

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

Bioprocessing Equipment

AN INTERNATIONAL STANDARD



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Mechanical Engineers**

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CONTENTS

Foreword	vii
Statements of Policy	viii
Committee Roster	ix
Summary of Changes	xii
Part GR General Requirements	1
GR-1 Introduction	1
GR-2 Scope	1
GR-3 Inspection	1
GR-4 Inspector/Examiner	1
GR-5 Responsibilities	1
GR-6 Access for Inspectors	2
GR-7 Manufacturer's Quality Assurance Program	2
GR-8 Metric	2
GR-9 References	2
GR-10 Terms and Definitions	3
Part SD Design for Sterility and Cleanability	9
SD-1 Introduction	9
SD-2 Scope and Purpose	9
SD-3 General Guidelines	9
SD-4 Specific Guidelines	20
SD-5 Testing and Inspection	54
SD-6 Documentation	55
SD-7 Responsibilities	55
Part DT Dimensions and Tolerances for Stainless Steel Automatic Welding and Hygienic Clamp Tube Fittings and Process Components	56
DT-1 Scope	56
DT-2 Pressure Rating	56
DT-3 Marking	56
DT-4 Materials	56
DT-5 Metal Thickness	56
DT-6 Fitting Dimensions	56
DT-7 Tests	57
DT-8 Tolerances	57
DT-9 Welding Ends	57
DT-10 Hygienic Clamp Ends	57
DT-11 Heat Treatment	57
DT-12 Surface Condition	57
DT-13 Packaging	57
DT-14 Minimum Examination Requirements	57
Part MJ Material Joining	76
MJ-1 Scope	76
MJ-2 Materials	76
MJ-3 Joining Processes and Procedures	76
MJ-4 Weld Joint Design and Preparation	77
MJ-5 Filler Material	77
MJ-6 Weld Acceptance Criteria	78
MJ-7 Inspection, Examination, and Testing	78
MJ-8 Procedure Qualification	84



MJ-9	Performance Qualification	84
MJ-10	Documentation Requirements	84
MJ-11	Passivation	85
Part SF	Stainless Steel and Higher Alloy Product Contact Surface Finishes	86
SF-1	Scope	86
SF-2	Objective	86
SF-3	Applications	86
SF-4	Material	86
SF-5	Inspection and Techniques Employed in the Classification of Product Contact Surface Finishes	86
SF-6	Surface Condition	86
SF-7	Electropolishing Procedure Qualification	87
SF-8	Passivation	87
Part SG	Equipment Seals	89
SG-1	Scope and Purpose	89
SG-2	Seal Classes	89
SG-3	General Provisions for Seals in Bioprocessing Service: User Basic Design Requirement	90
SG-4	Special Provisions for Seals in Bioprocessing Service	99
Part PM	Polymer-Based Materials	103
PM-1	Introduction	103
PM-2	Design Considerations for Polymeric Piping, Tubing, Fittings, Valve Bodies, and Other Components	103
PM-3	Polymer Material Joining	106
PM-4	Polymer Interior Product Contact Surfaces of Piping, Tubing, Fittings, Valve Bodies, and Coated or Lined Vessels	109
PM-5	Materials of Construction	109
Figures		
SD-1	Hygienic Connections	11
SD-2	Nonhygienic Connections	13
SD-3	Flat Gasket Applications	14
SD-4	Recommended and Preferred Drop Designs	18
SD-5	Double Block-and-Bleed Valve Assembly	19
SD-6	Instrument Location Detail: Hygienic Design	20
SD-7	Flexible Hygienic Hose Design	22
SD-8	Tank/Vessel Vent Filters	23
SD-9	Nozzle Design	25
SD-10	Sidewall Instrument Ports	26
SD-11	Dip Tube	27
SD-12	Vessel Design Tangential Nozzles	27
SD-13	Vessel Sight Glass Design	28
SD-14-1	Dip Tube Nozzles: Removable Designs	29
SD-14-2	Side and Bottom Connections	30
SD-15	Agitator Mounting Flanges	31
SD-16	Sight Glass Design	32
SD-17	Internal Support Members	33
SD-18	Mitered Fittings	34
SD-19	Typical Nozzle Detail	34
SD-20	Double Tubesheet Heat Exchanger Bonnet Design	35
SD-21-1	Shaft Coupling Construction	36
SD-21-2	Shaft Coupling Seal Arrangement	37
SD-21-3	Fastener Seal Arrangements	38
SD-21-4	Shaft Steady Bearing	39
SD-21-5	Magnetically-Coupled Mixer (Typical Bottom-Mount)	40
SD-21-6	Double Mechanical Cartridge Seal With Debris Well	42



SD-22-1	Typical Clean Steam System Isometric	43
SD-22-2	Clean Steam Point-of-Use Design	44
SD-22-3	Steam Traps for Clean Steam Systems	45
SD-23	Point-of-Use Piping	46
SD-23-1	Physical Break in Point-of-Use Piping	47
SD-24	Transfer Panel Tolerances	51
SD-25	Transfer Panel Looped Headers	52
SD-26	Transfer Panel Jumpers	53
MJ-1	Acceptable and Unacceptable Weld Profiles for Tube Welds	82
SG-1	Basic Components of a Seal	92
SG-2	Single Dry Running Contacting Seal	93
SG-3	Internally Mounted, Process Lubricated Contact Seal	93
SG-4	Externally Mounted, Process Lubricated Contact Seal	94
SG-5	Double Seal Installation	95
SG-6	Tandem Seal Installation	95
SG-7	Seal Piping and Lubrication Plans	96
SG-8	Gas Lubricated Noncontacting Double Seal	97
SG-9	Tandem Seal With Barrier System	98
SG-10	Typical Packing Installation	98
SG-11	V-Ring Packing for Reciprocating Applications	99
SG-12	Open Cross-Sectional Lip Seal	99
SG-13	Labyrinth Seal	99
SG-14	Typical Angle Valve With Rolling Diaphragm and Orifice	100
SG-15	Example of Sampling Valve With Uniformly Loaded Sliding Seal	101
SG-16	Typical In-Line Diaphragm Valve With Weir	101
SG-17	Typical Ball Valve Configuration	102
PM-1	Acceptable and Unacceptable Weld Profiles for Beadless Welds	108

Tables

SD-1	<i>L/D</i> Dimensions for Flow-Through Tee: Full-Size Standard Straight Tee With Blind Cap	15
SD-2	<i>L/D</i> Dimensions for Flow-Through Tee: Short Outlet Reducing Tee With Blind Cap	16
SD-3	Slope Designations for Gravity-Drained Lines	19
SD-4	Annular Spacing Recommendations for Hygienic Dip Tubes	26
SD-5	Recommended Flow Rates to Achieve 5 fps (1.52 mps)	49
SD-6	Recommended Flow Rates for Cleaning Vertical Cylindrical Vessels Having Dished Heads	49
SD-7	Transfer Panel and Jumper Tolerances	50
DT-1	Nominal O.D. Tubing Sizes	59
DT-2	Hygienic Unions	60
DT-3	Chemical Composition for Automatic Weld Ends, %	60
DT-4	Tangent Lengths	60
DT-5	Final Tolerances for Mechanically Polished Fittings and Process Components	61
DT-5.1	Hygienic Clamp Ferrule Standard Dimensions and Tolerances	62
DT-6	Final Tolerances for Electropolished Fittings and Process Components	63
DT-7	Automatic Tube Weld: 90-deg Elbow	63
DT-8	Automatic Tube Weld: 45-deg Elbow	63
DT-9	Automatic Tube Weld: Straight Tee and Cross	64
DT-10	Automatic Tube Weld: Reducing Tee	64
DT-11	Automatic Tube Weld: Concentric and Eccentric Reducer	65
DT-12	Automatic Tube Weld: Hygienic Clamp Joint, 90-deg Elbow	65
DT-13	Automatic Tube Weld: Hygienic Clamp Joint, 45-deg Elbow	66
DT-14	Automatic Tube Weld: Short Outlet Hygienic Clamp Joint Reducing Tee	66
DT-15	Automatic Tube Weld: Short Outlet Hygienic Clamp Joint Tee	67



DT-16	Hygienic Clamp Joint: 90-deg Elbow	67
DT-17	Hygienic Clamp Joint: 45-deg Elbow	68
DT-18	Hygienic Clamp Joint: Straight Tee and Cross	68
DT-19	Hygienic Clamp Joint: Reducing Tee	69
DT-20	Hygienic Clamp Joint: Short Outlet Reducing Tee	69
DT-21	Hygienic Clamp Joint: Concentric and Eccentric Reducer	70
DT-22	Automatic Tube Weld: Ferrule	71
DT-23	Automatic Tube Weld: 180-deg Return Bend	72
DT-24	Hygienic Clamp Joint: 180-deg Return Bend	72
DT-25	Hygienic Mechanical Joint: Short Outlet Run Tee	73
DT-26	Hygienic Clamp Joint: Tube Weld Concentric and Eccentric Reducer	73
DT-27	Hygienic Clamp Joint: Short Outlet Tee	74
DT-28	Automatic Tube Weld: Instrument Tee	74
DT-29	Hygienic Clamp Joint: Instrument Tee	74
DT-30	Automatic Tube Weld: Cap	74
DT-V-1	Hygienic Clamp Joint: Weir Style Diaphragm Valve	75
MJ-1	Acceptance Criteria for Welds on Pressure Vessels and Tanks	79
MJ-2	Acceptance Criteria for Welds on Pipe	80
MJ-3	Acceptance Criteria for Welds on Tube	81
MJ-4	Acceptance Criteria for Tube-Attachment Welds	83
SF-1	Acceptance Criteria for Stainless Steel and Higher Alloy Mechanically Polished Product Contact Surface Finishes	87
SF-2	Acceptance Criteria for Mechanically Polished and Electropolished Product Surface Finishes	88
SF-3	R_a Readings for Product Contact Surfaces	88
SG-1	Common Rotary Seal Materials for Biochemical and Sterile Service	96
PM-1	Size Comparison of Common Thermoplastic Sizing Standards	105
Nonmandatory Appendices		
A	Commentary: Slag	111
B	Material Examination Log and Weld Log	112
C	Slope Measurement	117
Index	118



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.



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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).

<i>Page</i>	<i>Location</i>	<i>Change</i>
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



<i>Page</i>	<i>Location</i>	<i>Change</i>
	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



<i>Page</i>	<i>Location</i>	<i>Change</i>
	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 override 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.

