

June 2009

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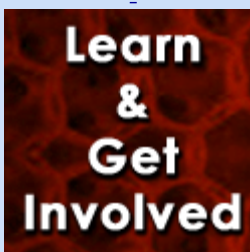
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LETTER FROM THE BPE CHAIR

- Jay Ankers



The BPE-2009 is almost ready and ASME BPE's Project 2012 is off to a strong start.

I am writing this message as I, along with all the BPE Committee members and guests prepare for another successful week of ASME Bioprocessing Seminars and ASME BPE committee meetings in Dublin, Ireland. The weak global economy is having little effect on the participation and energy level exhibited by the BPE subcommittees and task groups. It is great to see the activity after recently completing the BPE-2009 edition in January and focusing our attention on Project 2012, the next edition.

In the following articles, you will see the result of 2 years worth of incredible work by over 200 industry experts from around the globe. Most importantly, these 200 individuals, with diverse technical backgrounds, from different companies, generated the information for your BPE Standard, gaining the consensus of their peers, critics, and in some cases their competitors in the industry.

Next, Project 2012 will take our international bioprocessing standard and make it more user-friendly, readable, and add better graphics. We are also adding a whole new section on Process Instrumentation and putting together a comprehensive list of documentation requirements for all our components and systems with the help of end users and suppliers. We have listened to our readers around the globe from Singapore to San Francisco, from Tokyo to Philadelphia, and from Cork to San Juan. The feedback was great from both young and old. The BPE was confirmed to be useful to the readers and they want more.

All of this has created an interesting problem for our BPE members: How do we encourage participation from industry experts around the globe in over 12 time zones? I am contacted almost weekly from someone in China, India, Europe, or the Middle East asking me how they can get involved and contribute to our standard. This is a nice challenge for the leadership team of a group of volunteers. We are looking for more ways to work electronically and encouraging members to use our C&S Connect web system. The ASME is working with our leadership to pick meeting locations that are accessible to many.

Join us this year in Dublin and Boston, and San Juan the beginning of next year and see what I am talking about. I am looking forward to the next 3 years of working with the best in our industry as we prepare the ASME BPE for more and more use around the world.

Warmest regards,



Jay Ankers

ASME Bioprocessing Equipment Standard Chair
Director – Process Mechanical
LifeTek Solutions, Inc
jankers@LifeTek.com

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Plus more. Visit the BPE website at www.asme.org/communities/technical/bpe

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October 5-9, 2009: BPE Committee Meetings in Boston, MA All meetings are open to the public as space will allow. For more details, please contact Paul Stumpf at 212-591-8536 or stumpfpa@asme.org

October 26-29, 2009: Attend the 22nd Annual Bioprocess Technology Seminars & Exhibition to be held at the Hyatt Regency in Montreal, Canada. The event will feature 10 in-depth seminars covering the latest topics related to the design and operations of today's bioprocessing facilities. For more details, go to www.asmeconferences.org/bioprocess09 or contact Jennifer Delda, Program Manager, at 212-591-7108.

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Certification Program News

Chair: Richard D. Campbell, PHD, PE
Email: rdcampbe@bechtel.com



The ASME BPE Standard provides the requirements applicable to the design, fabrication, installation, testing, examination, inspection, and marking of hygienic equipment, tubing, fittings, and other components. Since the scope of the Standard is beyond that of general industry standards, a Certification Program is being established particular to the rules of the bioprocessing, pharmaceutical and personal care product industries. This program will be for the certification of organizations which provide components and other items in accordance with this standard. The 2009 edition incorporates a new Part CR which provides the requirements for this program.

Through this program, a Certificate of Authorization will be issued to qualified applicants to confirm that the Certificate Holder has systems in place to ensure compliance with this Standard. A Symbol Stamp will be issued to the Certificate of Authorization Holder to mark components as being in compliance with this Standard. As such, this Certification Program also sets forth requirements that will regulate the use of the ASME BPE Symbol Stamp. The Certification Program will be adopted in phases, starting with tubing and fitting manufacturers.

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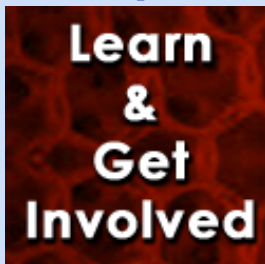
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Design Part SD News

Chair: David Marks, PE

Email: david.marks@dmealliance.com



The 2009 edition, Part SD, will include substantial new content on equipment and process systems plus significant updates to existing sections. These changes will include several new sections with requirements for the design of bioreactors/fermentors, sterilizers/autoclaves, CIP distribution systems, and process gas distribution systems. The entire CIP Systems and Design section (SD-4.15) has been revised to meet current industry standards and expand requirements for CIP skid design, CIP flow rates, cleaning process vessels, CIP supply & return headers, and CIP spray devices. Part SD has also been updated with enhanced content on the design of hygienic pumps, ball valves, O-ring connections, top-entering mixers, and steaming for bioburden control.

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Dimensions & Tolerances Part DT News

Chair: Frank Manning
Email: cmanning@vnecorp.com



Part DT has had a good amount of additions / deletions going into the 2009 Edition. There are over 20 items changed, added, or deleted. The major items are as follows:

- Added Automatic Tube Weld Cap Table DT- 30 and minimum ID control portion note
- Added Hygienic Clamp Solid End Cap Table DT- 31
- Added Table DT-5.2 Hygienic Clamp Ferrule: Design Criteria showing gauging width, Gauging and contact dimensions.
- Added Type A & B Hygienic Ferrule face design in Table DT 5.1
- Added "New" Nominal one inch fitting design, dimensional criteria in Table DT-5.1
- Added Figure DT-1 showing Hygienic Clamp conditions at installation.
- Added centerline radius values to Table DT-5 for elbows
- Deleted all eccentric / concentric reducer fittings having more than 2:1 reductions in Table's DT-11, 21, and 26

Future work includes a major effort to reduce the length's on all eccentric and concentric reducing fittings. We are continuing to work jointly with MJ on tolerance issues at hygienic weld joints in a newly developed task group.

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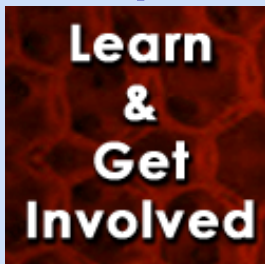
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General Requirements Part GR News

Chair: Ernie Benway
Email: erniedewelder@gmail.com



In the 2009 Edition, Part GR will see the addition of the definitions of 40 new terms such as, "mechanical seal", "bioburden", "biofilm", and "rouge" to name a few. The scope is being revised to clarify new construction versus existing construction and installations between them. References to a dozen standards including ASTM, EHEDG and ISO, primarily dealing with elastomers, has been added.

There is also the addition of Part GR-4 that deals with the qualifications of the Inspector Delegates. It sets the documented training requirements and the 4 levels of qualification (Trainee, QID-1, QID-2 and QID-3) along with the required capabilities of the personnel involved in the Inspection of Bio-Processing, Pharmaceutical, and other systems involving high degrees of Bio-Burden control.

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A graphic with a dark red, textured background. The text "Learn & Get Involved" is written in white, bold, sans-serif font, centered on the graphic.

Material Joining Part MJ News

Chair: Chris Trumbull
Email: ctrumbull@muel.com

For 2009, Part MJ has added notes on the use of duplex alloys, clarified Sample Weld criteria, and added Welding Operator Qualification requirements. We have members working together with the Subcommittee on MMoC on filler metal requirements, the Subcommittee on DT on ovality and mismatch, and B31.3 regarding various issues. We will be working with the Subcommittee on SD on Process Gas Systems in the near future.



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Metallic Materials of Construction Part MMoC News

Chair: Ken Kimbrel
Email: kenk@ultracleanep.com



The 2009 Edition will include a new Part MMoC, which will identify metallic materials of construction commonly used in hygienic service. This part will identify materials, their associated testing standards, mechanical and chemical properties, appropriate surface finish that may be applicable above and beyond that listed in Part SF, fabrication guidelines that may be applicable above and beyond that listed in Part MJ, and other attributes necessary for use in hygienic service. Additionally, this part will define a method by which other metallic materials of construction, both listed and unlisted, can be submitted and evaluated for inclusion into the BPE Standard. Non-Mandatory Appendices are also being added to address commonly used corrosion tests, ferrite impact and measurement, and electropolishing procedure qualification.

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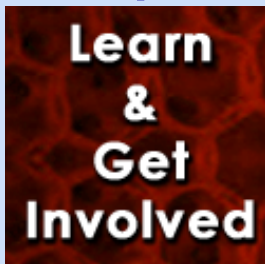
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Polymers and Elastomers Part PM News

Chair: Ted Hutton
Email: ted.hutton@arkema.com



The 2009 publication of Part PM will include new sections on Elastomer Performance, Hose Assemblies, Single Use Application, Surface Finish of Polymers, and a Non-Mandatory Appendix on Interpretation of Elastomer Material Property Changes. Looking forward to the next edition, a task group is working to add to the Single Use section. New task groups are working to address Chromatography, Filtration, Leachables and Extractables, Lined Vessels, Support of Polymer Pipe and Mold in Place/Flare Through connections for hose. Part PM will be reorganized for the next edition to make it more user-friendly.

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Process Instrumentation Part PI News

Chair: Dan Klees

Email: dan.klees@us.endress.com

This is a new part to be included in the 2012 Edition, and will focus on requirements applicable to the proper design, installation, and use of Process Instrumentation. It will address any process instrumentation and associated integrally mounted components in direct contact with the product, raw materials, or product intermediates.



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Seals Part SG News

Chair: James D. Vogel
Email: jdvpe@cox.net



Part SG has been enhanced in the 2009 edition of the standard. We have added the following:

1. A section was added for the application of Seals for Centrifugal Compendia Water Pumps. This provides better guidance on this specific application in the areas of configuration, drainability, and materials of construction.
2. Standard Process Test Conditions have been suggested to assess a seal's fitness for use. Typical test conditions are provided to simulate bioprocess SIP and CIP, as well as acceptance criteria for Hygienic Fitting Seal performance, in this appendix. Both Equipment suppliers and End Users are encouraged to perform testing to assess a seal's performance.
3. An Application Data Sheet has been added to the appendix of the standard to facilitate communication between End Users, Equipment Manufacturers, and Contractors. It provides a standard framework for listing process conditions to select the correct materials of construction and process configurations.
4. A section was added to describe expectations on O-ring joining.
5. A reference was added to the standard to the ISO 10993 biocompatibility test requirements.

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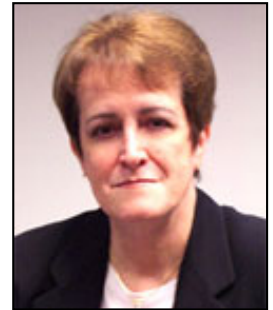
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Surface Finish Part SF News

Chair: Michelle Gonzalez, PE
 Email: atmg@roadrunner.com



I am very proud to announce all the substantive changes to Part SF to be included in the 2009 Edition. These changes were made possible by the hard work and dedication of members and non-members of the Surface Finish Subcommittee; these learned colleagues helped bring to fruition a very personal goal of mine, the one of adding important and critical information in the fields of "passivation", "electropolish", and the ever so controversial, "rouge".

Following are the most notable changes:

1. Section SF-7 Electropolishing Procedure Qualification was revised and augmented; this revision included reference to the NEW! Nonmandatory Appendix H – Electropolishing Procedure Qualification.
2. Section SF-8 Passivation was substantially revised and augmented; this revision included reference to the NEW! Nonmandatory Appendix E – Passivation Procedure Qualification.
3. Section SF-9 Normative References was added, and includes references to important National and International Standards regarding terms, definitions and parameters for the determination of surface texture (roughness, waviness and primary profile) by profiling methods.
4. Section SF-10 Rouge and Stainless Steel was added; this Section includes brief information on factors that may affect its formation, how a system may have to be evaluated so not affect the product quality and the valuable NEW! Nonmandatory Appendix D – Rouge and Stainless Steel.
5. Table SF-4 Acceptance Criteria for Passivated Product Contact Finishes was added; this table reinforces statements made in Section SF-8.
6. Subsection SF-P Polymer Product Contact Surface Finishes was added; this Subsection was generated by the members of the Subcommittee on PM and includes information regarding applications, materials, inspection techniques and surface conditions; it also include two tables relating to acceptance criteria parameters, and readings for product contact surfaces.

Future work of the Subcommittee will include critical information relating to mechanical polishing terms, techniques, materials and methods utilized in the manufacturing of equipment for the bioprocessing, pharmaceutical, and personal care product industries. This information is being gathered and discussed by the Mechanical Polishing Task Group. At the same time, another group, the Alloy Task Group, is endeavoring to clarify the complex issues relating to acceptance criteria for higher alloys, including polishing methods and treatments tested to achieve repeatable surfaces, safe for use in hygienic applications.