BIOPROCESSING PIPING AND EQUIPMENT DESIGN

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BIOPROCESSING PIPING AND EQUIPMENT DESIGN

A COMPANION GUIDE FOR THE ASME BPE STANDARD

William M. (Bill) Huitt

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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.

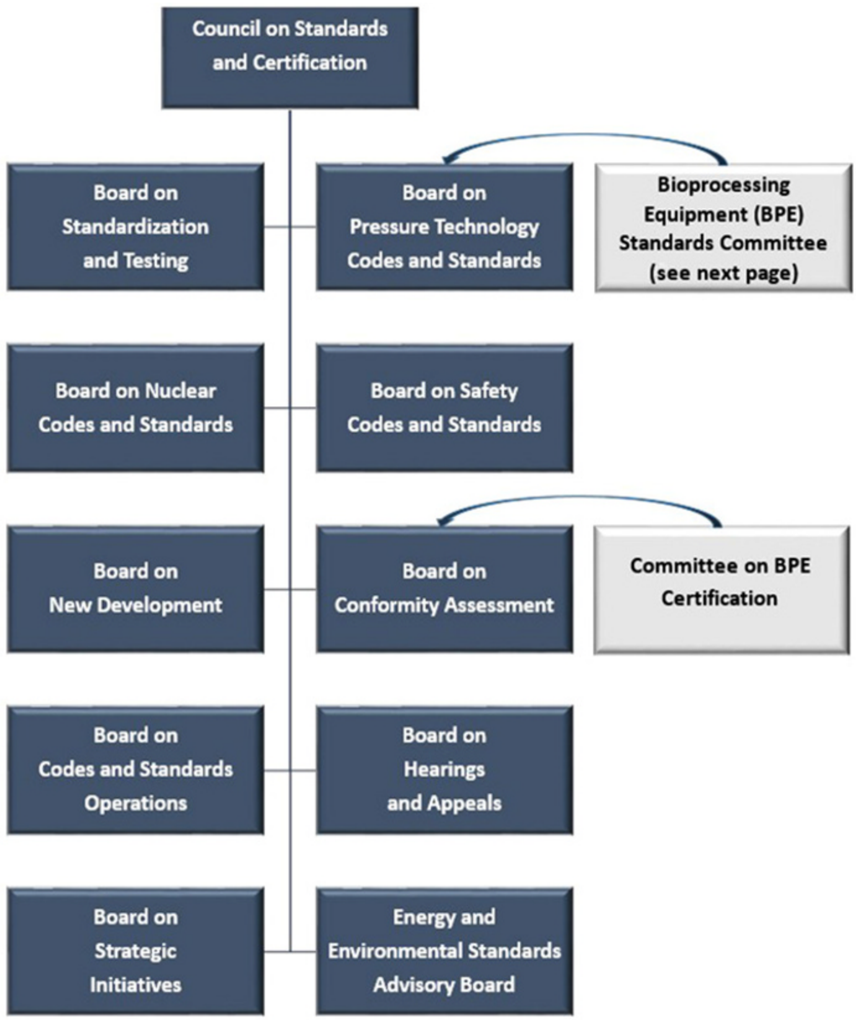

Figure 1 ASME boards and governing groups

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.

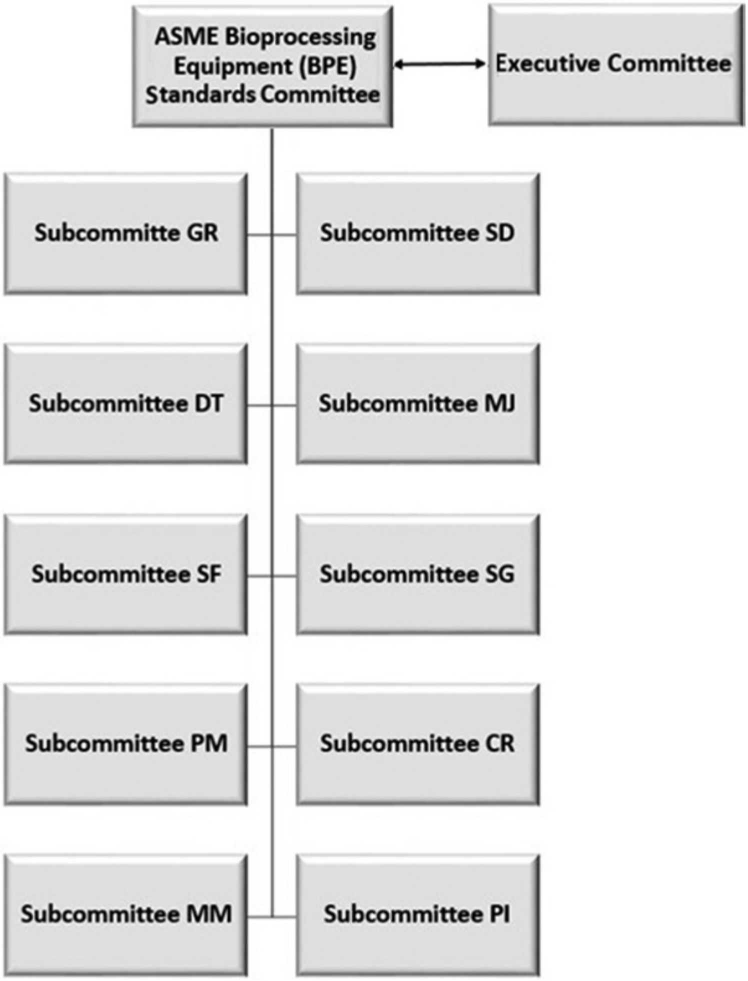

Figure 2 ASME BPE Standards Committee

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	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		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, William P.	DECCO Inc.			MJ	GR	MJ			
Cagne, William H.	JSG, LLC				SC	EC	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				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				
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	SD[1]	
Dyrness, 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						
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				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	
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				
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		
Kubera, 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*)

Mathien, 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[1]				
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				
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				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.								
Seiler, 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	Fristam Pumps				SG				
Zinkowski, Richard J.	RJZ Alliances, LLC				S	EC	SG	SD	
Zuehlke, Dr. Simon	Endress & Hauser CmbH 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.

In an effort to make this book work in a somewhat logical manner, a manner that coincides more with the way a facility would be designed and constructed rather than the way the standard itself is structured, this book will flow in the following manner: (i) It will first of all provide information on the history of the BPE Standard immediately following this introduction to the book; (ii) following that it will describe the BPE Standard and then discuss codes and standards in general; (iii) the design and engineering aspect of the book will begin with materials of construction, both metallic and nonmetallic; and (iv) it will then touch on components. (v) After components it will get into fabrication, assembly, and installation of piping systems. (vi) It will then roll into examination, inspection, and testing; (vii) next it will discuss the ASME BPE Certification process. (viii) And finally it will bring it all together by discussing system design.

Much of the safety aspects of the BPE Standard are relegated to the ASME B31.3 Process Piping Code through references. This relates to such topics as leak testing, weld criteria, inspection, examination, and so on. Where such topics are touched on, B31.3 will be brought into the discussion. B31.3 will also be referenced in conjunction with Chapter X, the B31.3 high-purity safety arm of BPE.

Information contained in this book is based on content found in the 2014 edition of the ASME BPE Standard. It will also reveal some of the relevant supplemental data not included in the standard. Such information is residual to the large amount of accumulated data obtained during research, testing, and development as part of the process in qualifying content that ultimately finds its way into the standard through a long and arduous process, a process you can learn about in this chapter under Section C—Creating and Maintaining an American National Standard (ANS).

A small amount of essential and useable information is distilled from the macro-data that is accumulated throughout the ongoing process of improving the standard and in keeping current with ever-evolving technology. The compiled macro-data resulting from such research, testing, and development is distilled down to its elemental properties. That essential data and information destined to be included in the standard is then formed into a proposal and submitted to consensus committees in seeking approval to be added to the standard. The data and information that does not find its way into the standard is considered supplemental or residual to that found in the standard, and while it is good, viable data and information, it is simply not suitable or practical as content in an industry standard or for an industry code.

Also woven into the pages of this book are lessons learned by over five decades of work in the piping design and engineering field by the author. These are lessons not found in codes or standards, but are instead methods and procedures developed by the author to enhance the execution of a project.

ASME codes are typically not written to serve as design guides and are stated as such in their introduction. The BPE Standard though is very different in this respect as design of high-purity systems is at the very heart of the BPE Standard. This too will be made clear as you make your way through this book.

Early History and Development of the ASME BPE Standard

The foreword of ASME codes and standards contains a brief, key-point history for each code or standard. The history included in the foreword of these codes and standards contains only the essential elements of that document's creation and development with no narrative beyond that. The telling of the history of the BPE in this book will contain the names of the individuals responsible for its creation and development and will include some of the original documentation and communication of those early days. That documentation, as referenced in the following as Ref. 01, Ref. 03, and so on, can be found in Appendix K.

> *To recognize that the greatest error is not to have tried and failed, but that in trying, we did not give it our best effort*
>
> Gene Kranz—NASA Flight Director during the Gemini & Apollo programs from 1969 to 1974

Paul Kantner of Jefferson Airplane/Starship fame famously quipped that "If you can remember the 60's then you weren't really there." Well, you can take it from me that I was "really" there and I do remember those days. A huge part of the 1960s, that is, if you weren't spending most of your time stoned at some antiwar rally, was the space program. And one of the rock stars, yes, right up there with Jim Morrison and Joe Cocker, was a guy by the name of Gene Kranz. While the press and most of the public were fixated on the astronauts and the spectacle of the Apollo launches, many of us were transfixed on Gene Kranz. As NASA Flight Director (1969–1974) he was calling the shots and running the show on the ground from the Mission Operations Control Center in Houston, TX.

Gene was an unassuming technical rock star who came to full notoriety during the Apollo 13 crisis. And I still, to this day, am in awe of their very publically documented meetings and their live camera feeds during that nail-biting space emergency that placed their discussions and decision-making process, throughout that crisis, under the public microscope—talk about pressure. That was an era of exciting things, monumental engineering feats in which massive rockets were blasted into space and men actually walked on the moon. This was the time of Apollo 13 in which engineers and technicians, guided by the indefatigable Gene Kranz, created magic and saved lives with chewing gum and bailing wire changing certain defeat into a lifesaving victory.

In my mind Mr. Kranz has since become an analogy. One against which other people and other actions are measured. To say that there are no engineers, technicians, or managers among us that do not measure up to Gene Kranz today and in years past would be a mistake. There *are* men and women involved at the many levels and facets of our little niche in the world—bioprocessing—that do perform such work, but go, for the most part, unnoticed, doing work that perhaps may not rise to the grand scale of building and launching manned Apollo rockets, but nonetheless do take on daunting tasks that others choose to ignore, feel inadequate for the job, or simply shy away from such perceived challenges because the task seems too overwhelming.

But people analogous to Gene Kranz do seem to appear from nowhere and seemingly at the right moment in time. They are the same individuals who first founded ASME in 1880, who initiated discussion on the creation of the Boiler and Pressure Vessel Code (BPVC) first published in 1914/1915, and who have taken on tasks throughout the years to create the B31 Piping Codes, the B16 Standards, and many other meaningful documents used throughout the world. Typically these are unassuming but internally dynamic individuals who understand the critical need for something and have the intellect, work ethic, and conviction to step forward and be the driving force in creating that something from nothing.

Contained in the foreword of documents such as the B31 Piping Codes and the BPE Standard, there can be found a history of that particular document in timeline form. Meaning, it provides a very clinical interpretation of the history of the document in nothing more than an almost bulleted format. There are no names mentioned and there are certainly no real specifics, and justifiably so. The foreword in a technical standard or code is not the proper place to expound on a detailed history of how that document was conceived and developed. But that does not preclude the fact that the names and details of how such work was accomplished should be captured in some narrative written perhaps under separate cover. This is just such a narrative.

With the full support of their sponsoring company, many of the individuals who have spent countless hours of their own time and incurred the cost to spearhead the creation and development of the codes and standards we are all so familiar with will, most likely, never be known beyond their immediate associates. In that same context it must also be said that ASME and other such organizations do go to great lengths to recognize as many individuals as practical who have dedicated their time and effort in their ongoing work on codes and standards in a multitude of capacities.

For those that might otherwise go unrecognized along with the story behind the work they have done, a story to most likely be filed away in the back of a dusty file cabinet and shoved into the back room of history, their narrative, at least in this case, is herein documented before being lost through attrition. This narrative describes the inception and development of the BPE Standard with information taken from interviews with some of the key forward-thinking individuals involved in the difficult task of turning a need into an idea, into a plan, into a committee, and finally into the BPE Standard.

This narrative will take you through the very moments that the need was recognized, the idea came to light, a plan was formed, a committee was assembled, and the BPE Main Committee approved. In addition to those key moments in the history of the BPE Standard, we will also read about anecdotal moments that show both the resilience of its members and the development of friendships, friendships, in many cases, made for a lifetime, a quite unexpected bonus forged of hard work, long hours, and dedication to a singular objective.

Origins

In the mid-1980s Genentech had invested in a start-up by the name of Verax Corporation. Verax at the time was developing a design for a continuous fluidized-bed bioreactor. Bill Cagney, working for Genentech during that period, was assigned to support Verax in converting their bench research prototype into a pilot plant skid design suitable for scale-up GMP manufacturing.

Genentech had recently completed the design and construction of a large-scale cell culture manufacturing facility for recombinant human tissue plasminogen activator (rhtPA) that Bill had been involved in and had, like most of us at that time, gone through significant struggles to obtain the high-purity equipment and achieve the type of high-purity piping system design needed for a system of this type to function properly.

These were issues that anyone designing, engineering, or constructing high-purity systems had to deal with at the time. In order to obtain acceptable, high-quality welds on a consistent and acceptable basis, orbital welding, which was just coming into its own in those years, was the preferred method of welding. However, in order to achieve such consistent and acceptable welds on a repeatable basis between two welded components, the sulfur content of 316L stainless steel, the preferred material of construction then and now, had to be within a very narrow range, a range requirement that was nonexistent at the time. In the years prior to 1995, the maximum limit of 0.030% sulfur was indicated in the American Society for Testing and Materials (ASTM) material specification without option.

In order to dance around this issue, it was necessary to specify that all welded components had to be purchased from the same heat of material, meaning that suppliers would have to corral all weld fittings for a specific project with documentation verifying that they were manufactured from the same material heat. If this was not achievable, it was acceptable to alternately use weld fittings from heats of material in which the content of their sulfur was all reasonably close in comparison. “Reasonably close” was at the owner’s direction; there were no industry recommended, much less standard values for such a range. Some companies also took the approach of developing techniques and procedures using mixed gases to overcome these same welding issues.

Aside from the welding issues, there were also issues with hygienic clamps not fitting properly over the ferrules. Poorly fitting clamps would leave installers with a false sense of having created a leak-tight seal. In many cases a clamp could be tightened against its own metal (metal to metal) and still spin loosely over the ferrules leaving less than a desirable compression load at the ferrule and gasket interface. In order to increase the odds of a clamp fitting properly over mated ferrules and gasket, the clamps were specified to come from the same manufacturer as that of the ferrules. This created logistical issues when having to purchase replacement parts in later years by having to return to the same manufacturer time and again, essentially eliminating competitive pricing and no options when delivery was an issue.

In addition there were no standard guidelines for high-purity pressure vessel design, no standards on fitting dimensions and tolerances, and no standard guidelines or requirements for slope, drainability, dead legs, and surface finishes, and the list goes on. The 3A Food and Dairy Standards somewhat filled the gap, but fell way short of what was really needed for the bioprocessing industry and pharmaceutical industry in general.

As Mr. Cagney worked with Verax, he conveyed his concern to them over these same issues. Those concerns reached the ear of Robert C. (Bob) Dean, Jr., founder of Verax. Bob had been very involved with ASME over the years and was actually an ASME Fellow, becoming a recipient of the ASME Gold Medal in 1996. But in 1988 he confided in Mr. Cagney that he was surprised to discover that there were no industry standards to guide the requirements for the design of equipment for pharmaceutical use.

Rather than keeping the issue internal to his company by choosing to simply develop their own set of specifications in order to rectify and move through the problems posed by Bill for that particular project and move on, like most of us did back then, Bob went the extra distance. He decided to take action by asking Bill if he would be interested in running an industry forum at the upcoming ASME 1988 Winter Annual Meeting in Chicago to test the waters and perhaps solicit industry support in developing a standard for the emerging bioprocessing industry. This singular action that Bob took in approaching Bill with this idea was the genesis of the BPE Standard. If you are looking for the spark of life for the BPE, this was the moment.

Bill Cagney did indeed accept the opportunity to chair the panel discussion at the 1988 ASME Winter Annual Meeting. In preparation for that meeting in Chicago, Bob had worked with the ASME meeting facilitators in getting the panel forum onto the WAM meeting agenda and invited the following individuals to participate in the discussion panel. They were:

William H. (Bill) Cagney (Panel Chair)—Genentech
Tony Wolk—US FDA
Ivy Logsdon—Eli Lilly
Dave Delucia—Verax
Dave Cowfer—Southwest Research Institute
Rick Zinkowski—ITT Grinnell
Cas Perkowski—Stearns Catalytic
Bob Greene—Fluor Daniel
Mel Green—ASME

Dave Delucia was one of the main facilitators at this meeting and helped drive the meeting. In addition, two individuals involved with the work being done at Verax were present as audience participants. They were:

Frank J. (Chip) Manning—TEK Supply, Inc.
Randy Cotter—Cotter Bros.

The 1988 Winter Annual Meeting was one in which the panel sat on an elevated dais and the audience were assembled in a theater-type seating arrangement. After much active discussion and debate from both the audience and the panel, the unanimous consensus, from all participants, was that a standard was most certainly needed and it was agreed that the process of developing a BPE Standard should move forward to the next step in its development.

At an interim meeting it was decided that an Ad Hoc BPE Committee would be formed. Dave Smith, who had recently guided a new ASME Standard for Reinforced Thermoset Plastic Corrosion-Resistant Equipment, ASME RTP-1, through development and approval, was tapped to serve as chair of this new Ad Hoc BPE Committee, and he accepted. On December 6, 1989, a letter notifying Dave (Ref. 01) that he had been appointed chair and a letter notifying Bill Cagney that he had been appointed vice-chair of the Ad Hoc BPE Committee had been sent out.

Leading up to the 1989 Winter Annual Meeting, various companies heavily invested in the pharmaceutical industry at the time had been contacted inquiring as to their assistance in recommending and supporting the nomination of employee delegates to participate as members in the new Ad Hoc BPE Committee.

Lloyd Peterman recalls that:

> *…someone, or some group, I don't recall which, solicited resume's of people who might be qualified for the first ad hoc group. I knew that several people within Tri-Clover, as well as several other companies, had applied. I believe I was selected because I started working with Upjohn and Eli Lilly in 1972 to replace their glass lines with stainless.*

At the 1989 Winter Annual Meeting in San Francisco, CA, resumés were received in response to the solicitation and were reviewed. From that review a list of potential members was developed. To that small but talented group of designees, acceptance letters then went out (Ref. 02). These were like-minded individuals who could bring experience and know-how to the committee in helping to create something from nothing. Many of them answered the call and agreed to participate in the development of the BPE Standard. On February 23, 1990, letters went out (Ref. 03) to those respondents, which included the following:

Hans Koning-Bastiaan—Genentech, Inc.
Frank J. (Chip) Manning—TEK Supply, Inc.
Richard E. Markovitz—Trinity Industries, Inc.
Theodore Mehalko—Kinetic Systems, Inc.
Joseph Van Houten—Merck & Company, Inc.
Ivy Logsdon—Eli Lilly and Company
Lloyd Peterman—Tri-Clover, Inc.
Frederick D. Zikas—Parker Hannifin Corp.

The letters notified them that they had been appointed as members to the Ad Hoc BPE Committee.

On March 1, 1990, the Ad Hoc BPE Committee held its first meeting in the ASME offices in New York. The minutes of that meeting (Ref. 04) reflected attendance of the following members:

David Smith (Chair)—United Engineers and Constructors
William H. (Bill) Cagney (V. Chair)—Biogen, Inc.

Hans Koning-Bastiaan—Genentech, Inc.
Frank J. (Chip) Manning—TEK Supply, Inc.
Richard E. Markovitz—Trinity Industries, Inc.
Theodore Mehalko—Kinetic Systems, Inc.
Joseph Van Houten—Merck & Company, Inc.
Ivy Logsdon—Eli Lilly and Company
Lloyd Peterman—Tri-Clover, Inc.
Mark E. Sheehan—ASME Secretary
Frederick D. Zikas—Parker Hannifin Corp.

Visitors attending that first meeting, as reflected in the minutes, included:

Pat Banes—Oakley Services, Inc.
David Baram—Vanasyl Valves, Inc.
Nigel Brooks—Fluor Daniel
Anthony (Tony) Cirillo—Jacobs Engineers
Randy Cotter—Cotter Corp.
Robert Daggett—Allegheny Bradford Corp.
William M. Dodson—Precision Stainless
Randolph Greasham—Merck & Co.
Barbara Henon—Arc Machines, Inc. (AMI)
Peter Leavesley—Membrex, Inc.
Julie Lee—ASME BPEP Manager
Tom Ransohoff—Dorr-Oliver
Arlene Spadafino—ASME Codes and Standards
Rick Zinkowski—ITT Engineered Valves

The purpose of that first meeting, as stated in the meeting minutes, was to:

> *…determine the need for a standard and to initiate preparation of a presentation to the Board on PTCS describing said need. Since these meetings are to be conducted under ASME policies, all meetings are open to the public and guests are invited to participate in discussions, but not in voted actions.*

The minutes went on to state, under Para. 90-3-5, that:

> *This Ad Hoc Committee has been charged with the development of a recommendation to the Board on PTCS with respect to the formation of a Main Committee to develop and administer Standards for bioprocessing equipment. The scope of such standards was stated by the Council as follows:*

> *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 adoption of other ASME and related national standards and when so referenced become a part of the standard.*

The minutes go on to state:

> *Assuming that this committee determines that there is a need for these standards and that the Board on PTCS approves the formation of a new Main Committee, the next task for this group would be to develop a proposed charter for the committee and subsequently develop preliminary operating procedures for the Main Committee. The development of the charter may involve some fine tuning of the scope of the standards to be developed.*

The March 1990 issue of the Bioprocess Engineering Program (BPEP) Newsletter (Ref. 04-13) had captured the highlights of the pre-Ad Hoc BPE Committee meeting during the 1989 ASME Winter Annual Meeting at which the group discussed a path forward. The article describes the meeting as follows:

> *The annual session at the ASME Winter Annual Meeting has become a popular venue for informal public discussions between all interested parties involved with bioprocess equipment. A panel-facilitated dialog culminated in a consensus that further pursuit of standards and references for bioprocess equipment is essential to the industry.*

The article then went on to include key points discussed at the meeting in addition to the organization of "the ASME Ad Hoc Standards Writing Committee" and also provided information for application to join the committee.

It was also noted in the meeting minutes that there would be "…three meetings a year for starters with a basic format consisting of one day of subcommittee meetings followed by a second day when the Main Committee would meet."

In that same Para, 90-3-11 of the minutes, the chairman noted that, in anticipation of "*…timely action by the Board on PTCS, it was decided to hold a meeting as soon as possible after the Board takes action*." That next meeting was scheduled for June 27, 1990, at the ASME offices in New York. On June 4, 1990, the Board on PTCS met and "*Based on the presentation prepared by the Ad Hoc Bioprocessing Equipment Committee and presented by* [Dave Smith] *as Chairman* (Ref. 11)*, the Board on Pressure Technology Codes and Standards (BPTCS), at its 6/4/90 meeting, took action to:…*" and it goes on to say that it recommended to CCS "*…the formation of the Bioprocessing Equipment Main Committee (BPE) with a scope to read: Design, materials, construction, inspection, and testing of vessels, piping, and related accessories such as pumps, valves, and fittings for use in the biopharmaceutical industry.*" Along with that the board on PTCS also approved the officers and members.

The very next day, on June 5, 1990, the Council on Codes and Standards (CCS) met and approved the recommendation of the board on PTCS creating the BPE Main Committee. On June 26, 1990, letters (Ref. 05) reaffirming the membership of officers and members to the newly created BPE Main Committee were sent out. Those letters went to:

David Smith (Chair)—United Engineers and Constructors
William H. (Bill) Cagney (V. Chair)—Biogen, Inc.

Hans Koning-Bastiaan—Genentech, Inc.
Frank J. (Chip) Manning—TEK Supply, Inc.
Richard E. Markovitz—Trinity Industries, Inc.
Theodore Mehalko—Kinetic Systems, Inc.
Joseph Van Houten—Merck & Company, Inc.
Ivy Logsdon—Eli Lilly and Company
Lloyd Peterman—Tri-Clover, Inc.
Mark E. Sheehan—ASME Secretary
Frederick D. Zikas—Parker Hannifin Corp.

At the second meeting, held on June 27, 1990, Lloyd Peterman made meticulous notes for his in-house report (Ref. 12) to Tri-Clover. In it he writes:

> *Ten of the twelve original committee members were present, and we were immediately informed that this is no longer an ad hoc committee inasmuch as this comm. was accepted by the Board of ASME to become a full-fledged committee which will probably last a lifetime. Our official designation within ASME is BPE-1. Further the original 12 members (writer included) had our terms approved for a five-year period ending June 30, 1995.*

Lloyd goes on to write, in those same notes:

> *One of the visitors, but who also was elected to the permanent committee, Randy Greashman, Director, Bio-Process Research, Merck & Co., in Rahway, NJ, is really pushing frantically for quick results of this comm. He actually stated he wd. prefer a document by the end of 1990; however, the group as a whole, especially those with more experience with these types of meetings, said they would be quite happy with a document by the end of 1991.*

I tend to think that the group's naïveté worked in the industry's favor. Had they known what lay ahead, there may have been a very different outcome.

At the following meeting that took place in Dallas, TX, November 28–30, Lloyd writes in his notes (Ref. 13):

> *"At this meeting, the (4) Task Groups assigned at the previous meeting were scheduled to give a brief report on their activities during the last two months." He goes on to say, "All these (4) Task Groups were voted upon to become full-fledged subcommittees. The writer [Lloyd] was selected as Chairman for the sub-comm. on gaskets and seals.*

Contained in the May 1991 issue of the BPEP Newsletter (Ref. 06) was an article on the fledgling BPE Standard. It read, in part:

> *The ASME BPE Standards Writing Committee continues to expand and formalize its subcommittees.*

There are currently 23 members on the main committee divided into the following 6 subcommittees: Dimensions and Tolerances; Material Joining; Gaskets and Seals; Surface Finish; General Requirements; and the newly formed subcommittee, Equipment Design for Sterility and Cleanability.

Later that same year the ASME PR machine went to work soliciting members and notifying interested parties of this new standard. A pamphlet (Ref. 07) produced by Lloyd Peterman and mailed out in late 1991 stated up front that:

"The ASME Committee of Bio-Processing Equipment (BPE) is actively soliciting participation of all interested parties involved in bioprocessing. The BPE committee was formally established and approved by the ASME Board of Pressure Technology Codes and Standards (BPTCS) in June 1990 to create a standard 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 standards may provide for adaption of other ASME and related national standards, and when so referenced become a part of the standard.

The pamphlet also announced that the BPE Committee had met six times since their "*establishment*" in June 1990, their most recent meeting having been September 12, 1991. It went on to list the officers and subcommittee chairs on the BPE Main Committee at that time. That list included:

David Smith (Chair)—United Engineers
William H. (Bill) Cagney (Vice Chair)—Abbott Biotech
Frank J. (Chip) Manning (Dimensions and Tolerances Chair)—TEK Supply
Randy Cotter (Welding Chair)—Cotter Corp.
Lloyd Peterman (Seals Chair)—Tri-Clover, Inc.
Ted Mehalko (Surface Finishes and Cleanliness Chair)—Kinetic Systems
Casimir A. (Cas) Perkowski (General Requirements Chair)—United Engineers
Nigel Brooks (Equipment Design for Sterility and Cleanability Chair)—Fluor Daniel

After six years of earnest work in establishing the framework of a main committee and six subcommittees, creating a formula for functioning in a harmonized manner and creating content for what would become the international benchmark standard for the bioprocessing and pharmaceutical industry, an initial draft (Ref. 08) of the first ASME BPE Standard was finally pulled together and printed on April 16, 1996. A final proof of the standard was issued on February 14, 1997, and on May 20, 1997, the American National Standards Institute (ANSI) approved the first edition of the ASME BPE Standard. On May 21, 1997, the ANSI Board of Standards Review submitted a letter of approval (Ref. 09) to Ms. Silvana Rodriguez-Bhatti, Manager, Standards Administration, ASME, acknowledging approval of the ASME BPE Standard. The standard was finally printed on October 17, 1997, followed five months later by an ASME press release (Ref. 10) issued on March 14, 1998.

It has since grown and improved with every edition since, which includes a 2000 Addenda, a new edition in 2002, a 2004 Addenda, and subsequent editions in 2005, 2007, 2009, and 2012. In that time period from the inaugural 1997 issue to the 2012 issue, the BPE Standard grew from 108 pages in 1997 to 292 pages in the 2012 issue. Membership reflected in the 1997 issue lists fifty-nine personnel and includes the following:

D. Smith, *Chair*, Raytheon Engineers & Constructors
A. P. Cirillo, *Vice Chair*, Life Sciences International
P. D. Stumpf, *Secretary*, the ASME
D. S. Alderman, Waukesha Cherry-Burrell
W. R. Anton, Advance Fittings
G. A. Attenborough, Fluor Daniel, Inc.
M. A. Atzor, Bayer Corp.
D. D. Baram, Consultant
H. D. Baumann, *Chair SG*, H. D. Baumann Assoc., Ltd.
R. Becker, Tri-Clover, Inc.
E. A. Benway, Cajon Co.
I. Bemberis, W. R. Grace Amicon, Inc.
W. K. Black, Cashco
R. L. Boraski, Robert James Sales
N. R. Brooks, *Chair SD*, Fluor Daniel, Inc.
C. R. Brown, Whitey Co.
W. H. Cagney, IDC
R. D. Campbell, Welding Solutions
G. W. Christianson, Ribi ImmunoChem Research, Inc.
D. C. Coleman, ICOS Corp.
R. A. Cotter, *Chair MJ*, Cotter Corp.
S. D. Dean, Pall Trinity Micro Corp.
J. A. Declark, Trent Tube
P. G. El-Sabaaly, *Chair SF*, Alloy Products Corp.
D. F. Fijas, American Precision Industries
B. E. Fisher, Waukesha Cherry-Burrell
T. J. Gausman, Nupro Co.
K. Gilson, Kinetic Systems
G. C. Grafinger, ITT Standard
J. W. Harrison, Rath Manufacturing Co.
B. K. Henon, AMI
M. A. Hohmann, Eli Lilly & Co.
T. Hoobyar, Asepco
V. L. Horswell, G&H Products, Corp.
S. T. Joy, Jenson Fittings Corp.
M. W. Keller, Amgen, Inc.
A. G. Leach, APV Crepaco, Inc.
J. T. Mahar, Dorr-Oliver
J. R. Maurer, Allegheny Ludlum Steel

F. J. Manning, *Chair DT*, TEK Supply, Inc.
T. Mehalko, TMA
F. Menkel, Bayer Corp.
M. C. Miller, FST Consulting Group
J. P. Netzel, John Crane, Inc.
C. A. Perkowski, Promega Corp.
L. J. Peterman, Tri-Clover, Inc.
E. L. Sandstrom, Pall Trinity Micro Corp.
A. Shekofski, Lederle-Praxis Biologicals
D. P. Sisto, Purity Systems, Inc.
T. Sixsmith, Advanced Ind.
P. Smith, Spirax Sarco
S. R. Swanson, Tri-Clover, Inc.
D. Todhunter, The Seal Source, Inc.
R. E. Trub, Alfa Laval Separations
C. A. Trumbull, Cotter Corp.
W. J. Uridel, Badger Metal Sales
R. T. Warf, Merck & Co.
J. A. Yoakam, Advanced Microfinish, Inc.
R. J. Zinkowski, ITT

In comparison the 2012 issue of the BPE Standard lists a membership of 185, a growth in excess of 300%.

One group of individuals that cannot be left out of the telling of this narrative are the ASME BPE secretaries. These men and women have been and still are instrumental in guiding the leadership and assisting the BPE general membership in so many facets of the functioning of an organization such as the ASME BPE Standard. In the years leading up to the first edition of the BPE Standard in 1997, in which Paul Stumpf served as secretary, there were five others that preceded him. They include:

Mark Sheehan
S. Weinman
G. Eisenberg
J. Gonzalez
Christine Krupinsky

Like Paul, his predecessors served as an irreplaceable and integral part of the BPE Standard Committee helping the leadership as well as the general membership of the BPE Standard with any myriad of things from guiding committees through the procedural spider web of regulatory conformance issues to assisting on balloting protocol and mediating hotel meeting room issues.

Throughout Paul's tenure with the BPE Standard, he has also become a good friend and colleague of the BPE leadership teams whom he has traveled the globe with. Paul is always on call serving as the standard's short-term and long-term memory for each sitting BPE chair, reflecting the attributes of a chief of staff rather than a secretary.

Exceptional Leadership Time and Again

Typically leadership walks a fine line between cajoling and harassment of, in this case, a volunteer membership in attempting to reach a specific set of goals. What seems to occur with the role of chair in the BPE organization is something tantamount to a NASCAR driver sitting perched in a Formula 1 race car; he is certainly someone who has driven fast before, but not like this. With a membership made up largely of self-made type A individuals, whoever takes on the leadership role of such a membership group has to be prepared to meet the challenge or get the pointy end of the spear. From its very beginning the BPE has been fortunate in both the availability and its selection of chairs and vice-chairs.

The hard, timely, and diligent work of the BPE Standard membership, and in particular its leadership, has made it the poster child, or benchmark if you will, for standards development. As Tony Cirillo, past chairman (1999–2005), has said, and I paraphrase, "*The BPE has set the bar for the time it takes to develop a new standard and for its inroads into the international marketplace*."

As you will notice in the text outline that follows, but is more readily discernible in Figure 1, is the overlap of personnel in the vice-chair and chair offices throughout the years. This overlap has provided a great deal of continuity in the passing of responsibility that has not gone unnoticed. The various individuals who have selflessly given of their time and expertise in serving as chair and vice-chair for the BPE Standards Committee include Dave Smith, the first chair of the BPE Standard, being transitioned into that office by the CCS in June of 1990 and continued as chair of BPE until June 1999. William H. (Bill) Cagney served as vice-chair under Dave until 1993 at which time Anthony P. (Tony) Cirillo was elected as vice-chair. He would serve in that capacity until 1999. At that time Tony was then voted in as chair of the BPE Standards Committee. Tony served three consecutive three-year terms and retired from that position in June 2008. Barbara Henon served as vice-chair under Tony from 1999 to 2005 when Rick Zinkowski was elected as vice-chair. Rick would serve as vice-chair under the remainder of Tony's term as chair until 2008. Jay Ankers was duly elected as chair of the BPE Standards Committee in 2008 with Rick Zinkowski continuing to serve as vice-chair. Rick would step down in 2011 to be replaced by Marc Pelletier as vice-chair under Jay.

The nominating committee for the upcoming 2014 elections for the offices of chair and vice-chair of the BPE Standards Committee nominated both Jay and Marc to continue serving in their respective positions. This decision was arrived after all prospective nominees had been interviewed and chose to waive the right to be nominated on the presupposition that Jay and Marc would continue for another term in their respective positions, a huge vote of confidence.

A Never Ending Work in Progress

In the early stages of development, thinking among the fledgling membership at that time quickly coalesced into establishing six primary categories or parts for the standard, SD being the last. These six parts would supposedly cover all of the

1990 – 1993	• Chair — Dave Smith • Vice-chair — William H. (Bill) Cagney
1993 – 1996	• Chair — Dave Smith • Vice-chair — Anthony P. (Tony) Cirillo
1996 – 1999	• Chair — Dave Smith • Vice-chair — Anthony P. (Tony) Cirillo
1999 – 2002	• Chair — Anthony P. (Tony) Cirillo • Vice-chair — Barbara K. Henon
2002 – 2005	• Chair — Anthony P. (Tony) Cirillo • Vice-chair — Barbara K. Henon
2005 – 2008	• Chair — Anthony P. (Tony) Cirillo • Vice-chair — Rick Zinkowski
2008 – 2011	• Chair — Jay Ankers • Vice-chair — Rick Zinkowski
2011 – 2014	• Chair — Jay Ankers • Vice-chair — Marc Pelletier
2014 – 2017	• Chair — Jay Ankers • Vice-chair — Marc Pelletier

Figure 1 Personnel having served as chair and vice-chair 1990 through 2014

criteria identified as applicable to what the BPE Standard should encompass. The 1997 issue of the BPE Standard reflected that thinking by publishing the standard with the following six parts:

1. General requirements (Part GR)
2. Design relating to sterility and cleanability of equipment (Part SD)
3. Dimension and tolerances (Part DT)
4. Material joining (Part MJ)
5. Surface finishes (Part SF)
6. Seals (Part SG)

As Tony Cirillo, vice-chair at the time, recalls, in Philadelphia at the 1996 meeting, the decision was made to publish the standard the following year in 1997. At the executive meeting, chaired by then vice-chair of the BPE Standard Committee Tony Cirillo, Tony went around the table of subcommittee chairs and asked where each one was with relation to their part being complete.

Each announced that their respective parts were ready, that is, until he got to Nigel Brooks who confessed that he was still working on expanding SD. Tony then stood up and said to everyone, "*…as of right now stop. Everything you're doing, stop. Tweak it. Make it right; because we're going into publication next year*." There was simply so much low-hanging fruit for Nigel and the SD group; it was like kids in a candy store. And as you will see in the following paragraph, and quite simply throughout the various issues themselves over the years, a line had to be drawn in the sand at some point or the standard would have never been published; it is to this day still expanding.

To provide some basic understanding of the continued expansion of the standard, following its inaugural issue, Part PM for polymers and elastomers was added in 2002. This effort was championed by Ted Hutton the standard's resident nonmetallic guru. In 2009 Part MMOC, spearheaded by the untiring Ken Kimbrel, was added to house the specifics on materials being used in the industry. Also in 2009 Part CR for certification, a segment of the standard that required the strong will and determination of Rich Campbell to forge into place, became a reality. The addition of Part CR was prompted in response to having to gain an upper hand on the issue of nonconforming components being manufactured and distributed as being BPE compliant when in fact there was nothing in place to assure that compliance. And again in that same year, the subcommittee for Part PI was introduced, guided by the hard work and tireless effort of Dan Kleese. Part PI was finally published in the 2012 edition. And by not identifying the hard work and tireless effort of all the general membership also involved in the process does not deny their major role in creating these segments of the standard. Leadership is only as good as those that support it.

Shepherding these various parts of the standard from inception to publication is a long and arduous undertaking, three to five years on average, an undertaking that requires a dedication to its concept, a full understanding of the need for its particular subject matter to be included in the pages of the standard, and a desire to ensure that its content provide the essential elements needed for the industry. This is no small task.

Anecdotal Recollections

Back in 1988 Barbara Henon recalls that she:

> *… received a brochure about a meeting in Chicago that would discuss materials to be used in the newly developing bioprocessing industry.*

She attended the meeting and:

> *… one of the materials being promoted was Al-6XN. The presenter said that Al-6XN required the use of filler metal during welding to prevent loss of corrosion resulting from molybdenum segregation. Since orbital welding with filler metal is not used in biopharmaceutical applications, I arranged to get some of the material and weld*

some autogenously and some using Hastelloy C-22 insert rings. Allegheny Ludlum did corrosion tests on the welds and I wrote a paper with Jack Maurer of Allegheny Ludlum at that time on these corrosion studies [in preparation for] the ASME Winter Annual Meeting in 1989. Randy Cotter was also a presenter at this same venue. I gave presentations at the ASME Bioprocessing Seminars, which at that time were being held at the University of Virginia and, for a couple of years, at organized ASME Bioprocessing Conferences being held at the ASME Winter Annual Meetings.

Barbara goes on to recall that:

I attended early BPE meetings but don't know exactly when I became a member. Randy, Chip Manning, Tony Cirillo were already on the committee at the time I joined. Dave Smith was Chair. The entire committee could go to dinner together after the meeting.

As mentioned in the opening dialogue, one of the more pressing issues that the BPE chose to address early on was that of welding issues and more specifically orbital welding. This was and still is a crucial aspect in the construction of hygienic piping systems.

Arguably one of the biggest issues pertaining to orbital welding was the max. 0.030% sulfur content in 316L stainless steel stipulated by ASTM. Resolution of this issue took place just prior to 1995, but in knowing its beginnings we actually have to go further back to 1984.

Barbara Henon worked for AMI at the time. She recalls that back in 1984:

…my boss, Lou Reivydas, handed me a paper by Fihey and Simoneau at Ontario Hydro describing the effects of sulfur on welds of 304 stainless steel. Later, in 1985 I did some research on the sulfur content of heats of tubing material supplied to me by AMI customers. Following the research I issued a memo to those same customers advising them to specify heats of 316 or 304 with a sulfur content range of between 0.005 and 0.017 wt%. This did not go over well with some suppliers or steelmakers.

When I joined MJ in the early 1990's I presented the findings on the sulfur data to them. With help from Tony and Randy, we were then able to propose this change to Chip who was chairing DT at the time who in-turn proposed it to ASTM.

Barbara goes on to say that:

… this really paved the way for achieving repeatable orbital welds in the biopharmaceutical industry. While an individual can't change an industry, a group working together can make big positive changes.

Under the leadership of Frank J. (Chip) Manning as chair of the DT subcommittee and material experts such as Jack Declark, with Trent Tube at the time and also a member of DT, the DT subcommittee hit the ground running and began to impact the industry soon after its subcommittee was organized, years before publication of the 1997 BPE Standard.

In order for the orbital welding of 316L stainless steel tubing to be used to its utmost benefit, the sulfur content between two butt weld components has to be within a range much more refined than the 0.030% max. allowed under ASTM standards as written at that time. Barbara Henon, as mentioned in the foregoing paragraphs, had handed a resolution to the DT subcommittee. Jack Declark, a member of the DT subcommittee, was also a member of the ASTM A 270 standard. The DT subcommittee realized that the best approach in mitigating the issue was to affect the root cause and add a modifier to the mill specifications. The data that Barbara had handed to DT was the answer.

The DT subcommittee, through Jack Declark, petitioned the ASTM A 270 committee for a supplement that would provide a more explicit option for weldable material to be used in high-purity piping systems. DT was looking for an A 270 option that refined both sulfur content and surface finishes that would be more compatible with the needs of the pharmaceutical industry. This petition and Jack's appeal to the committee convinced ASTM that this supplement was indeed needed. In 1995, three years prior to the actual publication of the first issue of the BPE Standard, ASTM issued a revised A 270 containing the S2 supplement stipulating the option for a much refined 0.005–0.017% sulfur content requirement.

In 2001 Tony Cirillo, chair of the BPE Standard Committee during that period, was contacted by a European tube and fitting manufacturer requesting a meeting with regard to the inclusion of a DIN material specification into the BPE. The meeting took place during the May 2001 BPE meeting at the Hilton Anatole Hotel in Dallas, TX. Uncertain as to what to expect, Tony, in preparation for the meeting, armed himself with Chip Manning and Dr. Rich Campbell.

What this visiting group wanted to discuss was the addition of the DIN equivalent to 316L stainless steel containing a sulfur range of 0.003–0.005% into the BPE Standard. Rich conveyed to the European representatives that the BPE Standard could not recommend a stainless steel chemical composition with a sulfur content in that range. As Rich explained, and I paraphrase, "*Such a low sulfur content would inhibit weld flow and penetration, providing less than acceptable results for the BPE Standard*." Chip then went on to explain, and I paraphrase, "*We worked extremely hard with ASTM in getting acceptance and inclusion of the S2 supplements into the ASTM A 270 standard. We then worked on the mills to gain acceptance by the manufacturers. We would therefore request that you do the same in order to get DIN to meet the supplemental requirements of BPE*."

Things were not quite the same after that. Through that meeting the BPE was fortunate enough to gain an addition to its membership that still exists to this day in the form of Dr. Jan Rau, one of the two European representatives at the meeting. Jan has since been a selfless advocate in the giving of his time and dedication to the betterment of the BPE Standard, helping to keep it aligned with the needs of the international community.

Many of the industry-accepted criteria, in the days prior to the BPE Standard, were taken as sacrosanct, but had indeed no substantive basis of origin. These anecdotal criteria were nevertheless carried over into the standard until such time as the industry-accepted values could be researched. One such criterion was the slope issue.

For hygienic requirements, such as those to be included in the BPE Standard, the need to establish clarity for cause and foundational empirical data in creating a baseline of values for slope requirements, and any other requirements for that matter, was and still remains critical to the BPE's goal of getting it right.

It was because of this tenet that Cotter Corp., guided by Randy Cotter back in 1992, elected to sponsor testing that established slope requirement values that are the basis and determinant factor for slope requirements used in the BPE Standard and elsewhere around the globe.

This testing and analysis takes into account the variables in surface tension between mechanically polished and electropolished stainless steel as well as weld joint concavity and convexity. Like the work that Barbara had done with the sulfur content issue, these were early signs that the content within the BPE Standard would be content that would not only change the industry but also do so at a level of scrutiny and consideration that would be hard to match.

In 1999, soon after Tony Cirillo became chair of the BPE Standards Committee, he approached Ernie Benway, who worked for Swagelok at the time, about how many facilities Swagelok had around the world. When Ernie told him about their facilities in Europe and Asia, Tony then went to Paul Stumpf and asked that ASME provide Ernie with as many BPE Standards as he could use in distributing them on his overseas trips. The same was done with others such as Lloyd Peterman who was uniquely invested in Asia. This effort expedited acceptance of the BPE Standard throughout the world.

In a 2003 e-mail between Tony and Lloyd Peterman, Tony is imploring Lloyd, who is now working for United Industries, who by the way became the first recipient of the BPE Certification Program in January of 2013, saying that "*I once again need your help. We need to get moving on promoting the standard internationally*" asking Lloyd if he could put together a list of countries that are using the standard. In response Lloyd provided a list of 19 countries that at the time were using the standard.

Tony recalls that at the Raleigh meeting back in January of 2001, Nigel Brooks cornered him between meetings exclaiming that he "… *simply could not continue to chair SD. It is becoming too much so I will need you to find someone to replace me*." To understand the angst that was apparently being felt by Nigel, it would help to at least understand the person to a very limited extent. Along those lines Barbara Henon writes:

> *I do remember Nigel Brooks showing slides of mechanical seals that were so complex they rivaled diagrams of Intel chips. He was a very intense individual.*

After his angst-filled conversation with Nigel, Tony's thoughts immediately turned to a recent attendee by the name of Jay Ankers as a potential replacement. Jay had attended only two other BPE meetings that had taken place in May 2000 at Atlantic City followed by a September meeting in San Francisco. In those first two meetings, Jay had made quite an impression on the SD membership and apparently had impressed a few others outside of SD. Word had gotten back to

Tony, and fortunately for the BPE he drew the right conclusion and approached this, fresh off the boat, member who had barely gotten his feet wet in his work with the standard—talk about getting tossed into the deep end of the pool, one full of sharks.

Jay recalls that:

…the first meeting I attended was in Atlantic City with Thys Smit, my friend from Fluor Daniel who worked with Nigel Brooks and I in the U.S. and South Africa. Thys and I heard about the BPE from Nigel while at Fluor Daniel. He had invited us to our first meeting. The SD Subcommittee meeting was in a HUGE room with 7-8 people. We went through the WHOLE SD Part with David Baram making editorial comments…, that were actually all very good.

He remembers Tony talking to him during the 2001 Raleigh meeting about taking over SD. It helps to imagine this new guy being asked to take over a subcommittee with only two meetings under his belt. He has to be thinking this is probably normal…right? How little he knew.

Fortunately for the BPE Jay could not have possibly known what he was getting into and accepted the position of SD chair. In thinking back he recalls that:

When Nigel Brooks handed me his files (box and electronic) he handed me an OLDER version of the SD Part, the one that had the Sprayball Testing from before the update that Tony Cirillo added. After it was published in the 2002 issue and we next met in San Diego Tony called me into a meeting with just him and me to ask, "What the hell happened?!?" That was my first publication as Chair of Part SD and Nigel got me good! We issued an errata revision immediately.

That erratum went out in 2004.

It is difficult to say, but Marc Pelletier was apparently a bad influence on Jay during his early days in the BPE. He caused Jay to become addicted to golf during some of the early meetings in Puerto Rico. You can almost picture Marc "the pusher" Pelletier standing at the first tee, 9 iron in hand pushing his drug of choice on to Jay: ahhh the feel of the soft tropical breeze against sun-tanned skin, the smell of hibiscus in the air as you drive through the lush green, undulating fairways chasing that white dimpled object that just won't go the distance or won't stop hooking to the right, who wouldn't fall victim to that. As Jay recalls:

… we used to play the old Bahia Beach course, located just east of San Juan. Before the SD Subcommittee meetings Marc and I could get in several rounds of golf; showing a severe lack of commitment to Tony.

He goes on to say that:

When Tony and Humphrey [Murphy] planned the big launch to Europe, starting in Cork Ireland [in 2001] Marc and I planned a one week golf trip around Ireland with our wives. We rented a van and played a great Irish course each day the whole week, staying in different B&Bs and towns every night. That did not go over well with Tony, especially when we rolled into Cork just before the meeting started on that Tuesday;

or worse yet, during the meetings when several of us would get up early to go play a scheduled round. Years later in Dublin [June 2004], Tony took us out to the countryside for a meeting. The hotel had a golf course with the first tee near the front door! I remember walking into the Executive meeting with my golf shoes on and grass stains on my pants.

In 2005 Tony would be going into his third three-year term, which would end in 2008. At the May 2005 meeting in Dublin, Tony, along with Paul Stumpf and Jennifer Delda, pulled Jay to the side as he did in Raleigh and asked him, once again, to step up to the plate and allow his name to be nominated for chair of the BPE Standards Committee.

Jay of course said yes and has proven over his past two terms that Tony was right once again. This was confirmed in a statement contained in his letter of nomination from the Nominating Committee for the 2014 elections, which states:

Mr. Ankers has proven, throughout his past two terms in that office, to be a dedicated and passionate leader and advocate of the BPE Standard. He has guided the growth and continued development of the BPE Standard during a time in which it experienced a 215% growth in content from its 2007 edition through its 2012 edition. During that same period the BPE Standard has been acknowledged and accepted into the 2012 edition of the B31.3 Process Piping Code, and has experienced a substantial increase in its acceptance and impact as an internationally accepted industry standard.

During Jay's first two terms, the BPE's expansion and use throughout Asia and South America as well as the involvement from both regions has substantially increased as an offshoot of the international push under Tony's watch and Jay's persistence. As Jay puts it:

There is no question that Lloyd Peterman blazed the trail for the BPE in Asia and SE Asia. Sei Murakami, our BPE Japan delegate, connected ASME to all the engineering codes and standards in Japan better than anyone ever could or, I expect, ever will. Let's just say the ASME BPE was well established across the Pacific when I started working full time in Singapore in 2006.

Folks like Lloyd Peterman, Chuck Chapman with Gemu and Carl [Kettermann] with Rath were writing articles (I am sure there were many others I am forgetting). I had a couple of Large Biopharm Projects in Singapore and I was the Chairman at the time, so it was as easy for me in SE Asia as when Tony was building projects in Ireland to expand the BPE. Those two little islands (with no natural resources) allowed a US standard and US goods to flow naturally.

He goes on to say that:

We set up many of our BPE folks with Singapore reps. who capitalized on the 4–5 large biopharm projects within a 5-block area in Tuas. I think I had over 50 BPE colleagues visit Singapore in three years. We changed sections of the BPE based on Ministry of Manpower requirements (some on the fly as Roche was building ECP-1 *and needed "re-closable relief devices that were BPE compliant" The re-write was approved and literally FLOWN to Singapore the next week to show the officials. Not procedurally correct…but hey…it showed ASME's responsiveness.*

When we had minor welding issues, Barbara Henon would answer questions that same day. The BPE was used in every step of the process by Kenyon Engineering, our Singapore high-purity contractor and they got the full support of all our BPE suppliers.

Our expansion into China was really the hard work of Lloyd Peterman and Jason Kuo with King Lai. King Lai Fittings and Tubing invited the chair and vice chair to present at China Pharm in 2011. They additionally arranged for some very high profile meetings with China's FDA and the US Consulate. Our BPE and its active China Delegate and active membership from China got the attention of their FDA leaders when we had a sit down meeting with the deputy director of China's FDA and explained that the ASME BPE Standard was developed with China and Japan.

During my first two terms we have appointed the China Delegate and recently the Brazil Delegate. I feel strongly about the fact that they are young, but VERY qualified to fill their Delegate roles. I have also closed the European Subcommittee. Europe was leading our subcommittees, including our main committee and didn't need to be a separate subcommittee.

Probably one of the things I am most proud of with respect to the BPE organization is the number of women engineers, scientists, and business leaders that our standard has attracted and elevated to the highest levels in our committees and subcommittees. I think Barbara is the only woman that I have not nominated to Main committee. She was there before me.

Lead-Up to the BPE Standard

In the years leading up to that first panel discussion held in 1988 at the ASME Winter Annual Meeting were a few dogged individuals beating the drum and curing the ills of the industry at that time. Unbeknownst to them, during the early 1980s these future members would be the vanguard of an organization that was nothing more than a vague concept in their minds' eye, a not yet formed idea just beyond their mental grasp. Most of us in the industry at that time were up to our eyeballs dealing with issues that the BPE Standard would eventually rectify in coming years, too busy in fact to travel around and educate others on what we knew.

But as part of a marketing effort, with a bent toward educating the industry, these future BPE members such as Barbara Henon, Randy Cotter, Pat Banes, and others were running interference, unknowingly in advance of the BPE, by holding seminars in concert with the University of Virginia and at the ASME Winter Annual Meetings, as well as at other venues. The interaction among this small contingent of individuals and the ASME, not to mention the interrelated work these same folks were doing on capital projects throughout the world, would eventually bring them together in the late 1980s at the ASME Winter Annual Meetings to eventually coalesce into the genesis of the BPE Standards Committee.

The essentials of the BPE Standard, in the form of individuals who were expert in their respective field, had been coming together throughout the early 1980s. The frustration we all felt at having to repeatedly work without a net in designing and constructing pharmaceutical and emerging bioprocessing industry facilities was the catalyst. The spark was the interaction between individuals at Genentech and Verax that prompted the panel discussion at the 1988 ASME Winter Annual Meeting.

Beyond 2014

As mentioned in the outset of this narrative, people like Gene Kranz seem to come out of nowhere to be at the right place at the right time. Just as Gene served as NASA Flight Director at the right time in NASA's history, so too have people arrived on the doorstep of the BPE in a timely manner. Key proponents of this standard were there at the very beginning, people such as Bill Cagney, Chip Manning, Randy Cotter, Barbara Henon, Lloyd Peterman, Tony Cirillo, Pat Banes, Dave Delucia, Rick Zinkowski, David Baram, the late Cas Perkowski, and several others no longer associated with the standard.

This was an eclectic group of individuals that arrived from various corners of the industry spectrum, bringing with them their own perspective and knowledge of the pharmaceutical and bioprocessing industries, and it worked. They can each be proud that they came together as a cohesive team to work on a single objective: to improve an industry for the common good. And that is not a simple rhetorical statement.

While I heard similar statements made at motivational talks at a pharmaceutical company years earlier, a statement using the same refrain was repeatedly made and reinforced by Tony in saying to people at BPE meetings:

> *I know you are out there to make money, we all are; it's a necessity. But while you're doing that and while you are involved in these meetings realize one thing, that what you are doing here, your work on the BPE Standard, directly or indirectly impacts not only the well-being, but the essential lives of people around the world. The medications they are required to take in order to live a long and healthy life depend a great deal on what we do here, in these meetings.*

Whether these are indeed noble efforts we are all involved in, whether we are protecting our own interests, or whether we are simply networking remains to be seen for each of us. What I do suspect is that there is a core group of people that are more deeply involved in the sustaining and continuing improvement of this standard than even they may realize. It is those individuals that magically bind the 185 plus individuals that currently make up the BPE Standard into a single cooperative effort that far and away exceeds the earliest expectations of those who sat in on a panel discussion back in 1988 and decided to do something.

In Remembrance

They say that history is written by the victors, or in this case by those that remain. The dates, names, places, and accounts of what occurred in the founding and development of the BPE Standard, as recorded in this narrative, are based on related documentation that has survived by the grace of those who were intent on saving those documents or they were simply laid aside years ago and forgotten about until this project brought them to light again. My thanks to those that did share this information.

Individuals who have come and gone over the twenty-five-year history of the BPE Standard, while not all having been identified within the pages of this narrative, are no less remembered than those who *are* listed herein. The list of names has simply grown too numerous to list in such a casual writing as this.

There are, however, those in the past who remain an integral part of the BPE Standard, having dedicated their time, their intellect, and indeed their heart to a piece of work they indelibly left their mark on. While each of their lives gave us strength in their presence, their passing has imbued us with a staunch realization that they left us with a legacy, one that demands we do not forget them and that we make every attempt to meet the excellence they imprinted on a document we are all a part of:

Lest We Forget

In Memorium

Paul Smith
Theodore (Theo) Wolfe
Casimir (Cas) Perkowski
John Henry
Tom Hoobyar

To those who provided their personal experiences and firsthand information in the writing of this history, I wish to thank you for your recollections, your stories, and your documents, documents which lend credence and substance to the telling of this history.

To the BPE membership in general, documenting the history of the BPE had been parked on the back burner of my brain for at least the past three years prior to this writing. I had approached Chip Manning one morning outside the Starbucks at the Caribe Hilton back in January 2011 hoping we could cut out a time for an interview to discuss his BPE-related experience. Chip was certainly agreeable, but neither of us could find the time during that meeting. I had planned on successive interviews with the others listed on the cover requesting an interview next with Lloyd Peterman in Baltimore at the October 2012 meeting. But again, due to the hectic schedules at these meetings, that interview never took place either. Not until the upcoming 25-year anniversary was announced at the October 2013 meeting in Kansas City did the urgency of this project hit home. And only then was time made to pull this narrative together with the help of those listed on the front cover.

Looking back on the unfolding events as the BPE came to life in the late 1980s and early 1990s, it is not difficult to recognize key moments or key individuals who perpetuated and sustained such an effort. Many would say that work such as creation of the BPE Standard achieves a certain momentum that tends to drive it forward on its own. This sounds a lot like perpetual motion, which is a theoretical impossibility, and so too is the assumption that this is what drives the success of the BPE. Continuous hard work and dedication from all those involved are what sustains the momentum and serves as the driving force necessary to make the BPE Standard the success that it is, a force that is tangible at each and every meeting. It has been an absolute pleasure for me to have had the opportunity to discover and document this history with those directly involved in its making.

Understanding Codes and Standards

In an effort to keep this as brief but as informative as possible, I will keep it relative to the chemical process industry (CPI). The term "CPI" characterizes a broad set of industries that utilize and/or manufacture chemicals in a myriad of ways. This includes such industries as pharmaceutical and bioprocessing along with the conversion of raw materials and intermediates into chemicals and petrochemicals, fats and oils, paints and coatings, food and beverages, the refining of petroleum, and the manufacture of biofuels.

To expand on this subject matter would be to bring into the discussion elements of legislative regulations that can be found under the Code of Federal Regulations (http://www.ecfr.gov/cgi-bin/ECFR?page=browse). Those regulations are codified under the US Code (http://uscode.house.gov/), thus becoming statutory law or code. This would be considered top-down regulation whereby government legislates and passes down such regulations as the Clean Air Act of 1963, the Clean Water Act of 1972, and other such national regulatory precepts and edicts. These are broad sweeping laws that affect the entire country and could only be mandated from the top down.

But there are industry-specific standards and codes, which are created and promulgated from the bottom up, meaning that they are typically generated from the affected industry, defined, vetted through an accredited organization, and published as an industry standard for the use and adoption of end users, states, and municipalities if they so choose. When adopted and enacted by the legislative branch of a government, such industry standards become statutory law (code). If integrated into a performance contract, they become legally binding whether required by regulatory compliance or not.

Aside from one small subtlety, there is essentially no difference between a published code and a published standard. That small, but impactful subtlety refers to the wording and phrasing used to convey a requirement rather than a suggestion, recommendation, or option. The fact that ASME B31.3 is titled "ASME Code for

Pressure Piping" does not mean to imply that, although it is written and titled as a code, any work performed within the United States and within the limits and boundaries of the defined scope of B31.3 has to automatically adhere to its requirements. B31.3 or the BPVC do not become legally enforceable documents until they are adopted by state or local governments or specified as an integral part of a contract.

Case in point: As you can see in Table C1 in the succeeding text, compiled from the National Board Synopsis of Boiler and Pressure Vessel Laws, Rules and Regulations, there are ten states that have adopted only the Boiler Code; thirty-eight states, Puerto Rico, and all of the provinces in Canada have adopted both the Boiler Code and the Pressure Vessel Code. Only one state, Wyoming, has adopted only the Pressure Vessel Code, and only one state, Idaho, has adopted neither code. What it means in stating that they have adopted the Boiler Code and/or the Pressure Vessel Code is this: If they have adopted just the Boiler Code, it means they have adopted Sections I, II, IV, V, VI, and VII of the BPVC. Adopting both the Boiler Code and the Pressure Vessel Code indicates that they have adopted Section VIII of the BPVC in addition to the other sections, point being that these documents only become code upon adoption or by inclusion into a contract.

The 2015 National Board Synopsis Map (Figure 2) graphically reflects, with the exception of indicating adoption of B31.1 and B31.3, the data shown in Table C1.

To date four states including California, Kentucky, Michigan, and Oregon and all of the Canadian provinces have adopted B31.3 as their piping code for CPI-related piping. Adoption of the B31.3 Process Piping Code by a state is typically done indirectly through a state's boiler code. The other 46 states, choosing not to adopt, apparently have not felt the need to require such regulatory dictates and have left that decision to the engineer or end user.

Because steam, steam condensate, water, and other utility piping systems are ancillary to the function of a boiler, the B31.1 Power Piping Code is usually adopted by reference in various state boiler codes. What typically happens, with regard to CPI-type facilities whose piping requirements cover a much broader range of utility and process services than B31.1 can accommodate, is that some state inspection boards feel the need to establish a basic set of rules and regulations for the design, fabrication, and construction of these types of facilities as well. As mentioned in the preceding text, they do this by referencing B31.3 in their boiler code, which therefore makes it a statutory requirement through reference as part of their adopted boiler code. As an example the following is an excerpt from a state boiler code:

R 000.0000 Non-boiler external piping; power boilers; adoption of standards by reference.

Rule 32.

(1) The owner shall ensure that the installation of piping not covered by the ASME boiler and pressure vessel code, section I, 2007 edition, and its 2008a addenda is installed as prescribed by the ASME code for pressure piping, B31.1, 2007 edition, adopted by reference in R 408.4025.

Table C1 – ADOPTION OF THE BPVC BY STATE, PROVINCE, TERRITORY, AND COUNTRY									
UNITED STATES & PUERTO RICO –BASED ON 2015 NATIONAL BOARD DATA									
State	Boiler Code Only	B& PVC	B31.1	B31.3	State	Boiler Code Only	B& PVC	B31.1	B31.3
Alabama		■	■		Nebraska		■	■	
Alaska		■	■		Nevada		■	■	
Arizona		■	■		New Hampshire[3]		■	■	
Arkansas		■			New Jersey		■		
California[1]		■	■	■	New Mexico	■		■	
Colorado		■	■		New York		■		
Connecticut	■				North Carolina		■	■	
Delaware		■	■		North Dakota		■	■	
Florida	■		■		Ohio		■	■	
Georgia		■	■		Oklahoma		■	■	
Hawaii		■	■		Oregon[1]		■	■	■
Idaho					Pennsylvania		■		
Illinois		■	■		Puerto Rico		■		
Indiana		■			Rhode Island		■	■	
Iowa[3]		■	■		South Carolina	■			
Kansas		■	■		South Dakota	■			
Kentucky[3]		■	■	■	Tennessee		■	■	
Louisiana	■				Texas	■			
Maine		■	■		Utah		■	■	
Maryland		■	■		Vermont		■		
Massachusetts		■			Virginia		■		
Michigan	■		■	■	Washington		■		
Minnesota		■	■		West Virginia	■			
Mississippi		■			Wisconsin[5]		■	■	
Missouri		■	■		Wyoming		Note 8		
Montana	■								
CANADIAN PROVINCES and TERRITORIES									
Alberta		■	■	■	Nova Scotia		■		
British Columbia[1]		■	■	■	Nunavut Territory[6]		■	■	■
Manitoba[4]		■	■	■	Ontario[5]		■	■	■
New Brunswick[5]		■	■	■	Prince Edward Island[7]		■	■	■
Newfoundland[1]		■	■	■	Quebec[7]		■	■	■
Labrador[1]		■	■	■	Saskatchewan		■	■	■
Northwest Territories		■	■	■	Yukon Territory[6]		■	■	■

Notes:
1. Also adopted ASME B31.5 and B31.9
2. Also adopted ASME B31.5 Plastic pipe unacceptable unless permitted by specific safety orders.
3. Also adopted ASME B31.9
4. Also adopted ASME B31.4, B31.5, B31.8, and B31.9
5. Also adopted ASME B31.5
6. Also adopted ASME B31.4, B31.5, and B16.5
7. Also adopted ASME B31.2, B31.4, and B31.5
8. Wyoming has adopted only the Pressure Vessel Code Section VIII

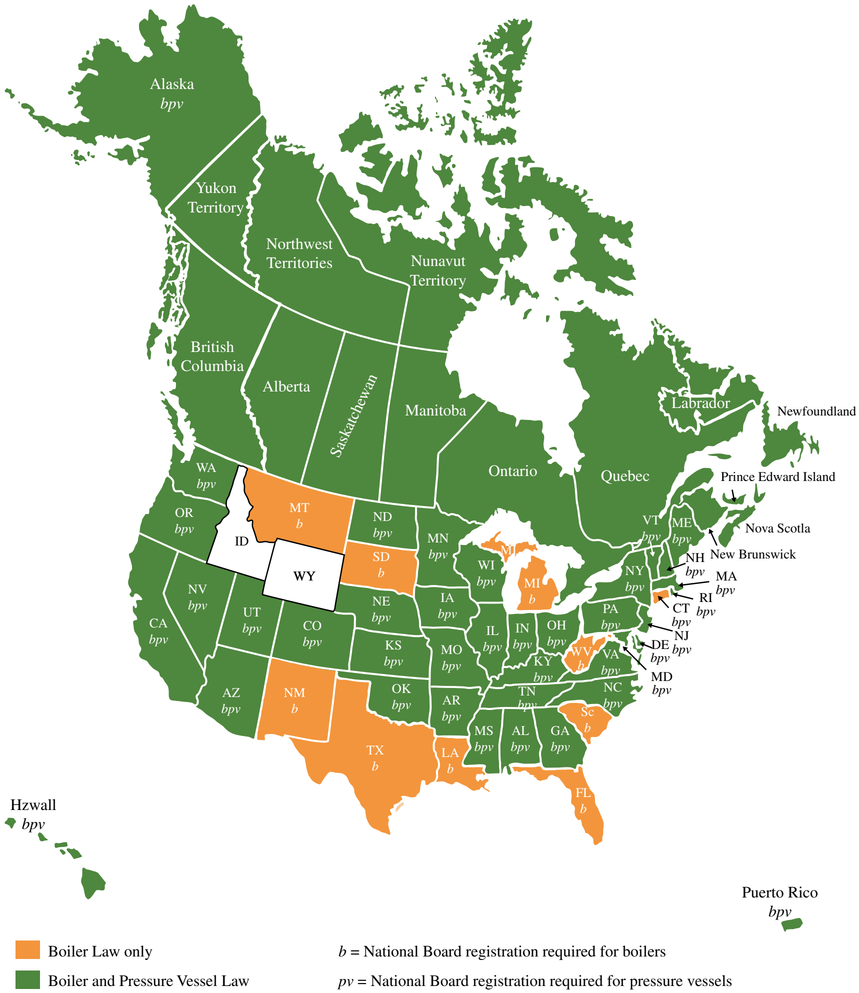


Figure 2 2015 National Board synopsis map. *Source*: National Board of Boiler and Pressure Vessel Inspectors (National Board), https://www.nationalboard.org/ © 2016

(2) The owner of a chemical plant or petroleum refinery shall comply with subrule (1) of this rule or shall ensure the installation is installed as prescribed by the ASME code for chemical plants and petroleum refineries, B31.3, 2007 edition.

(3) A licensee under this rule is not required to possess an ASME code symbol stamp, but shall hold a valid installer's license.

(4) The owner shall ensure that the installation of all of the following piping is in accordance with subrule (1) of this rule:

(a) Blowoff piping beyond the second valve out to the safe point of discharge.

(b) Steam piping out to the load.

(c) Feed-water piping from the pump.

(d) Condensate piping

As you can see in the earlier state code excerpt, paragraph (2) gives the option of compliance under B31.1 or B31.3, leaving the final decision to the owner or end user.

Rather than attempt to regulate these requirements, as the four states mentioned earlier have done, the majority of states simply leave the CPI-related piping code selection process to the owner or engineer of record (EOR). EOR refers to an engineering firm who has assumed responsibility, through contractual obligation, of adhering to the fundamental rules of good engineering practice and compliance with all governing codes and regulations in the design and construction of a CPI facility. They will henceforth become the EOR for their scope of work within a facility. If that work is modified by others, then those that engineered the modifications will then assume responsibility for those modified systems, essentially relieving the initial engineer of those obligations. This, of course, is all contractual with final determination of responsibilities made clear in such contracts. Responsibility, I might add, of the fabrication, installation, and testing of piping systems is generally that of the contractor or contractors performing such work.

Having assumed such responsibility they, the EOR, then becomes the responsible party for the design elements of a CPI-type plant or facility. Shifting responsibility of code assignment to the EOR does then have some merit, the thinking being that the entity responsible for the design and engineering of a plant or facility will have skin in the game (liability) and would therefore be more diligent in selecting the most appropriate codes and standards by which to build a facility, allowing regulation in effect to take place from the bottom up.

In those states that have adopted B31.3 as their piping code, it then becomes a requirement by law, and, unless amended otherwise by the state, any work performed in conjunction with a facility characterized as a CPI-type facility has to be done in accordance with B31.3. In the other 46 states, B31.3 has to be adopted by an engineer, contractor, or owner through contract stipulation and/or integration into specifications embedded into a contract, work order, or a facility's SOP, which would then be included by reference.

The Language of Codes and Standards

Statements have been made declaring that when a code or standard has been adopted through legislation or by contract that the engineer would have to comply with everything in the standard or code—not true. This is not true because not everything in the standard or code is a compliance requirement. Using the B31.3 Process Piping Code as further example, the difference between the B31.3 code and the BPE Standard is basically in the wording. Within a code actions are written as either "requirements" or "recommendations" and they have to be declared as such, one way or the other. A "requirement" is written in such a manner as to make an action specific and without variation. This is done by preceding the action with the word "shall." A recommendation is declared by preceding the action with such words as "should" or "may." See example Ex.1 in the succeeding text from B31.3 Para. 301.2.2*(a)*:

> *Provision* ***shall*** *be made to safely contain or relieve (see para. 322.6.3) any expected pressure to which the piping may be subjected. Piping not protected by a pressure relieving device, or that can be isolated from a pressure relieving device,* ***shall*** *be designed for at least the highest pressure that can be developed.* Ex. 1

In the earlier paragraph the word "shall" in both cases makes this statement an imperative and therefore a requirement. Furthermore, in example Ex. 2 in the succeeding text, B31.3 states the following in Para. 302.2.4(i):

> *The application of pressures exceeding pressure–temperature ratings of valves may under certain conditions cause loss of seat tightness or difficulty of operation. The differential pressure on the valve closure element* ***should*** *not exceed the maximum differential pressure rating established by the valve manufacturer. Such applications are the owner's responsibility.* Ex. 2

Stating that the "…differential pressure on the valve closure element ***should*** not exceed…" makes it a suggestion or recommendation, not a requirement. These nuances, between requirements and recommendations in B31.3 and the other B31 codes have been developed and vetted over time to ensure that what needs to be a "requirement" is stated as an imperative. And where an action has some flexibility it is simply a recommendation, a suggestion as to how to accomplish an action.

When a state, province, country, engineer, or end user adopts a standard such as BPE they do so with the assumption that when they write a specification or contract stating that "the engineer or constructor shall comply with the BPE standard" there will be no conflicting information within the standard and there will be clear indications as to what is considered a "requirement" and what is merely a "recommendation" or "suggestion." They are assuming that each "shall" and each "should" will be applied in the proper context. But, unlike the B31 codes, such an assumption may not be entirely valid with regard to the BPE Standard.

As shown in the following example Ex. 3 from BPE, Para. SD-3.4.4*(a)* states:

> *Butt welds* ***should*** *be used, if possible, minimizing lap joint welds and eliminating stitch welding.* Ex. 3

When adopted as a code or contractual standard the above statement should not be a recommendation as indicated by the word "should," but should instead be a code requirement written as "shall" with a stated caveat if needed as shown in example Ex. 4:

Butt welds ***shall*** *be used* ***unless the following occurs:***
(1) ***A circumstance in which a butt weld cannot be made and the alternative of which is approved by the owner or owner's engineer.*** Ex. 4

The level of hygienics required in the bioprocessing industry demand the use of butt welds in piping, equipment, and components except for special circumstances, which should require owner approval. From a code standpoint this is not conveyed in the current wording or phrasing. The end user or engineer adopting the BPE standard is relying on and indeed depending on the fact that the content of the standard is not soft on those requirements that are needed to make their system hygienic and cleanable.

The same can be said of Para. SD-3.4.4 *(b)*, as referenced below in example Ex. 5:

Flanges are not recommended, and their use shall be minimized. *The bore of weld …* Ex. 5

As with the above mentioned butt weld requirement the same applies here as well. In referring to example Ex. 5, the soft suggestion in recommending that flange joints should not be used is a statement that is not in line with BPE's characterization of hygienic requirements. With exception of the hygienic clamp joint union, flange joints, along with other types of mechanical joints, are not suitable for hygienic piping systems unless, on a limited basis, there is no other alternative. As a code the statement should be more explicit and definitive as in the following, shown in example Ex. 6:

Flange joints shall not be used unless first approved by the owner or owner's engineer. If approved their use shall be minimized. *The bore of weld …* Ex. 6

The other essential necessary in being considered as a code is in validating and providing supporting data for the quantitative values published within the standard, which is a process the BPE Standard is going through at this time. Publishing values for L/D and clamp joint union pressure ratings without the data to support those values is a luxury reserved for a standard, not a code. From a professional and pragmatic standpoint, such information should also be included in a published standard as well. A code requires such published values to be supported by empirical and/or theoretical data. By performing empirical testing for dead leg and hygienic clamp joint union pressure rating analysis, the BPE Standard is moving in that direction.

The one glaring difference that separates the BPE Standard from B31 codes is the statement in the introduction of the B31 codes, which states: "*The designer is cautioned that the Code is not a design handbook…*" Such a statement does not apply to the BPE Standard because a big part of its benefit for industry lies in defining what constitutes the concept of hygienic design. The design aspect of this standard is integral to the requirements it conveys for component manufacture, system fabrication, and cleanability. This fact makes the BPE Standard a quasi-design handbook.

Serving this dual role should not interfere with the BPE Standard being accepted as a code or merely being adopted as a project or end user standard. Again, it comes down to appropriate content. One example is in design details.

A code does not represent what is not acceptable. Multiple *acceptable* variations of a design element can be provided, but one or more variations on design elements that are *not acceptable* are not a practical thing to do. Representing what is not acceptable is conceivably a never ending proposition. If an engineer or designer wishes to alter what is represented in the BPE Standard as an acceptable design, they either accept responsibility for that noncompliant alteration or they request an interpretation. If it turns out that their alteration is acceptable, it could then become an intent interpretation that actually precipitates a change in the standard. Bottom line is that any details representing nonacceptable design elements would need to be deleted from the BPE Standard in considering it as a code.

Summing Up

1. There are two reasons for which the design, construction, and maintenance[1] of a facility is required to comply with a code:
   - It has been adopted by the jurisdiction within which the facility resides.
   - It is stated in the design basis or specifications, which are made part of a project's contract.
2. If a code is not adopted by a state, province, or country in which a facility resides in or will reside in, then there is no legal or regulatory requirement to comply with the code, only good and practical judgment.
3. A code stipulates the minimum requirements of which a facility is designed, constructed, and maintained. Such documents are written in a manner that makes it explicit in what those requirements are with the basic precept that the document be an accredited set of rules that establish a set of minimum criteria of which a facility can be designed, constructed, and maintained in a manner which is conveyed by the code itself. If a rule is preceded by either the word "shall" or "must," it is imperative that the rule be met. If a rule is preceded by either the word "should"

[1]When referring to maintenance the reference is made to that pertaining to piping modifications or repair.

or "may," it is considered a suggestion or recommendation, but not a requirement. In saying that, it is inferred that not all statements of action in a code are a requirement.

4. A standard is essentially written to provide guidance and methodology within a specific set of parameters, but is typically not written in the same explicit manner as a code. This lends added flexibility to the writing of a standard. However, that is not to say that a standard may, and frequently does, adhere to the same rigorous rules of grammar as a code such as those written for material standards or component standards. A standard can be any document that attempts to standardize on a set of rules and methodology on a specific subject matter. It can be an accredited industry standard or a proprietary corporate standard. And while such a premise does not preclude an accredited industry standard from being adopted as a code or regulatory standard, its validity as such should be reviewed and considered carefully in the explicit nature of its words and phrases.
5. Any firm or legislative body wishing to adopt, as a contractual obligation or government regulation, a standard such as the BPE should consider whether or not they wish to allow some of the current soft spots to remain as is or whether such paragraphs need to be amended to be more explicit.

Creating and Maintaining an American National Standard

The American National Standards Institute (ANSI)

The BPE Standard, as well as any other code or standard created and maintained by ASME, is referred to as an American National Standard (ANS) or, more simply, a National Standard. Those organizations accredited by ANSI to develop such industry standards are referred to as American National Standards Developers or, again more simply put, Standards Developers, also referred to as Accredited Standards Developers.

There are currently over 200 Standards Developers that have created and maintain over 10,000 National Standards. And this is all done in accordance with a well-defined and strict set of rules, guidelines, and regulations created, set forth, and monitored by ANSI.

The ANSI organization was the precipitant culmination resulting from a meeting in 1916 called by the American Institute of Electrical Engineers (AIEE), predecessor, along with the Institute of Radio Engineers (IRE), of the Institute of Electrical and Electronics Engineers (IEEE). This meeting pulled together the ASME, American Society of Civil Engineers (ASCE), American Institute of Mining and Metallurgical Engineers (AIME), and ASTM to discuss the need for a monitoring organization. An autonomous group that would establish and oversee an impartial program and process by which all Standards Developers would adhere to in the development of industry standards and codes. This fledgling program would quickly develop into an internationally recognized accreditation program by which those organizations abiding by the rules and procedures set forth by ANSI would become ANSI accredited.

In the 1880s and 1890s, various professional organizations such as the AIEE and ASME began to emerge throughout the various facets of industry, driven in large part by the catastrophic and oftentimes fatal failures of equipment and machinery in the workplace. There were no standard methodologies at that time much less consensus-approved engineering methods that could establish any degree of assurance that electrical wiring was properly installed or that a boiler was properly designed and built. Everyone from equipment manufactures to electrical wiring contractors were doing what they thought to be right at the time. But without a cohesive set of rules and guidelines to go by or adhere to, it was like the Wild West of industrial growth. And at the turn of the century, growth in industry was rapid and expansive, quite often with deadly consequences.

It came down to the old chicken and egg analogy with regard to what had to happen first in getting manufacturing on the same page with good engineering and manufacturing/fabrication practices. Government, in the form of politicians trying to hold on to their political office, felt the need to do something, anything to stem the all-too frequent injuries and fatalities caused by a lack of regulation. However, without the necessary and proper standards written and ready to put into place, the government could not act. So two things had to happen in order for the safety and well-being of the general public and labor to be realized during this industrial and new technological boom: (i) Engineering standards had to be developed and galvanized by accredited Standards Developers, which would assure their validity, and (ii) government would have to adopt these standards and guidelines as code and then promulgate them as the rule of law.

Established in 1919 as the American Engineering Standards Committee (AESC), ANSI was, as the name implies, a simple committee. It had yet to prove itself as the autonomous and impartial accreditation organization it would eventually become. By 1928, nine years after its creation, ANSI outgrew its committee status and was reorganized and renamed the American Standards Association (ASA). In 1966 ASA was again reorganized and given the name of United States of America Standards Institute (USASI). For the brief time it existed as the USASI, the name was no more than a placeholder for its current name of ANSI, which the organization adopted three short years later in 1969. It still retains that name at the time of this writing.

One aspect of what ANSI does and doesn't do regards the development and publication of codes and standards. It may seem a little confusing, but ANSI does not develop or publish codes and standards. Their job is to instead provide procedural oversight, monitoring, and accreditation for those that do. However, there are information, articles, and Internet links that would make you think otherwise. With such statements as "ANSI Flanges," "ANSI Pumps," "ANSI B31.3," "ANSI B16.34," and others, many designers and engineers are inclined to believe that ANSI is developing and publishing many of these codes and standards. In actuality, stating "ANSI Standard" implies the standard is an accredited National

Standard. This same implication can also apply to flanges, pumps, and myriad other components and equipment.

Some of the confusion, as it relates to ANSI's role in codes and standards, has multiple sources for its cause. The first has to do with the evolution of a product, that product being the function of an organization, which in the case of ANSI is accreditation. In the years leading up to the days in which this book on the *Companion Guide to the BPE Standard* was written, codes and standards were initially published with ANSI being an integral part of the code or standard title. This was done to announce the fact that such codes and standards were indeed accredited by an official organization. It was also done to create familiarity or name recognition with the name ANSI and its predecessor titles. As shown in Figures 3 and 4, the early names of ANSI, such as ASA and USAS, were included in the title to indicate that they were respectfully ASA and USAS accredited standards.

By the 1980s both ANSI and the Standards Developer were indicated in the title. This is represented in such a case as seen in Figure 5 in which ANSI/ASME is represented in the title to indicate an ANSI-accredited ASME code. By the time the 1990s rolled around, the title included only the developer's name, or acronym as it were, as shown in Figure 6. By this time it was felt that ASME and many other Standards Developers were recognized on their own as being ANSI accredited without the need to continue announcing that fact in a standard's title.

Throughout those years in which ANSI, under its various organizational names, was front and center in the title of codes and standards, procedures and specs were written, catalogs were published, and all manner of marketing literature were produced and distributed. In such documents were the words everyone became familiar with in relation to codes and standards, that being ANSI. Not only did ANSI achieve name recognition, they did it so well that the acronym ANSI had essentially become "genericized" or synonymous with various accredited products, like referring to all facial tissue as "Kleenex." ANSI became so synonymous with various standards, and even products, that these documents and products are still quite frequently referred to as ANSI standards, which makes reference to ANSI accreditation, rather than the Standards Developer they were written and published by, or as ANSI Pumps, ANSI Flanges, and so on. These types of references are fine as long as all parties involved in a discussion on such topics as piping, pressure vessels, pumps, and so on are familiar with the implication.

Including ANSI in referencing standards or codes would not be considered a misnomer; a more practical way in which to refer to a standard or code today is by including the name of its developer only, such as in ASME B31.3, ASME BPE, or API RP520. The only time the date of the code or standard needs to be included would be when listing it as a compliant standard in a specific contract, stating that, as an example, "Piping specifications and requirements within the scope of this contract shall comply with the ASME B31.3-2014 Process Piping Code. All piping designated as high-purity fluid service shall additionally comply with the ASME BPE-2014 (Bioprocessing Equipment) Standard."

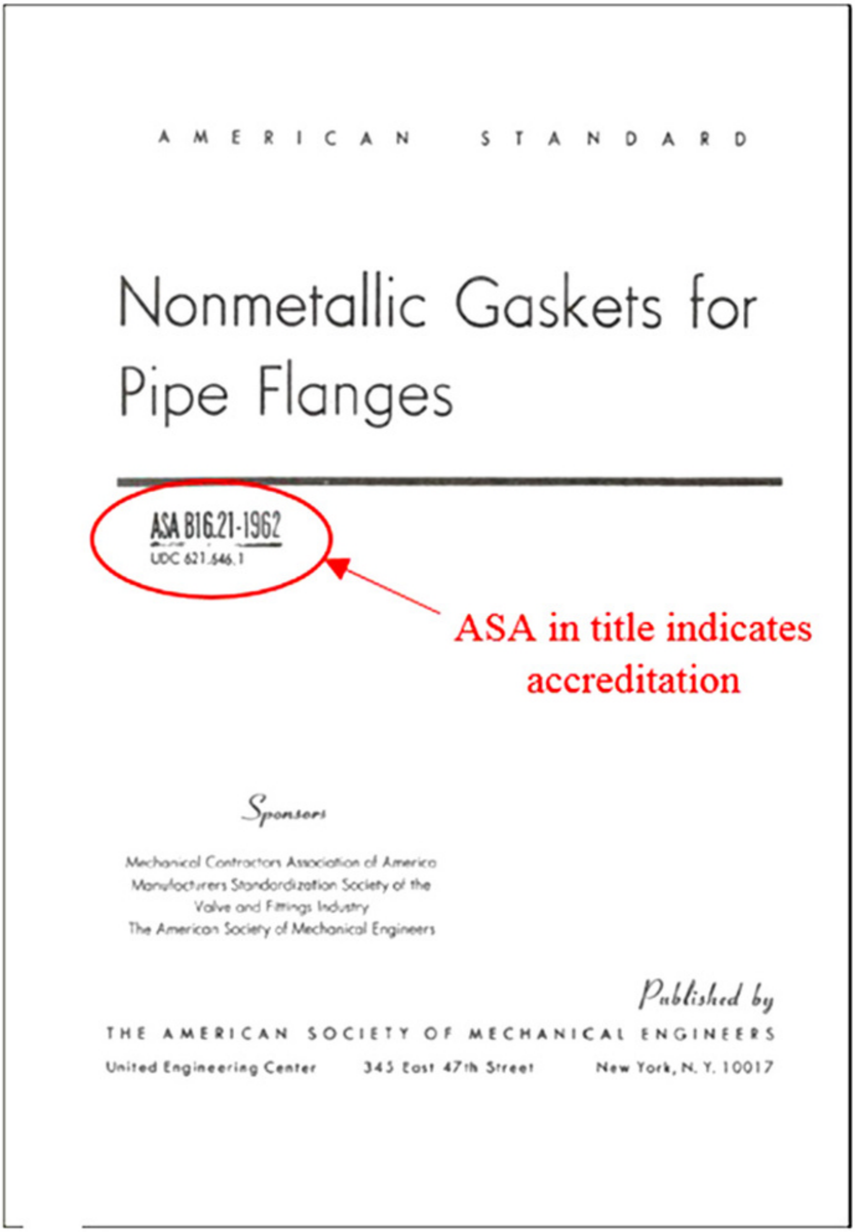


Figure 3 B16.21-1962 cover

Typically, any codes or standards listed in a company's standing portfolio of procedures and specifications, the type of documents that would be retained in a library of such design, engineering, and construction requirements, would contain a statement such as "Unless otherwise stated, the Codes and Standards referred to

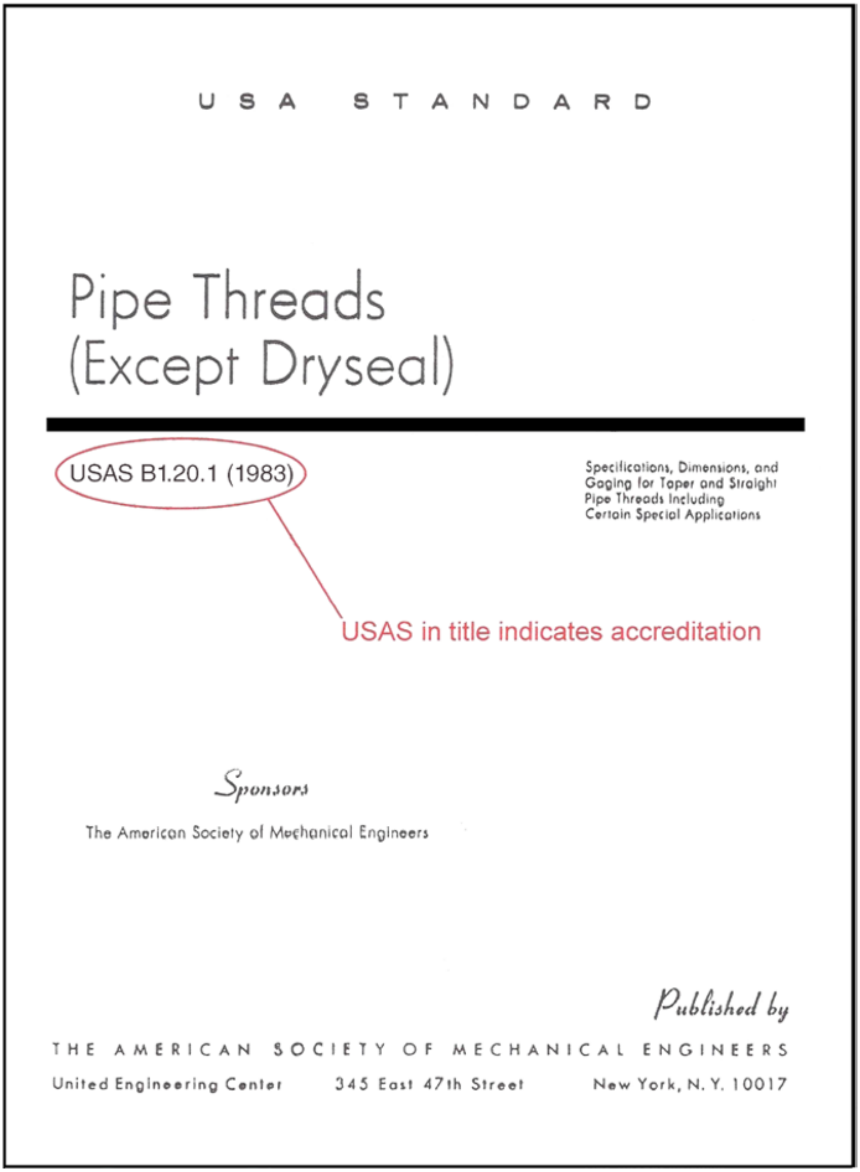
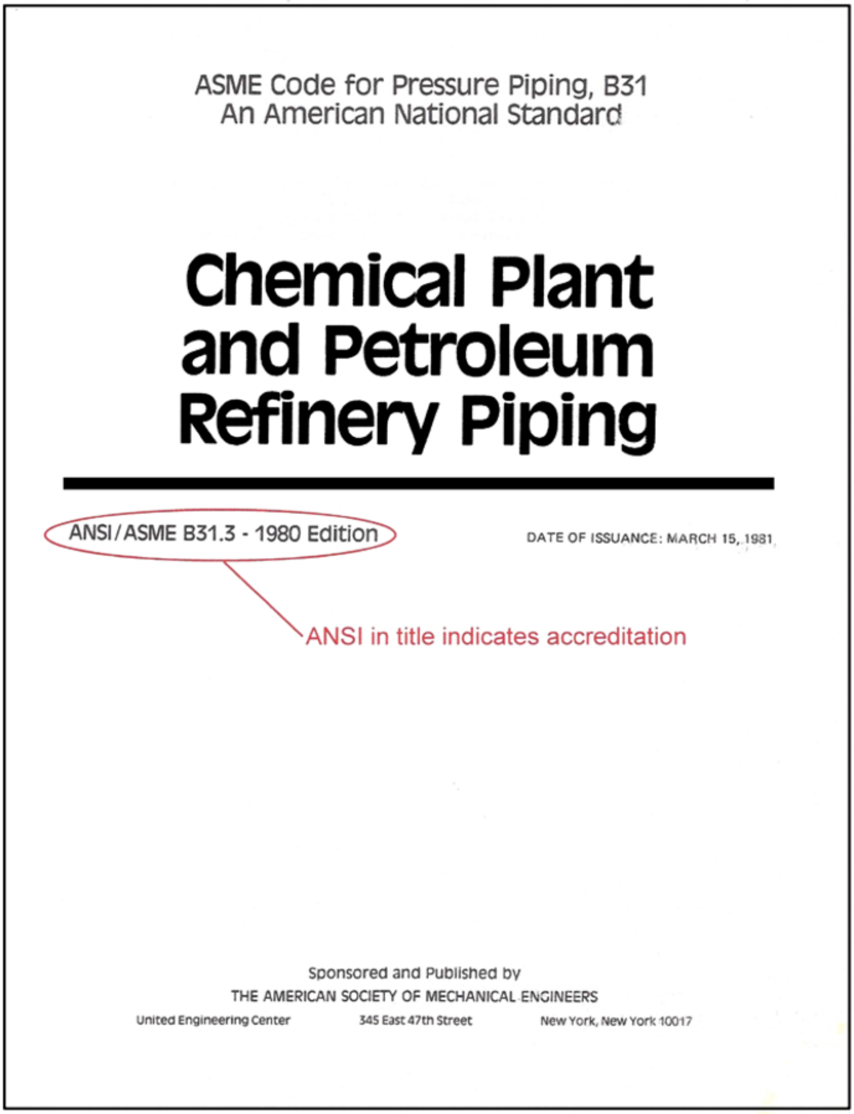


Figure 4 B2.1-1968 cover

herein shall be the most current version of such documents in effect at the time a contract goes into effect." This is due to the fact that such documents are maintained in a company's specification library over a period of years and decades. Rather than having to continuously update and issue such specs every time a standard or code is reissued, it is much more efficient to make the proclamation that


ASME Code for Pressure Piping, B31
An American National Standard

Chemical Plant
and Petroleum
Refinery Piping

ANSI/ASME B31.3 - 1980 Edition

DATE OF ISSUANCE: MARCH 15, 1981

ANSI in title indicates accreditation

Sponsored and Published by
THE AMERICAN SOCIETY OF MECHANICAL ENGINEERS
United Engineering Center 345 East 47th Street New York, New York 10017

Figure 5 B31.3-1980 cover

"…the most current version of such documents in effect at the time a contract goes into effect." When a project is rolled out, specific issue dates of standards and codes can be added.

Until such time as catalogs referring to ANSI are revised to instead make reference to the appropriate Standards Developer, there will still be a degree of misunderstanding involved.

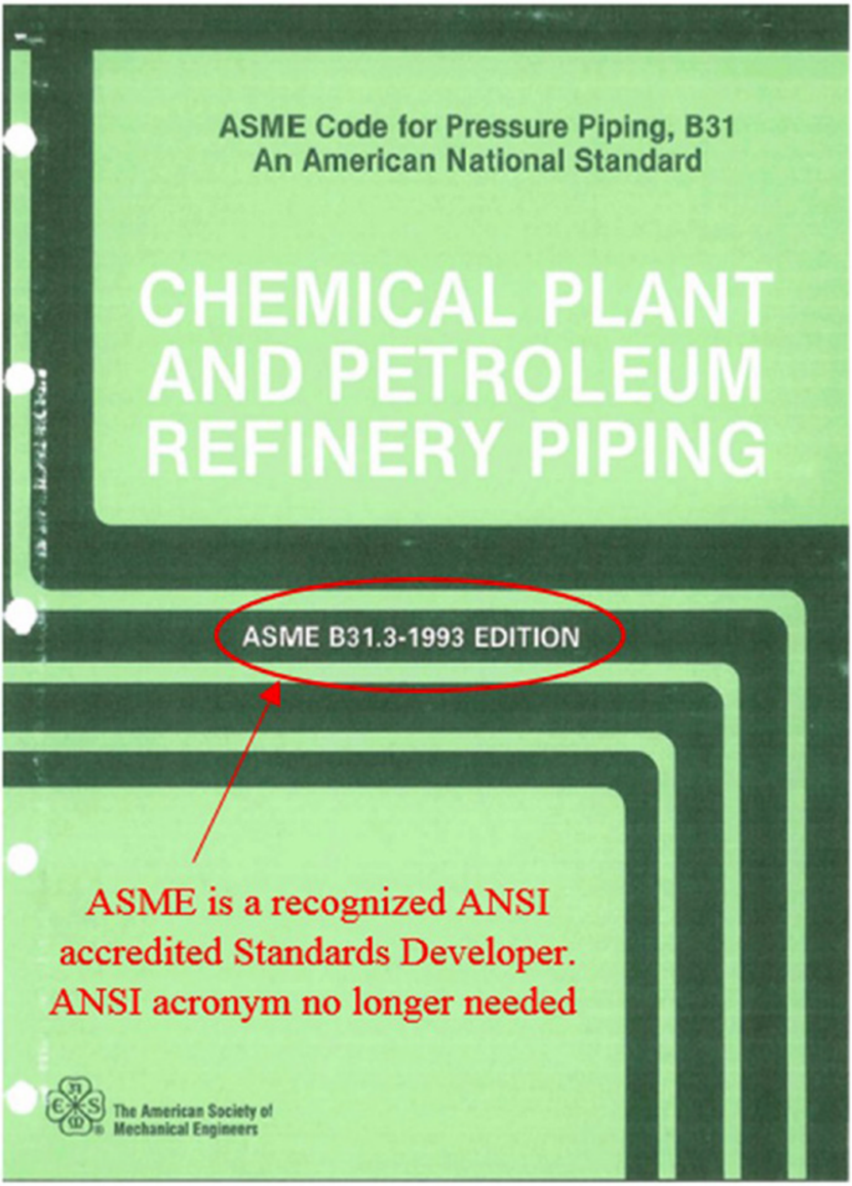


Figure 6 B31.3-1993 cover

The Process of Maintaining an ANSI-Accredited Code or Standard

Accreditation of an ANSI-accredited Standards Developer is the process by which, in the case of ASME, an organization proves, on an ongoing periodic basis, that they are competent to perform the duties and services they have elected and have committed to perform. In the case of codes and standards committees, such as the ASME BPE Committee, there are very strict rules with regard to developing and amending consensus standards as well as the process of responding to requests for interpretation with regard to the standard.

The ASME BPE Standard currently consists of a Standards Committee, Executive Committee, and ten subcommittees that are dedicated to sections of the standard referred to as parts. These same subcommittees found in other ASME codes and standards committees are referred to as subgroups. In addition to these main groups or committees within the BPE Standard, there are also ad hoc groups referred to as task groups. These are small focus groups assigned and dedicated to a specific task as it relates to a particular subcommittee. If resolution of an issue is too complex or requires added information in order for the subcommittee to make a decision on the issue, it is assigned to a task group. That task group will then resolve the issue between meetings, which, in the case of the BPE Standard, is three times per year. Results of that task are then written up as a proposal and submitted to the sponsoring subcommittee for review and comment or for approval. These ad hoc task groups can be made up of one or several people, and they can be resolved before the next meeting, or they may take five or more years to complete.

There are multiple sources that can affect change in a standard such as the BPE. And such sources include those from outside the membership of the standard as well as those within the membership of the standard. These standards, as well as the codes, are public documents and are therefore open to comment and recommendation from the public.

In a merciful attempt at avoiding the crushingly mundane explanation necessary to explain in any rational detail the process by which changes from minute editorial details to the addition of entire sections of the standard are orchestrated, I will default to only touching on a few key essential points. These ASME standards are referred to as consensus standards. This is in light of the fact that their approval at every stage of the process is done by consensus. From task group work to the subcommittee or subgroup, to the Standards Committee, the Supervisory Committee, and finally ANSI, voting is done by a balanced contingent of members at each of these voting plateaus.

Each voting group is required to maintain a balance of interest, referred to as "interest category or classification" among its membership. Meaning that no single interest group, such as those representing component manufactures or material suppliers or end users or any other specific group, is able to ostensibly hijack an issue and steer the results in their favor.

Before closing out on this section, I will leave you with some additional information. The ASME BPE Standards Committee currently meets three times per year in January, the May/June time frame, and the September/October time frame. There is a meeting notice sent out to members about one month prior to a meeting date giving the dates, hotel, discounted hotel rate, and other essential information. This notice is also posted on the BPE Committee web page at https://cstools.asme.org/csconnect/CommitteePages.cfm?Committee=N10120000. On the web page (Ref. Figure 7) under "Meetings" in the left-hand frame, single click on "BPE Meeting Notice" and you will be able to download and print the meeting notice.

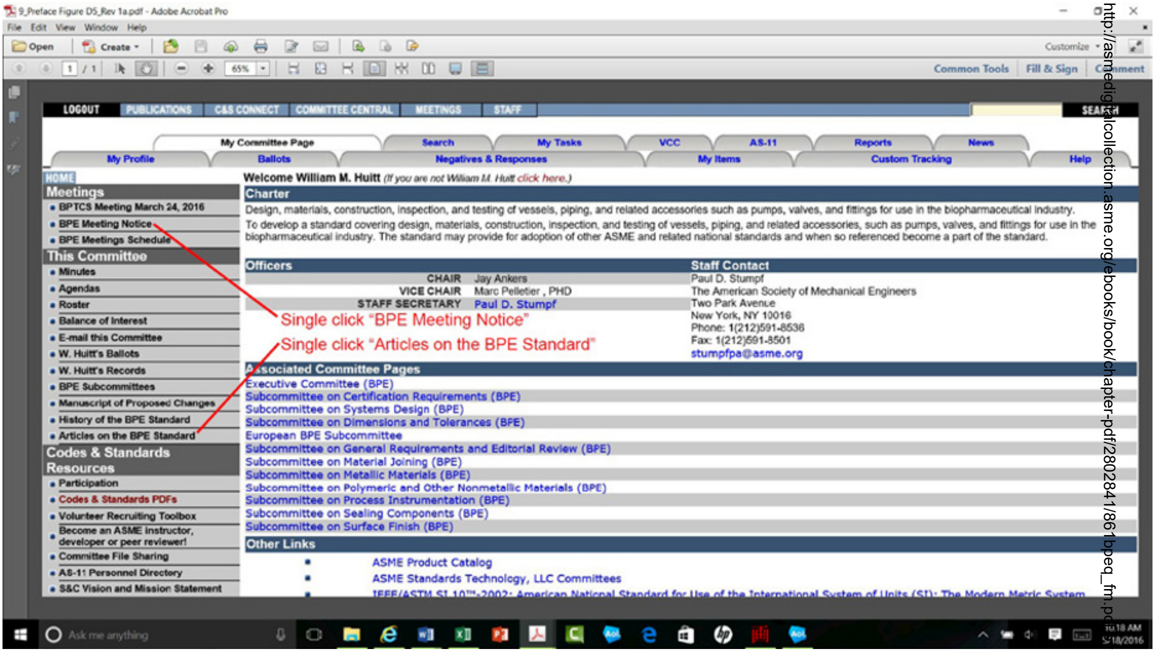


Figure 7 ASME BPE Committee web page

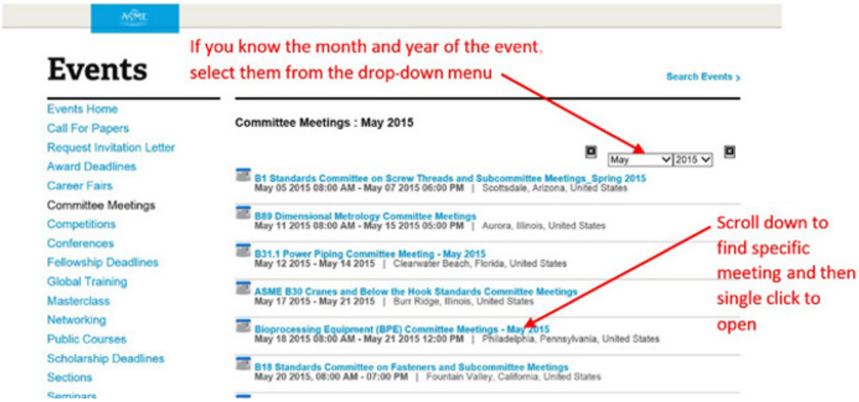


Figure 8 ASME BPE Committee meeting calendar

Meeting information can also be found at http://calendar.asme.org/home.cfm?EventTypeID=4 as shown in Figure 8. Upon reaching the linked page, enter the month and year of the meeting. After it jumps to that time period, scroll down until the specific meeting you are looking for is found then single click on it to open the page for that meeting.

In addition, there are a number of articles published by various members of BPE that can be found on the BPE web page. Referring to Figure 7, under “This Committee” in the left-hand frame, single click on “Articles on the BPE Standard.” This will take you to the page link shown in Figure 9 providing a listing of a number of downloadable articles and journal papers written by committee members and published by various means. These articles and papers cover topics that specifically relate to the BPE Standard and to high-purity piping in general. Double-click any of the articles to open and download as a .pdf file.

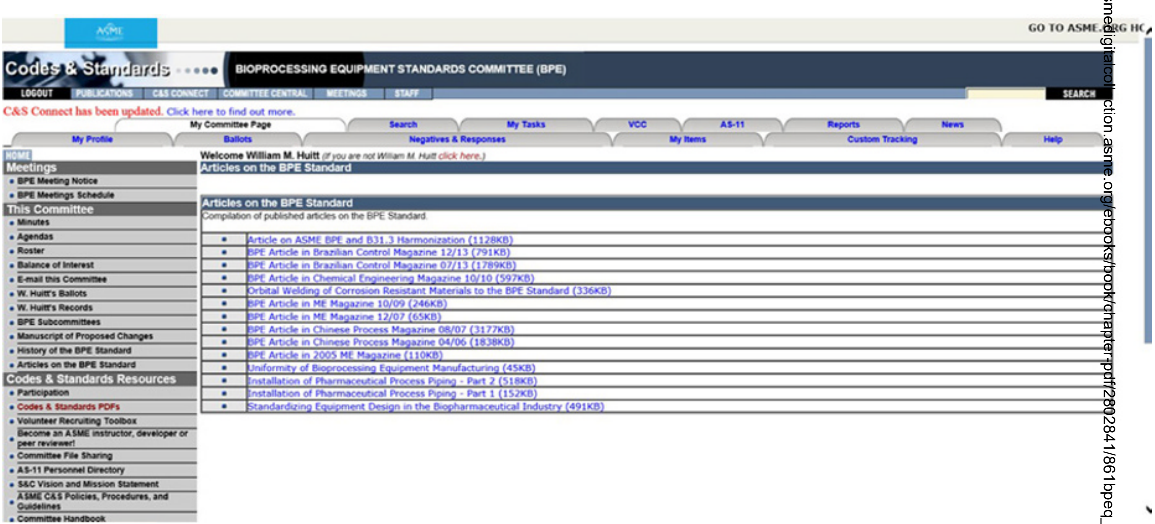


Figure 9 Articles currently listed on the BPE Standard

Acknowledgments

Chris Mahler and Mary Grace Stefanchik

A special thanks to Chris Mahler, Manager Business Development, Third-Party Sales with ASME, for initiating the onset of this book. We became acquainted in his marketing work with the Bioprocessing Equipment (BPE) Standard and more specifically his work with the BPE Certification Program. At the New Orleans BPE meeting in May of 2014, Chris approached me with the idea of my writing a companion guide to the BPE Standard, asking if I might be interested in such a project. I acknowledged that I did indeed have an interest in taking on such a project and had been sitting on the idea for some time. Having indicated my interest Chris then introduced me, by way of e-mail, to Mary Grace Stefanchik with ASME Press who was, from that point on, instrumental in guiding me through the ASME Press publication process. I am deeply grateful for the consideration and trust in me shown by Chris and for the help and understanding by Mary Grace. After a partnership between the American Society of Mechanical Engineers (ASME) and Wiley Publishing, Inc. was made apparent, Wiley became the primary editor/producer of this book. It was a wonderful experience working with Ramya, Vijay, and Sandra at Wiley.

Others

A book such as this is never done in a silo. The writing and development of such a project is done with the help of others. Others that over the years I have come to respect and know I can depend on, individuals that selflessly give off their time and knowledge to help others. These are individuals that have perfected the art of giving back as volunteers on multiple professional organizations and by serving relentlessly on multiple committees. My professional and personal life has been made better in knowing each of the following individuals who were true assets and resources in writing this book.

The following is a list of those who contributed firsthand accounts and documents that were so pertinent and essential to the historical accuracy in telling the story of the founding and development of the ASME BPE Standard in a narrative titled *Early History and Development of the ASME BPE Standard*. Those that provided recollections and documents from that period include the following in alphabetical order:

Jay Ankers—M + W Group
William H. (Bill) Cagney—JSG, LLC
Dr. Richard D. Campbell—Bechtel Corp.
Anthony P. (Tony) Cirillo—Cirillo Consulting Services, LLC
Randy Cotter—Cotter Bros.
Dr. Barbara K. Henon—Magnatech, LLC
Frank J. (Chip) Manning—VNE Corp.
Lloyd J. Peterman—United Industries, Inc.
Paul Stumpf—ASME Staff Secretary to the BPE Standard

As original founders and protagonists of the ASME BPE Standard, the earlier listed individuals, along with several others identified in this historical account, are the faces of those who, some 30 years ago, understood the need for such an industry standard and did something about it. At the publication of this book, those individuals, and many others named in the historical narrative found in the preface, are still very much involved these 30 years later. That alone speaks volumes with regard to the character and dedication of those individuals who are so much a part of the founding, development, and continued growth of the ASME BPE Standard.

The following also are people that helped keep my writing concise, accurate, and to the point by taking time out of their busy schedules to review many of the pages of this book, individuals whom I trust to give me their opinion in the most intelligent and forthright manner and without embellishment. It includes such individuals as:

Dr. Barbara K. Henon, a consultant, who I knew through her many fine articles on orbital welding long before I first met her in Cork, Ireland, in 2004. She has proven to be an invaluable part of the work we do on codes and standards as well as a trusted friend. Her deep knowledge and understanding of welding was a key resource for this book.

Mr. Richard Shilling is an expert on international export regulations, administration, and communication. He also has an unabashed love affair with his 1965 356C Porsche, a topic of which he lectures on around the country. Having been involved with orbital welding for many years, Richard was kind enough to perform a review on such subject matter providing insight and well-founded recommendations.

Dr. James D. Fritz, a metallurgist with TMR Stainless, provides the BPE Standard with his depth of knowledge and insight into the world of metallurgy playing a major role in the creation of the subcommittee on metallic materials.

Jim is outspoken and active in subcommittee meetings and always a source of reliable and in-depth information when it comes to metallic materials and a valuable resource for this book as well.

Mr. James D. Vogel, founder and director of the BioProcess Institute, past chair of the subcommittee on sealing components, and current vice-chair of the same subcommittee. Jim is a proponent of and has written many informative and timely articles on the subject of single-use systems. Jim was kind enough to share that knowledge in his review.

Mark Embry, with Asepco, is chair of the General Requirements Subcommittee. Mark has played a huge role in helping to harmonize the various sections of the BPE Standard, which does require constant oversight. From a general requirements standpoint, his responsibilities touch on every segment of the standard. With his understanding of general requirements, Mark provided insightful recommendations in the pages of this book he was kind enough to find time to review.

Ken Kimbrel, V. President Ultraclean Electropolish, Inc., has been a long time member of ASME BPE and spearheaded the creation and adoption of Part MM in the standard of which he is past chair. Unable to rest on his laurels, Ken currently chairs the subcommittee on surface finish. He provided knowledge and experience in his review of the manuscript on the topic of surface treatments and conditions.

John Kalnins, Technical Service Manager at Crane ChemPharma, is chair of the ASME B31.3 subgroup F on nonmetallics and metals lined with nonmetallics. He is also a member of the new ASME Nonmetallic Pressure Piping Systems (NPPS) subcommittee on thermoplastic piping. I have known John for a few decades now and have been impressed time and again with the depth of his knowledge regarding nonmetallic materials. John was kind enough to review and comment on the nonmetallic subject matter.

About the Author

William M. (Bill) Huitt has been involved in industrial piping design, engineering, and construction since 1965. Positions have included design engineer, piping design instructor, project engineer, project supervisor, piping department supervisor, engineering manager, and president of W. M. Huitt Co., a piping consulting firm founded in 1987. His experience covers both the engineering and construction fields and crosses industry lines to include petroleum refining, chemical, petrochemical, pharmaceutical, pulp and paper, nuclear power, biofuel, and coal gasification.

Mr. Huitt has written numerous procedures, guidelines, papers, and magazine articles on the topic of pipe design and engineering. He is a member of various industry-related organizations including the American Society of Mechanical Engineers (ASME) where he is a member of the B31.3 section committee, B31.3 Subgroup H on High-Purity Piping, and three ASME BPE subcommittees and several task groups, as well as the ASME Board on Conformity Assessment for BPE Certification where he serves as vice-chair. He was a member of the American Petroleum Institute (API) Task Group for the development of RP-2611; he additionally serves on two corporate specification review boards and was on the Advisory Board for ChemInnovations 2010, 2011, and 2012, a multi-industry Conference and Exposition.

Mr. Huitt authored the training program and provides training to ASME auditors for auditing BPE-compliant fitting manufacturers for BPE Certification. Bill has presented at the Annual ASME Consultants Meeting and at the Annual Inspectors Meeting for the National Board of Boiler and Pressure Vessel Inspectors. He has also presented at the ISPE Annual Meeting as part of the educational track.