ASME BPE-2012

(Revision of ASME BPE-2009)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD

The American Society of Mechanical Engineers

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Bioprocessing Equipment

AN INTERNATIONAL STANDARD

The American Society of Mechanical Engineers

Three Park Avenue • New York, NY • 10016 USA

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The next edition of this Standard is scheduled for publication in 2014. 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.

Errata to codes and standards may be posted on the ASME Web site 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.

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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

(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) Material 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 July 30, 2012.

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 CERTIFICATION 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 the Certification Mark for marking items or constructions that have been constructed and inspected in compliance with ASME Codes and Standards are issued Certificates of Authorization. It is the aim of the Society to maintain the standing of the Certification Mark for the benefit of the users, the enforcement jurisdictions, and the holders of the Certification Mark who comply with all requirements.

Based on these objectives, the following policy has been established on the usage in advertising of facsimiles of the symbols, Certificates of Authorization, and references to Codes or Standards construction. The American Society of Mechanical Engineers does not "approve," "certify," "rate," or "endorse" any item, construction, or activity and there shall be no statements or implications that might so indicate. An organization holding a Certification Mark and/or a Certificate of Authorization may state in advertising literature that items, constructions, or activities "are built (produced or performed) or activities conducted in accordance with the requirements of the applicable ASME Code or Standard." An ASME corporate logo shall not be used by any organization other than ASME.

The Certification Mark shall be used only for stamping and nameplates as specifically provided in the Code or Standard. However, facsimiles may be used for the purpose of fostering the use of such construction. Such usage may be by an association or a society, or by a holder of a Certification Mark who may also use the facsimile in advertising to show that clearly specified items will carry the Certification Mark. General usage is permitted only when all of a manufacturer's items are constructed under the rules of the applicable Code or Standard.

STATEMENT OF POLICY ON THE USE OF ASME MARKING TO IDENTIFY MANUFACTURED ITEMS

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 Certification Mark 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. Data Report Forms covering items not fully complying with ASME requirements should not refer to ASME or they should clearly identify all exceptions to the ASME requirements.

ASME's certification related to products means that the capability by the supplier to fulfill requirements in the applicable standard has been reviewed and accepted by ASME. The supplier is responsible for ensuring that products meet, and if applicable continue to meet, the requirements.

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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-2012
SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2012 was approved by the American National Standards Institute on July 30, 2012.

ASME BPE-2012 includes editorial changes, revisions, and corrections introduced in ASME BPE-2009 and a Supplement printed in June 2011, as well as the following changes identified by a margin note, **(12)**.

Page	*Location*	*Change*
1–16	Part GR	Revised in its entirety
17–19	Part SD	Title revised
	SD-1	Revised
	SD-2	Redesignated from previous SD-3 and revised
20–80	SD-3	(1) Revised in its entirety (2) All figure and table designators from previous edition renumbered in accordance with newly revised paragraph references
	SD-4	(1) Revised in its entirety (2) All figure and table designators from previous edition renumbered in accordance with newly revised paragraph references
	SD-5	(1) Revised in its entirety (2) All figure and table designators from previous edition renumbered in accordance with newly revised paragraph references
	SD-6	Revised
81–109	Part DT	Revised in its entirety
110, 111	MJ-2	Revised in its entirety
	MJ-3	Redesignated from previous MJ-4 and revised
	MJ-4	Redesignated from previous MJ-3 and revised
112–114	MJ-5	Redesignated from previous MJ-8 and revised
	MJ-6	Redesignated from previous MJ-9 and revised
	MJ-7	Revised
	MJ-8	Redesignated from previous MJ-6 and revised

Page	*Location*	*Change*
	MJ-9	Redesignated from previous MJ-10 and revised
	MJ-10	Redesignated from previous MJ-11 and revised
120	Fig. MJ-8.4-2	Added
121	Fig. MJ-8.4-3	Added
123–127	Part SF	(1) Title revised (2) Revised in its entirety
128–152	Part SG	(1) Title revised (2) Revised in its entirety
153–165	Part PM	(1) Title revised (2) Revised in its entirety
166	Fig. CR-2.3.1-1	Added
167, 168	Fig. CR-2.3.2-1	Redesignated and revised
	CR-2.3.3	Revised
	CR-2.3.4.1	Added
169	CR-3.2.1	Revised
	CR-3.2.2	Revised
170	CR-3.2.4	Added
	CR-3.2.5	Added
	CR-3.2.6	Added
	CR-3.2.7	Added
172–181	Part MM	(1) Redesignated from Part MMOC and title revised (2) Revised in its entirety
	Table MM-2.1-1	UNS Number N08904 added
	Table MM-2.1-2	Revised in its entirety
	Table MM-2.1-3	Revised in its entirety
	Table MM-5.1.2-1	Revised in its entirety
	Table MM-5.1.2-2	Revised in its entirety
182–197	Part PI	Added
199, 200	Mandatory Appendix I	Added
236	Nonmandatory Appendix J	Revised
241–243	Nonmandatory Appendix K	Added
244, 245	Nonmandatory Appendix L	Added
246	Nonmandatory Appendix M	Added
247	Nonmandatory Appendix N	Added
248	Nonmandatory Appendix O	Added
249–255	Nonmandatory Appendix P	Added

Page	*Location*	*Change*
256	Nonmandatory Appendix Q	Added
257–259	Nonmandatory Appendix R	(1) Added (2) Form J-1 redesignated as Form R-1
260–270	Index	Updated

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BIOPROCESSING EQUIPMENT

Part GR
General Requirements

(12)

GR-1 INTRODUCTION

The ASME Bioprocessing Equipment Standard was developed to aid in the design and construction of new fluid processing equipment used in industries that require a defined level of purity and bioburden control.

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

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. This Standard also provides requirements for single use systems and components.

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) material 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, fabrication, assembly techniques, and examination/inspection used in the manufacturing of bioprocessing equipment.