

ASME BPE-2019
(Revision of ASME BPE-2016)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD



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Mechanical Engineers**

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Two Park Avenue • New York, NY • 10016 USA

Date of Issuance: June 10, 2019

The next edition of this Standard is scheduled for publication in 2021. This Standard will become effective 6 months after the Date of Issuance.

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The American Society of Mechanical Engineers
Two Park Avenue, New York, NY 10016-5990

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CONTENTS

Foreword	xi	
Statements of Policy	iii	
Committee Roster	xv	
Correspondence With the BPE Committee	xviii	
Summary of Changes	xx	
Chapter 1	Introduction, Scope, and Definitions	1
Part GR	General Requirements	1
GR-1	Introduction	1
GR-2	Scope of the ASME BPE Standard	1
GR-3	Manufacturer's Quality Assurance Program	2
GR-4	Examination, Inspection, and Testing	2
GR-5	Documentation	6
GR-6	U.S. Customary and SI Units	8
GR-7	References	8
GR-8	Terms and Definitions	10
Chapter 2	Design	19
Part SD	Systems Design	19
SD-1	Purpose and Scope	19
SD-2	General Guidelines	19
SD-3	Process Components	23
SD-4	Process Utilities	61
SD-5	Process Systems	66
SD-6	Process Support Systems	85
SD-7	Design Conformance Testing	106
Chapter 3	Materials	108
Part MM	Metallic Materials	108
MM-1	Purpose and Scope	108
MM-2	Alloy Designations	108
MM-3	Uses of Specifications	108
MM-4	Referenced Specifications	111
MM-5	Base Metals and Filler Materials	113
MM-6	Mechanical Properties	115
MM-7	Positive Material Identification	115
MM-8	Corrosion-Resistance Requirements	122
MM-9	Minimum Requirements for Alloys in Part MM	122
Part PM	Polymeric and Other Nonmetallic Materials	124
PM-1	Purpose and Scope	124
PM-2	Materials	124

PM-3	Properties and Performance	128
PM-4	Applications	130
Chapter 4	Process Components	137
Part DT	Dimensions and Tolerances for Process Components	137
DT-1	Purpose and Scope	137
DT-2	Pressure Rating	137
DT-3	Wall Thickness	137
DT-4	Dimensions	137
DT-5	Materials	138
DT-6	Tests	138
DT-7	Tolerances	138
DT-8	Weld Ends	138
DT-9	Hygienic Clamp Unions	138
DT-10	Minimum Examination Requirements	139
DT-11	Marking	139
DT-12	Packaging	140
Part PI	Process Instrumentation	173
PI-1	Purpose and Scope	173
PI-2	Process Instrumentation General Requirements	173
PI-3	Instrument Receiving, Handling, and Storage	174
PI-4	Flowmeters	174
PI-5	Level Instruments	180
PI-6	Pressure Instruments	181
PI-7	Temperature Sensors and Associated Components	184
PI-8	Analytical Instruments	189
PI-9	Optical	195
Part SG	Sealing Components	199
SG-1	Purpose and Scope	199
SG-2	Sealing Component Types	199
SG-3	Sealing Components General Design Requirements (General Provisions)	216
SG-4	Seal Performance Requirements	222
SG-5	Seal Application	224
Chapter 5	Fabrication, Assembly, and Erection	227
Part MJ	Materials Joining	227
MJ-1	Purpose and Scope	227
MJ-2	Materials	227
MJ-3	Join. Design and Preparation	228
MJ-4	Joining Processes and Procedures	229
MJ-5	Procedure Qualifications	229
MJ-6	Performance Qualifications	229
MJ-7	Examination, Inspection, and Testing	230
MJ-8	Acceptance Criteria	231
MJ-9	Joining of Polymeric Materials	232
MJ-10	Documentation Requirements	246
MJ-11	Passivation	246

Part SF	Process Contact Surface Finishes	247
SF-1	Purpose and Scope	247
SF-2	Metallic Applications	247
SF-3	Polymeric Applications	250
Chapter 6	Certification	252
Part CR	Certification Requirements	252
CR-1	Purpose and Scope	252
CR-2	General	252
Mandatory Appendices		
I	Submittal of Technical Inquiries to the Bioprocessing Equipment (BPE) Committee	254
II	Standard Units	255
III	Single-Use Components and Assemblies	256
IV	Nomenclature	260
Nonmandatory Appendices		
A	Commentary: Slag and Oxide Islands	262
B	Material and Weld Examination/Inspection Documentation	263
C	Slope Measurement and Joint Misalignment	267
D	Rouge and Stainless Steel	268
E	Passivation Procedure Qualification	276
F	Corrosion Testing	284
G	Ferrite	287
H	Electropolishing Procedure Qualification	288
J	Vendor Documentation Requirements for New Instruments	290
K	Standard Process Test Condition (SPTC) for Seal Performance Evaluation	293
L	Standard Test Methods for Polymers	303
M	Spray Device Coverage Testing	306
N	Commentary: UNS S31600 Weld Heat-Affected Zone Discoloration Acceptance Criteria	308
O	Guidance When Choosing Polymeric and Nonmetallic Materials	309
P	General Background/Useful Information for Extractables and Leachables	310
Q	Temperature Sensors and Associated Components	313
R	Instrument Receiving, Handling, and Storage	315
S	Application Data Sheet	316
T	Guidance on Polymer Applications: Chromatography Columns and Filtration	318
U	Guidance for the Use of U.S. Customary and SI Units	321
W	Positive Material Identification	323
Y	Procurement Sources	326
Z	Quality Management System	327
AA	Static Seals Application Guide for Compensial Water Systems	331
Bb	Mechanical Seal Face Material Selection for Compensial Water Pumps	334
Cc	Examination, Inspection, and Cross References	336
DD	Conductivity Sensor Selection Guide	339

Figures

SD-3.1.1-1	Flat Gasket Applications	24
SD-3.1.2.2-1	Accepted Point-of-Use Designs	28
SD-3.1.2.3-1	Double Block-and-Bleed Valve Assembly	29
SD-3.2.1-1	Flexible Hygienic Hose Design	31
SD-3.3.2.2-1	Pump Impeller Configurations	32
SD-3.3.2.2-2	Acceptable Impeller Attachments	32
SD-3.3.2.2-3	Casing Drain Configurations	33
SD-3.3.2.2-4	Casing Drain L/d Ratios	33
SD-3.3.2.4-1	Rotary Lobe Pump Rotor Attachment	34
SD-3.4.2-1	Nozzle Design	35
SD-3.4.2-2	Side and Bottom Connections	36
SD-3.4.2-3	Sidewall Instrument Ports	36
SD-3.4.2-4	Vessel Design Tangential Nozzles	37
SD-3.4.2-5	Typical Nozzle Detail	38
SD-3.4.3-1	Accepted Nozzle Penetrations	39
SD-3.4.3-2	Internal Support Members	40
SD-3.4.6-1	Sight Glass Design (Accepted)	42
SD-3.5.1-1	Agitator Mounting Flanges	43
SD-3.5.2-1	Shaft Coupling Construction	44
SD-3.5.2-2	Shaft Coupling Seal Arrangements	45
SD-3.5.2-3	Fastener Seal Arrangements: Alternative Bolting Designs	46
SD-3.5.5-1	Shaft-Steady Bearing	47
SD-3.5.5-2	Magnetically Coupled Mixer (Typical Bottom-Mount)	48
SD-3.6.1-1	Double Tubesheet Heat Exchanger Bonnet Design	50
SD-3.7.1-1	Transfer Panel Looped Headers	51
SD-3.7.2-1	Transfer Panel Tolerances (Reference Table DT-7-3)	52
SD-3.7.4-1	Transfer Panel Jumpers	53
SD-3.9.1-1	Dynamic Spray Device: Single Axis	55
SD-3.9.1-2	Two-Axis Dynamic Spray Device	56
SD-3.9.2.1-1	Static Spray Device	57
SD-3.9.2.1-2	Flow Rate Guideline for Vertical Cylindrical Vessels	57
SD-3.9.2.1-3	Flow Rate Guideline for Horizontal Cylindrical Vessels	58
SD-3.9.2.3-1	Impact Pattern Buildup	59
SD-3.12-1	Steam Traps for Clean Steam Systems	60
SD-4.1.2.1-1	Point-of-Use Piping	62
SD-4.1.2.2-1	Physical Break in Point-of-Use Piping	63
SD-4.2.2-1	Typical Clean Steam System Isometric	64
SD-4.2.2-2	Clean Steam Point-of-Use Design	65
SD-5.1.4.4-1	Gas Sparging Assembly — Lance	67
SD-5.1.4.4-2	Gas Sparging Assembly — Sintered	68
SD-5.1.4.4-3	Gas Sparging Assembly — Ring	69
SD-5.1.4.4-4	Gas Sparging Assembly — Single Orifice	70
SD-5.1.4.7-1	Exhaust Gas Condenser	72
SD-5.1.4.7-2	Exhaust Gas Heater	72

SD-5.1.4.7-3	Electrically Heat Traced Filter Housing	73
SD-5.1.5-1	Fermentor Sterile Envelope	74
SD-5.1.5-2	Bioreactor Sterile Envelope	75
SD-5.4.4-1	Tank/Vessel Vent Fillers	78
SD-5.6.2-1	Typical Lyophilizer Component Assembly	80
SD-5.6.3-1	Lyophilizer Sterile Boundary	83
SD-6.3.4.6-1	CIP Looped Header (Supply or Return)	9
SD-6.3.4.6-2	Zero-Static Chain	93
SD-6.3.4.6-3	Swing Elbow Arrangement	93
SD-6.4.1.1-1	Example of HTST Process Flow Schematic Diagram	95
SD-6.4.1.1-2	Example of Direct Steam Injection UHT Process Flow Schematic Diagram	96
SD-6.4.4.5-1	Example of Additional Retention Tube Length Required to Account for Axial Mixing	98
SD-6.5.4.2-1	Immersion Tank Side Nozzle Design	101
DT-2-1	Clamp Conditions at Installation	141
PI-2.2.1-1	In-Line and At-Line Instrument Installation Examples	174
PI-2.2.2-1	Accepted Insertion Device Installation Examples	175
PI-4.1.3.2-1	Manifold or Flow Splitter for Dual-Tube Construction Flowmeters and Potential for Product Holdup	176
PI-4.1.3.3-1	Concentrically Reducing Process Connection	177
PI-4.1.4.3-1	Vertical Installation	177
PI-4.1.4.4-1	Minimum Angle of Inclination, α	178
PI-4.2.2-1	Typical Turbine Flowmeters	179
PI-5.1.2.1-1	Bulb, Horn, Isolated Horn, and Rod-Style Mounting	181
PI-5.1.3.3-1	Dead Band, Measuring Range, and Mounting Location	182
PI-6.1.2-1	Accepted Orientation and Flow	183
PI-7.3-1	Typical Installation Styles	185
PI-7.3.4-1	Accepted Elbow Orientations and Flow Directions	186
PI-7.3.4-2	Accepted Nonintrusive Orientations and Flow Directions	186
PI-7.3.5-1	Sensor Insertion Lengths for Tee Installations	187
PI-7.3.5-2	Sensor Insertion Lengths for Elbow Installations	188
PI-8.1.2-1	Conductivity-Type Examples	190
PI-8.1.3-1	Accepted Installations for Conductivity Sensors	191
PI-8.1.3.6-1	Installation Clearance Requirements	191
PI-8.2.2-1	pH Sensor Components	192
PI-8.2.3-1	Accepted pH Sensor Installations	193
PI-8.2.3.4-1	Accepted Mounting Orientations	194
PI-8.2.3.5-1	Insertion Length or Depth	195
PI-9.1.3.3-1	Vessel Light Glass Design and Mounting	197
PI-9.1.3.5-1	In-Line Insertion Length	198
PI-9.1.3.5-2	Insertion Probe Length	198
SG-2.2.2-1	Hygienic Union per Table DT-7-1	200
SG-2.2.2-2	Hygienic Clamp Union per Table DT-7-1	200
SG-2.2.2-3	Hygienic Union per DIN 11864	200
SG-2.2.2-4	Hygienic Clamp Union per DIN 11864	201
SG-2.2.2-5	Nonhygienic Connections	202

SG-2.3.1.2-1	Weir Valves	204
SG-2.3.1.2-2	Radial Valves	204
SG-2.3.1.2-3	Weirless Diaphragm Valve	205
SG-2.3.1.2-4	Linear Control Valves	205
SG-2.3.1.2-5	Regulator Valve	206
SG-2.3.1.3-1	Ball Valves	206
SG-2.3.1.4-1	Rising Stem Single, Double-Seat Mix-Proof, and Needle Valves	207
SG-2.3.1.5-1	Butterfly Valve	207
SG-2.3.1.7-1	Back Pressure Control Valve	207
SG-2.3.1.8-1	Pinch Valve	208
SG-2.3.1.9-1	Pressure Relief and Check Valves	209
SG-2.3.1.10-1	Plug Valve	211
SG-2.3.2.2-1	Single Mechanical Seal	211
SG-2.3.2.2-2	Single Seal for Top-Entry Agitator	211
SG-2.3.2.3-1	Dual Pressurized Mechanical Seal for Pumps	211
SG-2.3.2.3-2	Dual Pressurized Mechanical Seal for Top-Entry Agitator	211
SG-2.3.2.3-3	Dual Unpressurized Mechanical Seal for Pumps	211
SG-2.3.2.4-1	Flush Plan 01	213
SG-2.3.2.4-2	Flush Plan 02	213
SG-2.3.2.4-3	Flush Plan 03	213
SG-2.3.2.4-4	Flush Plan 11	213
SG-2.3.2.4-5	Flush Plan 32	213
SG-2.3.2.4-6	Flush Plan 52 for Pump	214
SG-2.3.2.4-7	Flush Plan 52 for Top-Entry Agitator	214
SG-2.3.2.4-8	Flush Plan BPE52 for Pump	214
SG-2.3.2.4-9	Flush Plan 53 for Pump	214
SG-2.3.2.4-10	Flush Plan 53 for Top-Entry Agitator	214
SG-2.3.2.4-11	Flush Plan 54 for Pump	215
SG-2.3.2.4-12	Flush Plan 54 for Top-Entry Agitator	215
SG-2.3.2.4-13	Flush Plan 55 for Pump	215
SG-2.3.2.4-14	Flush Plan 55 for Top-Entry Agitator	215
SG-2.3.2.4-15	Flush Plan 74 for Pump	215
SG-2.3.2.4-16	Flush Plan 74 for Top-Entry Agitator	215
SG-3.3.2.2-1	Examples of Static O-Ring Grooves	218
SG-3.3.2.3-1	Seals for Rising Stem Valves	220
SG-4.2-1	Typical Hygienic Clamp Union: Allowable Gasket Intrusion	223
MJ-8.4-1	Acceptable and Unacceptable Weld Profiles for Groove Welds on Metallic Tube-to-Tube Butt Joints	238
MJ-8.4-2	Discoloration Acceptance Criteria for Welds and Heat-Affected Zones on Electropolished UNS S31603 Tubing	239
MJ-8.4-3	Discoloration Acceptance Criteria for Welds and Heat-Affected Zones on Mechanically Polished UNS S31603 Tubing	240
MJ-8.4-4	Acceptable and Unacceptable Metallic Weld Bead Width and Meander on Non-Process Contact Surfaces of Groove Welds on Tube-to-Tube Butt Joints	241
MJ-8.5-1	Acceptable Weld Profiles for Metallic Tube-Attachment Fillet Welds	244
MJ-9.7.1-1	Acceptable and Unacceptable Weld Profiles for Polymeric Beadless Welds	245

CR-1-1	ASME Certification Mark With BPE Designator	252
K-1.3.2.1-1	Weir-Style Diaphragm	296
K-1.3.2.1-2	Weir-Style Body	299
K-1.3.2.1-3	Radial-Style Body	299
K-1.3.2.1-4	Manual Bonnet	299
K-1.3.2.1-5	Pneumatic	299
P-4-1	Flowchart of Bioprocessing Equipment/Component Evaluation Related to Extractables and Leachables Characterization	312
BB-1-1	Mechanical Seal Face Material Selection for Compensial Water Pumps	314
DD-2.1.1-1	Conductivity Scale	340

Tables

GR-4.2-1	Inspector's Delegate Capabilities	4
SD-2.4.3.1-1	Slope Designations for Gravity-Drained Lines	21
SD-3.1.2.2-1	<i>L/d</i> Dimensions for Flow-Through Tee: Full-Size Standard Straight Tee With Blind Cap	25
SD-3.1.2.2-2	<i>L/d</i> Dimensions for Flow-Through Tee: Short-Outlet Reducing Tee With Blind Cap	26
SD-3.4.3-1	Annular Spacing Recommendations for Hygienic Dip Tubes	38
SD-6.3.5.2-1	Flow Rates to Achieve 5 ft/sec (1.52 m/s)	93
MM-2.1-1	Wrought Stainless Steels: Nominal Compositions (wt. %)	109
MM-2.1-2	Wrought Nickel Alloys: Nominal Compositions (wt. %)	110
MM-2.1-3	Stainless Steel and Nickel Alloy Cast Designations	111
MM-2.1-4	Wrought Copper: Nominal Compositions (wt. %) (Cleaned for Oxygen Service)	111
MM-5.2.1.2-1	Predicted Ferrite Number (FN) Ranges for Various Austenitic Stainless Steel Product Forms and Welds	114
MM-5.2.6-1	Materials for OEM Equipment	115
MM-5.3-1	Filler Metals	116
MM-5.3-2	Consumable Inserts for Superaustenitic and Duplex Stainless Steels	120
MM-5.3.3-1	Brazing Filler Metals for Copper	121
MM-5.4-1	Solution Anneal Heat Treatment Requirements for Superaustenitic and Duplex Stainless Steels	122
PM-2.1.1-1	Common Thermoplastic Polymers and Applications	125
PM-2.1.2-1	Common Thermoplastic Polymers and Applications	125
PM-2.1.3-1	Examples of Nonmetallics	126
PM-2.2.1-1	Content Required on the Certificate of Compliance	127
PM-2.2.3.2-1	Change Levels and Minimum Change Notification Requirements	128
PM-4.2.1-1	Size Comparison of Common Thermoplastic Sizing Standards	131
DT-2-1	Metallic Hygienic Unions: Rated Internal Working Pressure	140
DT-3-1	Final Tolerances for Mechanically Polished Fittings and Process Components	142
DT-3-2	Final Tolerances for Electropolished Fittings and Process Components	143
DT-4-1	Nominal O.D. Tubing Sizes	143
DT-4.1-1	Tangent Lengths	143
DT-4.1.1-1	Automatic Tube Weld: 90-deg Elbow	144
DT-4.1.1-2	Automatic Tube Weld: Hygienic Clamp Joint, 90-deg Elbow	145
DT-4.1.1-3	Hygienic Clamp Joint: 90-deg Elbow	145
DT-4.1.1-4	Automatic Tube Weld: 45-deg Elbow	146
DT-4.1.1-5	Automatic Tube Weld: Hygienic Clamp Joint, 45-deg Elbow	147

DT-4.1.1-6	Hygienic Clamp Joint: 45-deg Elbow	147
DT-4.1.1-7	Automatic Tube Weld: 180-deg Return Bend	148
DT-4.1.1-8	Hygienic Clamp Joint: 180-deg Return Bend	148
DT-4.1.2-1	Automatic Tube Weld: Straight Tee and Cross	149
DT-4.1.2-2	Automatic Tube Weld: Short-Outlet Hygienic Clamp Joint Tee	149
DT-4.1.2-3	Hygienic Mechanical Joint: Short-Outlet Run Tee	150
DT-4.1.2-4	Hygienic Clamp Joint: Straight Tee and Cross	151
DT-4.1.2-5	Hygienic Clamp Joint: Short-Outlet Tee	151
DT-4.1.2-6	Automatic Tube Weld: Reducing Tee	152
DT-4.1.2-7	Automatic Tube Weld: Short-Outlet Hygienic Clamp, Joint Reducing Tee	153
DT-4.1.2-8	Hygienic Clamp Joint: Reducing Tee	154
DT-4.1.2-9	Hygienic Clamp Joint: Short-Outlet Reducing Tee	155
DT-4.1.2-10	Automatic Tube Weld: Instrument Tee	155
DT-4.1.2-11	Hygienic Clamp Joint: Instrument Tee	156
DT-4.1.3-1	Automatic Tube Weld: Concentric and Eccentric Reducer	157
DT-4.1.3-2	Hygienic Clamp Joint: Tube Weld Concentric and Eccentric Reducer	158
DT-4.1.3-3	Hygienic Clamp Joint: Concentric and Eccentric Reducer	159
DT-4.1.4-1	Automatic Tube Weld: Ferrule	160
DT-4.1.5-1	Automatic Tube Weld: Cap	160
DT-4.1.5-2	Hygienic Clamp Joint: Solid End Cap	161
DT-4.4.1-1	Hygienic Clamp Joint: Weir-Style Diaphragm Valve	162
DT-4.5.1-1	Tapered Locking Tab Retainer: Recessed	163
DT-4.5.2-1	Tapered Locking Tab Retainer: External	164
DT-7-1	Metallic Hygienic Clamp Ferrule Standard Dimensions and Tolerances	165
DT-7-2	Polymeric Hygienic Clamp Ferrule Standard Dimensions and Tolerances	168
DT-7-3	Transfer Panel and Jumper Tolerances	171
DT-9.3-1	Hygienic Clamp Ferrule: Design Criteria	172
MJ-6.3-1	Metallic Tube/Pipe Diameter Limits for Orbital GTAW Performance Qualification	230
MJ-6.3-2	Metallic Weld Thickness Limits for Orbital GTAW Performance Qualification	230
MJ-8.2-1	Visual Examination Acceptance Criteria for Welds on Metallic Pressure Vessels and Tanks	233
MJ-8.3-1	Visual Examination Acceptance Criteria for Welds on Metallic Pipe	234
MJ-8.4-1	Visual Examination Acceptance Criteria for Groove Welds on Metallic Tube-to-Tube Butt Joints	235
MJ-8.5-1	Visual Examination Acceptance Criteria for Metallic Tube-Attachment Welds	242
SF-2.2-1	Acceptance Criteria for Metallic Process Contact Surface Finishes	248
SF-2.2-2	Additional Acceptance Criteria for Electropolished Metallic Process Contact Surface Finishes	249
SF-2.4.1-1	R_a Readings for Metallic Process Contact Surfaces	249
SF-2.6-1	Acceptance Criteria for Metallic Passivated Process Contact Surface Finishes	250
SF-3.3-1	Acceptance Criteria for Polymeric Process Contact Surface Finishes	251
SF-3.4-1	R_a Readings for Polymeric Process Contact Surfaces	251
II-1	Standard Units	255
D-2-1	Considerations That Affect the Amount of Rouge Formation During the Fabrication of a System	270
D-2-2	Considerations That Affect the Amount of Rouge Formation During the Operation of a System	271

D-3.1-1	Process Fluid Analyses for the Identification of Mobile Constituents of Rouge	272
D-3.2-1	Solid Surface Analyses for the Identification of Surface Layers Composition	273
D-4.1-1	Rouge Remediation Processes Summary	274
E-3.2-1	Minimum Surface Requirements for Process Qualification Samples	277
E-3.2-2	Passivation Processes	278
E-5-1	Test Matrix for Evaluation of Cleaned and/or Passivated Surfaces	280
F-1-1	ASTM Corrosion Tests	285
F-3-1	PRE Numbers for Some Alloys	286
H-3.3-1	Minimum Surface Requirements for Process Qualification Samples	289
J-1.1-1	Vendor Documentation Requirements for New Instruments: Section 1, VDR Definitions . . .	291
J-1.2-1	Vendor Documentation Requirements for New Instruments: Section 2, Instrument Types and Required Documents	292
L-3-1	Thermoset Polymer Test Properties	304
L-4-1	Interpretation of Thermoset Material Property Changes	305
AA-1-1	Static Seals for Use in Compendial Water Systems (SG-2.2.1)	332
DD-2.6-1	Technological Considerations	340
 Forms		
MEL-1	Material Examination Log	264
MER-1	Material Examination Record	265
WEL-1	Weld and Examination Inspection Log	266
S-1	Application Data Sheet	317

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 3-A 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) Metallic Materials

(4) Polymeric and Other Nonmetallic Materials

(5) Dimensions and Tolerances for Process Components

(6) Process Instrumentation

(7) Sealing Components

(8) Materials Joining

(9) Process Contact Surface Finishes

(10) Certification Requirements

The first edition of this Standard was approved as an American National Standard on May 20, 1997. This edition was approved by ANSI on February 27, 2019.

STATEMENT OF POLICY ON THE USE OF THE ASME SINGLE CERTIFICATION MARK 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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General. ASME Standards are developed and maintained with the intent to represent the consensus of concerned interests. As such, users of this Standard may interact with the Committee by requesting interpretations, proposing revisions or a case, and attending Committee meetings. Correspondence should be addressed to:

Secretary, BPE Standards Committee
The American Society of Mechanical Engineers
Two Park Avenue
New York, NY 10016-5990
<http://go.asme.org/Inquiry>

Proposing Revisions. Revisions are made periodically to the Standard to incorporate changes that appear necessary or desirable, as demonstrated by the experience gained from the application of the Standard. Approved revisions will be published periodically.

The Committee welcomes proposals for revisions to this Standard. Such proposals should be as specific as possible, citing the paragraph number(s), the proposed wording, and a detailed description of the reasons for the proposal, including any pertinent documentation.

Proposing a Case. Cases may be issued to provide alternative rules when justified, to permit early implementation of an approved revision when the need is urgent, or to provide rules not covered by existing provisions. Cases are effective immediately upon ASME approval and shall be posted on the ASME Committee web page.

Requests for Cases shall provide a Statement of Need and Background Information. The request should identify the Standard and the paragraph, figure, or table number(s), and be written as a Question and Reply in the same format as existing Cases. Requests for Cases should also indicate the applicable edition(s) of the Standard to which the proposed Case applies.

Interpretations. Upon request, the BPE Standards Committee will render an interpretation of any requirement of the Standard. Interpretations can only be rendered in response to a written request sent to the Secretary of the BPE Standards Committee.

Requests for interpretation should preferably be submitted through the online Interpretation Submittal Form. The form is accessible at <http://go.asme.org/InterpretationRequest>. Upon submittal of the form, the Inquirer will receive an automatic e-mail confirming receipt.

If the Inquirer is unable to use the online form, he/she may mail the request to the Secretary of the BPE Standards Committee at the above address. The request for an interpretation should be clear and unambiguous. It is further recommended that the Inquirer submit his/her request in the following format:

Subject:	Cite the applicable paragraph number(s) and the topic of the inquiry in one or two words.
Edition:	Cite the applicable edition of the Standard for which the interpretation is being requested.
Question:	Phrase the question as a request for an interpretation of a specific requirement suitable for general understanding and use, not as a request for an approval of a proprietary design or situation. Please provide a condensed and precise question, composed in such a way that a "yes" or "no" reply is acceptable.
Proposed Reply(ies):	Provide a proposed reply(ies) in the form of "Yes" or "No," with explanation as needed. If entering replies to more than one question, please number the questions and replies.
Background Information:	Provide the Committee with any background information that will assist the Committee in understanding the inquiry. The Inquirer may also include any plans or drawings that are necessary to explain the question; however, they should not contain proprietary names or information.

Requests that are not in the format described above may be rewritten in the appropriate format by the Committee prior to being answered, which may inadvertently change the intent of the original request.

Moreover, ASME does not act as a consultant for specific engineering problems or for the general application or understanding of the Standard requirements. If, based on the inquiry information submitted, it is the opinion of the Committee that the Inquirer should seek assistance, the inquiry will be returned with the recommendation that such assistance be obtained.

ASME procedures provide for reconsideration of any interpretation when or if additional information that might affect an interpretation is available. Further, persons aggrieved by an interpretation may appeal to the cognizant ASME Committee or Subcommittee. ASME does not “approve,” “certify,” “rate,” or “endorse” any item, construction, proprietary device, or activity.

Attending Committee Meetings. The BPE Standards Committee regularly holds meetings and/or telephone conferences that are open to the public. Persons wishing to attend any meeting and/or telephone conference should contact the Secretary of the BPE Standards Committee.

ASME BPE-2019 SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2019 was approved by the American National Standards Institute on February 27, 2019.

ASME BPE-2019 includes the following changes identified by a margin note, **(19)**.

<i>Page</i>	<i>Location</i>	<i>Change</i>
xviii	Correspondence With the BPE Committee	Moved from Mandatory Appendix I and revised in its entirety
1	GR-1	New last paragraph added
2	GR-3	New last paragraph added
2	GR-4	Revised in its entirety
8	GR-7	References updated
10	GR-8	(1) Definitions of <i>direct visual examination</i> , <i>examination</i> , <i>High Efficiency Particulate Air (HEPA) filter</i> , <i>inspection</i> , <i>interrupted electropolish</i> , <i>ISO class 1–9</i> , <i>remote visual examination</i> , <i>testing</i> , <i>Ultra-Low Penetration Air (ULPA) filter</i> , and <i>videoscope</i> added (2) Definitions of <i>borescope</i> , <i>dead leg</i> , and <i>haze</i> revised (3) Definitions of <i>audit</i> and <i>survey</i> deleted
18	GR-9	Added
19	SD-2	Second paragraph revised and new third and fourth paragraphs added
19	SD-2.3	Revised in its entirety
20	SD-2.4.1.1	First sentence in first paragraph revised
20	SD-2.4.2	Subparagraphs (a)(1) and (b)(2) revised
22	SD-2.5	Added
23	SD-3.1.1	Subparagraph (d) revised
23	SD-3.1.2.2	Title and first paragraph revised
23	SD-3.1.2.3	Subparagraphs (g) and (i) revised
30	SD-3.2.3	Subparagraph (c) revised
37	SD-3.4.4	First sentence of subpara. (b) revised
41	SD-3.5.1	Subparagraphs (a) and (e) revised
46	SD-3.5.5	Second sentence of subpara. (a) revised
48	SD-3.5.6	Second sentence of subpara. (b) revised
48	SD-3.6.1	Subparagraphs (a), (c), (e), and (g)(3) revised
49	SD-3.7.2	Subparagraph (g) revised
50	Figure SD-3.6.1-1	Note (1) revised
52	Figure SD-3.7.2-1	Subtitle revised
52	SD-3.7.3	Subparagraph (a) revised
52	SD-3.7.4	Subparagraphs (c) and (e) revised

54	SD-3.7.6	Subparagraph (e) revised
58	SD-3.9.2.3	Subparagraph (a) revised
60	SD-3.13	Second sentence of subpara. (d) revised
61	SD-4.1	Subparagraph (b) revised
61	SD-4.1.1	Second sentence of subpara. (b) revised
61	SD-4.1.2.2	Subparagraph (d) revised
63	SD-4.2.1	Second sentence of subpara. (b) revised
65	SD-4.3.1	First paragraph revised
66	SD-5	Revised in its entirety
85	SD-6	New SD-6 added
106	SD-7	Former SD-6 redesignated
108	MM-1	Second sentence revised
109	Table MM-2.1-1	Under Duplex Stainless Steels, values for UNS S32101 added
108	MM-3.2	Revised
108	MM-3.3	Cross reference in subpara. (a) revised
108	MM-3.5	Revised
114	MM-5.2.2	Second paragraph revised
114	Table MM-5.2.1.2-1	Under Product Form column, third and fourth entries revised
114	MM-5.2.3	Second paragraph revised
115	Table MM-5.2.6-1 T	UNS Number N07718 added
115	MM-7	Former MM-6 revised and redesignated
116	Table MM-5.3-1	Under Duplex Stainless Steels, values for UNS S32101 added
120	Table MM-5.3-2	Under Duplex Stainless Steels, values for UNS S32101 added
122	Table MM-5.4-1	Under Duplex Stainless Steels, values for UNS S32101 added
122	MM-8	Former MM-7 redesignated
122	MM-9	Former MM-8 revised in its entirety and redesignated
124	PM-1	paragraph revised
125	PM-2.2	First paragraph revised
126	PM-2.2.3	Revised in its entirety
127	Table PM-2.2.1-1	General Note revised
128	Table PM-2.2.3.2-1	Added
129	PM-3.2	Revised in its entirety
130	PM-4.1	Revised in its entirety
136	PM-4.6	Revised
136	PM-4.6.1.2	Revised
136	PM-4.6.2	Revised in its entirety
137	DT-3	Second sentence of second paragraph revised
142	Table DT-3-1	(1) In graphic, callout T revised as T_L (2) General Note (d) revised
137	DT-4.1	In third paragraph, T revised as T_L
137	DT-4.1.4	Revised
143	Table DT-4.1-1	In second column head, T revised as T_L
148	Table DT-4.1.1-8	For Nominal Size $2\frac{1}{2}$ in., value in last column revised Values
151	Table DT-4.1.2-4	revised for Nominal Size $\frac{1}{2}$ in. and $\frac{3}{4}$ in.
151	Table DT-4.1.2-5	Values revised for Nominal Size $\frac{1}{2}$ in. and $\frac{3}{4}$ in. under column A

154	Table DT-4.1.2-8	Under column B, values in SI column revised in 27th and 28th lines
138	DT-7	First paragraph revised
138	DT-8	First sentence revised
139	DT-11.1	Subparagraph (a) revised
140	DT-11.1.1	Subparagraph (a) revised
140	DT-11.2	Subparagraph (a) revised
140	DT-11.2.1	Subparagraphs (a) and (b) revised
165	Table DT-7-1	Revised in its entirety
168	Table DT-7-2	New Table DT-7-2 added
171	Table DT-7-3	Former Table DT-7-2 redesignated
178	PI-4.2	Added
181	PI-6.1	Added
209	Figure SG-2.3.1.9-1	Illustration (c) revised
218	SG-3.3.2.3	Subparagraph (a)(7) revised
223	SG-4.3.1.1	Revised in its entirety
224	SG-5.1	Last two paragraphs added
224	SG-5.1.1	Added
225	SG-5.3	Revised in its entirety
225	SG-5.4	Revised in its entirety
228	MJ-3.5	Subparagraph (b)(2) revised
229	MJ-6.3	Last paragraph revised
230	Table MJ-6.3-2	Variable t revised as T_w throughout
232	MJ-8.4	First paragraph revised
233	Table MJ-8.2-1	In fourth row, fourth column revised
234	Table MJ-8.3-1	In fourth row, fourth column revised
235	Table MJ-8.4-1	(1) In fourth row, second column revised (2) In fifteenth row, last column revised (3) In seventeenth row, first column revised (4) Note (4) revised (5) Note (8) added
241	Figure MJ-8.4-4	General Note revised
242	Table MJ-8.5-1	(1) In fourth row, second and fourth columns revised (2) Note (9) revised
246	MJ-11	Revised
247	SF-2.3	Revised in its entirety
247	SF-2.4	Revised in its entirety
248	Table SF-2.2-1	(1) In first column, first two entries revised (2) Last row revised
249	Table SF-2.2-2	Revised
249	Table SF-2.4.1-1	Former Table SF-2.4-1 revised and redesignated
250	Table SF-2.6-1	In second column, second entry revised
250	SF-3.3	First paragraph and subparas. (a) and (a)(2) revised
252	CR-2	Revised in its entirety
254	Mandatory Appendix I	Information relocated to the Correspondence With the BPE Committee page in the front matter

256	Mandatory Appendix III	Added
260	Mandatory Appendix IV	Added
264	Form MEL-1	Fourth column head revised
268	D-3	Revised
268	D-4.1	Third paragraph revised
269	D-4.4	First sentence of second paragraph revised
270	Table D-2-1	In second column, first and third entries revised
274	Table D-4.1-1	Under Comments column and in Notes (2) and (4), “product contact surface” revised as “process contact surface”
276	E-1	In first paragraph, UNS Number S31503 revised to read S31600
279	E-5.1	Penultimate paragraph revised
280	Table E-5-1	In second column, first entry revised
288	H-1	Revised
289	Table H-3.3-1	First column entries revised
290	Nonmandatory Appendix J	Former Nonmandatory Appendix I redesignated
293	Nonmandatory Appendix K	(1) Former Nonmandatory Appendix J redesignated (2) In former J-1.1, first paragraph revised (3) Former J-1.2.1 and J-1.2.2 revised in their entirety (4) K-1.2.4 added
303	Nonmandatory Appendix L	Former Nonmandatory Appendix K redesignated
306	Nonmandatory Appendix M	Former Nonmandatory Appendix L redesignated
308	Nonmandatory Appendix N	Former Nonmandatory Appendix M redesignated
309	Nonmandatory Appendix O	(1) Former Nonmandatory Appendix N redesignated (2) In former N-1.1, first sentence revised
310	Nonmandatory Appendix P	Former Nonmandatory Appendix O redesignated
313	Nonmandatory Appendix Q	Former Nonmandatory Appendix P redesignated
315	Nonmandatory Appendix R	Former Nonmandatory Appendix Q redesignated
316	Nonmandatory Appendix S	Former Nonmandatory Appendix R redesignated
318	Nonmandatory Appendix T	Former Nonmandatory Appendix S redesignated
321	Nonmandatory Appendix U	Former Nonmandatory Appendix T redesignated
323	Nonmandatory Appendix W	(1) Redesignated from former Nonmandatory Appendix U (2) In former U-1, title revised (3) In former U-2, subpara. (a) and third paragraph of subpara. (b) revised (4) In former U-3, second paragraph revised (5) In former U-7, first sentence revised (6) In former U-8, first sentence of second paragraph revised
326	Nonmandatory Appendix Y	Former Nonmandatory Appendix V redesignated and third paragraph revised
327	Nonmandatory Appendix Z	Added
331	Nonmandatory Appendix AA	Added
334	Nonmandatory Appendix BB	Added
336	Nonmandatory Appendix CC	Added
339	Nonmandatory Appendix DD	Added
341	Index	Added

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CHAPTER 1

INTRODUCTION, SCOPE, AND DEFINITIONS

PART GR

GENERAL REQUIREMENTS

(19) GR-1 INTRODUCTION

The ASME Bioprocessing Equipment (BPE) 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 Standard.

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.

New editions of the ASME BPE Standard may be used beginning with the date of issuance and become effective 6 months after the date of issuance.

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 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. 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, such as a retrofit, modification, or repair, 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.