

Bioprocessing Piping and Equipment Design

A Companion Guide for the ASME BPE Standard

William M. (Bill) Huitt



WILEY

BIOPROCESSING PIPING AND EQUIPMENT DESIGN

Wiley-ASME Press Series List

Introduction to Dynamics and Control in Mechanical Engineering Systems	То	March 2016
Fundamentals of Mechanical Vibrations	Cai	May 2016
Nonlinear Regression Modeling for Engineering Applications	Rhinehart	September 2016
Modeling, Model Validation, and Enabling Design of Experiments Stress in ASME Pressure Vessels	Jawad	November 2016
Combined Cooling, Heating, and Power Systems	Shi	January 2017

BIOPROCESSING PIPING AND EQUIPMENT DESIGN

A COMPANION GUIDE FOR THE ASME BPE STANDARD

William M. (Bill) Huitt

This Work is a co-publication between ASME Press and John Wiley & Sons, Inc.





Copyright © 2017, The American Society of Mechanical Engineers (ASME), 2 Park Avenue, New York, NY, 10016, USA (www.asme.org). All rights reserved

Published by John Wiley & Sons, Inc., Hoboken, New Jersey

Published simultaneously in Canada

No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, scanning, or otherwise, except as permitted under Section 107 or 108 of the 1976 United States Copyright Act, without either the prior written permission of the Publisher, or authorization through payment of the appropriate per-copy fee to the Copyright Clearance Center, Inc., 222 Rosewood Drive, Danvers, MA 01923, (978) 750-8400, fax (978) 750-4470, or on the web at www.copyright.com. Requests to the Publisher for permission should be addressed to the Permissions Department, John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ 07030, (201) 748-6011, fax (201) 748-6008, or online at http://www.wiley.com/go/permissions.

Limit of Liability/Disclaimer of Warranty: While the publisher and author have used their best efforts in preparing this book, they make no representations or warranties with respect to the accuracy or completeness of the contents of this book and specifically disclaim any implied warranties of merchantability or fitness for a particular purpose. No warranty may be created or extended by sales representatives or written sales materials. The advice and strategies contained herein may not be suitable for your situation. You should consult with a professional where appropriate. Neither the publisher nor author shall be liable for any loss of profit or any other commercial damages, including but not limited to special, incidental, consequential, or other damages.

For general information on our other products and services or for technical support, please contact our Customer Care Department within the United States at (800) 762-2974, outside the United States at (317) 572-3993 or fax (317) 572-4002.

Wiley also publishes its books in a variety of electronic formats. Some content that appears in print may not be available in electronic formats. For more information about Wiley products, visit our web site at www.wiley.com.

Library of Congress Cataloging-in-Publication Data

Names: Huitt, William M., 1943- author.

Title: Bioprocessing piping and equipment design: a companion guide for the ASME BPE standard / William M. (Bill) Huitt.

Description: Hoboken, New Jersey: John Wiley & Sons, Inc., [2017] | Includes bibliographical references and index.

Identifiers: LCCN 2016024930l ISBN 9781119284239 (cloth) | ISBN 9781119284253 (ePub) | ISBN 9781119284246 (Adobe PDF)

Subjects: LCSH: Biochemical engineering-Equipment and supplies-Standards-Handbooks, manuals, etc. | Chemical plants-Piping-Standards-Handbooks, manuals, etc.

Classification: LCC TP157 .H\87 2017 | DDC 660.6/3–dc23 LC record available at https://lccn.loc.gov/2016024930

Printed in the United States of America

Set in 10/12pt Times by SPi Global, Pondicherry, India

ASME BPE 2014

Its Organization and Roster of Members

Organization

The ASME Bioprocessing Equipment (BPE) Standards Committee membership in 2014 was made up, in whole, of 195 members holding membership to anywhere from one to five committee/subcommittee memberships. The ASME BPE Standards Committee is, as self-described, considered a "committee," referring to itself as the ASME BPE Standards Committee, or simply Standards Committee. As indicated in Figure 1, organizational chart, the ASME BPE Standards Committee reports to the ASME Board on Pressure Technology Codes and Standards (BPTCS). Aside from the BPE Standards Committee, reporting also to the BPTCS are the Boiler and Pressure Vessel Code (BPVC) Committees, the B16 and B31 Committees, and other committees related to pressure containing subject matter.

The ASME BPE Committee is divided into a set of subtier groups of interest referred to as subcommittees. In other Standards Committees these subtier groups are referred to as "subgroups," not so with the BPE Standards Committee. Among this group of subcommittees there is no hierarchy. They are simply divided by and focused on the various subject matter interests of the BPE Standard and report directly to the BPE Standards Committee. These subject matter interests are referred to as Parts with the following identifiers as referenced in Table 1.

Referring to Figure 2, it is apparent that each of the subcommittee groups reports to the BPE Standards Committee. The work these subcommittees do, whether it's maintaining an existing part in the standard, respective of the subcommittee's part title, or in developing a new part for the standard, there is an ongoing liaison effort that takes place between all of the subcommittees. This helps in diverting conflicts among the various subcommittees and in improving content of the standard as a whole.

vi ASME BPE 2014

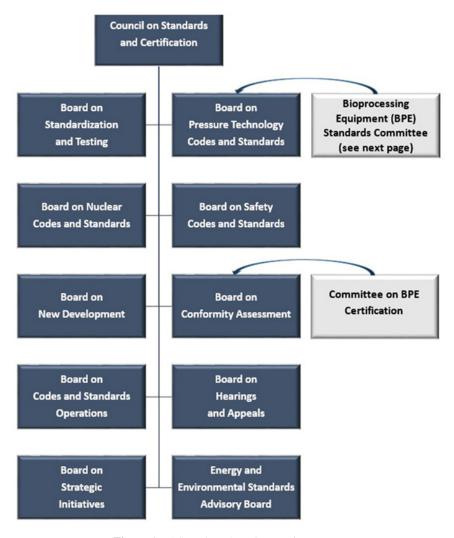


Figure 1 ASME boards and governing groups

 Table 1
 Subcommittee subject matter part identifiers

Part	Title	Part	Title
GR	General requirements	SG	Sealing components
SD	Systems design	PM	Polymeric materials
DT	Dimensions and tolerances	CR	Certification
MJ	Materials joining	MM	Metallic materials
SF	Surface finishes	PI	Process instrumentation

ASME BPE 2014 vii

Each of the subcommittees is made up of a balanced membership wherein each member is assigned an interest category as follows:

- Designer/constructor (AC)—An organization performing design or designrelated services, fabrication or erection, or both
- General interest (AF)—Consultants, educators, research and development organization personnel, and public interest persons
- Manufacturer (AK)—An organization producing components or assemblies
- Material manufacturer (AM)—An organization producing materials or ancillary material-related accessories or component parts
- User (AW)—An organization utilizing processes and/or facilities covered by the applicable standards

No one classification shall be represented by more than one-third of the subcommittee membership. By maintaining this balanced membership, no single interest group, whether it be a manufacturer or end user, or any other group, can monopolize the decisions made and the topics discussed in the subcommittee meetings.

Heading up the committees and subcommittees are elected officers of those groups. Each committee, subcommittee, and task group will have a chair and vice-chair. And depending on the size and complexity of any subcommittee, they may also have multiple vice-chairs and a secretary. The secretary for the BPE Standards Committee is an ASME staff secretary that not only provides a direct in-house link to ASME but also helps the entire membership maneuver through the procedural maze now and then when such procedural questions arise.

A subtier of groups under that of the subcommittees are the task groups. These are ad hoc groups that are assembled for a specific task and report to a particular subcommittee. These groups are where the majority of work gets done in standards development and maintenance. Some projects these groups are tasked to do are relatively small. But rather than take up time trying to resolve an issue during a subcommittee meeting, the issue or task will be assigned a temporary number, and volunteers are asked to work on resolving such issues offline or outside the confines of the subcommittee meeting.

Other task group issues are much more complex and involved. These tasks may take years to resolve and prepare for the balloting process. The balloting process itself is rigorous in that a proposal has to obtain consensus approval at multiple stages of the balloting process. That is, a proposal is balloted at the subcommittee level, then at the standards committee level, then to the board level, and finally to ANSI for procedural approval.

At each step of the process, a consensus has to be reached and each negative response has to be responded to with an attempt made to resolve all objections. But a consensus does not require unanimous approval. It does require approval by a simple majority of all of those voting. And to document all of this, ASME uses a system titled C&S Connect, the C&S standing for Codes and Standards. The basis for these procedures is consistent with the principles established for the World Trade Organization's Technical Barriers to Trade Committee.

viii ASME BPE 2014

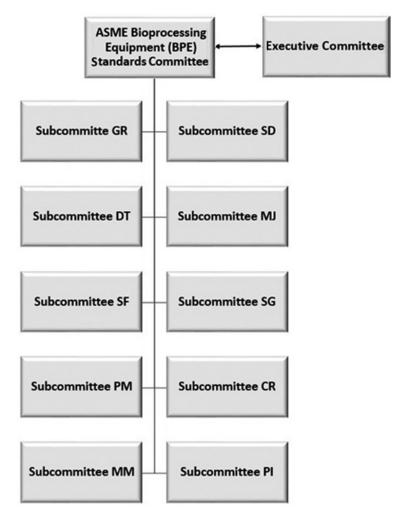


Figure 2 ASME BPE Standards Committee

The BPE Executive Committee, as seen in Figure 2, is a direct subset of the Standards Committee. This group is responsible for recommending approval or discharge of personnel and the governing of administrative items or actions as they relate to ASME policy and procedures. The vice-chair of the Standards Committee automatically serves as chair of the Executive Committee, and the chair of the Standards Committee automatically serves as vice-chair of the Executive Committee. Subcommittee chairs automatically hold membership to the Executive Committee, but membership on the Executive Committee beyond that does not require being a member of the Standards Committee.

In referring to Figure 1, there is an adjunct committee that is closely related to the Part CR subcommittee with the title of "Committee on BPE Certification" (CBPEC). This is a committee on its own and reports, as shown, to the Board on Conformity

ASME BPE 2014 ix

Assessment (BCA). I will refer you to Section 1.2 of this book for a very brief synopsis of the scope of Part CR and all of the other subcommittees. But to clarify here how these two groups, Part CR and the CBPEC, work together is relatively simple.

The Part CR subcommittee is the group that developed and maintains Part CR in the standard, which intrinsically defines what BPE Certification is and how it interacts with the standard. It defines what the requirements are for BPE Certification and provides guidance on how to become a BPE Certificate Holder.

The CBPEC is the assessment and enforcement arm of the certification process. This is the group that, in working with the BCA, performs audits of those applying for BPE Certification; they review the subsequent auditor's assessment report and then make a determination, based on the auditor's report and deliberation, whether or not to recommend approval of the applicant. The final decision on that point is made by the BCA.

BPE Standards Committee Meetings

All committee and subcommittee meetings of the BPE Standard are open to the public. The only meetings not open to the public are those meetings in which discussions and decisions regarding personnel are held. The CBPEC meetings are closed, but these are conformity assessment meetings that typically follow the meetings of the CR subcommittee and are not BPE meetings.

The BPE Standards meetings follow an evolved schedule that runs for four days, Monday through Thursday. The Monday meetings typically include sub-committees CR and GR and task group meetings for any active task groups that need to discuss and finalize any outstanding issue relating to a task group's work.

Most task group activity takes place between the three committee meetings each year via conference calls and e-mail communication. Depending on the complexity and scope of a task group, some discussions and resolution need to take place in a face-to-face setting. These are the meetings that are scheduled for the Monday task group meetings. Tuesday and Wednesday are the two days in which the balance of subcommittees will meet. Thursday is the Standards Committee meeting at which the Standards Committee reports and all subcommittees report on what transpired at each of their meetings during the week.

As mentioned, all meetings are generally open to the public. New attendees should know that they are free to visit any meeting at any time except as explained previously. Only members are permitted to vote on subcommittee business. But any visitor is free to voice an opinion or make a point during a tabled discussion. It should also be known that visitors to these meetings are eligible to participate in task group work. If a visitor is considering membership, their work on task groups elevates their possibility of being approved.

Up until 2016 the BPE Standards Committee met three times each year. These meetings were held each year in January, May/June, and September/October. As a trial run it was voted on and planned that the committee hold only two meetings in 2016, one meeting in January and a second meeting in September. This was to test the waters to see if the committee could maintain the same level of efficiency and production of work on the standard with only two meetings per year.

X ASME BPE 2014

A decision as to whether or not to remain with a two meeting per year format would not be decided upon until possibly the January 2017 meeting. That decision, I suspect, will be based largely on what is accomplished during 2016 and to what extent, good or bad, did the missing third meeting play a part.

Roster of Members

The following is a listing of all members of the ASME BPE Standards Committee and members of subcommittees reporting to the Standards Committee. The names are in alphabetical order and indicate if that person is a chair, vice-chair, or secretary of a committee or subcommittee and which subcommittees they are members of:

		ARDS COMMITTEE A		JBCC	ммі	TTEE	MEN	BERS	3		
Abbreviations and Terminology used b EC = Executive Committee		Systems Design									ibution to
DT = Dimensions and Tolerances		Surface Finishes									ntributing
GR = General Requirements	SG =	Sealing Components	member		ossess th	e technic	al qualifi	ications n	ecessary f	or individi	ual voting
MJ = Materials Joining					al is co	nsidered	a "Dele	oate " wh	ich impli	ec that the	ey are an
MM = Metallic Materials PI = Process Instrumentation											of experts
PM = Polymeric Materials											a clearly
SC = Standards Committee			defined	interest	in partic	ipating or	n BPE su	bcommitt	ees.		
				١.,	V. CHAIR	2					
NAME		AFFILIATION		🖺	≩	1 2		CLID	COMMI	TTEER	
NAME		AFFILIATION		CHAIR	5	E E		SUB	COMMI	TTEES	
				~	>	SECRETAR					
					_	S					
Allard, Michael		NewAge Industries		_	_		PM	-	-	-	-
Anant, Janmeet		EMD Millipore		_	_	_	PM	-	-	-	-
Anderson, Paul		Northland Stainless Inc.		_			MM	-	-	-	-
Andrews, Jacob		Zenpure Americas, Inc.		_	_		PM	-	-	-	-
Andrews, Todd		Colder Products Company		00	no.	_	PM	DI.	-	-	-
Ankers, Jay		Ocean Alloys LLC		SC	EC	<u> </u>	SD	PI1	-	-	-
Anton, George		Qualtech Inc.		_	_		PI	on	-	-	-
Avery, Richard E.		Nickel Institute		_	on	_	MM	SF	-	-	-
Balmer, Melissa L.		Sanofi Pasteur		_	SD	_	SC	-	-	-	-
Banes, Patrick H.		Astro Pak Corp.			SF		001	0.01	-	-	-
Baram, David		Clifton Enterprises		_	_	_	SC1	SG1	2411	-	-
Benway, Ernest A.		Ironwood Specialist Inc.					SC1	GR ¹	MJ ¹	-	-
Bhaila, Kadeem		ITT Engineered Valves, LLC	:	_	MJ	_	277	or	-	-	-
Bickel, Neill		Genentech				_	MJ	SF	D.T.	l op	-
Billmyer, Bryan A. Blumenthal, Joel		Central States Industrial Equ	ıp.	_		_	SC	CR SG	DT	SD	-
Bond, Richard		Perceptual Focus LLC Anderson Instrument Co.		-	-	_	PI PI	SG	-	-	-
Bradley, Jeffrey L.		Eli Lilly and Co.		-	-	-	SD1	GR1	MJ ¹	-	-
Bragg, Chuck J.		Burns Engineering, Inc.		-	_	_	PI.	GK.	MJ.	-	-
Brockmann, Dan		Alfa Laval Inc.		-	-	-	CR	DT	SF	-	-
Burg, William P.		DECCO Inc.		_	_	MJ	GR	MJ	SF	-	_
Cagne, William H.		JSG, LLC		-	_	IVIJ	SC	EC	GR	-	_
Campbell, Dr. Richard D., PE		Bechtel		MJ	-		SC	EC	GR	CR	MM
Canty, Thomas		J M Canty Inc.		1817	PI	_	SD1	EC	OK	CK	INTINI
Carl A. Johnson		Genentech Inc.		-	111		SD	_	-	-	_
Chapman, Chuck		Gemu Valves					DT	SD	-	-	-
Chih-Feng, Kuo		King Lai International					SF	50	-	-	
Cirillo, Anthony P.		Cirillo Consulting Services I	LC				SC1	EC1	GR1	-	
Cohen, Donald K.		Michigan Metrology, LLC					SF1	1	-		
Conley, Indumathi		DPS Engineering					SD				
Conn, Carlyle C.		Top Line Process Equipment	Co.				SF				
Cook, Todd J.		T & C Stainless, Inc.					MJ	SF			
Cooper, Mark		United Stainless					SF				
Cosentino, Rodolfo		Giltec Ltda					DT	PI			
Cotter, Randolph A.		Cotter Brothers Corporation					SC	MJ	SD		
Crawley, Jere		Jacobs Engineering Group, I	nc.				SD				
Daly, James		BSI Engineering					SD				
Daniels, James R., PE		ITT Engineered Valves, LLC	2				SG	SF			
Davis, Kenneth R.		Nordson Medical					DT	PM			
Defeo, John W.		Hoffer Flow Controls Inc.					PI				
Defusco, Sean J.		Integra Companies Inc.					PM	SG			
Dubiel, Robert J.		Parker Hannifin					SG				
Dunbar, Peter M.		VNE Corporation					CR	DT			
Dvorscek, James		Abbott Laboratories		MJ			SC	EC	CR	SD1	
Dymess, Albert D., PE		Advent Engineering Inc.			SD		SD				
Elbich, Robert		Exigo Manufacturing					CR	DT			

(Continued)

ASME BPE 2014 xi

Elkins, Curtis W.	Central States Industrial Equip.				MJ	SF		$\overline{}$	
Embury, Mark	ASEPCO	GR			EC	EC	SD		
Esbensen, Preben	Alfa Laval Kolding A/S				SG				
Evans, Greg	Ace Sanitary				PM				
Featherston, Jan-Marc	Weed Instrument Co.				PI				
Feldman, Jason	Yula Corporation				SD				
Fisher, E. Burrell	Fisher Engineering	_	_	_	SC	SD	_		
Fitts, Robert B.	Spraying Systems Co	-	_	-	DT	GR	-	-	
Foley, Gerard P.	PBM, Inc.	-	_	_	SG	SD	-	-	
Foley, Raymond F.	DPS Engineering	-	-	-	DT	SD	-	-	
Fortin, Jonathan Franks, John W.	Lonza Group Electrol Specialties Company	+-	-	-	SD MM	SD	-	-	_
Fridman Tamara	Vanasyl LLC.	+-	PM	GR	NINI	SD	-	-	
Fritz, James	TMR Stainless	+-	FNI	OK	MJ	MM	-	-	
Gallagher, Eoghan	Alkermes Pharma Ireland Ltd	-	_	_	ES	IVIIVI	_	-	
Galvin, Paul G.	GF Piping Systems LLC	-		PM	PM	_	_	-	
Gayer, Ms. Evelyn L.	Holloway America	$\overline{}$		1	CR	MJ	SF	-	
George, Daryl	Hallam ICS	-			SD	1	-	-	
Gerra, Ronn	Shire Pharmaceuticals				SD				
Giffen, Jay	PBM Inc.				SG	SF		$\overline{}$	
Gillespie, David A.	BMW Constructors				CR	MJ	MM		
Gleeson, John	Hamilton Company				PI				
Gonzalez, Michelle M., PE	Engineering Consultant				SC1	CR1	SF1		
Gorbis, Vladimir	Genentech / Roche		CPI						
Govaert, Roger	Mettler Toledo Process Anal.				PI				
Gregg, Bradley D.	Top Line Process Equipment				SG				
Gu, Mr. Zhenghui ²	Shanghai Morimatsu Pharma		_		SC	SD			
Guttzeit, Maik	GEA Lyophil GmbH		_	_	SD	_	_		
Haman, Scott	Fristam Pumps	+	on.	-	SG	-	—	-	
Hamilton, Jody	RathGibson	-	SF	-	00	1	op.	-	
Hanselka, Reinhard, PhD, PE	CRB Engineers	+	-	-	SC GR	MJ	SD	-	
Harper, Larry	Wika Instruments, Ltd Harrison Electropolishing, LP	-	-	-		SG SF	-	-	_
Harrison, S. Tom Hartner, Scott M., PE		_	-	-	MM SD	SF	-	-	_
Harvey, Tom	Baxalta US, Inc. Gemu Valves, Inc.	+-	-	-	SG	-	-	-	_
Helmke, Dennis R.	Flow Products LLC	-		_	CR	SG	_	-	
Henon, Dr. Barbara K.	Magnatech LLC	-	_	_	SC1	MJ ¹	SF1	-	
Hobick, Troy L.	Holland Applied Technologies	-	CR	_	SD	1112	- 51	-	
Hogenson Dr. David	Amgen	-			SD		-	-	
Hohmann, Michael A.	Quality Coalescence	-			SC	CR	GR	MJ	
Huitt William M.	W. M. Huitt Company	-			GR	CR	MJ	MM	
Hutton, L. T.	Arkema Inc.		PM		SC	CR	MJ		
Inoue, Mikio	Fujikin Inc.				SG	SD			
Irish, Declan	Carten-Fujikin				SG				
Jain, Mukesh K.	W.L. Gore & Associates				PM				
Janousek, John	Abbott				SD				
Jensen, Bo B. B.	Alfa Laval		SD		SD				
Johnson, Carl A.	Genentech Inc.				SC	SG			
Johnson, Michael W.	Entegris	_	_	-	PM	-	-	-	
Juritsch, Daniel	Zeta Biopharma Gmbh	_	_	-	MJ	an.	-	-	
Kelleher, Ciaran	Janssen Supply Chain	on	-	-	SG	SD		1,07	_
Kettermann, Carl Kimbrel, Kenneth D.	RathGibson Ultraclean Electropolish Inc.	CR SF	-	-	SC SC	EC	MJ CR	MM	
Klees, Daniel T.	Magnetrol International, Inc.	PI	_	_	SC	EC	CK	-	
Klitgaard, Lars Beck	NNE Pharmaplan	PI	\vdash	-	SD	EC	-	-	_
Knox, Marianne	W. L. Gore & Associates	+	_	_	PM	_	_	-	
Kollar, Csilla	Dow Corning Corporation	-	-	_	PM	_	-	-	
Kranzpiller, Johann	GEA Tuchenhagen GmbH	-	-		ES	-	_	-	
Kresge, Ms. Denise	CRB Consulting Engineers	-	_	_	PI	_	_	-	
Kroehnert, Gerhard	Neumo	$\overline{}$			DT	DT	SF	-	
Kubera, Paul M.	ABEC, Inc.	-			SG	SD	1	-	
Kwilosz, David	Elanco Global Engineering	-		PI	GR	PI		-	
Lamore, Andrew	Burkert Fluid Control Systems				PI				
Larkin, Thomas Jr.	Amgen				PM				
Larson, John D.	DCI, Inc.				SD				
Lisboa, Ivan ²	RathGibson				SC	DT			
Mahar Jeffrey T.	3M Purification				SC	SD	PM		
Manfredi, Marcello	ZDL Componentes De Proc.				DT				
Manning, Frank	VNE Corp		DT		SC	SF1			
Manser, Rolf	DCI, Inc.				SD				
Marks, David M., PE	DME	SD			SC	EC	_	_	
Marshall, Jeff	Perrigo-Inc.	1	I		SG				
Matheis, Kenneth J. Sr.	Complete Automation Inc.	_	_	-	CR.	MJ	MM		

(Continued)

xii ASME BPE 2014

National Inc.	Int: a	Lom		_		Lno			
Mathien, Daniel J.	Behringer Corp.	DT	_	_	SC	EC	-	-	-
McCauley Nicholas S.	A&B Process Systems	-	_	_	MJ	-	-	-	-
McClune, Paul L., Jr.	ITT Pure-Flo	\vdash	_	_	DT	op.	-	-	-
McCune, Daniel P.	Allegheny Bradford Corp	0.0	_	_	MM	SD	-	-	-
McFeeters, Milena	Steridose	SG	_	_	SC	PM	-	-	-
McGonigle, Robert	Active Chemical Corp.	\vdash	_	an.	SF1	0.0	op.	-	-
Michalak, Ryan A.	Eli Lilly and Co.	-	_	SD	S	SG	SD	-	-
Minor, John W., PE	Paul Mueller Co	\vdash	_	_	GR	SD	-	-	-
Mogul, Rehan	Crane Flow Technologies Ltd	\vdash		_	PM	SG			_
Monachello, John F.	SP INDUSTRIES	\vdash		_	SD	_			
Mondello, Matthew	MECO				SF				
Montgomery. Gabe	Tank Components Industries	\perp			DT				
Mortensen, Michael	NNE Pharmaplan A/S				SD				
Muller, Scott R.	GE Healthcare Bio-Sciences				SD				
Murakami, Sei ²	Hitachi, Ltd.				S				
Nerstad, Joseph Richard	SOR, Inc.				PI				
Norton, Vickie L.	T&C Stainless				GR				
Obertanec, Andrew R.	Clark-Reliance Corporation				CR	SG	SD		
O'Connor, Tom	Central States Industrial Equip	-			MJ	MM			
Ortiz, William	Eli Lilly and Co.	-			GR1	SD1			
Pacheco, Christopher N., PE	Amgen	-			SC	SG	SD		
Page, George W. Jr.	Page Solutions	-			SG	SD	UD	_	-
Parker, Alton K. Jr	W.L. Gore and Associates Inc.	-			SG	0.0	_	_	_
Pelletier, Marc PHD	CRB Engineers	EC	SC		GR	SD	_	_	_
	United Industries Inc.	EC	30		SC	DT	SF	_	_
Peterman, Lloyd J. Petrillo, Peter A.	Millennium Facilities Resources	-	_	_	PI	SF	or	_	_
		_		_		SF	_	_	_
Pierre, Philippe R.	Pierre Guerin SAS	\vdash	_	_	ES	-	-	-	-
Pitchford, Ernie	Parker Hannifin Corp.	-	_	_	PM	-	-	-	-
Pitolaj, Steve	Garlock Sealing Technologies	\vdash		_	SG	_	_	_	_
Placide, Gilbert	Crosspoint Engineering				PI				
Pouliot, Jeffrey	Amgen				SG				
Powell, Alan L.	Merck & Co, Retired				SG	SD			
Priebe, Paul	Sartorius Stedim Biotech				PM				
Raney, Robert K.	Ultraclean Electropolish Inc.				SF				
Rau, Dr. Jan	Dockweiler AG		MM		SF				
Reinhold, Herman	AM Technical Solutions				MJ				
Rieger, Robert	John Crane Inc.				SG				
Roll, Daryl L., PE	Astro Pak Corporation	-			MM		-	-	-
Roth, William L., PE	Procter & Gamble Company	-	MJ		SC	CR	MM		-
Sams, William R.	Richards Industries	-	1110		SG	- CIC	1-11-1	_	
Schmidt, Neil A., PE	Boccard Life Sciences	-		MM	MM	_	_	_	_
Schnell, Russell W.	DuPont Company	-		141111	PM	SG	_	-	-
Schroder, Richard	Newman Gasket	-			PM	SG	_	_	_
Sedivy, Paul D.	RathGibson	-			SF	30	_	_	_
Seibert, Kathy	Abec Inc.	-		_	Sr.	_	_	_	_
Seiler, David A.	Arkema Inc.	-	_	_	PM	_	_	_	_
Shankar, Ravi	Endress + Hauser USA	-	_	_	PI	_	-	_	-
		-	_	_		SD	-	-	-
Sharon, Steven	Genentech, Inc.	-	_	_	PI	SD	-	-	-
Sisto, David P.	Purity Systems Inc.	\vdash	_	_	MJ	-	-	-	-
Smith, Robert A.	Flowserve Corp.	_		_	SG		_	_	_
Snow, Robert A.	Sanofi Global	_			SC	PM	SD	_	_
Solamon, Michael S.	Feldmeier Equipment Inc.	\vdash			MJ	SF		_	_
Stumpf, Paul D.	ASME	_	_	SC		-	-		_
Sturgill, Paul	Sturgill Welding and Code Cnsltg.	MM			S	EC	GR	MJ	_
Tabor, Glyn	Eli Lilly & Co				MJ				
Tamara Fridman	Vanasyl LLC.	PM			SC				
Tanner, Scott	Garlock Sealing Technologies				SG				
Tischler, Gregory	VEGA Americas				PI				
Trumbull, Christopher A.	Paul Mueller Company				S	MJ	SF		
Van Der Lans, Albert	Janssen Biologics BV				ES				
Villela, Fernando Garcia	Stockval Tecno Comercial Ltda				DT				
Vitti, John	CraneChemPharma Flow Solution				SG				
Vogel, James D.	The BioProcess Institute		SG		PM	Т	Т	Т	Т
Wagner, Paul	Anderson Instrument	-			PI		_	_	_
Warn, Robert A.	Commissioning Agents Inc.	+			SD		_		_
Watson-Davies, Stuart J.	PBM Inc.	-			ES		_	_	_
Weeks, Cullen	CRB Builders, LLC	-			MJ		_	_	_
Westin, Karl-johan	Roplan Sales Inc.	-	_	SG	SD	_	_	_	_
Wilson Thomas G	Consultant	-	_	30	DT1	_	_	_	_
Wilson, Thomas G.		-	GR	_	DT.	_	-	-	_
Winter, Thomas	Winter Technologies	-	GK	_		-	-	-	-
Wise, Daniel	Genentech, Inc.	-	_	_	SG	-	-	-	-
Woods, Gary	Cross Point Engineering Grp.	\vdash	_		PI	-	-	-	-
Wu, Nanping	Fristam Pumps	_			SG	-	-		_
Zinkowski, Richard J.	RJZ Alliances, LLC				S	EC	SG	SD	
ZHKOWSKI, KICHRIU J.	TOE Tunuico, DEC	-							
Zuehlke, Dr. Simon	Endress & Hauser CmbH Co. KG				PI				
Zuehlke, Dr. Simon Zumbrum, Michael A.	Endress & Hauser CmbH Co. KG Maztech, Inc.	PM			PI SC	EC	SG		

OI.	General Redunements	-	ocume components
SD	Systems Design	PM	Polymeric Materials
DT	Dimensions and Tolerances	CR	Certification
MJ	Materials Joining	MM	Metallic Materials
SF	Surface Finishes	PI	Process Instrumentation

To my wife
Doris
My children and their spouses
Monique and Michael
Robert and Daryl
And my grandchildren
Connor, Shayfer, and Willamina
I thank each and every one of you. Having your
faith and trust inspires me to do more.

Contents

Li	st of l	Figures		XX
Li	st of '	Tables		xxix
Li	st of l	Forms		xxxi
Se	ries I	reface		xxxii
Pr	eface			xxxiii
A	knov	vledgm	ents	lxxvii
Al	out t	he Autl	hor	lxxx
1	Intr	oductio	on, Scope, and General Requirements of the BPE	1
	1.1	Introd	uction	1
	1.2	Scope	of the ASME BPE Standard	2
	1.3	Intent	of the BPE Standard	6
	1.4	ASMI	E B31.3 Chapter X	7
	1.5	Terms	and Definitions	8
	1.6	Qualit	ty Assurance	11
			Documentation	13
	1.7	An Es	sential Understanding of Codes and Standards	17
	1.8		e of BPE Content	20
		1.8.1	Government Regulations	20
		1.8.2	Generally Accepted Principals and	
			Practices of the Industry	21
		1.8.3	Research and Testing Done by the BPE Membership	21
	1.9		E B31.3 Process Piping Code Chapter X	22
			B31.3 Chapter X as Supplement to the Base Code	23
		1.9.2	Harmonization of the BPE Standard and B31.3 Chapter X	24

xvi Contents

2	Mat	erials		25
	2.1	Scope	of this Chapter	25
	2.2		ials of Construction	25
	2.3	Metal	lic Materials	26
		2.3.1	Understanding ASTM Material Designations	27
		2.3.2	Stainless Steel	36
		2.3.3	The World of Crystallography	37
		2.3.4	Pitting Resistance Equivalent Number (PREn)	42
		2.3.5	Alloying Constituents in Austenitic Stainless Steel	45
		2.3.6	Dual Certified Stainless Steels	46
		2.3.7	So Why 316L Stainless Steel?	47
	2.4	Nonm	etallic Materials	49
		2.4.1	What Are Nonmetallic Materials?	49
		2.4.2	Extractables and Leachables	52
		2.4.3	Single-Use Systems and Components	54
	2.5	Surfac	ee Finish	57
	2.6	Rouge		63
		2.6.1	Class I Rouge	64
			Class II Rouge	65
			Class III Rouge	66
			Background on Rouge	68
		2.6.5	Source of Rouge	69
	2.7	Electr	opolishing	70
		2.7.1	Irregularities or Flaws in Electropolishing	74
	2.8	Passiv	ration	76
3	Pro	cess Co	mponents	81
	3.1	Proces	ss Components	81
	3.2	Pressu	are Ratings	81
		3.2.1	Pressure Ratings of Welded Components	81
		3.2.2	Pressure Ratings and Other Fundamentals	
			of Hygienic Clamp Joint Unions	86
	3.3	Hygie	nic Clamp and Automatic Tube Weld Fittings	89
	3.4	Sanita	ry Valves	101
	3.5	Seals		102
	3.6	Instru	ments	105
			Coriolis Flow Meter	106
			Radar Level Instruments	106
			Pressure Instruments	106
		3.6.4	Temperature Instruments	106
		3.6.5		106
		3.6.6	Optical Devices	107

Contents xvii

4	Fab	rication, Assembly, and Installation	108				
	4.1	Scope and Introduction to this Chapter	108				
		4.1.1 Scope	108				
		4.1.2 Introduction	108				
	4.2	Fabrication	111				
		4.2.1 Fabrication Drawings and Spool Pieces	111				
	4.3	Fabrication of Metallic Tubing	116				
		4.3.1 Welding Documentation and Retention	116				
		4.3.2 Welding for Piping Systems	119				
	4.4	Fabrication of Nonmetallic Piping and Tubing	126				
		4.4.1 Fabrication of Polymeric Components	126				
	4.5	Assembly and Installation	131				
		4.5.1 General	131				
		4.5.2 Characteristics of the Hygienic Clamp Joint	131				
	4.6	The Piping Installation Process	140				
		4.6.1 Field Assembly and Installation (Stick Built)	140				
		4.6.2 As-Built and Other Drawings	142				
		4.6.3 Skid or Module Fabrication	144				
5	, ,						
	5.1	Examination, Inspection, and Testing	147				
	5.2	Examination	148				
		5.2.1 Weld Examination	150				
	5.3	Inspection	153				
	5.4	Leak Testing of Piping	155				
6	Equ	ipment and Component Quality	157				
	6.1	Assured Quality	157				
	6.2	BPE Certification	157				
	6.3	A Quality Management System	161				
	6.4	Purpose	164				
7	Desi	ign	166				
	7.1	BPE Scope of Design	166				
	7.2	Intent of Part SD	167				
	7.3	It's a Bug's Life	168				
		7.3.1 Perspective on Bacteria	168				
	7.4	A Preamble to Design	177				
		7.4.1 Undeveloped Subject Matter	177				
		7.4.2 Containment	177				
		7.4.3 Working with BPE and B31.3	180				
		7.4.4 Fabrication	183				

xviii Contents

		7.4.5	Materials of Construction	185
		7.4.6	Cleanability and Drainability	186
		7.4.7	Bioprocessing System Boundaries	186
	7.5	Design		186
		7.5.1	The System	187
8	BPF	E Append	lices	202
	8.1	Mandat	ory and Nonmandatory Appendices	202
	8.2	Mandat	fory Appendices	203
		8.2.1	Mandatory Appendix I: Submittal of Technical	
			Inquiries to the BPE Committee	203
		8.2.2	Mandatory Appendix II: Standard Units	204
	8.3		ndatory Appendices	204
		8.3.1	Nonmandatory Appendix A—Commentary: Slag	204
		8.3.2	Nonmandatory Appendix B: Material	
			and Weld Examination/Inspection Documentation	204
		8.3.3	Nonmandatory Appendix C: Slope Measurement	204
		8.3.4	Nonmandatory Appendix D: Rouge and Stainless Steel	204
		8.3.5	Nonmandatory Appendix E: Passivation Procedure	
			Qualification	205
		8.3.6	Nonmandatory Appendix F: Corrosion Testing	205
		8.3.7	Nonmandatory Appendix G: Ferrite	205
		8.3.8	Nonmandatory Appendix H: Electropolishing	205
		0.2.0	Procedure Qualification	205
		8.3.9	Nonmandatory Appendix I: Vendor Documentation	206
		0 2 10	Requirements for New Instruments	206
		8.3.10	Nonmandatory Appendix J: Standard Process Test	206
		8.3.11	Conditions (SPTC) for Seal Performance Evaluation	200
		0.3.11	Nonmandatory Appendix K: Standard Test Methods for Polymers	206
		8.3.12	Nonmandatory Appendix L: Spray Device	200
		0.3.12	Coverage Testing	207
		8.3.13	Nonmandatory Appendix M—Commentary: 316L Weld	207
		0.5.15	Heat-Affected Zone Discoloration Acceptance Criteria	207
		8.3.14	Nonmandatory Appendix N: Guidance When Choosing	207
		0.3.14	Polymeric and Nonmetallic Materials	207
		8.3.15	Nonmandatory Appendix O: General Background/Useful	207
		0.5.15	Information for Extractables and Leachables	207
		8.3.16	Nonmandatory Appendix P: Temperature Sensors and	207
		0.0.10	Associated Components	208
		8.3.17	Nonmandatory Appendix Q: Instrument Receiving,	_00
		0.0.17	Handling, and Storage	208
		8.3.18	Nonmandatory Appendix R: Application Data Sheet	208
		8.3.19	Nonmandatory Appendix S—Polymer Applications:	
			Chromatography Columns	208
		8.3.20	Nonmandatory Appendix T: Guidance for the Use of US	
			Customary and SI Units	208

Contents xix

Appendices		
Appendix A	Cleaning and Leak Testing Procedure	209
Appendix B	Biotechnology Inspection Guide Reference Materials and Training Aids	251
Appendix C	Guide to Inspections of High Purity Water Systems	286
Appendix D	Guide to Inspections of Lyophilization of Parenterals	304
Appendix E	Guide to Inspections and Validation of Cleaning Processes	322
Appendix F	Guide to Inspections of Dosage Form Drug Manufacturer's—CGMPR's	331
Appendix G	Guide to Inspections Oral Solutions and Suspensions	349
Appendix H	Guide to Inspections of Sterile Drug Substance Manufacturers	356
Appendix J	Guide to Inspections of Topical Drug Products	366
Appendix K	BPE History—Letters and Notes	375
Appendix L	Component Dimensions	420
Further Read	ding	44(
Index		445

List of Figures

1	Asivie boards and governing groups	VI
2	ASME BPE Standards Committee	viii
1	Personnel having served as chair and vice-chair	
	1990 through 2014	xlvii
2	2015 National Board synopsis map. Source: National	
	Board of Boiler and Pressure Vessel Inspectors (National Board),	
	https://www.nationalboard.org/ © 2016	1x
3	B16.21-1962 cover	lxviii
4	B2.1-1968 cover	lxix
5	B31.3-1980 cover	lxx
6	B31.3-1993 cover	lxxi
7	ASME BPE Committee web page	lxxiii
8	ASME BPE Committee meeting calendar	lxxiv
9	Articles currently listed on the BPE Standard	lxxv
.2.1	Main segments of the BPE standard	3
.6.1	Mill to market of tube and fitting products	14
.7.1	From plant surveillance camera 90 s after ignition.	
	Courtesy: U.S. Chemical Safety and Hazard	
	Investigation Board	18
.7.2	View of PDA unit pipe rack. Courtesy: U.S. Chemical Safety	
	and Hazard Investigation Board	19
.7.3	Aerial view of PDA unit with PDA extractor columns in	
	the upper right. Courtesy: U.S. Chemical Safety	
	and Hazard Investigation Board	19
2.3.1	ASTM material standard designator description for A106	29
2.3.2	ASTM material standard designator description for A270	30
2.3.3	Table 1 of ASTM A270-03	32

List of Figures xxi

2.3.4	Table 1 of ASTM A213-A213M-03b	33
2.3.5	Table 2 of ASTM A336A-336M-03b alloy steel forgings	34
2.3.6	Graphic representation of crystallographic structures:	
	(a) body-centered cubic and (b) face-centered cubic	38
2.3.7	Wire-frame representation of crystallographic structures:	
	(a) body-centered cubic, (b) face-centered cubic,	
	and (c) body-centered tetragonal	38
2.4.1	Content required on the certificate of compliance.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	54
2.5.1	Biofilm at 2000×. Source: Reproduced with	
	permission of Frank Riedewald (2004)	58
2.5.2	Staphylococcus biofilm at 2363×	58
2.5.3	Acceptance criteria for metallic process contact surface finishes.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	60
2.5.4	Additional acceptance criteria for EP metallic process contact	
	surface finishes. Source: https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	61
2.5.5	Acceptance criteria for polymeric process contact	
	surface finishes	61
2.5.6	Surface roughness produced by common production methods.	
	Source: https://www.asme.org/. © The American	
	Society of Mechanical Engineers	62
2.6.1	Class I and II rouge in pump casing. Source:	
	Tom Hanks, CRB Consulting Engineers, Inc.,	
	presentation to ASME BPE	65
2.6.2	Class II rust-colored rouge in pump casing.	
	Source: Tom Hanks, CRB Consulting Engineers, Inc.,	
	presentation to ASME BPE	66
2.6.3	Class II purple-colored rouge in pump casing.	
	Source: Tom Hanks, CRB Consulting Engineers, Inc.,	
	presentation to ASME BPE	67
2.6.4	Class III rouge. Source: Tom Hanks, CRB Consulting	
	Engineers, Inc., presentation to ASME BPE	67
2.7.1	Schematic of electropolishing bath	71
2.7.2	Profile of pre-electropolished 316L stainless steel	72
2.7.3	Profile of post-electropolished 316L stainless steel	73
2.7.4	316L stainless steel mechanically polished Ra 20.	
	Source: http://ultracleanep.com/.	
	© 2015 Ultraclean Electropolish, Inc.	73

xxii List of Figures

2.7.5	316L stainless steel electropolished Ra 7. Source:	
	http://ultracleanep.com/. © 2015 Ultraclean Electropolish, Inc.	73
2.7.6	Example of frosting of electropolished 316L	74
2.7.7	Example of cloudiness of electropolished 316L	75
2.7.8	Example of orange peel 316L on stainless steel resulting	
	from electropolishing	75
2.8.1	(a-d) Listing of various testing methods for cleanliness	
	and passivation. Source: https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	77
3.2.1	Longitudinal weld joint strength reduction or quality factor by	
	weld type. Source: https://www.asme.org/. © The American Society of	
	Mechanical Engineers	83
3.2.2	Longitudinal weld joint strength reduction or quality factor	
	by material. Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American Society of	
	Mechanical Engineers	84
3.2.3	Weld joint strength reduction factor. Source: https://www.asme.org/	
	products/codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	85
3.3.1	Automatic tube weld 90° elbow. Source: https://www.asme.org/	
	products/codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	91
3.3.2	Automatic tube weld×hygienic clamp joint, 90° elbow.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American Society of	0.1
2 2 2	Mechanical Engineers	91
3.3.3	Hygienic clamp joint 90° elbow. <i>Source</i> : https://www.asme.org/	
	products/codes-standards/bpe-2014-bioprocessing-equipment.	02
224	© The American Society of Mechanical Engineers	92
3.3.4	Automatic tube weld 45° elbow. <i>Source</i> : https://www.	
	asme.org/products/codes-standards/bpe-2014-	
	bioprocessing-equipment.	92
3.3.5	© The American Society of Mechanical Engineers Automatic tube weld×hygienic clamp joint, 45° elbow.	92
3.3.3	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	93
3.3.6	Hygienic clamp joint 45° elbow. <i>Source</i> : https://www.asme.org/	93
3.3.0	products/codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	93
3.3.7	Automatic tube weld 180° return bend.	75
5.5.1	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	94

List of Figures xxiii

3.3.8	Hygienic clamp joint 180° return bend. Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	94
3.3.9	(a) Automatic tube weld straight tee and	71
3.3.7	(b) automatic tube weld cross.	
	Source: https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	95
3.3.10	Automatic tube weld short outlet hygienic clamp joint tee.	93
3.3.10		
	Source: https://www.asme.org/products/codes-standards/bpe-2014-bioprocessing-equipment. © The American	
		05
2 2 11	Society of Mechanical Engineers	95
3.3.11	Hygienic clamp joint short outlet run tee.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	0.0
2 2 12	Society of Mechanical Engineers	96
3.3.12	(a) Hygienic clamp joint straight tee and (b) hygienic	
	clamp joint cross. <i>Source</i> : https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	0.0
2 2 12	© The American Society of Mechanical Engineers	96
3.3.13	Hygienic clamp joint short outlet tee.	
	Source: https://www.asme.org/	
	products/codes-standards/bpe-2014-bioprocessing-equipment.	0.7
2211	© The American Society of Mechanical Engineers	97
3.3.14	Automatic tube weld reducing tee.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	97
3.3.15	Automatic tube weld×short outlet hygienic clamp joint	
	reducing tee. <i>Source</i> : https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	97
3.3.16	Hygienic clamp joint reducing tee.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	98
3.3.17	Hygienic clamp joint short outlet reducing tee.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	98
3.3.18	Automatic tube weld instrument tee.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	98

xxiv List of Figures

3.3.19	Hygienic clamp joint instrument tee.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	99
3.3.20	Automatic tube weld concentric and eccentric.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	99
3.3.21	Hygienic clamp joint×tube weld concentric and eccentric	
	reducers. Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	99
3.3.22	Hygienic clamp joint concentric and eccentric reducers.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	100
3.3.23	Automatic tube weld ferrule three standardized lengths.	
0.0.20	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	100
3.3.24	Automatic tube weld cap. Source: https://www.asme.org/	100
	products/codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	100
3.3.25	Hygienic clamp joint solid end caps.	100
3.3.23	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	101
3.5.1	Flush plan BPE52 for pump	104
3.6.1	Conductivity probe examples	107
4.1.1	Rules for process system retrofit modification and repair.	10,
	(a) Schematic of closed loop piping system,	
	(b) Buttweld existing tube × new tube connection,	
	(c) Buttweld existing tube × new ferrule connection, and	
	(d) existing clamp × new clamp connection	110
4.2.1	Fabrication drawing or isometric	112
4.2.2	Spool drawing	114
4.2.3	Single plane and isometric spool drawings	115
4.2.4	Simple isometric fabrication drawing	116
4.3.1	Effect of sulfur on fluid flow of molten weld pool.	
	(a) Flow direction of a weld pool with negative temperature	
	coefficient of surface tension and (b) flow direction of a weld	
	pool with positive temperature coefficient of surface tension	122
4.3.2	Effect of sulfur on welding 316L stainless tubing.	
-	(a) Symmetrical weld joint of two tubes having similar	
	sulfur content. (b) Asymmetrical weld joint of two tubes	
	having dissimilar sulfur content.	
	· · · · · · · · · · · · · · · · · · ·	

List of Figures xxv

	Source: http://www.arcmachines.com/. © 2016 Arc	
	Machines, Inc.	123
4.3.3	Weld head of orbital welding machine.	
	Source: http://www.arcmachines.com/. © 2016 Arc Machines, Inc.	124
4.3.4	Tube weld tolerances. (a) Acceptable, (b) misalignment	
	(mismatch), (c) OD concavity, (d) I.D. concavity (suckback),	
	(e) lack of penetration, and (f) convexity.	
	Source: https://www.asme.org/products/codes-standards/bpe-2014-	
	bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	125
4.4.1	Acceptable weld profile for a beadless weld.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	128
4.4.2	Unacceptable cracks or crevices in weld profile of a	
	beadless weld. <i>Source</i> : https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	129
4.4.3	Unacceptable pits or pores in weld profile of a beadless weld.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	129
4.4.4	Unacceptable voids (microbubbles) in weld area of a	
	beadless weld. Source: https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	129
4.4.5	Misalignment tolerance in weld area of a beadless weld.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	130
4.4.6	Unacceptable inclusions in weld area of a beadless weld.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	130
4.4.7	Discoloration in weld area of a beadless weld.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	130
4.4.8	Tolerance for internal weld concavity of a beadless weld.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	130
4.5.1	Type A ferrule	132
4.5.2	Type B ferrule	132
4.5.3	Forces acting for and against containment	133
4.5.4	Forces acting to seal the joint	133

xxvi List of Figures

4.5.5	Three-piece double-pin clamp joint assembly	135
4.5.6	Two-bolt high-pressure clamp joint	135
4.5.7	ASME BPE-2014 paragraph SG-4.2	138
4.5.8	Allowable gasket misalignment Ref. BPE fig. SG-4.2-1.	136
4.5.0		
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	120
1.6.1	Society of Mechanical Engineers	139
4.6.1	Simple isometric fabrication drawing	141
4.6.2	Weld map drawing	143
4.6.3	Slope map drawing	143
4.6.4	Filtration skid. <i>Source</i> : http://cotterbrother.com. 2016	
	© Cotter Brothers Corporation	145
4.6.5	Filtration skid close up. Source: http://cotterbrother.com.	
	2016 © Cotter Brothers Corporation	146
5.2.1	Discoloration samples electropolished 316L.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	151
5.2.2	Discoloration samples of mechanically polished 316L SS.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	152
6.2.1	(a and b) Opening window of BPE Certificate Holder search	
	and (c) list of current BPE Certificate Holders	158
6.2.2	ASME certification mark and certification designator.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	159
6.2.3	Cover of CA-1. Source: https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	160
6.3.1	General certification timeline. <i>Source</i> : https://www.asme.org/	
	products/codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	163
7.1.1	Relationship of BPE parts	167
7.3.1	Rhinovirus at 1000000×	169
7.3.2	Ebola virus at 100 000×. Source: Cells Alive,	
	http://www.cellsalive.com/. © 2015 James A. Sullivan	170
7.3.3	Various items at 10000×. Source: Cells Alive,	
,,,,,,	http://www.cellsalive.com/. © 2015 James A. Sullivan	170
7.3.4	Various items at 7000×. Source: Cells Alive,	1,0
,	http://www.cellsalive.com/. © 2015 James A. Sullivan	170
7.3.5	Various items at 1000×. Source: Cells Alive,	1,0
1.5.5	http://www.cellsalive.com/ © 2015 James A. Sullivan	171

List of Figures xxvii

7.3.6	Various items at 100×. Source: Cells Alive,	
	http://www.cellsalive.com/. © 2015 James A. Sullivan	171
7.3.7	Various items at 70×. Source: Cells Alive,	
	http://www.cellsalive.com/. © 2015 James A. Sullivan	171
7.3.8	Various items at 10×. Source: Cells Alive,	
	http://www.cellsalive.com/. © 2015 James A. Sullivan	172
7.3.9	All on a 2 mm dia pin head. Source: Cells Alive,	
	http://www.cellsalive.com/. © 2015 James A. Sullivan	172
7.3.10	Biofilm at 2000×. Source: Reproduced with permission	
	of Frank Riedewald (2004)	173
7.3.11	Biofilm life cycle. Source: Don Monroe,	
	http://search.proquest.com/openview/f3f6bf29fc610d664df82f0	
	1f6576b7a/1?pq-origsite=gscholar. Used under CC-BY-SA 2.5	173
7.3.12	Staphylococcus biofilm at 2363×	174
	Cluster of yeast cells in pit. (a) Three pits in 316L stainless steel	
	and (b) single pit with cluster of yeast cells. Source:	
	http://www.dockweiler.com/en/. © Dockweiler AG.	
	Reproduced with permission from Dr. Jan Rau	176
7.4.1	Relationship between the BPE Standard and the B31.3 Code	181
7.4.2	Interconnections of BPE and B31.3 Section VIII	184
7.5.1	Kinked hose with rise. <i>Source</i> : https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	190
7.5.2	Hose pocket. Source: https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	190
7.5.3	Proper hose installation. <i>Source</i> : https://www.asme.org/	1,0
,	products/codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	190
7.5.4	Proper integration of end connection. <i>Source</i> : https://www.asme.	1,0
,	org/products/codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	192
7.5.5	Pump impeller designs. (a) Open, (b) semiopen, and	1,2
7.0.0	(c) shrouded/closed. <i>Source</i> : https://www.asme.org/products/	
	codes-standards/bpe-2014-bioprocessing-equipment.	
	© The American Society of Mechanical Engineers	192
7.5.6	The high-purity differences between P3-A-003 and ASME B73.1.	1,2
7.5.0	Source: 3-A Sanitary Standards, Inc., http://www.3-a.org/.	
	© P3-A® End Suction Centrifugal Pumps for Active	
	Pharmaceutical Ingredients, P3-A 003	196
7.5.7	(a) Transfer panel front and its nomenclature and	170
1.5.1	(b) transfer panel back and its nomenclature.	
	Source: http://www.csidesigns.com. © 2004, Central States	
	Industrial Equipment and Service, Inc.	198
	muusutai Equipment anu seivice, mc.	198

xxviii List of Figures

7.5.8	Large and complex transfer panel. $Source$: http://cotterbrother.com.	
	© 2016 Cotter Brothers Corporation	199
7.5.9	Acceptable design for a transfer panel looped manifold.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	199
7.5.10	Acceptable design concepts for jumper drains.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	200
7.5.11	Multiple position jumpers with adjustable drain valve spool.	
	Source: https://www.asme.org/products/codes-standards/	
	bpe-2014-bioprocessing-equipment. © The American	
	Society of Mechanical Engineers	200
1	Circulating Loop	289
2	Organisms in a Water System	291
3	WFI System Type A	292
4	WFI System Type B	293
5	WFI System Type C	294
6	Older WFI System	296
7	Schematic of Older WFI System	296
8	Older RO Unit	297
9	RO Unit	298
10	Purified Water System	300
11	Problematic Purified Water System_1	300
12	Problematic Purified Water System_2	301
13	One Way Purified Water System with UV	302