BPE News

Newsletter of the ASME BioProcessing Equipment (BPE) International Standard

www.asme.org/communities/technical/bpe

November 2007

What's in this Issue?

Send BPE-related news items and articles to: Jennifer Delda

SPOTLIGHT ON: ASME Dedicated Service Award

In recognition of his outstanding performance and dedicated leadership, Frank 'Chip' Manning was presented with an ASME Dedicated Service Award this year. The award, established by the Board of Governors in 1983, honors unusual dedicated voluntary service to the Society marked by outstanding leadership, prolonged and committed service, devotion, enthusiasm and loyalty.

Chip is Sales Director, BioPharmaceuticals Products USA, for the VNE Corporation and has been an active member of the BPE Committee since 1988. He currently chairs the BPE Subcommittee on Dimensions & Tolerances (D&T), and a contributing member of the Subcommittee on Surface Finish.

Having been a BPE member since its inception in 1988, "Chip's knowledge of (BPE) historical events has been invaluable", according to BPE Chair Tony Cirillo. "Chip is a dedicated leader who goes beyond the call of duty in his volunteer efforts. His leadership and contributions to the D&T Subcommittee has been the cornerstone of its continued success." Congratulations, Chip!

EXECUTIVE CORNER: BPE, its beginnings and the road ahead

~ Rick Zinkowski, Chair, BPE Executive Committee

The ASME BioProcessing Equipment (BPE) Standard, first published in 1997, is one of the youngest standards in ASME's roster of over 500 codes and standards. Keeping pace with industry's rapid growth the BPE quickly elevated to international level, now recognized in over 30 countries serving the needs of those involved in the bioprocessing, pharmaceutical, and personal care product industries. Click here to read more

HOT TOPIC: Why is good stainless turning color? Rouging, what is it?

~ James Dean Vogel, Task Group Leader, Rouging

The BPE Subcommittee on Surface Finish recently formed a task group to address Rouging. The task group is charged to provide a definition of what Rouge is, and how it is formed. It will identify and recommend methods to measure the formation and progression of Rouge, with the objective to monitor and predict preventative maintenance intervals. The task group will also identify and recommend methods to minimize and remediate the formation, development, and distribution of Rouge within systems. Click here to read more

BPE DIMENSIONS & TOLERANCES: Major changes in progress

~ Frank 'Chip' Manning, Chair, BPE Subcommittee on Dimensions & Tolerances

Some major changes are being worked on within the Dimensions and Tolerances subcommittee and will be included in the future ASME BPE standards. All subcommittee meetings are open to the public and the opportunity to become involved in these new changes is better than ever. Changes in progress are in the areas of Concentric & Eccentric fittings and Hygienic Clamp & Ferrule Assembly. Click here to read full article.

New BPE 2007 Edition - Coming Soon!

The new edition of the ASME BPE Standard is presently in publication and is expected out by the end of the year. Significant changes to appear in the new edition impact parts covering Dimensions and Tolerances, Design, Surface Finish, Seals, Polymers, and Material Joining. Contact **Paul Stumpf** at stumpfpa@asme.org

LEARN AND GET INVOLVED! Participate in BPE Task Groups

The ASME BPE has numerous task groups formed to discuss specific topic assignments. Participation is open to the public Click here for a listing of current BPE Task Groups and their objectives.

BENEFITS OF PARTICIPATING IN ASME CODES & STANDARDS ACTIVITIES

For over 100 years, industries worldwide have depended on ASME for the promulgation of technically sound and state of art codes and standards. Participation by volunteer members in the standards development process, with the support of their employers, is the foundation of ASME Codes & Standards. Click here to read more

---

UPCOMING EVENTS

- **January 21-24, 2008: ASME BPE Committee Meetings,** San Juan, Puerto Rico. Contact Paul Stumpf
- **June 23- 27, 2008: 2nd European Bioprocess Technology Seminars & Exhibition** in conjunction with **ASME BPE Committee Meetings**, Stockholm, Sweden. Please contact Jennifer Delda

---

ASME

BPE News

Newsletter of the ASME BioProcessing Equipment (BPE) International Standard

www.asme.org/communities/technical/bpe

November 2007

What's in this Issue?

Send BPE-related news items and articles to: Jennifer Delda

Executive Corner: The BPE, its beginnings and the road ahead

- Rick Zinkowski, Chair, BPE Executive Committee

The ASME BioProcessing Equipment (BPE) Standard, launched in 1997, is one of the youngest standards in ASME's roster of over 500 codes and standards. Keeping pace with industry's rapid growth the BPE quickly elevated to international level, now recognized in over 30 countries serving the needs of those involved in the bioprocessing, pharmaceutical, and personal care product industries.

ITS BEGINNINGS - The genesis of the ASME-BPE Standard evolved from the inability of component and equipment manufacturers to manufacture fittings, tubing, process components and equipment to the same critical dimensions and/or standards. In the early eighty's there was simply no widely accepted standard addressing this issue for the Bioprocessing industry. It was not uncommon for fittings, tubing and process components to be un-weldable in field installations. In the fall of 1988, a group of manufacturers and end-users met at the ASME Winter Meeting (WAM) in San Francisco to begin discussions related to creating meaningful standards for the Bioprocessing industry. In June of 1989, the ASME Council on Codes and Standards approved the project. The first sub-committee meetings were held in 1990 with the first BPE Standard being published in 1997.

As the needs of the BioPharm industry have evolved, so has the BPE Standard. In addition to defining dimensions and tolerances for fittings, tubing and process components; the Standard also addresses: designs relating to sterility and cleanability, material joining, surface finish, seals, metallic materials of construction and polymer-based materials as related to fittings, components and equipment.

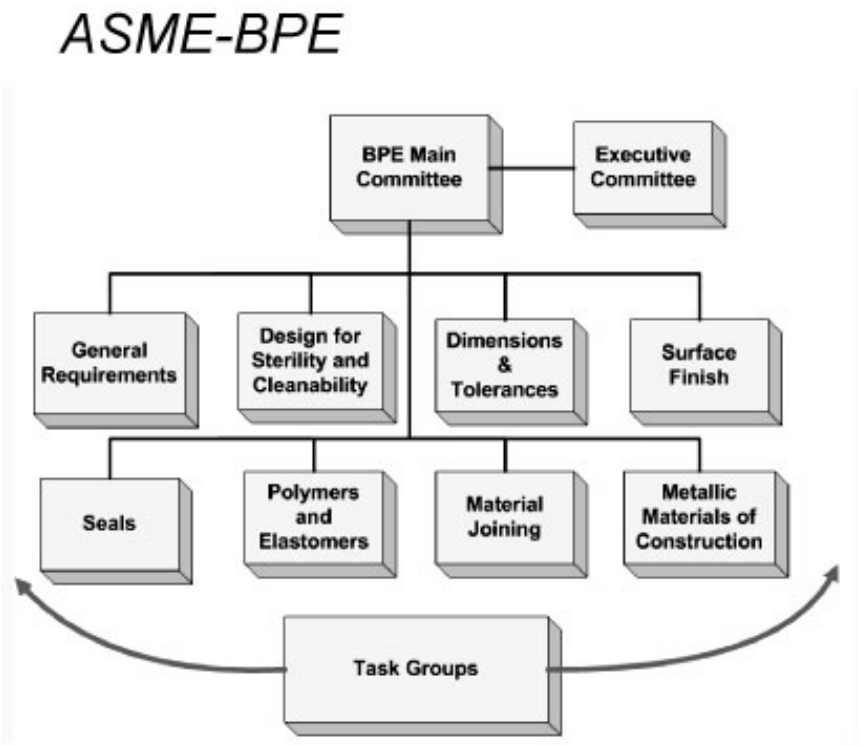
CHARTER - **The scope of the ASME-BPE Standard is as follows;**
"This Standard deals with the requirements of the bioprocessing, pharmaceutical, and personal care product industries as well as other applications with relatively high levels of hygienic requirements, covering directly or indirectly the subjects of materials, designs, fabrication, pressure systems (vessels and piping), examinations, inspections, testing, and certifications."

The BPE Standards Committee is by charter, a balanced committee established with volunteers from the following industry segments; Industry Users, Designer / Constructors, Material Manufacturers, Equipment Manufacturers, Insurance / Regulatory and General Interest. The organization is comprised of a Main Standards Committee, Sub Committees and Task Groups see figure #1. Task Groups, of which there are currently forty six (46), report directly to their sponsored Sub-Committee. In short, information that is requested for possible inclusion in the standard begins at the task group level. This information is then bubbled up to the Sub-Committee where the merits of inclusion of this information are reviewed, discussed and formally voted upon. Once approved at the Sub-Committee level, the document is forwarded to the Executive and then the Main Committee for review and ballot for inclusion as part of the Standard or as non-mandatory appendices associated with the Standard.

PROCESS - The BPE Standard is currently on a two (2) year publishing cycle.

The 2007 Standard will be available in December of this issue. A typical two year publishing cycle includes; the approval cycle of the BPE Standards organization mentioned above, ANSI Public Review, Review by the ASME Board of Pressure Technology Codes and Standards and finally ANSI Board of Standards review. In addition, the BPE maintains liaison reporting activities with other industry organizations such as ISPE, P3A, 3A, DIN, and EHEDG. The resulting Standard is therefore assured to be substantive and meet the critical review of established standards organizations.

The development of a scope for the Certification of fittings, tubing, process components and equipment is currently underway. The intent is to have a phased integration of the Certification program beginning with tubing and fittings which will appear in the 2009 ASME-BPE Standard. This program will emulate the ASME RTP-1 Standard's Accreditation Program.



THE ROAD AHEAD - The ASME BPE is currently finishing up a global marketing study which will assist in framing the future for BPE.

The future for the ASME BPE is indeed bright. Through the hard work of its volunteer organization, this globally recognized document will continue to address the needs of the BioPharm industry providing a clear and substantive Standard to meet the future challenges and opportunities of this industry.

I offer you an invitation to attend our next ASME BPE meeting and actively participate in the discussion as well as the creation of this industry recognized document.

Rick Zinkowski, Chair, BPE Executive Committee

ASME

BPE News

Newsletter of the ASME BioProcessing Equipment (BPE) International Standard

www.asme.org/communities/technical/bpe

November 2007

What's in this Issue?

Send BPE-related news items and articles to: Jennifer Delda

HOT TOPIC - Why is good stainless turning color? Rouging, what is it?

- James Dean Vogel, Task Group Leader, Rouging

The BPE Subcommittee on Surface Finish recently formed a task group to address Rouging. The task group is charged to provide a definition of what Rouge is, and how it is formed. It will identify and recommend methods to measure the formation and progression of Rouge, with the objective to monitor and predict preventative maintenance intervals. The task group will also identify and recommend methods to minimize and remediate the formation, development, and distribution of Rouge within systems.

A presentation on the “Origination of Rouge in a New Biotech Facility” will be given at the next BPE committee meeting, to be held on January 21-25, 2008, in San Juan, Puerto Rico. Participation is open to the public.

The presentation will discuss the discovery, identification, and investigation of corrosion in 316L and AL6XN equipment and distribution systems. Process, Clean Steam and WFI systems were evaluated in an effort to determine the phases of development and remediation. The case study material covers 4+ years of observation and testing and seeks to categorize the conclusions of that effort. The material should be helpful to anyone involved in preliminary diagnosis of corrosion problems. It should also provide some insight into the development cycle of iron and chromium oxides and how oxide layers develop with time and temperature.

LEARN AND GET INVOLVED!

Task Group Leader:
James Dean Vogel
President, Process Facilities Services Incorporated
jdvpe@cox.net

ASME

BPE News

Newsletter of the ASME BioProcessing Equipment (BPE) International Standard

www.asme.org/communities/technical/bpe

November 2007

What's in this Issue?

Send BPE-related news items and articles to: Jennifer Delda

BPE DIMENSIONS & TOLERANCES: Major changes in progress

~ Frank 'Chip' Manning, Chair, BPE Subcommittee on Dimensions & Tolerances

Some major changes are being worked on within the Dimensions and Tolerances subcommittee and will be in the future ASME BPE standards. All subcommittee meetings are open to the public and the opportunity to become involved in these new changes is better than ever.

- **BPE Concentric & Eccentric fittings** - The committee has a full task group looking at Concentric & Eccentric fittings to evaluate shortening the overall length allowing for better drain ability and reducing dead legs in bioprocess systems. So far the concentric reducers have been evaluated and in most cases cut in length to 50% of the old dimensions. Current work is now being done on eccentric fittings with testing done on internal angles and pressure drop issues. We are also evaluating the DIN standards to see if their current dimensions can be incorporated thereby allowing some harmonization.

- **Hygienic Clamp & Ferrule assembly** - A current task group is looking at the hygienic clamp and ferrule assembly for a more precision fit up as well as preventing gasket intrusions. This task group has accomplished putting together a full nominal dimensional of all sizes of hygienic ferrule faces through size 6 inches. This was the start for accomplishing the difficult task of a hygienic and repeatable joint when assembled. Currently we are developing absolute pressure point dimensions for each size of clamp so that when assembled to the ferrule assemblies they repeat the same pressure and grip point where by giving a joint free of intrusions or a depression where cleaning can become an issue.

- **Nominal 1" "New" size clamp and ferrule assembly -** The hygienic fitting task group has been developing a "new" 1" size fitting and clamp assembly. Currently the 1" hygienic clamp assembly is using a 1.5" clamp and a fitting with a 1.5" end connection that has a 1" water bore with a wide face filled with a 1" modified gasket. This setup allows for a large area to be filled by the elastomer or rubber gasket being used thereby allowing a space for harboring un-cleanable areas. The task group has designed a nominal 1" ferrule and will use a 35MM clamp available currently in DIN standards. This will allow process engineers to design 1" systems with a fitting assembly that will be completely cleanable.

The Dimensions and Tolerance committee is responsible for all process components dimensions, tolerances, pressure ratings, marking and packaging. We continue to evaluate and work towards bettering the process components used in the critical industries of biotechnology, pharmaceutical and personal care. Remember our standard is a "living document" and it is never too late to join and participate in real critical issues for today's ASME BPE. Contact: Chip Manning at cmanning@vnecorp.com

ASME BPE
Subcommittee Task Groups

BPE Subcommittee Task Groups are formed to address specific assignments. Participation is open to the public. Contact listed Task Group Leaders.

TASK GROUP	BRIEF SCOPE	LEADER	E-MAIL ADDRESS
Active Pharmaceutical Ingredients	Liaison TG with P3A	Ray Foley	Raymond.Foley@parsons.com
Instrumentation	To provide general overview of applicable process measurement instrumentation used in the pharmaceutical, biotech, and personal care products industries with regards to proper design, installation guidelines, orientation, and connection to maintain hygienic operation and serviceability	Dan Klees	Dan.Klees@us.endress.com
Agitators & Related Components	Revise & expand SD-4.8	Paul Kubera	pkubera@abec.com
Clean-In-Place	Revise & expand SD-4.15	Chris Pacheco	cpacheco@amgen.com
Fermentor & Bioreactor Systems	Develop system-specific requirements for the cleanability and sterilizability of bioreactors	Joe Rotman	jrotman@ipsdb.com
Pumps	Revise & expand SD-4.5, including pump orientation, casing drains, configuration, seal design	Milena McFeeters	milena.mcfeeters@roplan.com
Clean/Medical Grade Gases	Develop standards for design of distribution systems for Clean/Medical Grade gases	Randy Cotter	randolphcotter@aol.com
Autoclaves	Revise & expand SD-4.14	Marc Pelletier	mpelletier@mppbiodesigns.com
Glasswashers	Develop standards for design of glasswashers (SD-4.17)	Marc Pelletier	mpelletier@mppbiodesigns.com
System / Component Integrity	Develop standards for (SD-2, 3.2) & new sections defining bioburden control.	Marc Pelletier	mpelletier@mppbiodesigns.com

ASME BPE
Subcommittee Task Groups

BPE Subcommittee Task Groups are formed to address specific assignments. Participation is open to the public. Contact listed Task Group Leaders.

TASK GROUP	BRIEF SCOPE	LEADER	E-MAIL ADDRESS
Terms & Definitions	Develop recommendations for GR for index & definitions.	Marc Pelletier	mpelletier@mppbiodesigns.com
Sampling Devices	Develop standards for cleanability and sterilizability of sampling devices	Todd Marchefka	tmarchefka@hygeniks.com
Sanitary Ball Valves	Revise & expand SD-3.11.18	Jerry Foley	jpfoley@ix.netcom.com
System/Component Integrity	Revise & expand SD-2, 3.2 & new sections defining bioburden control.	Marc Pelletier	mpelletier@mppbiodesigns.com
SD Language Review	Review SD section use of “should” and “shall”; review illustration labels – “preferred”/”accepted”/”not recommended”	Mark Embury	mark.embury@asepco.com
Reynolds Number vs. velocity	Review and revise SD-6 to incorporate CIP flow rate criteria based upon N_{RE} instead of fluid velocity.	Jon Fortin / Johan Westin	jonathan.fortin@bms.com / jwestin@alphabio.com
Code 7 Filter Housings	Develop section for design for cleanability and sterility of Code 7 filter housings	Wei Huang	wei.huang@fluor.com
Sterility / Bioburden Control	Resolve proposed language transition from sterility to bioburden control; establish designations for levels of bioburden control.	Scott Hartner	scott.hartner@sanofipasteur.com
Examination/inspection language	Review SD section use of examination/inspection and examiner/inspector	Paul Kubera	pkubera@abec.com

ASME BPE
Subcommittee Task Groups

BPE Subcommittee Task Groups are formed to address specific assignments. Participation is open to the public. Contact listed Task Group Leaders.

TASK GROUP	BRIEF SCOPE	LEADER	E-MAIL ADDRESS
Passivation	Provide general direction on processes involved in the passivation of product contact surfaces of newly installed or modified stainless steel systems and finished components.	Barbara Henon	barbarah@arcmachines.com
Rouge	Define what Rouge is and how it is formed in 316L stainless steel components, identify and recommend methods to measure its formation and progression, and identify and recommend methods to minimize it and remediate its formation.	Jim Vogel	jdvpe@cox.net
Biofilm	TBD	Judy Arnold	judy.arnold@ars.usda.gov
Seal Performance	Define the standard test exposure conditions (reasonable and typical, based on industrial processes and practices) to assist in the qualification and selection and specification of seals.	Jim Vogel	jdvpe@cox.net
Pump Seals	Review and develop requirement for pump seal including those used for compendial water system.	Milena McFeeters	milena.mcfeeters@roplan.com
Polymers - Disposables	Develop section for single use disposables	Tom Warf	warfs@comcast.net
Polymer Materials of construction - elastomers	Determine evaluation methods for elastomers	Russ Schnell	Russell.w.schnell@dupont.dow.com
Polymer materials of construction - nonelastomers	Determine evaluation methods for polymer nonelastomers	Lily Lei	Lily.lei@saint-gobain.com

ASME BPE
Subcommittee Task Groups

BPE Subcommittee Task Groups are formed to address specific assignments. Participation is open to the public. Contact listed Task Group Leaders.

TASK GROUP	BRIEF SCOPE	LEADER	E-MAIL ADDRESS
Process vessels	Section defining polymer process vessels	Pradip Khaladkar	Pradip.r.khaladkar@usa.dupont.com
Polymer surface finishes	Develop test procedure and values for polymers for SF	Paul Galvin	Paul.galvin@georgfischer.com
Flex hose	Define polymer flex hose	Pradip Khaladkar	Pradip.r.khaladkar@usa.dupont.com
Thermal expansion & support systems		Roger Govaert	Roger.govaert@mt.com
Fittings	Reducers (concentric and eccentric) and Tube end caps-design length	Roger Klemp	rklemp@advancefittings.com
Hygienic Clamp Union	Further expand on the hygienic clamp union fitting requirements to improve control of fitting make-up by developing clamp requirements and through design optimize reduce intrusion.	Bob Elbich	relbich@exicomfg.com
Diaphragm Valves	Identify a standardized OAL of diaphragm valves with clamp ends	Carl Taylor	Carl_taylor@cranevalve.com
End Grain Effect	Study cause and explore solution to end grain affect found on bar and components	Keith Raney	rkraney@rkraney.com
MMOC General Requirements & Scope	Part Development	Bill Huitt	wmhuitt@aol.com
MMOC Alloy Designations	Part Development	Jim Fritz	jfritz@tmr-inc.com

ASME BPE
Subcommittee Task Groups

BPE Subcommittee Task Groups are formed to address specific assignments. Participation is open to the public. Contact listed Task Group Leaders.

TASK GROUP	BRIEF SCOPE	LEADER	E-MAIL ADDRESS
MMOC Reference Specification	Part Development	Carl Kettermann	carkkettermann@rathgibson.com
MMOC Mechanical Properties	Part Development	Ken Kimbrel	kenk@ultracleanep.com
MMOC Fabrication	Part Development	Jim Fritz	jfritz@tmr-inc.com
MMOC Filler Metals	Part Development	Ken Kimbrel	kenk@ultracleanep.com
MMOC Corrosion Resistance	Part Development	Hira Ahluwalia	hira@doctormetals.com
MMOC Surface Finish	Part Development	Tom Winter	winter@winter-technologies.com
MMOC Heat Treatment	Part Development	Ken Kimbrel	kenk@ultracleanep.com

BPE News
Newsletter of the ASME BioProcessing Equipment (BPE) International Standard
www.asme.org/communities/technical/bpe

November 2007

What's in this Issue?

Send BPE-related news items and articles to: Jennifer Delda

Benefits of Participating in ASME Codes & Standards Activities

For over 100 years, industries worldwide have depended on ASME for the promulgation of technically sound and state of art codes and standards. Participation by volunteer members in the standards development process, with the support of their employers, is the foundation of ASME Codes & Standards.

In addition to making valuable contributions to industry, Codes & Standards participation also benefits the participants, their employers, and the general public.

Benefits to Participants - Participants can have a significant influence on the direction and quality of Codes & Standards. Representation by many different organizations from around the world in the standards development process ensures that all interests are fully considered. Contributing to Codes & Standards committees is personally and professionally rewarding; these personal rewards include those derived from the following opportunities:

- Interacting with and learn from the foremost technical experts in a given field.
- Creating a personal network of contacts for valuable technical advice.
- Becoming aware of revisions to standards prior to publication
- Becoming aware of technical issues in the industry, and learning how others are dealing with them. Participants are able to avoid similar problems within their own organizations or prepare solutions in advance.
- Becoming intimately knowledgeable with the codes and standards used in a particular industry. Participants are able to be more thorough and confident in their application of code rules, leading to increased efficiency and the ability to get work done expeditiously.
- Realizing the satisfaction of having one's work incorporated into a globally recognized standard.
- Gaining experience in the arts of consensus building and teamwork.
- Learning how to run meetings that are productive and focused.
- Developing technical leadership skills by heading up a task group, subcommittee, or standards committee.
- Enhancing communication skills and the ability to persuade others in a technical forum.
- Broadening their understanding of other segments of their industry, both in the U.S. and globally.
- Receiving complimentary access to the ASME Codes & Standards related to committee work.
- Becoming familiar with the ASME Electronic Tools, including the C&S Connect portal for access to document and revision status, balloting, and more.
- Satisfying requirements for "continuing education" or "professional development hours" in some parts of the world. Within the U.S., this may include the specific State requirements for Professional Engineering registration.

Benefits to Supporting Organizations

Organizations realize direct and indirect benefits when they support the membership of their employees active in ASME Codes & Standards. These benefits include:

- Ensuring that the organization's interests, practices, and experience are thoroughly considered in developing and updating requirements in Codes & Standards.
- Reducing the risk that a code or standard will contain requirements that are incompatible with your products or services. This could help avoid costly design, fabrication, pattern, and tooling modifications, while gaining the ability to implement early compliance with critical requirements.
- Improving the business, technical, leadership and communication skills of the participants, which in turn increases their performance and contribution as employees.
- Ensuring that your organization is aware of revisions to standards and an understanding of the technical basis.
- Attaining early and ongoing awareness of technical issues in the industry and how others are dealing with them, permitting organizations to avoid these issues or prepare solutions in advance.
- Improving their employee's understanding of applicable Codes & Standards, allowing organizations to be more thorough and confident in their application of rules and leading to increased efficiency and reduced cost.
- Enhancing knowledge of ASME services.
- Gaining opportunities for shared participation in research and development.
- Realizing new benchmarking opportunities.
- Interacting with other technical experts from around the world.
- Providing input for related International Organization for Standardization (ISO) standards development in certain industries.

Benefits to the Public

- Enhancing public health, safety and welfare.
- Reducing barriers to trade, reducing the cost of goods and services worldwide.

Here are some specific examples of how individuals, companies, and industries have benefited from ASME Codes & Standards committee participation.

Specific Case Illustrations

- Changes in a standard have resulted in products that are less expensive and higher quality.
- "Special" requirements in company specifications have been reduced, resulting in improved service life and reduced cost all without reducing safety or reliability.
- Employing performance-based approaches within Codes & Standards have resulted in less costly changes to an organization's manufacturing process and to the cost of using the product.
- A pending change to a standard was incorporated into a new product line that resulted in virtually no extra cost to the organization.
- Design changes incorporated into new products, based on pending changes to a standard, have resulted in earlier product releases.
- Early knowledge of a new Code Case has saved organizations money on various projects.
- Solutions to many proprietary conflicts with Codes & Standards have been found through committee discussion.