-1	General Note (b) revised
277	Chapter 7	Added
280	Chapter 8	Added
282	Chapter 9	Added
284	Mandatory Appendix I	Deleted
286	Mandatory Appendix III	Information revised and relocated to Parts SU, SC, and SJ
287	Mandatory Appendix IV	Last <i>L/d</i> cross-reference updated
294	C-2	Subparagraph (b) revised
296	D-4.3	First sentence revised
296	D-4.4	First paragraph revised
297	Table D-2-1	Considerations for “Alloy composition” revised
298	Table D-2-2	(1) Variable “High-shear/velocity environment (pump impeller, sprayball, tees, etc.)” revised (2) Considerations for “Operating temperature and temperature gradients” revised
299	Table D-3.1-1	Revised
300	Table D-3.2-1	Revised
301	Table D-4.1-1	“Conditions of Process” column and Note (3) revised
303	E-1	First paragraph revised
303	E-2.2	First sentence added
304	E-3.1	Third paragraph revised
304	E-3.2	Subparagraph (a)(2) deleted and subsequent subparagraphs redesignated
304	E-4.1	First paragraph revised
305	Table E-3.2-2	Revised
306	E-5.1	Title and first sentence revised
307	Table E-5-1	Revised
311	F-3	First sentence revised
312	Table F-1-1	“Purpose of Test” revised for ASTM A262, Practice C; ASTM A923, Method C; and ASTM G48, all methods
313	Table F-3-1	Revised in its entirety
318	Table J-1.1-1	Revised in its entirety
320	K-1.1	First paragraph revised
320	K-1.2	(1) First paragraph revised in its entirety (2) In K-1.2.1, subparas. (b), (c)(1) through (c)(5), (d), (e), and (g) revised (3) K-1.2.2 deleted and subsequent paragraphs redesignated (4) K-1.2.3.2 deleted (5) In K-1.2.3 (formerly K-1.2.4), first paragraph revised and subpara. (c) added
353	Nonmandatory Appendix Y	JIS procurement contact information added
354	Z-2	Revised
355	Z-3.2	Subparagraphs (b) and (c)(8) revised

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355	Z-3.5	(1) Second paragraph revised (2) Third paragraph added
356	Z-3.8	(1) Subparagraphs (b)(1), (b)(1)(-a), and (b)(2) revised (2) Subparagraph (b)(2)(-e) added
357	Z-3.12	Subparagraph (c) revised
363	Nonmandatory Appendix CC	Title and “General, Personnel, and Procedures” and “Inspection” sections of table revised
366	DD-2	Title corrected by errata
368	Nonmandatory Appendix EE	Added
378	Nonmandatory Appendix FF	Added
383	Nonmandatory Appendix GG	Added
385	Index	Updated

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CHAPTER 1

INTRODUCTION, SCOPE, AND GENERAL REQUIREMENTS

(22)

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 biopharmaceuticals, where a defined level of purity and bioburden control is required.

The Standard typically applies to

(a) components that are in contact with the product, raw materials, or product intermediates during manufacturing, development, or scale-up

(b) systems that are a critical part of product manufacture [e.g., water-for-injection (WFI), clean steam, filtration, and intermediate product storage]

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

Items or requirements that are not specifically addressed in this Standard are not prohibited. Engineering judgments must be consistent with the funda-

mental 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

(22)

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

This Standard applies to

(a) new system (and component) design and fabrication

(b) definition of system boundaries

(c) specific metallic, polymeric, and elastomeric (e.g., seals and gaskets) materials of construction

(d) component dimensions and tolerances

(e) surface finishes

(f) materials joining

(g) examinations, inspections, and testing

(h) certification

This Standard is intended to apply to new fabrication and construction. If the provisions of this Standard are optionally applied by an owner/user to existing, in-service equipment, other considerations may be necessary. For installations between new construction and an existing, in-service system, such as a retrofit, modification, or repair, the boundaries and requirements must be agreed to among the owner/user, engineer, installation contractor, and inspection contractor.