



Bioprocessing Equipment  
Standards Committee

**Visitor / New Member  
Welcome Packet**



## Bioprocessing Equipment Standards Committee

Dear Visitor / New Member

It gives me great pleasure to welcome you to the ASME Bioprocessing Equipment Standards Committee meetings. The ASME BPE is the leading standard world wide for guidance in the design and manufacturing of Bio Pharmaceutical Processing Equipment. By becoming involved, you will be a part of new and revolutionary designs that help to maintain the health and safety of the general public. You will develop and drive new guidelines through the approval process, review and modify existing guidelines, and be part of an organization you can take pride in knowing is making a difference.

The best way to jump-start your positive experience at BPE is to become active with one of our committees. Those committees consist of:

- *SUBCOMMITTEE ON GENERAL REQUIREMENTS AND EDITORIAL REVIEW*
- *SUBCOMMITTEE ON SYSTEMS DESIGN*
- *SUBCOMMITTEE ON DIMENSIONS AND TOLERANCES*
- *SUBCOMMITTEE ON MATERIALS JOINING*
- *SUBCOMMITTEE ON SURFACE FINISH*
- *SUBCOMMITTEE ON SEALING COMPONENTS*
- *SUBCOMMITTEE ON POLYMERS AND OTHER NONMETALLIC MATERIALS*
- *SUBCOMMITTEE ON METALLIC MATERIALS*
- *SUBCOMMITTEE ON CERTIFICATION REQUIRMENTS*
- *SUBCOMMITTEE ON PROCESS INSTRUMENTATION*

A description of each subcommittee and list of officers for those will be included in subsequent pages. I encourage you to visit each subcommittee to find those that are of the most interest to you.

Sincerely,

*Jay Ankers*

Jay Ankers, Chairman ASME BPE



**The Beginning:**

The ASME—BPE started as a panel discussion in 1988 and then with the formation of an Ad Hoc committee holding its first meeting on March 1, 1990 at the ASME offices in New York City. The first meeting was attended by 11 members of the Ad Hoc committee and 14 visitors. From that original meeting, there was consensus concerning the need to develop standards that would meet the requirements of operational bioprocessing, including:

- The need for equipment design that are both cleanable and sterilizable
- The need for special emphasis on the quality of weld surfaces once the required strength is present
- The need for standardized definitions that can be used by material suppliers, designers / fabricators, and users
- The need to integrate existing standards covering vessels, piping, appurtenances, and other equipment necessary for the biopharmaceutical industry without infringing on the scopes of those standards

Throughout the development of the standard, close liaison was made with the European CEN, ASTM, and the 3-A Dairy Standards with the purpose to develop an ASME Standard that would be distinctive, germane, and not in conflict with other industry standards.

From those auspicious beginnings, the BPE has grown to hundreds of members and visitors worldwide that meet annually two to three times per year.



## **Scope of the ASME BPE STANDARD**

The ASME BPE Standard provides requirements for systems and components that are subject to cleaning and sanitization and/or sterilization including systems that are cleaned in place (CIP'd) and/or steamed in place (SIP'd) and/or other suitable processes used in the manufacturing of biopharmaceuticals. This Standard also provides requirements for single use systems and components used in the above listed systems and components. This Standard may be used, in whole or in part, for other systems and components where bioburden risk is a concern.

This Standard applies to:

- new system (and component) design and fabrication
- definition of system boundaries
- specific metallic, polymeric, and elastomeric (e.g., seals and gaskets) materials of construction
- component dimensions and tolerances
- surface finishes
- materials joining
- examinations, inspections, and testing
- certification

This Standard is intended to apply to new fabrication and construction. It is not intended to apply to existing, in-service equipment. If the provisions of this Standard are optionally applied by an owner/user to existing, in-service equipment, other considerations may be necessary. For installations between new construction and an existing, in-service system, the boundaries and requirements must be agreed to among the owner/user, engineer, installation contractor, and inspection contractor.

For a system or component to be BPE-compliant, adherence to all applicable parts of this Standard is required.



**Ethics:**

The ASME requires ethical practice by each of its members and has adopted the a Code of Ethics as referenced in the ASME Constitution, Article C2.1.1.



P-15.7  
2/1/12

**SOCIETY POLICY**

**ETHICS**

ASME requires ethical practice by each of its members and has adopted the following Code of Ethics of Engineers as referenced in the ASME Constitution, Article C2.1.1.

**CODE OF ETHICS OF ENGINEERS**

**The Fundamental Principles**

Engineers uphold and advance the integrity, honor and dignity of the engineering profession by:

- I. using their knowledge and skill for the enhancement of human welfare;
- II. being honest and impartial, and serving with fidelity their clients (including their employers) and the public; and
- III. striving to increase the competence and prestige of the engineering profession.

**The Fundamental Canons**

- 1. Engineers shall hold paramount the safety, health and welfare of the public in the performance of their professional duties.
- 2. Engineers shall perform services only in the areas of their competence; they shall build their professional reputation on the merit of their services and shall not compete unfairly with others.
- 3. Engineers shall continue their professional development throughout their careers and shall provide opportunities for the professional and ethical development of those engineers under their supervision.
- 4. Engineers shall act in professional matters for each employer or client as faithful agents or trustees, and shall avoid conflicts of interest or the appearance of conflicts of interest.
- 5. Engineers shall respect the proprietary information and intellectual property rights of others, including charitable organizations and professional societies in the engineering field.
- 6. Engineers shall associate only with reputable persons or organizations.



## Bioprocessing Equipment Standards Committee

2

P-15.7  
2/1/12

7. Engineers shall issue public statements only in an objective and truthful manner and shall avoid any conduct which brings discredit upon the profession.
8. Engineers shall consider environmental impact and sustainable development in the performance of their professional duties.
9. Engineers shall not seek ethical sanction against another engineer unless there is good reason to do so under the relevant codes, policies and procedures governing that engineer's ethical conduct.
10. Engineers who are members of the Society shall endeavor to abide by the Constitution, By-Laws and Policies of the Society, and they shall disclose knowledge of any matter involving another member's alleged violation of this Code of Ethics or the Society's Conflicts of Interest Policy in a prompt, complete and truthful manner to the chair of the Ethics Committee.

The Ethics Committee maintains an archive of interpretations to the ASME Code of Ethics (P-15.7). These interpretations shall serve as guidance to the user of the ASME Code of Ethics and are available on the Committee's website or upon request.

Responsibility: Committee of Past Presidents/Ethics Committee

Reassigned from Centers Board of Directors/Center for Career and Professional Advancement/Committee on Ethical Standards and Review

Reassigned from Centers Board of Directors/Center for Professional Development, Practice and Ethics/Committee on Ethical Standards and Review 4/23/09

Reassigned from Council and Member Affairs/Board on Professional Practice & Ethics 6/1/05

Adopted: March 7, 1976

Revised: December 9, 1976  
December 7, 1979  
November 19, 1982  
June 15, 1984  
(editorial changes 7/84)  
June 16, 1988  
September 12, 1991  
September 11, 1994  
June 10, 1998  
September 21, 2002  
September 13, 2003  
(editorial changes 6/1/05)  
November 5, 2006  
(editorial changes to the responsible unit 4/09)  
(Unit Realignment Due to Reorganization 2/12)



**ASME Committees**

The ASME-BPE is made up of one Standards Committee, one Executive Committee and ten subcommittees. All meetings are open to visitors and general members unless noted below.

**Standards Committee**

*Jay Ankers—Chair      Marc Pelletier –Vice Chair      Paul Stumpf-Secretary*

The Standards Committee is comprised of the Subcommittee chairs and members of the general membership that have a history of involvement and good working knowledge of the BPE Standard. Each member of the Standards Committee goes through a vetting process designed to gauge their commitment to developing the standard and continuing support of the work required to move the standard forward. Membership in this committee is by nomination and vote of the existing membership of the Standards Committee.

**Executive Committee**

*Marc Pelletier—Chair      Jay Ankers-Vice Chair*

The Executive Committee is comprised of the Subcommittee chairs, chairman, vice chairman and secretary of the ASME-BPE. The purpose of this committee is guide the Subcommittees in areas of the direction of the standard, and personnel. In addition, this meeting allows the Subcommittee chairs to meet prior to and after the subcommittee meetings to advise each of any works ongoing in their committees that may affect another committee. These meetings are open to all visitors and members with the exception of when personnel matters are being discussed. *This committee is closed to visitors and general membership during personnel discussions.*

**SUBCOMMITTEE ON GENERAL REQUIREMENTS AND EDITORIAL REVIEW—GR**

*Mark Embury-Chair      Tom Winter-Vice Chair*

This Subcommittee is primarily responsible for all the general requirements throughout the standard. Information on reference specifications, codes and other standards can be found here as well as all terms and definitions used throughout the Standard.

**SUBCOMMITTEE ON SYSTEMS DESIGN—SD**

*David Marks-Chair      Melissa Balmer-Vice Chair      Bo Jensen-Vice Chair      Albert Dyrness-Vice Chair*

*Ryan Michalak-Secretary*

The purpose of Part SD is to provide requirements for the specification, design, fabrication and verification of process equipment and systems which are fit for intended use, and minimize risk to the product. Part SD also provides design guidelines which should be applied at the discretion of the owner/user on the basis of assessed risk to the product.

The scope of Part SD encompasses requirements for equipment, process systems and utilities which could potentially impact product quality. Specific guidance is provided for bioburden control in manufacturing processes, including design requirements for cleaning, sanitization and/or sterilization of bioprocess systems.



### **SUBCOMMITTEE ON DIMENSIONS AND TOLERANCES—DT**

*Dan Mathien-Chair      Frank “Chip” Manning-Vice Chair      Bryan Billmyer-Secretary*

The purpose of this Part is to provide requirements that ensure process components fit-up and compatibility. This part specifies dimensions, tolerances, and all supplementary conditions for process components.

### **SUBCOMMITTEE ON MATERIALS JOINING—MJ**

*Jim Dvorscek-Chair      William Roth-Vice Chair      Kadeem Bhaila –Vice Chair      Bill Burg-Secretary*

The purpose of this Part is to provide requirements for the joining of metallic and polymeric materials. This includes joining methods, welding procedure and performance qualifications, examination, inspection, testing, and acceptance criteria.

### **SUBCOMMITTEE ON PROCESS CONTACT SURFACES—SF**

*Ken Kimbrel-Chair      Pat Banes-Vice Chair      Jody Hamilton-Vice Chair*

The purpose of this Part is to provide process contact surface finish guidelines acceptance criteria for metallic and polymeric materials.

### **SUBCOMMITTEE ON SEALING COMPONENTS—SG**

*Melena McFeeters-Chair      Jim Vogel-Vice Chair      Johan Westin-Secretary*

The purpose of this Part is to provide requirements for the sealing components of seals, valves, and fittings used in the bioprocessing industry. This part defines the design of seals, valves, and fittings.

### **SUBCOMMITTEE ON POLYMERS AND OTHER NONMETALLIC MATERIALS—PM**

*Mike W. Johnson-Chair      Paul Galvin-Vice Chair      Marianne Knox-Vice Chair      Greg Evans-Secretary*

The Standards section on polymeric and other nonmetallic materials provides material characterization criteria, application guidance and product requirements for bioprocessing components and systems made of non-metallic materials of construction. Polymeric components and systems are the main focus but this section also considers materials such as ceramics and composites. Requirements for both multi-use and single-use components and systems are included within.

### **COMMITTEE ON BPE CERTIFICATION—ASME CA-1**

*Rich Campbell - ASME CA-1 Chair*

### **SUBCOMMITTEE ON CERTIFICATION—CR**

*Carl Kettermann-CR Chair      Troy Hobick—CR Vice Chair      Bill Huitt-CR Secretary*

Part CR and ASME CA-1, Conformity Assessment Requirements, together establish requirements for organizations, providing components in accordance with the BPE Standard to obtain a Certificate of Authorization and the ASME Certification Mark. *The ASME CA-1 committee is a closed meeting to visitors and general membership due to the discussion of applicants and sensitive information regarding authorized certificate holders.*





### **SUBCOMMITTEE ON METALLIC MATERIALS—MM**

*Lynn Sturgill-Chair      Dr. Jan Rau-Vice Chair      Neil Schmidt-Secretary*

The purpose of this Part is to identify metallic materials considered acceptable for use in hygienic service. It identifies material specifications, grades and alloys, matching filler metals, fabrication guidelines and other attributes necessary for this service.

### **SUBCOMMITTEE ON PROCESS INSTRUMENTATION—PI**

*Andrew Lamore-Chair      Vladimir Gorbis-Vice Chair      Dave Kwiloz-Secretary*

The purpose of this Part is to provide requirements for process instrumentation. This part defines the minimum requirements for the application of process instrumentation in hygienic systems.

#### **Membership on a Subcommittee:**

Membership on a Subcommittee is a three year commitment. Each prospective member is required to submit paperwork consisting of ASME forms PF-1, PAF-1, a letter of support from you sponsoring organization and a resume to the committee leadership. Forms PF-1 and PAF-1 can be found at the end of this publication.

Membership requirements for each subcommittee is at the discretion of each separate subcommittee chairperson. All subcommittees have a minimum requirement that prospective members must attend 3 consecutive meetings after submission of paperwork to the subcommittee chairperson, or officer in charge of personnel. Each Subcommittee Chairperson is considerate of the balance of industry representation on his/her subcommittee and may impose additional requirements, such as participation and involvement in working task groups of the subcommittee.

Each prospective member is encouraged to become involved and participate in a subcommittee of interests task groups to become familiar with the inner workings of the subcommittee and ASME. This allows prospective members to participate closely with other members of the sub committee and leadership.

**ASME-BPE can be a rewarding experience for all individuals involved. We are pleased you are here and have an interest in the work being done. We encourage you to become involved!**



## Bioprocessing Equipment Standards Committee

If you have questions in regards to membership or simply want an introduction to the leadership of a committee, you may reach out to any member of the Steering Committee. Those members are listed below.



Randolph Cotter / e-mail: [Randolpcotter@aol.com](mailto:Randolpcotter@aol.com)



Dan Mathien / e-mail: [danm@behringersystems.com](mailto:danm@behringersystems.com)



Frank "Chip" Manning / e-mail: [cmanning@vnecorp.com](mailto:cmanning@vnecorp.com)



Ken Kimbrel / e-mail: [kenk@ultracleanep.com](mailto:kenk@ultracleanep.com)



Reinhard Hanselka / e-mail: [Reinhard.hanselka@crbusa.com](mailto:Reinhard.hanselka@crbusa.com)