ASME BPE-2009

(Revision of ASME BPE-2007)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD

The American Society of Mechanical Engineers

ASME SETTING THE STANDARD

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Date of Issuance: October 20, 2009

The next edition of this Standard is scheduled for publication in 2012. There will be no addenda issued to this edition.

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 Code Cases. Code Cases and interpretations are published on the ASME Web site under the Committee Pages at http://cstools.asme.org as they are issued.

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 subcommittees are

(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 includes the following Parts:

(1) General Requirements
(2) Design for Sterility and Cleanability
(3) Dimensions and Tolerances for Stainless Steel Automatic Welding and Hygienic Clamp Tube Fittings
(4) Material Joining
(5) Stainless Steel and Higher Alloy Product Contact Surface Finishes
(6) Equipment Seals
(7) Polymer-Based Materials
(8) Certification
(9) Metallic Materials of Construction

The first edition of this Standard was approved as an American National Standard on December 22, 2005. The second edition was approved by ANSI on October 9, 2007. This edition was approved by ANSI on August 31, 2009.

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

STATEMENT OF POLICY ON THE USE OF ASME MARKS AND CODE AUTHORIZATION IN ADVERTISING

ASME has established procedures to authorize qualified organizations to perform various activities in accordance with the requirements of the ASME codes and standards. It is the aim of the Society to provide recognition of organizations so authorized. An organization holding authorization to perform various activities in accordance with the requirements of the codes and standards may state this capability in its advertising literature.

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ASME's role as an accrediting rather than certifying organization shall be made clear on stampings, labels, or nameplate markings by inclusion of the words: Certified by _____.
(Fabricator)

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ASME BPE-2009
SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2009 was approved by the American National Standards Institute on August 31, 2009.

ASME BPE-2009 includes editorial changes, revisions, and corrections introduced in ASME BPE-2007, as well as the following changes identified by a margin note, **(09)**.

Page	*Location*	*Change*
1–6	GR-1(b)	Revised
	GR-4	Revised in its entirety
	GR-9	Revised
	Table GR-1	Added
7–13	GR-10	Revised
14	SD-2	Revised
	SD-3	Revised
	SD-3.1.7	Revised
	SD-3.1.8	Revised
15	SD-3.2	Revised in its entirety
	SD-3.4	Subparagraphs SD-3.4.1 through SD-3.4.3 revised
	SD-3.5.2	Second paragraph revised
	SD-3.6.1	Last paragraph revised
16	SD-3.6.4	Revised
	SD-3.7.8	Revised
	SD-3.7.9	Revised
	SD-3.7.10	Added
	SD-3.7.11	Added
17	SD-3.8(m)	Revised
	SD-3.10	Revised in its entirety
	SD-3.11.1	First paragraph revised
	SD-3.11.6	Revised
18	SD-3.12.1	First paragraph revised
	SD-4.1.1(d)	Revised
19	SD-4.1.2	Revised in its entirety
	SD-4.1.3(b)	Revised

Page	*Location*	*Change*
	SD-4.1.4(a)(4)	Revised
	SD-4.2.1(d)	Revised
	SD-4.2.2(c)	Revised
20	SD-4.3.1	Subparagraphs (a) through (d) and (g) revised
	SD-4.3.2	Subparagraphs (a) and (b) revised
	SD-4.4	Subparagraphs (a), (c), and (d) revised
	SD-4.5	Revised in its entirety
21	SD-4.6	Title revised
	SD-4.6.1(b)	Revised
	SD-4.6.4	Added
22	SD-4.7.1(h)	Revised
	SD-4.7.2	(1) Subparagraphs (b), (d), (h), (j), and (m) revised (2) Subparagraph (q) deleted (3) Fig. SD-14-1 deleted (4) Subparagraphs (r) through (t) redesignated as (q) through (s) (5) New subparagraph (r) revised
	SD-4.7.3(c)	Revised
	SD-4.7.4(c)	Revised
23	SD-4.8.1(f)	Revised in its entirety
25	SD-4.9.1	Subparagraphs (c), (c)(2), (g)(2), (g)(3), and (i) revised
	SD-4.9.2	Revised in its entirety
26	SD-4.11.1(e)	Revised
	SD-4.11.3(c)	Revised
	SD-4.11.4(a)	Revised
27–32	SD-4.14	Revised in its entirety
	SD-4.15	Revised in its entirety
	SD-4.16.1(b)	Revised
	SD-4.16.2	Subparagraphs (b) and (d) revised
33–36	SD-4.16.6	Subparagraphs (b) through (d) revised
	SD-4.17	Added
	SD-4.18	Added
37	SD-5.2	Revised in its entirety
	SD-6	Third paragraph revised
39	Fig. SD-1	Revised in its entirety
40	Fig. SD-2	Illustration (f) revised
45	Fig. SD-7-1	Fig. SD-7 redesignated as Fig. SD-7-1

Page	*Location*	*Change*
	Fig. SD-7-2	Added
46	Fig. SD-7-3	Added
	Fig. SD-7-4	Added
47	Fig. SD-7-5	Added
52	Fig. SD-14	Fig. SD-14-2 redesignated as Fig. SD-14
53	Fig. SD-15	Illustration (c) added
66	Fig. SD-23-1	Fig. SD-23 redesignated as Fig. SD-23-1
67	Fig. SD-23-2	Fig. SD-23-1 redesignated as Fig. SD-23-2
	Fig. SD-23-3	Added
68	Fig. SD-23-4	Added
	Fig. SD-23-5	Added
69	Fig. SD-23-6	Added
73	Fig. SD-27-1	Added
74	Fig. SD-27-2	Added
	Fig. SD-28-1	Added
75	Fig. SD-28-2	Added
76	Fig. SD-28-3	Added
	Fig. SD-28-4	Added
77	Fig. SD-29-1	Added
	Fig. SD-29-2	Added
	Fig. SD-30	Added
80	Table SD-5	Added
81	Table SD-6	Added
82, 83	DT-1	Third paragraph moved to DT-6
	DT-6	(1) First paragraph revised (2) Last paragraph added
	DT-8	First and third paragraphs revised
	DT-10	Revised in its entirety
85	DT-V-4	Second paragraph revised
	DT-V-8	Revised
86	Fig. DT-1	Added
87	Table DT-2	Title and General Notes revised
88	Table DT-4	General Note revised
89	Table DT-5-1	(1) Table DT-5 redesignated as Table DT-5-1 (2) Last two columns added (3) General Note revised
90, 91	Table DT-5-2	(1) Table DT-5-1 redesignated as Table DT-5-2

Page	*Location*	*Change*
		(2) Revised in its entirety
92	Table DT-5-3	Added
93	Table DT-8	Callout added to illustration
95	Table DT-11	Twelve rows deleted
96	Table DT-13	Callout added to illustration
98	Table DT-17	Callout added to illustration
101	Table DT-21	Nine rows deleted
104	Table DT-26	Nine rows deleted
105	Table DT-30	(1) Illustration revised (2) General Note added (3) Note (1) deleted
106	Table DT-31	Added
108	MJ-2	(1) Subparagraphs MJ-2.3 through MJ-2.6 redesignated as MJ-2.4 through MJ-2.7, respectively (2) New subparagraph MJ-2.3 added
110	MJ-6.4.1	Revised
112	Table MJ-2	In fourth column, last entry revised
116	MJ-7.2.3	Last paragraph revised
117, 118	MJ-8.4	Added
	Table MJ-5	Added
	Table MJ-6	Added
	MJ-9.2	Revised
	MJ-9.3	Revised in its entirety
120	SF-5	Subparagraphs (c) and (d) revised
121	Table SF-1	Title and General Note (b) revised
123–125	Table SF-4	Added
	SF-7	Revised
	SF-8	Revised
	SF-9	Added
	SF-10	Added
	Subsection SF-P	Added
127	SG-3.1.6	Revised
	SG-3.1.8	Added
128	SG-3.4.1	Revised
	SG-3.4.2	(1) Subparagraphs (e) and (h) revised (2) Penultimate paragraph revised
132	SG-4.2	Added
	SG-4.3	Added
142	Fig. SG-18	Added
150	PM-4	Revised
151–154	PM-6	Added
	PM-7	Added
	Table PM-2	Added
	PM-8	Added
155–158	Part CR	Added
159–167	Part MMOC	Added
176–184	Nonmandatory Appendix D	Added
185–194	Nonmandatory Appendix E	Added
195–197	Nonmandatory Appendix F	Added
198	Nonmandatory Appendix G	Added
199, 200	Nonmandatory Appendix H	Added
201–204	Nonmandatory Appendix I	Added
205–208	Nonmandatory Appendix J	Added
209, 210	Nonmandatory Appendix K	Added
211–213	Index	Updated

BIOPROCESSING EQUIPMENT

Part GR
General Requirements

GR-1 INTRODUCTION

This Standard provides the requirements applicable to the design of equipment used in the bioprocessing, pharmaceutical, and personal care product industries, including aspects related to sterility and cleanability, materials, dimensions and tolerances, surface finish, material joining, and seals. These apply to

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

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

This Standard applies to new construction only. It is not intended to apply to the operation, examination, inspection, testing, maintenance, or repair of piping/tubing, or equipment that has been placed in service. The provisions of this Standard may be optionally applied for those purposes, although other considerations may be necessary. For installations between new construction that ties into an existing system that has been placed in service, the boundaries and requirements must be agreed to between the owner/user and contractor and inspection contractor.

This Standard does not apply to those components of the system that are not in contact with the finished product or are a part of the intermediate manufacturing stages (e.g., computer systems, electrical conduits, and external system support structures).

Steam sterilized systems normally meet pressure vessel design codes. Other equipment or systems as agreed to by the manufacturer and owner/user may not require adherence to these codes.

When operating under pressure conditions, the systems shall be constructed in accordance with the ASME Boiler and Pressure Vessel Code (BPVC), Section VIII, Division 1, and the ASME B31.3, Process Piping Code, respectively. The owner/user can stipulate additional specifications and requirements. 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. However, all the previously mentioned construction codes shall be satisfied including those instances where these codes are not referred to in the current BPE Standard (e.g., weld acceptance criteria, inspection requirements, pressure testing, etc.).

GR-2 SCOPE

This Standard deals with the requirements of the bioprocessing, pharmaceutical, and personal care product industries as well as other applications with relatively high levels of hygienic requirements, covering directly or indirectly the subjects of materials, design, fabrication, pressure systems (vessels and piping), examinations, inspections, testing, and certifications. Items or requirements that are not specifically addressed in this Standard cannot be considered prohibited. Engineering judgments must be consistent with the fundamental principles of this Standard. Such judgments shall not be used to overrride mandatory regulations or specific prohibitions of this Standard.

GR-3 INSPECTION

The inspection requirements are specified in each Part of this Standard. If an inspection or examination plan is required, it shall be developed and agreed to by the owner/user, contractor, inspection contractor, and/or engineer ensuring that the systems and components meet this Standard.

GR-4 INSPECTOR/EXAMINER (09)

Inspector and examiner in this Standard shall be defined for the following:

(a) Pressure Vessels. Authorized Inspector, as defined in ASME BPVC, Section VIII, Division 1, para. UG-91.

(b) Piping, Tubing, and Non-Code Vessels. Owner's inspector, as defined in ASME B31.3, paras. 340.4(a) and (b). Inspector's Delegate, as defined in GR-10, meets the additional requirements listed in GR-4.1.