STAINLESS STEEL TRENDS

- Standards Materials Installation

- Presented by Barry Gascoigne, BDM Prochem Pipeline Products
- August 2018

National GMP & Validation Forum

Hosted by PharmOut

PharmOut

POXXXX Course Agenda

- Module 1 – Introduction
- Module 2 – STANDARDS - ASME BPE & DIN 11866
- Module 3 – HP MATERIALS – Pricing, Corrosion Resistance & Surface Finish
- Module 4 – INSTALLATION – Weldability, Pre Manufacture & Site Welding
- Module 5 – Questions

Guidelines

Please contribute

Please stop me to ask a question

Please relax and enjoy yourself

Please place your phone on silent mode

The World of Prochem:

Making a world of difference

Barry Gascoigne
Business Development Manager

Prochem Pipeline Products

- 63 years in Australia manufacturing, importing & distributing Stainless Steel products
  - Piping Products
  - Instrumentation, measurement and flow control
  - Valves
- Across many industries
  - Mining, Oil & Gas, Food & Bev, Water, Chemicals, Power and Utilities, R&D, Medical and General Industry
- Service provided by 6 branches in Australia & 1 in NZ
- In 2018 expand to include Bio-Pharmaceutical - High Purity and Ultra High Purity Tube & Fittings
- Australian & New Zealand distribution for Dockweiler Stainless Steel Products

PROCHEM
PIPELINE PRODUCTS

Dockweiler:
Focus on Pharma

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A pon company

Leader for High-Purity Tube Systems

- Founded: 1955 in Hamburg
- Current Family Owners: 1973
- Production in Germany & Thailand
- Employees:
  - → 200 in Neustadt-Glewe
  - → 350 worldwide
- Turnover: $75m AUD
- Group : $155m AUD
- Reputation for Quality & Supplying to Industry Standards

First Products for Pharma Industry

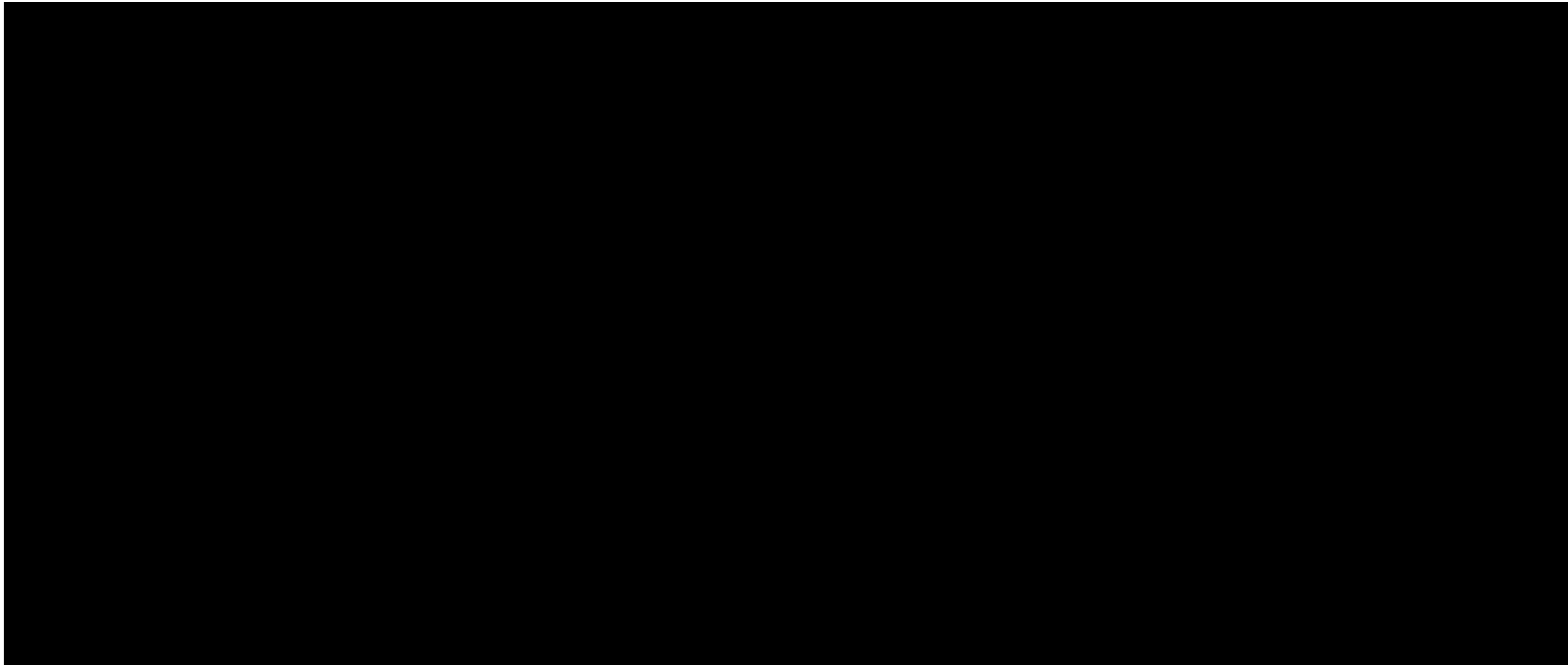
» Weldtron & Safetron 1992

- Standard DIN 11865/66
  - Material: 1.4404 & 1.4435 UNS S31603 (316L); 1.4539/UNS N08904 (TP 904L); DIN 11665/6
- Ra≤0.80µm bright finished (H3) Weldtron
- Ra≤0.80µm Anodically Clean (H3) Weldtron
- Ra≤0.40µm bright finished (H4) Safetron
- Ra≤0.25µm E-polished (HE5) Safetron EP

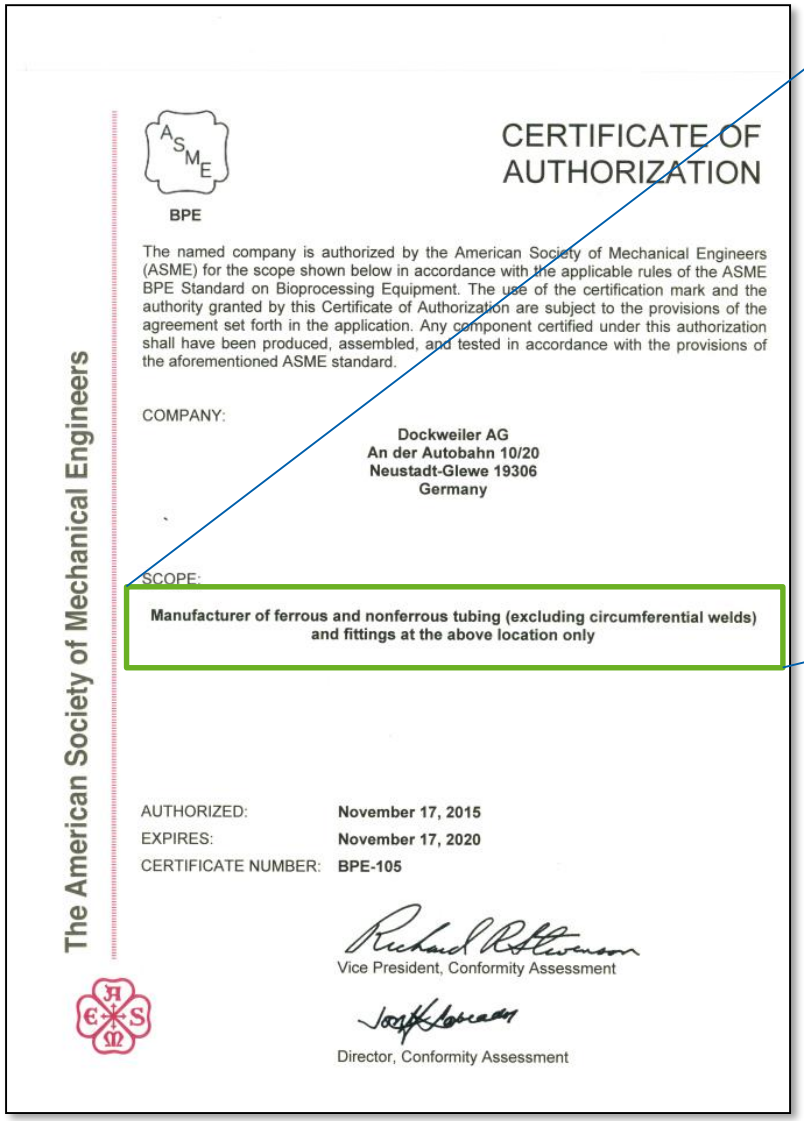
More Focus on ASME BPE Products

- 2002 Commenced *bpe-direct* an ASME BPE product range
- After an entry into USA showed they needed to be more cost competitive
- Established a factory in Thailand 2012, since doubled in size
- QA Manager Dr Jan Rau has become a Senior Committee member at ASME
- Broadened product range introducing Evans Components Ball Valves then Gaskets and more recently Pharma Hoses
- Increasingly applying Expertise from the Semi Con Fab industry where 'Cleanliness is King ', to Pharmaceutical special manufacture components like drain angle Elbows, compact spools with short dead-legs
- Researching Corrosion effects, surface finish and Weld Quality
- .\Dockweiler Presentations\3D-Welding_EN.mp4

Orbital Welding from Inside Tube



Dockweiler ASME BPE



CERTIFICATE OF AUTHORIZATION

BPE

The named company is authorized by the American Society of Mechanical Engineers (ASME) for the scope shown below in accordance with the applicable rules of the ASME BPE Standard on Bioprocessing Equipment. The use of the certification mark and the authority granted by this Certificate of Authorization are subject to the provisions of the agreement set forth in the application. Any component certified under this authorization shall have been produced, assembled, and tested in accordance with the provisions of the aforementioned ASME standard.

COMPANY:

Dockweiler AG
An der Autobahn 10/20
Neustadt-Glewe 19306
Germany

SCOPE:

Manufacturer of ferrous and nonferrous tubing (excluding circumferential welds) and fittings at the above location only

AUTHORIZED: November 17, 2015
EXPIRES: November 17, 2020
CERTIFICATE NUMBER: BPE-105

Vice President, Conformity Assessment

Director, Conformity Assessment

The American Society of Mechanical Engineers

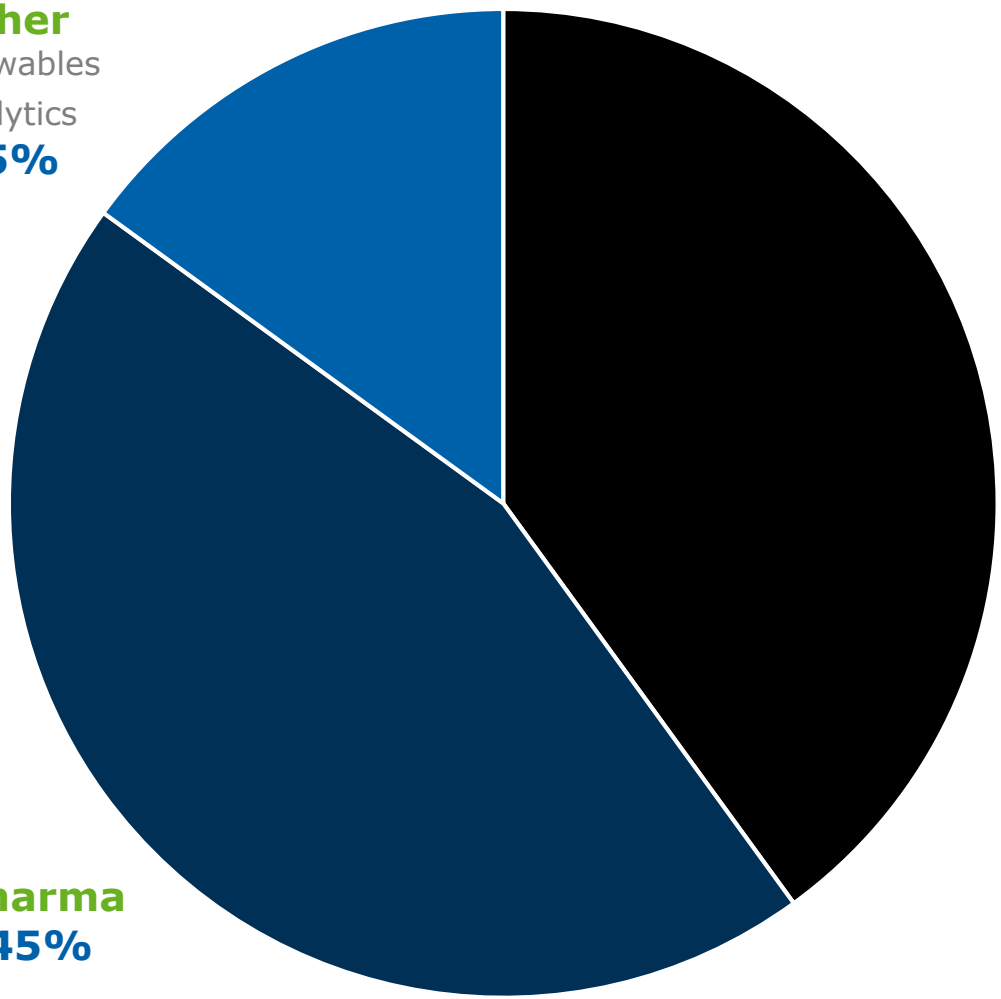
Manufacturer of ferrous and nonferrous tubing (excluding circumferential welds) and fittings at the above location only

THE ONE AND ONLY!!!

ASME BPE Quality Assurance

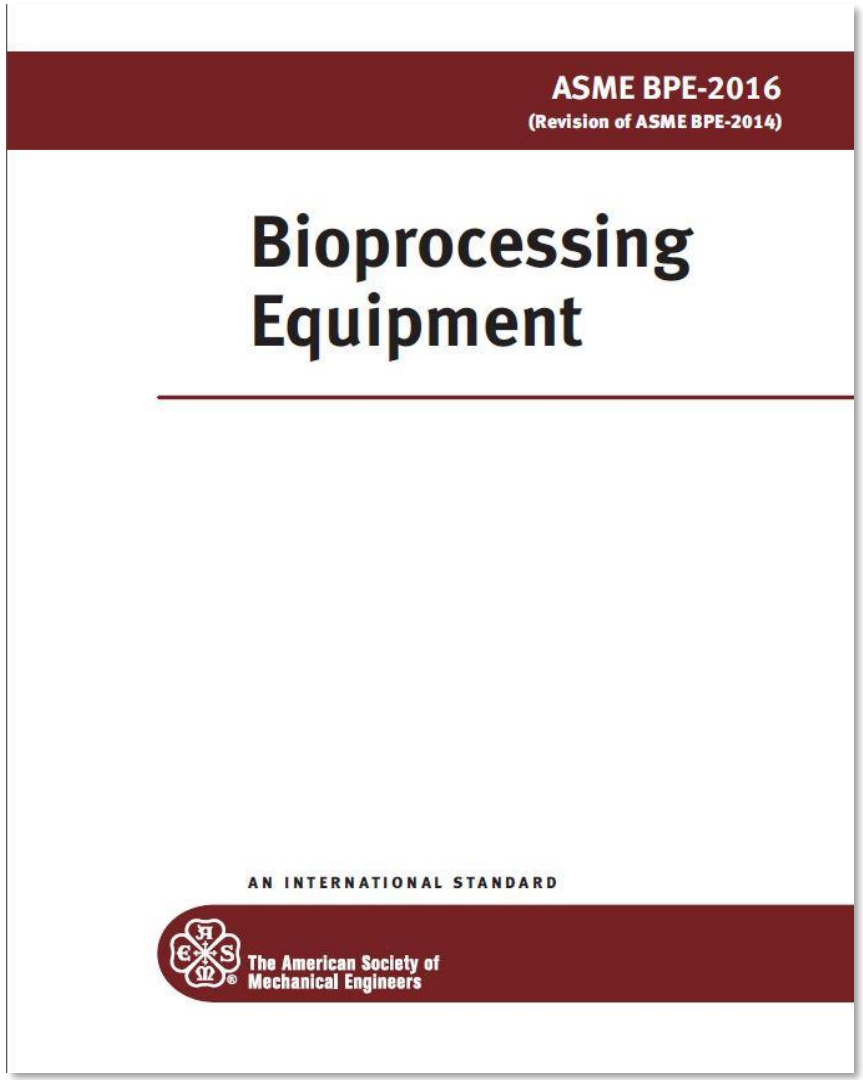
- Use of the ASME BPE chevron has been hard won
- German *think* and Euro standards meets American *think*

Turnover by Segments



Up from 30% in 2015

What is ASME BPE?



- Consensus Standard
- Developed and maintained by a balanced group of industry experts
- Sets the standard for bioprocessing & pharmaceutical industries which require a high level of hygienic quality

ASME BPE Committee

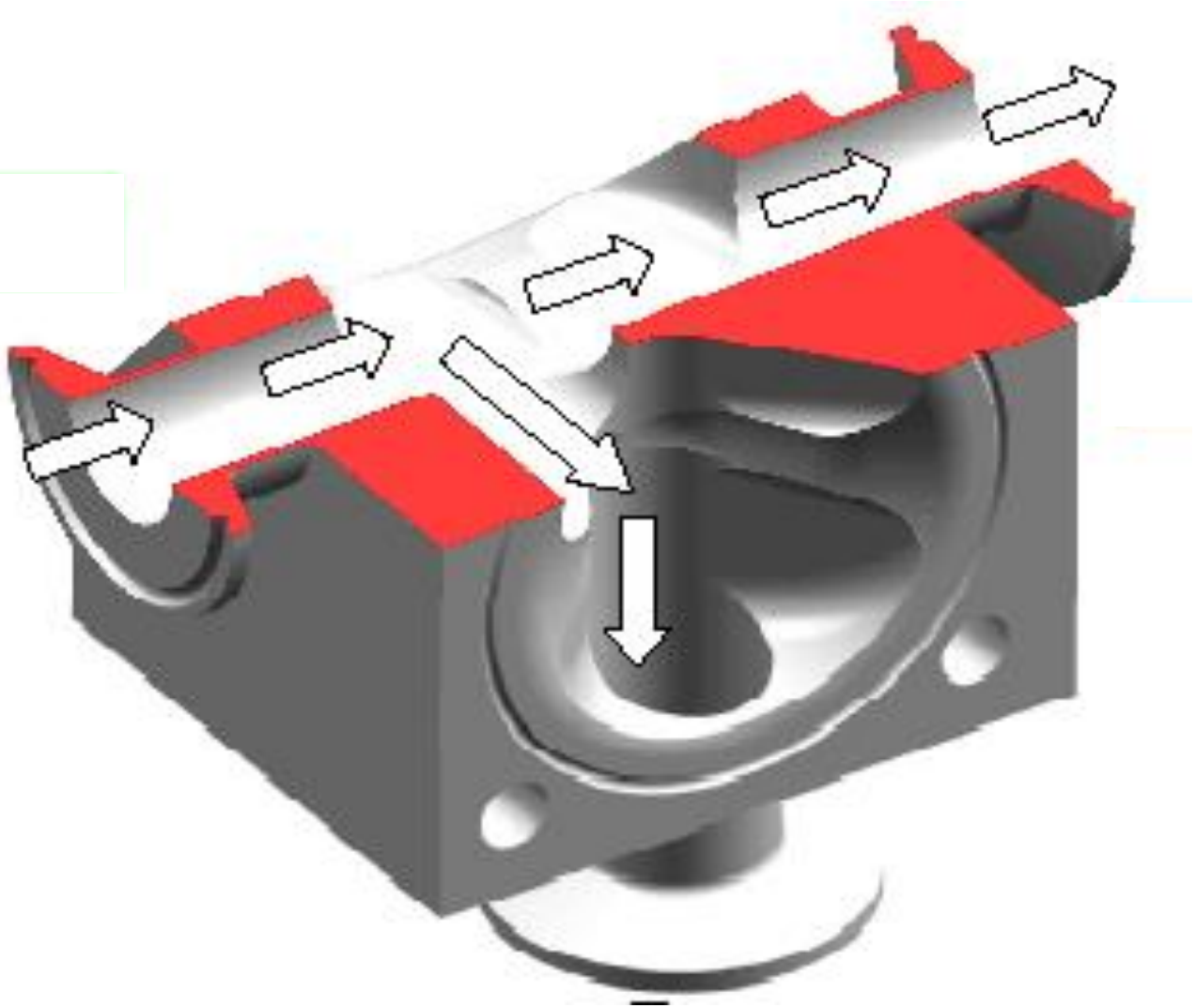
- Standards committee (Main committee), Executive committee
  - 10 Subcommittees with numerous task groups
- Volunteers from all of the following industry segments:
  - End Users (Biopharmaceutical Manufacturers)
  - Designer/Constructors (Engineering Firms)
  - Manufacturers (Equipment Vendors / Fabricators)
  - Material Manufacturers (Tubing & Fitting Manufacturers)
  - General Interest (Consultants, Inspectors, etc.)
  - International members in all categories

ASME BPE Standard

- ASME Bioprocessing Equipment Standard = ASME BPE
- The ASME BPE Standard provides requirements for systems and components that are subject to cleaning and sanitization and/or sterilization including systems that are cleaned in place (CIP'd) and/or steamed in place (SIP'd) and/or other suitable processes. This standard also provides requirements for single use systems and components.

Sources: ASME BPE-2012, GR-2; Jay Ankers, *How the ISPE and the BPE can address trends in our industry*, seminar session at the ISPE Boston Area Chapter Product Show, Foxboro, Massachusetts, October 7, 2009

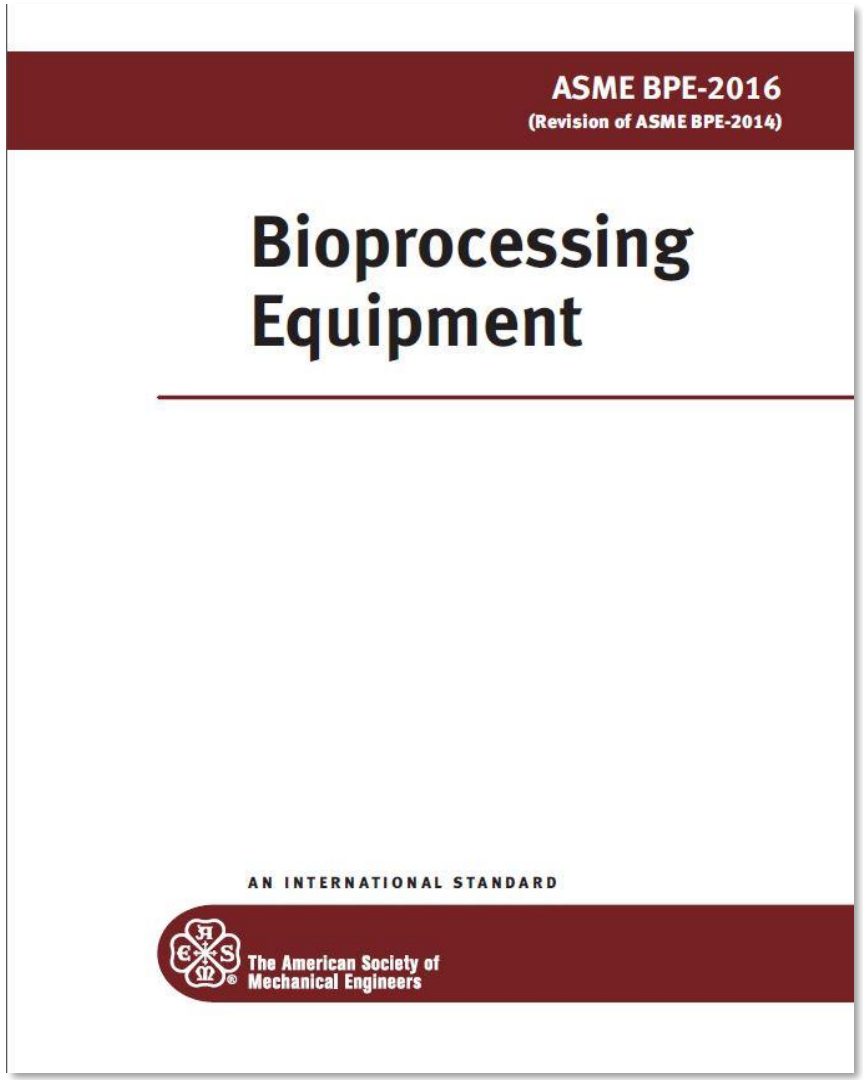
ASME BPE Standard



- Internationally accepted “Acceptance Criteria”
- Scientifically proven
- Not too restrictive or expensive
- Consideration for the 5-10 year old system – Not just the “new system” (they are only new for a short time)
- Updated regularly to reflect the current acceptance criteria

Source: Jay Ankers, *How the ISPE and the BPE can address trends in our industry*, seminar session at the ISPE Boston Area Chapter Product Show, Foxboro, Massachusetts, October 7, 2009.

ASME BPE-2016



- New revision
- Issued Oct 27, 2016 328 pages
- Effective April 2017
- Contents, foreword, statement of policy on the use of ASME marking, committee, summary of changes
- 6 Chapters
- 10 parts
- 2 mandatory appendices
- 22 non mandatory appendices

ASME BPE-2016

- 1 INTRODUCTION
  - PART GR – General Requirements
- 2 DESIGN
  - PART SD – Systems Design
- 3 MATERIALS
  - PART MM – Metallic Materials
  - PART MJ – Material Joining

ASME BPE-2016

- 4 PROCESS COMPONENTS
  - PART DT – Dimensions and Tolerances for Process Components
  - PART PI – Process Instrumentation
  - PART SG – Sealing Components
- 5 FABRICATION
  - PART SF – Product Contact Surface Finishes
  - PART PM – Polymeric and Other Nonmetallic Components
- 6 CERTIFICATION
  - PART CR – Certification

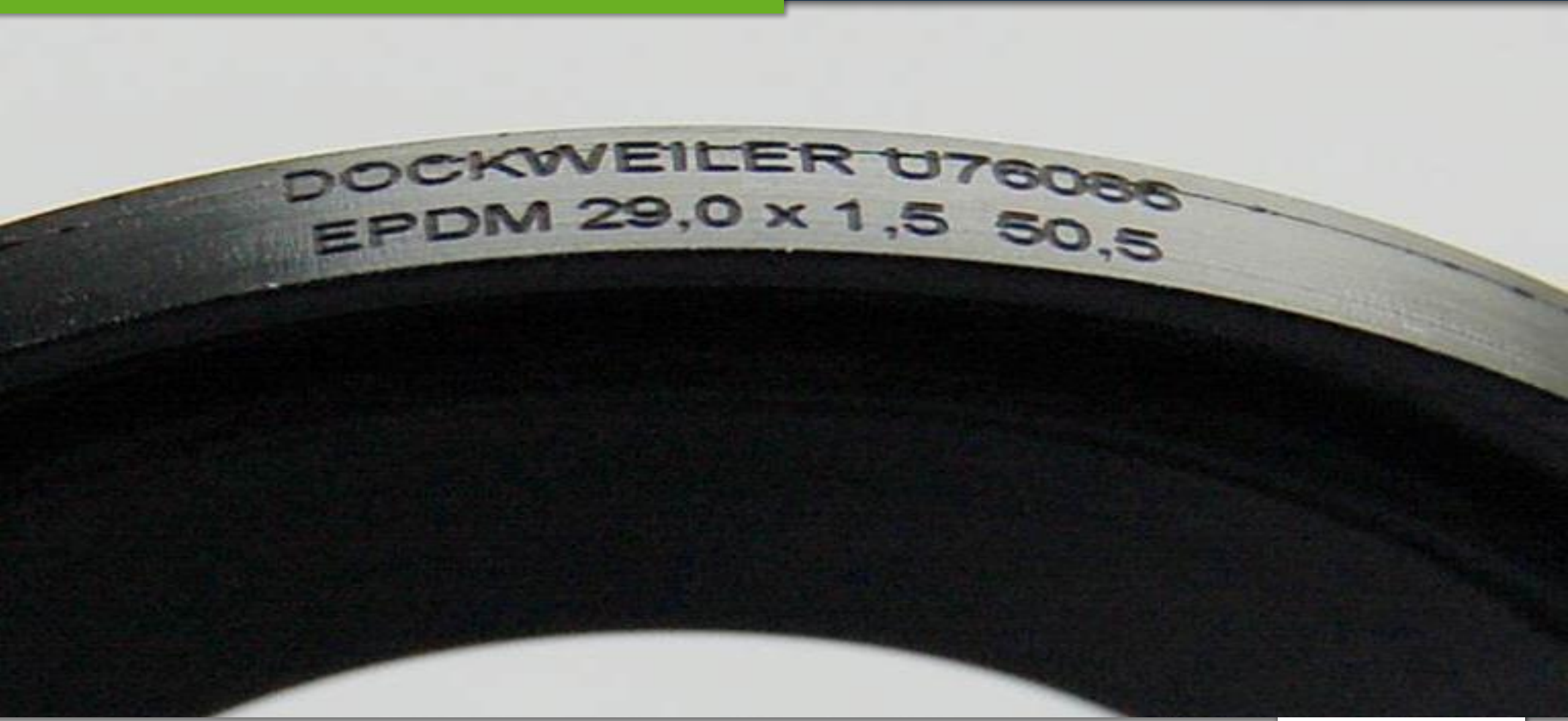
SG-3.5 Seal Identification

Marking on the seal package should include all items listed in SG-3.4.2.

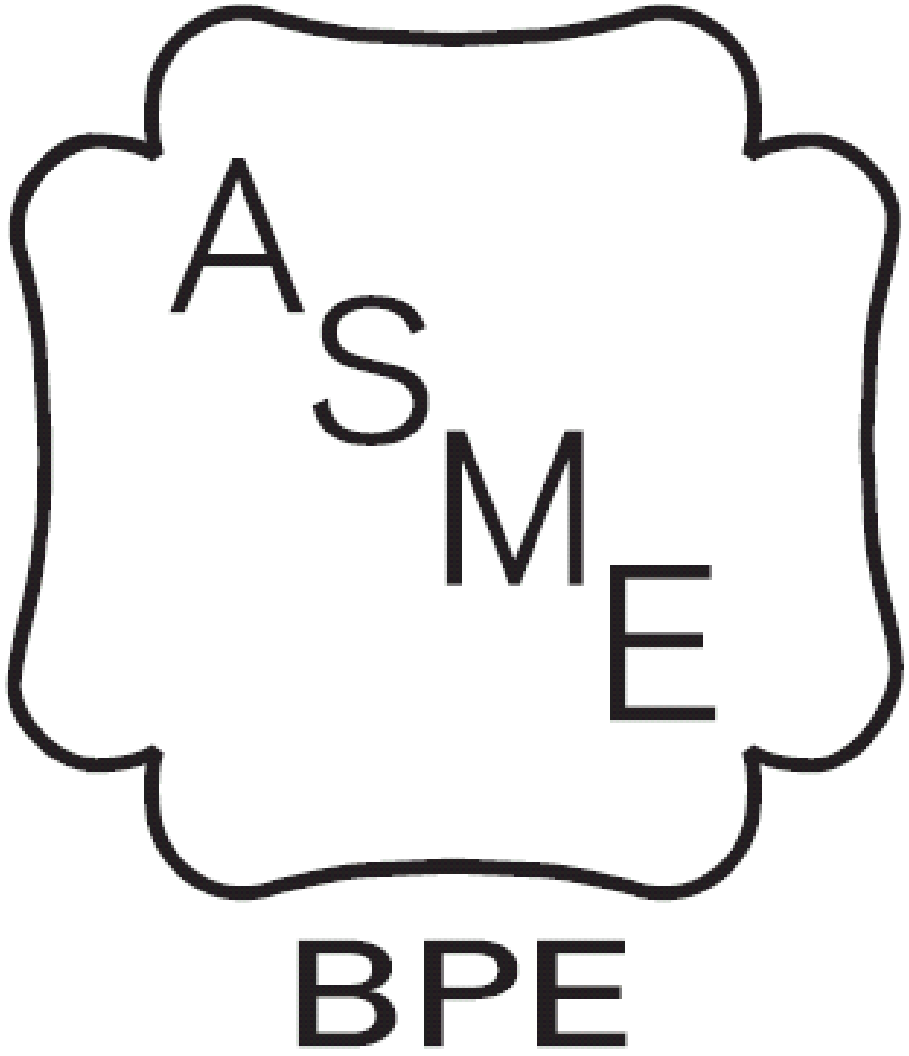
Manufacturer's name and lot number shall be marked on either the seal itself or the seal package containing the seal. The lot number should enable the manufacturer to identify the raw material and processing conditions used to fabricate the article. Manufacturers are encouraged to mark the seal itself to avoid potential loss of traceability and to aid in positive identification of seals after removal from a process stream. When marking diaphragms, any marking shall be done on those portions of the diaphragm that are not exposed beyond the sealing portion of the housing.

[redacted]Manufacturers are encouraged to mark the seal itself to avoid potential loss of traceability and to aid in positive identification of seals after removal from a process stream.[redacted]

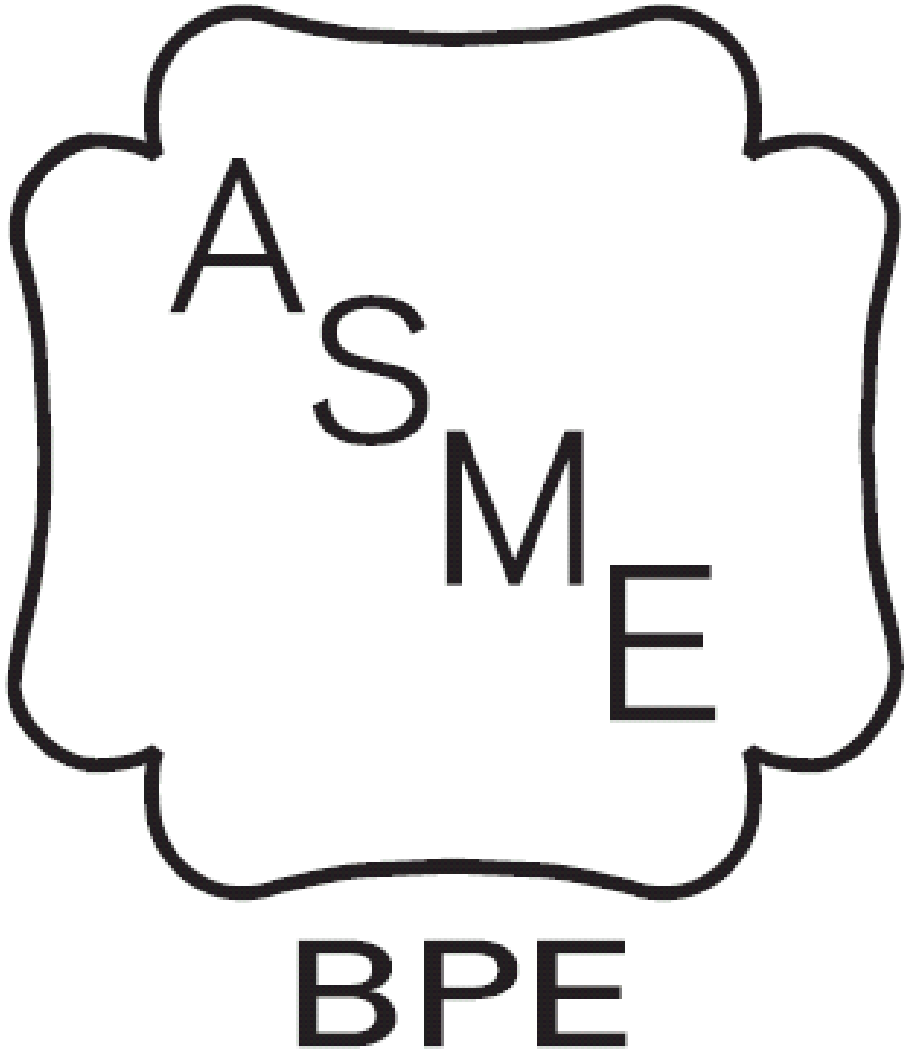
Chapter 4 – Process Components



Chapter 6 - Certification



- **Part CR – Certification**
- Program for certification of organizations providing tubing and fittings
- Authorization of organizations to mark with the ASME BPE symbol stamp
- Certification program will be conducted by ASME Board of Conformity Assessment (BCA). Six ASME auditors are trained for the BPE certification. Two auditors based in the US, two in Europe, and two in Asia.



- Part DT – Dimensions and Tolerances for Process Components
- DT-11.1 Fitting Marking Information

(e) process contact surface designation for the appropriate BPE specification [only one surface finish (SF) designation allowed]

(d) reference to this Standard (BPE)

(1) ASME BPE Certificate of Authorization holders shall mark the reference to this Standard by applying their ASME Mark with BPE Designator. Refer to Fig. CR-1-1.

(2) Non-ASME BPE Certificate of Authorization holders shall only mark "BPE."

Global ASME BPE certificate holders

- United : Manufacturer of ferrous & nonferrous tubing, excluding circumferential (cf) welds
- EGMO: Manufacturer of ferrous fittings and supplier of ferrous tubing
- Rath Gibson: Manufacturer of ferrous & nonferrous tubing, excluding cf welds
- King Lai: Manufacturer of ferrous tubing (excluding cf welds) and fittings (Were Suspended by ASME in 2018)
- Dockweiler: **Manufacturer of ferrous and nonferrous tubing** (excluding cf welds) **and fittings**
- Alfa Laval : Manufacturer of ferrous fittings
- Asflow Co Ltd : Manufacturer of ferrous tubing (excluding cf welds) and fittings
- WSG Co Ltd : Manufacturer of ferrous tubing and supplier of ferrous fittings
- Ferrous: Steel (Ferrum based alloys)
- Nonferrous: Nickel based alloys

Trends in ASME BPE

» **ASME-BPE standard**

- Working with European DIN 11866 to harmonize
- Getting increasing input from EHEDG

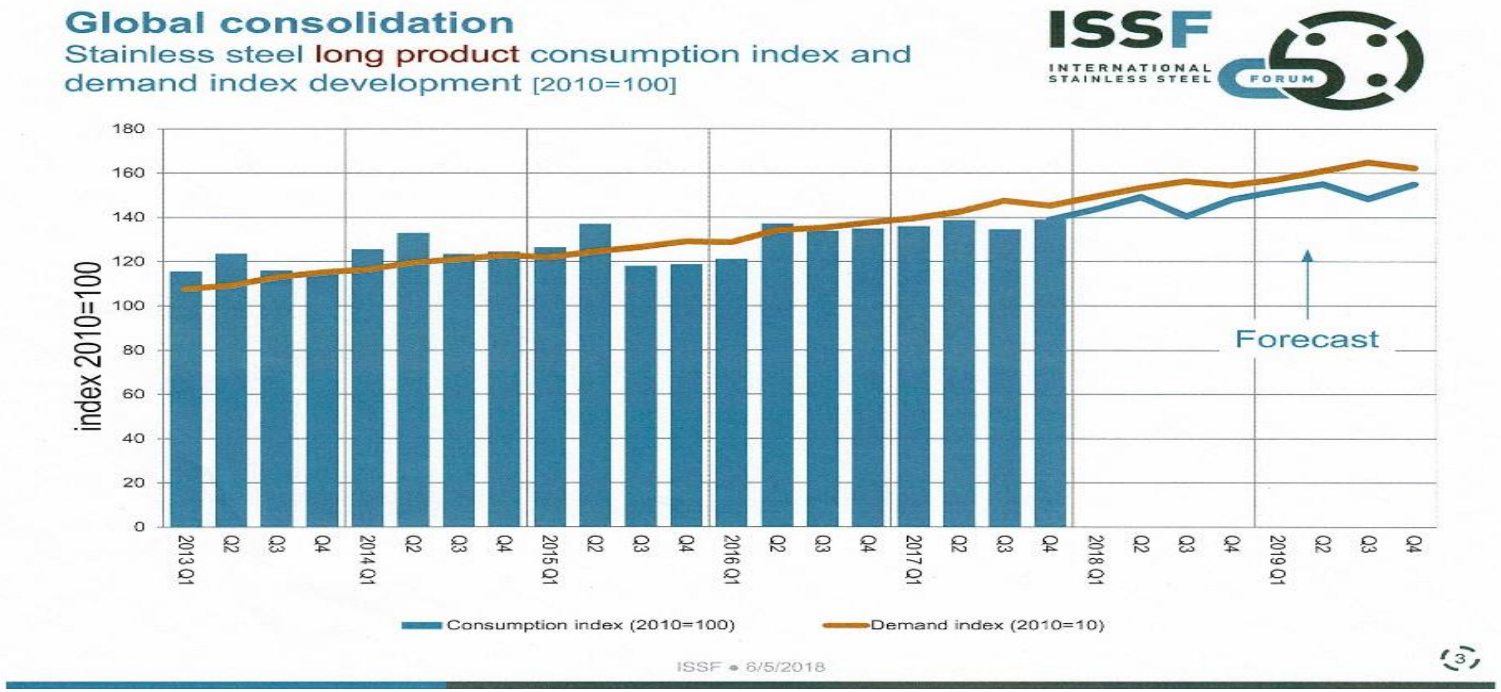
NEW in ASME BPE

- 316L Alloy **1.4435 available in SF1 & SF4**
- Higher alloyed steels - superaustenitic 904L AL6XN
- Hastelloy C22
- **Now recognising SF0** for BA Tube & Fittings
- Increased emphasis on Delta Ferrite

Trends in Materials

- **Demand** for Long Products exceeds Supply
  - And the position may well get worse?
- China: Fab Boom or Bust *" article in Manufacturing & Process Technology 6 Multinationals & 14-22"*
- Chinese companies building Semi-con Fabs means:
  - EP demand exceeds Production Capacity 4 to 3
  - SMLS availability very tight - Quality of Tube FALLS
- USA trade Tariffs already increasing Tube prices out of US
- **Prices**
- Base Metals up Ni, Cr, rapid increase, Fe higher than a lot of forecasts

Trends in Materials



Trends in Materials

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Trends in Materials

Quality

- Supply pressure has lead to some corner cutting and lesser quality and QA struggles to detect
- On EP tube Dockweiler's internal rejection rate has increased 5% this year
- At Prochem we have seen welded tube where Seam wanders like a snake with hit and miss points … *the likely cause ……. uncontrolled Sulphur content*

Availability

- Lead time from Quality Mills past 180 days
- Dockweiler are quoting large project offerings SMLS Tube at 6-8 months ex works

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Trends in Materials

- What are some of the possibilities to reduce the effect of these Material trends and still maintain a quality installation?

- Piping Projects will need better planning and Longer Lead-times
- Review Alloy selections…. Broader alloy selection now meets ASME BPE
- Select for Corrosion Resistant properties
- Consider surface finish options

Reasons for Drug Recalls by FDA

Date	Brand Name	Product Description	Reason/ Problem
11/18/2016	Tri-Coast Pharmacy Inc.	Sterile drug products	Concern for lack of sterility assurance
11/18/2016	Cantrell Drug Company	Sterile drug products	Concern for Lack of Sterility Assurance
09/20/2016	Wells Pharmacy Network	Sterile human compounded products	Concern for Lack of Sterility Assurance
09.08.2016	GlucaGen® HypoKit®	Glucagon [rDNA origin] for injection	Detached needles on the syringe in the kit
09.07.2016	Family Care	Eye Wash	Microbial contamination
09.06.2016	Rugby, Major	Eye irrigating solution and Eye wash	Possible microbial contamination
08/18/2016	Sagent Pharmaceuticals, Inc.	Oxacillin for Injection, USP, 10 g	May contain small, dark particulate matter (iron oxide)
08.05.2016	Hospira	0.25% Bupivacaine injection, USP	Due to the presence of particulate matter
07/21/2016	Talon Compounding Pharmacy	HCG and Sermorelin	Lack of sterility assurance
04/19/2016	Pharmakon Pharmaceuticals, Inc.	Sterile compounded products	Lack of sterility assurance
04/13/2016	Hospira	50% Magnesium Sulfate Injection, USP	Particulate Matter
03/28/2016	B. Braun Medical Inc.	5% Dextrose Injection USP	Leakage and visible particulate matter
03/18/2016	Hospira	8.4% Sodium Bicarbonate Injection, USP	Presence of particulate matter
02/17/2016	Baxter	0.9% Sodium Chloride Solution	Particulate Matter
01/26/2016	Baxter	0.9% Metronidazole Injection and Clinimix	Leaking containers and particulate matter
01/16/2016	Abbott's Compounding Pharmacy	Injectable medications, sterile solutions	Lack of Sterility Assurance
12/18/2015	Baxter	IV solutions: 0.9% Sod. Chloride Injection	Potential presence of particulate matter.

» Corrosion

Estimation of Corrosion Properties

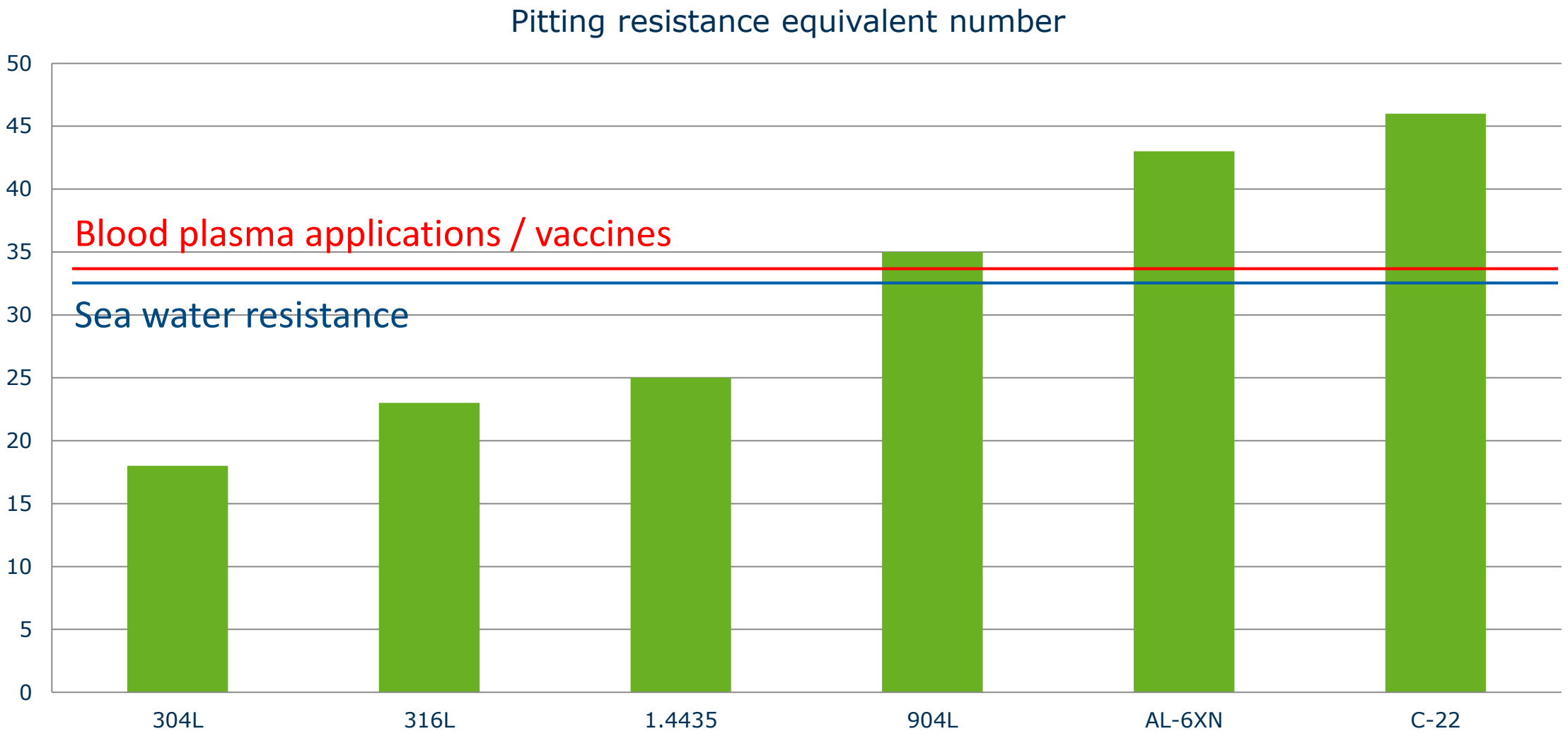
- **Empirical Data**
- Outokumpu Stainless Corrosion Handbook
- Euro Inox & Nickel Institute Technical Handbooks
- **Pitting resistance equivalent number PREN**:
  - Stainless steels: PREN = %Cr + 3,3 (%Mo + 0,5 %W) + 16 %Ni
  - Nickel-based alloys: PREN = %Cr + 1,5 (%Mo + %W + %Ni)
  - Estimate: PREN > 33 is deemed seawater-proof
- Indirect or direct **test method** to gain knowledge about corrosion behaviour
  - Determination of Cr/Fe ratio by XPS/ESCA acc. to SEMI F60 or measure the depth of chromium oxide enriched passive layer by AES acc. to SEMI F72
  - Exposure test acc. to ASTM G 31, determination of **Critical Pitting Potential** (CPP) acc. to ASTM G 61

Classification DIN EN 10027-2

Elements*:	C	Cr	Ni	Mo	further
1.4404 (316L)	≤ 0,03	16,5 – 18,5	10,0 – 13,0	2,0 – 2,5	
1.4435 (316L)	≤ 0,03	17,0 – 19,0	12,5 – 15,0	2,5 – 3,0	
1.4539 (904L)	≤ 0,02	19,0 – 21,0	24,0 – 26,0	4,0 – 5,0	Cu = 1,2 – 2,0
Al6XN (N08367)	≤ 0,03	20,0 – 22,0	23,5 – 25,5	6,0 – 7,0	Cu = 0,75 N = 0,18 – 0,25
2.4602 (C22)	≤ 0,01	14,5	57	15	

* Figures in mass %

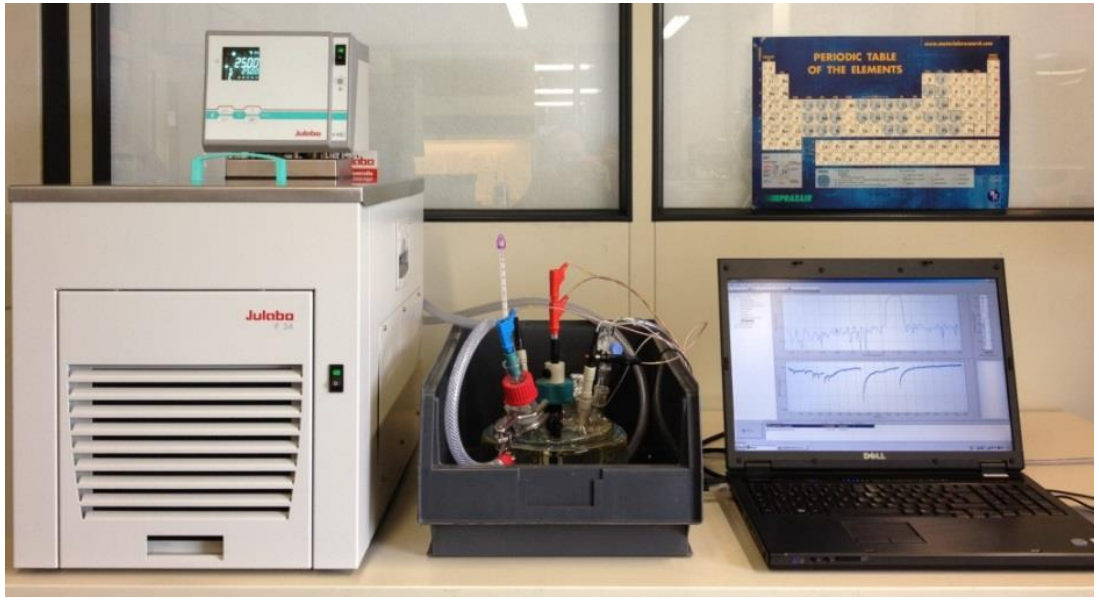
Corrosion Properties



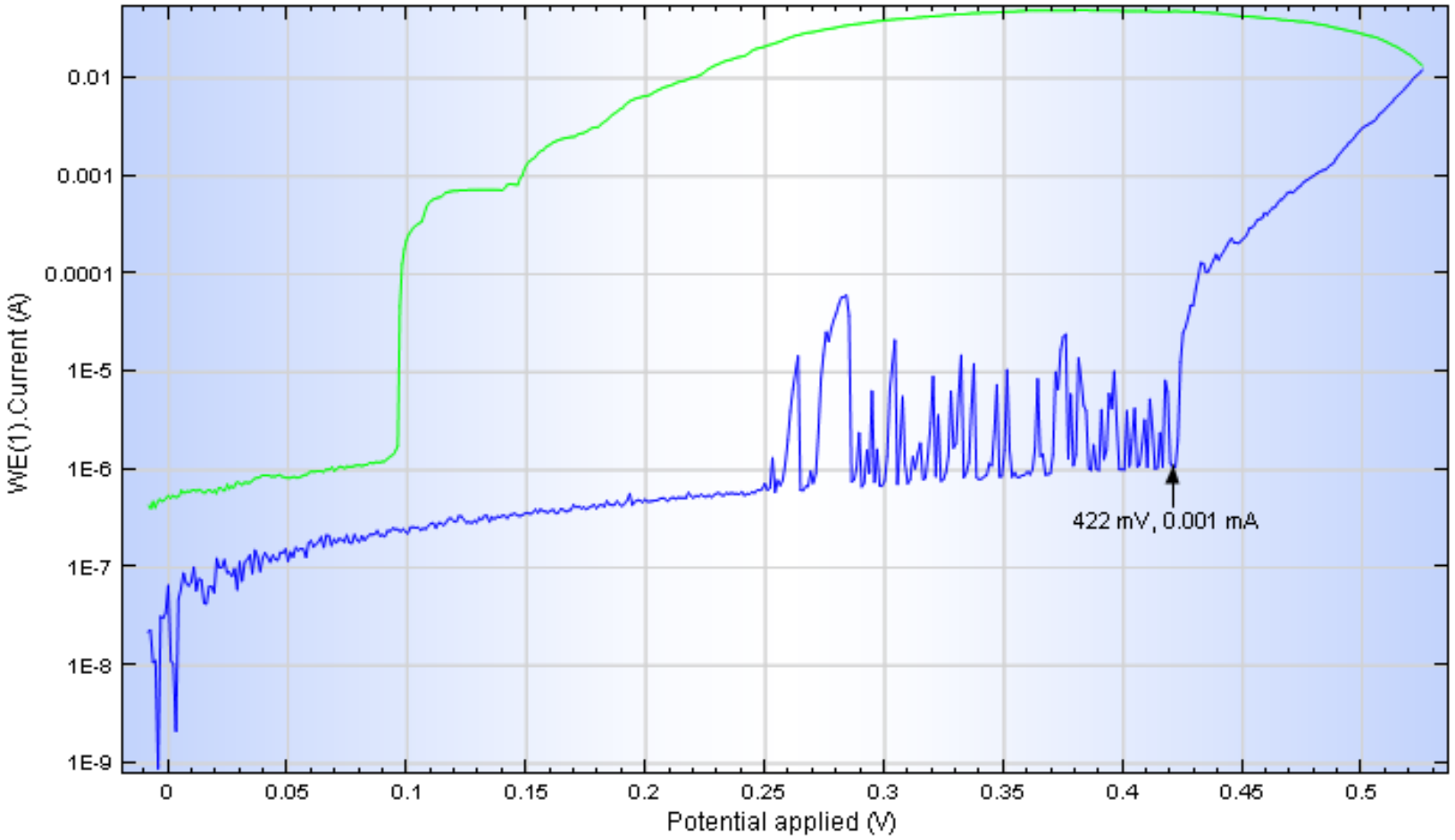
DECKWEILER
connecting flow to purity

Determination of Critical Pitting Potential (CPP) by cyclic polarization acc. to ASTM G 61

- Exposed surface area of test specimen 1 cm²
- DI water with 3.56 weight% NaCl (concentration of sea water)
- Temp. control of electrolyte at 25.0 °C
- Nitrogen purge of electrolyte for at least 1 h to remove dissolved O_2 and CO_2

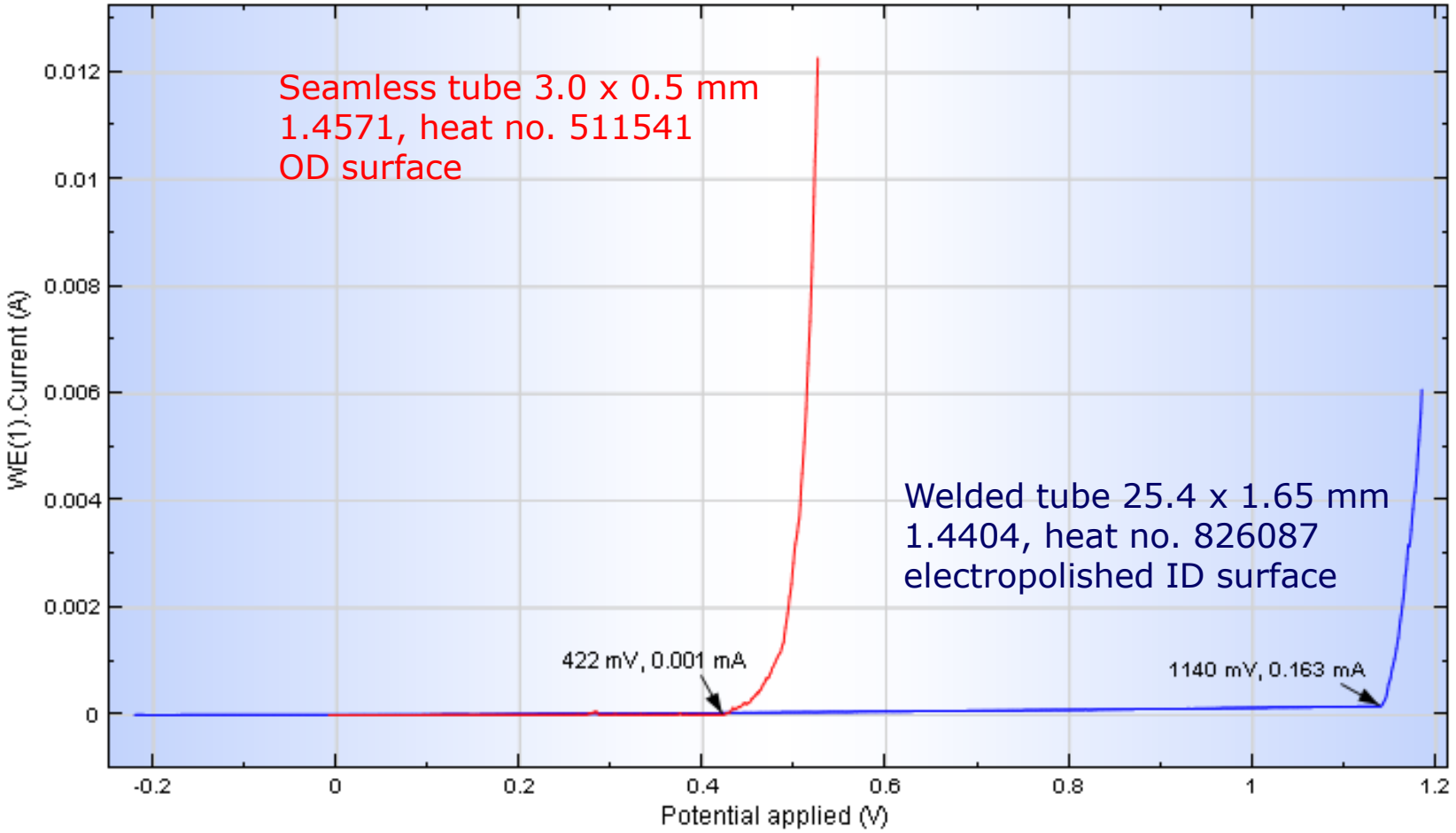


Cyclic polarization acc. to ASTM G 61



Polarization diagram in 3.56 weight% NaCl at ambient temperature, seamless tube 3.0 x 0.5 mm, 1.4571, heat no. 511541, OD surface

Cyclic polarization acc. to ASTM G 61



Polarization diagram in 3.56 weight% NaCl at ambient temperature

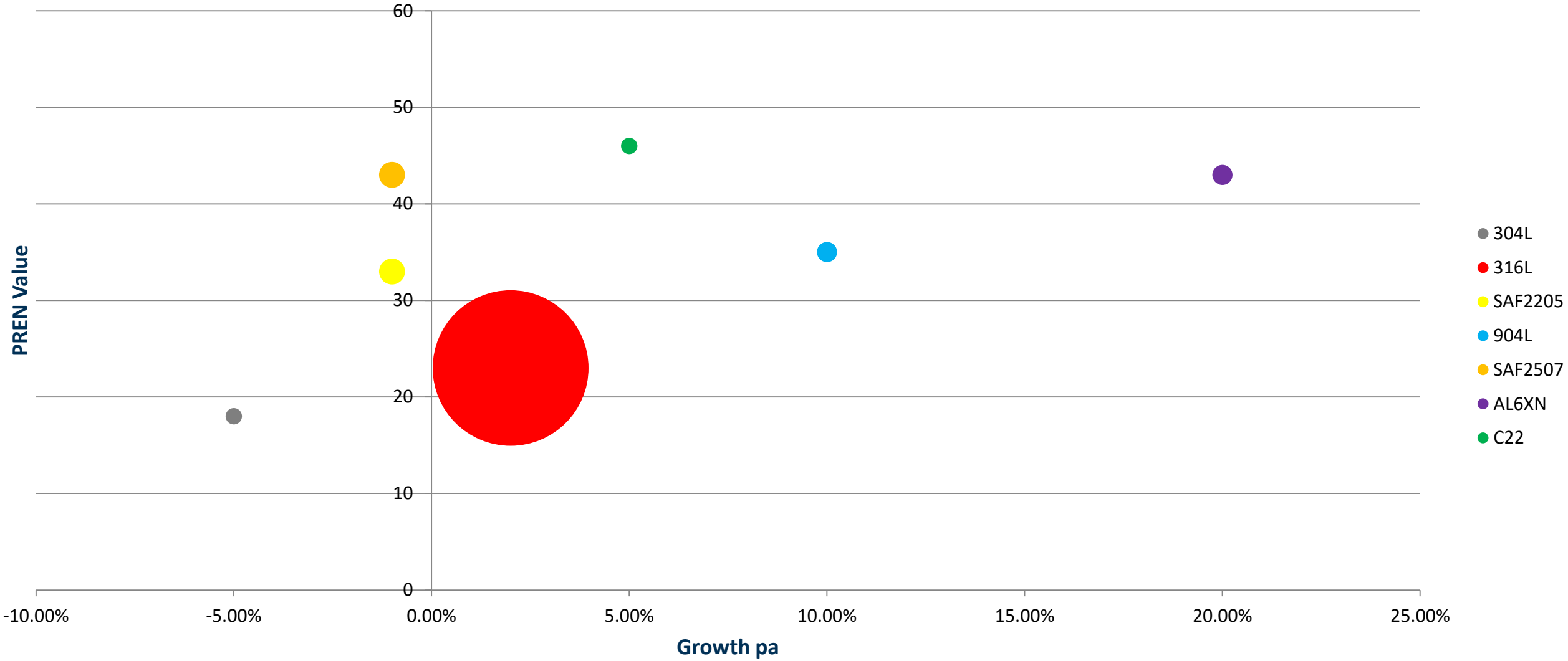
» RED: 1.4571 bright annealed

» BLUE: 1.4404 electropolished

Application Protection Layer

Optimized Application			Contaminated Application
	Design Optimization	SD	
	Material Optimization	MM	
	Material Qualification		
	Welding Performance	MJ	
	Surface Optimization	SF	
	Polymer Materials	SG	

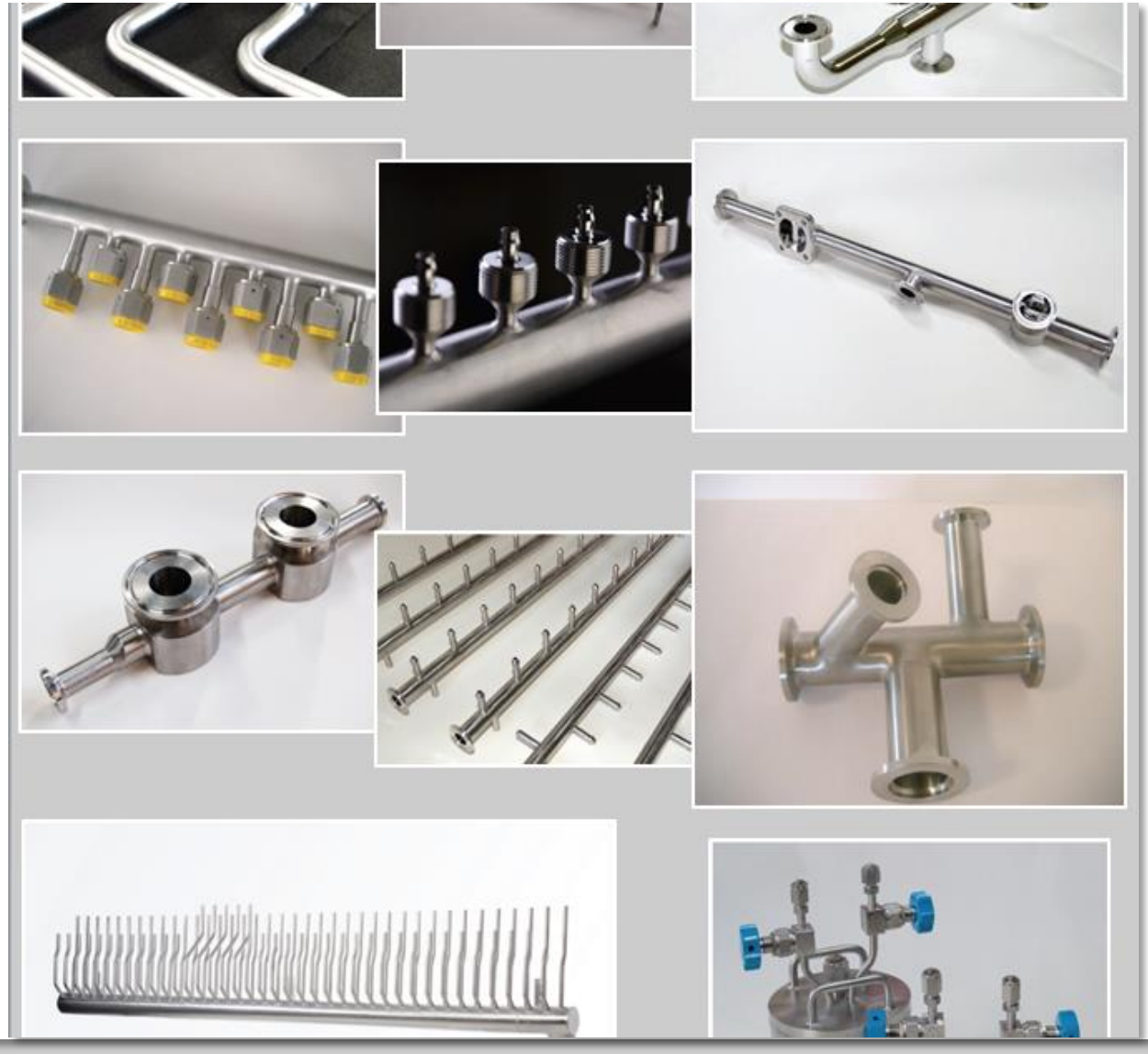
Pharmaceutical Alloy Forecast



» Fabrication & Installation

- Pre-manufacturing
- Control welding parameters
- Cut gas use & site time Ecopurge
- Weld parameters direct to QA pack
- On line QA Materials Cert management Webcert

Advantages



» Pre-manufacturing – advantages are:

- On time delivery for complex production spools
- Components – ready to install
- Components with high specification: requirements for
  - Material and surfaces
  - Simpler Documentation
  - Dimension tolerances.
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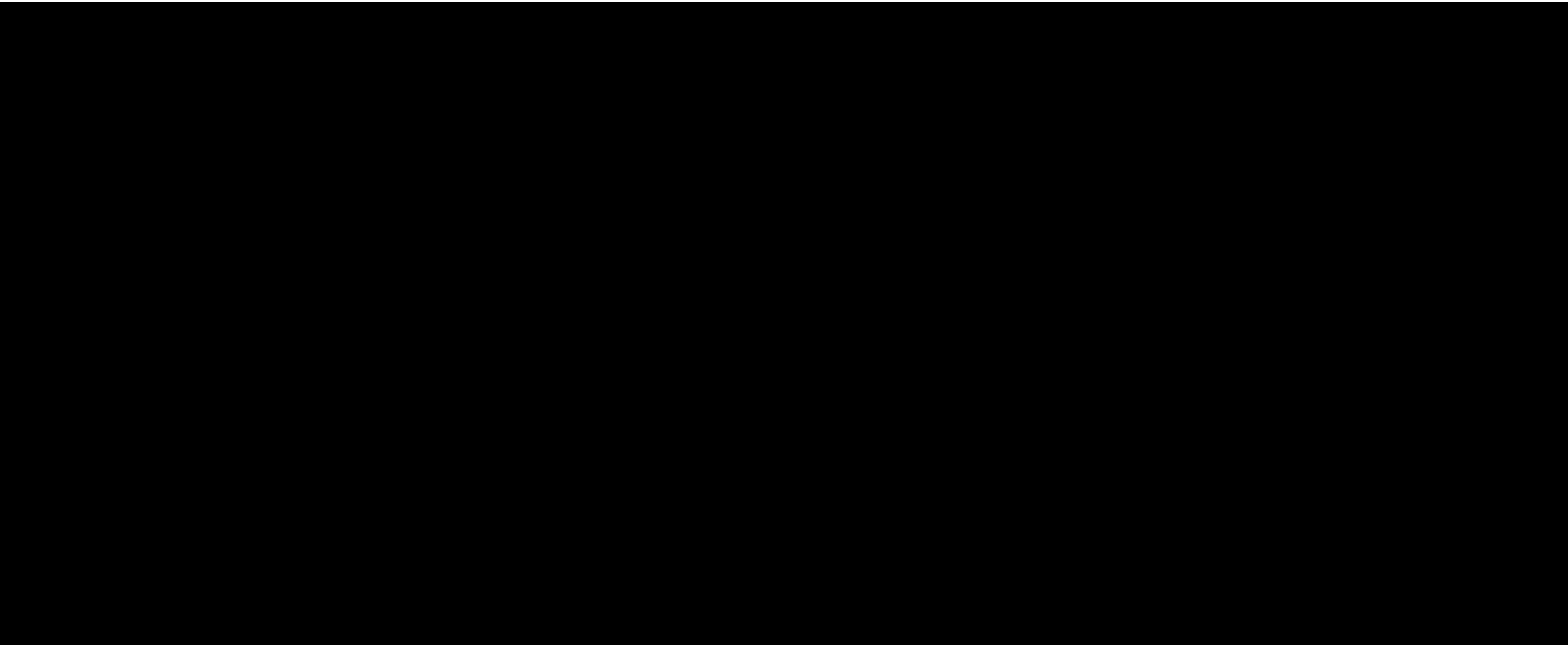
Complex Shapes - No Weld Bending



Discoloration Acceptance Criteria for Welds and HAZ

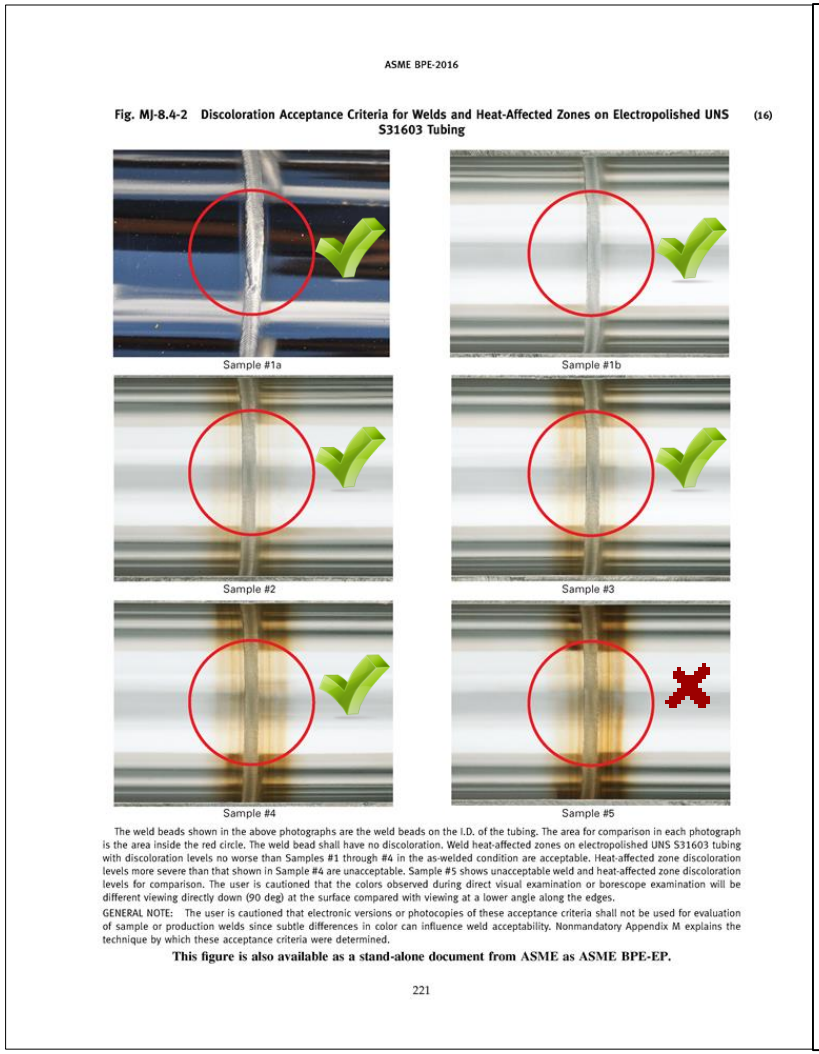


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Fig. MJ-8.4-2 Discoloration Acceptance Criteria for Welds and Heat-Affected Zones on Electropolished UNS S31603 Tubing (16)

Sample #1a Sample #1b

Sample #2 Sample #3

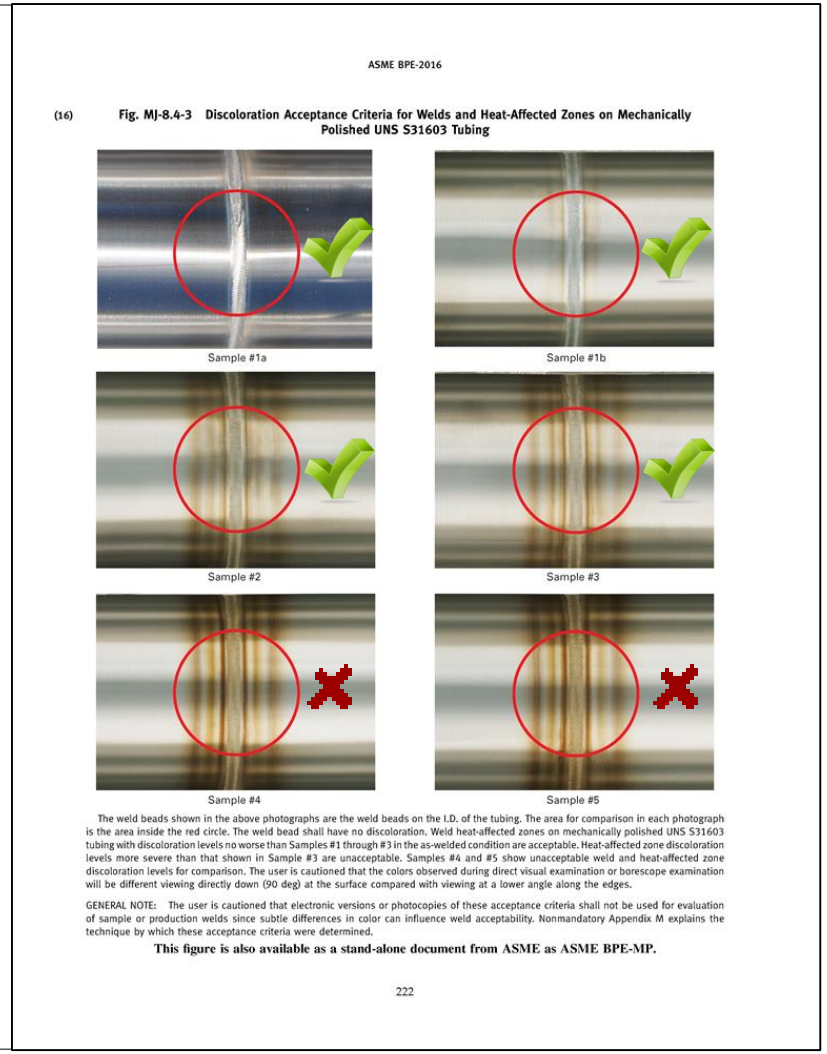
Sample #4 Sample #5

The weld beads shown in the above photographs are the weld beads on the I.D. of the tubing. The area for comparison in each photograph is the area inside the red circle. The weld bead shall have no discoloration. Weld heat-affected zones on electropolished UNS S31603 tubing with discoloration levels no worse than Samples #1 through #4 in the as-welded condition are acceptable. Heat-affected zone discoloration levels more severe than that shown in Sample #4 are unacceptable. Sample #5 shows unacceptable weld and heat-affected zone discoloration levels for comparison. The user is cautioned that the colors observed during direct visual examination or borescope examination will be different viewing directly down (90 deg) at the surface compared with viewing at a lower angle along the edges.

GENERAL NOTE: The user is cautioned that electronic versions or photocopies of these acceptance criteria shall not be used for evaluation of sample or production welds since subtle differences in color can influence weld acceptability. Nonmandatory Appendix M explains the technique by which these acceptance criteria were determined.

This figure is also available as a stand-alone document from ASME as ASME BPE-EP.

221



ASME BPE-2016

(16) Fig. MJ-8.4-3 Discoloration Acceptance Criteria for Welds and Heat-Affected Zones on Mechanically Polished UNS S31603 Tubing

Sample #1a Sample #1b

Sample #2 Sample #3

Sample #4 Sample #5

The weld beads shown in the above photographs are the weld beads on the I.D. of the tubing. The area for comparison in each photograph is the area inside the red circle. The weld bead shall have no discoloration. Weld heat-affected zones on mechanically polished UNS S31603 tubing with discoloration levels no worse than Samples #1 through #3 in the as-welded condition are acceptable. Heat-affected zone discoloration levels more severe than that shown in Sample #3 are unacceptable. Samples #4 and #5 show unacceptable weld and heat-affected zone discoloration levels for comparison. The user is cautioned that the colors observed during direct visual examination or borescope examination will be different viewing directly down (90 deg) at the surface compared with viewing at a lower angle along the edges.

GENERAL NOTE: The user is cautioned that electronic versions or photocopies of these acceptance criteria shall not be used for evaluation of sample or production welds since subtle differences in color can influence weld acceptability. Nonmandatory Appendix M explains the technique by which these acceptance criteria were determined.

This figure is also available as a stand-alone document from ASME as ASME BPE-MP.

222

Fig. MJ-8.4-2 Electropolished 316L tubing

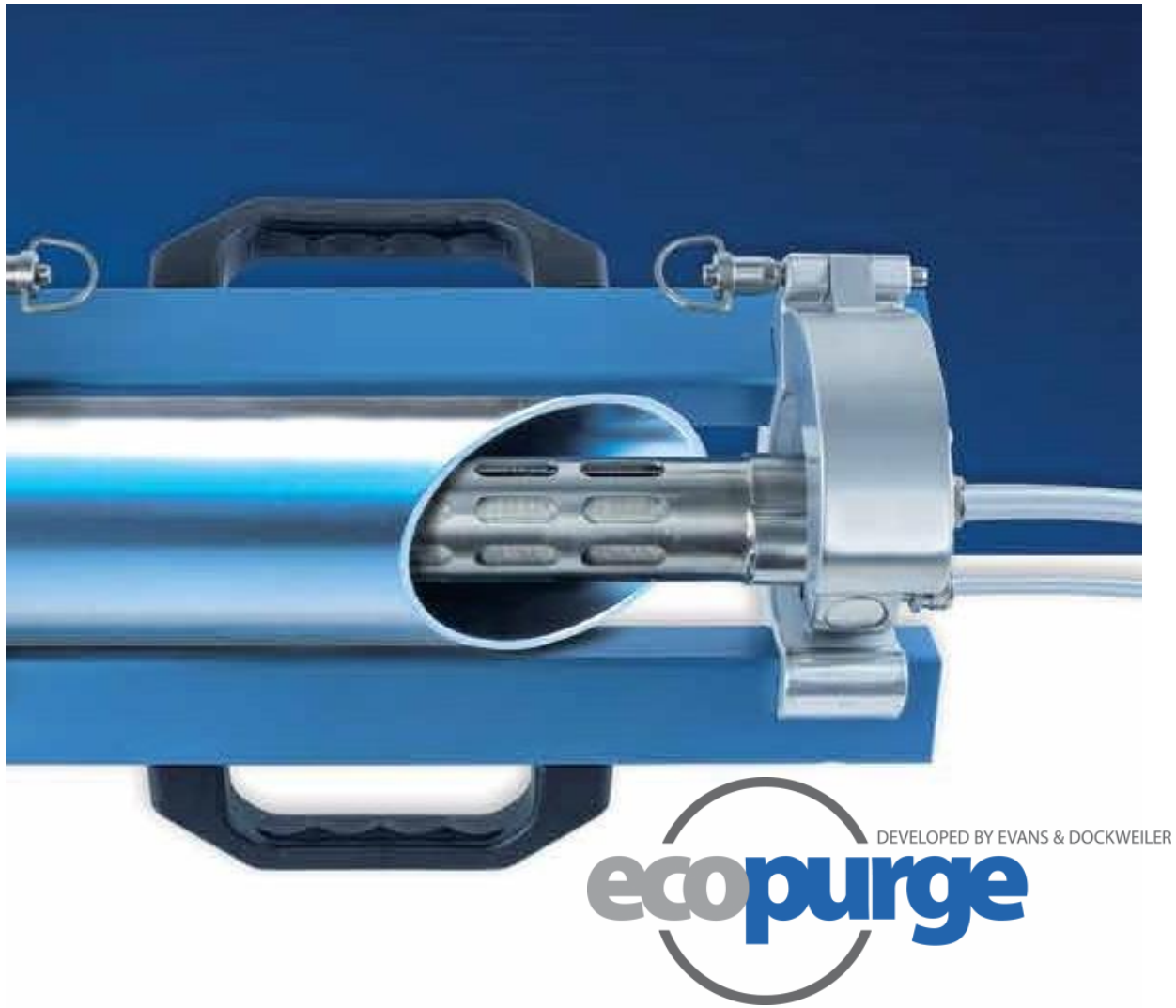
Fig. MJ-8.4-3 Mechanically polished 316L tubing

Source: ASME BPE-2016 *Bioprocessing Equipment*

4.0 Smart Technology in Welding

- The latest technology in Orbital welding eg Orbitalum® Smart Welder brings full data recording & traceability, 4.0 Technology
- All welding data can be sent directly via a wireless LAN network and be compiled directly into QA pack
- Real-time productivity monitoring is also possible
- Significant time and human error saved through automating a lengthy manual process

Eco-Purge – Maximum reduction



- Uses one purge dam
- Creates a trapped volume within the piping system for a controlled oxygen environment
- **Benefits:**
  - Reduces purge gas consumption during welding
  - Reduces Purge time
  - Real time oxygen and pressure monitoring improves weld quality
  - ..\Dockweiler Presentations\EcoPurge.wmv

Ecopurge

Dockweiler WebCert

» *„The simple solution for everyone who manages their certificates digitally."*

» Benefits:

- → E-Mail or paperwork
- → Via WebCert Portal
- → Access pre goods arrival
  - Flexible searching
  - Unlimited document archiving

DOCKWEILER
connecting flow to purity

Thank you
for your attention

Dockweiler AG
An der Autobahn 10/20
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QUESTIONS