High Purity Process Piping: Harmonization of ASME Codes and Standards

by Barbara Henon, Vince Molina, Richard Campbell, and William Huitt

This article presents interactions between the ASME Bioprocessing Equipment (BPE) Standard and ASME B31.3 Process Piping Code Committees following the addition of Chapter X High Purity Piping to the 2010 Edition of B31.3. This collaboration of ASME Committees will help to assure both safety and cleanability of high purity piping systems.

Following the introduction of the ASME Bioprocessing Equipment (BPE) Standard in 1997, most new pharmaceutical and biotechnology plants around the world have been constructed using the ASME BPE Standard.1,2 The original scope of this standard, as approved in 1989 by the ASME Council on Codes and Standards stated:

“This standard is intended for design, materials, construction, inspection, and testing of vessels, piping, and related accessories...for use in the biopharmaceutical industry.”

The ASME B31.3 Process Piping Code also includes piping in pharmaceutical plants as being within its scope.3 The BPE Standard references ASME B31.3, but there are inherent differences between the two ASME documents that have only recently been addressed. While the focus of the Code is primarily on safety issues, the 2010 Edition of ASME B31.3 introduced a new chapter, Chapter X High Purity Piping. Chapter X covers piping in high purity industries including the semiconductor and bioprocessing industries that have a particular need for cleanliness and/or cleanability of their piping systems, but also must meet the safety requirements of the Code.

Although the ASME B31.3 Code and the ASME BPE Standard have been developed independently, it is important going forward that they do not contradict or conflict with one another. The addition of Chapter X is an essential first step in closing the gap between the requirements and intent of the ASME BPE Standard and the Code. Even before the publication of Chapter X, members of both ASME Committees have been working together to harmonize the two ASME documents for which the latest editions of both are 2012.

High Purity Piping

The need for a chapter in the ASME Process Piping Code to address high purity concerns became apparent in 2004 when an engineer and a member of the B31.3 Code Committee started to write a specification for an Ultra-High Purity (UHP) piping installation using the ASME B31.3 Code. He found that process piping systems typically used in semiconductor plants were not adequately addressed in the Code. This was the case even though the Code identifies piping in semiconductor plants as within the intended scope. The semiconductor industry uses standards written by Semiconductor Equipment and Materials International (SEMI) that reference ASME B31.3.4,5 The emphasis of the SEMI standards is on cleanliness rather than the basic safety considerations of ASME B31.3.
Semicontactor industry practices are based on the requirements of fabrication facilities for UHP fluids that are used in the process tools. Achieving UHP levels of cleanliness in fabrication of process gas lines was necessary in order to increase the yield of semiconductor integrated circuits. Gas storage and delivery systems must not add impurities to the fluids that typically range in purity from 99.9999% to 99.999999% for chemical and particulate contaminants. These gases may be highly toxic, pyrophoric (spontaneously combustible in air) or corrosive. Major advances in fluid handling and fabrication technology were essential to meet the demands for both purity and safety.

**Orbital Welding Technology**

In the 1980s and 1990s, fabricators in the semiconductor industry began using autogenous orbital Gas Tungsten Arc Welding (GTAW) for joining process gas lines because the smooth inner weld bead resulted in cleaner systems than could be achieved with manual welding. Orbital welding was part of the drive to reduce particulate contamination to very low levels. Welds that are fully penetrated to the Inside Diameter (ID) surface with a smooth inner weld bead are far less likely to entrap particulates than the manual socket welds that were previously used, and cleaner systems were essential to achieving higher product yields.

Ultra-High Purity (UHP) and High Purity (HP) semiconductor piping installations use mostly small diameter Type 316L stainless steel tube, 0.250 inch, 0.375 inch, and 0.500 inch Outside Diameter (OD) rather than pipe. Tube is more suitable than pipe for high purity applications since it is manufactured with tighter dimensional tolerances than pipe, thus increasing the repeatability of automatic welds. Fittings, valves, and other components for semiconductor systems are highly specific to the type of application.

Piping systems in other industries covered in the ASME B31.3 Code include piping typically found in petroleum refineries, chemical, textile, and paper plants that, for the most part, consist of metallic pipe installed with multipass manual welds with filler metal added to the weld. Orbital welds on tubing are typically single pass welds with a flat or slightly concave OD profile. Neither automatic orbital welding nor helium mass spectrometer leak testing, commonly used for testing of semiconductor process gas lines, had been addressed by the ASME B31.3 Code. The initial impetus that eventually led to the development of the ASME Bioprocessing Equipment (BPE) Standard was bioprocessing equipment imported from Europe that had manual welds that did not meet the quality standards that were routinely achieved by installers in the United States using orbital welding equipment.

Volunteers working on the ASME BPE Standard committee have helped to systematize the installation of biopharmaceutical process tubing. The Subcommittee on Dimensions and Tolerances specified controlled material chemistry, especially sulfur, to minimize heat-to-heat variability in the weldability of tubing and fittings made from Type 316L stainless steel (and other austenitic stainless steels) and by standardizing the dimensions of weld ends on fittings and other process components to be orbitally welded.

The Subcommittee on Surface Finish set standards for smoothness of product contact surfaces while the Materials Joining (MJ) Subcommittee established weld criteria for product and non-product contact surfaces of orbital tube welds. Acceptance criteria for welds on tubing systems do not allow cracks, lack of fusion, incomplete penetration, porosity open to the surface, inclusions open to the surface nor undercut. Systems made from nominal diameter pipe are seldom used for the higher purity requirements in the biopharmaceutical industry. If they are used, the welds are made in accordance with ASME B31.3 Table 341.3.2 with additional acceptance criteria of the ASME BPE Standard in which cracks, lack-of-fusion and incomplete penetration are prohibited.

The MJ Subcommittee also established methods of weld examination and inspection that are not used routinely in other industries. The ASME BPE Standard requires visual examination of the outside diameter surface of 100% of tube welds and the use of borescopic or direct visual examination to view the ID of 20% of the tube welds. BPE requires sample welds or coupons be performed prior to production welding and at specified times. Weld logs and weld coupon logs are
part of quality assurance with every weld numbered, documented and identified on an isometric drawing or weld map. The ASME BPE is now an International Standard used in 30 countries. The application of the ASME BPE Standard has resulted in very efficient installations of large scale biotechnology facilities such as Amgen, Eli Lilly, Genentech, and others that may have orbital welds numbering in the 30,000s.9

ASME B31.3 Chapter X High Purity Piping

A presentation was made to the ASME B31.3 Section Committee in 2005 to point out the gaps in the Code with regard to UHP pressure piping. Permission was obtained from the ASME to begin writing a new Chapter for ASME B31.3. An Ultra-High Purity Piping Task Group (Subgroup H) was formed to examine differences in piping requirements between the practices in the semiconductor and the more established industries covered by ASME B31.3. Since the fabrication practices in the biopharmaceutical industry and the semiconductor industry share commonalities, Subgroup H was expanded to include individuals having expertise in the biopharmaceutical as well as semiconductor industry, and the name was changed to Subgroup H High Purity Piping in keeping with the broader scope.

In writing Chapter X, Subgroup H went through the entire ASME B31.3 Code and identified each paragraph that applied to high purity piping and assembled those paragraphs as well as new paragraphs into the new chapter. Paragraphs in Chapter X have the prefix “U” as, prior to publication, Chapter X was called Ultra-High Purity Piping. Since the term Ultra-High Purity refers to the most critical level of semiconductor cleanliness and has very specific sets of standards that define these requirements, the name UHP Piping was later changed to High Purity Piping so that Chapter X could be applied to a broader range of industries.9

ASME B31.3 Fluid Services

Chapter X introduced a new fluid service category, High Purity Fluid Service, to the 2010 Edition of the Code. When an owner designs a piping system to the ASME B31.3 Code, it is his responsibility to select an appropriate fluid service as defined by B31.3. Metallic pipe in the B31.3 Base Code, Chapters I to VI, is typically in Normal or Category D fluid service. Other chapters that were previously added to the code have introduced other fluid service categories such as Category M for piping carrying toxic materials, and High Pressure Fluid Service for piping systems designated by the owner to be in High Pressure Fluid Service. Figure M300 Guide to Classifying Fluid Service is a flow chart provided to help the owner determine the appropriate fluid service for his application.

High Purity Fluid Service is defined as “a fluid service that requires alternative methods of fabrication, inspection, examination, and testing not covered elsewhere in the Code, with the intent to produce a controlled level of cleanliness. The term thus applies to piping systems defined for other purposes as high purity, ultra-high purity, hygienic, or aseptic.”

High Purity Fluid Service can thus include UHP and HP semiconductor process piping as well as hygienic bioprocess piping or aseptic piping for food and diary applications. Piping systems in the chemical processing industry that may require a high level of cleanliness or cleanability can be declared high purity by the owner. The owner must declare the system to be in HP Fluid Service and then comply with all of the requirements of Chapter X.10,11

Weld Coupon Examination in Lieu of 5% Radiography

Chapter X paragraph U341.4.1 provides for Coupon Examination of welds in lieu of the required 5% random radiography, ultrasonic, or in-process examination when orbital welding is used in fabrication. For the 2012 Edition of Chapter X, paragraph U341.4.1 has been modified to allow coupon examination when autogenous orbital welding is used in fabrication or when a consumable insert is used in conjunction with orbital welding.

Borescopic examination is now listed in Chapter X as an approved method of visual examination of orbital welds. This type of examination is effective in detecting both lack of penetration and slight amounts of weld discoloration that are not seen with radiography. Even slight amounts of weld discoloration have been shown to reduce the corrosion resistance of stainless steel and corrosion can have an adverse affect on pharmaceutical products.12,13

ASME BPE Fittings Referenced in ASME B31.3

In addition to metallic and nonmetallic face seal fittings used in semiconductor process gas lines, ASME BPE orbital butt weld fittings and ASME BPE hygienic clamp fittings that are used for mechanical joints in biopharmaceutical applications, are now referenced in ASME B31.3. Hygienic clamp type fittings are mentioned in Chapter X paragraph U306.6 Tube Fittings and also have been listed in ASME B31.3 Table 326.1 Component Standards. Note (3) of this table refers back to BPE “Part DT of ASME BPE covers dimensions and tolerances for stainless steel automatic welding and hygienic clamp tube fittings and process components.” In order to be listed, a component must be shown to meet the requirements of ASME B31.3 for structural integrity.

Drawings of hygienic clamp fittings are shown in ASME BPE-2012, Figure DT-2-1, and similarly in ASME B31.3-2012, Figure U-335.8 - Figure 1. These clamp assemblies that are used in conjunction with specific types of gaskets, are quite different from the typical flanged and bolted con-
Connections used in normal ASME B31.3 piping systems.

In accordance with B31.3 each installed piping system shall be tested to assure tightness. The test shall be a hydrostatic test in accordance with B31.3 para. 345.4 except as otherwise provided. At the owner’s option, Chapter X has added helium mass spectrometer testing which is common in the semiconductor industry.

When a new term is added to an ASME Code or Standard, a definition more in line with its intended use must be added to the list of definitions in that publication. Definitions were added to ASME B31.3 paragraph 300.2 for orbital welding, face seal fitting, weld coupon, weld coupon examination, and hygienic clamp joint in the 2010 Edition and a definition of autogenous welding was added in 2012.

Harmonization of ASME BPE and ASME B31.3

Interactions between ASME BPE and B31.3 Subgroup H began in 2006 when a member of the ASME BPE Standards Committee and the BPE Subcommittee on Materials Joining (MJSC) attended an ASME B31.3 meeting in Atlanta, Georgia. The Chair and another member of the Subgroup H subsequently were invited to attend the ASME BPE Materials Joining Subcommittee (MJSC) meeting in Philadelphia in October 2007 where the Subgroup H members made a PowerPoint presentation to the MJSC. They stressed the ASME B31.3 emphasis on safety comparing it to BPE’s concern with cleanability and control of bioburden. At that meeting, the MJSC appointed an official liaison to interface between the ASME BPE and ASME B31.3 Committees. Since then, liaison reports have been made at meetings of both ASME committees. Other members of BPE have joined B31.3 Committees and these volunteers have worked consistently to bring the two ASME documents closer together.

Many members of the ASME B31.3 Committees were unfamiliar with high purity piping and orbital welding so the members of Subgroup H organized a PowerPoint presentation to the B31.3 Section Committee on this topic in Phoenix, Arizona in 2010. At the same meeting, live demonstrations of autogenous orbital welding were given for all the B31.3 subgroups. Samples of the types of UHP and HP fittings, valves and clamps used in semiconductor and bioprocessing systems, some of which have now been listed in Table 326 of ASME B31.3, were on display.

ASME BPE/B31.3 Harmonization Task Group

Knowing that Chapter X was in preparation, the ASME BPE Materials Joining Subcommittee formed a task group to identify all of the references to ASME B31.3 in the ASME BPE Standard to determine how these references might be affected by the addition of Chapter X to the Code. The Harmonization Task Group met for several years at BPE meetings and reported their activities to ASME B31.3 Subgroup H at their meetings. The task group found a total of 41 references to ASME B31.3 in the 2009 BPE Standard. As a result, several references in Part MJ in the 2012 Edition of BPE refer to the “appropriate fluid service” which will most likely be High Purity Fluid Service as defined in the 2010 Edition of ASME B31.3 for hygienic systems. References in ASME BPE to specific ASME B31.3 paragraph numbers were changed to general references to ASME B31.3.

A statement was added to the General Requirements section (Part GR-1) in the Scope of the 2012 Edition of the ASME BPE Standard to alert users that for hygienic systems in bioprocessing plants they could now specify High Purity Fluid Service as defined in ASME B31.3. A ballot was approved first by the MJSC then by the BPE Subcommittee on
General Requirements (SCGR), but took several attempts for approval by the ASME BPE Standards Committee. These ASME Codes and Standards are by consensus so all comments on the ballots must be answered and all negatives resolved at each successive level of the record. This process works surprisingly well and the negatives are usually constructive with improved wording and clarity the typical outcome. The final, approved reference in BPE Part GR-1 for 2012 is as follows:

“\textbf{This Standard shall govern the design and construction of piping systems for hygienic service.} For process piping systems designed and constructed in accordance with ASME B31.3, \textit{it is the owner’s responsibility to select a fluid service category for each fluid service. Should any fluid service meet the definition of high purity fluid Service (ASME B31.3, Chapter X) it is recommended that such fluid service be selected and the requirements of this Standard and ASME B31.3, Chapter X be met.”}

This statement gives ASME BPE the authority to set standards for design and construction of hygienic systems and when a piping (or tubing) system is to be used for hygienic or high purity service that meets the definition of the ASME B31.3 High Purity Fluid Service, that fluid service should be selected. Prior to the introduction of Chapter X, most of these systems were classified as ASME B31.3 Normal Fluid Service. The statement demands that the design and construction requirements of both ASME BPE and ASME B31.3 be met. Thus it is essential that there be no inherent conflicts between the two ASME documents.

Radiographic vs. Coupon Examination

The 2012 ASME BPE Standard (MJ-7.3.3) requires “\textit{Examinations shall be performed in accordance with the provisions of the specified fluid service in ASME B31.3}.” BPE has never required radiographic examination of tube welds. The ASME BPE requirement is for 100% visual examination of the outside diameter surfaces plus a minimum of 20% random borescopic examination of the inside diameter of tube welds while the ASME B31.3 Normal Fluid Service requirement is a minimum of 5% visual examination and 5% random radiography or ultrasonic examination.

Because of the difference in these requirements, there was always some vague concern that BPE requirements were not in full compliance with the Code. However, prior to the introduction of Chapter X, users of BPE and B31.3 who did not specify 5% radiography were not necessarily “violating” the ASME B31.3 Code if they specified \textit{in-process examination} (B31.3 paragraph 344.7) instead of radiography.

With the new Chapter X and by selection of High Purity Fluid Service in ASME B31.3, users of ASME BPE can now perform weld coupon examination \textit{in lieu of} the 5% radiography or ultrasonic examination and be in undisputed compliance with ASME B31.3.

The requirement for 100% visual examination of the outside surface and 20% borescopic examination of the inside by ASME BPE is still in effect for welds in hygienic service referencing the ASME BPE Standard. One could argue that this is a more stringent requirement than the 5% radiographic or ultrasonic examination required by ASME B31.3 Normal Fluid Service.

How Weld Coupons are Made

The semiconductor industry has defined requirements for how weld coupons to be used for weld coupon examination are made and examined. While weld coupons are made to qualify welding procedures (WPS and PQR) and welding operators (WOPQ) to ASME Sect. IX of the Boiler and Pressure Vessel Code, as modified by ASME B31.3, those coupons are used to qualify a range of wall thicknesses, diameters and alloys and may be performed long before construction begins.

\textit{Primary weld coupons} used for weld coupon examination are made prior to the start of production with sections of tubing of the same alloy, diameter and wall thickness as is being used in production to serve as a quality benchmark for welds made during production. \textit{Production weld coupons} are made during production to assure that the weld parameters from the qualified welding procedure (WPS) and orbital welding equipment continue to result in acceptable welds throughout the installation.

The BPE Standard requires that sample (coupon) welds be made and examined “on a regular basis” to verify that the welding equipment is functioning properly and that the ID purge is sufficient to prevent weld discoloration. Many installers using the BPE Standard make Bead on Pipe (BOP) or Bead on Tube (BOT) welds which are made from a single section of tubing without an actual joint. The members of Subgroup H feel that an actual joint is required for weld coupons made during production, for the purpose of weld coupon examination, to show that the end preparation and fit up of weld components is good enough to result in proper joint alignment. This is consistent with the requirements for \textit{in-process examination} as defined by ASME B31.3 paragraph 344.7 where fit up and joint alignment of production welds are checked prior to welding. The next editions of BPE and B31.3 will attempt to clarify and provide more consistent requirements for weld coupons.

Method of Examination

While the procedure for weld coupon examination in the semiconductor industry requires the examiner to section or cut open the coupon for visual examination as seen in Figure 2 top, coupon examination in bioprocess applications may be an indirect visual examination using a borescope, or more
likely, a direct visual examination as seen in Figure 2 bottom. A member of ASME BPE MJSC proposed that borescopic examination of coupon welds be allowed by ASME B31.3 in lieu of sectioning. This was approved first at the subcommittee level and then by the ASME B31.3 Section Committee and is in effect in the 2012 Edition of ASME B31.3.

Acceptance Criteria for Autogenous Welds
Chapter X states that weld acceptance criteria for the referencing code, e.g., ASME BPE or SEMI, shall apply, but welds also must meet the acceptance criteria of ASME B31.3 paragraph 341.3.2. Autogenous orbital welds on tubing generally have a flat OD profile, but may have some OD concavity, especially on heavier wall thicknesses. The BPE Standard makes some allowance for this for tube welds, but refers to B31.3 for welds on pipe. Weld acceptance criteria for B31.3 are based on multipass welds on pipe with the addition of filler wire to the weld, and while they do address OD and ID reinforcement, there is no mention of OD concavity. This is generally interpreted to mean none allowed.

This issue was brought to the attention of the ASME B31.3 Subgroup E, Fabrication, Examination and Testing. This item, to permit some amount of OD concavity on welds made without filler metal, is being evaluated for inclusion in the ASME B31.3 2014 Edition. If approved, this would not only aid in the harmonization of ASME BPE and ASME B31.3, but also will help to extend the use of Chapter X to industries other than biopharmaceutical that reference ASME BPE 2012 Edition

The 2012 Edition of the BPE Standard is the first edition of BPE to specifically reference the new High Purity Fluid Service and its associated Chapter X. This edition of BPE has been completely reorganized since the 2009 edition. ASME B31.3 does not address weld discoloration, but the BPE Materials Joining Part (Part MJ) has a new color chart showing permissible and unacceptable levels of weld Heat Affected Zone (HAZ) discoloration for welds on electropolished and mechanically polished 316L stainless steel tubing.

While welding destroys the passive layer and results in some loss of corrosion resistance, the loss can be minimized by proper inert gas purging during welding which limits the amount of discoloration since the loss of corrosion resistance increases with increasing amounts of discoloration.

Acceptance levels for HAZ discoloration were established based on corrosion resistance in the ASTM G150 test and a modified ASTM G61 Potentiodynamic Polarization Corrosion test. At similar levels of HAZ discoloration, the corrosion resistance of welds on electropolished tubing was higher than that on mechanically polished tubing. The techniques and oxygen levels used for the ID purge are detailed in Nonmandatory Appendix M. Previous studies have shown that while passivation can help to restore the passive layer that is damaged by welding it cannot compensate for loss of corrosion resistance caused by poor inert gas purging.

Conclusion
The Scope of BPE 2012 has been broadened to say, “The ASME BPE Standard provides requirements for systems and components that are subject to cleaning and sanitation and/or sterilization including systems that are cleaned in place (CIP’d) and/or steamed in place (SIP’d) and/or other suitable processes.”

The current scope should open up the BPE Standard to other high purity applications that can benefit from fabrication technology including orbital welding of tubing systems, specialized components, examination and testing methods common to the semiconductor and bioprocess industries, but not previously addressed by ASME B31.3.
By specifying High Purity Fluid Service and using coupon examination of welds in lieu of the 5% radiography or ultrasonic examination requirement of ASME B31.3, users of ASME BPE can now be indisputably Code compliant, and because the scope of BPE has been broadened, the use of BPE should no longer be limited to use by the biopharmaceutical or bioprocessing industry.

There was close collaboration between members of ASME BPE and ASME B31.3 during the development of Chapter X that was published in 2010. This collaboration continued to further implement changes that brought these documents into closer alignment for the 2012 Editions and this work is continuing for the 2014 Editions. This is a classic example of how cooperation between volunteers from two different ASME committees can work together to improve safety standards for piping systems with benefits to both industry and society.

At the Denver meeting of ASME B31.3 in September, 2011, the ASME awarded each member of Subgroup H who had contributed to the writing of Chapter X with a Certificate of Excellence in appreciation for their work.

References

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Barbara Henon is a graduate of Mt. Holyoke College, has an MA in zoology from Columbia University, and a PhD in biological sciences from the University of Southern California. After postdoctoral work in the Division of Neurosciences at the Beckman Research Institute at the City of Hope in Duarte, California, in 1984 she joined Arc Machines, Inc. in Pacoima, California. Dr. Henon helped to develop the Arc Machines Training Department and wrote training manuals for the orbital welding equipment manufactured by Arc Machines, Inc. Now retired from Arc Machines, she represents Magnatech LLC on the ASME B31.3 Committee. She is the author of numerous articles including Pharmaceutical Engineering Article of the Year in 1999. Dr. Henon received the American Welding Society (AWS) Image of Welding Award in the Individual category in 2008. Dr. Henon joined the ASME Bioprocessing Equipment (BPE) Committee in 1989 and served for two terms as Vice Chair of the BPE Standards Committee. She is currently a member of the BPE Materials Joining and Surface Finishes Subcommittees, the Subcommittee on General Requirements and the Executive Committee. Until this year, she was the official Liaison between.
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