PIPING NEWS

A Newsletter published by W. M. Huitt Co.
for designers and engineers involved with process piping

IN THIS ISSUE:

NEW LAUNCH DATE

In attempting to squeeze as much information into the online Piping Training Course, the course that was announced last month, it has ended up pushing back the launch date beyond the end of April.

We are making every effort to have this done by May 17, 2019. Just prior to the ASME BPE meeting being held the week of May 20 in Portland, OR.

A note at the end of the brochure/Syllabus, found at the end of this Newsletter, explains the following:

The 10 plus hours of this online course contains the same essential information as you would get from a 3-day classroom course. When you remove the break times, lunch times, study times and lengthy face to face discussion time, a 3-day classroom course boils down to 10.5 hours of instruction.

The benefit of the online course for the student is in being able to go back over some of the discussion that may not have registered in the first pass. You can simply pause and replay that discussion. You can't do *that* in a classroom.■

AN EXCERPT

This is the continuation of an excerpt from an article on the multiple industry application of the ASME BPE Standard titled "Crossover Applications for the ASME Bioprocessing Equipment Standard," written by W. M. Huitt and published by Chemical Engineering magazine.

What a project's Codes & Standards requirements may look like graphically is represented in the rather simplistic Venn diagram of Fig. 1, shown on the following page. What this shows is a basic representation of the necessary piping Codes and Standards needed for a CPI type project and how they overlap and comingle within the framework of a project, or within the infrastructure of plant operations and maintenance. In actuality this graphic would be a great deal more complex due to the sheer volume of Codes and Standards a project or plant operations would require.

The ASME-BPE Standard

The conceptual intent, the basis for what drove a group of engineers in the late 1980's to petition the ASME Council on Codes and Standards for the approval to create what is now titled the ASME-Bioprocessing Equipment (BPE) Standard, was the real need and necessity to inject some sense of continuity and standardization into an industry that sorely needed it — the pharmaceutical industry. However, while the initial impetus for the creation of the BPE Standard was, and still remains, a need in the pharmaceutical industry its content is more universal and can be utilized in other CPI's aside from that of the pharmaceutical industry itself.

Figure 1 – Venn Diagram of C&S Requirements

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 six Parts, which included:

Part GR – General Requirements
Part SD – Design for Sterility and Cleanability
Part DT – Dimensions and Tolerances
Part MJ – Material Joining
Part SF – Surface Finishes
Part SG – Equipment Seals

The latest version of the BPE Standard, which at this writing is the 2019 issue (Yet to be issued.), looks much different than its inaugural predecessor with content that is much more encompassing and wide-ranging with four additional subject matter sections referred to as Parts. They are:

Part PM – Polymer based Material (Added in the 2002 edition.)

Part MM – Metallic Materials (Added in the 2009 edition as Part MMOC.)

Part CR – Certification (Added in the 2009 edition.)

Part PI – Process Instrumentation (Added in the 2012 edition.)

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 cleanable, to a microscopic level. Residual hold-up of product, a system that cannot be properly cleaned or sterilized in place, or a system that facilitates the onset and growth of bioburden (a colony of microorganisms) cannot be tolerated in pharmaceutical piping systems. The same can

be said for various segments of cellulosic biofuel processing and other CPI type facilities, but for altogether different reasons.

As an example, the initial stages of fermentation in a cellulosic bioethanol process uses a hybrid fungal enzyme to break down and convert the much tougher cellulosic base, as compared to breaking down a much simpler starch from corn kernels. These hybrid enzymes are generally a suite of enzymes called cellulases that work in concert with one another as catalysts for the fermentation process in the manufacture of sugars from the cellulose.

In the fermentation process, that of converting cellulose to sugar, there is a resident hold time for the manufactured sugar. This is prior to yeast being added to the sugar in the next step of the process, which then starts the conversion of sugar to ethanol. During its resident hold time the sugar is susceptible to bacteria that thrive in that same environment. If the bacteria are permitted to go unchecked it will infect the sugar causing a yield loss thereby creating a major negative impact on production.

In order to keep the detrimental bacteria in check and allow the process to remain stable and viable it is imperative that a segment of the piping system be sterilized in place (SIP) at frequent time intervals. Comparatively there is a need in the ethanol manufacturing process to clean in place (CIP) the fermenters, the beer well, the filtrate tanks, propagators as well as other segments of the process. The CIP step in the process is an efficient means of controlling residue buildup on equipment and piping.

The CIP process itself is a procedure by which a cleaning solution is pumped through a piping system at scheduled intervals to kill and clean out all accumulated bacteria and process residue. The SIP process performs essentially the same procedure using steam with the intent to sterilize the system.

In designing a process system that requires CIP or SIP there are specific piping and equipment design requirements that need to be met. Requirements such as minimum slope, maximum acceptable dead-leg, internal weld finish, fitting and fabrication tolerances, surface finishes, etc. are all necessary to accommodate those procedures. By not understanding the need for these requirements and therefore not integrating them into the design of a system that requires CIP or SIP the goal of cleaning or sterilization will not be met. All of those requirements necessary for this type of design can be found in the BPE Standard.

A process system that may not be concerned with bacteria, but may have a need for sloped piping and a requirement for maximum acceptable dead-legs to minimize the opportunity for entrained particulates to settle out and create blockage problems can also utilize the BPE Standard. There are fabrication requirements and fitting standards within BPE that address these issues as well.

Establishing control of material, fabrication, examination, and testing on a project requires documentation. A CPI project, one that is outside the boundaries of what could be characterized as a bioprocessing type facility, will not necessarily require a documentation trail to the extent necessary for a pharmaceutical type project. They may, nonetheless, require a portion of that documentation for safety and conformity requirements, documentation which can be selected from the BPE Standard.

The laundry list of documentation specified in the BPE Standard is one that can be selectively utilized by other industries simply by reference. And this is where the real benefit of industry Standardization becomes apparent. Rather than writing out a requirement that may already exist in an industry Standard simply reference the respective paragraph in a Standard containing the needed requirement.

Content of the BPE Standard

As alluded to earlier, the BPE Standard, while it dovetails with and references many aspects of B31.3, it is markedly different in both layout and content. You will see, as we touch on a few key

elements of the nine current Parts of the BPE Standard, how universal the Standard actually is.

PART GR

The General Requirements section of the Standard sets the tone and defines the scope of the Standard. This section provides definitions for terminology that may be specific to the bioprocessing industry, or it could be a term used elsewhere, but with different implications in the BPE Standard. Terminology defined elsewhere and adopted by the BPE Standard under that definition, will have the definition referenced rather than re-written or paraphrased in the BPE Standard.

PART SD

The section on Design for Sterility and Cleanability is one aspect of the BPE which departs from the main focus of the B31.3 format. Whereas, B31.3 is developed around the cornerstone of safety and system integrity, it is necessary for the BPE to broaden its content to also include acceptable criteria for system design as well as safety and system integrity.

In doing so, the SD subcommittee, since its inception, has taken on the task of researching industry design practices currently being used in the bioprocessing industry. This is an effort to validate and, where necessary, rectify those largely unqualified design practices and criteria, while at the same time developing new and appropriate design criteria for adoption into the BPE Standard.

Some of the topics covered by PART SD are clear concepts 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 it also touches on testing fundamentals for spray balls, drainability, cleanability, and sterility. There is also a listing of documentation that can be selected by and used for industries beyond that of bioprocessing.

PART DT

The Dimensions and Tolerances section has basically standardized the bioprocessing industry. Prior to the BPE and PART DT there were no Standard dimensions on fittings and valves. Nor were there a common set of manufacturing tolerances. This meant that components from one manufacturer to the next were not necessarily interchangeable. This presented a logistical nightmare for a project in which all fittings had to be purchased from the same manufacture to ensure compatibility and fit-up.

PART MJ

The Material Joining section touches on all aspects of the welding of pressure vessels, tanks, tube, and fittings. It takes the reader from acceptable material requirements through inspection, examination, and testing requirements. In between it discusses such topics as joining processes and procedures, weld joint design and preparation, weld acceptance criteria, procedure and performance qualification, and documentation requirements. Included are Tables listing weld acceptance criteria and detail graphics on acceptable/ unacceptable welds.

PART SF

A crucial element in the ability to attain and maintain a clean system is in the quality of the product contact Surface Finish. Whether in the bioprocessing industry or other industries in which at least a segment of the processing scheme is biological, such as the biofuel industry, the cleanability of the product contact surface is crucial to the efficiency and effectiveness of the process itself. Not only has PART SF brought to the CPI methods by which surface finishes are classified, it also provides acceptance criteria that can be specified for compliance.

PART SG

PART SG covers Equipment Seals, and in so doing has provided a classification describing

the required integrity of a seal under specific service conditions.

PART PM

Added to the Standard in 2002, this section on Polymer-Based Material includes both thermoplastics and thermosetting materials. It touches on design considerations, joining methods, interior product contact surfaces, and materials of construction.

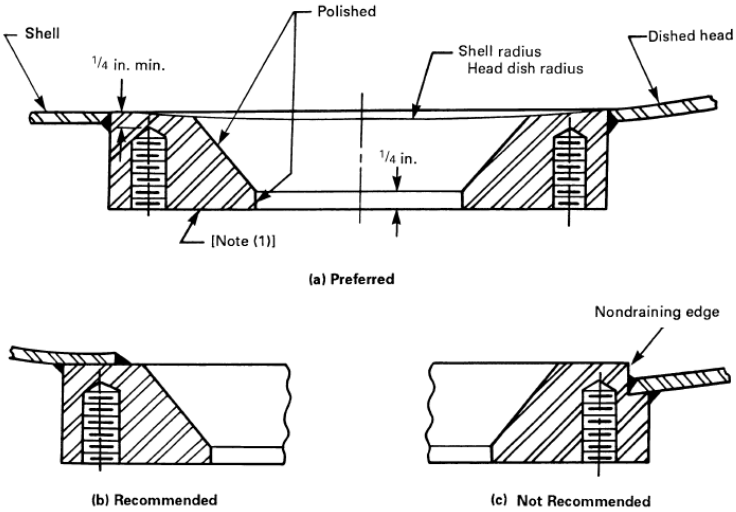

Figure 2 – Side and Bottom Nozzle Pads
(Fig. SD-3.4.2-2 in the BPE Standard)

PART MM

The section on Metallic Materials of Construction was first published in the 2009 issue of the BPE Standard. Its incorporation into the Standard was driven by the need to keep abreast of industry's continuing search for alternative materials of construction, beyond that of 316L stainless steel. The main objective of Part MM is to improve system quality and sustainability as well as improve compatibility for fluids too aggressive for 316L.

Adding PART MM allowed the Standard to elaborate and expand its information on metallic material in a way that would otherwise have been too segmented and convoluted. As it turns out, this section on metallic materials provides, not only a definitive listing of acceptable material in its various forms, but also provides such information as PREn (Pitting Resistance Equivalent Number) Rankings, Corrosion Test references for Alloys, discussion points on Superaustenitics, duplex stain-less steels, nickel alloys, ferrite content restrictions, and much more.

PART CR

This Part on Certification was first published in the 2009 issue as a means of providing a program that would assure end users that tubing

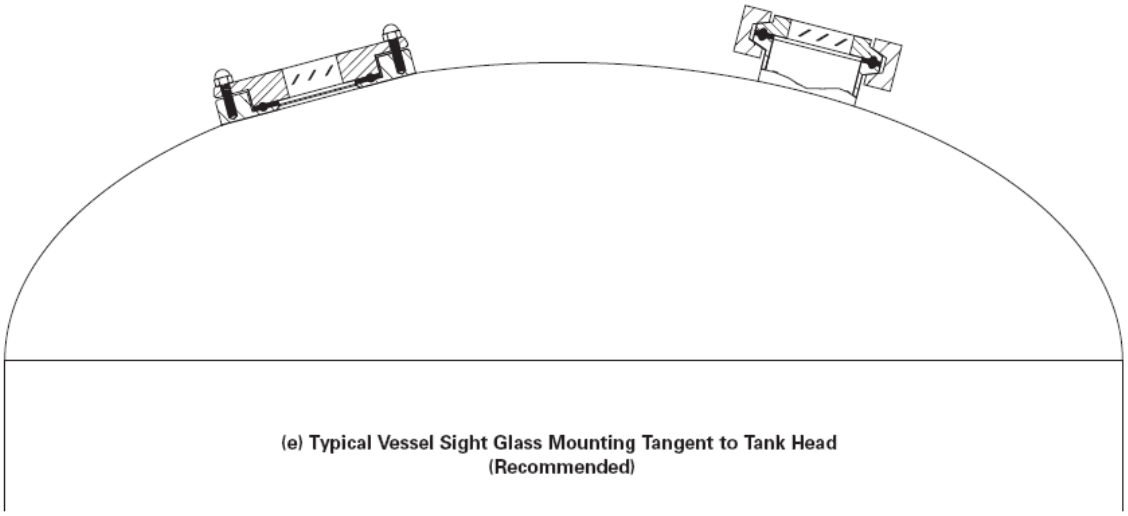

Figure 3 – Sight Glass Mounting
(Fig. SD-3.4.6-1(e) in the BPE Standard)

and fittings they purchase are compliant with the BPE. This is accomplished through a well-defined and implemented certification program for compliance of the BPE Standard by those manufactures, fabricators, and service providers who qualify. The certification process is a multi-faceted program based on an in-depth Quality Management System (QMS) that is defined in PART CR.

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 protocol, material handling procedures (from receiving through manufacturing and shipping), segregation of materials, inspection personnel qualification, reject resolution, documentation, and much more.

FIGURES, TABLES AND NON-MANDATORY APPENDIXES

The BPE Standard is loaded with over 139 Figures, over 89 Tables, 4 Forms, 4 Mandatory Appendices, and 27 Non-Mandatory Appendixes, all in an effort to make very clear what it is the user needs to comply with. The Figures graphically represent everything from fitting dimensions to mechanical seals.

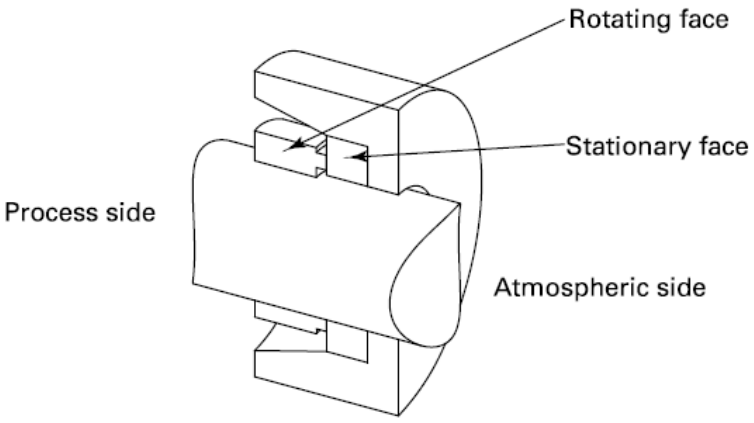

Figure 5 – Single Mechanical Seal
(Fig. SG-2.3.2.2-1 in the BPE Standard)

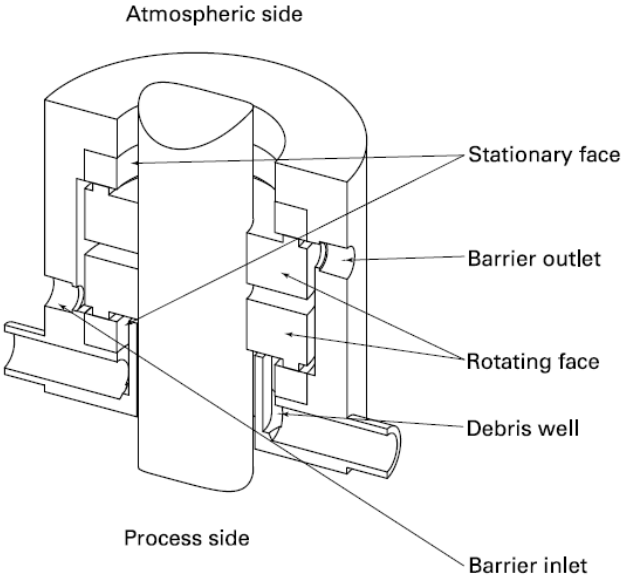

Figure 4 – Dual Pressurized Mechanical Seal for Top-Entry Agitator
(Fig. SG-2.3.2.3-2 in the BPE Standard)

It also includes acceptable nozzle projections, side and bottom nozzle pads (Ref Fig. 2), vessel sight glass mounting design (Ref. Fig. 3), Dual Pressurized Mechanical Seal (Ref. Fig. 4), single mechanical seal (Ref. Fig. 5), weld profiles, design diagrams, and much more.

In addition to the many Tables on dimensions and tolerances for the manufacture of fittings there are tables that include such information as Weld Acceptance Criteria for: welds on Pressure Vessels and Tanks; welds on Pipe; welds on Tubing; and Tube Attachment Welds. There is also a Table for Acceptance Criteria for Stainless Steel and Higher Alloy Mechanically Polished Product Contact Surface, and a Table of Surface Finish Designations (Table 1 Pg. 8).

The Tables, Graphics, and intellectual information that end up in the BPE Standard are the product of a very structured data refining process. The information that makes it into the BPE Standard is typically distilled from a much larger data source compiled over time as a result of research performed or directed by personnel within its membership, who, I might add, very often absorb the time and expense in executing this research. A great deal of that research information is very useful, but cannot be

considered as suitable for the body of the Standard.

Not wanting this useful information to end up residing in a file box or to sit idly on a hard drive, and therefore not get shared with industry, the BPE has added a Section for Non-Mandatory Appendixes. This is a section of the Standard in which information, deemed useful to readers of the Standard, but not appropriate for codification, can be posted for use while remaining segregated from the requirements of the Standard should the entire Standard be adopted as Code.

The Non-Mandatory Appendices covers such topics as:[1]

Appendix A – Commentary: Slag and Oxide Islands

Appendix B – Material and Weld Examination/ Inspection Documentation

Appendix C – Slope Measurement and Joint Misalignment

Appendix D – Rouge and Stainless Steel

Appendix E – Passivation Procedure Qualification

Appendix F – Corrosion Testing

Appendix G – Ferrite

Appendix H – Electropolishing Procedure Qualification

Appendix J – Vendor Documentation Requirements for New Instruments

Appendix K – Standard Process Test Conditions (SPTC) for Seal Performance Evaluation

Appendix L – Standard Test Methods for Polymers

Appendix M – Spray Device Coverage Testing

Appendix N – Commentary: UNS S31603 Weld Heat-Affected Zone Discoloration Acceptance Criteria

Appendix O – Guidance When Choosing Polymeric and Nonmetallic Materials

Appendix P – General Background/Useful Information for Extractables and Leachables

Appendix Q – Temperature Sensors and Associated Components

Appendix R – Instrument Receiving, Handling, and Storage

Appendix S – Application Data Sheet

Appendix T – Guidance on Polymer Applications: Chromatography Columns and Filtration

Appendix U – Guidance for the Use of U.S. Customary and SI Units

Appendix W – Positive Material Identification

Appendix Y – Procurement Sources

Appendix Z – Quality Management System

Appendix AA – Static Seals Application Guide for Compendial Water Systems

Appendix BB – Mechanical Seal Face Material Selection for Compendial Water Pumps

Appendix CC – Examination, Inspection, and Cross References

Appendix DD - Conductivity Sensor Selection Guide

Here too are the Mandatory Appendices, not present at the time this article was written:

Appendix I – Submittal of Technical Inquiries to the Bioprocessing Equipment (BPE) Committee

Appendix II – Standard Units

Appendix III – Single-Use Components and Assemblies

Appendix IV - Nomenclature

[1]At the time this article was initially written the Nonmandatory Appendices extended only to what is now Appendix J. It was felt that this much more extensive Appendices needed to be updated to what is currently going to be represented in the 2019 edition.

And Finally

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.■

Surface Designation	Mechanically Polished [Note (1)] R_a Max. µ-in.	Mechanically Polished [Note (1)] R_a Max. µm
SF0	No finish requirement	No finish requirement
SF1	20	0.51
SF2	25	0.64
SF3	30	0.76
	Mechanically Polished [Note (1)] and Electropolished	
	R_a Max. µin.	R_a Max. µm
SF4	15	0.38
SF5	20	0.51
SF6	25	0.64

GENERAL NOTES:
(a) This table replaces previously published Tables SF-2, 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 R_a 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.

Table 1 – R_a Readings for Metallic Process Contact Surfaces
(Fig. SF-2.4.1-1 in the BPE Standard)

CHANGES TO THE BPE FOR THE 2019 EDITION

In the front matter of each issue of the BPE Standard is a "Summary of Changes." Not unlike a summary of changes listed in a drawing revision block or project specifications and procedures.

The summary in the BPE provides an itemized listing that gives the reader a glimpse into what has been changed or added to the Standard since its last edition.

This listing of 146 changed or added items within the Standard in no way captures the magnitude of these changes, or the amount of work that went into their making.■

QUESTION OR COMMENTS

If you would like us to address a specific topic or simply answer a question, related or unrelated to the content of this Newsletter, please contact us at: staff@wmhuittco.com. In the subject line of the email please enter "Newsletter Question/Comment."

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