

**ASME BPE-2014**  
**(Revision of ASME BPE-2012)**

# Bioprocessing Equipment

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**AN INTERNATIONAL STANDARD**



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Mechanical Engineers**

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**The American Society of  
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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 AAA 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) Dimensions and Tolerances for Process Components
- (4) Materials Joining
- (5) Product Contact Surface Finishes
- (6) Sealing Components
- (7) Polymeric and Other Nonmetallic Materials
- (8) Certification
- (9) Metallic Materials of Construction
- (10) Process Instrumentation



The first edition of this Standard was approved as an American National Standard on May 20, 1997. This edition was approved by ANSI on May 30, 2014.

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-2014 SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2014 was approved by the American National Standards Institute on May 30, 2014.

ASME BPE-2014 includes editorial changes, revisions, and corrections introduced in ASME BPE-2012, as well as the following changes identified by a margin note, (14).

<i>Page</i>	<i>Location</i>	<i>Change</i>
1	GR-1	First paragraph revised
	GR-2	First paragraph and subpara. (f) revised
2	GR-4.1	Subparagraph (a) revised
3, 4	Table GR-4.2-1	Welder and/or Welding Operator title and entry revised
5	GR-4.2.3	Subparagraph (d) revised
	GR-4.3.1	Revised
6–16	GR-5	Revised in its entirety
	GR-6	Revised
	GR-7	Revised
	GR-8	(1) Definitions of <i>biopharmaceuticals</i> , <i>bioprocessing</i> , <i>buffing</i> , <i>heat-affected zone</i> , <i>hygienic clamp joint</i> , <i>hygienic joint</i> , and <i>product contact surface</i> revised (2) Definitions of <i>bioprocess</i> , <i>expiration date</i> , <i>luster</i> , <i>material manufacturer</i> , <i>material test report</i> , <i>mechanical polishing</i> , <i>process contact surface</i> , <i>shelf life</i> , <i>significant change (polymeric)</i> , and <i>variance in luster</i> added (3) Definition of <i>star burst</i> deleted
17	SD-1	Revised
	SD-2	Revised
	SD-2.1	Revised
	SD-2.3.1.1	Second paragraph revised
	SD-2.4	First and third paragraphs revised
18	SD-2.4.2	Revised in its entirety
19, 20, 26	SD-2.4.3.2	Subparagraph (a) revised
	SD-2.4.3.3	Revised
	SD-2.4.4.3	Revised
	SD-3.1.1	(1) Subparagraphs (c), (e), and (h) revised (2) Subparagraph (i) added
	SD-3.1.2.3	First word in subpara. (i) revised



<i>Page</i>	<i>Location</i>	<i>Change</i>
21	Fig. SD-3.1.1-1	Revised
25	Fig. SD-3.1.2.2-1	(1) Notes added (2012 Errata) (2) Revised
27	SD-3.2.1	Subparagraphs (a) and (b) revised
	SD-3.2.2	Subparagraphs (a) and (b) revised
	SD-3.3.2.1	Second word in subpara. (b) revised
28	Fig. SD-3.2.1-1	Revised
	SD-3.3.2.4	Second word in subpara. (e) revised
29	Fig. SD-3.3.2.2-2	Revised
30	Fig. SD-3.3.2.2-4	Revised
31	Fig. SD-3.3.2.4-1	Revised
	SD-3.4.1	Subparagraph (d) revised
32	Fig. SD-3.4.2-1	Revised
33	Fig. SD-3.4.2-2	Revised
	Fig. SD-3.4.2-3	Revised
34	Fig. SD-3.4.2-4	Revised
35	Fig. SD-3.4.2-5	Revised
37	Fig. SD-3.4.2-7	Revised
	SD-3.4.5	First word in subpara. (b) revised
38	Fig. SD-3.4.3-1	Revised
39	SD-3.5.1	Subparagraphs (a), (b), (f)(3), and (h) revised
40	Fig. SD-3.5.1-1	Revised
41	Fig. SD-3.5.2-1	Revised
42	Fig. SD-3.5.2-2	Revised
43, 45, 47	Fig. SD-3.5.2-3	Revised
	SD-3.6.1	Subparagraphs (b), (c)(1), (g)(1), (h)(2), and (h)(3) revised
	Fig. SD-3.5.5-2	Revised
	SD-3.6.2	Second word in subpara. (a) revised
	SD-3.7.1	Subparagraph (a) revised
49	Fig. SD-3.7.2-1	Revised
50	Fig. SD-3.7.4-1	Revised
51	SD-3.8	Added
53, 55	SD-3.9.2	First word in subpara. (j) revised
54	Fig. SD-3.9.1-2	Revised
56	Fig. SD-3.9.2.1-1	Revised



<i>Page</i>	<i>Location</i>	<i>Change</i>
58	Fig. SD-3.12-1	Revised
59	SD-3.13	Revised in its entirety
	SD-3.15	Revised in its entirety
61	Fig. SD-4.1.2.1-1	Revised
62	SD-4.2.3	Subparagraph (b) revised
63	Fig. SD-4.2.2-1	Revised
64	Fig. SD-4.2.2-2	Revised
68	Fig. SD-5.1.1.2.3-1	Revised
69	Fig. SD-5.1.1.2.3-2	Revised
70	Fig. SD-5.1.1.2.3-3	Revised
71	Fig. SD-5.1.1.2.3-4	Revised
74	Fig. SD-5.1.1.3.1-3	Revised
76	SD-5.1.3.2	Title revised
	SD-5.2.1.1	Subhead moved and retitled
	SD-5.2.1.1.2	Subparagraph (a) revised
	SD-5.2.1.2	Redesignated
	SD-5.2.1.3	Redesignated
	SD-5.2.1.4	Redesignated
77	SD-5.2.3.2.1	Revised
78	SD-5.3.2.3.1	Subparagraph (c) revised
82	Fig. SD-5.3.3.5.1-1	Revised
83–89	SD-5.4	Added
	SD-6	SD-6, SD-6.1, SD-6.3, and SD-6.4 revised in their entireties
90	DT-4	Revised
	DT-4.1.4	Revised
	DT-4.3	Revised
91, 92	DT-7	Third paragraph revised
	DT-9.1	Revised
	DT-10.1	(1) Subparagraph (e) revised (2) Subparagraphs (f)(1) and (f)(2) added
	DT-11.1	(1) First paragraph and subparas. (a) and (e) revised (2) Subparagraphs (d)(1) and (d)(2) added
	DT-11.2	(1) First paragraph and subpara. (f) revised (2) Subparagraphs (e)(1) and (e)(2) added
93	DT-11.3	Added



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96	Table DT-3-1	General Note (c) revised
108	Table DT-4.1.3-1	(1) Designation revised (2) Table DT-4.1.3-1(a) deleted
109	Table DT-4.1.3-2	(1) Designation revised (2) Table DT-4.1.3-2(a) deleted
110	Table DT-4.1.3-3	(1) Designation revised (2) Table DT-4.1.3-3(a) deleted
112	Table DT-4.1.5-2	Revised in its entirety
114, 115	Table DT-7-1	(1) In Groove Detail for Type A, second arrowhead for R4 callout added (2012 Errata) (2) Under Type B, Nominal Size, in., first entry corrected to read "1" (2012 Errata) (3) Also under Type B, for Nominal Size 6, I.D. Bore, B, in., value for Dimension corrected to read 5.782 (2012 Errata)
117	Table DT-9.3-1	With callout at top center of right illustration, "Clearance per DT-9.4(e)," arrow placement corrected (2012 Errata)
118–139	Part MJ	Revised in its entirety
140–144	Part SF	Revised in its entirety
149, 155	SG-2.3.1.2	Subparagraphs (a) and (b) revised
	SG-2.3.1.9	Revised in its entirety
154	Fig. SG-2.3.1.9-1	Revised
155, 156	SG-2.3.2.3	Subparagraph (b)(1) revised
157–159	SG-2.3.2.4	New subparagraphs (c) and (j) added, and subsequent subparagraphs redesignated
	Fig. SG-2.3.2.4-3	Added, and subsequent SG-2.3.2.4 figures redesignated
160	Fig. SG-2.3.2.4-13	Added, and subsequent SG-2.3.2.4 figures redesignated
	Fig. SG-2.3.2.4-14	Added, and subsequent SG-2.3.2.4 figures redesignated
161	SG-3.2.1	Subparagraph (a) revised
	SG-3.2.2	First paragraph revised
162–165	SG-3.3.2.1	Subparagraph (b) revised
	SG-3.3.2.2	Revised in its entirety
	SG-3.3.2.3	Subparagraphs (a)(3), (a)(4), (c)(1)(-a)(-1), and (e) revised
168	SG-4.3.1.1	Added



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170	PM-2.1.2	Third paragraph revised
171	Table PM-2.1.1-1	Third entry in third column revised
	PM-2.2	Second paragraph revised
172	Table PM-2.1.3-1	Fourth entry in third column added
	PM-3.1	Second paragraph revised
173	Table PM-2.2.1-1	(1) Title and fourth entries in eighth and ninth columns revised (2) Eleventh column added
	PM-3.2.1	Revised
	PM-3.2.3.1	First and fourth paragraphs revised
	PM-3.2.3.2	Fourth paragraph revised
174, 175	PM-3.2.4.4	Added
	PM-3.7	Added
	PM-3.8	Added, and subsequent paragraph redesignated
	PM-4.1.2	Revised
	PM-4.1.4	First paragraph revised
176	PM-4.1.5.1	Revised in its entirety
	PM-4.1.6	Added
	PM-4.2.3	Definition of $\Delta T$ under first equation revised
178	PM-4.2.5	Paragraphs PM-4.2.6 through PM-4.2.9 deleted
	PM-4.3.2.5	Subparagraph (c) revised
179–181	PM-4.4	Added
	PM-4.6	Added
	PM-4.7	Added
182–186	Part CR	Revised in its entirety
187	MM-2.1	Revised
	MM-3.3	Second paragraph added
	MM-3.6	Revised
188	Table MM-2.1-1	Revised in its entirety
190, 191	Table MM-2.1-3	(1) Fifth row under Austenitic Stainless Steels deleted (2) First row under Superaustenitic Stainless Steels added
	Table MM-2.1-4	Added
	MM-4.2	Revised

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192, 193	MM-4.7	Added
	MM-5.1.1	Revised
	MM-5.1.2	Revised
	MM-5.1.4	Revised
	MM-5.1.5	Revised
	MM-5.1.6	Added
194, 195	Table MM-5.1.2-1	Revised in its entirety
196	Table MM-5.1.2-2	(1) First six rows under Superaustenitic Stainless Steels revised (2) General Note (b) deleted (3) Note (1) added
	Table MM-5.1.5-1	Added
197	Table MM-5.2.5-1	Added
	MM-5.2.5	Added
	MM-5.3	Revised
	MM-5.4	Revised
	MM-6.2	Revised
	MM-6.3	Title revised
	MM-6.4	Revised
198	MM-6.5	Revised
	MM-8	(1) Title and subparas. (a), (b), and (d) revised (2) Subparagraph (c) deleted, and remaining subparagraphs redesignated
202	PI-4.1.2	Second paragraph revised
204–211	PI-5	Added
	PI-7	Added
214	PI-8.1.5	Subparagraph (c) revised
219	PI-9.1.3.2	First word revised
225	Mandatory Appendix II	Added
227–230	Nonmandatory Appendix B	Revised in its entirety
232	D-1	Revised in its entirety
234	Table D-2-1	Electropolishing entry revised
235	Table D-2-2	Gaseous phase composition entry revised
239, 240	Table D-4.1-1	Revised in its entirety
241–250	Nonmandatory Appendix E	Revised in its entirety
261–267	J-1	Revised in its entirety
272	Table K-3-1	Fourth entries in first and second columns and eighth entry in second column revised



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277	Nonmandatory Appendix N	N-1 head and section N-2 added
278	Nonmandatory Appendix O	(1) Title revised (2) O-1 head and sections O-2 and O-3 added
279, 280	Nonmandatory Appendix P	Revised in its entirety
285	Nonmandatory Appendix S	Added
286, 287	Nonmandatory Appendix T	Added
289–301	Index	Updated



# BIOPROCESSING EQUIPMENT

## Part GR General Requirements

### (14) 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

(14)

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. It is not intended to apply to existing, in-service equipment. 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, 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.

### GR-3 MANUFACTURER'S QUALITY ASSURANCE PROGRAM

The manufacturer shall implement a quality assurance program describing the systems, methods, and procedures used to control materials, drawings, specifications,