ASME BPE-2014

(Revision of ASME BPE-2012)

# 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

Two Park Avenue • New York, NY • 10016 USA

Date of Issuance: October 10, 2014

The next edition of this Standard is scheduled for publication in 2016. 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 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.

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 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 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 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)**.

| *Page* | *Location* | *Change* |
|---|---|---|
| 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 *biopharmaceuticals*, *bioprocessing*, *buffing*, *heat-affected zone*, *hygienic clamp joint*, *hygienic joint*, and *product contact surface* revised<br>(2) Definitions of *bioprocess*, *expiration date*, *luster*, *material manufacturer*, *material test report*, *mechanical polishing*, *process contact surface*, *shelf life*, *significant change (polymeric)*, and *variance in luster* added<br>(3) Definition of *star burst* 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<br>(2) Subparagraph (i) added |
| | SD-3.1.2.3 | First word in subpara. (i) revised |

| *Page* | *Location* | *Change* |
|---|---|---|
| 21 | Fig. SD-3.1.1-1 | Revised |
| 25 | Fig. SD-3.1.2.2-1 | (1) Notes added (2012 Errata)<br>(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 |

| *Page* | *Location* | *Change* |
|---|---|---|
| 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<br>(2) Subparagraphs (f)(1) and (f)(2) added |
| | DT-11.1 | (1) First paragraph and subparas. (a) and (e) revised<br>(2) Subparagraphs (d)(1) and (d)(2) added |
| | DT-11.2 | (1) First paragraph and subpara. (f) revised<br>(2) Subparagraphs (e)(1) and (e)(2) added |
| 93 | DT-11.3 | Added |

| *Page* | *Location* | *Change* |
|---|---|---|
| 96 | Table DT-3-1 | General Note (c) revised |
| 108 | Table DT-4.1.3-1 | (1) Designation revised<br>(2) Table DT-4.1.3-1(a) deleted |
| 109 | Table DT-4.1.3-2 | (1) Designation revised<br>(2) Table DT-4.1.3-2(a) deleted |
| 110 | Table DT-4.1.3-3 | (1) Designation revised<br>(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)<br>(2) Under Type B, Nominal Size, in., first entry corrected to read "1" (2012 Errata)<br>(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 |

| *Page* | *Location* | *Change* |
|---|---|---|
| 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<br>(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<br>(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<br>(2) General Note (b) deleted<br>(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<br>(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<br>(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,