

# ASME BPE Newsletter-May 2011

**Letter from the Chair**

Jay Ankers

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**ASME BPE's *Project 2012* is coming together with less than 7 months to go.**

With the start of 2011, the team at our ASME BioProcessing Equipment Standard Committee looked like a bunch of tense newspaper editors and film directors, as they organize the new materials and updated graphics for our BPE-2012. Each of them will tell you that they knew what they were getting into back in 2009 when we, as a group, decided to embark on what we termed: ***Project 2012*** a three-year-long complete update/renewal of our **22-year-old** International Standard. Three years sounded like a long time in 2009. Besides, work was slow in our industry, and most of our folks were looking for a challenge to keep them active and connected in our industry.

***Project 2012***, and the work you will read about in the following pages, did just that: It has unified our group of 200+ industry professionals into a tighter team, who are each contributing to this Standard and our industry in a variety of ways. This new publication will take our well known bioprocessing standard and make it more user-friendly, readable, and add better graphics. Sections are being updated and organized, to be more familiar looking to end-users, contractors, engineers, and suppliers in our expanding global industry. We are also adding a whole new section on Process Instrumentation and putting together a comprehensive list of documentation and certification requirements for all our components and systems with the help of our end-users and suppliers. We have listened to our readers around the globe. The BPE was confirmed to be useful to the readers and they wanted more.

Looking forward to future editions of the ASME BPE, past this 2012 edition, our leadership team, with input from our members and "customers" has been planning what the ASME BPE should address in the future. Making sure that our standard provides the information that is valuable and correlates well with other accredited codes and standards used around the world.

Join us this year in San Francisco and Philadelphia as we put the finishing touch on the new publication. I am personally looking forward to next year when the BPE-2012 is published and available for use. As always, I truly enjoy working with my ASME BPE Colleagues, catching up with old friends, and most importantly: meeting new people at our meetings.

Warmest regards,

A handwritten signature in blue ink, appearing to be 'JA', written in a cursive style.

Jay Ankers

**Certification**  
**Part CR**

**Chair- Carl Kettermann**

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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 and pharmaceutical industries. This program will be for the certification of **organizations** which provide components and other items in accordance with this standard. The 2012 edition of Part CR includes additional information regarding the conduct of audits.

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. This Certification Program also sets forth requirements that will regulate the use of the ASME Certification Mark. The Certification Program will be adopted in phases, starting with tubing and fitting manufacturers.

**Design**  
**Part SD**

**Chair- David Marks, PE**

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The layout of BPE Part SD, Design for Sterility and Cleanability, has been completely renovated in anticipation of the 2012 publication. The 2012 edition will feature newly reorganized content that is much more internally consistent and user-friendly. Part SD figures have been updated and clarified to better illustrate design principals explained in the standard. The current L/D requirement for dead legs in hygienic piping systems will be clarified in the next publication. Content currently under development for part SD includes new requirements for hygienic pumps, static & dynamic spray devices, pipe hangers in clean space, code 7 filters, and a new non-mandatory appendix on spray device coverage testing. Part SD task groups are also developing new requirements for hygienic piping dead legs, chromatography and filtration systems.

**Dimensions & Tolerances**  
**Part DT**

**Chair- Dan Mathien**

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Part DT has undergone a complete redesign for the 2012 Edition. There have been several items added or changed. Here are the highlights:

- Sub-Sections formatted to meet current ASME numbering guidelines
- Purpose and Scope redefined
- Added new Tables for shorter length concentric and eccentric reducers
- Type A and Type B Ferrules now in separate Tables for ease of identification

Future work of the Subcommittee on DT includes establishing Hygienic Joint pressure ratings for both ambient and elevated temperatures along with standardizing dimensions for the standard heavy-duty, 3-piece and high pressure Hygienic Clamps.

**General Requirements**  
**Part GR**

**Chair- Mark Embury**

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For the 2012 Edition, Part GR, the most significant change is the revised Introduction and Scope. This change clarifies and expands the Scope of the Standard, including items such as, a new reference to B31.3 Chapter X, High Purity Piping. There are also several new and updated definitions such as, "blistering", "end grain", "spray device", and "Ra" to name a few.

**Material Joining**  
**Part MJ**

**Chair- Richard D. Campbell, PHD, PE**

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Part MJ will be slightly reorganized for the 2012 Edition and the Purpose and Scope (MJ-1) will be aligned with the rest of the BPE document. Part MJ will also be revised to be in alignment with the new ASME B31.3 High Purity Piping, Chapter X.

All welding terms and definitions will be evaluated for consistency and accuracy with other ASME and AWS documents.

MJ-2 will now be divided into two sections to show the addition of guidance for the use of Filler Metals.

Table MJ-1 addressing misalignment will be revised to address mismatch on the OD of 4" and 6" tubing.

MJ-6 will be revised to reference the new color chart for weld acceptance criteria on both electropolished and mechanically polished tubing. The new chart will replace the current AWS D18.2 color chart.

Tables MJ-1 through MJ-4, Acceptance criteria for welds on Vessels, Pipe, Tube, and Tube attachments will be updated with additional information.

MJ 7.2 will be reorganized and rewritten to better describe and differentiate between Examination and Inspection of piping, tubing, and vessels. Vision test requirements will be updated to require both visual acuity and color contrast examinations to be performed on an annual basis by a Board Certified Ophthalmologist or Optometrist.

MJ-10 Documentation, will be revised to reference the new section in GR that will address the requirements for material and weld documentation.

**Metallic Materials**  
**Part MMoC**

**Chair- Lynn Sturgill**

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For the 2012 edition of the ASME BPE Standard, the Metallic Materials Subcommittee will be expanding on the basic information published in the 2009 edition. The list of material specifications will be refined to eliminate redundant specifications while adding both domestic and German specifications. In a further attempt to support our international users, our alloy tables will be reorganized to more clearly group comparable European and US alloys. In support of efforts to make the ASME BPE Standard more user friendly, a number of more subtle changes will be made. These include the movement of welding-specific requirements for higher alloy materials into the Material Joining (MJ) Part of the Standard, along with the movement of base metal requirements from Part MJ into Part MMOC. An important part of these harmonization activities with the MJ Subcommittee is the mutual decision to move all filler metal specifications and classifications, including those for 316L,

into Part MMOC. These will be organized such that filler metals will be paired with base metals as "matching" in order to give readers of the Standard baseline guidance for selection of filler metals for compatible corrosion resistance when higher alloys are needed.

**Polymers and Elastomers**  
**Part PM**

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Bioprocessing with polymeric materials continues to grow, especially with single-use systems, bags, tubing sets, molded components, etc. The focus of the subcommittee on Polymers and Elastomers for the 2012 publication is on the requirements for selecting and using polymeric materials. The Part describes in greater detail the types of polymers, identifies various methods for characterizing polymers, and details the requirements by application. Part PM includes requirements for both single-use and multi-use components. The updated Part is much easier to navigate and contains clear requirements for BPE compliance.

**Process Instrumentation**  
**Part PI**

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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.

**Seals**  
**Part SG**

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Part SG, Equipment Seals is being significantly improved for the 2012 Edition of the BPE. The Part is being thoroughly reorganized. This includes the movement of some portions from Part SD, specifically applicable to seals, to provide better reference for the BPE Community.

The 2012 table of contents is being changed to the following:

SG-1 PURPOSE AND SCOPE

SG-2 SEALS TYPES

SG-3 SEAL GENERAL DESIGN REQUIREMENTS (GENERAL PROVISIONS)

The design requirements are being thoroughly reorganized. Some material will be removed, clarified/rewritten, reorganized or relocated to a different area of the Standard.

**SG-4 SEAL PERFORMANCE**

The seal performance criteria and methods of testing for gaskets, o-rings, diaphragms and mechanical seals in biopharmaceutical applications will be enhanced and/or added. Performance criteria include chemical (process) compatibility, physical requirements and compliance requirements. Standards for determining seal performance will also be developed including pass/fail criteria where appropriate. Testing methods will be added to the Appendix of the Standard to help guide the BPE community.

**SG-5 SEAL APPLICATIONS**

Seal Applications will be added and/or enhanced to provide a usage and selection reference for primary systems within a Biopharmaceutical Facility. Types of seals will take into consideration the primary process/utility fluids and associated parameters impacting seal usage. Subsections include: Compendia Water, Pure/Clean Steam, CIP and Process Fluids. This section is intended to be used in conjunction with the Application Data Sheet and directly link to Section SD where the Seals Components (e.g. Gaskets, O-Rings, Valves, and Mechanical Seals) will be utilized in the Process and Utility systems.

Appendix J-Standard Process Test Conditions (SPTC) for Seal Performance Evaluation

Appendix K-Application Data Sheet

**Surface Finish**  
**Part SF**

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The ASME BPE 2012 edition, Part SF, will include the following changes:

- Complete renumbering of Part SF and Non-Mandatory Appendix D, E, & H making it easier to read and locate references from tables to text
  - Addressed the use of Animal Derived Ingredient (ADI) within Part SF "Surface Condition" section
  - Clarified "Welds" under Acceptance Criteria Table
  - Further separated Part SF by Metallic and Polymeric product contact surfaces for an easier read
  - Rewrote Part SF Scope and Objective as a single "Purpose and Scope" to co-inside with GR
  - Condensed Part SF heading to "Surface Finishes for Product Contact Surfaces"
  - Added metric dimensions to tables
- Future changes the SF Subcommittee will undertake will be to review the non-mandatory Appendix D, E & H for current information.