ASME BPE-2024

(Revision of ASME BPE-2022)

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

Date of Issuance: April 29, 2024

The next edition of this International Standard is scheduled for publication in 2026. This International Standard will become effective 6 months after the Date of Issuance.

This international code or standard was developed under procedures accredited as meeting the criteria for American National Standards and it is an American National Standard. The standards committee that approved the code or standard was balanced to ensure that individuals from competent and concerned interests had an opportunity to participate. The proposed code or standard was made available for public review and comment, which provided an opportunity for additional public input from industry, academia, regulatory agencies, and the public-at-large.

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The endnotes and preamble in this document (if any) are part of this American National Standard.

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ASME Single Certification Mark

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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 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 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
Chapter 9, Fabrication, Assembly, and Erection for Single-Use
Part SJ, Joining Methods for Single-Use
Part SI, Single-Use Process Instrumentation

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 5, 2024.

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(The following is the roster of the committee at the time of approval of this standard.)

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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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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.

ASME BPE-2024
SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2024 was approved by the American National Standards Institute on April 5, 2024.

ASME BPE-2024 includes the following changes identified by a margin note, **(24)**.

Page	*Location*	*Change*
1	GR-1	Revised
1	GR-2	Revised
2	GR-4	Cross-references to GR-8 updated to GR-11
2	GR-4.2.1	Subparagraph (c) revised
6	GR-4.3.2	Title revised
6	GR-5.2	Revised in its entirety
7	GR-5.3	Revised in its entirety
8	GR-5.4	Former GR-5.5 redesignated
8	GR-5.5	Added
8	GR-6	Added
9	GR-7	Added
9	GR-8	Added
9	GR-9	Former GR-6 redesignated
9	GR-10	Former GR-7 redesignated and updated
11	GR-11	Former GR-8 redesignated and revised
20	GR-12	Former GR-9 redesignated
21	Table CR-1-1	Revised
22	CR-2.1	(1) Subparagraphs (b) and (d) revised (2) Subparagraph (e) added
22	CR-2.2.3	Revised
23	CR-2.3.2	Subparagraph (b) revised
25	Table MM-2.1-1	S32750 added
27	Table MM-2.1-3	J93404 added
28	MM-4.2	Updated
29	MM-4.3	Updated
29	MM-4.4	Updated
29	MM-4.5	Updated
30	MM-4.6	Updated
30	MM-5.2.1.1	Subparagraph (a) revised
31	Table MM-5.2.1.1-1	References in notes updated
31	MM-5.2.1.3	Second paragraph revised
32	Table MM-5.2.5-1	Note (3) revised
35	Table MM-5.3-2	Revised

Page	*Location*	*Change*
36	Table MM-5.3-3	S32750 added
38	Table MM-5.3-5	Revised
40	Table MM-5.4-1	S32750 added
40	MM-8.2	Last paragraph added
40	MM-9.1	Revised
40	MM-9.1.1	Revised
41	MM-9.1.2	Revised
42	Part PM	PM-4.3 revised and redesignated as MC-5
42	PM-2.1	Revised
48	PM-4.2	Revised
48	PM-4.2.1	Revised in its entirety
48	PM-4.2.2	Revised
49	PM-4.2.4.1	Revised in its entirety
49	PM-4.2.4.2	Revised
49	PM-4.2.5	Revised in its entirety
50	SD-1	First paragraph revised
50	SD-2	Revised
50	SD-2.2	First paragraph revised
50	SD-2.3	Subparagraph (b) revised in its entirety
51	SD-2.4	Revised
52	SD-2.4.2	Subparagraphs (a)(1) and (a)(2) revised
53	SD-2.4.3.4	In subpara. (a), last sentence added
53	SD-2.4.4.2	First paragraph and subparas. (d), (g), (j), and (m) revised
54	SD-2.5	First sentence revised
54	SD-2.6	Deleted
54	SD-3.1.1	Subparagraph (c) revised
56	SD-3.1.2.2	Last paragraph revised
59	Figure SD-3.1.2.2-1	Revised in its entirety
66	SD-3.4	(1) Title revised (2) In SD-3.4.1, first paragraph and subpara. (c) revised (3) In SD-3.4.2, subpara. (c) added and subsequent subparagraphs redesignated (4) In SD-3.4.6, subpara. (a) revised
68	Figure SD-3.4.2-2	Note (2) revised
96	SD-3.13	Subparagraphs (a) and (d) revised
99	SD-3.19	Added
105	SD-5.1.4	(1) Redesignated in its entirety (2) Figures SD-5.1.4.4-1 through SD-5.1.4.4-4 and SD-5.1.4.7-1 through SD-5.1.4.7-3 redesignated as Figures SD-5.1.4.1.3-1 through SD-5.1.4.1.3-4 and SD-5.1.4.2.1-1 through SD-5.1.4.2.1-3, respectively
119	SD-5.3.5.5	Revised in its entirety
121	SD-5.5.2	Added
122	SD-5.5.4	Added
122	SD-5.5.5	Revised in its entirety
123	SD-5.5.6	Added

Page	*Location*	*Change*
123	SD-5.5.7	Added
134	SD-6.2.4.7	Revised
135	SD-6.3.3.3	Revised
137	SD-6.3.4.2	Revised in its entirety
140	SD-6.3.5.1	Revised in its entirety
140	SD-6.3.5.2.1	Subparagraph (c) revised
140	SD-6.3.5.2.2	(1) Subparagraphs (b) and (d) revised (2) Subparagraph (c) deleted and subsequent subparagraphs redesignated
141	SD-6.3.5.3	Added
141	SD-6.3.5.4	Added
141	SD-6.3.6	Revised in its entirety
141	SD-6.3.7	Revised in its entirety
153	SD-7.1	Last paragraph revised
155	DT-2	Revised
155	DT-4	Cross-reference to GR-6 updated to GR-9
156	DT-7.2	Revised
158	Table DT-2-1	General Notes revised
170	Table DT-4.1.2-6	Editorially reformatted
171	Table DT-4.1.2-7	Editorially reformatted
172	Table DT-4.1.2-8	Editorially reformatted
173	Table DT-4.1.2-9	Editorially reformatted
175	Table DT-4.1.2-13	Revised
180	Table DT-4.1.5-1	Revised in its entirety
191	Table DT-7.2-1	Added
204	PI-5	(1) Revised in its entirety (2) Figures PI-5.1.2.1-1 and PI-5.1.3.3-1 redesignated as Figures PI-5.1.5-1 and PI-5.1.1.1-1, respectively
217	PI-8.4	Added
221	MC-2.2.2	Revised
222	Figure MC-2.2.2-1	Revised
222	Figure MC-2.2.2-2	Title revised
231	Figure MC-2.3.1.9-1	Revised in its entirety
234	MC-2.3.2.4	(1) Revised in its entirety (2) Titles of Figures MC-2.3.2.4-1 through MC-2.3.2.4-16 revised (3) Figures MC-2.3.2.4-1 and MC-2.3.2.4-2 revised (4) Figure MC-2.3.2.4-8 redesignated as Figure MC-2.3.2.4-13 and Figures MC-2.3.2.4-9 through MC-2.3.2.4-13 redesignated as Figures MC-2.3.2.4-8 through MC-2.3.2.4-12, respectively
245	MC-4.1	Last paragraph added
245	MC-4.2	Second paragraph and subpara. (b) revised
247	MC-5	Former PM-4.3 redesignated and revised
250	MJ-3.1	Third paragraph added
251	Figure MJ-3.1-1	Added
250	MJ-3.4	Revised
254	MJ-5.4	Revised

Page	*Location*	*Change*
267	Figure MJ-8.4-4	Captions for illustrations (b) and (c) and General Note revised
276	SF-2.5	Revised in its entirety
276	SF-2.6	First paragraph revised
276	SF-2.7	Updated
276	SF-2.8	In penultimate paragraph, cross-reference updated
279	SU-3	Revised in its entirety
281	SU-9	Revised in its entirety
281	SU-10	(1) Subparagraphs (a) and (b) revised (2) Subparagraph (c) added
282	SU-12	Added
284	SC-3.1.1	Added
284	SC-3.2.1	Added
284	SC-3.2.2	Added
284	SC-4	Revised
284	SC-5	Added
291	Part SI	Added
293	Mandatory Appendix III	Deleted
296	Nonmandatory Appendix A	Title revised
311	Table E-3.2-1	Revised
311	E-4	E-4.2 deleted
312	E-5.1	Last two paragraphs revised
320	Table F-1-1	(1) First column heading revised (2) ASTM A1084 and ISO 3651-2 added
322	Table F-3-1	S32750 added
324	Nonmandatory Appendix H	Revised in its entirety
341	Nonmandatory Appendix L	L-1 and L-2 updated
346	Nonmandatory Appendix N	Title and subparas. (a), (f), (i), and (j) revised
347	O-1.1	Former PM-2.1.1 redesignated
347	O-1.2	Former PM-2.1.2 redesignated
348	Table O-1.1-1	Former Table PM-2.1.1-1 redesignated
348	Table O-1.2-1	Former Table PM-2.1.2-1 redesignated
349	Table O-1.3-1	Former Table PM-2.1.3-1 redesignated
348	O-1.3	Former PM-2.1.3 redesignated
348	O-1.4	Former O-1.1 redesignated
350	P-1	Updated
367	Z-1	Revised
368	Z-3.4	Subparagraph (c) added
368	Z-3.5	(1) Second paragraph added by errata (2) Last two paragraphs revised by errata
369	Z-3.8	Subparagraph (b)(2)(-e) revised
369	Z-3.9	Subparagraph (a) revised
370	Z-3.10	Subparagraph (b) editorially revised
371	Nonmandatory Appendix AA	Revised in its entirety
377	Nonmandatory Appendix BB	Deleted

Page	*Location*	*Change*
393	Nonmandatory Appendix FF	(1) Revised in its entirety (2) Table FF-1 revised and redesignated as Table FF-1-1 (3) Table FF-2 revised and redesignated as Table FF-1-2
401	Nonmandatory Appendix HH	Added
404	Nonmandatory Appendix JJ	Added
405	Table JJ-1	Former Table PM-4.2.1-1 redesignated
406	Index	Updated

CHAPTER 1
INTRODUCTION, SCOPE, AND GENERAL REQUIREMENTS

PART GR
GENERAL REQUIREMENTS

GR-1 INTRODUCTION (24)

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 (24)

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