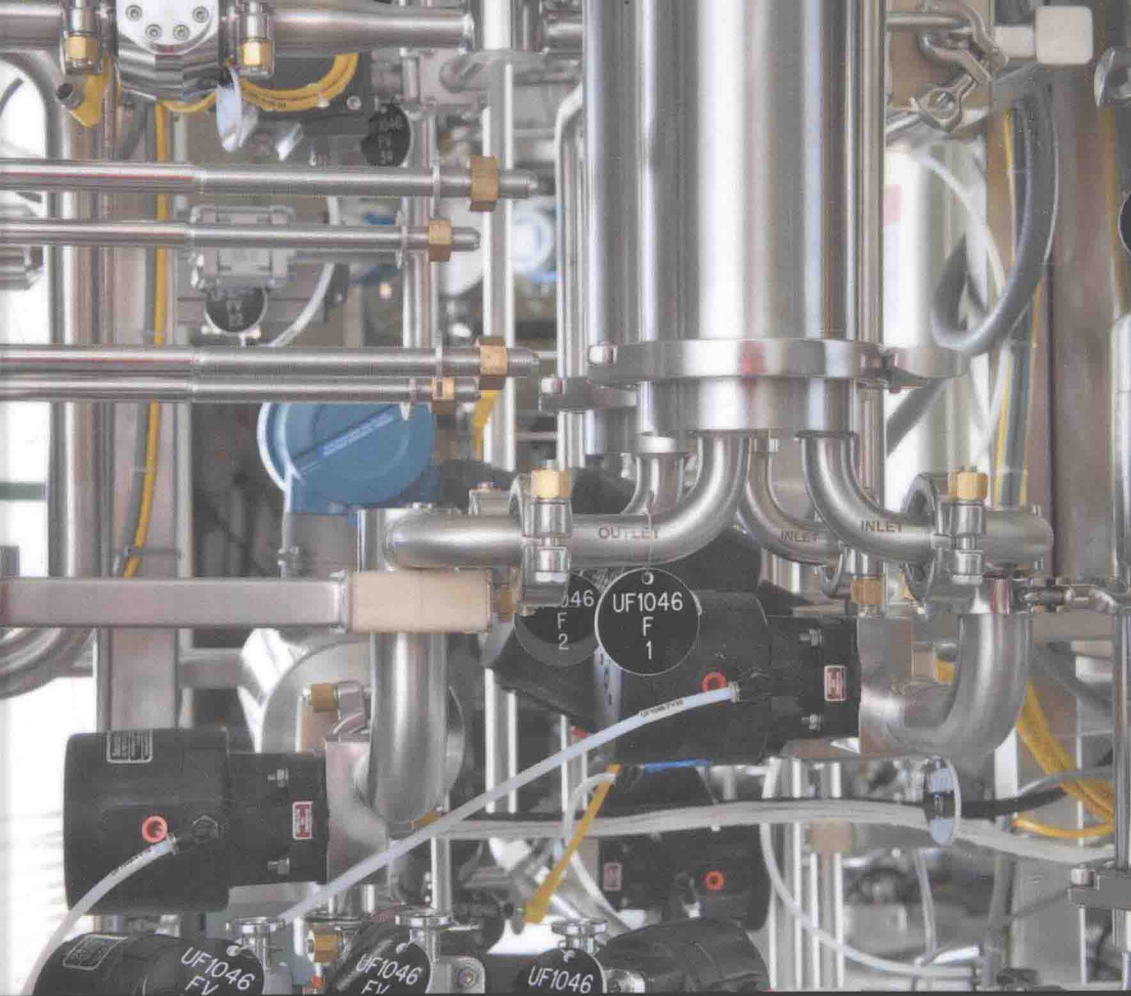

Bioprocessing Piping and Equipment Design

A Companion Guide for the ASME BPE Standard

William M. (Bill) Huitt

ASME PRESS

WILEY

BIOPROCESSING PIPING AND EQUIPMENT DESIGN

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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.

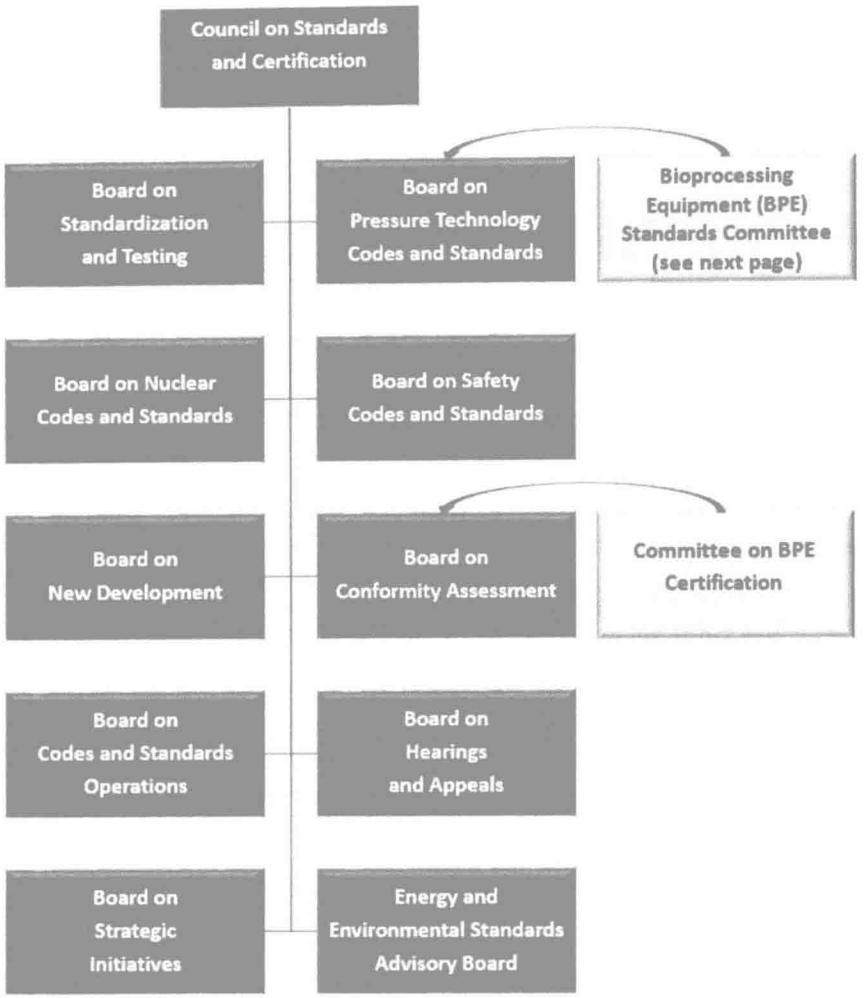

Figure 1 ASME boards and governing groups

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

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 design-related 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.

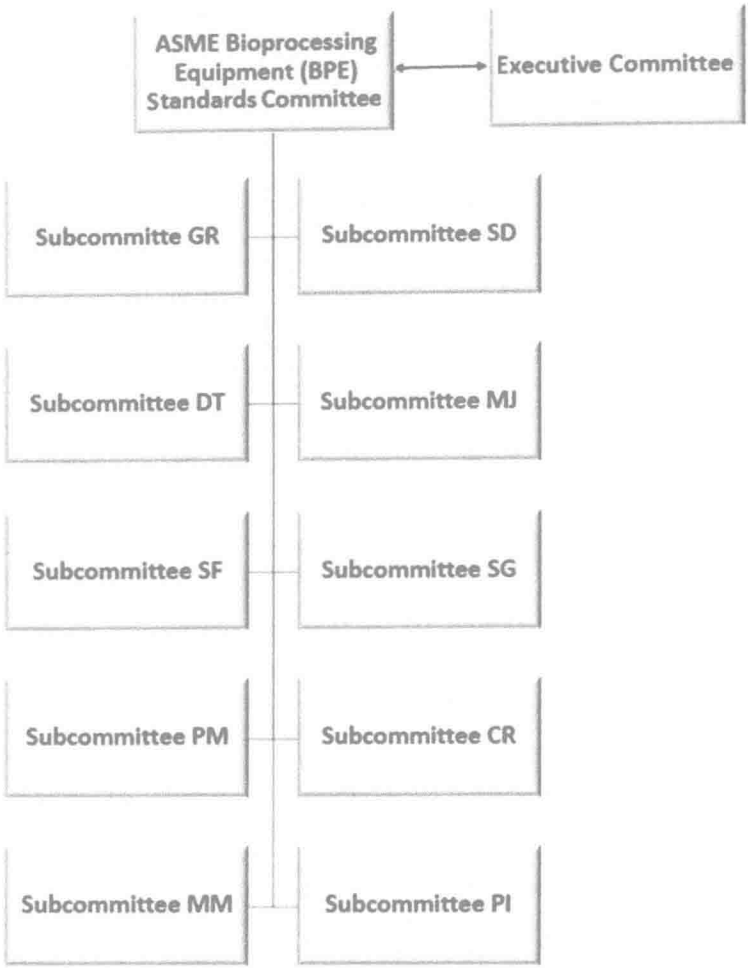

Figure 2 ASME BPE Standards Committee

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

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 subcommittees 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.

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:

BPE STANDARDS COMMITTEE AND SUBCOMMITTEE MEMBERS

Abbreviations and Terminology used below

EC = Executive Committee
DT = Dimensions and Tolerances
GR = General Requirements
MJ = Materials Joining
MM = Metallic Materials
PI = Process Instrumentation
PM = Polymeric Materials
SC = Standards Committee
SD = Systems Design
SF = Surface Finishes
SG = Sealing Components

Notes:

1. Contributing Member: an individual non-voting member whose contribution to a committee is through reviews and comments on proposals. Contributing members shall possess the technical qualifications necessary for individual voting members.
2. This individual is considered a "Delegate," which implies that they are an individual selected by the Standards committee to represent a group of experts outside of the U.S. and Canada. Each group represented has provided a clearly defined interest in participating on BPE subcommittees.

NAME	AFFILIATION	CHAIR	V. CHAIR	SECRETARY	SUBCOMMITTEES				
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				PM				
Ankers, Jay	Ocean Alloys LLC[1]	SC	EC		SD	PI[1]			
Anton, George	Qualtech Inc				PI				
Avery, Richard E.	Nickel Institute				MM	SF			
Balmer, Melissa L.	Sanofi Pasteur		SD		SC				
Banes, Patrick H.	Astro Pak Corp.		SF						
Baram, David	Clifton Enterprises				SC[1]	SG[1]			
Benway, Ernest A.	Ironwood Specialist Inc.				SC[1]	GR[1]	MJ[1]		
Bhaila, Kadeem	ITT Engineered Valves, LLC[1]		MJ						
Bickel, Neill	Genentech				MJ	SF			
Billmyer, Bryan A.	Central States Industrial Equip				SC	CR	DT	SD	
Blumenthal, Joel	Perceptual Focus LLC				PI	SG			
Bond, Richard	Anderson Instrument Co.				PI				
Bradley, Jeffrey L.	Eli Lilly and Co.				SD[1]	GR[1]	MJ[1]		
Bragg, Chuck J.	Burns Engineering, Inc				PI				
Brockmann, Dan	Alfa Laval Inc				CR	DT	SF		
Burg, Wilham P.	DECCO Inc.			MJ	GR	MJ			
Cagne, William H.	JSG, LLC[1]				SC	EC[1]	GR		
Campbell, Dr. Richard D., PE	Bechtel	MJ			SC	EC	GR	CR	MM
Canty, Thomas	J M Canty Inc		PI		SD[1]				
Carl A. Johnson	Genentech Inc				SD				
Chapman, Chuck	Gemu Valves				DT	SD			
Chih-Feng, Kuo	King Lai International				SF				
Cirillo, Anthony P.	Cirillo Consulting Services LLC				SC[1]	EC[1]	GR[1]		
Cohen, Donald K.	Michigan Metrology, LLC[1]				SF[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, Inc.				SD				
Daly, James	BSI Engineering				SD				
Daniels, James R., PE	ITT Engineered Valves, LLC				SG	SF			
Davis, Kenneth R.	Nordson Medical				DT	PM			
Defeo, John W.	Hoffer Flow Controls Inc				PI				
Deftsco, 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	SD[1]	
Dymess, Albert D., PE	Advent Engineering Inc.		SD		SD				
Elbich, Robert	Exigo Manufacturing				CR	DT			

(*Continued*)

Elkins, Curtis W	Central States Industrial Equip				MJ	SF			
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	Lonza Group				SD				
Franks, John W	Electrol Specialties Company				MM	SD			
Fridman Tamara	Vanasyl LLC		PM	GR					
Fritz, James	TMR Stainless				MJ	MM			
Gallagher, Eoghan	Alkermes Pharma Ireland Ltd				ES				
Galvin, Paul G	GF Piping Systems LLC			PM	PM				
Gayer, Ms. Evelyn L	Holloway America				CR	MJ	SF		
George, Daryl	Hallam ICS				SD				
Gerra, Ronn	Shire Pharmaceuticals				SD				
Giffen, Jay	PBM Inc				SG	SF			
Gillespie, David A	BMW Constructors				CR	MJ	MM		
Gleeson, John	Hamilton Company				PI				
Gonzalez, Michelle M., PE	Engineering Consultant				SC[1]	CR[1]	SF[1]		
Gorbis, Vladimir	Genentech / Roche		CPI						
Goyaert, Roger	Mettler Toledo Process Anal				PI				
Gregg, Bradley D	Top Line Process Equipment				SG				
Gu, Mr. Zhenghui	Shanghai Morimatsu Pharma				SC	SD			
Guttzeit, Maik	GEA Lyophil GmbH				SD				
Haman, Scott	Finstam Pumps				SG				
Hamilton, Jody	RathGibson		SF						
Hanselka, Reinhard, PhD, PE	CRB Engineers				SC	MJ	SD		
Harper, Larry	Wika Instruments, Ltd				GR	SG			
Harrison, S. Tom	Harrison Electropolishing, LP				MM	SF			
Hartner, Scott M., PE	Baxalta US, Inc				SD				
Harvey, Tom	Gemu Valves, Inc				SG				
Helmke, Dennis R	Flow Products LLC				CR	SG			
Henon, Dr. Barbara K	Magnatech LLC				SC[1]	MJ[1]	SF[1]		
Hobick, Troy L	Holland Applied Technologies		CR		SD				
Hogenson Dr. David	Amgen				SD				
Hohmann, Michael A	Quality Coalescence				SC	CR	GR	MJ	
Hiutt William M	W. M. Hiutt 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				
Juntsch, Daniel	Zeta Biopharma Gmbh				MJ				
Kelleher, Ciaran	Janssen Supply Chain				SG	SD			
Kettermann, Carl	RathGibson	CR			SC	EC	MJ	MM	
Kimbrel, Kenneth D	Ultraclean Electropolish Inc	SF			SC	EC	CR		
Klees, Daniel T	Magnetrol International, Inc	PI			SC	EC			
Klitgaard, Lars Beck	NNE Pharmaplan				SD				
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				DT	DT	SF		
Kuhera, Paul M	ABEC, Inc				SG	SD			
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	SF[1]			
Manser, Rolf	DCI, Inc				SD				
Marks, David M., PE	DME	SD			SC	EC			
Marshall, Jeff	Perrigo-Inc				SG				
Matheis, Kenneth J. Sr	Complete Automation Inc				CR	MJ	MM		

(*Continued*)

Mathisen, Daniel J.	Behringer Corp.	DT			SC	EC			
McCauley Nicholas S.	A&B Process Systems				MJ				
McClune, Paul L., Jr.	ITT Pure-Flo				DT				
McCune, Daniel P.	Allegheny Bradford Corp.				MM	SD			
McFeeters, Milena	Steridose	SG			SC	PM			
McGonigle, Robert	Active Chemical Corp.				SF				
Michalak, Ryan A.	Eli Lilly and Co.			SD	S	SG	SD		
Minor, John W., PE	Paul Mueller Co.				GR	SD			
Mogul, Rehan	Crane Flow Technologies Ltd.				PM	SG			
Monachello, John F.	SP INDUSTRIES				SD				
Mondello, Matthew	MECO				SF				
Montgomery, Gabe	Tank Components Industries				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.				GR[1]	SD[1]			
Pacheco, Christopher N., PE	Amgen				SC	SG	SD		
Page, George W. Jr.	Page Solutions				SG	SD			
Parker, Alton K. Jr.	W.L. Gore and Associates Inc.				SG				
Pelletier, Marc PHD	CRB Engineers	EC	SC		GR	SD			
Peterman, Lloyd J.	United Industries Inc.				SC	DT	SF		
Petrillo, Peter A.	Millennium Facilities Resources				PI	SF			
Pierre, Philippe R.	Pierre Guerin SAS				ES				
Pitchford, Ernie	Parker Hannifin Corp.				PM				
Pitolaj, Steve	Garlock Sealing Technologies				SG				
Placide, Gilbert	Crosspoint Engineering				PI				
Poulton, 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				SG				
Schmidt, Neil A., PE	Boccard Life Sciences			MM	MM				
Schnell, Russell W.	DuPont Company				PM	SG			
Schroder, Richard	Newman Gasket				PM	SG			
Sedivy, Paul D.	RathGibson				SF				
Seibert, Kathy	Abec Inc.								
Sealer, David A.	Arkema Inc.				PM				
Shankar, Ravi	Endress + Hauser USA				PI				
Sharon, Steven	Genentech, Inc.				PI	SD			
Sisto, David P.	Purity Systems Inc.				MJ				
Smith, Robert A.	Flowserve Corp.				SG				
Snow, Robert A.	Sanofi Global				SC	PM	SD		
Solamon, Michael S.	Feldmeier Equipment Inc.				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				
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				DT[1]				
Winter, Thomas	Winter Technologies		GR		DT				
Wise, Daniel	Genentech, Inc.				SG				
Woods, Gary	Cross Point Engineering Grp.				PI				
Wu, Nanping	Enstam Pumps				SG				
Zinkowski, Richard J.	RJZ Alliances, LLC				S	EC	SG	SD	
Zuehlke, Dr. Simon	Endress & Hauser GmbH Co. KG				PI				
Zumbrum, Michael A.	Maztech, Inc.	PM			SC	EC	SG		

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

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.

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Series Preface

The *Wiley-ASME Press Series in Mechanical Engineering* brings together two established leaders in mechanical engineering publishing to deliver high-quality, peer-reviewed books covering topics of current interest to engineers and researchers worldwide. The series publishes across the breadth of mechanical engineering, comprising research, design and development, and manufacturing. It includes monographs, references, and course texts. Prospective topics include emerging and advanced technologies in engineering design, computer-aided design, energy conversion and resources, heat transfer, manufacturing and processing, systems and devices, renewable energy, robotics, and biotechnology.

Preface

Scope and Intent of this Book with Early BPE History

Scope and Intent of this Book

This book is not meant to replace or act as a substitute for the American Society of Mechanical Engineers (ASME) Bioprocessing Equipment (BPE) Standard. It is instead a companion guide to the standard in providing clarification and to give basis and background for much of what is covered in the BPE Standard. And, in so doing, it has to be made clear that the dialogue and inferences made in this book are those of the author and not those of ASME. What is contained in this book are the results of decades of experience and insights from firsthand involvement in the field of industrial piping design, engineering, construction, and management, which includes the bioprocessing industry.

It is intended that this book both explain and go beyond the content of the ASME BPE Standard in helping to clarify much of its subject matter. Industry codes and standards are written in a manner that goes to the heart of a requirement or guideline without embellishment. They do not explain the reason why some statements in the standard are requirements while others are simply suggestions or recommendations. Neither does a code nor standard describe how something should be done. The reader is left with the requirement, but not the means to achieve it. This book is meant to close that gap of ambiguity to a large degree and make clear not only the standard itself but also its intent.

As various topics are discussed, you, the reader, will learn the reasons why certain things are done in a particular manner, such as electropolishing or orbital welding, and what those terms actually mean. Why are some materials passivated and others not and what does the term passivation really mean? Why mechanically polish tubing and why should piping be sloped? How much slope is sufficient and what is hold-up volume? These questions and more will be discussed and their answers made clear as we move through this book.