

ASME BPE-2009
(Revision of ASME BPE-2007)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD



**The American Society of
Mechanical Engineers**



Copyright © 2009 by the American Society of Mechanical Engineers.
No reproduction may be made of this material without written consent of ASME.



ASME BPE-2009
(Revision of ASME BPE-2007)

Bioprocessing Equipment

AN INTERNATIONAL STANDARD



**The American Society of
Mechanical Engineers**



Copyright © 2009 by the American Society of Mechanical Engineers.
No reproduction may be made of this material without written consent of ASME.



Date of Issuance: October 20, 2009

The next edition of this Standard is scheduled for publication in 2012. 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.

ASME is the registered trademark of The American Society of Mechanical Engineers.

This code or standard was developed under procedures accredited as meeting the criteria for American National Standards. The Standards Committee that approved the code or standard was balanced to assure that individuals from competent and concerned interests have had an opportunity to participate. The proposed code or standard was made available for public review and comment that provides an opportunity for additional public input from industry, academia, regulatory agencies, and the public-at-large.

ASME does not “approve,” “rate,” or “endorse” any item, construction, proprietary device, or activity.

ASME does not take any position with respect to the validity of any patent rights asserted in connection with any items mentioned in this document, and does not undertake to insure anyone utilizing a standard against liability for infringement of any applicable letters patent, nor assume any such liability. Users of a code or standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, is entirely their own responsibility.

Participation by federal agency representative(s) or person(s) affiliated with industry is not to be interpreted as government or industry endorsement of this code or standard.

ASME accepts responsibility for only those interpretations of this document issued in accordance with the established ASME procedures and policies, which precludes the issuance of interpretations by individuals.

No part of this document may be reproduced in any form,
in an electronic retrieval system or otherwise,
without the prior written permission of the publisher.

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

Copyright © 2009 by
THE AMERICAN SOCIETY OF MECHANICAL ENGINEERS
All rights reserved
Printed in U.S.A.



CONTENTS

Foreword	ix	
Statements of Policy	x	
Committee Roster	xi	
Summary of Changes	xv	
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	3
GR-6	Access for Inspectors	3
GR-7	Manufacturer's Quality Assurance Program	3
GR-8	Metric	3
GR-9	References	3
GR-10	Terms and Definitions	7
Part SD	Design for Sterility and Cleanability	14
SD-1	Introduction	14
SD-2	Scope and Purpose	14
SD-3	General Guidelines	14
SD-4	Specific Guidelines	18
SD-5	Testing	37
SD-6	Documentation	37
SD-7	Responsibilities	38
Part DT	Dimensions and Tolerances for Stainless Steel Automatic Welding and Hygienic Clamp Tube Fittings and Process Components	82
DT-1	Scope	82
DT-2	Pressure Rating	82
DT-3	Marking	82
DT-4	Materials	82
DT-5	Metal Thickness	82
DT-6	Fitting Dimensions	82
DT-7	Tests	83
DT-8	Tolerances	83
DT-9	Welding Ends	83
DT-10	Hygienic Clamp Unions	83
DT-11	Heat Treatment	83
DT-12	Surface Condition	84
DT-13	Packaging	84
DT-14	Minimum Examination Requirements	84
DT-V-1	Scope	84
DT-V-2	Pressure Rating	84
DT-V-3	Marking	84
DT-V-4	Materials	85
DT-V-5	Metal Thickness	85
DT-V-6	Valve Dimension	85
DT-V-7	Tests	85
DT-V-8	Tolerances	85
DT-V-9	Welding Ends	85



DT-V-10	Hygienic Clamp Ends	85
DT-V-11	Surface Condition	85
Part MJ	Material Joining	108
MJ-1	Scope	108
MJ-2	Materials	108
MJ-3	Joining Processes and Procedures	108
MJ-4	Weld Joint Design and Preparation	109
MJ-5	Filler Material	110
MJ-6	Weld Acceptance Criteria	110
MJ-7	Inspection, Examination, and Testing	110
MJ-8	Procedure Qualification	117
MJ-9	Performance Qualification	117
MJ-10	Documentation Requirements	118
MJ-11	Passivation	119
Part SF	Stainless Steel and Higher Alloy Product Contact Surface Finishes	120
SF-1	Scope	120
SF-2	Objective	120
SF-3	Applications	120
SF-4	Material	120
SF-5	Inspection and Techniques Employed in the Classification of Product Contact Surface Finishes	120
SF-6	Surface Condition	120
SF-7	Electropolishing Procedure Qualification	120
SF-8	Passivation Procedure	123
SF-9	Normative References	123
SF-10	Rouge and Stainless Steel	123
SF-P-1	Scope	124
SF-P-2	Objective	124
SF-P-3	Applications	124
SF-P-4	Materials	124
SF-P-5	Inspection and Techniques Employed in the Classification of Product Contact Surface Finishes	124
SF-P-6	Surface Condition	124
Part SG	Equipment Seals	126
SG-1	Scope and Purpose	126
SG-2	Seal Classes	126
SG-3	General Provisions for Seals in Bioprocessing Service: User Basic Design Requirement	127
SG-4	Special Provisions for Seals in Bioprocessing Service	131
Part PM	Polymer-Based Materials	144
PM-1	Introduction	144
PM-2	Design Considerations for Polymeric Piping, Tubing, Fittings, Valve Bodies, and Other Components	144
PM-3	Polymer Material Joining	146
PM-4	Polymer Interior Product Contact Surfaces of Piping, Tubing, Fittings, Valve Bodies, and Coated or Lined Vessels	150
PM-5	Materials of Construction	150
PM-6	Elastomer Performance Properties	151
PM-7	Single-Use Components and Assemblies	151
PM-8	Hose Assemblies	153
Part CR	Certification	155
CR-1	Introduction	155
CR-2	General	155
CR-3	Acquiring an ASME BPE Certificate	157



CR-4	Requirements Subject to Change	158
Part MMOC	Metallic Materials of Construction	159
MMOC-1	General	159
MMOC-2	Alloy Designations	159
MMOC-3	Uses of Specifications	159
MMOC-4	Referenced Specifications	161
MMOC-5	Fabrication	163
MMOC-6	Mechanical Properties	166
MMOC-7	Corrosion Resistance Requirements	166
MMOC-8	Surface Finish Requirements	167
MMOC-9	Unlisted Alloys	167
Figures		
SD-1	Hygienic Connections	39
SD-2	Nonhygienic Connections	40
SD-3	Flat Gasket Applications	41
SD-4	Recommended and Preferred Drop Designs	42
SD-5	Double Block-and-Bleed Valve Assembly	43
SD-6	Instrument Location Detail: Hygienic Design	44
SD-7-1	Flexible Hygienic Hose Design	45
SD-7-2	Pump Impeller Configurations	45
SD-7-3	Acceptable Impeller Attachments	46
SD-7-4	Casing Drain Configurations	46
SD-7-5	Casing Drain <i>L/D</i> Ratios	47
SD-8	Tank/Vessel Vent Filters	47
SD-9	Nozzle Design	48
SD-10	Sidewall Instrument Ports	49
SD-11	Dip Tube	49
SD-12	Vessel Design Tangential Nozzles	50
SD-13	Vessel Sight Glass Design	51
SD-14	Side and Bottom Connections	52
SD-15	Agitator Mounting Flanges	53
SD-16	Sight Glass Design	54
SD-17	Internal Support Members	55
SD-18	Mitered Fittings	56
SD-19	Typical Nozzle Detail	56
SD-20	Double Tubesheet Heat Exchanger Bonnet Design	57
SD-21-1	Shaft Coupling Construction	58
SD-21-2	Shaft Coupling Seal Arrangements	59
SD-21-3	Fastener Seal Arrangements	60
SD-21-4	Shaft Steady Bearing	61
SD-21-5	Magnetically Coupled Mixer (Typical Bottom-Mount)	62
SD-21-6	Double Mechanical Cartridge Seal With Debris Well	63
SD-22-1	Typical Clean Steam System Isometric	64
SD-22-2	Clean Steam Point-of-Use Design	65
SD-22-3	Steam Traps for Clean Steam Systems	65
SD-23-1	Point-of-Use Piping	66
SD-23-2	Physical Break in Point-of-Use Piping	67
SD-23-3	Static Spray Device	67
SD-23-4	CIP Looped Header (Supply or Return)	68
SD-23-5	Zero-Static Chain	68
SD-23-6	Swing Elbow Arrangement	69
SD-24	Transfer Panel Tolerances	70
SD-25	Transfer Panel Looped Headers	71
SD-26	Transfer Panel Jumpers	72
SD-27-1	Fermentor Sterile Envelope	73
SD-27-2	Bioreactor Sterile Envelope	74



SD-28-1	Gas Sparging Assembly — Lance	74
SD-28-2	Gas Sparging Assembly — Sintered	75
SD-28-3	Gas Sparging Assembly — Ring	76
SD-28-4	Gas Sparging Assembly — Single Orifice	76
SD-29-1	Exhaust Gas Condenser	77
SD-29-2	Exhaust Gas Heater	77
SD-30	Electrically Heat Traced Filter Housing	77
DT-1	Clamp Conditions at Installation	86
MJ-1	Acceptable and Unacceptable Weld Profiles for Tube Welds	115
SG-1	Basic Components of a Seal	133
SG-2	Single Dry Running Contacting Seal	134
SG-3	Internally Mounted, Process Lubricated Contact Seal	134
SG-4	Externally Mounted, Process Lubricated Contact Seal	135
SG-5	Double Seal Installation	135
SG-6	Tandem Seal Installation	136
SG-7	Seal Piping and Lubrication Plans	137
SG-8	Gas Lubricated Noncontacting Double Seal	138
SG-9	Tandem Seal With Barrier System	138
SG-10	Typical Packing Installation	139
SG-11	V-Ring Packing for Reciprocating Applications	139
SG-12	Open Cross-Sectional Lip Seal	139
SG-13	Labyrinth Seal	139
SG-14	Typical Angle Valve With Rolling Diaphragm and Orifice	140
SG-15	Example of Sampling Valve With Uniformly Loaded Sliding Seal	141
SG-16	Typical In-Line Diaphragm Valve With Weir	141
SG-17	Typical Ball Valve Configuration	142
SG-18	Example of Secondary Seal Design	142
PM-1	Acceptable and Unacceptable Weld Profiles for Beadless Welds	149
CR-1	Options for Certification of Organizations	156
Tables		
GR-1	Inspector's Delegate Capabilities	4
SD-1	L/D Dimensions for Flow-Through Tee: Full-Size Standard Straight Tee With Blind Cap	78
SD-2	L/D Dimensions for Flow-Through Tee: Short Outlet Reducing Tee With Blind Cap	79
SD-3	Slope Designations for Gravity-Drained Lines	80
SD-4	Annular Spacing Recommendations for Hygienic Dip Tubes	80
SD-5	Recommended Flow Rates to Achieve 5 ft/sec (1.52 m/s)	80
SD-6	Recommended Flow Rates to Static Spray Devices to Ensure Coverage of Vertical Process Vessels	81
SD-7	Transfer Panel and Jumper Tolerances	81
DT-1	Nominal O.D. Tubing Sizes	87
DT-2	Hygienic Unions: Rated Internal Working Pressure	87
DT-3	Chemical Composition for Automatic Weld Ends, %	88
DT-4	Tangent Lengths	88
DT-5-1	Final Tolerances for Mechanically Polished Fittings and Process Components	89
DT-5-2	Hygienic Clamp Ferrule Standard Dimensions and Tolerances	90
DT-5-3	Hygienic Clamp Ferrule: Design Criteria	92
DT-6	Final Tolerances for Electropolished Fittings and Process Components	93
DT-7	Automatic Tube Weld: 90-deg Elbow	93
DT-8	Automatic Tube Weld: 45-deg Elbow	93
DT-9	Automatic Tube Weld: Straight Tee and Cross	94
DT-10	Automatic Tube Weld: Reducing Tee	94
DT-11	Automatic Tube Weld: Concentric and Eccentric Reducer	95
DT-12	Automatic Tube Weld: Hygienic Clamp Joint, 90-deg Elbow	95



DT-13	Automatic Tube Weld: Hygienic Clamp Joint, 45-deg Elbow	96
DT-14	Automatic Tube Weld: Short Outlet Hygienic Clamp Joint Reducing Tee	96
DT-15	Automatic Tube Weld: Short Outlet Hygienic Clamp Joint Tee	97
DT-16	Hygienic Clamp Joint: 90-deg Elbow	97
DT-17	Hygienic Clamp Joint: 45-deg Elbow	98
DT-18	Hygienic Clamp Joint: Straight Tee and Cross	98
DT-19	Hygienic Clamp Joint: Reducing Tee	99
DT-20	Hygienic Clamp Joint: Short Outlet Reducing Tee	100
DT-21	Hygienic Clamp Joint: Concentric and Eccentric Reducer	101
DT-22	Automatic Tube Weld: Ferrule	102
DT-23	Automatic Tube Weld: 180-deg Return Bend	103
DT-24	Hygienic Clamp Joint: 180-deg Return Bend	103
DT-25	Hygienic Mechanical Joint: Short Outlet Run Tee	104
DT-26	Hygienic Clamp Joint: Tube Weld Concentric and Eccentric Reducer	104
DT-27	Hygienic Clamp Joint: Short Outlet Tee	105
DT-28	Automatic Tube Weld: Instrument Tee	105
DT-29	Hygienic Clamp Joint: Instrument Tee	105
DT-30	Automatic Tube Weld: Cap	105
DT-31	Hygienic Clamp Joint: Solid End Cap	106
DT-V-1	Hygienic Clamp Joint: Weir Style Diaphragm Valve	107
MJ-1	Acceptance Criteria for Welds on Pressure Vessels and Tanks	111
MJ-2	Acceptance Criteria for Welds on Pipe	112
MJ-3	Acceptance Criteria for Welds on Tube	113
MJ-4	Acceptance Criteria for Tube-Attachment Welds	114
MJ-5	Tube/Pipe Diameter Limits for Orbital GTAW Performance Qualification	117
MJ-6	Weld Thickness Limits for Orbital GTAW Performance Qualification	117
SF-1	Acceptance Criteria for Stainless Steel and Higher Alloy Mechanically Polished Product Contact Surface Finishes	121
SF-2	Acceptance Criteria for Mechanically Polished and Electropolished Product Contact Surface Finishes	122
SF-3	R_a Readings for Product Contact Surfaces	122
SF-4	Acceptance Criteria for Passivated Product Contact Surface Finishes	123
SF-P-1	Acceptance Criteria for Polymer Product Contact Surface Finishes	125
SF-P-2	R_a Readings for Product Contact Surfaces	125
SG-1	Common Rotary Seal Materials for Biochemical and Sterile Service	143
PM-1	Size Comparison of Common Thermoplastic Sizing Standards	145
PM-2	Thermoset Elastomers Test Properties	152
MMOC-1	Wrought Stainless Steels: Nominal Compositions = (wt. %)	160
MMOC-2	Wrought Nickel Alloys: Nominal Compositions = (wt. %)	160
MMOC-3	Stainless Steel and Nickel Alloy Cast Designations	161
MMOC-4	Chemical Composition for 316L Automatic Weld Ends	164
MMOC-5	Filler Metals	165
MMOC-6	Consumable Inserts for Super-Austenitic and Duplex Stainless Steels	165
MMOC-7	Predicted Ferrite Number (FN) Ranges for Various 316 Product Forms and Welds	166
Nonmandatory Appendices		
A	Commentary: Slag	169
B	Material Examination Log and Weld Log	170
C	Slope Measurement	175
D	Rouge and Stainless Steel	176
E	Passivation Procedure Qualification	185
F	Corrosion Testing	195
G	Ferrite	198
H	Electropolishing Procedure Qualification	199



I	Vendor Documentation Requirements for New Instruments	201
J	Standard Process Test Conditions (SPTC) for Seal Performance Evaluation	205
K	Interpretation of Elastomer Material Property Changes	209
Index	211



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 subcommittees are

- (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 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 Product Contact Surface Finishes
- (6) Equipment Seals
- (7) Polymer-Based Materials
- (8) Certification
- (9) Metallic Materials of Construction

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. This edition was approved by ANSI on August 31, 2009.

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.

Based on these objectives, the following policy has been established on the usage in advertising of facsimiles of the symbols, certificates, 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 Symbol Stamp and/or a Certificate 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.”

The ASME Symbol Stamp 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 Symbol Stamp who may also use the facsimile in advertising to show that clearly specified items will carry the symbol. General usage is permitted only when all of a manufacturer’s items are constructed under the rules of the applicable code or standard.

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

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 Symbol Stamp described in the governing code or standard.

Markings such as “ASME” and “ASME Standard” or any other marking including “ASME” or the various Symbol Stamps shall not be used on any item that is not constructed in accordance with all of the applicable requirements of the code or standard.

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 _____
(Fabricator)



ASME BIOPROCESSING EQUIPMENT COMMITTEE

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

STANDARDS COMMITTEE OFFICERS

J. Ankers, *Chair*
R. J. Zinkowski, *Vice Chair*
P. D. Stumpf, *Secretary*

STANDARDS COMMITTEE PERSONNEL

J. Ankers , LifeTek Solutions, Inc.	K. D. Kimbrel , UltraClean Electropolish, Inc.
D. D. Baram , Clifton Enterprises	D. T. Klees , Endress + Hauser
E. A. Benway , Ironwood Specialist, Inc.	J. T. Mahar , Cuno, Inc.
C. R. Brown , Swagelok Co.	F. J. Manning , VNE Corp.
W. H. Cagney , Johnson & Johnson	D. M. Marks , DME Alliance, Inc.
R. D. Campbell , Bechtel National, Inc.	S. Murakami , Hitachi Plant Technologies Ltd.
A. P. Cirillo , Jacobs Field Services	H. Murphy , Global Stainless Ltd.
R. A. Cotter , Cotter Brothers Corp.	M. Pelletier , CRB
J. Dvorscek , Abbott Laboratories	L. J. Peterman , United Industries, Inc.
E. B. Fisher , Fisher Engineering	W. L. Roth , Procter & Gamble
M. M. Gonzalez , BioPharm Engineering Consultant	P. L. Sturgill , SWCC
R. Hanselka , IES, Inc.	P. D. Stumpf , The American Society of Mechanical Engineers
B. K. Henon , Arc Machines, Inc.	C. A. Trumbull , Paul Mueller Co.
M. A. Hohmann Consultant	J. D. Vogel , Process Facilities Services, Inc.
L. T. Hutton , Arkema, Inc.	R. J. Zinkowski , Burkert Fluid Control Systems

EXECUTIVE COMMITTEE

R. J. Zinkowski , <i>Chair</i> , Burkert Fluid Control Systems	L. T. Hutton , Arkema, Inc.
J. Ankers , <i>Vice Chair</i> , LifeTek Solutions, Inc.	K. D. Kimbrel , UltraClean Electropolish, Inc.
E. A. Benway , Ironwood Specialist, Inc.	D. T. Klees , Endress + Hauser
W. H. Cagney , Johnson & Johnson	F. J. Manning , VNE Corp.
R. D. Campbell , Bechtel National, Inc.	H. Murphy , Global Stainless Ltd.
A. P. Cirillo , Jacobs Field Services	D. Smith , Consultant
M. M. Gonzalez , BioPharm Engineering Consultant	C. Trumbull , Paul Mueller Co.
B. K. Henon , Arc Machines, Inc.	J. D. Vogel , Process Facilities Services, Inc.

SUBCOMMITTEE ON GENERAL REQUIREMENTS AND EDITORIAL REVIEW

E. A. Benway , <i>Chair</i> , Ironwood Specialist, Inc.	M. Embury , ASEPCO
P. W. Ainsworth , Burkert Fluid Control Systems	B. K. Henon , Arc Machines, Inc.
W. H. Cagney , Johnson & Johnson	M. A. Hohmann Consultant
R. D. Campbell , Bechtel National, Inc.	M. Pelletier , CRB
A. P. Cirillo , Jacobs Field Services	K. Seibert , ABEC, Inc.

SUBCOMMITTEE ON DESIGN RELATING TO STERILITY AND CLEANABILITY OF EQUIPMENT

D. M. Marks , <i>Chair</i> , DME Alliance, Inc.	M. Embury , ASEPCO
M. Pelletier , <i>Vice Chair</i> , CRB	E. B. Fisher , Fisher Engineering
J. Ankers , LifeTek Solutions, Inc.	G. P. Foley, Sr. , PBM, Inc.
M. L. Balmer , Sanofi Pasteur	R. F. Foley , Parsons Corp.
B. A. Billmyer , Central States Industrial Equipment	J. Fortin , BMS
T. M. Canty , JM Canty Associates, Inc.	M. Gagne , AlphaBio, Inc.
C. Chapman , GEMU Valves	J. N. Haldiman , MECO
R. A. Cotter , Cotter Brothers Corp.	R. Hanselka , IES, Inc.
J. Daly , Jacobs Engineering	S. M. Hartner , Sanofi Pasteur
J. Davis , GE Healthcare	J. Henon , Behringer
J. Dvorscek , Abbott Laboratories	T. L. Hobick , Holland Applied Technologies



M. Inoue, Fujikin of America, Inc.
M. J. Kennedy, Glaxosmithkline
A. J. Kranc, Tech Source
P. M. Kubera, Associated Bioengineers & Consultants
J. D. Larson, DCI, Inc.
G. Lewandowski, Purity Systems, Inc.
J. Mahar, Cuno, Inc.
R. Manser, Bioengineering, Inc.
K. Matheis, Jr., Complete Automation, Inc.
D. P. McCune, Allegheny Bradford Corp.
M. McFeeters, Raplan, Inc.
R. Michalak, Eli Lilly & Co.
K. Milton, Alfa Laval
J. W. Minor, Paul Mueller Co.

L. Munda, Genentech
A. Nemenoff, Habonim Industrial Valves Ltd.
T. Nixon, Amgen/Jacobs Engineering
A. Obertanec, LJ Star, Inc.
W. Ortiz, Eli Lilly & Co.
C. N. Pacheco, Amgen, Inc.
G. Page, Jr., Nicholson Steam Trap
P. R. Pierre, Pierre Guerin SAS
J. J. Rotman, Integrated Project Services
R. T. Warf, K. W. Tunnell
A. Wells, Spirax Sarco
K. J. Westin, Roplan
M. T. Wilson, Lonza Biologics
R. J. Zinkowski, Burkert Fluid Control Systems

SUBCOMMITTEE ON DIMENSIONS AND TOLERANCES

F. J. Manning, *Chair*, VNE Corp.
D. J. Mathien, *Vice Chair*, Behringer Corp.
B. A. Billmyer, Central States Industrial Equipment
D. Brockman, Alfa Laval, Inc.
C. H. Carnes, Purity Systems, Inc.
J. Chapek, Swagelok Co.
C. Chapman, GEMU Valves
P. M. Dunbar, VNE Corp.
R. J. Elbich, Exigo Manufacturing
R. F. Foley, Parsons Corp.
M. M. Gonzalez, BioPharm Engineering Consultant

R. P. Klemp, Advance Fittings Corp.
G. Kroehnert, Neumo
I. Lisboa, Stockval Tecno Comercial Ltda.
P. McClune, ITT Engineered Valves
H. P. G. Montgomery, Tank Components Ind.
H. Murphy, Global Stainless Ltd.
L. J. Peterman, United Industries, Inc.
D. Perona, Advance Fittings Corp.
C. Taylor, Crane Process Flow Technologies
T. G. Wilson, Top Line Process Equipment Co.
T. J. Winter, Winter Technologies

SUBCOMMITTEE ON MATERIAL JOINING

C. A. Trumbull, *Chair*, Paul Mueller Co.
R. D. Campbell, *Vice Chair*, Bechtel National, Inc.
E. A. Benway, Ironwood Specialist, Inc.
W. P. Burg, DECCO, Inc.
J. Cosentino, MECO
R. A. Cotter, Cotter Brothers Corp.
R. G. Duran, QAM
J. Dvorscek, Abbott Laboratories
C. W. Elkins, Central States Industrial Equipment
E. L. Gayer, Holloway America
B. K. Henon, Arc Machines, Inc.
M. A. Hohmann, Consultant

W. M. Huitt, W.M. Huitt Co.
C. E. Kettermann, Rath Gibson
K. Matheis, Jr., Complete Automation, Inc.
W. Ortiz, Eli Lilly & Co.
H. Reinhold, Purity Systems, Inc.
W. L. Roth, Procter & Gamble
J. A. Shankel, BMW Constructors, Inc.
D. P. Sisto, Purity Systems, Inc.
P. L. Sturgill, SWCC
B. J. Uhlenkamp, DCI, Inc.
R. Vermillion, Genentech
C. Weeks, CRB Builders, LLC
J. Williams, Enerpipe Systems, Inc.

SUBCOMMITTEE ON SURFACE FINISH

M. M. Gonzalez, *Chair*, BioPharm Engineering Consultant
C. H. Carnes, *Vice Chair*, Purity Systems, Inc.
R. E. Avery, Nickel Institute
P. H. Banes, Astro Pak Corp.
E. R. Blessman, Plymouth Tube
D. Brockmann, Alfa Laval, Inc.
J. Consentino, MECO
J. R. Daniels, ITT Engineered Valves
C. W. Elkins, Central States Industrial Equipment
E. L. Gayer, Holloway America
J. Hamilton, Rath Gibson
S. T. Harrison, Harrison Electropolishing L.P.
B. K. Henon, Arc Machines, Inc.
G. Kroehnert, Neumo
C. F. Kuo, King Lai International

M. Lechevet, SPX-Process Equipment
L. Lei, Saint-Gobain Performance Plastics
F. J. Manning, VNE Corp.
D. J. Mathien, Behringer Corp.
R. McGonigle, Active Chemical Corp.
H. Murphy, Global Stainless Ltd.
D. Perona, Advance Fittings Corp.
L. J. Peterman, United Industries, Inc.
P. A. Petrillo, Millenium Facilities Resources
R. K. Raney, UltraClean Electropolish, Inc.
J. Rau, Dockweiler AG
P. D. Sedivy, Rath Gibson
M. S. Solamon, Feldmeier Equipment, Inc.
C. Taylor, Crane Saunders
C. A. Trumbull, Paul Mueller Co.



SUBCOMMITTEE ON SEALS

J. D. Vogel, *Chair*, Process Facilities Services, Inc.
D. D. Baram, Clifton Enterprises
L. Bongiorno, Flow Smart, Inc.
M. L. Bridge, Swagelok
C. Brown, Swagelok
S. J. Defusco, Integra Companies, Inc.
D. Donnelly, James Walker & Co. Ltd.
J. Drago, Garlock Sealing Technologies
P. Esbensen, Alfa Laval Kolding A/S
G. P. Foley, PBM, Inc.
M. C. Gagne, AlphaBio, Inc.
T. Harvey, Gemu Valves, Inc.
D. Helmke, Flow Products LLC
F. Hinlopen, Alfa Laval, Inc.
L. T. Hutton, Arkema, Inc.
D. T. Klees, Endress + Hauser

M. McFeeters, Roplan, Inc.
R. A. Michalak, Eli Lilly & Co.
D. W. Newman, Newman Sanitary Gasket Co.
A. R. Obertanec, LJ Star, Inc.
C. N. Pacheco, Amgen
G. Page, Jr., Nicholson Steam Trap
A. K. Parker, Jr., W. L. Gore & Associates, Inc.
M. Pelletier, CRB
R. W. Schnell, DuPont Performance Elastomers
R. A. Smith, Flowserve Corp.
E. Souliere, Fisher Controls International, LLC
J. Vitti, Crane/Saunders Bio-Pharm
P. J. Warren, James Walker & Co., Ltd.
K. J. Westin, Roplan, Inc.
R. J. Zinkowski, Burkert Fluid Control Systems
M. A. Zumbrum, Maztech, Inc.

SUBCOMMITTEE ON POLYMERS AND ELASTOMERS

L. T. Hutton, *Chair*, Arkema, Inc.
R. Hanselka, *Vice Chair*, IES
J. K. Argasinski, Solvay Solexis
J. Davis, GE Healthcare
S. J. DeFusco, Integra Companies, Inc.
D. Donnelly, James Walker & Co. Ltd.
J. Drago, Garlock Sealing Technologies
M. W. Eggers, W. L. Gore & Associates, Inc.
T. B. Fridman, Vanasyl, LLC
P. G. Galvin, George Fischer, Inc.
R. Govaert, Asahi America, Inc.
P. R. Khaladkar, DuPont

D. M. Marks, DME Alliance, Inc.
R. Pembleton, DuPont Fluoropolymer
E. Pitchford, Parker Page
R. W. Schnell, DuPont Performance Elastomers
R. P. Schroder, Newman Gasket
D. A. Seiler, Arkema, Inc.
J. Stover, NewAge Industries, Inc./AdvantaPure
E. Tam, Teknor Apex Co.
P. Tollens, Endress + Hauser
J. D. Vogel, Process Facilities Services, Inc.
P. Warren, James Walker & Co. Ltd.
M. A. Zumbrum, Maztech, Inc.

SUBCOMMITTEE ON METALLIC MATERIALS OF CONSTRUCTION

K. D. Kimbrel, *Chair*, UltraClean Electropolish, Inc.
P. L. Sturgill, *Vice Chair*, SWCC
R. Anderson, Northland Stainless, Inc.
R. E. Avery, Nickel Institute
J. R. Daniels, ITT Engineered Valves
J. D. Fritz, TMR Stainless
S. T. Harrison, Harrison Electropolishing L.P.
W. M. Huitt, W. M. Huitt Co.

C. E. Kettermann, Rath Gibson
K. J. Matheis, Sr., Complete Automation, Inc.
D. P. McCune, Allegheny Bradford Corp.
R. McGonigle, Active Chemical Corp.
J. Rau, Dockwelier AG
H. Reinhold, Purity Systems
B. J. Uhlenkamp, DCI, Inc.
R. Vermillion, Genentech
T. J. Winter, Winter Technologies



EUROPEAN BPE SUBCOMMITTEE

H. Murphy, *Chair*, Global Stainless Ltd.
Y. Binenfeld, EGMO Ltd.
D. Birch, Crane Process Flow Technologies
E. Gallagher, Elan Pharma
J. Henry, Advanced Couplings Ltd.
J. Kranzpillar, Tuchenhausen GmbH

G. Kroehnert, Neumo
R. P. Pierre, Pierre Guerin SAS
F. Riedewald, CEL International Ltd.
A. van der Lans, Centocor BV
S. J. Watson-Davies, PBM, Inc.
P. Williams, Crane Process Flow Technologies Ltd.

SUBCOMMITTEE ON CERTIFICATION

R. D. Campbell, *Chair*, Bechtel National, Inc.
T. L. Hobick, *Vice Chair*, Holland Applied Technologies
C. E. Kettermann, *Vice Chair*, Rath Gibson
B. A. Billmyer, Central States Industrial Equipment
D. Brockmann, Alfa Laval, Inc.
P. M. Dunbar, VNE Corp.
J. Dvorscek, Abbott Laboratories
R. J. Elbich, Exigo Manufacturing
E. L. Gayer, Holloway America
M. M. Gonzalez, BioPharm Engineering Consultant
D. R. Helmke, Flow Products LLC
M. A. Hohmann, Consultant

W. M. Huitt, W. M. Huitt Co.
L. T. Hutton, Arkema, Inc.
K. D. Kimbrel, UltraClean Electropolish, Inc.
D. T. Klees, Endress + Hauser
R. P. Klemp, Advance Fittings Corp.
A. Landolt, Enerfab, Inc.
K. J. Matheis, Sr., Complete Automation, Inc.
D. J. Mathien, Behringer Corp.
D. P. McCune, Allegheny Bradford Corp.
A. R. Obertanec, LJ Star, Inc.
W. L. Roth, Procter & Gamble
J. A. Shankel, BMW Constructors, Inc.
T. G. Wilson, Top Line Process Equipment Co.

SUBCOMMITTEE ON PROCESS INSTRUMENTATION

D. T. Klees, *Chair*, Endress + Hauser
T. M. Canty, *Vice Chair*, J. M. Canty, Inc.
J. Cheatham, *Secretary*, Weed Instruments
B. B. Bailey, Flow Products, LLC
R. Bond, Anderson Instrument Co.

P. E. Canty, Swagelok Biopharm Services Co.
J. M. Featherston, Weed Instrument Co.
R. Govaert, Mettler-Toledo/Ingold
D. Kwilosz, Eli Lilly & Co.
M. Robinson, Endress + Hauser



ASME BPE-2009 SUMMARY OF CHANGES

Following approval by the ASME BPE Committee and ASME, and after public review, ASME BPE-2009 was approved by the American National Standards Institute on August 31, 2009.

ASME BPE-2009 includes editorial changes, revisions, and corrections introduced in ASME BPE-2007, as well as the following changes identified by a margin note, **(09)**.

<i>Page</i>	<i>Location</i>	<i>Change</i>
1–6	GR-1(b)	Revised
	GR-4	Revised in its entirety
	GR-9	Revised
	Table GR-1	Added
7–13	GR-10	Revised
14	SD-2	Revised
	SD-3	Revised
	SD-3.1.7	Revised
	SD-3.1.8	Revised
	SD-3.2	Revised in its entirety
15	SD-3.4	Subparagraphs SD-3.4.1 through SD-3.4.3 revised
	SD-3.5.2	Second paragraph revised
	SD-3.6.1	Last paragraph revised
	SD-3.6.4	Revised
	SD-3.7.8	Revised
16	SD-3.7.9	Revised
	SD-3.7.10	Added
	SD-3.7.11	Added
	SD-3.8(m)	Revised
	SD-3.10	Revised in its entirety
17	SD-3.11.1	First paragraph revised
	SD-3.11.6	Revised
	SD-3.12.1	First paragraph revised
18	SD-4.1.1(d)	Revised
	SD-4.1.2	Revised in its entirety
19	SD-4.1.3(b)	Revised



<i>Page</i>	<i>Location</i>	<i>Change</i>
	SD-4.1.4(a)(4)	Revised
	SD-4.2.1(d)	Revised
	SD-4.2.2(c)	Revised
20	SD-4.3.1	Subparagraphs (a) through (d) and (g) revised
	SD-4.3.2	Subparagraphs (a) and (b) revised
	SD-4.4	Subparagraphs (a), (c), and (d) revised
	SD-4.5	Revised in its entirety
21	SD-4.6	Title revised
	SD-4.6.1(b)	Revised
	SD-4.6.4	Added
22	SD-4.7.1(h)	Revised
	SD-4.7.2	(1) Subparagraphs (b), (d), (h), (j), and (m) revised (2) Subparagraph (q) deleted (3) Fig. SD-14-1 deleted (4) Subparagraphs (r) through (t) redesignated as (q) through (s) (5) New subparagraph (r) revised
	SD-4.7.3(c)	Revised
	SD-4.7.4(c)	Revised
23	SD-4.8.1(f)	Revised in its entirety
25	SD-4.9.1	Subparagraphs (c), (c)(2), (g)(2), (g)(3), and (i) revised
	SD-4.9.2	Revised in its entirety
26	SD-4.11.1(e)	Revised
	SD-4.11.3(c)	Revised
	SD-4.11.4(a)	Revised
27–32	SD-4.14	Revised in its entirety
	SD-4.15	Revised in its entirety
	SD-4.16.1(b)	Revised
	SD-4.16.2	Subparagraphs (b) and (d) revised
33–36	SD-4.16.6	Subparagraphs (b) through (d) revised
	SD-4.17	Added
	SD-4.18	Added
37	SD-5.2	Revised in its entirety
	SD-6	Third paragraph revised
39	Fig. SD-1	Revised in its entirety
40	Fig. SD-2	Illustration (f) revised
45	Fig. SD-7-1	Fig. SD-7 redesignated as Fig. SD-7-1



<i>Page</i>	<i>Location</i>	<i>Change</i>
	Fig. SD-7-2	Added
46	Fig. SD-7-3	Added
	Fig. SD-7-4	Added
47	Fig. SD-7-5	Added
52	Fig. SD-14	Fig. SD-14-2 redesignated as Fig. SD-14
53	Fig. SD-15	Illustration (c) added
66	Fig. SD-23-1	Fig. SD-23 redesignated as Fig. SD-23-1
67	Fig. SD-23-2	Fig. SD-23-1 redesignated as Fig. SD-23-2
	Fig. SD-23-3	Added
68	Fig. SD-23-4	Added
	Fig. SD-23-5	Added
69	Fig. SD-23-6	Added
73	Fig. SD-27-1	Added
74	Fig. SD-27-2	Added
	Fig. SD-28-1	Added
75	Fig. SD-28-2	Added
76	Fig. SD-28-3	Added
	Fig. SD-28-4	Added
77	Fig. SD-29-1	Added
	Fig. SD-29-2	Added
	Fig. SD-30	Added
80	Table SD-5	Added
81	Table SD-6	Added
82, 83	DT-1	Third paragraph moved to DT-6
	DT-6	(1) First paragraph revised (2) Last paragraph added
	DT-8	First and third paragraphs revised
	DT-10	Revised in its entirety
85	DT-V-4	Second paragraph revised
	DT-V-8	Revised
86	Fig. DT-1	Added
87	Table DT-2	Title and General Notes revised
88	Table DT-4	General Note revised
89	Table DT-5-1	(1) Table DT-5 redesignated as Table DT-5-1 (2) Last two columns added (3) General Note revised
90, 91	Table DT-5-2	(1) Table DT-5-1 redesignated as Table DT-5-2



<i>Page</i>	<i>Location</i>	<i>Change</i>
		(2) Revised in its entirety
92	Table DT-5-3	Added
93	Table DT-8	Callout added to illustration
95	Table DT-11	Twelve rows deleted
96	Table DT-13	Callout added to illustration
98	Table DT-17	Callout added to illustration
101	Table DT-21	Nine rows deleted
104	Table DT-26	Nine rows deleted
105	Table DT-30	(1) Illustration revised (2) General Note added (3) Note (1) deleted
106	Table DT-31	Added
108	MJ-2	(1) Subparagraphs MJ-2.3 through MJ-2.6 redesignated as MJ-2.4 through MJ-2.7, respectively (2) New subparagraph MJ-2.3 added
110	MJ-6.4.1	Revised
112	Table MJ-2	In fourth column, last entry revised
116	MJ-7.2.3	Last paragraph revised
117, 118	MJ-8.4	Added
	Table MJ-5	Added
	Table MJ-6	Added
	MJ-9.2	Revised
	MJ-9.3	Revised in its entirety
120	SF-5	Subparagraphs (c) and (d) revised
121	Table SF-1	Title and General Note (b) revised
123–125	Table SF-4	Added
	SF-7	Revised
	SF-8	Revised
	SF-9	Added
	SF-10	Added
	Subsection SF-P	Added
127	SG-3.1.6	Revised
	SG-3.1.8	Added
128	SG-3.4.1	Revised
	SG-3.4.2	(1) Subparagraphs (e) and (h) revised (2) Penultimate paragraph revised
132	SG-4.2	Added
	SG-4.3	Added
142	Fig. SG-18	Added
150	PM-4	Revised
151–154	PM-6	Added
	PM-7	Added
	Table PM-2	Added
	PM-8	Added
155–158	Part CR	Added
159–167	Part MMOC	Added
176–184	Nonmandatory Appendix D	Added
185–194	Nonmandatory Appendix E	Added
195–197	Nonmandatory Appendix F	Added
198	Nonmandatory Appendix G	Added
199, 200	Nonmandatory Appendix H	Added
201–204	Nonmandatory Appendix I	Added
205–208	Nonmandatory Appendix J	Added
209, 210	Nonmandatory Appendix K	Added
211–213	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
- (09) (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 applies to new construction only. It is not intended to apply to the operation, examination, inspection, testing, maintenance, or repair of piping/tubing, or equipment that has been placed in service. The provisions of this Standard may be optionally applied for those purposes, although other considerations may be necessary. For installations between new construction that ties into an existing system that has been placed in service, the boundaries and requirements must be agreed to between the owner/user and contractor and inspection contractor.

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

(09)

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

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

(b) *Piping, Tubing, and Non-Code Vessels*. Owner's inspector, as defined in ASME B31.3, paras. 340.4(a) and (b). Inspector's Delegate, as defined in GR-10, meets the additional requirements listed in GR-4.1.

