Crossover Applications for the ASME-Bioprocessing Equipment Standard

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The content of the ASME-BPE Standard is universal and can be applied broadly throughout the CPI to meet the needs of complex engineering designs and operations

Because the global chemical process industries (CPI) encompass so many varied industry segments — including the conversion of raw materials and intermediates into chemicals and petrochemicals, fats and oils, paints and coatings, food and beverages, the refining of petroleum, the production of pharmaceuticals and others — there is considerable overlap in terms of the types of equipment, instrumentation, pipe, tubing and design elements, as well as industry codes (mandatory) and standards (voluntary) that are used during the design, construction and operation of CPI facilities. In many cases, a given set of codes and standards created for one industry segment will, quite possibly, contain content that is meaningful and relevant to facilities operating in other sectors. For instance, the ASME-Bioprocessing Equipment (BPE) Standard was created for the pharmaceutical industry but can be useful in the biofuel and chemical industries, too.

Across the spectrum of the more than 200 American National Standard (ANS) developers (organizations accredited by the American National Standards Institute, ANSI) to develop industry standards, and the more than 10,000 American National Standards that are published by ANS developers, there is ongoing effort to ensure harmonization among those standards.

As a result of this harmonization effort, engineers at a CPI facility can readily make use of multiple industry standards on a single project without concern about conflicting statements between those standards. That is not to say that a more stringent requirement will not exist in one standard over another. Such a situation is easily rectified by including, in proprietary specifications and guidelines, a statement that specifies that "the more stringent requirement shall govern."

When adopting existing industry standards, the project team draws upon the consensus of committees of industry experts whose efforts have been undertaken to ensure that the pertinent subject matter has been thoroughly assessed, analyzed, debated, and voted on at multiple levels, reaching broad consensus and culminating in the publication of the accredited standards.

What this means for the end user is that unless a project is regulated by a specific code that has been adopted as part of a prevailing federal, state or municipal regulation, the project team is free to specify — through contract stipulations or project specifications — the most appropriate set of codes and standards that are required to meet the varied requirements of a project or facility. For example, the project team may specify ASME B31.3 – Process Piping as the main compliance piping code for a given project, with or without exceptions. In addition, the project requirements will likely dictate the need to reference specific requirements published in other relevant codes and standards — beyond those spelled out in B31.3.

For instance, the project requirements may include standards for components and materials of construction (MOC), as well as specialized needs from other standards, such as the BPE Standard, or requirements for boiler external piping, which is not covered by B31.3 but is instead covered by ASME B31.1 – Power Piping. Component- and material-related standards — that is, different standards related to such items as pipe, fittings and flanges — are generally adopted in their entirety. However, users may also pick and choose optional, individual manufacturing requirements contained within those standards when those requirements are specifically needed.

When adopting a piping code such as B31.3 as a base code for a project, other piping codes and standards can be referenced for compliance when the following occurs:

1. The referenced requirement is not already contained in the base code
2. The referenced requirement is more stringent than that contained in the base code, or
3. The referenced requirement does not conflict with a "not permitted" statement in the base Code. For example: B31.3 Para. 306.4.4(c) a flared lap is not permitted under severe cyclic conditions

Even though a project has adopted

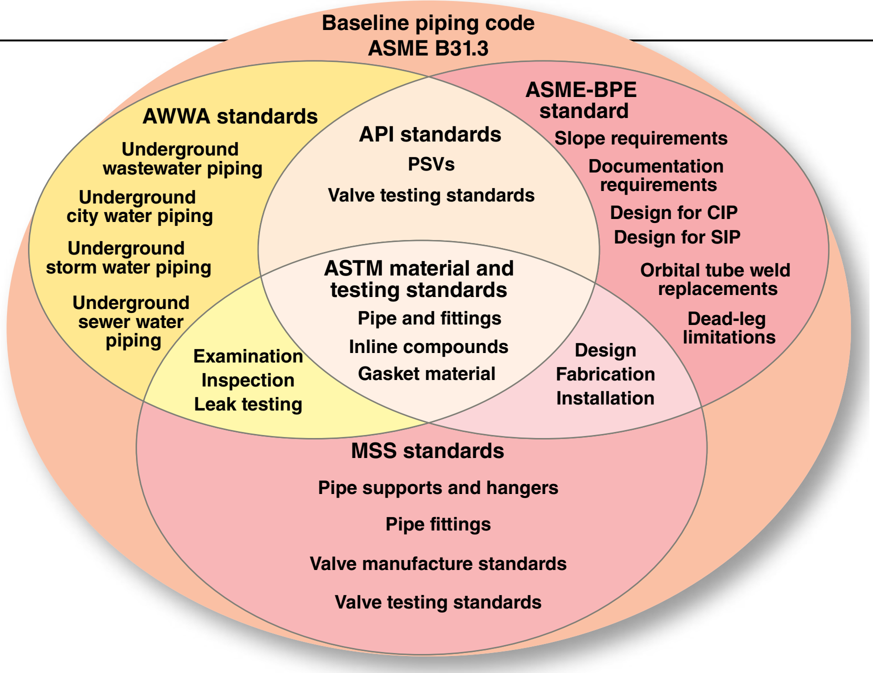


FIGURE. This rather simplistic Venn diagram provides a basic representation of the possible codes and standards used on a project in a CPI facility

a base piping code (either by the authority of government regulation or by decision of the project team), the engineer should look to other relevant standards to help define additional project requirements beyond those covered in the base code. Rather than spending time and money defining requirements that may be needed but are not covered by ASME B31.3 or ASME B31.1, the engineer should look to other existing standards that are able to provide detailed, vetted requirements to match the project's needs. A good case in point is the BPE Standard.

The Figure (above) shows how a given project's many codes and standards requirements may be represented graphically in a rather simplistic Venn diagram. Such a diagram shows the necessary piping codes and standards for a given CPI project and shows how they overlap and commingle within the framework of the project or within the infrastructure of plant operations and maintenance. In actuality, such a diagram will be much more complex due to the volume of codes and standards that are required by any CPI project or plant.

Where the BPE applies

The BPE Standard was developed in an effort to instill a sense of continuity and standardization into an industry that seriously needed it — the pharmaceutical industry. However, while the initial impetus for the creation of the BPE Standard was, and still remains, to meet the needs of the pharmaceutical industry, its content is more universal and can be used in many other CPI sectors.

In fact, the BPE Standard, first issued in 1997, dovetails nicely with the ASME B31.3 Process Piping Code, the essential piping code for the CPI. The initial BPE Standard consisted of the following six parts, which is discussed in greater detail further on:

- Part GR — General Requirements
- Part SD — Design for Sterility and Cleanability
- Part DT — Dimensions and Tolerances for Stainless Steel Automatic Welding and Hygienic Clamp Tube Fittings
- Part MJ — Material Joining
- Part SF — Stainless Steel and Higher Alloy Surface Finishes
- Part SG — Equipment Seals

The most recent version of the BPE Standard (which, at this writing, is the 2009 issue) looks much different than its inaugural predecessor, and has content that is much more encompassing and broad-ranging with the addition of these three parts:

- Part PM — Polymer-Based Material (added in the 2002 issue)
- Part MMOC — Metallic Materials of Construction (added in 2009)
- Part CR — Certification (added in the 2009 issue)

In the next publication of the BPE Standard, there will be an additional section added: Part PI — Process Instrumentation. This Part will cover requirements for the design, installation, and application of process instrumentation. The word "process" in the title of this Part also includes utility fluids, such as purified water, water for injection (WFI), clean steam and other utilities that come in contact either directly with the product or indirectly through contact with the product-contact surface during cleaning or sanitization (Note: The product-contact surface includes the internal tubing, component and equipment surface that comes in contact with raw materials and utilities that also come in contact with the product).

Hygienic operations. At the core of the BPE Standard is the need to install piping systems and equipment that will become (and will remain) hygienically clean by making them drainable and easily cleanable to a microscopic level. Residual hold-up of product cannot be tolerated in pharmaceutical operations, nor can a system that facilitates the onset and growth of bioburden. As a result, such systems must be designed in a way that allows them to be properly cleaned or sterilized in place.

Certain aspects of cellulosic biofuel processing and other CPI processes have a need for such hygienic operations, but for altogether different reasons. For instance, in bioprocessing operations, it is necessary to create an environment that will promote the growth and activity of a living organism or bacteria, in order to perform a step in the process.

The problem lies in the fact that the environment created for the selected bacteria is also beneficial to bacteria that may be detrimental to the process. In order to keep detrimental bacteria in check and allow the process to remain stable and viable, it is imperative that a segment of the piping system have sterilize-in-place (SIP) capabilities, to allow the needed cleaning to be carried out at periodic time intervals. Similarly, ethanol manufacturing processes must be designed with clean-in-place capabilities (CIP) for the fermenters, the beer well, the filtrate tanks and propagators as well as other segments of the process stream, to prevent residue buildup on equipment and piping.

When designing a process that requires CIP or SIP capabilities, there are specific piping and equipment design requirements that need to be met. These include requirements related to minimum slope, maximum acceptable dead-leg, internal weld finish, fitting and fabrication tolerances, surface finishes, and so on. These are all design considerations needed to accommodate CIP or SIP protocols. The design attributes needed to integrate CIP and SIP into a system can be found in the BPE Standard.

Sloped piping and maximum acceptable dead-leg criteria. Similarly, designing a process system that may not necessarily be concerned with bacteria may still have a need for sloped piping and maximum acceptable dead-leg criteria. The criteria for these design elements exists as vetted information within the BPE Standard, and thus can simply be referenced in a specification drawn from the BPE Standard, rather than basing design criteria on some arbitrary rule-of-thumb principal.

Documentation requirements. Meanwhile, while facilities that are outside the realm of strict biopharmaceutical manufacturing may not require the same exacting documentation trail all CPI facilities do require varying degrees of documentation related to material, fabrication, examination, and testing. Nonetheless, facilities whose documentation records are not required to be as extensive as those required by the biopharmaceutical industry can still benefit from the portion of the standard that relates to documentation requirements.

Specifically, the laundry list of documentation that is specified in the BPE Standard can be utilized by other industries simply by selectively referencing that part of the standard. Rather than a company having to write out a proprietary requirement — one that may already be contained in a vetted industry standard — the company can simply reference the respective segment of the standard that spells out the needed requirement.

Content of the standard

As noted earlier, while the BPE Standard dovetails with, and references to, many aspects of B31.3, it is markedly different in both layout and content. Nonetheless, the discussion below shows how universal the nine current parts of the BPE Standard are for many diverse facilities throughout the CPI.

Part GR — General Requirements. This section sets the tone and defines the scope of the standard. It defines terms that are specific to the bioprocessing industry and other terms that may have originated elsewhere and been adopted by the BPE standard with a slightly different interpretation.

Part SD — Design for Sterility and Cleanability. Part SD provides discussion on how to design cleanability and sterility into a system. It also covers specific design issues with regard to instrumentation, hose assemblies, filtration and other equipment. In addition to hydrostatic testing, this section also touches on testing fundamentals for spray balls, drainability, cleanability and sterility. It also provides a listing of documentation that can be selected by, and used for, industries beyond bioprocessing.

This section is one place in which the BPE Standard diverges from the main focus of the B31.3 format. For instance, while B31.3 is developed around the cornerstone of safety and system integrity, the BPE, while integrating safety and integrity, is focused mainly on providing acceptable criteria for system design.

Since its inception, the SD subcommittee has taken on the task of researching accepted industry design practices that are currently being used in the bioprocessing industry. This is an effort to validate, and, where necessary, rectify those largely unqualified design practices and criteria, through the development of new and appropriate design criteria for adoption into the BPE Standard.

Part DT — Dimensions and Tolerances. This section has basically standardized many of the practices in the bioprocessing industry. Prior to the availability of the BPE Standard and Part DT, there were no industry-standard dimensions on fittings and valves, and no common set of manufacturing tolerances. This meant that components from one manufacturer to the next were not necessarily interchangeable — a situation that has long presented a nightmare for many projects — and that all fittings had to be purchased from the same manufacturer to ensure compatibility.

Part MJ — Material Joining. This section touches on all aspects of the welding of pressure vessels, tanks, tubes and fittings, and provides guidance on acceptable requirements related to material selection, inspection, examination and testing. It also discusses joining processes and procedures, weld joint design and preparation, weld-acceptance criteria, procedure and performance qualification and documentation requirements. Several tables list weld-acceptance criteria, and detailed graphics illustrate acceptable and unacceptable welds.

Part SF — Surface Finish. A crucial element in the ability to attain and maintain a clean system is in the quality of the finish on the product-contact surface. Whether in the bioprocessing industry or other sectors in which at least a segment of the processing scheme involves bioprocessing (such as biofuels production),

TABLE. R_a READINGS FOR PRODUCT-CONTACT SURFACES

Mechanically polished		
R_a max.		
Surface designation	μ-in	μm
SF0	No finish requirement	No finish requirement
SF1	20	0.51
SF2	25	0.64
SF3	30	0.76
Mechanically polished[1] and electropolished		
R_a max.	μ-in.	μm
SF4	15	0.38
SF5	20	0.51
SF6	25	0.64

General notes: (a) This table replaces previously published Tables SF02, SF-4, SF-6, SF-8, and SF-10.
(b) All R_a readings are taken across the lay, wherever possible.
(c) No single R_a reading shall exceed the Ra max value in this table
(d) Other R_a readings are available if agreed upon between owner/user and manufacturer, not to exceed values in this table.
Note: (1) or any other finishing method that meets the R_a max

Source: ASME-Bioprocessing Equipment (BPE) Standard.

the cleanability of the product-contact surface is crucial (Table). In addition to Part SF providing the methods by which surface finishes are classified, it also spells out the acceptance criteria for compliance.

Part SG — Equipment Seals. This part covers equipment seals, and provides a classification scheme that describes the required integrity of a seal under specific service conditions.

Part PM — Polymer-based Materials. Added to the Standard in 2002, this section covers criteria related to both thermoplastics and thermosetting materials. It touches on design considerations, joining methods, interior product-contact surfaces and materials of construction.

Part MMOC — Metallic Materials of Construction. This section was first published in the 2009 issue of the BPE Standard. Its incorporation into the standard was driven by the growing importance of alternative materials of construction beyond Type 316L stainless steel. The main objective of this section is to help system designers and facility owners improve system quality and sustainability, and to improve compatibility with fluids that are too aggressive for Type 316L stainless steel.

Adding Part MMOC allows the standard to elaborate and expand its information on metallic materials in a centralized and comprehensive way. This section offers a definitive listing of acceptable materials in their various forms, and provides further information on Pitting Resistance Equivalent Number Rankings (PREn), corrosion test references for alloys, discussion points on superaustenitics, duplex stainless steels, nickel alloys, ferrite content restrictions and much more.

Part CR — Certification. This part was first included in the 2009 publication of the standard, and gives users a way to ensure that the tubing and fittings they purchase are compliant with BPE Standard requirements. This is achieved through a well-defined and implemented certification program for compliance with the BPE Standard by those manufactures, fabricators, and service providers that qualify. The certification process is a multi-faceted program based on an in-depth Quality

Management System (QMS) program that is defined in Part CR.

Specifically, the program requires that the applicant for certification create a QMS manual, as defined in the BPE Standard, which is expected to mirror the quality program actually being used in their production process. Among many other requirements, the manual should reflect a company's organizational hierarchy, inspection protocols, materials-handling procedures (from receiving through manufacturing and shipping), process for segregation of materials, inspection-personnel qualifications, reject-resolution and documentation needs.

Extras within the Standard

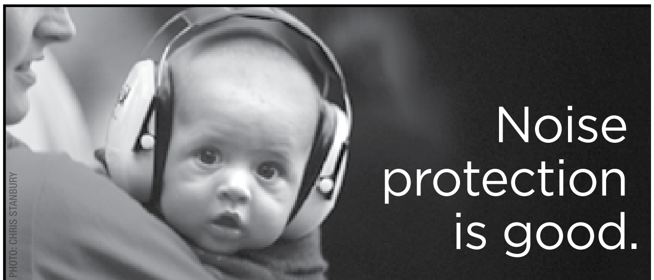
The 2009 publication of the BPE Standard contains more than 60 figures, 60 tables and 9 non-mandatory appendixes — all developed to make the compliance requirements more explicit for the user. The figures represent everything from fitting dimensions to mechanical seals, and include acceptable nozzle projections, side- and bottom-nozzle pads, vessel sight-glass mounting design, double mechanical-cartridge-seal design, single dry-running contact seal, weld profiles, design diagrams and more.

In addition to the many tables on dimensions and tolerances for the manufacture of fittings, additional tables provide weld-acceptance criteria for: welds on pressure vessels and tanks, welds on pipe, welds on tubing, and tube-attachment welds. Another table provides acceptance criteria for the mechanically polished product-contact surface of stainless steel and higher alloys, and a table of surface-finish designations.

The tables, graphics, and intellectual information contained in the BPE Standard are the product of a very structured data-refining process. The supporting research data, while not necessarily included in the body of the standard, is, in many cases, valued information. The Non-Mandatory Appendices section houses much of this information. This section contains information that is deemed to be useful to readers, but is not appropriate for codification. Presented in this way, the information in this section can be published for use while still remaining segregated from the requirements of the standard, should the entire standard be adopted as code.

For instance, some of the topics covered in the Non-Mandatory Appendixes include:

- Appendix A – Slag
- Appendix B – Material Examination Log and Weld Log
- Appendix C – Slope Measurement
- Appendix D – Rouge and Stainless Steel
- Appendix E – Passivation Procedure Qualification
- Appendix F – Corrosion Testing



- Appendix G – Ferrite
- Appendix H – Electropolishing Procedure Qualification
- Appendix I – Vendor Documentation Requirements for New Instruments

Wrap up

While this article provides a cursory overview of the BPE Standard, the major take-away should be the understanding that a great deal of useful, vetted information is available in the many American National Standards that are available today. While some may require compliance from a regulatory standpoint, others may be adopted and specified voluntarily.

As noted earlier, it is not necessary to adopt an entire standard if all you need are isolated sections. If, for example, a given project only needs some or all of the content on CIP requirements from the BPE Standard, then users can reference just that segment, which will then become a part of the contractual requirements for a project or facility.

The same holds true if your project is handling, say, hydrogen gas. There may be circumstances in which it may be practical to require compliance with isolated segments of a Compressed Gas Assn. (CGA) Standard such as G-5 "Hydrogen" and/or G-5.4 "Standard for Hydrogen Piping Systems at Consumer Locations." It would then be appropriate to adopt and reference that segment of the CGA standard.

There are numerous standards (from ASME, API, CGA, and others) that are required to deliver the necessary codes and standards to a project. Without harmonization efforts by the developers of today's standards, the usefulness of industry standards would most likely be diminished by conflicting requirements and overlapping stipulations. However, with harmonization and self-familiarization, the engineers' effort to select and employ the many available standards is made much easier and more relevant today. ■

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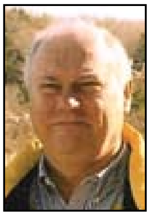

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