

2007 Edition ASME BPE Standard Presentation & Review Lloyd J. Peterman, Director, International United Industries Inc.

Presented For

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ASME BPE-2007 (Revision of ASME BPE-2005)

Bioprocessing Equipment

ASME Bioprocessing Equipment Standard

Or

AN INTERNATIONAL STANDARD



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ASME BPE

2007 Edition



Introduction

The standard was started in 1988 with a small task group at the ASME Annual meeting

ASME BPE Standard is a worldwide standard for the Biopharmaceutical, Personal Care, API industries and other hygienic industries



Why Develop a Standard?

- The lack of applicable industry standards for biopharmaceutical in 1988
- Industry demands for higher quality associated with hygienic process systems and sterilization needs
- First ASME BPE Standard was issued in 1997, the fastest standard published in the history of ASME



Why American Society of Mechanical Engineers (ASME) ?



- > History of Establishing Codes and Standards
- Started in 1800's with Boiler Code
- International Reputation for Acceptable Standards
- Great need for mechanical engineers in industry



ASME BPE Scope

This Standard deals with the requirements of the bioprocessing, pharmaceutical, and personal care product industries as well as other applications with relatively high levels of hygienic requirements, covering directly or indirectly the subjects of materials, design, fabrication, welding inspections, testing, and certifications.







BPE Standards Committee Voluntary Consensus Standard

- Developed and maintained by a balanced group of experts
- Multiple stages of approval before publication
- Continuously updated to support industry accepted practices
- Corrections and clarifications can be requested by anyone



BPE Standards Committee

- Balanced standards committee is established with volunteers from the following Industry segments:
 - Industry Users (Biopharmaceutical Manufacturers)
 - Designer/Constructors (Engineering Firms)
 - > Manufacturers (Equipment Vendors)
 - Material Manufacturers (Tubing & Fitting Mfrs.)
 - > General Interest (Consultants, Inspectors, etc.)
 - Insurance / Regulatory (FDA)



BPE Standards Committee

- > BPE meets 3 times annually
 > Review subcommittee progress
 > Coordinate efforts
 > Between subcommittees
- Review liaison reports with other organizations to include:

ISPE, P3A, ASTM, DIN, EHEDG & ISO

Invite guest speakers / experts for educational purposes at subcommittee level



ASME BPE Main Committee



ASME

5 Stages in Approval Process for BPE

> ASME Subcommittee development

- > ASME BPE Main Committee
- > ANSI Public Review
- ASME Board on Pressure Technology Codes & Standards
- ANSI Board of Standards Review
- Next ASME BPE publication

Above stages could take 18-24 months depending on issue date



BPE Subcommittee General Requirements Part **GR**

This subcommittee coordinates and reviews the drafts produced by all subcommittees



- It is responsible for developing a lexicon of terms encompassing all the different parts of the standard
- Coordinates and reviews all terms and definitions for the standard



BPE Subcommittee General Requirements Part **GR**

Provides the standard's introduction

- This subcommittee covers the general requirements applicable to the standard
- Covers references to all standards applicable to ASME BPE Standards

Is responsible for the BPE Standard's index





This subcommittee develops criteria for BPE equipment and systems to establish industry requirements for cleanability, Sterility, and Aseptic Processing

Establishes design guidelines applicable to bioprocessing equipment, components, assemblies and systems











> The BPE SD part is not intended to limit new and possibly better designs > The BPE SD part covers "new construction" and should not be used to the acceptability of existing equipment The new 2007 BPE part SD had 21 changes from the 2005 edition



BPE Subcommittee on Dimensions & Tolerances Part **DT**

This subcommittee is responsible for establishing requirements for the overall dimensions, tolerances, pressure ratings, marking and packaging of all BPE fittings, tube and process components

All fittings are standardized and are nominal OD tube conforming to BPE part DT



Tube standards for BPE were developed with ASTM A-270 as a supplemental S2 addition





BPE Subcommittee on Dimensions & Tolerances Part **DT**

O Dimensions & Tolerances:

Dimensions as specified in ASME BPE Part DT.

Nominal OD Size		1⁄2"	3⁄4"	1"	11⁄2"	2"	21/2"	3"	4"	6"
O.D. Tolerance	±.005	±.005	±.005	±.008	±.008	±.010	±.010	±.015	±.030	
Nominal Wall Thickness		.065	.065	.065	.065	.065	.065	.065	.083	.109
Wall Thickness Tolerance before EP		+.005008	+.005008	+.005008	+.005008	+.005008	+.005008 +.005008		+.008010	+.015015
Wall Thickness Tolerance after EP	+.005010	+.005010	05010 + .005010 + .005010 + .005010 + .005010 + .005 -		+.005010	+.008012	+.015017			
Control Length	©	.750	.750	.750	.750	.750	.750	.750	.750	.750
Tangent Length	\odot	1.500	1.500	1.500	1.500	1.500	1.500	1.750	2.000	2.500
Squareness Face to Tangent	₿	.005	.005	.008	.008	.008	.010	.016	.016	.030
Off Angle	0	.014	.018	.025	.034	.043	.054	.068	.086	.135
Off Plane	P	±.030	±.030	±.030	±.050	±.050	±.050	±.050	±.060	±.060

Roundness





Off Angle

Wall Thickness





• Off Plane





Required ASME BPE fitting inspections

BPE Subcommittee on Dimensions & Tolerances Part **DT**

Working to shorten all Concentric and Eccentric reducers for dead leg reduction.



Developing the 1" nominal "true size" hygienic joint similar to DIN 20MM

Working on hygienic clamp pressure points through dimensioning to solve gasket intrusion



BPE Subcommittee on Dimensions & Tolerances Part **DT**

- Part DT- 6.1 covers "off Angle" special fittings
- The dimensions in metric units are conversions from U.S. customary units, and are listed for reference onlyThe new 2007 BPE part DT had 18 changes from the 2005 edition
- The new 2007 BPE part DT had 18 changes from the 2005 edition





BPE Subcommittee on Material Joining Part **MJ**

- MJ Subcommittee establishes requirements for material joining (welding) associated with BPE equipment
- It develops requirements for orbital and manual welding, weld acceptance / rejection criteria, fit up, concavity and weld geometry
- Develops weld procedures and performance qualifications





BPE Subcommittee on Material Joining Part **MJ**

>weld map (Isometric drawing) fully traceable back to the original components

>heat number codes

>date it was welded

➤welder's ID number

≻if the weld was inspected.





BPE Subcommittee on Material Joining Part **MJ**

- BPE part MJ shall be used in conjunction with the requirements of ASME BPVC, sections VIII, and IX, and ASME B31.3, as applicable
- The new 2007 BPE part MJ had 16 changes from the 2005 edition







BPE Subcommittee on Surface Finish Part **SF**

SF establishes surface finish Ra designations that can be qualified and inspected

SF developed finish requirements that will enhance efficient cleaning and sterilizing procedures

SF Developed acceptance criteria for mechanical and electro polished surfaces



BPE Subcommittee on Surface Finish Part **SF**



ASME

Part SF covers product contact surfaces only

BPE Subcommittee on Surface Finish Part **SF**

This part shall be referenced when specifying surface finishes for specific systems including, but not limited to vessels and distribution piping system components

Change in surface finish codes developed for 2007 edition, SF0 through SF6

The new 2007 BPE part SF had 11 changes / deletions from the 2005 edition



BPE Subcommittee on Equipment Seals Part **SG**

- SG subcommittee establishes design and material requirements for various mechanical seals and gaskets used in BPE equipment
- Included but not limited to pumps, valves, rotating and reciprocating equipment, pressure vessels and hygienic process piping
- Develop seal classes defining the level of integrity for a given service





BPE Subcommittee on Equipment Seals Part **SG**

Seals are defined as those elements that create or maintain process boundaries between system components / subassemblies in order to ensure system integrity in a validated process.



The new 2007 BPE part SG had 6 changes / deletions from the 2005 edition



BPE Subcommittee on Polymer Based Materials Part **PM**

- SG subcommittee establishes requirements that are applicable to polymer based materials used within bioprocess systems and components
- Polymer based materials include thermoplastics and thermosetting materials in both virgin and composite forms

The objective of this part is to describe and outline accepted practices for the use of polymer based materials for clean and sterile bioprocess applications



BPE Subcommittee on Metallic Materials Part *MM (2009)*

Metallic Materials subcommittee establishes requirements for selection of acceptable metallic materials in hygienic process applications

Looking at acceptable ferrite levels

> MM will additionally list all mechanical and physical properties for these alloys

Alloys being considered are, ALX6N, Hastalloy, DIN, BN and ISO versions of 316 / 316L ASME BPE 2007 Nonmandatory Appendix > Appendix A: Commentary... Slag

Appendix B: Material examination log and weld log

> Appendix C: Slope measurement



Certification

- Under development, timeline 2009 edition
- > Purpose

Establish a certification and accreditation program for suppliers of products (components and equipment) and services to ASME BPE end users.

Modeled after ASME-RTP-1 Standard's Accreditation Program



Certification / Accreditation

> Discussions include:

- Accrediting manufacturers of fittings and tubing. Eventually will include vessels manufacturers, skid manufacturers, etc.
- Develop audit checklist for specific areas of accreditation.
- Enforcement
- Application requirements



International Participation

European Subcommittee

- Established in 2003
- Developed to address European Philosophies and Methods of Design and Installations Practices
- Coordinate / Communicate with US Subcommittees
- Number one challenge is addressing harmonization : DIN vs. BN vs. EHEG vs. ISO vs. CE

Asian membership – Delegate Program (Japan group now active)



We want YOU!

International Participation

(ASME-BPE)				(ISO 1127)				(DIN 11850,ser. 2)			
	DIN 11866 , part C			DIN 11866 , part B				DIN 11866 , part A			
BS EN 13312 - 1 to 6 : 2001											
OD	OD x WT	OD x WT		DN	OD x WT	OD x WT		DN	OD x WT	OD x WT	
nominal size	(mm)	(inch)		nominal size	(mm)	(inch)		nominal size	(mm)	(inch)	
1/4"	6,35x0,89	1/4" x 0,035"		4				4	6,0x1,0	0,236"x0,039"	
				6				6	8,0x1,0	0,315"x0,039"	
3/8"	9,53x0,89	3/8" x 0,035"		8	13,5x1,6	0,532"x0,063"		8	10,0x1,0	0,394"x0,039"	
1/2"	12,7x1,65	1/2" x 0,065"		10	17,2x1,6	0,678"x0,063"		10	13,0x1,5	0,512"x0,059"	
3/4"	19,05x1,65	3/4" x 0,065"		15	21,3x1,6	0,839"x0,063"		15	19,0x1,5	0,749"x0,059"	
				20	26,9x1,6	1,060"x0,063"		20	23,0x1,5	0,906"x0,059"	
1"	25,4x1,65	1" x 0,065"		25	33,7x2,0	1,328"x0,079"		25	29,0x1,5	1,143"x0,059"	
				32	42,4x2,0	1,671"x0,079"		32	35,0x1,5	1,379"x0,059"	
1 1/2"	38,1x1,65	1 1/2" x 0,065"		40	48,3x2,0	1,903"x0,079"		40	41,0x1,5	1,615"x0,059"	
2"	50,8x1,65	2" x 0,065"		50	60,3x2,0	2,376"x0,079"		50	53,0x1,5	2,088"x0,059"	
2 1/2"	63,5x1,65	2 1/2" x 0,065"		65	76,1x2,0	2,998"x0,079"		65	70,0x2,0	2,758"x0,079"	
3"	76,2x1,65	3" x 0,065"		80	88,9x2,3	3,503"x0,091"		80	85,0x2,0	3,349"x0,079"	
4"	101,6x2,11	4" x 0,083"		100	114,3x2,3	4,503"x0,091"		100	104,0x2,0	4,098"x0,079"	
				125	139,7x2,6	5,504"x0,102"		125	129,0x2,0	5,083"x0,079"	
6"	152,4x2,77	6" x 0,109"		150	168,3x2,6	6,631"x0,102"		150	154,0x2,0	6,068"x0,079"	
				200	219,1x2,6	8,633"x0,102"		200	204,0x2,0	8,038"x0,079"	



Future of BPE > Next Edition, ASME BPE 2009 scheduled to be published by February 2009 > Scope expanded to include: Personal Care Products \succ Challenges: Worldwide Recognition & Acceptance Harmonization of Standards Certification / Accreditation Program in place by 2009 edition



ASME BPE Membership

> All members are volunteers > Membership on ASME Committees require a commitment from both prospective member and financial guarantee from their employer > Members are appointed to the committee for a term of 5 years attending 3 meetings per calendar year

Meeting locations are decided on by the Main committee



BPE Future Meetings

January 19 - 22, 2009, Caribe Hilton San Juan, Puerto Rico, USA Territory

May 25-29, 2009, Crowne Plaza Hotel, Dublin, Ireland

October 5-9, 2009 Radisson Boston Hotel, Boston. MA, USA

January 18-21, 2010 Rio Mar Beach Resort San Juan, Puerto Rico

May/June 2010 – Europe (not decided) London or Amsterdam



ASME BPE 2007 Standard Ordering Information

http://catalog.asme.org/home.cfm?CATEGORY=CS&TaxonomyI temID=2968&ProductFormat=DigitalBook

BPE - 2005 Bioprocessing Equipment



The ASME BPE Standard standardizes specifications for the design, manufacture, installation, inspection and acceptance of equipment used in the pharmaceutical and biologic products industries. **List Price: \$205.00**

Format: Buy Print or Buy PDF

No. of pages: 128





AN INTERNATIONAL STANDARD



BPE wants questions / suggestions

If you have a question please contact me

Suggested changes give to me

I will deliver to the appropriate BPE subcommittee Chairperson for formal debate

>Thanks for your attention today!



