

BIOPROCESSING EQUIPMENT

CHAPTER 1 INTRODUCTION, SCOPE, AND DEFINITIONS

(16)

Part GR General Requirements

GR-1 INTRODUCTION

The ASME Bioprocessing Equipment Standard was developed to aid in the design and construction of new fluid processing equipment used in the manufacture of biopharmaceuticals, where a defined level of purity and bioburden control is required.

The Standard typically applies to

- (a) components that are in contact with the product, raw materials, or product intermediates during manufacturing, development, or scale-up
- (b) systems that are a critical part of product manufacture [e.g., water-for-injection (WFI), clean steam, filtration, and intermediate product storage]

The General Requirements Part states the scope of the ASME BPE Standard and provides references and definitions that apply throughout the document.

When operating under pressure conditions, systems shall be constructed in accordance with the ASME Boiler and Pressure Vessel Code (BPVC), Section VIII, and/or ASME B31.3 Process Piping Code or applicable local, national, or international codes or standards. The owner/user may stipulate additional or alternative specifications and requirements.

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, 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.

When an application is covered by laws or regulations issued by an enforcement authority (e.g., municipal, provincial, state, or federal), the final construction requirements shall comply with these laws.

Items or requirements that are not specifically addressed in this Standard are not prohibited. Engineering judgments must be consistent with the fundamental principles of this Standard. Such judgments shall not be used to override mandatory regulations or specific prohibitions of this Standard.

GR-2 SCOPE OF THE ASME BPE STANDARD

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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 used in the manufacturing of biopharmaceuticals. This Standard also provides requirements for single-use systems and components used in the above listed systems and components. This Standard may be used, in whole or in part, for other systems and components where bioburden risk is a concern.

This Standard applies to

- (a) new system (and component) design and fabrication
- (b) definition of system boundaries
- (c) specific metallic, polymeric, and elastomeric (e.g., seals and gaskets) materials of construction
- (d) component dimensions and tolerances
- (e) surface finishes
- (f) materials joining
- (g) examinations, inspections, and testing
- (h) certification

This Standard is intended to apply to new fabrication and construction. If the provisions of this Standard are optionally applied by an owner/user to existing, in-service equipment, other considerations may be necessary. For installations between new construction and an

existing, in-service system, such as a retrofit, modification, or repair, the boundaries and requirements must be agreed to among the owner/user, engineer, installation contractor, and inspection contractor.

For a system or component to be BPE-compliant, adherence to all applicable parts of this Standard is required.

GR-3 MANUFACTURER'S QUALITY ASSURANCE PROGRAM

The manufacturer shall implement a quality assurance program describing the systems, methods, and procedures used to control materials, drawings, specifications, fabrication, assembly techniques, and examination/inspection used in the manufacturing of bioprocessing equipment.

GR-4 INSPECTION

The inspection requirements are specified in each Part of this Standard. If an inspection or examination plan is required, it shall be developed and agreed to by the owner/user, contractor, inspection contractor, and/or engineer ensuring that the systems and components meet this Standard.

GR-4.1 Inspector/Examiner

Inspector and examiner in this Standard shall be defined for the following:

(a) *Pressure Vessels*. Authorized Inspector, as defined in ASME BPVC, Section VIII.

(b) *Piping, Tubing, and Non-Code Vessels*. Owner's Inspector, as defined in ASME B31.3, paras. 340.4(a) and (b). Inspector's Delegate, as defined in GR-8, meets the additional requirements listed in GR-4.2.

(c) *Piping and Tubing*. Examiner, defined as a person who performs quality control examinations for a manufacturer as an employee of the manufacturer as defined in ASME B31.3, para. 341.1.

When local regulations require that pressure equipment be designed and constructed in accordance with standards other than ASME codes/standards, the inspector in this Standard is defined as one who is acceptable to the relevant regulatory authority.

GR-4.2 Inspector's Delegate

Inspector's Delegate qualifications shall be in accordance with the requirements listed herein. The employer of the Inspector's Delegate shall have documented training and qualification programs to ensure the qualifications and capabilities of personnel are met.

The capabilities requirements are listed in Table GR-4.2-1. It is required that a capability listed for a lower level of qualification is also required for subsequent higher levels of qualification.

GR-4.2.1 Levels of Qualification. There are four levels of qualification for Inspector's Delegate. Examination personnel qualifications are not covered in this section but shall be in accordance with ASME B31.3, para. 342.

(a) *Trainee*. An individual who is not yet certified to any level shall be considered a trainee. Trainees shall work under the direction of a certified Quality Inspector Delegate and shall not independently conduct any tests or write a report of test results.

(b) *Quality Inspector Delegate 1 (QID-1)*. This individual shall be qualified to properly perform specific calibrations, specific inspections, and specific evaluations for acceptance or rejection according to written instructions. A QID-1 may perform tests and inspections according to the capabilities' requirements under the supervision of, at a minimum, a QID-2.

(c) *Quality Inspector Delegate 2 (QID-2)*. This individual shall be qualified to set up and calibrate equipment and to interpret and evaluate results with respect to applicable codes, standards, and specifications. The QID-2 shall be thoroughly familiar with the scope and limitations of the inspection they are performing and shall exercise assigned responsibility for on-the-job training and guidance of trainees and QID-1 personnel. A QID-2 may perform tests and inspections according to the capabilities' requirements.

(d) *Quality Inspector Delegate 3 (QID-3)*. This individual shall be capable of establishing techniques and procedures; interpreting codes, standards, specifications, and procedures; and designating the particular inspection methods, techniques, and procedures to be used. The QID-3 shall have sufficient practical background in applicable materials, fabrication, and product technology to establish techniques and to assist in establishing acceptance criteria when none are otherwise available. The QID-3 shall be capable of training personnel. A QID-3 may perform tests and inspections according to the capabilities' requirements.

GR-4.2.2 Qualification Requirements. The qualification requirements listed herein shall be met prior to consideration for examination/certification.

(a) *Trainee*

(1) be a high school graduate or hold a state or military approved high school equivalency diploma

(2) receive a minimum of 8 hr of relevant documented training (total 8 hr), including as a minimum the requirements shown in Table GR-4.2-1

(b) *QID-1*. To be considered as a QID-1, personnel shall meet the following:

(1) be a trainee for a minimum of 6 mo of documented relevant industry experience. Alternate methods for meeting the work experience requirement are at least one of the following:

(-a) prior or current certification as a QID-1

Table GR-4.2-1 Inspector's Delegate Capabilities

Capability	Trainee	QID-1	QID-2	QID-3
Materials				
(a) Identify materials				
(1) Fitting type	X
(2) Tube/pipe	X
(3) Filler materials	...	X
(4) Elastomers	...	X
(5) Process components	...	X
(b) Verify material marking to standard	X
(c) Measure material dimensions	X
(d) Measure material surface finish	X
(e) Verify material documentation				
(1) Material Test Reports (MTR)	...	X
(2) Certificates of compliance	...	X
(3) Instrument calibration records	...	X
(4) Elastomers	...	X
(f) Evaluate to acceptance criteria	...	X
(g) Verify material compliance to specification	...	X
(h) Verify material storage/handling compliance	X	...
Equipment Use				
(a) Mirrors/magnifiers	X
(b) Measuring devices
(1) Steel rule	X
(2) Calipers (dial, digital)	X
(3) Fillet gauge	...	X
(4) Radius gauge	...	X
(5) Temperature-sensitive crayon (tempilstick)	...	X
(6) Slope level	...	X
(7) Undercut gauge	...	X
(c) Borescope/fiberscope	...	X
(d) Profilometer	X
(e) Positive material identification (PMI)	X	...
(f) Calibration records (inspection equipment)	...	X
Knowledge and Skills				
Understand inspection fundamentals				
(a) Effective oral and written communication	...	X
(b) Quality procedures				
(1) Prepare documentation control requirements	X
(2) Develop inspection procedures	X
(c) Review of specifications	X	...
(d) Codes and Standards (training)				
(1) ASME BPE	GR/DT/SF	MJ/SD 3.12	X	...
(2) ASME B31.3	Chapter VI	X
(3) ASME BPVC Section IX	X	...
(e) Interpret welding symbols and drawings				
(1) Detail drawings (mechanical)	X	...
(2) P&ID	X	...
(3) Single line isometric drawings (weld maps)	...	X
(4) Isometric drawings (slope maps)	...	X
(5) General/fabrication arrangement drawings (details)	X	...
(6) Interpret welding symbols	X	...
(f) Prepare documents/reports in accordance with GR-5.3				
(1) Material examination log	...	X
(2) Nonconformance reports	...	X
(3) Visual weld inspection	...	X
(4) Slope verification (isometric)	...	X
(5) Pressure test	X	...

Table GR-4.2-1 Inspector's Delegate Capabilities (Cont'd)

Capability	Trainee	QID-1	QID-2	QID-3
Knowledge and Skills (Cont'd)				
(g) Turnover package				
(1) Assemble	X	...
(2) Review	X
(h) Basic understanding of NDT/NDE				
(1) PT	X	...
(2) UT	X	...
(3) RT	X	...
(4) Eddy current	X	...
(5) Pressure/leak testing	X	...
Inspection				
(a) Perform visual inspection (other than weld inspection)	...	X
(b) Perform weld inspection	...	X
(c) Evaluate weld inspection results	X	...
(d) Perform slope verification	...	X
(e) Witness pressure tests	X	...
(f) Verify inspection compliance	X	...
(g) Review inspection reports	X	...
(h) Verify nonconformance disposition	X	...
(i) Perform installation verification				
(1) Installation per P&ID	X	...
(2) Check for cold spring	X	...
(3) Hanger verification	...	X
(4) Component installation per manufacturer's recommendations	X	...
Vessel Inspection (additional to above)				
(a) Verify surface finish	X	...
(b) Verify drainability	X	...
(c) Cleanability (CIP/riboflavin/sprayball testing)	X
(d) Verify dimensions and orientation	X
(e) Compliance with ASME Code (U-1)	X
(f) Documentation review	X	...
Welding Procedure Qualification				
Verify welding procedures (WPS/PQR) compliance	X
Welder and/or Welding Operator Performance Qualification				
Verify welder and/or welding operator performance qualification compliance	X	...
Project Planning				
(a) Review contract requirements	X
(b) Prepare weld inspection criteria	X
(c) Review specifications	X
(d) Prepare purchase specifications	X
(e) Develop inspection plan	X
Training				
(a) Provide on-the-job training for Quality Inspectors	X	...
(b) Maintain records of training	X	...
Audit				
(a) Perform vendor audits	X
(b) Perform fabricator audits	X
(c) Prepare audit and surveillance plan	X

(-b) completion with a passing grade of at least 2 yr of engineering or science study in a university, college, or technical school

(-c) possess an AWS CWI certificate¹ or ACCP Level II VT certificate² or international equivalent

(-d) 2 yr of documented relevant experience in inspection, examination, or testing activities

(2) receive a minimum of 16 additional hr of relevant documented training (minimum total = 24 hr), including as a minimum the requirements shown in Table GR-4.2-1

(3) pass a written test and practical performance examination, including as a minimum the requirements shown in Table GR-4.2-1 for this level

(c) QID-2. To be considered as a QID-2, personnel shall meet the following:

(1) be a QID-1 for a minimum of 6 mo of documented relevant industry experience. Alternate methods for meeting the work experience requirement are at least one of the following:

(-a) prior or current certification as a QID-2

(-b) completion with a passing grade of at least 4 yr of engineering or science study in a university, college, or technical school

(-c) possess an AWS CWI certificate¹ or ACCP Level II VT certificate² or international equivalent

(-d) 2 yr of documented relevant experience in inspection, examination, or testing activities of high-purity/hygienic systems

(2) receive a minimum of 16 additional hr of relevant documented training (minimum total = 40 hr), including as a minimum the requirements shown in Table GR-4.2-1

(3) pass a written test and practical performance examination, including as a minimum the requirements shown in Table GR-4.2-1 for this level

(d) QID-3. To be considered as a QID-3, personnel shall meet the following:

(1) be a QID-2 for a minimum of 24 mo of documented relevant industry experience. Alternate methods for meeting the work experience requirement are at least one of the following:

(-a) prior or current certification as a QID-3

(-b) 3 yr of documented relevant experience in inspection, examination, or testing activities of high-purity/hygienic systems

(2) receive a minimum of 40 additional hr of relevant documented training, including as a minimum the requirements shown in Table GR-4.2-1 (minimum total = 80 hr)

(3) pass a written test and practical performance examination, including as a minimum the requirements shown in Table GR-4.2-1 for this level

GR-4.2.3 Certification. The employer is responsible for training, testing, and certification of employees. The employer shall establish a written practice in accordance with the guidelines of ASNT SNT-TC-1A including

(a) the requirements listed in Table GR-4.2-1

(b) training programs

(c) certification testing requirements

(d) eye examinations as follows:

(1) *Near Vision Acuity.* The individual shall have natural or corrected near distance acuity in at least one eye such that the individual is capable of reading a minimum of a Jaeger Number 2 or equivalent type and size letter at a distance designated on the chart but no less than 12 in. (305 mm). This test shall be administered initially and at least annually thereafter.

(2) *Color Contrast.* The individual shall demonstrate the capability of distinguishing and differentiating contrast among colors. This test shall be administered initially and, thereafter, at intervals not exceeding 3 yr.

These examinations shall be administered by an ophthalmologist, optometrist, medical doctor, registered nurse or nurse practitioner, certified physician assistant, or other ophthalmic medical personnel and shall include the state or province (or applicable jurisdictional) license number.

(e) certification documentation

The owner/user is responsible for verifying the requirements of this section are met.

GR-4.2.4 Recertification. A QID-1, QID-2, or QID-3 whose employment has been terminated may be recertified to their former level of qualification by a new or former employer based on examination, provided all of the following requirements are met:

(a) The employee has proof of prior certification.

(b) The employee was working in the capacity to which certified within 6 months of termination.

(c) The employee is being recertified within 6 months of termination.

If the employee does not meet the listed requirements, additional training as deemed appropriate by the owner's Inspector shall be required.

GR-4.3 Responsibilities

The responsibilities of inspection personnel are defined in GR-4.3.1 and GR-4.3.2.

GR-4.3.1 Pressure Vessels. The responsibilities of the owner's Inspector shall be the same as the inspector in ASME BPVC, Section VIII.

GR-4.3.2 Piping, Tubing, and Non-Code Vessels. The responsibilities of the owner/user's Inspector shall be in accordance with ASME B31.3, para. 340.2.

¹ Certifications from the American Welding Society (AWS). CAWI is a Certified Associate Welding Inspector, and CWI is a Certified Welding Inspector.

² Certifications from the American Society of Nondestructive Testing (ASNT). ACCP is the ASNT Central Certification Program.

GR-4.4 Access for Inspectors

Manufacturers of bioprocessing equipment and components shall allow free access to owner/user and authorized inspection personnel at all times while work on the equipment or components is being performed. The notification of an impending inspection should be mutually agreed to by the manufacturer and the inspector. Access may be limited to the area of the manufacturer's facility where assembly, fabrication, welding, and testing of the specific equipment or components are being performed. Inspectors shall have the right to audit any examination, to inspect components using any examination method specified in the Design Specification (including Purchase Order), and to review all certifications and records necessary to satisfy the requirements of GR-5. The manufacturer shall provide the Inspector with work progress updates.

GR-5 DOCUMENTATION**GR-5.1 General**

Documentation requirements shall be agreed to at the beginning of a design project and shall be made available upon request or submitted at the agreed-upon time to support the requirements of this Standard, as agreed to by the owner/user and manufacturer/contractor.

(16) GR-5.2 Document Requirements

Material Test Reports (MTRs) for all metallic process components shall be verified to be in compliance with the applicable specification. Certificates of Compliance (C of Cs) for all polymeric and other nonmetallic process components shall be provided. In addition, the following documentation shall be provided to the owner/user or their designee.

GR-5.2.1 General List of Documents**GR-5.2.1.1 Metallic Materials****(16) GR-5.2.1.1.1 Turnover Package Documentation.**

Documentation required for cGMP-validated distribution systems, including the vessels, tubing systems on modules, super skids, skids, the shop or field fabrication of tubing, etc., includes the following:

(a) Materials Documentation

- (1) Material Test Reports
- (2) Certificates of Compliance
- (3) Material Examination Logs
- (4) Identification of the filler metal or consumable insert used

(b) Welding, Inspection, and Examination Qualification Documentation (not required for standard fittings, valves, and components unless specifically required by the owner/user)

- (1) Welding Procedure Specifications/Parameters (WPS/P)

- (2) Procedure Qualification Records (PQRs)
- (3) Welder Performance Qualifications (WPOs)
- (4) Welding Operator Performance Qualifications (WOPQs)

- (5) Examiner qualifications

(6) documentation of approval of the above by the owner/user's representative prior to welding

- (7) Inspector qualifications

(8) documentation of the approval of para. GR-5.2.1.1.1(b)(7) by the owner/user prior to welding

(c) Weld Documentation (not required for standard fittings, valves, and components unless specifically required by the owner/user)

- (1) weld maps

- (2) weld logs

- (3) weld examination and inspection logs

- (4) coupon logs

(d) Testing and Examination Documentation (as applicable)

- (1) passivation reports

- (2) spray device coverage testing

- (3) pressure testing

- (4) final slope check documentation

- (5) calibration verification documentation

- (6) purge gas certifications

- (7) signature logs

- (8) number of welds — both manual and automatic

(9) number of welds inspected expressed as a percentage (%)

(10) heat numbers of components that must be identified, documented, and fully traceable to the installed system

- (11) surface finish C of Cs

- (12) NDE (nondestructive examination) reports

(e) System/Equipment

(1) standard operating and maintenance procedures and manuals

- (2) installation procedures

- (3) piping and instrumentation diagrams

- (4) detail mechanical drawings and layouts

(5) technical specification sheets of components and instrumentation

- (6) original equipment manufacturer's data

- (7) manufacturer's data and test reports

(8) any documentation that is specifically needed for the owner/user's qualification of a system

GR-5.2.1.1.2 Technical support information to support the design, operation, and maintenance of equipment may include, but is not limited to, the following:

- (a) material handling procedures

- (b) mechanical and electropolishing procedures

- (c) shop passivation procedures

GR-5.3 Material Test Reports/Certificates of Compliance

- (16) **GR-5.3.1 Metallic Materials.** The combination of documents, including C of Cs and MTRs, for all valves and fittings having process contact surfaces shall include the following information, as a minimum:

- (a) ASME BPE Standard, including year date
- (b) material type
- (c) heat number or code traceable to the original heat
- (d) chemical composition
- (e) AWS classification of filler metal, if used
- (f) alloy designation and material specification of insert, if used
- (g) postweld heat treatment documentation, if applicable
- (h) mechanical properties are not required, but if included, must be accurate to the raw material specification

MTRs for other components made to a material specification shall contain the minimum information specified by the material specification incorporated by reference.

GR-5.3.2 Polymeric and Other Nonmetallic Material Components. The manufacturer of polymeric and other nonmetallic components shall issue a Certificate of Compliance that the components meet requirements as shown in Table PM-2.2.1-1.

- (16) **GR-5.3.2.1 Seal Documentation.** Seal manufacturers shall provide, upon owner/user request, documentation (test report) of the USP <88> Biological Reactivity Test In Vivo, Class VI and the USP <87> Biological Reactivity Test In Vitro testing on final manufactured seals.

A Certificate of Compliance shall be issued by the seal manufacturer to certify compliance to this Standard when required by the owner/user. The Certificate of Compliance shall contain the information listed in Table PM-2.2.1-1. Additional agreements may be required.

GR-5.3.2.2 Sealed Unions. The seal manufacturer shall provide, upon request of the owner/user, a certificate of design conformance that the sealed union meets the intrusion requirements of SG-4.2.

GR-5.3.3 Electropolishing. The electropolishing vendor, if requested by the owner/user, shall provide a Certificate of Compliance with each type of component(s) that shall include, but is not limited to, the following:

- (a) vendor's company
- (b) owner/user's name
- (c) description of component(s)
- (d) identification of the electropolishing procedure used
- (e) final surface finish report (R_a if required by the owner/user)

GR-5.3.4 Passivation. The passivation provider shall supply a Certificate of Compliance for each system or set (type) of component(s) that shall include, but not be limited to, the following:

- (a) owner/user's name
- (b) description of system or component(s)
- (c) service provider's company name
- (d) qualified passivation method used
- (e) documentation of passivation process, as follows:
 - (1) written qualified procedure
 - (2) documentation of process control of essential variables
 - (3) instrument calibration records
 - (4) certificates of analysis for all chemicals used
 - (5) process testing and verification
- (f) postpassivation verification method(s) used
- (g) for material manufacturers/suppliers of components whose surfaces have been electropolished and/or passivated, a Certificate of Compliance for Passivation and/or Electropolishing stating that standard industry practices, such as ASTM A967 or ASTM B912, as applicable, have been used. If required by the owner/user, the manufacturer or supplier may be required to demonstrate the effectiveness of their procedure by a method mutually agreed upon.

GR-5.4 Weld and Examination/Inspection Log (16)

The results of the welding, examination, and inspection shall be recorded on a Weld and Examination/Inspection Log. The information required to be on the Weld Log may be in any format, written or tabular, to fit the needs of the manufacturer/supplier, installing contractor, inspection contractor, and owner/user as long as all required information is included or referenced. Form WEL-1 (see Nonmandatory Appendix B) has been provided as a guide for the Weld and Examination/Inspection Log. This form includes the required data plus some other information that is not required. The minimum requirements are as follows:

- (a) isometric drawing number (including revision number)
- (b) weld number
- (c) date welded
- (d) welder and/or welding operator identification
- (e) size
- (f) examination
 - (1) date
 - (2) type of examination
 - (3) acceptance/rejection
 - (4) initials
- (g) inspection
 - (1) date
 - (2) type of examination
 - (3) acceptance/rejection
 - (4) initials
- (h) identification of blind welds

- (i) identification of manual welds
- (j) basis of rejection

In addition, heat numbers (or other identification system for material traceability) and slope shall be recorded on the Weld and Examination/Inspection Log, an isometric drawing, or other owner/user-approved document.

GR-5.5 Records Retention

GR-5.5.1 Vessel Documentation. For all Bioprocessing ASME Code-stamped vessels, National Board registration is recommended to maintain vessel data on file. Manufacturing documentation shall be maintained throughout the design and manufacture for each component, assembly, part, or unit.

All documentation shall be retained by the owner/user. As agreed to by the owner/user and manufacturer, documentation from the manufacturer will be retained for the agreed-upon duration of time but not less than 3 yr after manufacture.

GR-5.5.2 Welding Documentation

(a) *Piping and Tubing.* Records and retention of records associated with piping and tubing shall be in accordance with ASME B31.3.

(b) *Pressure Vessels and Tanks.* Records and retention of records for code vessels shall be in accordance with ASME BPVC, Section VIII.

GR-6 U.S. CUSTOMARY AND SI UNITS

This Standard uses standard units listed in Mandatory Appendix II. Nonmandatory Appendix T has been provided as a guide for U.S. Customary and SI unit conversion.

(16) GR-7 REFERENCES

For this Standard, the most recent approved version of the following referenced standards shall apply:

3-A, Sanitary Standards

Publisher: 3-A Sanitary Standards, Inc., 6888 Elm Street, Suite 2D, McLean, VA 22101 (www.3-a.org)

ANSI/AWS A3.0, Standard Welding Terms and Definitions

ANSI/AWS QC1, Standard for AWS Certification of Welding Inspectors

AWS B2.4, Specification for Welding Procedure and Performance Qualification for Thermoplastics

AWS G1.10M, Guide for the Evaluation of Hot Gas, Hot Gas Extrusion, and Heated Tool Butt Thermoplastic Welds

Publisher: American Welding Society (AWS), 8669 NW 36 Street, No. 130, Miami, FL 33166 (www.aws.org)

ASME B31.3, Process Piping

ASME B46.1, Surface Texture (Surface Roughness, Waviness, and Lay)

ASME Boiler and Pressure Vessel Code, Section V, Nondestructive Examination

ASME Boiler and Pressure Vessel Code, Section VIII, Rules for Construction of Pressure Vessels

ASME Boiler and Pressure Vessel Code, Section IX, Welding, Brazing, and Fusing Qualifications

ASME PTC 19.3 TW, Thermowells

ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy

Publisher: The American Society of Mechanical Engineers (ASME), Two Park Avenue, New York, NY 10016-5990 (www.asme.org)

Material specifications for metallic materials are listed by product form in Part MM.

ASTM A380, Practice for Cleaning, Descaling, and Passivation of Stainless Steel Parts, Equipment, and Systems

ASTM A967, Standard Specification for Chemical Passivation Treatments for Stainless Steel Parts

ASTM B912, Standard Specification for Passivation of Stainless Steels Using Electropolishing

ASTM D395, Standard Test Methods for Rubber Property — Compression Set

ASTM D412, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension

ASTM D471, Standard Test Method for Rubber Property — Effect of Liquids

ASTM D624, Standard Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers

ASTM D2240, Standard Test Method for Rubber Property — Durometer Hardness

ASTM D2657, Standard Practice for Heat Fusion Joining of Polyolefin Pipe and Fittings

ASTM E112, Test Methods for Determining Average Grain Size

ASTM E220, Standard Test Method for Calibration of Thermocouples by Comparison Techniques

ASTM E230/E230M, Standard Specification and Temperature-Electromotive Force (emf) Tables for Standardized Thermocouples

ASTM E644, Standard Test Methods for Testing Industrial Resistance Thermometers

ASTM E1137/E1137M, Standard Specification for Industrial Platinum Resistance Thermometers

ASTM E2500, Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment

Publisher: American Society for Testing and Materials (ASTM International), 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959 (www.astm.org)

- DVS 2202-1, Imperfections in Thermoplastic Welding Joints; Features, Descriptions, Evaluation
 Publisher: DVS-Verlag GmbH (German Welding Society), Aachener Strasse 172, D-40223 Dusseldorf, Germany (dvn.ddb.de)
- European Hygienic Engineering & Design Group (EHEDG), Document No. 18 — Passivation of Stainless Steel
 Publisher: European Committee for Standardization (CEN), Avenue Marnix 17, B-1000, Brussels, Belgium (www.cen.eu)
- FDA, 21 CFR, Parts 210 and 211, Current Good Manufacturing Practices
 GMP: Current Good Manufacturing Practices, Title 21 of the Food and Drug Administration
 Publisher: U.S. Food and Drug Administration (FDA), 10903 New Hampshire Avenue, Silver Spring, MD 20993 (www.fda.gov)
- IEC 60751, Industrial Platinum Resistance Thermometers and Platinum Temperature Sensors
 Publisher: International Electrotechnical Commission (IEC), 3, rue de Varembe, Case Postale 131, CH-1211 Geneva 20, Switzerland/Suisse (www.iec.ch)
- ISO 34-1, Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces
 ISO 34-2, Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 2: Small (Delft) test pieces
 ISO 37, Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties
 ISO 48, Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)
 ISO 815-1, Rubber, vulcanized or thermoplastic — Determination of compression set — Part 1: At ambient or elevated temperatures
 ISO 815-2, Rubber, vulcanized or thermoplastic — Determination of compression set — Part 2: At low temperatures
 ISO 816, Superseded by ISO 34-2
 ISO 1817, Rubber, vulcanized — Determination of the effect of liquids
 ISO 10993, Biological evaluation of medical devices
 ISO 11137, Sterilization of health care products — Radiation — Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
 Publisher: International Organization for Standardization (ISO), Central Secretariat, Chemin de Blandonnet 8, Case Postale 401, 1214 Vernier, Geneva, Switzerland (www.iso.org)
- ISPE Baseline® Pharmaceutical Engineering Guide for Water and Steam Systems — Volume 4
 Publisher: International Society for Pharmaceutical Engineering (ISPE), 3109 W. Dr. Martin Luther King, Jr. Blvd., Tampa, FL 33607 (www.ispe.org)
- NIH (BL-1/BL-4), Biohazard Containment Guidelines
 Publisher: National Institutes of Health (NIH), 9000 Rockville Pike, Bethesda, MD 20892 (nih.gov)
- Recommended Practice (RP) No. SNT-TC-1A, Personnel Qualification and Certification in Nondestructive Testing
 Publisher: American Society for Nondestructive Testing (ASNT), 1711 Arlingate Lane, P.O. Box 28518, Columbus, OH 43228 (www.asnt.org)
- United States Pharmacopeia and National Formulary (USP-NF)
 Publisher: U.S. Pharmacopeia Convention (USP), 12601 Twinbrook Parkway, Rockville, MD 20852-1790 (http://www.usp.org/usp-nf)

GR-8 TERMS AND DEFINITIONS

(16)

annealing: a treatment process for steel for reducing hardness, improving machinability, facilitating cold working, or producing a desired mechanical, physical, or other property.

anomaly: a localized surface area that is out of specifications to the surrounding area, and is classified as abnormal.

arc gap: for orbital GTAW, the nominal distance, measured prior to welding, from the tip of the electrode to the surface of the weld joint or insert.

arc strike: a discontinuity consisting of any localized remelted metal, heat-affected metal, or change in the surface profile of any part of a weld or base metal resulting from an arc, generated by the passage of electrical current between the surface of the weld or base material and a current source, such as a welding electrode, magnetic particle prod, or electropolishing electrode.

aseptic: free of pathogenic (causing or capable of causing disease) microorganisms.

aseptic processing: operating in a manner that prevents contamination of the process.

audit: an on-site evaluation by an ASME-appointed team to review and report evidence of compliance of the applicant with regard to the requirements of the ASME BPE Standard, “after” issuance of a certificate.

autogenous fillet weld: a fillet weld that is produced without the addition of filler metal. (See also *seal weld*.)

autogenous weld: a weld made by fusion of the base material without the addition of filler. (See also *gas tungsten-arc welding*.)

automatic welding: welding with equipment that performs the welding operation without adjustment of the

controls by a welding operator. The equipment may or may not perform the loading and unloading of the work. (See also *machine welding*.)

barrier fluid: a fluid used to separate environment from product such as water or condensate in a double mechanical seal.

bioburden: the number of viable contaminating organisms per product unit.

biofilm: a film of microorganisms or cell components adhering to surfaces submerged in or subjected to fluid environments.

biologics: therapeutic or diagnostic products generated and purified from natural sources.

biopharmaceuticals: pharmaceuticals manufactured by biotechnology methods, with the products having biological sources, usually involving live organisms or their active components. Biopharmaceuticals generally include recombinant proteins, (monoclonal) antibodies, vaccines, blood/plasma-derived products, nonrecombinant culture-derived proteins, and cultured cells and tissues.

bioprocess: technique or operation used in the manufacture and/or purification of biopharmaceuticals or other biological materials, such as products derived from microbial fermentation (e.g., yeast, mold, bacteria), cell culture (e.g., insect, mammalian, plant), tissue culture, blood, or milk fractionation.

bioprocessing: see *bioprocess*.

bioprocessing equipment: equipment, systems, or facilities used in the creation of products utilizing living organisms.

blind weld: a weld joint by design that cannot feasibly be visually inspected internally.

blister (polymeric): a localized imperfection on a polymer surface, containing a pocket of fluid.

blistering (metallic): a localized delamination within the metal that has an appearance of chipped or flaked-off areas. Per SEMI F019-0304, section 4.2.1.

borescope: a device for indirect visual inspection of difficult-to-access locations such as equipment and pipes.

break: a discontinuity in the face of a fitting.

buffing: a metal finishing process for smoothing the surface using a grease-suspended abrasive.

burn-through: excessive melt-through or a hole through the root bead of a weld.

burr: excess material protruding from the edge typically resulting from operations such as cutting or facing.

butt joint: a joint between two members lying approximately in the same plane.

cartridge seal: a self-contained seal assembly.

cavitation: a condition of liquid flow where, after vaporization of the liquid, the subsequent collapse of vapor bubbles can produce surface damage.

certificate: a Certificate of Authorization issued by ASME.

certificate holder: an organization holding a Certificate of Authorization issued by the Society upon satisfactory completion of evaluation of ability to comply with the requirements of this Standard.

Certificate of Authorization: a document issued by ASME that authorizes the use of an ASME BPE Symbol Stamp for a specified time and for a specified scope of activity.

certification: documented testimony by qualified authorities that a system qualification, calibration, validation, or revalidation has been performed appropriately and that the results are acceptable.

cGMPs: current Good Manufacturing Practices. Current design and operating practices developed by the pharmaceutical industry to meet FDA requirements as published in the Code of Federal Regulations, Chapter 1, Title 21, Parts 210 and 211.

chromatography: the purification of substances based on the chemical, physical, and biological properties of the molecules involved.

clean: a condition achieved by removal of dirt, residues, detergents, or other surface contaminants.

cleaning: operations by which dirt, residues, detergents, or other surface contaminants are removed to achieve predetermined surface attributes.

clean-in-place (CIP): cleaning of process contact surfaces of a system or component without disassembly beyond the removal of single-use components.

clean steam: steam free from boiler additives that may be purified, filtered, or separated. Usually used for incidental heating in pharmaceutical applications.

closed head: for orbital GTAW, a welding head that encapsulates the entire circumference of the tube/pipe during welding and that contains the shielding gas.

cloudiness: the appearance of a milky white hue across some portion of a surface resulting from the electropolish process.

cluster of pits: two or more pits, the closest distance between each being less than the diameter of any one pit.

cluster porosity: porosity that occurs in clumps or clusters.

compendial water: purported to comply with USP and/or any other acknowledged body of work related to the quality, manufacture, or distribution of high-purity water.

compression set: permanent deformation of rubber after subscription in compression for a period of time, as typically determined by ASTM D395.

concavity: a condition in which the surface of a welded joint is depressed relative to the surface of the tube or pipe. Concavity is measured as a maximum distance from the outside or inside diameter surface of a welded joint along a line perpendicular to a line joining the weld toes.

consumable insert: a ring of metal placed between the two elements to be welded that provides filler for the weld, when performed with fusion welding equipment. A consumable insert can also be used for the root pass in a multiple pass weld with the addition of filler wire (also called insert ring).

convexity: a condition in which the surface of a welded joint is extended relative to the surface of the tube or pipe. Convexity is measured as a maximum distance from the outside or inside diameter surface of a welded joint along a line perpendicular to a line joining the weld toes.

corrosion: a chemical or electrochemical interaction between a metal and its environment, which results in changes in the property of the metal. This may lead to impairment of the function of the metal, the environment, and/or the technical system involved.

cracks: fracture-type discontinuities characterized by a sharp tip and high ratio of length and width to opening displacement. A crack may not be detected with a stylus. A linear crack will produce a liquid penetrant indication during liquid penetration inspection, X-ray, or ultrasound.

crater: a depression at the termination of a weld bead.

crater cracks: cracks that form in the crater, or end, of the weld bead.

creep: a time-dependent permanent deformation that occurs under stress levels below the yield stress.

dead leg: an area of entrapment in a vessel or piping run that could lead to contamination of the product.

defects: discontinuities that by nature or accumulated effect (for example, total crack length) render a part or product unable to meet minimum applicable acceptable standards or specifications. This term designates rejectability. (See also *discontinuity*.)

deionized water: a grade of purified water produced by the exchange of cations for hydrogen ions and anions for hydroxyl ions.

delamination: separation into constituent layers.

demarcation: a localized area that is dissimilar to the surrounding areas with a defined boundary.

dent: a large, smooth-bottomed depression whose diameter or width is greater than its depth and that will not produce an indication.

descaling: the removal of heavy, tightly adherent oxide films resulting from hot-forming, heat-treatment, welding, and other high-temperature operations such as in steam systems.

dirty: a relative term indicating the condition of being contaminated.

discoloration: any change in surface color from that of the base metal. Usually associated with oxidation occurring on the weld and heat-affected zone on the outside diameter and inside diameter of the weld joint as a result of heating the metal during welding. Colors may range from pale bluish-gray to deep blue, and from pale straw color to a black crusty coating.

discontinuity: interruption of the typical structure of a weldment, such as a lack of homogeneity in the mechanical, metallurgical, or physical characteristics of the material or weldment. A discontinuity is not necessarily a defect.

distribution system: centralized system for the delivery of fluids from point of generation or supply to point of use.

downslope: that part of an automatic orbital weld sequence during which the welding current is gradually reduced prior to extinguishing of the welding arc. The downslope portion of a welded joint is seen as a tapering of the end of the weld bead with a reduction of penetration from the beginning to the end of the downslope so that the final weld bead is small with minimal penetration.

duplex stainless steel: a group of stainless steels whose chemical composition is designed to produce a room-temperature microstructure that is a mixture of austenite and ferrite.

durometer: measurement of hardness related to the resistance to penetration of an indenter point in to a material as typically determined by ASTM D2240.

dynamic seal: seal with a component that is in motion relative to a second surface.

dynamic spray device: a moving device, designed to produce a nonstationary spray pattern.

elastomer: rubber or rubberlike material possessing elasticity. (See also *elastomeric material*.)

elastomeric material: a material that can be stretched or compressed repeatedly and, upon immediate release of stress, will return to its approximate original size.

electropolishing: a controlled electrochemical process utilizing acid electrolyte, DC current, anode, and cathode to smooth the surface by removal of metal.

end grain effect: a surface discontinuity of small diameter (or linear) cavities located perpendicular to the rolling direction of the material and appearing after electropolishing.

etching: the process of removing a layer of metal from its surface using a chemical and/or electrolytic process.

ethical pharmaceutical: a controlled substance for the diagnosis or treatment of disease.

excessive penetration: weld penetration that exceeds the acceptance limit for inside diameter convexity. (See also *convexity*.)

expiration date: the date after which the shelf life has been exceeded.

extractables (polymeric): chemicals that can be removed from polymeric articles using appropriate solvents.

fermentation: the biochemical synthesis of organic compounds by microorganisms or cultivated cells.

fermentor (fermenter): a vessel for carrying out fermentation.

finishing marks: any surface texture or pattern resulting from cutting, machining, forming, grinding, polishing, and/or other finishing methods.

fixture marks: an area on an electropolished component where the electrical connection was made for the processing of the component.

flash electropolish: an electrochemical process done for a very short duration of time with a low current density, which neither significantly alters the surface of the material nor meets the acceptance criteria as set forth in Table H-3.3-1 in Nonmandatory Appendix H of this Standard.

fluoropolymer: polymer material having a carbon chain either partially or completely bonded to fluorine atoms.

flushing (rinsing): the flowing of water over the process contact surfaces of system components for the removal of particulates or water-soluble contaminants.

full penetration: a weld joint is said to be fully penetrated when the depth of the weld extends from its face into the weld joint so that the joint is fully fused. For a tube-to-tube weld, no unfused portions of the weld joint shall be visible on the inside diameter of a fully penetrated weld.

fusion: the melting together of filler metal and base metal, or of base metal only, that results in coalescence.

fusion welding: welding in which the base material is fused together without the addition of filler material to the weld. (See also *gas tungsten-arc welding*.)

gasket: static seal made from deformable material compressed between two mating surfaces.

gas tungsten-arc welding (GTAW): an arc welding process that produces coalescence of metals by heating them with an arc between a tungsten (nonconsumable) electrode and the work. Shielding is obtained from a gas or gas mixture. (This process is sometimes called TIG

welding, a nonpreferred term.) GTAW may be performed by adding filler material to the weld, or by a fusion process in which no filler is added.

GMP facility: a facility designed, constructed, and operated in accordance with cGMP guidelines established by the FDA.

grain boundary: an interface separating two grains, where the orientation of the lattice structure changes from that of one grain to that of the other. Per SEMI F019-0304, section 4.8.2.

harvesting: the separation of cells from growth media. This can be accomplished by filtration, precipitation, or centrifugation.

haze: a localized diminished surface brightness, commonly produced by gassing or air pockets, during electropolishing.

heat-affected zone: that portion of the base metal or polymer that has not been melted, but whose microstructure or mechanical properties have been altered by the heat of welding or cutting.

heat number: an alphanumeric identification of a stated tonnage of metal obtained from a continuous melting in a furnace.

heat tint: coloration of a metal surface through oxidation by heating. (See also *discoloration*.)

higher alloy: a metal containing various alloying constituents formulated to provide enhanced corrosion resistance and possibly improved mechanical properties beyond those that are typically observed in UNS S31603 stainless steel.

holdup volume: the volume of liquid remaining in a vessel or piping system after it has been allowed to drain.

hydrotest: a pressure test of piping, pressure vessels, or pressure-containing parts, usually performed by pressurizing the internal volume with water at a pressure determined by the applicable code.

hygienic: of or pertaining to equipment and piping systems that by design, materials of construction, and operation provide for the maintenance of cleanliness so that products produced by these systems will not adversely affect human or animal health.

hygienic clamp joint: a tube outside diameter union consisting of two neutered ferrules having flat faces with a concentric groove and mating gasket that is secured with a clamp, providing a nonprotruding, recessless process contact surface.

hygienic joint: a tube outside diameter union providing a nonprotruding, recessless process contact surface.

icicles: localized regions of excessive penetration, which usually appear as long, narrow portions of weld metal on the weld underbead. (See also *convexity* and *excessive penetration*.)

inclusions: particles of foreign material in a metallic or polymer matrix.

incomplete fusion (or lack of fusion): a weld discontinuity in which fusion did not occur between weld metal and faces or between adjoining weld beads. Also, in welding of tubing, when the weld fully penetrates the wall thickness but misses the joint, leaving some portion of the inner (inside diameter) weld joint with unfused edges.

incomplete penetration (or lack of penetration): a groove weld in which the weld metal does not extend completely through the joint thickness.

indication: a condition or an anomaly of a localized area that has not been classified as being accepted or rejected.

Inspector's Delegate: a person who is delegated by an owner's inspector to perform inspection functions as referenced in ASME B31.3, para. 340.4(c).

joint penetration: the depth that a weld extends from its face into a joint, exclusive of reinforcement.

lack of fusion after reflow: a discontinuity in welding of tubing where, after a reflow or second weld pass has been made, the original joint has still not been consumed, leaving the weld joint with unfused edges on the inner surface.

lamellar tears: terrace-like fractures in the base metal with a basic orientation parallel to the wrought surface; caused by the high stress in the thickness direction that results from welding.

laminations: elongated defects in a finished metal product, resulting from the rolling of a welded or other part containing a blowhole. Actually, the blowhole is stretched out in the direction of rolling.

leachables (polymeric): typically a subset of extractables, these chemicals migrate from polymeric articles into the product or process fluid.

linear porosity: porosity that occurs in a linear pattern. Linear porosity generally occurs in the root pass from inadequate joint penetration.

liquid penetrant indication: refer to ASME BPVC, Section V, Article 6, para. T-600, for testing an anomaly or an indication.

luster: the state or quality of shining by reflecting light. (See also *variance in luster*.)

machine welding: welding with equipment that performs the welding operation under the constant observation and control of a welding operator. The equipment may or may not perform the loading and unloading of the works. (See also *automatic welding*.)

manual welding: welding in which the entire welding operation is performed and controlled by hand.

material manufacturer: an organization responsible for the production of products meeting the requirements of the material specification(s).

Material Test Report (mill test report or MTR): a document in which the results of tests, examinations, repairs, or treatments required by the material specification to be reported are recorded. This document includes those of any supplementary requirements or other requirements stated in the order for the material. This document may be combined with a Certificate of Compliance as a single document. When preparing a Material Test Report, a material manufacturer may transcribe data produced by other organizations, provided he accepts responsibility for the accuracy and authenticity of the data.

material type: a commercial designation for a given chemistry range.

maximum working pressure: the pressure at which the system is capable of operating for a sustained period of time.

maximum working temperature: the temperature at which the system must operate for a sustained period of time. The maximum working temperature should relate to the maximum working pressure and the fluids involved.

meandering: of or pertaining to a weld bead that deviates from side to side across the weld joint rather than tracking the joint precisely.

mechanical polishing: a process by which abrasive media is applied to a surface until the specified surface roughness (R_a) is achieved.

mechanical seal: a device used for sealing fluids with rotating shafts. A mechanical seal is a prefabricated or packaged assembly that forms a running seal between flat surfaces.

micron (1 μ) or micrometer (1 μm): one-millionth of a meter.

misalignment (mismatch): axial offset of the joint members.

miter: two or more straight sections of tube matched and joined in a plane bisecting the angle of junction so as to produce a change of direction.

molded seal: a seal that is manufactured by forming in a mating cavity.

mold flash: excess material that is greater than the designed geometry of a part that is formed in the molding process.

nick: a surface void anomaly caused by material removal or compression from the surface, whose bottom surface is usually irregular.

nominal outside diameter: a numerical identification of outside diameter to which tolerances apply.

nominal wall thickness: a numerical identification of wall thickness to which tolerances apply.

nonsliding seal: a seal that does not have transverse or rotational movement between the seal and mating surface(s).

nonuniform mechanical polishing marks: a localized surface polishing pattern that is dissimilar to the surrounding area.

off angle: a measurement of face-to-face squareness.

off plane: a measurement of the offset between part centerlines or two planes.

open head: for orbital GTAW, a welding head that is open to the atmosphere external to the tube/pipe being welded and that does not enclose the shielding gas, which is still provided through the torch.

orange peel: large-featured, roughened type of surface visible to the unaided eye whose surface appearance pattern is like that of an orange peel.

orbital welding: automatic or machine welding of tubes or pipe in-place with the electrode rotating (or orbiting) around the work. Orbital welding can be done with the addition of filler material or as a fusion process without the addition of filler.

O-ring: ring seal of circular cross section.

outboard seal: a seal that is outside the product area in the outermost part of a mechanical seal assembly.

overlap: the protrusion of weld metal beyond the weld toes or weld root. Also, in an orbital weld, that amount by which the end of the weld bead overlaps the beginning of the weld bead (not including the downslope) on a single-pass weld.

owner/user: the body upon which final possession or use rests.

oxidation: a common form of electrochemical reaction that is the combining of oxygen with various elements and compounds.

oxide island: a concentration of nonmetallic impurities (often oxides or nitrides) that may form in the weld pool and solidify on the underbead or weld top surface.

oxide layer: an area usually located in the heat-affected zone of the weldment where an oxidation reaction has taken place.

packing: a type of shaft seal formed into coils, spirals, or rings that is compressed into the seal cavity.

passivation: removal of exogenous iron or iron from the surface of stainless steels and higher alloys by means of a chemical dissolution, most typically by a treatment with an acid solution that will remove the surface contamination and enhance the formation of the passive layer.

passive layer: a chromium-enriched oxide layer on a stainless steel surface that improves the corrosion resistance of the base metal.

passivity: the state in which a stainless steel exhibits a very low corrosion rate. The loss (or minimizing) of chemical reactivity exhibited by certain metals and alloys under special environmental conditions.

PE: polyethylene, polymer material composed of carbon and hydrogen.

penetration: see *full penetration*, *incomplete penetration*, and *joint penetration*.

personal care products: products used for personal hygiene or cosmetic care.

PFA: perfluoroalkoxy, copolymer of tetrafluoroethylene and perfluorovinyl ether.

pharmaceutical: relating to the use and/or manufacture of medical drugs or compounds used to diagnose, treat, or prevent a medical condition.

pickling: a chemical process for cleaning and descaling stainless steel and other alloy parts, equipment, and systems.

pipe: pipe size is determined by diameter and schedule, series, or SDR. For bioprocessing equipment, pipe does not include tube.

pit: a small surface void resulting from a localized loss of base material.

pitch: to cause to be set at a particular angle or slope. Degree of slope or elevation.

polymer: a molecule consisting of many smaller groups. They can be synthesized either through chain reactions or by templating. Some examples of polymers are plastics, proteins, DNA, and dendrimers.

polymeric materials: a natural or synthetic material whose molecules are linked in a chain.

polypropylene (PP): polymer material composed of carbon and hydrogen.

porosity: cavity-type discontinuities formed by gas entrapment during solidification.

pressure rating: pressure at which a system is designed to operate, allowing for applicable safety factors.

process component: a component that contacts the product or process fluid. Process components include, but are not limited to, piping, fittings, gaskets, vessels, valves, pumps, filter housings, and instruments.

process contact surface: a surface under design operating conditions that is in contact with, or has the potential to be in contact with, raw materials, in-process materials, APIs, clean utilities (e.g., WFI, CIP, pure steam, process gases), or components (e.g., stoppers) and where there is a potential for the surface to affect product safety, quality, identity, strength, or purity.

product contact surface: a process contact surface that is in contact with, or has the potential to be in contact with, a product where product is defined by the owner/user. Examples of product contact surfaces may include the interior surfaces of bioreactors, transfer tubing, chromatography columns, vessels, and recirculating segments of CIP systems.

profilometer: an instrument for the measurement of the degree of surface roughness.

progressive polishing: a mechanical grinding procedure where a coarse grit material is used first and the successive operations use a finer and finer grit until the desired surface roughness is achieved.

PTFE: polytetrafluoroethylene, homopolymer material of tetrafluoroethylene.

pure steam: steam that is produced by a steam generator that, when condensed, meets requirements for water-for-injection (WFI).

purified water (PW): a classification of water according to compendial standards.

PVDF: polyvinylidene fluoride, homopolymer, and/or copolymer material composed of carbon, hydrogen, and fluorine.

pyrogen: a fever-producing substance.

R_a : log of the arithmetic mean of the surface profile.

$R_a \text{ max.}$: the highest value of a series of R_a readings.

reflow: a second weld pass made to correct a lack of fusion or missed joint.

reinforcement: see *convexity*.

rouge: a general term used to describe a variety of discolorations in high-purity stainless steel biopharmaceutical systems. It is composed of metallic (primarily iron) oxides and/or hydroxides. Three types of rouge have been categorized.

Class I rouge: a rouge that is predominantly particulate in nature that tends to migrate downstream from its origination point and can deposit on process contact surfaces. It is generally orange to red-orange in color. These particles can be wiped off a surface and are evident on a wipe. Surface composition under the rouge remains unchanged.

Class II rouge: a localized form of active corrosion. It occurs in a spectrum of colors (orange, red, blue, purple, gray, black). It can be the result of chloride or other halide attack on the surface of the stainless steel.

Class III rouge: a surface oxidation condition occurring in high-temperature environments such as pure steam systems. The system's color transitions to gold, to blue, to various shades of black, as the layer thickens. This surface oxidation initiates as a stable layer and is rarely particulate in nature. It is an extremely stable form of magnetite (iron sesquioxide, Fe_3O_4).

sanitary: see *hygienic*.

sanitary (hygienic) weld: generally considered to be a groove weld in a square butt joint made by the GTAW (or plasma) process as a fusion weld without the addition of filler material. A sanitary weld must be completely penetrated on the weld I.D., with little or no discoloration due to oxidation, and be otherwise without defects

that would interfere with maintenance in a clean and sterile condition.

schedule: dimensional standard for pipe as defined by ASTM.

scratch: an elongated mark or groove cut in the surface by mechanical means, not associated with the predominant surface texture pattern.

SDR: standard dimension ratio, a sizing system for polymer piping systems that relates wall thickness to pressure rating as defined by ISO.

seal chamber: see *stuffing box*.

seal face: surface point on which a seal is achieved.

seal point: location of process boundary created by components in contact (seal), having sufficient contact stress/load to create media or environmental isolation.

seal weld: a weld used to obtain fluid tightness as opposed to mechanical strength. (See also *autogenous fillet weld*.)

seat leakage: a quantity of test fluid passing through an assembled valve in the closed position under the defined test conditions.

self-draining: the elimination of all fluid from the system due to the force of gravity alone.

SEM: scanning electron microscope.

semi-automatic arc welding: arc welding with equipment that controls only the filler metal feed. The advance of the welding is manually controlled.

service life: the life expectancy or number of cycles for which the unit will maintain its performance.

shelf life: the duration, under specified storage conditions, from the date of manufacture to the last date the product can be placed in service without having an unacceptable effect on performance.

shell leakage: a quantity of test fluid passing from the inside of a component externally to atmosphere under the defined test conditions.

significant change (polymeric): a change that may affect form, fit, or function.

size classification: the size of surface deficits is classified in two groups: macro, referring to indications that can be seen in adequate lighting without magnification, and micro, referring to indications that can be seen only with the aid of magnification.

slag: a nonmetallic product resulting from the mutual dissolution of flux and nonmetallic impurities in some welding and brazing operations.

sliding seal: a seal that has transverse or rotational movement between the seal and mating surface(s).

slope: an incline or deviation from the horizontal. A tube or pipe installed in the horizontal plane is said to slope if one end is positioned higher than the other.

sprayer: a device used to agitate, oxygenate, or aerate a liquid by means of compressed air or gas.

spatter: the metal particles expelled during welding that do not form part of a weld.

spot electropolishing: a localized electrochemical process that is capable of producing the correct Cr to Fe ratios on the surface of a material and meeting the requirements of Table H-3.3-1 in Nonmandatory Appendix H.

spray device: device for the directed distribution (delivery) of liquids to defined process contact surfaces of equipment. (See also *static spray device* and *dynamic spray device*.)

square cut: a tube end cut perpendicular to the tangent plane.

squareness: face-to-face perpendicularity.

static seal: a stationary sealing device.

static spray device: a stationary device, designed to produce a fixed directional spray pattern.

steam-in-place (SIP): the use of steam to sanitize or sterilize a piece of equipment without the use of an autoclave.

stem seal: a seal element that is used on a shaft.

sterile: free from living organisms.

sterility: the absence of all life forms.

stringer indication: a linear void resulting from the removal of an elongated nonmetallic inclusion or secondary phase.

stuffing box: in shaft seals, the casing containing the sealing material. Seal chamber for shaft seals. (See also *packing*.)

superaustenitic stainless steel: a subgroup of austenitic stainless steels having elevated levels of nickel, chromium, and molybdenum compared with standard austenitic stainless steels (e.g., UNS S31603) and that may have other additions (e.g., nitrogen and/or copper) to increase strength and resistance to pitting corrosion and stress corrosion cracking in the presence of chlorides.

super duplex stainless steel: those duplex stainless steels whose chemical composition is designed to result in a pitting resistance equivalent number (PREN) of at least 40.

surface finish: all surfaces as defined by Part SF of the current ASME BPE Standard and/or the owner/user or manufacturer and expressed in R_a inches or meters.

surface inclusion: particles of foreign material in a metallic matrix. The particles are usually compounds such as oxides, sulfides, or silicates, but may be a substance foreign to and essentially insoluble in the matrix.

surface residual: a foreign substance that adheres to a surface by chemical reaction, adhesion, adsorption, or ionic bonding (e.g., corrosion, rouging, and staining).

survey: an announced on-site evaluation by an ASME-appointed team to review and report evidence of compliance of the applicant with regard to the requirements of the ASME BPE Standard "before" issuance or renewal of a certificate.

system volume: total volume of liquid in the system, including equipment, piping, valving, and instrumentation.

tack weld: a weld made to hold parts of a weldment in proper alignment until the final welds are made.

thermoplastic: long-chain polymers that are usually not connected by crosslinks. Once formed, these materials can be reshaped.

thermoset: long-chain polymers that are usually connected by crosslinks. Once formed, these materials cannot be reshaped.

transfer panel: a panel to which process and/or utilities are piped that mechanically precludes erroneous cross-connections.

tube: tube is sized by its nominal outside diameter. For bioprocessing equipment, tube does not include pipe.

tungsten inclusions: tungsten particles transferred into the weld deposit by occasional touching of the tungsten electrode used in the gas tungsten-arc process to the work or to the molten weld metal. These inclusions are often considered defects that must be removed and the weld repaired prior to final acceptance. Tungsten inclusions may be invisible to the unaided eye, but are readily identified in a radiograph.

unacceptable leakage: leakage level above which the system performance is considered unacceptable by the system user and applicable regulating body.

undercut: a groove melted into the base metal adjacent to the weld toe or weld root and left unfilled by weld metal.

underfill: a depression on the weld face or root surface extending below the adjacent surface of the base metal. (See also *concavity*.)

uniformly scattered porosity: porosity that is distributed in a weldment in a uniform pattern.

user: see *owner/user*.

validation: establishing documented evidence that the system does what it purports to do.

variance in luster: the appearance of a different shine or reflectivity resulting from the examination or inspection technique or from the preconditioning or conditioning of the electropolished surface.

waviness: undulations or rippling of the surfaces.

welding operator: one who operates machine or automatic welding equipment.

weld joint design: the shape, dimensions, and configuration of the weld joint.

weld whitening: a difference in appearance of grain structure between weld metal and base metal after electropolishing.

WFI: water-for-injection, a classification of water according to compendial standards.