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B31.3 Chapter X
High Purity Piping
Its Standardization and Application

It is in this environment, that of High Purity, that ASME B31.3 Process Piping proves its adaptability in keeping pace with technology.

In the emerging and ever expanding technology of bioprocessing, and the supercritical purity requirements of the Semiconductor industry, comes the need to standardize on the essentials of achieving process systems that meet the highly refined cleanability requirements these industries demand. Coupled with those cleanability requirements is the irrefutable need to integrate safety into the DNA of High Purity design philosophy and standardization.

Keeping Pace with Industry

The food industry, by necessity, through the cooperative effort of the International Association of Food Industry Suppliers (IAFIS) (now the Food Processing Suppliers Association), the International Association for Food Protection (IAFP), and the Milk Industry Foundation (MIF), formed the 3-A Sanitary Standards organization, or simply "3-A", back in the 1920's. 3-A was instrumental in establishing the first set of Standards, protocols, and methodologies that would enhance the ability of that industry to produce food products, on a repeatable basis, that would be free from pathogenic bacteria. Bacteria potentially derived from contaminated piping systems as a result of an inadequate cleanability design, insufficient cleaning, and/or cross contamination of product.

Up until the late 1990's the Standards initiated by 3-A were widely utilized by two other industries that are very different in nature, but demand an even higher degree of purity in their process and utility systems. Those industries are the pharmaceutical and semiconductor industries.

The pharmaceutical industry, like the food and dairy industry, goes to a great deal of effort to design, install, and maintain their process systems at a high degree of hygienic purity. These are systems that require added care and documentation in the manufacture of the components that make up these systems as well as the fabrication and installation of those systems. Each of the above mentioned industries require a very different set of rules in the design for cleanability of their piping systems, apart from that of general industrial piping design requirements.

The semiconductor industry, on the other hand, requires an even higher degree of purity for many of their piping systems, but for altogether different reasons than does the pharmaceutical industry. The reason for high purity in semiconductor manufacturing is not from a bacterial contamination standpoint, as it is in the food, dairy, and pharmaceutical industries, but is needed instead to mitigate the potential for particulate contamination. Microscopic particles in semiconductor, whether coming from equipment, tubing, or the various fluids used in the manufacture of silicon chips, can render a chip useless, or at the very least, out of spec.

It is in this environment, that of high purity, that ASME B31.3 Process Piping proves its adaptability in keeping pace with technology. The three primary industries, Food & Dairy, Semiconductor, and Pharmaceutical have served as protagonists in the development of Standards for each of their respective industries. These Standards developed by 3-A, SEMI, and ASME_BPE (Bioprocessing Equipment) led the way in establishing criteria for the component design, system design, fabrication, and installation requirements for their respective industries.

What these Standards Developers did not do was develop their own set of system integrity qualification

requirements. For these requirements the reader or user of the Standard is referred to the ASME B31.3 Standard.

In the harmonization of these Standards ASME recognized the fact that while many of the B31.3 Sections and Paragraphs referenced by 3-A, SEMI, and BPE applied as is there was concern that B31.3 did not meet all of the needs, and most particularly the high purity needs, required by the bioprocessing and semiconductor industries. This was the impetus for considering the need for a new Chapter in B31.3.

Introduction and Rollout of ASME B31.3 Chapter X High Purity Piping

ASME B31.3 Process Piping has developed over time to become the preeminent piping Code for the process industry. At the time of this writing its latest version, issued in 2008, consisted of nine Chapters. Chapters I through VI are considered the base Code. These Chapters are essentially written around metallic piping intended for fluid services that can be categorized as to what B31.3 defines as normal and Category D fluid services.

Requirements for Nonmetallic piping and piping lined with nonmetals are supplemental to the base Code and are found in Chapter VII. Nonmetals were initially introduced to the Code in its 1976 publication, but not allotted its own Chapter until the 1980 publication. The paragraphs in Chapter VII indicate the respective paragraphs of the base Code with the added prefix A to establish their connection with Chapter VII and the requirements for Nonmetallic Piping and Piping Lined with Nonmetals.

For the handling of toxic fluid services, defined by B31.3 as Category M fluid services, Chapter VIII, added in the 1976 publication, was developed to supplement the base Code for the more stringent requirements needed for those fluid services by adding Chapter VIII. The paragraphs in Chapter VIII indicate the respective paragraphs of the base Code with the added prefix M to establish their connection with Chapter VIII and Category M piping requirements.

For fluid services considered High Pressure by the Owner/User Chapter IX, added in the 1984 publication, provides supplemental requirements for those fluid services. The paragraphs in Chapter IX indicate the respective paragraphs of the base Code with the added prefix K to establish their connection with Chapter IX and High Pressure Piping requirements.

Adding to those supplemental Chapters is the new Chapter X High Purity Piping. This Chapter will be included in the 2010 issue of B31.3. As in Chapters VII, VIII, and IX Chapter X will be supplemental to the base Code in which the respective base Code paragraphs included in Chapter X will carry the added prefix U to establish their connection with Chapter X and High Purity Piping requirements.

Application and Use of Chapter X

As mentioned, Chapter X is a supplement to the base Code of B31.3. It augments those paragraphs in the base Code in which supplemental requirements are needed for High Purity applications. And being the preeminent piping Code that it is B31.3 is not a design guide. As stated in its Introduction, "*The designer is cautioned that the Code is not a design handbook; it does not do away with the need for the designer or for competent engineering judgment*."

Having made that cautionary statement, there are proprietary requirements for the bioprocessing and semiconductor industries that *do* dictate necessary design requirements. These are elements of the bioprocessing and semiconductor industries that are found outside the scope of B31.3, but do exist in the 3-A, SEMI, and ASME-BPE Standards. This is said in order to make the point that these ANS (American National Standards) Codes and Standards are written with the intent to harmonize rather than conflict from one to the other. It allows the user, where appropriate, to specify ASME B31.3 as the governing piping Code while augmenting that "parent " Code with more design oriented and industry specific Standards.

High Purity Fluid Service is defined in B31.3 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*".

The above definition touches on the relevant points in which supplemental B31.3 Chapter X requirements are needed in the application of High Purity piping systems. Namely: fabrication, inspection, examination, and testing. For material attributes and specific installation requirements the designer or engineer will need to go beyond Chapter X and refer to the specific industry design requirements, as mentioned earlier.

Chapter X in B31.3 integrates safety into high purity piping systems by adapting the B31.3 Code to the preferential nuances of those industries that utilize High Purity piping systems. It does so by characteristically adapting its basic philosophy for safety to that of the industry-specific components, material joining methods, and purity

requirements without compromising its adherence to safety.

Biochemical Processing

The addition of Chapter X could not be timelier. Over the past few decades bioprocessing has been coming into its own. With the growth of the biofuel industry, along with new and evolving biotechnology in the chemical processing industry (CPI) at large, the need for process systems able to handle biologics, both refined and industrial, has pushed out beyond the boundaries of the pharmaceutical industry. It has cascaded into industries typically unfamiliar with the aspects of system cleanability.

Maintaining such an environment for the intended bacteria and enzymes also provides a suitable environment for unwanted bacteria. If not prevented from taking hold the unwanted bacteria can devastate colonies of the desired bacteria contaminating the process. Preventing the contamination of a biochemical process, such as the one represented in Fig. 1, requires cleaning procedures and a system design that is conducive to CIP (Clean In Place) and/or SIP (Steam or Sanitize In Place).

Fig. 1 represents key stages in the manufacture of ethanol, a biochemical process. The only segments of this process that would require High Purity piping design concepts is in enzyme production (In many cases the

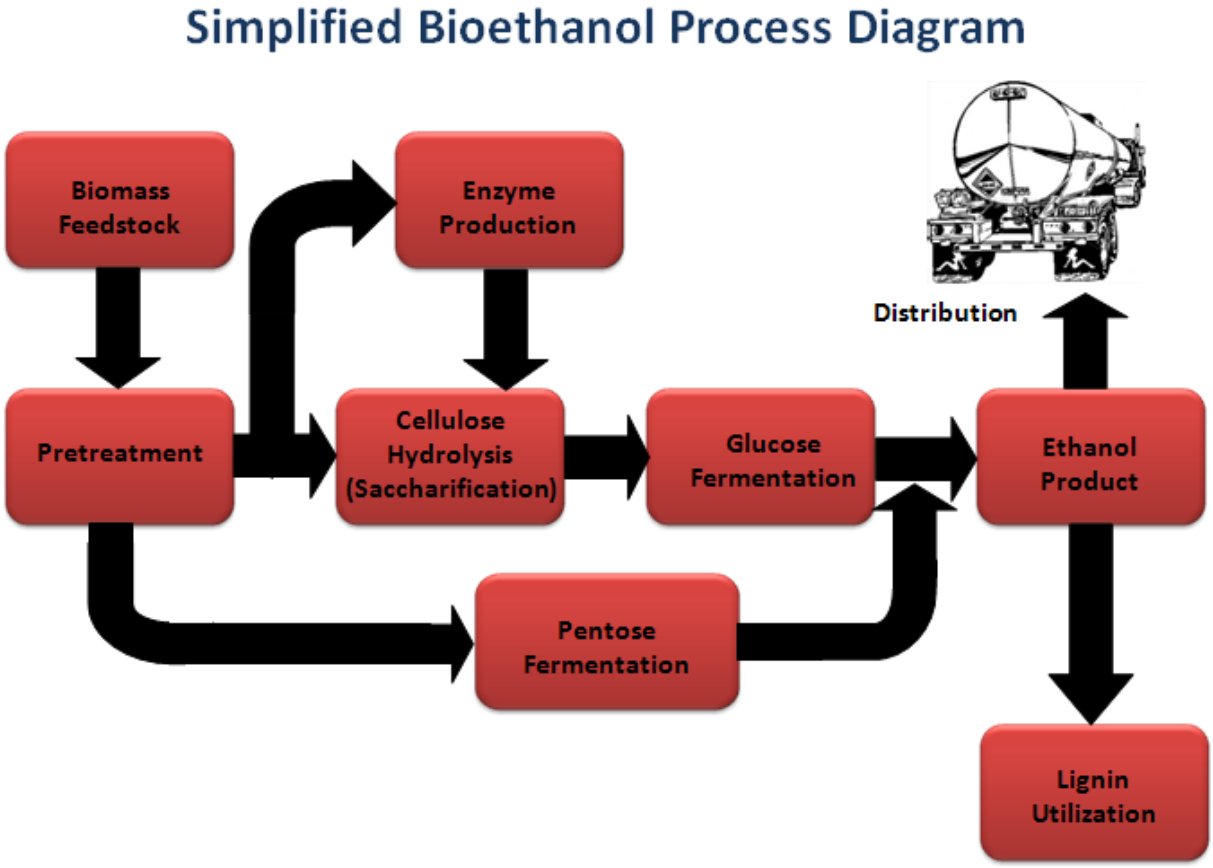

Figure 1 – Simplified Bioethanol Process Diagram

Biochemical processes utilizing hybrid cellulase enzymes and bacteria as catalysts demands a very different set of design guidelines than does a chemical process that does not use these living organisms. In biochemical processing an environment has to be maintained in which the specialized enzymes and bacteria can thrive and perform their consumption and processing of the pretreated feed stock.

supply of enzymes is outsourced from commercial enzyme producers rather than being produced on-site), Saccharification, and fermentation. These are segments of the process that handle enzymes, the catalyst for the process.

The term High Purity, in this case, should not be misconstrued for hygienic. In the production of ethanol,

for example, the process system does not have to achieve hygienic cleanliness. It does however, have to be cleanable. This is where ASME B31.3 Chapter X and BPE

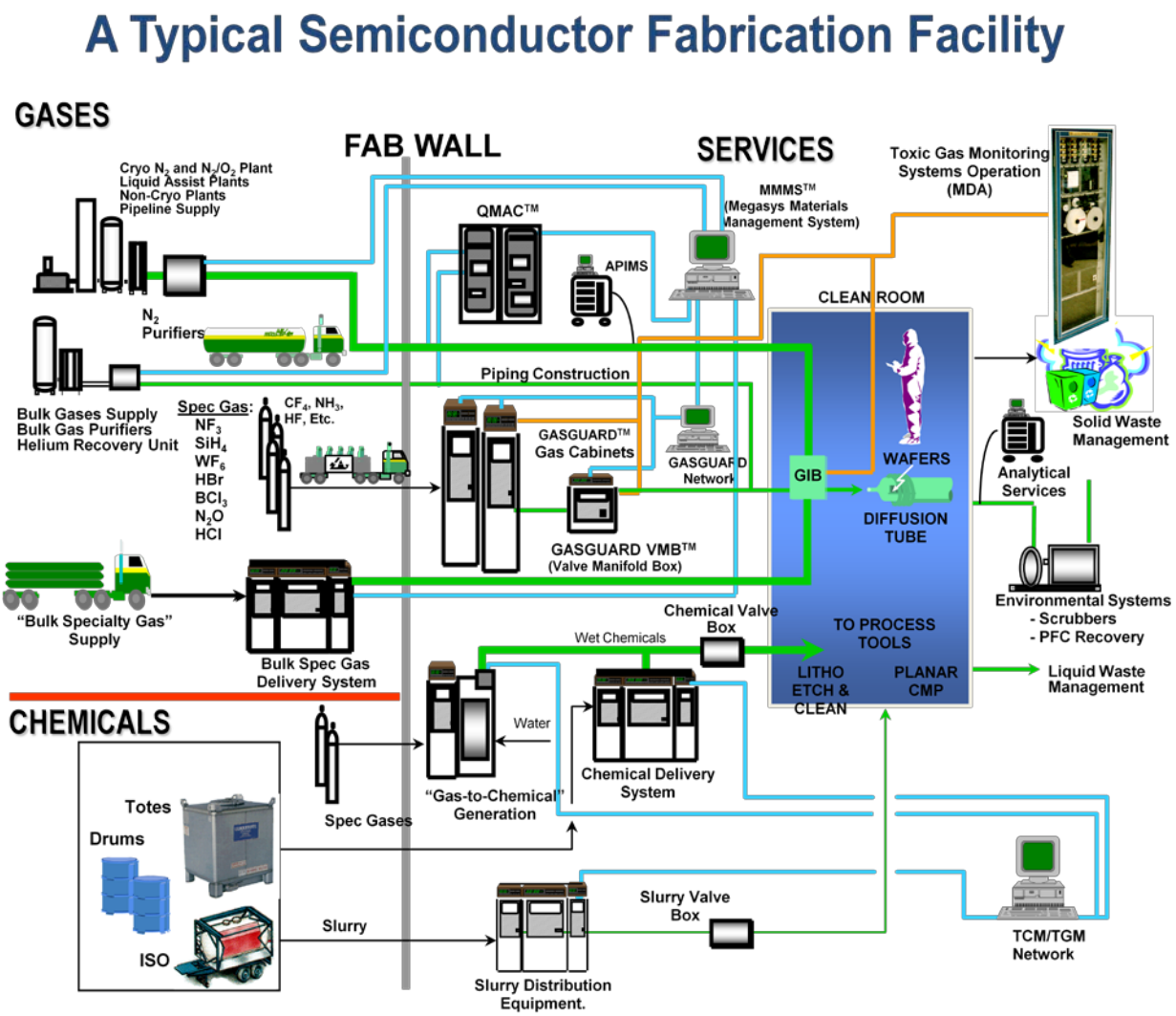

Figure 2 – Simplified Semiconductor Fab Schematic

work together to provide requirements and guidelines to achieve just that. These are criteria that define acceptable welds, surface finishes, mechanical joint connections, required slope, examination requirements, and much more.

Semiconductor

Unlike bioprocessing, semiconductor, as an industry, has a narrow bandwidth of technological requirements that are utilized by other industries; Meaning that the degree of purity, testing, and extremely sensitive instrumentation required by the semiconductor industry in their processing systems are operating criteria that do not readily translate into practical use for other industries. Semiconductor is autonomous in that respect. The degree of purity required in this industry far surpasses that required in general chemistry and more specifically the pharmaceutical industry. But that is changing for the pharmaceutical industry.

With some semiconductor manufacturers in production at the 90 nm and even 32 nm level, with research going on at the 15 nm level, it is not difficult to realize that the design, fabrication, and maintenance regarding the purity requirements of their process fluid distribution systems are paramount. Particularly when recognizing that the pharmaceutical industry has routinely worked at the micron (µ) level, but are making increasing gains in working with drug particles at the nanometer (nm) level (1µ = 1000 nm).

Referring to Fig. 2, this simplified semiconductor device fabrication (Fab) schematic provides a small degree of

insight into the types of Ultra-High Purity gases and various chemicals associated with this industry.

The many steps required in semiconductor device fabrication, such as dry etching, wet etching, plasma ashing, chemical vapor deposition, physical vapor deposition, chemical-mechanical planarization, etc., require, not only these fluids to be of ultra-high purity, but the tubing and components that distribute these fluids as well.

Utilizing B31.3 Chapter X in conjunction with the SEMI Standards brings together the necessary criteria to establish acceptable design attributes, acceptable material of construction (MOC), fabrication quality, testing protocols, validation, examination, and inspection requirements.

Chapter X and What That Means

As mentioned earlier, the addition of Chapter X to the content of B31.3 could not be timelier. It augments not only the B31.3 base Code, but the ASME-BPE and SEMI Standards as well, at a time when these industries are undergoing significant changes. This initial foray, for B31.3, into the realm of High Purity requirements is just that, and initial step.

Once a segment of industry is adopted by ASME in such a manner it adds a whole new set of experts bringing a whole new level of thinking and evaluation to that industry. This ongoing review process brings new insights and technological advances to the continuing development of the Standard.

Standards specifically developed for High Purity industries have, in the past, been driven by and guided by Standards committee members who are directly associated with the pharmaceutical and semiconductor industries. The addition of Chapter X now brings to light and piques the involvement of experts from more far reaching industries such as the biofuel industry specifically and the CPI in general.

This brings new vision to the table for the ongoing development of these industry Standards adding a whole new and much broader dimension to that of High Purity piping system standardization.

References:

3-A SSI: www.3-A.org
P3-A 002:2008 Pharmaceutical 3-A Sanitary/Hygienic Standards for Materials for Use in Process Equipment and Systems
P3-A 003:2008 P3-A End Suction Centrifugal Pumps for Active Pharmaceutical Ingredients

ASME: www.asme.org
ASME B31.3 2010
ASME-Bioprocessing Equipment (BPE) Standard 2009

SEMI: www.semi.org
SEMI E49.8-2003 Guide for High Purity and Ultrahigh Purity Gas Distribution Systems in Semiconductor Manufacturing Equipment.
SEMI F1-96 Specification for Leak Integrity of High-Purity Gas Piping Systems and Components.
SEMI F19-0310 Specification for the Surface Condition of the Wetted Surfaces of Stainless Steel Components.
SEMI F20-0706E Specification for 316L Stainless Steel Bar, Forgings, Extruded Shapes, Plate, and Tubing for Components Used in General Purpose, High Purity and Ultra-High Purity Semiconductor Manufacturing Applications.
SEMI F22-1102 Guide for Gas Distribution Systems.

Author Bios:

W. M. (Bill) Huitt has been involved in industrial piping design, engineering and construction since 1965. Positions have included design engineer, piping design instructor, project engineer, project supervisor, piping department supervisor, engineering manager and president of W. M. Huitt Co. a piping consulting firm founded in 1987. His experience covers both the engineering and construction fields and crosses industry lines to include petroleum refining, chemical, petrochemical, pharmaceutical, pulp & paper, nuclear power, biofuel, and coal gasification. He has written numerous specifications, guidelines, papers, and magazine articles on the topic of pipe design and engineering. Bill is a member of ISPE (International Society of Pharmaceutical Engineers), CSI (Construction Specifications Institute) and ASME (American Society of Mechanical Engineers). He is a member of three ASME-BPE subcommittees, several Task Groups, ASME B31.3 Subgroup H on High Purity Piping, API Task Group on RP-2611, sits on two corporate specification review boards, and currently serves on the advisory board for ChemInnovations. Bill can be reached at: W. M. Huitt Co., P O Box 31154, St. Louis, MO 63131-0154, (314)966-8919 wmhuitt@wmhuittco.com, www.wmhuittco.com

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Barbara K. Henon, Ph.D. is a contract employee for Arc Machines, Inc., a manufacturer of orbital GTAW tube and pipe welding equipment. She has over 15 years experience training orbital welding operators and engineers for pharmaceutical and semiconductor high purity applications. She has been an Instructor at the annual ASME Bioprocess Technology Seminars since 1989. Dr. Henon is the former Vice Chair of the ASME Bioprocessing Equipment (BPE) Main Committee and is a current member of the BPE Materials Joining, Surface Finishes, and General Requirements Subcommittees as well as the BPE Main Committee and Executive Committee. She is a member of the ASME B31.3 Process Piping Section Committee and a member of Subgroup H that developed Chapter X High Purity Piping for the ASME B31.3 Process Piping Code. She is also active on the AWS D18 and D10 Standards writing committees and was on the committee for writing the SEMI F81 and SEMI F78 standards for orbital welding of semiconductor fluid distribution systems.

Vicencio B. (Vince) Molina III is an Engineering Manager for the HYCO PST of Air Products & Chemicals, Inc. Vince has been a member of the ASME Section Committee since 1997 and currently the Chairman of ASME B31.3 Subgroup on High Purity Piping. Vince can be reached at: Air Products and Chemicals, Inc., 555 West Arrow Highway, Claremont CA 91711, (909)447-3976, molinav@airproducts.com.

Gerald A. (Jerry) Babuder has served with the Swagelok Company for the past 35 years as Senior Compliance Engineer. In addition to being a member of ASME B31.3, Jerry serves on the Gases Committee of Semiconductor Equipment and Materials International (SEMI) Standards as well as the Manufacturers Standardization Society (MSS). Jerry holds numerous patents in the design of instrumentation valves and fittings. He holds a BSME from Detroit University, an MSME from Cleveland State University, and is a Registered Professional Engineer in the state of Ohio. Jerry can be reached at Swagelok Company, 31400 Aurora Rd., Solon Ohio 44139, (440)649-4086. gerald.babuder@swagelok.com

Kenneth A. Nisly-Nagele, P.E. is a Senior Mechanical Engineer for Archer, Daniels, Midland, Co., ADM Design Services. Ken has designed and analyzed piping systems for chemical, pharmaceutical, biochemical and central utility plant industries and is currently a member of ASME B31.3 Subgroup H on High Purity Piping. Ken can be reached at: Archer, Daniels, Midland, Co., 1900 E. Eldorado St., Decatur, IL 62521; Phone: 217-451-3519; Email: Kenneth.Nisly-Nagele@adm.com.

Phillip E. Robinson, P.E. having retired as Group Vice President of Engineering after 41 years with Parker Hannifin continues to represent them at several Standards Development Organizations. His experience includes both domestic and international design, manufacturing, and sales for hydraulic and instrumentation valves and fittings and related products. As an independent consultant under P. E. Robinson, L.L.C. he has been involved in the following activities: offshore advance engineering and IT services, technical and market assessment of manufacturing companies, fluid power training modules, market assessment in metal treatment including unique surface hardening processes for stainless steel, and energy auditing. Phil holds a BSME from Purdue University and is a member of the following: International Organization for Standards (ISO), Society of Automotive Engineers (SAE), American Society for Testing and Materials (ASTM), Manufacturers Standardization Society (MSS), American Society of Mechanical Engineers (ASME), National Fluid Power Association (NFPA). He is a registered Professional Engineer for the state of Ohio. He can be reached at: P. E. Robinson, L.L.C., 7750 Woodlands Trail, Chesterland, Ohio 44026, (216) 570-7063 (cell), perobinsonllc@sbcglobal.net.

Philip Guerrieri, Sr. has been involved in the design, engineering and construction of industrial plants and facilities for over 40 years. This includes such industries as Pharmaceutical, Chemical, Water Treatment, Fossil Fuel and Nuclear power, as well as various Commercial type facilities. He serves on the Board of Directors and as a Technical Representative for the National Certified Pipe Welders Bureau Chapter 9 of Philadelphia and is past President of

Chapter 9 having served from 1996 to 2002. Phil is also a UA Certified Independent Witness for Joint UA/NCPWB Weld Testing and is a member of ASME (American Society of Mechanical Engineers)-B31.3 Process Piping, Chapter X Task Force on High Purity Piping, a member of ASHRAE (American Society of Heating Refrigeration and Air-Conditioning Engineers), and ISPE (International Society of Pharmaceutical Engineers).