ASME BPE-2026

(Revision of ASME BPE-2024)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD

The American Society of Mechanical Engineers

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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

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.

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(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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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

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

Page	*Location*	*Change*
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

Page	*Location*	*Change*
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

Page	*Location*	*Change*
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

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

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