ASME BPE-2016

(Revision of ASME BPE-2014)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD

The American Society of Mechanical Engineers

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The American Society of Mechanical Engineers
Two Park Avenue • New York, NY • 10016 USA

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The next edition of this Standard is scheduled for publication in 2018. This Standard will become effective 6 months after the Date of Issuance.

ASME issues written replies to inquiries concerning interpretations of technical aspects of this Standard. Periodically, certain actions of the ASME BPE Committee may be published as Cases. Cases and interpretations are published on the ASME Web site under the Committee Pages at http://cstools.asme.org/ as they are issued.

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The American Society of Mechanical Engineers
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FOREWORD

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

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

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

(1) the need for equipment designs that are both cleanable and sterilizable

(2) the need for special emphasis on the quality of weld surfaces once the required strength is present

(3) the need for standardized definitions that can be used by material suppliers, designers/fabricators, and users

(4) the need to integrate existing standards covering vessels, piping, appurtenances, and other equipment necessary for the biopharmaceutical industry without infringing on the scopes of those standards

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

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

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

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

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

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

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

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ASME BPE-2016
SUMMARY OF CHANGES

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

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

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

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

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

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

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

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

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

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

BIOPROCESSING EQUIPMENT

CHAPTER 1
INTRODUCTION, SCOPE, AND DEFINITIONS (16)

Part GR
General Requirements

GR-1 INTRODUCTION

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

The Standard typically applies to

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

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

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

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

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

When an application is covered by laws or regulations issued by an enforcement authority (e.g., municipal, provincial, state, or federal), the final construction requirements shall comply with these laws.

Items or requirements that are not specifically addressed in this Standard are not prohibited. Engineering judgments must be consistent with the fundamental principles of this Standard. Such judgments shall not be used to override mandatory regulations or specific prohibitions of this Standard.

GR-2 SCOPE OF THE ASME BPE STANDARD (16)

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

This Standard applies to

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

(b) definition of system boundaries

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

(d) component dimensions and tolerances

(e) surface finishes

(f) materials joining

(g) examinations, inspections, and testing

(h) certification

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