ASME BPE-2019

(Revision of ASME BPE-2016)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD

The American Society of Mechanical Engineers

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Two Park Avenue • New York, NY • 10016 USA

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The next edition of this Standard is scheduled for publication in 2021. 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 website under the Committee Pages at http://cstools.asme.org/ as they are issued.

Errata to codes and standards may be posted on the ASME website under the Committee Pages to provide corrections to incorrectly published items, or to correct typographical or grammatical errors in codes and standards. Such errata shall be used on the date posted.

The Committee Pages can be found at http://cstools.asme.org/. There is an option available to automatically receive an e-mail notification when errata are posted to a particular code or standard. This option can be found on the appropriate Committee Page after selecting "Errata" in the "Publication Information" section.

The American Society of Mechanical Engineers
Two Park Avenue, New York, NY 10016-5990

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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 February 27, 2019.

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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-2019
SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2019 was approved by the American National Standards Institute on February 27, 2019.

ASME BPE-2019 includes the following changes identified by a margin note, **(19)**.

Page	*Location*	*Change*
xviii	Correspondence With the BPE Committee	Moved from Mandatory Appendix I and revised in its entirety
1	GR-1	New last paragraph added
2	GR-3	New last paragraph added
2	GR-4	Revised in its entirety
8	GR-7	References updated
10	GR-8	(1) Definitions of *direct visual examination, examination, High Efficiency Particulate Air (HEPA) filter, inspection, interrupted electropolish, ISO class 1–9, remote visual examination, testing, Ultra-Low Penetration Air (ULPA) filter,* and *videoscope* added (2) Definitions of *borescope, dead leg,* and *haze* revised (3) Definitions of *audit* and *survey* deleted
18	GR-9	Added
19	SD-2	Second paragraph revised and new third and fourth paragraphs added
19	SD-2.3	Revised in its entirety
20	SD-2.4.1.1	First sentence in first paragraph revised
20	SD-2.4.2	Subparagraphs (a)(1) and (b)(2) revised
22	SD-2.5	Added
23	SD-3.1.1	Subparagraph (d) revised
23	SD-3.1.2.2	Title and first paragraph revised
23	SD-3.1.2.3	Subparagraphs (g) and (i) revised
30	SD-3.2.3	Subparagraph (c) revised
37	SD-3.4.4	First sentence of subpara. (b) revised
41	SD-3.5.1	Subparagraphs (a) and (e) revised
46	SD-3.5.5	Second sentence of subpara. (a) revised
48	SD-3.5.6	Second sentence of subpara. (b) revised
48	SD-3.6.1	Subparagraphs (a), (c), (e), and (g)(3) revised
49	SD-3.7.2	Subparagraph (g) revised
50	Figure SD-3.6.1-1	Note (1) revised
52	Figure SD-3.7.2-1	Subtitle revised
52	SD-3.7.3	Subparagraph (a) revised
52	SD-3.7.4	Subparagraphs (c) and (e) revised

54	SD-3.7.6	Subparagraph (e) revised
58	SD-3.9.2.3	Subparagraph (a) revised
60	SD-3.13	Second sentence of subpara. (d) revised
61	SD-4.1	Subparagraph (b) revised
61	SD-4.1.1	Second sentence of subpara. (b) revised
61	SD-4.1.2.2	Subparagraph (d) revised
63	SD-4.2.1	Second sentence of subpara. (b) revised
65	SD-4.3.1	First paragraph revised
66	SD-5	Revised in its entirety
85	SD-6	New SD-6 added
106	SD-7	Former SD-6 redesignated
108	MM-1	Second sentence revised
109	Table MM-2.1-1	Under Duplex Stainless Steels, values for UNS S32101 added
108	MM-3.2	Revised
108	MM-3.3	Cross reference in subpara. (a) revised
108	MM-3.5	Revised
114	MM-5.2.2	Second paragraph revised
114	Table MM-5.2.1.2-1	Under Product Form column, third and fourth entries revised
114	MM-5.2.3	Second paragraph revised
115	Table MM-5.2.6-1 T	UNS Number N07718 added
115	MM-7	Former MM-6 revised and redesignated
116	Table MM-5.3-1	Under Duplex Stainless Steels, values for UNS S32101 added
120	Table MM-5.3-2	Under Duplex Stainless Steels, values for UNS S32101 added
122	Table MM-5.4-1	Under Duplex Stainless Steels, values for UNS S32101 added
122	MM-8	Former MM-7 redesignated
122	MM-9	Former MM-8 revised in its entirety and redesignated Second
124	PM-1	paragraph revised
125	PM-2.2	First paragraph revised
126	PM-2.2.3	Revised in its entirety
127	Table PM-2.2.1-1	General Note revised
128	Table PM-2.2.3.2-1	Added
129	PM-3.2	Revised in its entirety
130	PM-4.1	Revised in its entirety
136	PM-4.6	Revised
136	PM-4.6.1.2	Revised
136	PM-4.6.2	Revised in its entirety
137	DT-3	Second sentence of second paragraph revised
142	Table DT-3-1	(1) In graphic, callout T revised as T_L (2) General Note (d) revised
137	DT-4.1	In third paragraph, T revised as T_L
137	DT-4.1.4	Revised
143	Table DT-4.1-1	In second column head, T revised as T_L
148	Table DT-4.1.1-8	For Nominal Size 2½ in., value in last column revised Values
151	Table DT-4.1.2-4	revised for Nominal Size ½ in. and ¾ in.
151	Table DT-4.1.2-5	Values revised for Nominal Size ½ in. and ¾ in. under column A

154	Table DT-4.1.2-8	Under column B, values in SI column revised in 27th and 28th lines
138	DT-7	First paragraph revised
138	DT-8	First sentence revised
139	DT-11.1	Subparagraph (a) revised
140	DT-11.1.1	Subparagraph (a) revised
140	DT-11.2	Subparagraph (a) revised
140	DT-11.2.1	Subparagraphs (a) and (b) revised
165	Table DT-7-1	Revised in its entirety
168	Table DT-7-2	New Table DT-7-2 added
171	Table DT-7-3	Former Table DT-7-2 redesignated
178	PI-4.2	Added
181	PI-6.1	Added
209	Figure SG-2.3.1.9-1	Illustration (c) revised
218	SG-3.3.2.3	Subparagraph (a)(7) revised
223	SG-4.3.1.1	Revised in its entirety
224	SG-5.1	Last two paragraphs added
224	SG-5.1.1	Added
225	SG-5.3	Revised in its entirety
225	SG-5.4	Revised in its entirety
228	MJ-3.5	Subparagraph (b)(2) revised
229	MJ-6.3	Last paragraph revised
230	Table MJ-6.3-2	Variable t revised as T_w throughout
232	MJ-8.4	First paragraph revised
233	Table MJ-8.2-1	In fourth row, fourth column revised
234	Table MJ-8.3-1	In fourth row, fourth column revised
235	Table MJ-8.4-1	(1) In fourth row, second column revised (2) In fifteenth row, last column revised (3) In seventeenth row, first column revised (4) Note (4) revised (5) Note (8) added
241	Figure MJ-8.4-4	General Note revised
242	Table MJ-8.5-1	(1) In fourth row, second and fourth columns revised (2) Note (9) revised
246	MJ-11	Revised
247	SF-2.3	Revised in its entirety
247	SF-2.4	Revised in its entirety
248	Table SF-2.2-1	(1) In first column, first two entries revised (2) Last row revised
249	Table SF-2.2-2	Revised
249	Table SF-2.4.1-1	Former Table SF-2.4-1 revised and redesignated
250	Table SF-2.6-1	In second column, second entry revised
250	SF-3.3	First paragraph and subparas. (a) and (a)(2) revised
252	CR-2	Revised in its entirety
254	Mandatory Appendix I	Information relocated to the Correspondence With the BPE Committee page in the front matter

256	Mandatory Appendix III	Added
260	Mandatory Appendix IV	Added
264	Form MEL-1	Fourth column head revised
268	D-3	Revised
268	D-4.1	Third paragraph revised
269	D-4.4	First sentence of second paragraph revised
270	Table D-2-1	In second column, first and third entries revised
274	Table D-4.1-1	Under Comments column and in Notes (2) and (4), “product contact surface” revised as “process contact surface”
276	E-1	In first paragraph, UNS Number S31503 revised to read S31600
279	E-5.1	Penultimate paragraph revised
280	Table E-5-1	In second column, first entry revised
288	H-1	Revised
289	Table H-3.3-1	First column entries revised
290	Nonmandatory Appendix J	Former Nonmandatory Appendix I redesignated
293	Nonmandatory Appendix K	(1) Former Nonmandatory Appendix J redesignated (2) In former J-1.1, first paragraph revised (3) Former J-1.2.1 and J-1.2.2 revised in their entirety (4) K-1.2.4 added
303	Nonmandatory Appendix L	Former Nonmandatory Appendix K redesignated
306	Nonmandatory Appendix M	Former Nonmandatory Appendix L redesignated
308	Nonmandatory Appendix N	Former Nonmandatory Appendix M redesignated
309	Nonmandatory Appendix O	(1) Former Nonmandatory Appendix N redesignated (2) In former N-1.1, first sentence revised
310	Nonmandatory Appendix P	Former Nonmandatory Appendix O redesignated
313	Nonmandatory Appendix Q	Former Nonmandatory Appendix P redesignated
315	Nonmandatory Appendix R	Former Nonmandatory Appendix Q redesignated
316	Nonmandatory Appendix S	Former Nonmandatory Appendix R redesignated
318	Nonmandatory Appendix T	Former Nonmandatory Appendix S redesignated
321	Nonmandatory Appendix U	Former Nonmandatory Appendix T redesignated
323	Nonmandatory Appendix W	(1) Redesignated from former Nonmandatory Appendix U (2) In former U-1, title revised (3) In former U-2, subpara. (a) and third paragraph of subpara. (b) revised (4) In former U-3, second paragraph revised (5) In former U-7, first sentence revised (6) In former U-8, first sentence of second paragraph revised
326	Nonmandatory Appendix Y	Former Nonmandatory Appendix V redesignated and third paragraph revised
327	Nonmandatory Appendix Z	Added
331	Nonmandatory Appendix AA	Added
334	Nonmandatory Appendix BB	Added
336	Nonmandatory Appendix CC	Added
339	Nonmandatory Appendix DD	Added
341	Index	Added

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CHAPTER 1
INTRODUCTION, SCOPE, AND DEFINITIONS

PART GR
GENERAL REQUIREMENTS

(19) 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 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.

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 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 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.

For a system or component to be BPE-compliant, adherence to all applicable parts of this Standard is required.