ASME BPE-2007

(Revision of ASME BPE-2005)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD

The American Society of Mechanical Engineers

ASME BPE-2007
(Revision of ASME BPE-2005)

Bioprocessing Equipment

AN AMERICAN NATIONAL STANDARD

The American Society of Mechanical Engineers
Three Park Avenue • New York, NY 10016

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The next edition of this Standard is scheduled for publication in 2009. There will be no addenda issued to this edition.

ASME issues written replies to inquiries concerning interpretations of technical aspects of this Standard. Interpretations are published on the ASME website under the Committee Pages at http://www.cstools.asme.org as they are issued.

The American Society of Mechanical Engineers
Three 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; and

(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; and

(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 Interior Surface Finishes;

(6) Equipment Seals; and

(7) Polymer-Based Materials.

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.

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.

Organizations that are authorized to use Symbol Stamps for marking items or constructions that have been constructed and inspected in compliance with ASME codes and standards are issued Certificates. It is the aim of the Society to maintain the standing of the Symbol Stamps for the benefit of the users, the enforcement jurisdictions, and the holders of the Stamps who comply with all requirements.

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The ASME logo, which is the cloverleaf with the letters ASME within, shall not be used by any organization other than ASME.

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The ASME codes and standards provide rules for the construction of various items. These include requirements for materials, design, fabrication, examination, inspection, and stamping. Items constructed in accordance with all of the applicable rules of ASME are identified with the official Symbol Stamp described in the governing code or standard.

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Items shall not be described on ASME Data Report Forms nor on similar forms referring to ASME which tend to imply that all requirements have been met when in fact they have not been met. Data Report Forms covering items not fully complying with ASME requirements shall not refer to ASME or they shall clearly identify all exceptions to the ASME requirements.

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 _____.
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(The following is the roster of the Committee at the time of approval of this Standard.)

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ASME BPE-2007
SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2007 was approved by the American National Standards Institute on October 9, 2007.

ASME BPE-2007 includes editorial changes, revisions, and corrections introduced in ASME BPE-2005, as well as the following changes identified by a margin note, **(07)**.

Page	*Location*	*Change*
2, 3	GR-9	References updated
11	Fig. SD-1	Illustration (e) title revised
15, 17, 19, 20	SD-3.11	(1) SD-3.11.2 deleted by errata and SD-3.11.3 through SD-3.11.19 redesignated as SD-3.11.2 through SD-3.11.18, respectively (2) Second sentence of newly redesignated SD-3.11.11 deleted
	SD-3.12.1	Revised in its entirety
	SD-3.12.3	Revised
	SD-3.12.5	Revised
	Table SD-3	Added
21	SD-4.3.2	Title revised
24, 26	SD-4.7.2(c)	Figure reference added
	SD-4.7.2(q)	Figure reference added
	SD-4.7.2(s)	Figure reference added
	Table SD-4	Redesignated from Table SD-3
28	Fig. SD-13	Vertical rule at left realigned
29–47	SD-4.7.5(b)	Revised
	Fig. SD-14	Redesignated as Fig. SD-14-2
	Fig. SD-15	Redesignated as Fig. SD-14-1 and new Fig. SD-15 added
	SD-4.8	Revised in its entirety
	Figs. SD-21 through SD-21-6	(1) Figure SD-21 deleted (2) Figures SD-21-1 through SD-21-6 added
	SD-4.11	Revised in its entirety
	Figs. SD-22 through SD-22-3	(1) Figure SD-22 deleted (2) Figures SD-22-1 through SD-22-3 added

Page	*Location*	*Change*
	Figure SD-23-1	Added
49, 50	Tables SD-5 through SD-7	Redesignated from Tables SD-4 through SD-6, respectively
56	DT-2	Second paragraph revised
	DT-3.1(e)	Revised
	DT-3.2(a)	Second sentence revised
	DT-5	(1) In first sentence of first paragraph, "must" replaced with "shall, and second Table reference revised (2) In second paragraph, new last sentence added
57	DT-8	First paragraph revised
	DT-12	Revised in its entirety
58, 59	DT-V-2	Second paragraph revised
	DT-V-3.1(f)	Revised
	DT-V-3.2(a)	In second sentence, "must" replaced with "shall"
	DT-V-5	(1) In first paragraph, first sentence revised (2) In second paragraph, last sentence added
	DT-V-6	Last paragraph added
	DT-V-8	In first paragraph, second table reference revised
	DT-V-9	Second sentence added
	DT-V-10	Revised
	DT-V-11	Revised
60	Table DT-4	General Note revised
72	Table DT-23	General Note added
75	Table DT-V-1	Added
77, 78	MJ-3.3	Revised
	MJ-4.5	Added
	MJ-5	Second paragraph revised
	MJ-6.4.1	Redesignated as MJ-6.4.2
	MJ-6.4.2	Redesignated as MJ-6.4.1
	MJ-6.5	Added
80, 81, 83	MJ-7.2.4	Added
	Table MJ-3	For Discoloration (weld bead), Product Contact Surfaces column revised
	Table MJ-4	Added
84	MJ-8.1	Revised

Page	*Location*	*Change*
	MJ-8.2	Revised
	MJ-8.3	Revised in its entirety
	MJ-9.1	Revised
	MJ-9.2	Revised
	MJ-9.3	Revised
	MJ-10.1	(1) Subparagraph (b)(5) revised (2) Subparagraphs (b)(7) and (b)(8) added
86	SF-1	First sentence revised
	SF-3	Revised in its entirety
	SF-4	Revised in its entirety
	SF-5	Added
	SF-6	Added
87	Table SF-1	Revised in its entirety
	SF-7	Revised
	SF-8	Revised
88	Table SF-2	Revised in its entirety
	Table SF-3	Revised in its entirety
	Tables SF-4 through SF-10	Deleted
89	SG-2.4	In first paragraph, first sentence revised
	SG-2.4.1	Added
91, 92	SG-3.3.1(d)(4)	Revised
	SG-3.4.2	(1) New subparas. (e) and (g) added, and remainder of subparagraphs redesignated accordingly (2) New second paragraph added (3) Last paragraph revised
	SG-3.4.3	Last sentence added
102	Fig. SG-17	Revised
104	PM-2.6.1	Added
117	Nonmandatory Appendix C	Added
118, 119	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

(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 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

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

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

(b) Piping, Tubing, and Non-Code Vessels. An owner/user's inspector, as defined in ASME B31.3, para. 340.4(a)

(c) Piping and Tubing. An examiner, defined as a person who performs quality control examinations for a manufacturer as an employee of the manufacturer as defined in ASME B31.3, para. 341.1.

When local regulations require that pressure equipment be designed and constructed in accordance with standards other than ASME codes/standards, the inspector in this Standard is defined as one who is acceptable to the relevant regulatory authority.

GR-5 RESPONSIBILITIES

The responsibilities of inspection personnel are defined as follows.