BIOPROCESSING EQUIPMENT

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ASME Standards and Certification
CHAPTER 1
INTRODUCTION, SCOPE, AND DEFINITIONS

PART GR
GENERAL REQUIREMENTS

GR-1 INTRODUCTION

The ASME Bioprocessing Equipment (BPE) 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 Standard.

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.

New editions of the ASME BPE Standard may be used beginning with the date of issuance and become effective 6 months after the date of issuance.

GR-2 SCOPE OF THE ASME BPE STANDARD

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.
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.

Nonmandatory Appendix Z, Quality Management System, provides guidance on quality assurance programs. This is only required for organizations that are ASME BPE Certificate Holders or applicants (see Part CR). However, it may be used by any organization that implements 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 Small Vessels. Owner’s Inspector, as defined in ASME B31.3, paras. 340.4(a) and 340.4(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 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
To be considered as a QID-1, personnel shall meet the following:

1. a trainee for a minimum of 6 months of documented relevant industry experience. Alternate methods for meeting the work experience requirement are at least one of the following:
   - prior or current certification as a QID-1
   - completion with a passing grade of at least 2 years of engineering or science study in a university, college, or technical school
   - possess an AWS CWI certificate
   - or ACCP Level II VT certificate or international equivalent
   - 2 years of documented relevant experience in inspection, examination, or testing activities

To be considered as a QID-2, personnel shall meet the following:

1. be a QID-1 for a minimum of 6 months of documented relevant industry experience. Alternate methods for meeting the work experience requirement are at least one of the following:
   - prior or current certification as a QID-2
   - completion with a passing grade of at least 4 years of engineering or science study in a university, college, or technical school
   - possess an AWS CWI certificate or ACCP Level II VT certificate or international equivalent
   - 2 years of documented relevant experience in inspection, examination, or testing activities of high-purity/hygienic systems

To be considered as a QID-3, personnel shall meet the following:

1. be a QID-2 for a minimum of 24 months of documented relevant industry experience. Alternate methods for meeting the work experience requirement are at least one of the following:
   - prior or current certification as a QID-3
   - 3 years of documented relevant experience in inspection, examination, or testing activities of high-purity/hygienic systems

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

2. receive a minimum of 16 additional hours 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

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:
   - 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.
   - 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.

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.

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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.
### Table GR-4.2-1 Inspector’s Delegate Capabilities

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<tr>
<th>Capability</th>
<th>Trainee</th>
<th>QID-1</th>
<th>QID-2</th>
<th>QID-3</th>
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<td>(4) Elastomers</td>
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<td>(5) Process components</td>
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<td>(c) Measure material dimensions</td>
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<td>(e) Verify material documentation</td>
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<td>(c) Borescope/fiberscope</td>
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<td>(d) Profilometer</td>
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<td>(f) Calibration records (inspection equipment)</td>
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<td><strong>Knowledge and Skills</strong></td>
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<td>Understand inspection fundamentals</td>
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<td>(a) Effective oral and written communication</td>
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<td>(b) Quality procedures</td>
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<td>(1) Prepare documentation control requirements</td>
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<td>(2) Develop inspection procedures</td>
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<td>(c) Review of specifications</td>
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<td>(d) Codes and Standards (training)</td>
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<td>(e) Interpret welding symbols and drawings</td>
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<td><strong>Knowledge and Skills (Cont’d)</strong></td>
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<td>(5) General/fabrication arrangement drawings (details)</td>
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<td>(6) Interpret welding symbols</td>
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<td>(f) Prepare documents/reports in accordance with GR-5.3</td>
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<td>(1) Material examination log</td>
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<td>(5) Pressure test</td>
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<td>(g) Turnover package</td>
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<td>(1) Assemble</td>
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<td>(2) Review</td>
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<td>(h) Basic understanding of NDT/NDE</td>
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<td><strong>Inspection</strong></td>
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<td>(a) Perform visual inspection (other than weld inspection)</td>
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<td>(b) Perform weld inspection</td>
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<td>(c) Evaluate weld inspection results</td>
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<td>(d) Perform slope verification</td>
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<td>(e) Witness pressure tests</td>
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<td>(f) Verify inspection compliance</td>
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<td>(g) Review inspection reports</td>
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<td>(h) Verify nonconformance disposition</td>
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<td>(i) Perform installation verification</td>
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<td>(a) Verify surface finish</td>
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<td>(b) Verify drainability</td>
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<td>(c) Cleanability (CIF/riboflavin/sprayball testing)</td>
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<td>(d) Verify dimensions and orientation</td>
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<td>(f) Documentation review</td>
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<td><strong>Welding Procedure Qualification</strong></td>
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<td><strong>Welder and/or Welding Operator Performance Qualification</strong></td>
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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.

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.

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

Project Planning

(a) Review contract requirements
(b) Prepare weld inspection criteria
(c) Review specifications
(d) Prepare purchase specifications
(e) Develop inspection plan

Training

(a) Provide on-the-job training for Quality Inspectors
(b) Maintain records of training

Audit

(a) Perform vendor audits
(b) Perform fabricator audits
(c) Prepare audit and surveillance plan

GR-5.2.1.1 Turnover Package Documentation.

ASME BPE-2019
(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 (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

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
(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

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.

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

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) identification of blind welds
(h) identification of manual welds
(i) 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 U has been provided as a guide for U.S. Customary and SI unit conversion.

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)

AWS A3.0M/A3.0, Standard Welding Terms and Definitions
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
AWS QC1, Standard for AWS Certification of Welding Inspectors
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 MFC-22, Measurement of Liquid by Turbine Flowmeters
ASME PTC 19.3 TW, Thermowells
ASME PVHO-1, Safety Standard 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 A1015, Standard Guide for Chemical Videoborescoping of Tubular Products for Sanitary Applications
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 Rubber Property — Elongation at Break
ASTM D2240, Standard Test Method for Rubber Property — Shore A 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 E644, Standard Test Method for Rubber Property — Tensile Elongation
ASTM E1515, Standard Guide for Use of Mass Spectrometers to Perform Leak Detection in the Probe Mode
ASTM E1586, Standard Test Method for Rubber Property — Tensile Stress—Strain Properties
ASTM E1621, Standard Test Method for Rubber Property — Hardness Between 10 IRHD and 100 IRHD
ASTM E2530, Standard Guide for Calibration of Ionization Gauges and Ionization Gauge Detectors
ASTM E2950, Standard Guide for Use of Mass Spectrometers to Perform Leak Detection in the Probe Mode
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, Standard Test Method for Rubber Property — Compression Set — Part 1: At ambient or elevated temperatures
ISO 816, Superseded by ISO 34-2
ISO 1817, Rubber, vulcanized — Determination of the effect of liquids
ISO 1402, Rubber and plastics hoses and hose assemblies — Hydrostatic testing
ISO 2859-1 Sampling procedures for inspection by attributes
DVS 2202-1, Imperfections in Thermoplastic Welding Joints; Features, Descriptions, Evaluation
DVS 2202-2, Imperfections in Thermoplastic Welding Joints; Acceptance Sampling Plans
DVS 2202-3, Imperfections in Thermoplastic Welding Joints; Features, Descriptions, Evaluation
DVS 2202-4, Imperfections in Thermoplastic Welding Joints; Acceptance Sampling Plans
DVS 2202-5, Imperfections in Thermoplastic Welding Joints; Acceptance Sampling Plans
Animal Derived Ingredients (ADI): Products or ingredients derived from tissues or secretions of animals susceptible to Transmissible Spongiform Encephalopathies (TSEs), primarily cattle's Bovine Spongiform Encephalopathy (BSE).

Animal Derived Products (ADP): products made from Animal Derived Ingredients (ADI)

audit: an ASME Certificate Holder’s documented evaluation of a supplier performed to verify, by examination of objective evidence, that those selected elements of a previously approved quality management system have been developed, documented, and implemented in accordance with specified requirements. A surveillance is not an audit.

audit (as performed by ASME or their designee on ASME BPE Certificate Holders and Applicants): See CA-1.

MSS-SP-72, Ball Valves with Flange or Butt-Welding Ends for General Service
MSS-SP-88, Diaphragm Valves
MSS-SP-110, Ball Valves Threaded, Socket-Welding, Solder Joint, Grooved and Flared Ends
Publisher: Manufacturers Valve and Fittings Industry, NE, Vienna, VA 22180

NIH (BL-1/BL-4), Biohazard Containment Guidelines
Publisher: National Institutes of Health (NIH), 9000 Rockville Pike, Bethesda, MD 20892

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 (www.usp.org/usp-nf)

PFI Standard ES-50 Internal Oxidation for Piping Welds
Publisher: Pipe Fabrication Institute (PFI), 5901 Coastal Hwy #27, Ocean City, MD 21842

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: generic term for a group of optical instruments for visual examinations. This includes rigid borescopes and flexible borescopes (fiberscopes). Often a camera chip is mounted to the borescope. (See also videoscope.)

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.

conformity: meeting, acting or behaving in accordance with a specification, procedure, method, stated rule or standard such as the ASME BPE Standard. Non-conformity is a process or action or system that does not conform to a stated quality requirement, specification requirement, procedure or standard such as the ASME BPE Standard that authorizes the use of an ASME BPE Symbol Stamp for a system or component. (See pure steam.)

Compliance: Performing a function or operation in a recognized way to abide by a law or legislative requirement such as complying with the Code of Federal Regulations (CFR). Compliance is externally imposed. Non-compliance is the failure to adhere to an act or law or regulation.

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Compliance: Performing a function or operation in a recognized way to abide by a law or legislative requirement such as complying with the Code of Federal Regulations (CFR). Compliance is externally imposed. Non-compliance is the failure to adhere to an act or law or regulation.
drainable: a designed characteristic of a component, equipment, or system that enables the removal of water by means of gravity except for that which remains due to surface adherence. Drain paths that become blocked due to surface-adhered water are not considered drainable.

dead leg: a space where system design and operating conditions result in insufficient process fluid flow, presenting a risk for particulate, chemical, or biological contamination.

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

deonized 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.

direct visual examination: a visual examination where there is an uninterrupted optical path from the observer’s eye to the area to be examined. This can be either unaided or aided via mirrors, lenses, etc.

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

discoloration: any change in surface color from that of the basemetal. 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 into 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.

examination: as it relates to pressure vessels, vessels not rated for pressure service, process piping, and process contact equipment: the quality control functions carried out by the manufacturer, fabricator, or erector in accordance with ASME BPVC Section VIII.

everse 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.
looped header: a piping ring with multiple branches for inlet or outlet. The branches on the ring can be closed by valves, caps or other means of flow isolation.
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 or compression from 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.

Multi-use: A term describing process contact components, equipment and systems that are designed to be cleaned, sanitized or sterilized, and used multiple times (also referred to as repeated use).

packing: a type of shaft seal formed into coils, spirals, or pressed into the seal cavity.

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 material: 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. Examples of process components include, but are not limited to, piping, fittings, gaskets, valves, and instruments.

process contact surface: a surface or area that is in contact with, or has the potential to be in contact with, raw materials, in-process materials, APIs, and/or process fluid. Process contact surfaces include, but are not limited to, tubes, fitting, gaskets, and filters.

process equipment: an assembly of components that, when combined, provide the platform for one or more process operations including, but not limited to, storage, momentum transfer, heat transfer, mass transfer and separation. Examples of process equipment include, but are not limited to, pumps, vessels, heat exchangers, chromatography columns, centrifuges, and filter housings.

sanitary: see hygienic.

process system: an assembly of components, equipment, and subsystems that, when integrated, provide a platform for one or more process operations to produce an output within predefined specifications. Examples of process systems include, but are not limited to, bioreactor, chromatography, CIP and purified water systems.

schedule: dimensional standard for pipe as defined by ASTM.

scratch: an elongated mark or groove cut in the surface by 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.)

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: Leakage inside of a process system that is defined as the flow of a fluid, either added to the system or present in the system from the time of manufacture, to the outside of the defined system.

Significant form, fit, or function change: A change that may affect the performance of a component, assembly, or system.

Size classification: A method of classifying materials based on their size, such as micro, having microscopic dimensions, and macro, having dimensions visible to the naked eye.

Spatter: The metal particles expelled during welding that do not form part of a weld.

Spangle: 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.

Sterile: Free from living organisms.

Sterility: The absence of all life forms.

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.

Testing (as it relates to vessels): A function of the manufacturer, fabricator, or erector, as witnessed by the examiner or Inspector and verified or witnessed by the owner's Inspector or the Inspector's Delegate including written documentation in accordance with ASME BPVC Section VIII (or equivalent for other applicable codes or standards).

Testing (as it relates to process piping): A function of the manufacturer, fabricator, or erector, as witnessed by the examiner or Inspector and verified or witnessed by the owner's Inspector or the Inspector's Delegate including written documentation in accordance with ASME BPVC Section VIII (or equivalent for other applicable codes or standards).

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

Testing (as it relates to process contact equipment): A function of the manufacturer, fabricator, or erector, as witnessed by the examiner or Inspector and verified or witnessed by the owner's Inspector or the Inspector's Delegate including written documentation in accordance with ASME BPVC Section VIII (or equivalent for other applicable codes or standards).

Testing (as it relates to pressure vessels): A function of the manufacturer, fabricator, or erector, as witnessed by the examiner or ASME Authorized Inspector and verified or witnessed by the owner's Inspector or the Inspector's Delegate including written documentation in accordance with ASME BPE or ASME BPVC Section VIII (or equivalent for other applicable codes or standards).

Testing (as it relates to vessels not rated for pressure): A function of the manufacturer, fabricator, or erector, as witnessed by the examiner or Inspector and verified or witnessed by the owner's Inspector or the Inspector's Delegate including written documentation in accordance with ASME BPVC Section VIII (or equivalent for other applicable codes or standards).

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

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.

Steam-in-place (SIP): A function of the manufacturer, fabricator, or erector, as witnessed by the examiner or Inspector and verified or witnessed by the owner's Inspector or the Inspector's Delegate including written documentation in accordance with ASME B31.3.
CHAPTER 2
DESIGN

PART SD
SYSTEMS DESIGN

SD-1 PURPOSE AND SCOPE

The purpose of Part SD is to establish design guidelines applicable to bioprocessing equipment. Wherever “equipment” is stated in this Part, it shall mean all bioprocessing equipment, components, assemblies, and systems.

The purpose of this Part is to provide requirements for the specification, design, fabrication, and verification of process equipment and systems that are fit for intended use, and to minimize risk to the product. Part SD also provides design guidelines that should be applied at the discretion of the owner/user on the basis of assessed risk to the product. Figures in this Part are intended to illustrate accepted applications of general design principles and are not intended to limit alternate designs.

The scope of Part SD encompasses requirements for equipment, process systems, and utilities that could potentially impact product quality. Specific guidance is provided for bioburden control in manufacturing processes, including design requirements for cleaning, sanitization, and/or sterilization of bioprocess systems.

SD-2 GENERAL GUIDELINES

All equipment and/or systems shall be designed according to the bioprocessing application, requirements, and specifications of the owner/user. It shall be the responsibility of the owner/user to specify the cleaning and/or sanitization requirements of the equipment or system.

Following installation, to remove construction debris and/or foreign bodies, process contact liquid-service systems should be flushed with deionized or better-quality water and/or chemically cleaned, per owner/user’s requirements, before being placed into service. This does not apply to single-use or precleaned components.

The design shall provide for the removal of components (e.g., pumps, control valves, spray devices, instrumentation) that may be damaged by construction debris during flushing. If removal is not practical, the design shall allow for a temporary strainer installed upstream of the component, sized to catch the debris.

The pipe design and the flushing sequence, including associated variables (e.g., velocity), shall meet the owner/user’s requirements.

SD-2.1 Containment

The containment level of the system or individual pieces of equipment should be specified and communicated by the owner/user.

The owner/user shall determine the containment level for the particular type of equipment in accordance with the Centers for Disease Control and Prevention (CDC) and guidelines of the National Institutes of Health (NIH) or directives of the applicable local codes or environments.

SD-2.2 Bioburden Control

(Reserved for future content)

SD-2.3 Bioburden Reduction

SD-2.3.1 Thermal Sanitization. Thermal sanitization is the application of heat to reduce bioburden in a system. Bioburden reduction can be accomplished by the appropriate application of moist heat or dry heat. Specific temperatures and exposure times depend on the objectives. Thermal sanitization includes the following: dry heat treatment, SIP for sanitization, SIP for sterilization, steam out of place (autoclaving), hot liquid sterilization, and hot liquid sanitization.

SD-2.3.1.1 Steam-in-Place. Equipment parts and components subjected to SIP should be designed and constructed to withstand continuous exposure to saturated steam at a minimum temperature of 266°F (130°C; representing 24 psig/1.65 bar under saturated steam conditions) for a duration of at least 100 hr under continuous steady-state conditions. All process contact surfaces subjected to SIP shall reach the required temperatures, under the required saturated steam conditions, during the SIP cycle. Executing SIP operations at temperatures exceeding 266°F (130°C) may cause degradation of elastomers and/or damage to other components.

This section specifies the design requirements for equipment that is sterilized or sanitized by the application of heat.
**SD-2.2 Bioburden Control**

Part SD provides recommended design features of components and equipment that should be incorporated into hygienic systems. These design elements, properly implemented and in conjunction with proper bioburden reduction measures such as CIP/SIP, etc., enable hygienic systems to control bioburden.

It is the owner/users’ responsibility to provide the following information for the designer to determine the design features required to maintain bioburden control:

a) the acceptable level of bioburden before, during, and at completion of a process step or sanitization interval.

b) the duration that bioburden control needs to be maintained whether in a closed-process or open-process system.

This part does not address self-sanitizing processes but addresses features of continuously operated systems such as hot water-for-injection and pure steam that control bioburden by continuous heat and are considered self-sanitizing process utility systems.
SD-2.3 Bioburden Reduction

Bioburden reduction is an activity performed with the purpose of achieving a measured reduction in bioburden levels, in the equipment or product, to allowable levels. Depending on the chosen methodology or goal, the activity may be performed prior to equipment use, between process steps, or during a process step.

For process operations in multi-use systems, bioburden reduction is typically accomplished by, but not limited to:

a) cleaning (with or without chemicals)
   1) clean-in-place (CIP)
   2) clean-out-of-place (COP)

b) steaming
   1) steam-in-place (SIP)
   2) autoclaving

c) dry heat

d) process heating
   1) batch heating
   2) pasteurization
   3) high temperature-short time (HTST)
   4) ultra-high temperature (UHT)

e) process filtration

f) chemical sanitization
   1) ozone
   2) vaporous hydrogen peroxide (VHP)
   3) chlorine dioxide
   4) other acids, bases, or solvents

g) ultraviolet light

For single-use systems, where sanitization/sterilization occurs prior to product contact, bioburden reduction is typically accomplished by, but not limited to:

a) gamma-irradiation
b) autoclaving
c) electron beam (E-beam)
d) ozone
e) ethylene oxide (ETO)
in reduction of overall equipment life. SIP conditions that are more stringent may be imposed by the owner/user. The use of elastomers (within a piece of equipment or certain process instrumentation) that could thermally degrade during SIP shall be evaluated by the owner/user.

**SD-2.3.1.1 Requirements.** Process systems subject to SIP shall be designed to

(a) provide for air removal within the SIP boundary
(b) provide for condensate drainage within the SIP boundary
(c) be drainable in conformance with SD-2.4.3
(d) have provisions in place for verification of SIP performance
(e) have no dead legs within the SIP boundary

SD-2.3.1.2 Recommendations. Process systems subject to SIP should be designed to

(a) avoid concurrent steam supplies from alternate locations to prevent stagnant zones/entrained air
(b) monitor temperature and pressure at appropriate locations (e.g., vessels) that confirm saturated steam conditions within the SIP boundary
(c) monitor temperature at every SIP boundary point during performance verification
(d) enable continuous verification or periodic confirmation of the validated state
(e) maintain the integrity of the system post-SIP

SD-2.3.2 Depyrogenation. [Reserved for future content]

SD-2.3.2 Chemical Sanitization. [Reserved for future content]

**SD-2.4 Fabrication**

Fabrication shall be performed in facilities where the process contact surfaces are protected from contamination. During field welding and assembly, surface contamination shall be prevented.

Systems, equipment, and components shall be cleaned with a suitable cleaning agent and covered for protection before shipment. The use of preservative fluids is not recommended.

Any process contact surfaces that require shipment with preservatives or coatings shall be

(a) mutually agreed to, in advance, by the owner/user and manufacturer
(b) clearly identified to all parties
(c) in compliance with FDA or other applicable regulations, as appropriate for the process

**SD-2.4.1 Materials of Construction**

SD-2.4.1.1 General. Generally, materials such as stainless steels (e.g., 316-type and 316L-type alloys), duplex stainless steels, and higher alloys have proven to be acceptable. The owner/user shall be responsible for the selection of the appropriate materials of construction for the specific process. Metallic materials of construction are listed in Part MM.

When nonmetallic materials are used (e.g., polymeric materials or adhesives), the owner/user shall specify which one of these materials shall carry a Certificate of Compliance. The conformance of material shall be explicitly stated (e.g., conforming to FDA 21 CFR 177 and USP Section #88> Class VI). Polymeric materials and other nonmetallic materials of construction are listed in Part PM.

**SD-2.4.1.2 Process Compatibility**

(a) Materials of construction shall be capable of withstanding the temperature, pressure, and chemical corrosiveness of the process.

(b) Materials shall be compatible with the stated bioprocessing conditions, cleaning solutions, and SIP conditions, etc., as specified by the owner/user.

(c) Surfaces exposed to bioprocessing fluids, cleaning, and SIP conditions must be

(1) homogeneous in nature
(2) impervious
(3) inert
(4) nonabsorbent
(5) nontoxic
(6) insoluble by process or cleaning fluids
(7) resistant to corrosion, scratching, scoring, and distortion

(d) Materials that are in contact with bioprocessing fluids shall be identified by an industry-recognized standard (see para. MM-4).

SD-2.4.1.3 Surface Coatings. Clad or electroplated surface coatings, plating, and surface preparatory chemicals may be used provided approval from the owner/user has been obtained. All surface coatings shall remain intact and be tolerant to the process, SIP and CIP fluids, and temperatures, without peeling or cracking.

**SD-2.4.2 Cleanability**

(a) The following provisions are applicable to tubing, equipment, or systems intended to be cleaned:

(1) All surfaces shall be cleanable. Surface imperfections (e.g., crevices, gouges, obvious pits) should be eliminated whenever feasible.

(2) All surfaces shall be accessible to the cleaning solutions and shall be accessible to establish and determine efficacy of the cleaning protocol.
Drainable

enable removal

enable condensate removal

Drainable

designed to be drainable

or capable of having energy applied (e.g., pressurized gas, vacuum, heat) to remove liquid.

Surface tension and surface adherence

BA1

Drainable

Drainable

Drainable

Drainable

Drainable

Decrease point drains and high-point vents for drainability

drained and vents

enable draining. For drainability

SD-2.4.3 Drainability

SD-2.4.3.1 General. For the purpose of bioburden control and cleaning, gravity is an effective way to facilitate drainage. To achieve gravity drainage, lines should be pitched to designated points at a specific slope. Refer to Nonmandatory Appendix C for suggested method of slope measurement. For gravity-drained piping/tubing systems, the owner/user may define the system slope in accordance with one of the designations listed in Table SD-2.4.3.1-1. Gravity-drained piping/tubing systems shall have a continuous pitch that is equal to or greater than the slope designation. Line sections up to 10 in. (25 cm) in length (or longer with advance approval of the owner/user) that are level or have a positive slope less than the slope designation are acceptable if the section is fitting-bound.

SD-2.4.3.2 Drainability Design Considerations. The system’s process requirements should be considered in the selection of slope designation.

(a) Process contact lines exposed to liquid should be sloped to facilitate pooling in the system.

(b) Lines that are steam sterilized in place should be sloped to facilitate gravity drainage of condensate.

(c) Lines that are cleaned in place should be sloped to facilitate gravity drainage of cleaning fluids.

The physical characteristics of the system (e.g., line size, materials, fluid viscosity, fluid surface tension) will influence drainability at a given slope and should also be considered. The owner/user may apply in the selection of slope designation to a factor such as product recovery or maintenance. Fluid retention due to capillary action should be considered when using tubing less than 3∕4 in. (20 mm). System leveling should be considered for mobile equipment that is gravity-drained.

SD-2.4.3.3 Slope Considerations. The recommended minimum slope designation for gravity-drained process contact lines is GSD2.

SD-2.4.3.4 Drain Points

(a) Piping and equipment should be installed with designated drain points to minimize self-draining properties. The number of drain points should be minimized. The equipment manufacturer shall indicate the proper orientation to optimize drainability. The owner/user shall ensure that proper orientation is achieved.

(b) Systems or equipment that cannot be gravity-drained shall use forced expulsion with pressurized gas where line drainability is required.

SD-2.4.4 Miscellaneous Design Details

SD-2.4.4.1 Lubricants

(a) Grease and other lubricating fluids that are used in gearboxes, drive assemblies, etc., shall be contained to prevent leakage of the lubricants or process, either directly or indirectly (e.g., through seepage, seal leaks).

(b) The equipment manufacturer shall specify the type of lubricants that are to be used for maintenance. If the specified lubricant is not accepted by the owner/user, the choice of an alternative shall be agreed to by the owner/user and the equipment manufacturer.

(c) The owner/user shall give his approval for the lubricants that could come in contact with the environment, and grade and shall conform to FDA or other regulatory codes.
**SD-2.4.4.2 Exterior Design.** Equipment located in clean areas is periodically cleaned by wash-down or manually cleaned by wipe-down with harsh cleaning solutions. Such equipment shall conform to the following:

(a) Materials of construction should be corrosion-resistant, easily maintained, cleaned, and sanitized without flaking or shedding.

(b) Finishes shall be compatible with the area/room classification as agreed to by the owner/user and manufacturer.

(c) Components shall be capable of being chemically cleaned, steam cleaned, or pressure washed.

(d) All burrs or weld marks shall be removed.

(e) Hinges should be easily removable and/or cleanable.

(f) Equipment mounted on cabinets that are exposed to the environment should be mounted flush.

(g) Skids should have no openings in the frame allowing water retention. Supporting skid frame structures and modules should be constructed from fully sealed tubes or pipes, which are easily cleaned. Frames should have rounded rather than sharp edges.

(h) Motors, gearboxes, and similar equipment should not retain fluids or cleaning solutions on their external surfaces.

(i) Nameplates for tagging equipment should be constructed from corrosion-resistant material, such as stainless steel or polymeric material, and should have minimal crevices. The nameplates should be attached and sealed or attached with a corrosion-resistant wire loop.

(j) There should be adequate clearance below or under the equipment for cleaning, and a clearance for discharge should be provided. Elevated equipment under open frames should have a minimum clearance of 6 in. (150 mm) for wash-down and cleaning. In other cases a minimum of 4 in. (100 mm) would be adequate.

(k) Joints and insulation materials shall be sealed and impervious to moisture and cleaning agents.

(l) Electrical enclosures and conduit should be cleanable and use materials of construction that are compatible with cleaning agents.

(m) Painted surfaces shall be identified by the fabricator and have the advance approval of the owner/user. All paint systems shall be FDA compliant.

**SD-2.4.4.3 Surface Finishes.** The finishes of process contact surfaces shall be specified by the owner/user in accordance with the definitions of **Part SF** in this Standard.

**SD-2.5 Hygienic System Design**

The hygienic design of the system shall incorporate the applicable functionality for passivation, cleaning, sanitization, steam-in-place, process fluid distribution, and process parameter measurement and control. The system’s hygienic physical (general arrangement) design shall be integral with its operations including, but not limited to, valve sequencing, parameter measurement, and controls. The owner/user and designer shall evaluate the design across all operations to confirm that the design mitigates contamination risk to the product and to identify installation, operational, and performance verification testing requirements.

**SD-2.5.1 Tube/Pipe Branches.** Tube/pipe branches that are closed (e.g., closed valve, capped branch tee) during an operation should be designed and installed to mitigate contamination risk. Tube/pipe branches closed during CIP/SIP operations, designed to meet the minimal dimensional and orientation criteria detailed in **SD-3.1.2.2**, are not dead legs if they are operated, cleaned, or sanitized under specified conditions (e.g., velocity, temperature, time). Tube/pipe branches that are open during CIP/SIP shall be designed to enable flow of cleaning/sanitizing fluids under specified conditions. Tube/pipe branches with valves that are cycled during processing operations should be designed to mitigate cross-contamination risk and are not dead legs if they are toggled, cleaned, or sanitized under specified conditions (e.g., flow/impingement, steam penetration, temperature, time).

**SD-2.5.2 Tube/Pipe Instruments.** Process tubing/piping instrumentation and associated connection points should be designed to mitigate the risk of contamination due to extended ferrule connections and any annular space around the sensor. Instrument tees or short-outlet tees conforming to **DT-4.1.2** should be used where feasible, maintaining \( L/A < 2 \) [see **Figure SD-3.4.3-1**, illustration (a)]. When an instrument tee or short-outlet tee is not used, the tee should be oriented such that cleaning and sanitization fluids circulate into the branch and annular space around the instrument sensor, and air is not trapped, to avoid the formation of a dead leg. The system designer shall identify instrument locations where \( L/A \) or \( L/d < 2 \) is not met.

**SD-2.5.3 Equipment Nozzles.** Equipment nozzles used to accommodate agitators, controls, instrumentation, or process fluid transfer should be designed to mitigate contamination risk due to extended connections or the annular space around the inserted appurtenance by meeting the dimensional and orientation criteria detailed in **SD-3.5.1** and **SD-3.4.3**. Equipment nozzles closed during CIP/SIP operations shall be designed to meet the minimal dimensional and orientation criteria detailed in **SD-3.4.2**.

**SD-2.6 Animal Derived Ingredients**

Process contact surfaces of components, equipment and systems shall be constructed from and processed with materials that are free from animal-derived ingredients/products (ADI/ADP), or shall be manufactured with materials that meet the conditions of the Committee for Medicinal Products for Human Use (CHMP formerly known as CPMP) Note for Guidance (EMA/410/01 rev 3).
SD-3 PROCESS COMPONENTS

SD-3.1 Connections, Fittings, and Piping

(a) Design of equipment should minimize the number of connections. Butt-welded connections should be used wherever practical.

(b) Connections to equipment shall use acceptable hygienic design connections, mutually agreeable to the owner/user and manufacturer.

(c) All connections shall be capable of CIP and SIP. Fittings shall be so designed that there will not be any crevices or hard-to-clean areas around the gasketed joint. ASME raised-face or flat-face flanged joints shall be avoided where possible (see Figure SD-3.1.1-1).

(d) Ferrules and ferrule connections should not constitute a dead leg. The use of short welding ferrules should be incorporated into the design to promote enhanced cleanliness and bioburden reduction of the system.

(e) All process contact fittings exposed to liquid should be self-draining when properly installed.

(f) Threaded fittings, exposed to process fluid, are not recommended (see Figure SD-3.1.1-1).

(g) The use of flat gaskets may be acceptable, when agreed to by the owner/user and manufacturer, for applications where it is considered self-sanitizing (i.e., in pure steam distribution systems).

(h) The centerline radius of factory-bent tubes shall be in accordance with Table DT-3.1, CLR, (R).

(i) Piping systems described in Part SD refer to hygienic tubing systems. Caution should be exercised if using pipe (instead of tube) to ensure that the requirements of this Standard are met. The requirements of hygienic tubing (e.g., surface finish, dimensions, and tolerances) are not typically met by pipe.

SD-3.1.2 System Design

SD-3.1.2.1 General

(a) Product holdup volume in the system should be minimized.

(b) Bioprocessing piping and tubing design should have routing and location priority over process and mechanical support systems.

(c) Piping and connections to in-line valves should be of all-welded construction where feasible, practical, and agreed to by the owner/user and manufacturer. To ensure the highest degree of hygienic design, the piping systems should use welded connections except where make-break connections are necessary.

SD-3.1.2.2 Closed Tube/Pipe Branches. Closed tube/pipe branches will be measured by the term L/d, where L is the leg extension from the I.D. wall normal to the flow pattern or direction, and d is the I.D. of the extension or leg of a tubing fitting or the nominal dimension of a valve or instrument. For valves, L shall be measured to the seal point of the valve. Tables SD-3.1.2.2-1 and SD-3.1.2.2-2 indicate L/d values based on the BPE definition for various tubing geometries and configurations.

There is evidence that an L/d of 2 or less may prevent the branch from being a dead leg; however, the size and shape of the branch are also important in determining if the branch could lead to contamination. With sufficient flow through a primary pipeline, a branch may not constitute a dead leg.

The orientation of a branch is critical to the cleanliness of the system. The branch shall be oriented to avoid a dead leg (e.g., a vertical branch with an L/d of 2 or less may still result in a dead leg with trapped gas or residual materials).

For high-purity water systems, an L/d of 2 or less is attainable with today’s manufacturing and design technology. For other bioprocessing systems, such as purification, filtration, and fermentation, having cluster, block, and multiport valves, an L/d of 2 or less is achievable. However, it may not be achievable with certain equipment and process configurations as they are currently manufactured. An L/d of 2 or less is recommended but shall not be construed to be an absolute requirement. The system designer and manufacturer shall make every attempt to eliminate system branches with an L/d greater than 2. It will be the responsibility of the system manufacturer or designer to identify where exceptions exist or where the L/d of 2 or less cannot be met.

An L/d of 2 or less may not be achievable for weir-type valves clamped to tees and certain sizes of close welded point-of-use valves, as shown in Figure SD-3.1.2.2-1, illustrations (a), (d), (e), (f), and (g). For the header and valve size combinations where the L/d of 2 cannot be met using these configurations, a specific isolation valve design, as shown in Figure SD-3.1.2.2-1, illustrations (b) and (c), may be required to achieve the desired ratio.

SD-3.1.2.3 System Piping

(a) Routing of piping should be as direct and short as possible to ensure a minimal quantity of CIP solution to fill a circuit and eliminate excessive piping and fittings.

(b) Cross-contamination of process streams shall be physically prevented. Methods of separation used in industry are

(1) removable spool piece
(2) U-bend transfer panel
(3) double block-and-bleed valve system (see Figure SD-3.1.2.3-1)
(4) mix-proof valving
(5) The use of fluid bypass piping (around traps, control valves, etc.) is not recommended.

(d) The use of redundant in-line equipment is not recommended due to the potential creation of dead legs.

(e) Eccentric reducers shall be used in horizontal piping to eliminate pockets in the system.
The system shall be designed to eliminate air pockets and prevent or minimize air entrainment.

Field bending of tubing is permitted for diameters up to and including ½ in. (15 mm). The centerline radius of field-bent tubes should be not less than 2.5 times the nominal tube diameter to mitigate the risk of interior surface damage (e.g., wrinkles, striations, and cracks). Field bending of tubing in larger diameters or smaller bend radii may be used with the approval of the owner/user when appropriate examination techniques and procedures (e.g., visual, borescope, and sectioning) are used.

Ball valves are not recommended in fluid hygienic piping systems. See SD-4.2.3(b) for further comments.

Passivation of electropolished surfaces is not required unless the surface has been altered (e.g., welded or mechanically polished) or exposed to external contamination after electropolishing.

The use of blind welds in piping systems should be avoided. Proper installation sequencing of the piping system can reduce the number of blind welds. See MJ-7.3.3(b) and GR-5.3.4 for further details.

SD-3.1.2.4 Hygienic Support Systems

Hygienic supports should be used within classified spaces. Hygienic support design should incorporate drainable geometry to facilitate cleanability, have no exposed threads, and have minimal potential for collecting and trapping debris or liquids on the hanger. Materials of construction shall be corrosion resistant and compatible with the chemical, thermal, and physical performance requirements of the installed location. The materials shall have adequate strength and durability to withstand the application of continuous and/or cyclic thermal exposure that may be encountered in the designed service.

The piping should maintain proper continuous slope for drainability. Hygienic support systems shall assist in maintaining the required slope and alignment under all operating conditions, taking into account thermal cycling, distortion, settling, moment loads,
fluid specific gravity, etc. The support system should be designed to distribute loads and stresses from any potential movement. The supports shall be installed without adding stress to the tube or pipe in an attempt to achieve a desired slope.

(c) The support systems shall provide for, and control, the intended movement of the system. The designer should take into account system and equipment movement when planning the design. Anchoring systems should be designed to avoid piping motion in any of the three Cartesian axes. Guiding systems should be designed to allow piping axial motion due to thermal loads. An anchor serves to secure the piping in place, and a guide will allow axial motion of the piping. The only exception is on short subassemblies using small-diameter tube (<1.000 in. outside diameter (O.D.)] that is installed in a drainable section and shall be manufactured with no sharp edges that may embed or cause damage to the pipe exterior. These are commonly available in stainless steel or fiber-glass reinforced plastic (FRP) materials. These supports cannot restrict axial movement of the piping and shall be approved by the owner/user.

SD-3.2 Hose Assemblies

SD-3.2.1 General

(a) Permanently installed hose assemblies shall be installed and supported to be self-draining [see Figure SD-3.2.1-1, illustrations (a) and (b)]. In temporary runs, hose assemblies may be manually drained after disconnecting.

(b) Hose assemblies shall be installed to avoid strain on end connections. Hose assemblies shall not be used as a substitute for rigid tube fittings or as tension or compression elements.

(c) Hose assembly length should be minimized and fitted for purpose.

(d) Hose assemblies shall be easy to remove for examination and/or cleaning.

(e) Hose assembly shall be clearly marked or tagged with the design-allowable working pressure/vacuum and design temperature range.

(f) Hose assemblies shall be inspected and maintained on a scheduled basis.

SD-3.2.2 Flexible Element

(a) The flexible element of the hose assembly shall be constructed of materials that permit the appropriate degree of movement or drainable offset at installation.

(b) The interior surface of the flexible element shall be cleanable and drainable.

(c) The materials used shall comply with the applicable requirements in Part PM and/or Part SC with regard to biocompatibility. The materials used must also be compatible with cleaning and/or SIP conditions.

SD-3.2.3 End Connections

(a) End connections shall be of a material and design sufficiently rigid to withstand the combined forces of the burst pressure rating of the flexible element and the compression forces required to affect the secure assembly with the flexible element. [Refer to Figure SD-3.2.1-1, illustrations (c) and (d)].

(b) End connections shall be of a material compatible with the process fluid, cleaning solutions, and steam where applicable. Materials shall meet the requirements of SD-2.4.1 or Part PM.

(c) End connections shall meet all surface finish requirements of Part SF.

(d) End connections shall be a hygienic connection design per SD-3.3.2.
SD-3.3 Pumps

SD-3.3.1 Diaphragm Pumps

(a) Diaphragm pumps may be used in positive-displacement pump applications. Some diaphragm pumps are available that provide low shear, constant flow or pressure, low pulsation, high turndown ratio (e.g., 1,000:1), and/or low particle generation.

(b) The owner/user shall evaluate whether holdup volume and drainability characteristics of a diaphragm pump are acceptable for the application. Some process applications require the process system, including the diaphragm pump, to remain continuously flooded with sanitizing solution instead of being drained.

(c) Process contact diaphragms, O-rings, gaskets, and seals shall comply with Part SG. Process contact metallic materials of construction shall comply with Part MM. Nonmetallic process contact surfaces including diaphragms shall comply with Part PM.

(d) Where applicable, check valves shall comply with SD-3.13

(e) Where used, diaphragm fasteners shall be attached within the pump head such that crevices or threads are not exposed to the process fluids.

(f) The owner/user should consider leak detection and/or leak path design of the pump to identify a failure that can lead to process contamination and/or biohazards.

SD-3.3.2 Hygienic Pumps

SD-3.3.2.1 General

(a) Pumps shall be cleanable. Pumps shall be selected according to the operating conditions determined by the owner/user (e.g., process, CIP, SIP, passivation).

(b) All process contact connections to the pump shall be of a hygienic design (see Figures SG-2.2.2-1, SG-2.2.2-2, SG-2.2.2-3, and SG-2.2.2-4).

SD-3.3.2.2 Centrifugal Pumps

(a) Hygienic centrifugal pumps shall be capable of CIP.

(b) All process contact surfaces shall be drainable without pump disassembly or removal.

(c) Shrouded/closed impellers should not be used. Figure SD-3.3.2.2-1 illustrates open, semi-open, and closed impeller configurations.

(d) The impeller shall be attached to the shaft in such a way that all crevices and threads are not exposed to the process. Threads, such as in an impeller nut/bolt, shall be sealed by an O-ring or hygienic gasket. Refer to Figure SD-3.3.2.2-2. The use of O-rings or hygienic gaskets shall be consistent with Part SG.

(e) Suction, discharge, and casing drain connections shall be an integral part of the pump casing.

(f) Casing drains shall be at the lowest point of the casing, to ensure drainage (see Figure SD-3.3.2.2-3).
The use of an elbow-type casing drain is not recommended without the use of an automatically controlled drain. The casing drain connection shall be designed to minimize the $L/d$ as shown in Figure SD-3.3.2.2-4.

The pump discharge connection should be tilted to allow for full venting of the casing (see Figure SD-3.3.2.2-3).

All pump seals should be designed to minimize seal material degradation.

Shaft seals shall conform to Part SG.

### SD-3.3.2.3 Positive Displacement Pumps

(a) When possible, positive displacement pumps should be configured with vertically mounted inlets and outlets to promote drainability and venting.

(b) When using internal bypass pressure relief devices, they shall be of a hygienic design. It is preferred that an external, piping-mounted relief device (hygienic rupture disk) rather than a pump-mounted bypass be used.

### SD-3.3.2.4 Rotary Lobe Pumps

(a) The owner/user shall specify the chemical, thermal, and hydraulic operating conditions of the pump (e.g., process, CIP, SIP) to ensure proper component selection. Hygienic rotary lobe pumps are temperature sensitive (e.g., rotor to casing contact due to thermal expansion).

(b) The pump should be designed and installed to minimize holdup volume.

(c) Rotor fasteners shall be attached to the shaft in a way that crevices and threads are not exposed to the process. Threads and crevices shall be isolated from the process fluid by an appropriate hygienic seal, such as an O-ring or hygienic gasket (see Figure SD-3.3.2.4-1).

(d) The pump cover shall seal against the pump body by means of an O-ring or hygienic gasket.

(e) All process contact O-rings, gaskets, and shaft seals shall comply with Part SG.

(f) If a pressure relief device is used, it shall be of hygienic design in conformance with SD-3.15.

### SD-3.4 Vessels

#### SD-3.4.1 General

This section defines the requirements that should be met in the design, fabrication, and supply of pressurized and nonpressurized biopharmaceutical vessels.

(a) Design and fabrication of vessels and internal parts shall ensure that surfaces are free of ledges, crevices, pockets, and other surface irregularities. If more restrictive tolerances are required, they shall be included as part of the fabrication specifications for the project.

(b) All heat transfer surfaces should be drainable and ventable.

(c) Reinforcing pads, doubler plates, poision pads, etc., should be constructed of the same material as the vessel. If the vessel material of construction is a superaustenitic stainless steel, 316L-type alloys or other higher alloy stainless steels may be used for these components on non-process contact surfaces only. No telltale holes are allowed on process contact surfaces and those that are outside should be cleanable.

(d) Vessels that are to be exposed to temperatures above 176°F (80°C) [e.g., SIP, hot water-for-injection (WFI), hot U.S. Pharmacopeia (USP) waters, and hot CIP solutions] should be designed for full vacuum service [maximum allowable working pressure-external of 15 psig (1 barg)].

(e) Top and bottom heads on vessels that are cleaned in place shall be self-draining. Dished heads such as ASME flanged and dished (F&D), elliptical, and hemispherical are the most common types. Flanged or conical heads should slope at not less than $\frac{1}{8}$ in./ft (10 mm/m) to a common drain.

(f) All internal surfaces should be sloped or pitched for drainability.

(g) Test protocols for drainability shall be agreed upon in advance by all the parties (see SD-7.4). All vessels should be checked for drainability during fabrication.

#### SD-3.4.2 Vessel Openings

(a) Nozzles that are designed to be cleaned by a spray device should have the smallest $L/d$ ratio possible. For non-flow through nozzles, an $L/d$ of 2 or less is recommended (see Figure SD-3.4.2-1).

(b) Nozzles less than 1 in. (25 mm) in diameter are not recommended unless the system design provides for SIP and CIP through the nozzle.

(c) Bottom-mounted agitators, valves, pads, etc., shall not interfere with the drainability of the vessel.

(d) All instrument probes and any sidewall penetrations (see Figure SD-3.4.2-2) shall be sloped for drainage, unless the instruments used require horizontal mounting (see Figure SD-3.4.2-3).

(f) If a pressure relief device is used, it shall be of hygienic design in conformance with SD-3.15.
Figure SD-3.4.2-1 Nozzle Design

NOTES:
(1) Less dead space.
(2) Better CIP/SIP capabilities.
(3) Potential problems with CIP and SIP with capped connections.
(4) Dead space: stagnant areas.
(5) All $L/d$ ratios to be calculated on long-side dimensions for vessel heads.
Figure SD-3.4.2-2 Side and Bottom Connections

Dished head or shell
Radius

(a) Accepted

Note (1)

(1) If a flat gasket is used, mismatch of diameters can result in crevices.
(2) Telltale hole required.

Figure SD-3.4.2-3 Sidewall Instrument Ports

Nondraining edge

(b) Accepted

(c) Not Accepted

Note (2)

(1) May also be pitched similar to illustration (b).

Nozzles

see changes to figure on next page
NOTES:
(1) May also be pitched per application.
(2) Installed plug, instrument, or device may require manual cleaning out of place.
(3) Direct CIP impingement required.
(4) Mounting hardware removed for clarity.

NOTE: (1) May also be pitched similar to illustration (b).
(l) As required by the process, inlet nozzles tangential to the vessel surface may be used (see Figure SD-3.4.2-4 and Figure PI-9.1.3.3-1).

(m) Manway covers should be dished rather than a flat design.

(n) Flanges that have metal-to-metal contact on the process contact side shall not be used.

(o) All nozzles should be flush with the interior of the vessel except where projections are required to ensure additives are directed into the process fluid (e.g., chemical addition) (see Figure SD-3.4.2-5).

**SD-3.4.3 Internal Components**

(a) Spargers and dip tubes shall be designed in accordance with SD-3.4.1(a), SD-3.4.1(d), SD-3.4.1(f), and SD-3.4.1(g). Spargers and dip tubes shall incorporate low-point drains (where applicable, i.e., horizontal lines should slope at not less than \(\frac{1}{8}\) in./ft (10 mm/m) and be properly supported to ensure drainability. Refer to Table SD-2.4.3.1-1 to determine the appropriate slope designation.

(b) Dip tubes and spargers mounted in the nozzle neck should have an annular space between the O.D. of the dip tube or sparger and the I.D. of the nozzle neck in accordance with Table SD-3.4.3-1. An \(L/A\) of 2 or less is recommended (see Figure SD-3.4.3-1). If a larger \(L/A\) exists, a method for cleaning this space shall be specified. In all cases, sufficient annular space to allow access for CIP coverage shall be provided.

(c) Internal support members shall be solid, rather than hollow, which have a higher risk of fatigue and contamination problems (see Figure SD-3.4.3-2).

(d) Mitered fittings for internal pipe work shall only be fitted with the prior agreement between the owner/user and manufacturer. When mitered joints are used, they shall be designed and fabricated in accordance with the appropriate Codes.

(e) Vessels shall drain to a common point and shall not have multiple draining points, unless agreed to between the owner/user and manufacturer.

**SD-3.4.4 Fabrication**

(a) For process contact surfaces, butt welds should be used and the use of lap joint welds should be minimized. Stitch welding shall not be used on process contact surfaces.

(b) Flanges are not recommended, and their use should be minimized. The bore of weld neck flanges shall be the same as the I.D. of the connected pipe or tubing to prevent ledges and nondrainable areas.

(c) Where slip-on nondrainable flanges are used, the bore-side bevel weld shall be designed to eliminate potential drainability and CIP difficulties.
Figure SD-3.4.3-2 Internal Support Members

(a) Hygienic Design
(Accepted: Sloped, Minimum Shadow, and Curved Surface)

(b) Nonhygienic Design
(Not Accepted: Flat Surfaces, Ledges, and CIP Shadows)

(c) Good Design
(Accepted)

(d) Poor Design
(Not Accepted)

(e) Positive Slope in All Directions
(Accepted)

(f) Positive Slope in Only One Direction
(Accepted)

see changes to figure on next page
(a) Hygienic Design
(Accepted: Sloped, Minimum Shadow, and Curved Surface)
- Continuous weld
- Drainable
- Welded pad or doubler plate
- Capable of CIP (no shadows)

(b) Nonhygienic Design
(Not Accepted: Fist Surfaces, Ledges, and CIP Shadows)
- Stitch intermittent weld:
  - not drainable crevice
  - Doubler plate
  - Not capable of CIP (shadow)

(c) Good Design
(Accepted)

(d) Poor Design
(Not Accepted)

(e) Positive Slope in All Directions
(Accepted)
- Droplet formation

(f) Positive Slope in Only One Direction
(Accepted)
**SD-3.4.5 Finishes**

(a) Surface finishes shall be specified in $R_a$ values (see Table SF-2.4.1-1) and measured as required by Part SF. Surface finish coupons shall be submitted when agreed to by the owner/user and manufacturer.

(b) Process contact surface finish specifications shall pertain to all the wetted or potentially wetted surfaces (e.g., vapor space, nozzle necks, agitators, thermowells, dip tubes, baffles).

(c) The polishing of a connection face, body flange, etc., shall extend up to the first seal point.

**SD-3.4.6 Sight Glasses**

(a) Sight glasses on the vessels should be designed with reference to SD-3.2(a). Sight glasses on vessels should be designed with the smallest $L/d$ possible and incorporate cleanable O-ring designs when applicable (see Figure SD-3.4.6-1).

(b) Refer to PI-9.1.2.3 for additional sight glass requirements.

(c) Surface finish for the metal frame shall meet the requirements of Part SF in this Standard.

(d) Sight glasses shall be marked with the glass type, maximum pressure, and temperature rating per DT-11.1 and DT-11.1.1.

(e) Part SG requirements shall be met when mounting a sight glass.

(f) Preferred sight glass mountings are shown in Figure SD-3.4.6-1.

**SD-3.4.7 Portable Tanks** Portable tanks shall be designed in accordance with SD-3.4.

(a) Casters shall be cleanable and compatible with the environment in which the tank shall be operated.

(b) The use of O-rings or hygienic gaskets to seal between mating surfaces shall be consistent with the current guidance provided in Part SF (see Figure SD-3.3.2.2-1).

(c) The selected mounting arrangement will support the agitator mounting design loads while achieving an appropriate seal.

(d) The flange and nozzle construction is consistent with requirements of other applicable codes and standards (e.g., ASME BPVC, Section VIII; ASME B31.3).

(e) The use of in-tank nonwelded connections (shaft couplings, impeller hub-to-shaft, impeller blade-to-hub, etc.) should be avoided to minimize potential cleanability issues.

**SD-3.5 Agitators and Mixers**

**SD-3.5.1 General**

(a) All process contact surfaces of agitators and mixers with their associated components shall be accessible to the cleaning fluids as specified by the owner/user for clean-in-place service (CIP; e.g., via spray, directed flow, immersion).

(b) Process contact surfaces should be self-draining and shall not inhibit drainage of the vessel.

(c) Machined transitions (shaft steps, coupling surfaces, wrench flats, etc.) should be smooth, with 15-deg to 45-deg sloped surfaces.

(d) The annular space between the agitator shaft and the agitator nozzle shall, for cleaning purposes, have an $L/A$ of 2 or less, or a minimum of 1 in. (25 mm) gap, whichever is larger, to facilitate CIP spray coverage (see Figure SD-3.4.3-1, illustration (b)).

(e) Cleaning and sterilization parameters shall be provided by the owner/user prior to design of the agitator. The manufacturers of agitators and mixers shall verify the cleanability of their equipment as specified and agreed to with the owner/user.

(f) Top-entering mixers with shaft seals are typically mounted to a vessel using a flanged or hygienic clamp connection (see Figure SD-3.5.1-1, illustrations (a), (b), and (c)). The designer shall ensure that

(i) The use of O-rings or hygienic gaskets to seal between mating surfaces shall be consistent with the current guidance provided in Part SF (see Figure SD-3.3.2.2-1).

(ii) The selected mounting arrangement will support the agitator mounting design loads while achieving an appropriate seal.

(iii) The flange and nozzle construction is consistent with requirements of other applicable codes and standards (e.g., ASME BPVC, Section VIII; ASME B31.3).

(iv) The use of in-tank nonwelded connections (shaft couplings, impeller hub-to-shaft, impeller blade-to-hub, etc.) should be avoided to minimize potential cleanability issues.

**SD-3.5.2 In-Tank Shaft Couplings**

(a) Welded in-tank shaft connections are preferred.

(b) The use of in-tank shaft couplings shall be agreed to by the owner/user.

(c) In-tank couplings shall be of an accepted hygienic design. See examples in Figure SD-3.5.2-1.

(d) In-tank coupling location should be driven by process and mechanical considerations.

(e) Threaded shaft connections are accepted for in-tank couplings (see Figure SD-3.5.2-1, illustration (a)).

(1) Shaft rotation is limited to a single direction for threaded shaft connections to ensure that shaft sections do not separate.

(2) The designer will ensure that the use of a threaded shaft connection is appropriate for the shaft diameter and design load.
SD-3.4 Vessels
SD-3.4.1 General. This section defines the requirements that are to be met in the design, fabrication, and supply of pressurized and nonpressurized biopharmaceutical vessels.

(a) Design and fabrication of vessels and internal parts/components shall ensure that surfaces are free of ledges, crevices, pockets, and other surface irregularities. If more restrictive tolerances are required, they shall be included as part of the fabrication specifications for the project.

(b) All heat transfer surfaces should be drainable and ventable.

(c) Reinforcing pads, doubler plates, poison pads, etc., should be constructed of the same material as the vessel. If the vessel material of construction is a superaustenitic stainless steel, 316L-type alloys or other higher alloy stainless steels may be used for these components. They should be installed on non-process contact surfaces only. No telltale holes are allowed on process contact surfaces and those that are outside should be cleanable.

(d) Vessels that are to be exposed to temperatures above 176°F (80°C) [e.g., SIP, hot water-for-injection (WFI), hot U.S. Pharmacopeia (USP) waters, and hot CIP solutions] should be designed for full vacuum service [maximum allowable working pressure-external of 15 psig (1 barg)].

(e) Top and bottom heads on vessels that are cleaned in place shall be self-draining drainable. Dished heads such as torispherical [e.g., ASME flanged and dished (F&D), 80:10 F&D], elliptical, and hemispherical are the most common types. Flat or conical heads should slope at not less than 1/8 in./ft (10 mm/m) to a common drain.

(f) All internal surfaces should be sloped or pitched for drainability.

(g) Test protocols for drainability shall be agreed upon in advance by all the parties (see SD-7.4). All vessels should be checked for drainability during fabrication.

SD-3.4.2 Vessel Openings
(a) Nozzles that are designed to be cleaned by a spray device should have the smallest \( L/d \) ratio possible. For non-flow through nozzles, an \( L/d \) of 2 or less is recommended (see Figure SD-3.4.2-1).

(b) Nozzles less than 1 in. (25 mm) in diameter are not recommended unless the system design provides for SIP and CIP through the nozzle.

(c) Bottom-mounted agitators, valves, pads, etc., shall not interfere with the drainability of the vessel.

(d) All sidewall instrument probes and nozzles any sidewall penetrations (see Figure SD-3.4.2-2) shall be sloped for drainage drainability, unless the instruments used require horizontal mounting (see Figure SD-3.4.2-2 and Figure SD-3.4.2-3).

(e) Blank covers or hygienic plugs used in process contact applications shall have the same finish as the vessel internals.

(f) Drain valves should be designed, sized, and installed to enable vessel drainability for all operations and minimize branch \( L/d \).

(g) The number and location of spray devices should be selected to eliminate shadowing at internal parts such as of components (e.g., manways, mixer shafts, dip tubes, and baffles, sidewall nozzles).

(h) The number of shell side nozzles and connections should be minimized.

(i) Manways should be located on the vessel top head and on the side shell of a vessel shall be installed only by agreement to the manufacturer. If sidewall side shell manways are required, they shall be sloped for drainage drainability.

(j) Sample valves shall be designed and installed in accordance with SD-3.11.

(k) Sample valves shall be designed and installed in accordance with SD-3.11.

(l) As required by the process, inlet nozzles tangential to the vessel surface may be used (see Figure SD-
3.4.2-4 and Figure PI-9.1.3.3-1).

(a) Manway covers should be dished rather than a flat design.

(b) Flanges that have metal-to-metal contact on the process contact side shall not be used.

(c) All nozzles should be flush and radiused with the interior of the vessel except where projections are required to direct additives into the process fluid (e.g., chemical addition) (see Figure SD-3.4.2-5).

(d) Flanges for bottom, centerline-mounted agitators should be designed in accordance with Nonmandatory Appendix XX (see XX-3.3).

SD-3.4.3 Internal Components

(a) Sparger and dip tubes shall be designed in accordance with SD-3.4.1(a), (d), (f), and (g). Sparger and dip tubes shall incorporate low-point drains [where applicable, i.e., horizontal lines should slope at not less than 1/8 in./ft (10 mm/m)] and be properly supported to ensure drainability. Refer to Table SD-2.4.3.1-1 to determine the appropriate slope designation.

(b) Dip tubes and spargers mounted in the nozzle neck should have an annular space between the O.D. of the dip tube or sparger and the I.D. of the nozzle neck in accordance with Table SD-3.4.3-1. An L/A of 2 or less is recommended [see Figure SD-3.4.3-1, illustration (a)]. If a larger L/A exists, a method for cleaning this space shall be specified. In all cases, sufficient annular space to allow access for CIP coverage shall be provided.

(c) Dip tubes shall be designed for CIP or cleaning out of place (COP). Spargers should be designed for CIP. Where the sparging device cannot be CIP’d, the device shall be removable for COP or replaceable.

(d) Removable dip tubes and spargers shall be designed to ensure that the installation orientation conforms with the design intent.

(e) Spray devices shall meet the requirements of SD-3.9.

(f) Internal support members shall be solid, rather than hollow, which have a higher risk of fatigue and contamination problems (see Figure SD-3.4.3-2).

(g) Mitered fittings for internal pipe work should be avoided and should only be fitted with the prior agreement between the owner/user and manufacturer. When mitered joints are used, they shall be designed and fabricated in accordance with the appropriate Codes.

(h) Vessels shall drain to a common point and shall not have multiple draining points, unless agreed to between the owner/user and manufacturer.

SD-3.4.4 Fabrication

(a) Weld joint designs shall comply with MJ-3.2. For process contact surfaces, butt joints should be used and the use of fillet lap joint joints should be minimized. Stitch welding intermittent welds shall not be used on process contact surfaces.

(b) Flanges are not recommended for process contact applications, and their use should be minimized. The bore of weld neck flanges shall be the same as the I.D. of the connected pipe or tubing components to prevent ledges and nondrainable areas.

(c) Where slip-on nondrainable flanges are used, the bore-side process contact bevel fillet weld shall be designed to eliminate potential for drainability and CIP difficulties.

SD-3.4.5 Finishes

(a) Surface finishes shall be specified in Rz values (see Table SF-2.4-1) and measured as required by Part SF. Surface finish coupons shall be submitted when agreed to by the owner/user and manufacturer.

(b) Process contact surface finish specifications shall pertain to all the wetted or potentially wetted surfaces (e.g., vapor space, nozzle necks, agitators, thermowells, dip tubes, baffles, etc.).
(c) The polishing of a connection face, body flange, etc., shall extend up to the first seal point.

SD-3.4.6 Sight Glasses
(a) Sight glasses on the vessels should be designed with reference to SD-3.4.2(a). Sight glasses on vessels should be designed with the smallest L/d possible and incorporate cleanable O-ring designs when applicable (see Figure SD-3.4.6-1).

(b) Refer to PI-9.1.2.3 for additional sight glass requirements.

(c) Surface finish for the metal frame shall meet the requirements of Part SF in this Standard.

(d) Sight glasses shall be marked with the glass type, maximum pressure, and temperature rating per DT-11.1 and DT-11.1.1.

(e) Part SG requirements shall be met when mounting a sight glass.

(f) Preferred sight glass mountings are shown in Figure SD-3.4.6-1.

SD-3.4.7 Portable Tanks, Vessels. Portable tanks shall be designed in accordance with SD-3.4.
(a) Casters shall be cleanable and compatible with cleaning solutions used for external cleaning.

(b) Casters should be designed for the environment in which the vessel will be used.

(c) Portable vessels should be designed to resist overturning during normal operating conditions.

(d) Flexible hoses used to connect portable vessels shall meet the requirements of SD-3.2.

(e) Provisions for static grounding should be evaluated and incorporated into the vessel design, if required.

The connections for static grounding should be designed to be cleanable.

SD-3.4.8 Media Bulk Containers. [Reserved for future content]

SD-3.4.9 Cryogenic Containers. [Reserved for future content]
(g) Bottom, centerline-mounted agitators should be designed in accordance with Nonmandatory Appendix XX (see XX-3.1).

(h) Socket head cap screws shall not be used in process contact applications.

(i) The design of agitator process contact parts should minimize the occurrence of void spaces. All voids should be closed by either fabrication (welding) or approved sealing techniques (0-ring seals, etc.).

(j) The use of in-tank nonwelded connections (shaft couplings, impeller hub-to-shaft, impeller blade-to-hub, etc.) should be avoided to minimize potential cleanability issues.

(k) Agitator mechanical seal performance and the seal’s ability to maintain a closed system for bioburden control, process containment, etc. is a function of agitator shaft and drive assembly mechanical integrity. Agitator design should address the dynamic forces that act upon the shaft and impeller assembly (e.g. maximum applied torque and impeller hydraulic forces) and the resonant frequency of the assembly to ensure that component alignment and deflection are within manufacturer’s tolerance. The agitator torque, bending moment and vertical downward mounting loads shall be provided by the manufacturer to support design of the associated vessel mounting flange/nozzle.
Figure SD-3.4.6-1 Sight Glass Design (Accepted)

(a) Full Flange Sight Glass on Hygienic Pad Connection
(b) Hygienic Clamp on Hygienic Pad Connection
(c) Hygienic Clamp Sight Glass
(d) Hygienic Cross Sight Flow Indicator
(e) Typical Vessel Sight Glass Mounting Tangent to Tank Head

see changes to figure on next page
(a) Full Flange Sight Glass on Hygienic Pad Connection

(b) Hygienic Clamp on Hygienic Pad Connection
(Mounting hardware removed for clarity)

(c) Hygienic Clamp Sight Glass

(d) Hygienic Cross Sight Flow Indicator

(e) Typical Vessel Sight Glass Mounting Tangent to Tank Head
Hollow shafts, if used, shall be of sealed (welded) construction, inspected for integrity, and accepted per criteria given in Part M prior to installation.

Keyways exposed to the process are not recommended.

Keyways, where employed due to mechanical design considerations, shall have edge radii as specified by SD-2.4.2(b)(3).

Keyways may require additional design and/or cleaning practice to ensure drainage and cleanability (e.g., spray ball and/or wand additions, increased CIP flow, and adjusted spray coverage).

Permanent shaft hardware, installed on the process contact side, that may be required for routine maintenance (e.g., support collars for mechanical seal installation and removal, lifting eyes for shaft and/or impeller installation and removal) shall be fully drainable and cleanable.

SD-3.5.4 Hubs and Impellers

All-welded impeller assemblies (e.g., hubs, blades) are preferred.

Impeller hubs welded to the shaft are preferred over removable hubs.

Removable, hygienic impellers may be used where impeller adjustment or substitution is required for process reasons or where impeller removal is required due to mechanical design and/or installation considerations.

Removable impellers may be one-piece or split hygienic construction.

Hub-to-shaft clearance for removable impellers shall be sufficient to preclude shaft surface finish damage during installation and removal.

SD-3.5.5 Impeller and Shaft Support Bearings

Normal operation of a shaft-steady bearing or a magnetically driven mixer with in-tank impeller or shaft support bearings (see Figures SD-3.5.5-1 and SD-3.5.5-2) generates particulate debris. It is the responsibility of the owner/user to establish compliance with applicable standards (e.g., USP limits for particulate material in injectables) as appropriate.

Tank plates that support bottom-mounted magnetically driven mixers shall not interfere with drainage of the vessel.

When an application mandates the use of shaft-steady/foot bearings, design features and/or procedures are required to ensure cleanability (e.g., drain holes, spray ball and/or wand additions, increased CIP flow, operating the steady bearing immersed in CIP fluid).

Shaft-steady bearings, where used, shall not interfere with the drainage of the vessel.

Shaft-steady bearing pedestal support members may be of solid or hollow construction. Hollow pedestal supports, if used, shall be of sealed (welded) construction,
Figure SD-3.5.5-2 Magnetically Coupled Mixer (Typical Bottom-Mount)

SD-3.5.6 Mechanical Seals

(a) Mechanical shaft seals shall incorporate design features for drainability, surface finish, material of construction, etc., as outlined in Part SD, and shall be suitable for the application (e.g., process, CIP, SIP, passivation).

(b) Normal operation of a mechanical seal generates particulate debris. It is the responsibility of the owner/user to establish compliance with applicable standards (e.g., USP limits for particulate material in injectables) as appropriate.

(c) Seal debris wells or traps (see Figure SC-2.3.23-2) may be used to prevent ingress of seal face wear particles that could contaminate the process fluid.

(d) Refer to Part SG of this Standard for specific seal design details.

SD-3.6 Heat Exchange Equipment

Plate-and-frame-type heat exchangers should be used only by agreement between owner/user and designer due to the difficulty of CIP and SIP.

SD-3.6.1 General

(a) Straight tube heat exchangers are easier to clean and inspect. The tubes can be seamless or full-finish welded, as agreed to by the owner/user and manufacturer.

(b) The heat exchanger process and non-process contact surface inspection shall be possible by conventional means.

(c) The technique used to form U-bend tubes shall ensure the bending process does not create structural imperfections (e.g., cracks, voids, delaminations). The technique should minimize surface imperfections (e.g., orange peel, rippling). If requested by the owner/user, the manufacturer shall supply a sectioned sample of the bend area.

(1) The sectioned sample should be from the same tube batch or heat that will be used to fabricate the heat exchanger.

(2) The sectioned sample shall be the smallest bend radius in the exchanger.

(3) The sample shall be sectioned so that the bend's centerline is visible.
The internal surface of the U-bends shall be free of relevant liquid penetrant indications, as defined by ASME BPVC, Section VIII.

(e) The I.D. of the U-bends shall be large enough for a borescopic examination.

(f) Minimum recommended bend radii for heat exchangers should be as follows:

<table>
<thead>
<tr>
<th>Nominal Tube O.D.</th>
<th>Minimum Bend Radius</th>
</tr>
</thead>
<tbody>
<tr>
<td>in.</td>
<td>mm</td>
</tr>
<tr>
<td>0.375</td>
<td>9.5</td>
</tr>
<tr>
<td>0.500</td>
<td>12.7</td>
</tr>
<tr>
<td>0.625</td>
<td>15.8</td>
</tr>
<tr>
<td>0.750</td>
<td>19.1</td>
</tr>
<tr>
<td>0.938</td>
<td>23.8</td>
</tr>
<tr>
<td>1.000</td>
<td>25.4</td>
</tr>
</tbody>
</table>

(g) Welded shell-and-tube heat exchangers shall be of a double tubesheet design to prevent contamination of the process in the event of a tube joint failure (see Figure SD-3.6.1-1).

(1) During fabrication, when the tubes are to be expanded into the inner and outer tubesheets, the process contact surface shall not be scored.

(2) Tubes shall be seal welded to the outer tubesheet.

(3) The distance between inner and outer tubesheets shall be sufficient to allow leak detection.

(4) Tubesheets and channels shall be drainable.

(h) The owner/user shall specify the orientation of the exchanger (i.e., horizontal or vertical), and the manufacturer shall ensure the complete draining of the process liquid from the process contact side of the heat exchanger at the specified orientation, other than the natural cohesive properties of said process liquid. If this holdup is unacceptable, then the manufacturer shall design some type of assist to aid draining, such as an air blowdown.

(1) In the specified orientation, the shell side shall also be drainable (e.g., WFI condensers).

(2) Transverse baffles with notches should be provided, when necessary, to allow for proper draining of the shell.

(3) The heat exchanger bonnet shall be match marked with the outer tubesheet for proper orientation to ensure drainability or cleanability.

(i) Heat exchanger thermal and mechanical calculations shall be performed for both operating and SIP cycles.

(j) In shell-and-tube heat exchangers, the design pressure for the process contact side shall be equal to or greater than the design pressure of the utility side.

(k) The type of connections to the utility side (shell side) shall be agreed to between the owner/user and manufacturer.

SD-3.6.2 Cleaning and Steaming

(a) The process contact surfaces shall be constructed to withstand CIP and SIP or other cleaning/bioburden control methods specified by the owner/user.

(b) The cleaning and steaming conditions shall be provided by the owner/user prior to the design of the heat exchanger.

SD-3.6.3 Gaskets and Seals

(a) Gaskets that are in contact with product shall be removable and self-positioning and shall have readily cleanable grooves.

(b) Channel/bonnet gaskets shall be of a cleanable design.

SD-3.7 Transfer Panels

SD-3.7.1 General

(a) The transfer panel shall be constructed so that the process contact surfaces can be cleaned by a CIP fluid or other method specified by the owner/user. The process contact surfaces shall be free of crevices, pockets, and other surface irregularities.

(b) The transfer panel nozzle elevation shall be properly designed with respect to the connecting equipment such as tank and pump to ensure drainability, cleanability, and bioburden control during process transfer, CIP, and SIP.

(c) Design and fabrication of the transfer panel and associated components must ensure that the piping system can be fully drained when properly installed. This is not to imply that panel nozzles and/or subheaders should be sloped (see Figure SD-3.7.1-1).

(d) Tagging/labeling of the transfer panel and its components shall be per SD-2.4.4.2(i). Tagging nozzles on the back side of panels will help reduce the number of incorrect piping connections during field installation.

SD-3.7.2 Nozzles or Ports

(a) Nozzle construction shall accommodate a design feature that will assist in the elimination of internal surface anomalies caused in part by joining the nozzle to the panel structure.

(b) The method of joining a nozzle into a panel structure shall be of hygienic design. Acceptance criteria for these welds shall meet the requirements of Table MJ-8.5-1.

(c) Each front nozzle connection shall be of a hygienic design and the horizontal projection minimized to optimize drainability.

(d) To ensure proper panel functionality and joint connection integrity, panel nozzles shall not be sloped (see Figure SD-3.7.2-1).

(e) Nozzle-to-nozzle clearance shall be such that jumper drain valve interference, if applicable, will not occur when jumpers are connected in all possible operating and cleaning configurations.

(f) Nozzles shall be capable of being capped. Caps may include bleed valves or pressure indicators for safety or operating purposes.
SD-3.6 Heat Exchanger Equipment

a) Required operating conditions should be established prior to the design or selection of the heat exchanger. The manufacturer’s design shall take into account the most demanding of these operating conditions.

(b) To reduce process contamination risk, systems utilizing heat exchangers should be designed such that the operating pressure for the process contact side is greater than the operating pressure of the non-process side.

(c) Process contact surface finishes shall be fully inspectable to confirm surface finish quality. When inspection is not practical, prior to fabrication or procurement, the manufacturer should provide inspectable samples representative of the fabrication process.

SD-3.6.1 Application Design Considerations

(a) The heat exchanger should be designed and fabricated to provide smooth, crevice-free process contact surfaces.

(b) For hygienic heat exchanger applications where crevices cannot be avoided (e.g., product on the shell side), the system shall be designed to mitigate contamination risk through operational controls (e.g., self-sanitizing conditions).

SD-3.6.2 Shell and Tube

(a) Shell and tube heat exchangers shall be of a double tubesheet design to prevent product contamination in the case of a tube to tubesheet joint failure (see Fig. SD-3.6.1-1).

(b) After the tubes are expanded into the inner and outer tubesheets, the process contact surface shall meet the specified surface finish requirement.

(c) Tubes shall be welded to the outer tubesheet to eliminate any crevices.

(d) The distance between inner and outer tubesheets shall be sufficient to allow leak detection.

(e) The process contact side of the heat exchanger system shall be drainable or capable of having liquid removed by other means (e.g., pressurized gas, vacuum, heat). The manufacturer should specify the required drainable orientation for the heat exchanger.

(f) When transverse baffles are required they should be notched to allow for drainage.

(g) The heat exchanger bonnet, tube bundle and shell shall have a positioning device or mark to ensure proper orientation and installation.

(h) The manufacturer’s performance calculations shall take into account any bonnet bypass implemented to aid drainage.

SD-3.6.2.1 Straight Tube Design

(a) Expansion or contraction for all specified differential thermal conditions shall be evaluated when designing the heat exchanger.

SD-3.6.2.2 U-Tube Design

(a) The technique used to form U-bend tubes shall ensure the bending process does not create structural imperfections (e.g., cracks, voids, gouges). The technique should minimize surface imperfections (e.g., orange peel, rippling).

(b) If requested by the owner/user, the manufacturer shall supply a sectioned sample of the bend area.

(c) The sectioned sample should be from the same tube batch or heat that will be used to
fabricate the heat exchanger.

(d) The sectioned sample shall be the smallest bend radius in the exchanger.

(e) The sample shall be sectioned so that the bend centerline is visible.

(f) The internal surface of the U-bends shall be free of relevant liquid penetrant indications, as defined by ASME BPVC, Section VIII.

(g) The I.D. of the U-bends should be large enough for a borescopic examination.

(h) Minimum recommended bend radii for heat exchangers should be as follows:

<table>
<thead>
<tr>
<th>Nominal Tube O.D.</th>
<th>Minimum Bend Radius</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>in.</td>
</tr>
<tr>
<td>0.375</td>
<td>9.5</td>
</tr>
<tr>
<td>0.500</td>
<td>12.7</td>
</tr>
<tr>
<td>0.625</td>
<td>15.8</td>
</tr>
<tr>
<td>0.750</td>
<td>19.1</td>
</tr>
<tr>
<td>1.000</td>
<td>25.4</td>
</tr>
</tbody>
</table>

For tubes not included in the table, a minimum bend radius of 1.5 times the tube diameter is recommended, however section SD-3.6(c) should be consulted.

SD-3.6.3 Plate and Frame
(a) Plate and frame type heat exchangers should be used only by agreement between owner/user and designer due to the difficulty of CIP and SIP.
Nozzle center-to-center and flatness tolerances are extremely critical to proper panel functionality and shall be agreed on by the manufacturer and owner/user. Recommended tolerances are per Table DT-7-3 and Figure SD-3.7.2-1.

**SD-3.7.3 Headers or Pre-Piped Manifolds**

(a) When a looped header design is employed, the branch length at capped or unused nozzles, or to the weir of the unused point-of-use valve, should be minimized. The dimension of the subheader leg to the nozzle face should not exceed an $L/d$ of 2 (see Figure SD-3.7.1-1). A dead-ended and/or unlooped subheader is not recommended.

(b) To optimize the drainability at all nozzles, regardless of use, subheaders and pre-piped manifolds shall not be sloped. All encompassing lines including long runs with the exception of subheaders, manifolds, and nozzles may be sloped as defined in SD-2.4.3.

**SD-3.7.4 Jumpers or U-Bends**

(a) Jumpers shall be constructed with hygienic connections on both ends designed to mate with the panel nozzles. Jumpers may have a low-point drain to provide liquid transfer, a vacuum break after the liquid transfer has been completed, and a drain design that incorporates the drain valve and vacuum break. Zero-static diaphragm valves are recommended for low-point drains if available from the manufacturer (see Figure SD-3.7.4-1). The branch $L/d$ of a low-point drain connection should be minimized.

(b) Jumpers shall be constructed with hygienic connections on both ends designed to mate with the panel nozzles. Jumpers may have a low-point drain to provide liquid transfer, a vacuum break after the liquid transfer has been completed, and a drain design that incorporates the drain valve and vacuum break. Zero-static diaphragm valves are recommended for low-point drains if available from the manufacturer (see Figure SD-3.7.4-1). The branch $L/d$ of a low-point drain connection should be minimized.

NOTES:
1. Flanges for nozzle and flange face tolerances defines the maximum gap allowed across the entire sealing surface relative to the inspection planes shown above.
2. Tolerances applied to related nozzles (defined by jumper paths).

**Figure SD-3.7.2-1. Transfer Panel Tolerances (Reference Table DT-7-3)**

NOTES:

1. Flatness tolerance defines the maximum gap allowed across the entire sealing surface relative to the inspection planes shown above.
2. Tolerances applied to related nozzles (defined by jumper paths).
Fig. SD-3.7.2-1  Transfer Panel Tolerances  (Reference Table DT 7-3)

NOTES:
(1) For flatness tolerance of singular sealing faces of ferrules, see Table DT-3-1.
(2) For parallelism tolerance Tol.1, see Table DT-7-3.
(3) For position tolerance Tol.2, see Table DT-7-3.
(4) For testing parallelism and position, the use of specifically made test panels is recommended.

Proposed new Fig. SD-3.7.2-1

DT-7.3-1

Ferrule appearance has been generalized

Note 4 callout has been added to Tol. 1 Notes
Proximity Switches

(a) Jumper center-to-center and flatness tolerances are extremely critical to proper panel functionality. Recommended tolerances are per Table DT-7-3 and Figure SD-3.7.2-1.

(b) The use of reducing jumpers is not recommended due to drainability concerns based on jumper orientation. Any reduction in line size should be made behind the primary nozzle connection (behind panel structure), thus allowing all connections to be the same size on the front of the panel.

(c) The overall panel design should be such that the quantity of unique jumper centerline dimensions is minimized.

(d) The same jumper should be used for process transfer, CIP, and SIP.

(e) If a pressure indicator is installed on a jumper, it shall be a hygienic design and mounted in a manner that maintains drainability in all jumper positions. The L/d should be 2 or less.

**SD-3.7.5 Drain or Drip Pans**

(a) Drain pans, if used, shall be built as an integral part of the transfer panel. The intended function is to collect spilled fluids that can occur during jumper or cap removal.

(b) Drain pans shall slope [preferred minimum of $1/4$ in./ft (21 mm/m)] to a low point and be piped to the process drain. The depth of the drain pan is determined by calculating the largest spill volume and accommodating it with a sufficient pan holding volume. Consideration should be given to increasing the drain port connection size in lieu of increasing pan depth. The preferred drain port location is central bottom draining or central back draining.

(c) The elevation of the pan should take into account the clearance required for the jumper drain valve position when a connection is made to the bottom row of nozzles. The pan should extend horizontally to accommodate the furthest connection and/or drain point from the face of the panel.

**SD-3.8 Filters**

SD-3.8.1 Code 7 Cartridge Lock Design. The ASME BPE Code 7 lock is designed to be used with filter cartridges using an SAE AS 568-226 double O-ring seal and a two-locking-tab design.

SD-3.8.1.1 Design Features. This design consists of the following features:

(a) a socket bore that is machined into a base or cartridge plate into which the filter cartridge O-ring adapter is inserted.

(b) a locking-tab retainer mechanism that captures the cartridge locking tabs when the cartridge is inserted into the socket bore.

(1) Table DT-4.5.1-1 shows a recessed tapered lock retainer design in which the locking tab retainers are machined into a plate and the machined recesses capture the cartridge locking tabs as the cartridge is rotated into position.

(2) Table DT-4.5.2-1 shows an external tapered lock retainer design in which a set of metal cages captures the cartridge locking tabs as the cartridge is rotated into position.

(c) the locking tab retainers shall be designed with a taper to provide a secure lock for the cartridge. The cartridge tabs shall travel through the narrowing tab retainers until a tight fit is achieved. The tab shall be on the upper portion of the tab retainer. Full capture of cartridge tabs by the locking tab retainers is not required to secure cartridges for operation.

(d) all surfaces of the cartridge socket shall meet the required finish for the wetted surfaces as specified by the owner/user.

(e) the cartridge O-ring(s) shall be completely contained within the socket bore.

**SD-3.8.1.2 Testing.** The cartridge manufacturer shall validate that its cartridge design fits, seals, and remains in place with one of the housing designs shown in Tables DT-4.5.1-1 and DT-4.5.2-1.
SD-3.8 Filters Filtration Element and Components

PM-4.5.1 SD-3.8.1 General. This section defines and recommends design elements related to hygienic filtration processes. This section includes aseptic and nonaseptic processes and includes the following filtration components: housings, holders, and elements. More information on filtration elements and components may be found in Nonmandatory Appendix T.

PM-4.5.2 SD-3.8.2 Filtration Formats. There are two basic modes of filtration: direct flow and tangential flow. For multipurpose filters, cleaning and/or sanitization should be considered. For single-use filters, sanitization requirements shall be determined by the owner/user.

PM-4.5.3 SD-3.8.3 Housing and Encapsulation. Filter housings and encapsulated components are wetted and are vessels operating under pressure. Requirements for vessels operating under pressure are found in ASME BPVC, Section VIII, as referred to in GR-1. The owner/user shall be responsible for informing the manufacturer of all expected operating conditions to which the filter housings may be exposed. The manufacturer shall be responsible for ensuring the filter housings and encapsulated components will operate safely under said conditions.

PM-4.5.3.1 SD-3.8.3.1 Housings. Housings shall be designed in accordance with SD-5.4.4 Materials used in the construction of filtration housings shall conform to Part MM for metallic materials or Part PM for polymeric materials. All dimensions of hygienic clamp ferrules on polymeric filter housings shall conform to Table DT-7.1-2.

PM-4.5.3.2 SD-3.8.3.2 Encapsulation. Encapsulated filtration elements are designed for handling purposes or in place of metallic housings. Materials used in the encapsulation of filtration elements shall conform to Part PM for polymeric materials or Part MM for metallic materials.

PM-4.5.3.2.1 SD-3.8.3.2.1 Holders. Materials used in the construction of holders shall conform to Part MM for metallic materials or Part PM for polymeric materials.

SD-3.8.3.3 Code 7 Cartridge Lock Design. The ASME BPE Code 7 lock is designed to be used with filter cartridges using an SAE AS 568-226 double O-ring seal and a two-locking-tab design.

SD-3.8.3.4 Design Features. This design consists of the following features:

(a) A socket bore that is machined into a base or cartridge plate into which the filter cartridge O-ring adapter is inserted.

(b) A locking tab retainer mechanism that captures the cartridge locking tabs when the cartridge is inserted into the socket bore.

(1) Table DT-4.5.1-1 shows a recessed tapered lock retainer design in which the locking tab retainers are machined into a plate and the machined recesses capture the cartridge locking tabs as the cartridge is rotated into position.

(2) Table DT-4.5.2-1 shows an external tapered lock retainer design in which a set of metal cages captures the cartridge locking tabs as the cartridge is rotated into position.

(c) The locking tab retainers shall be designed with a taper to provide a secure lock for the cartridge. The cartridge tabs shall travel through the narrowing tab retainers until a tight fit is achieved. The taper shall be on the upper portion of the tab retainer. Full capture of cartridge tabs by the locking tab retainers is not required to secure cartridges for operation.

(d) All surfaces of the cartridge socket shall meet the required finish for the wetted surfaces as specified by the owner/user.

(e) The cartridge O-ring(s) shall be completely contained within the socket bore.

PM-4.5.4 SD-3.8.4 Design for Cleaning and Sanitization

SD-3.8.4.1 Filter Elements

PM-4.5.4.1.1 Cleaning. Filtration elements shall be designed in accordance with SD-3.1 and shall be compatible with the cleaning agents (to be agreed by the manufacturer and owner/user).

PM-4.5.4.1.1.1 Walls, All walls shall conform to Part SPGM.

PM-4.5.4.1.2 SD-3.8.4.1.2 Exterior Surfaces. All exterior surfaces shall conform to SD-2.4.4.2.
PM-4.5.4.2 SD-3.8.5 Sanitization
SD-3.8.5.1 Filter Elements
PM-4.5.4.2.1 SD-3.8.5.1.1 Chemical Sanitization. Chemical sanitization processes are used to reduce bioburden. All product contact surfaces shall be compatible with the sanitization agents selected (to be agreed by the manufacturer and owner/user).

PM-4.5.4.2.2 SD-3.8.5.1.2 Thermal Sanitization. Thermal sanitization requirements should be considered during the design process. The components shall be designed to accommodate the elevated temperatures and the expansion and contraction during exposure and cooldown stages. Special consideration should be given when designing for potential vacuum situations. Filtration elements should be tested and verified for multiple steam cycles per vendor qualification methods. Filtration elements shall conform to SD-2.3.1.

PM-4.5.5 SD-3.8.6 Filtration Performance. The owner/user shall be responsible for informing the manufacturer of all the conditions under which the filter elements may be expected to operate. This shall include the methods, frequency, and duration of cleaning and sanitization procedures. In addition to the service temperature and pressure, any parameters that may affect the filtration performance shall be provided.

PM-4.5.5.1 SD-3.8.6.1 Service Temperature and Pressure. Filtration elements shall be capable of withstanding thermal and pressure cycling between the rated upper and lower temperature and pressure limits.

PM-4.5.5.2 SD-3.8.6.2 Routine Maintenance. To ensure continued filtration performance, consideration shall be given to the accessibility of all filtration components for routine maintenance.

PM-4.5.5.2.1 SD-3.8.6.2.1 Integrity Testing and Permeability
(a) Integrity Testing. Tests may be required to ensure that the filtration elements and components are integral and meet specific process requirements. Sterilizing-grade membranes should be tested to the specific bacterial retention protocol (refer to 2004 cGMP Filtration Guideline and ASTM F838). The following are typical integrity test procedures that may be performed:

(1) pressure decay test
(2) bubble point test
(3) diffusional flow test
(4) water intrusion test

Other integrity testing methods should be agreed on between the manufacturer and owner/user. Integrity testing may be performed either pre- or postprocess.

(b) Normalized Water Permeability. During tangential flow applications, a normalized water permeability test (NWP; see Nonmandatory Appendix T-2.5) or clean water flux test may be performed.

PM-4.5.6 SD-3.8.7 Installation. Installation shall be in accordance with the manufacturer's guidelines.

PM-4.5.7 SD-3.8.8 Compliance Conformance Requirements
PM-4.5.7.1 SD-3.8.8.1 General Requirements. A unique identifier shall be indelibly marked on the filtration element or support structure. The unique identifier shall enable the owner/user to identify the supplier and the supplier to identify the raw material and processing conditions used to fabricate the article. A Certificate of Compliance Conformance shall be issued by the filtration element manufacturer to certify compliance conformance to this Standard when required by the owner/user.

PM-4.5.7.2 SD-3.8.8.2 Certificate of Compliance Conformance. The Certificate of Compliance Conformance shall contain the following information:
(a) manufacturer’s name
(b) date of manufacture of the element
(c) unique identifier of the element
(d) material of construction of process contact items
(e) compliance to USP <87> (or ISO 10993-5) and USP <88> Class VI (or ISO 10993-6, -10, and -11)

Other certifications of compliance conformance should be agreed on by the manufacturer and owner/user.
SD-3.9 Spray Devices

SD-3.9.1 General. This section covers spray devices intended for use in bioprocessing equipment, intended to remain in place or be removed during production. Recommendations in this section are valid for water-based cleaning solutions. The flow rate recommendations in this section are for metallic vessels.

(a) Spray devices distribute rinse and cleaning solutions to interior surfaces of bioprocessing equipment by direct spray and use sheeting action for remaining targeted areas. Spray devices are also used in other applications [e.g., water systems to maintain coverage of the storage tank head space and in clean-out-of-place (COP) cabinet washers].

(b) The differential pressure across the spray device generates liquid velocity exiting through the spray device orifices, nozzles, or slots. Differential pressure and its resulting flow are key parameters of spray devices. Flow is the recommended control parameter because it is independent of temperature and location of the measurement device.

(c) The spray pattern, as it exits the device, is determined by the spray device design. Spray patterns are typically streams/jets or fans.

(d) The impact pattern is determined by the interaction over time of the spray pattern and the geometry of the equipment.

(e) During design, consideration should be given to the following in the selection of spray device(s):

1. residue characteristics
2. equipment geometry and appurtenances
3. physical location and orientation of spray device(s)
4. process requirements including air-purge and steaming, if applicable

(f) Spray devices are either static or dynamic. Static spray devices continuously produce a defined impact pattern by stationary direct spray. Static spray devices have no moving parts. Examples of static spray devices include static spray balls, stationary nozzles, and spray wands.

(g) Spray devices are designed as removable, retractable, or to remain in place.

(h) Spray device(s) are specific to the application and equipment. Spray devices are generally not interchangeable without considering the specific flow, pressure, equipment design, spray pattern, and drainability of the spray device(s).

SD-3.9.2 Spray Device Requirements

(a) Materials of construction shall comply with SD-2.4.1.2 or as otherwise agreed on with the owner/user.

(b) When installed, spray devices shall be drainable and cleanable inside and outside or otherwise as agreed on with the owner/user.

(c) Spray device(s) shall be installed per manufacturer’s instructions.

(d) When operated within specification, the spray device(s) shall produce repeatable effective coverage over a defined area of the equipment.

(e) Effective coverage shall not be affected by flow rate variations of 10% or otherwise agreed on by the owner/user.

(f) Spray devices shall be accessible for functionality verification, inspection, and maintenance.
vessel to ensure coverage of appurtenances and provide the sheeting action.

(f) Flow requirements for the specific application should be confirmed with the spray device and/or equipment manufacturer or other subject matter experts.

SD-3.9.2.2 Single-Axis Dynamic Spray Device Requirements

(a) Rotation and/or frequency verification shall be agreed on with the owner/user.

(b) Weld-on or self-cleaning slip-joint/clip-on connections are acceptable. Other hygienic alternatives shall be agreed on with the owner/user.

(c) The flow rate guideline for vertical cylindrical vessels with dished heads is 1.9 gal/min/ft to 2.3 gal/min/ft (23.6 L/min/m to 28.6 L/min/m) of inner vessel circumference. The majority of the flow is directed toward the upper head to ensure coverage of appurtenances and provide the sheeting action.

(d) The flow rate guideline for horizontal cylindrical vessels with dished heads is 1.4 gal/min/ft to 2.1 gal/min/ft (17.4 L/min/m to 26.1 L/min/m) of perimeter $(2L + 2d)$. The majority of the flow is directed toward the upper one-third of the vessel to ensure coverage of appurtenances and provide the sheeting action.

(e) Flow requirements for the specific application should be confirmed with the spray device and/or equipment manufacturer or other subject matter experts.

(f) High-velocity gas flow from air-blows or steam passing through liquid-driven spray devices can result in wear to bearing surfaces. Consideration should be taken to restrict gas flow through the spray device according to the manufacturer’s recommendation.

SD-3.9.2.3 Multiaxis Dynamic Spray Device Requirements

(a) Rotation and/or frequency verification shall be agreed on with the owner/user.

(b) The time to complete a full impact pattern (see Figure SD-3.9.2.3-1) at a specified pressure or flow rate shall be provided by the manufacturer.

(c) Weld-on or self-cleaning slip-joint/clip-on connections are acceptable. Other hygienic alternatives shall be agreed upon with the owner/user.

(d) The flow rate guideline for vertical cylindrical vessels with dished heads is 1.3 gal/min/ft to 1.5 gal/min/ft (16.1 L/min/m to 18.6 L/min/m) of inner vessel circumference to ensure coverage of appurtenances and provide the sheeting action.

(e) The flow rate guideline for horizontal cylindrical vessels with dished heads is 0.8 gal/min/ft to 1.2 gal/min/ft (9.9 L/min/m to 14.9 L/min/m) of perimeter $(2L + 2d)$ to ensure coverage of appurtenances and provide the sheeting action.

(f) Flow requirements for the specific application should be confirmed with the spray device and/or equipment manufacturer or other subject matter experts.

(g) High-velocity gas flow from air-blows or steam passing through liquid-driven spray devices can result in wear to bearing surfaces. Consideration should be taken to restrict gas flow through the spray device according to the manufacturer’s recommendation.

![Figure SD-3.9.2.1-3 Flow Rate Guideline for Horizontal Cylindrical Vessels](ASME BPE-2019)
SD-3.10 Disposables That Require Presterilization or Poststerilization

[Reserved for future content]

SD-3.11 Sampling Systems

SD-3.11.1 General

(a) Sampling equipment in the biopharmaceutical industry is used for the collection of samples that then undergo chemical or microbiological evaluation. Sampling may be either aseptic or nonaseptic.

(b) Sampling systems shall not adulterate the process fluid being sampled nor affect the sample characteristics being tested.

(c) Aseptic sampling systems shall be steamable or presterilized single-use.

(d) Hygienic sampling systems shall either be cleanable or single-use.

(e) Aseptic sampling systems shall be closed to isolate the process; protect the sample, sample container, and sample transfer process from the environment; and obtain representative samples.

SD-3.11.2 Aseptic Sampling Systems

SD-3.11.2.1 Basic Requirements

(a) Steamable sample systems shall meet the relevant requirements of SD-2.3.1.1.

(b) Sampling systems intended for multiple-use shall be cleanable.

(c) Sample valves shall meet the requirement of SD-3.3.2.3.

(d) In septum sample devices, the needles shall be sterilized prior to insertion into the vessel or process line.

(e) Collecting devices shall be designed, connected, and disconnected in ways that maintain the integrity of the sample.

SD-3.11.2.2 Installation. The sampling device shall be installed to maintain the aseptic barrier between the process fluid being sampled and the environment.

SD-3.11.3 Nonaseptic Sampling. [Reserved for future content]

Consideration should be given to ease of assembly and subsequent handling of the sample.

SD-3.11.2.3 Sample Collecting

(a) When using single-use collecting devices, consideration shall be given to maximum pressure ratings of valves, adaptors, and bags.

(b) Consideration should be given to the impact of absorption and off-gassing that could lead to nonrepresentative samples. Polymeric material requirements for leachables and extractables are listed in Part PM.

SD-3.12 Steam Traps

(a) Steam traps are not considered hygienic. Steam trap bodies shall have an internal surface finish (excluding the bellows assembly) as agreed to by all parties. Surface finish specification shall match the clean steam condensate tube finish specification unless the condensate downstream of the trap is used in the process or sampled for quality assurance.

(b) Where used in process systems, the traps shall be capable of effectively venting air.

(c) Where installed on process systems, traps shall be maintainable to allow easy examination and cleaning. Welded traps are acceptable if agreed to by the owner/user.

(d) The trap design and mode of operation shall be such that the risk of soil attachment to the wetted surfaces is minimized, especially around the bellows and seat (see Figure SD-3.12-1).

(e) The trap shall be sized and installed to operate such that there is no backup of condensate into the process equipment and clean steam system under operating conditions. Operating conditions include heat-up, hold, and cool down.

(f) The trap shall be designed such that the normal mode of mechanical failure will be in the open position.
Thermostatic steam traps, installed in vertical trap legs, are preferred for use in clean steam systems (see Figure SD-3.12-1).

Trap operation/reactivity should be improved by the installation of an uninsulated section of tubing upstream of the trap [suggested 12 in. (30 cm) as recommended by supplier] (see Figure SD-4.2.2-2).

**SD-3.13 Check Valves**

(a) Check valves that are used in product contact applications shall be of hygienic design. They shall be designed for CIP. Crevices and holdup volumes should be minimized.

(b) Check valves in process contact applications should be installed in a manner that permits self-draining. Non-self-draining valves may be used for liquid streams that flow continuously (e.g., a compendial water loop) or where valves are wetted with a sanitizing medium when not in use (e.g., chromatography system that is filled with sodium hydroxide solution between uses).

(c) The flow direction and required orientation for drainability should be clearly identified on the device. Where the valve is integral to equipment (e.g., diaphragm pumps, homogenizers) indication of the flow direction is not required.

(d) The use of check valves with springs in product contact should be avoided. The owner/user should determine whether check valves that use a spring are acceptable for other process contact applications. Applications where spring check valves are typically acceptable include condensate removal lines and dry process gases.

(e) Check valve design shall comply with SG-3.3.2.3.

**SD-3.14 Orifice Plates**

Orifice plates, when required and used in hygienic piping systems, shall be installed in a drainable position.

**SD-3.15 Relief Devices**

(a) Rupture disks (or other hygienic pressure relief devices approved by the owner/user) shall be installed in a hygienic manner without compromising the safety or efficiency of the system.

(b) The cleaning system design shall ensure that the rupture disk (or other hygienic pressure relief devices approved by the owner/user) will not be damaged by the cleaning process (e.g., mechanical forces, chemical compatibility).

(c) Rupture disk (or other hygienic pressure relief devices approved by the owner/user) installation shall comply with the L/d ratios mentioned in SD-3.1.2.2.

(d) Rupture disks shall be installed in the manufacturer’s recommended holder to ensure proper functionality and cleanability.

(e) Relief devices, including discharge piping, shall be installed in compliance with applicable codes (e.g., flammable liquids and combustibles in accordance with NFPA 30).

(f) Pressure relief valves that are used in product contact applications shall be of hygienic design on both sides of the valve seat. Crevices and holdup volumes should be minimized.

(g) Safety pressure relief valves that are used in product contact applications shall be of hygienic design up to the valve seat.

(h) Pressure and safety pressure relief valves shall be installed in a manner that permits self-draining on both the process and discharge sides of the valve seat.

(i) Pressure relief valves that are used in product contact applications shall be CIP capable. If required for CIP or SIP, an override that allows flow through the valve shall be included.

(j) Pressure relief valves that are used in product contact applications shall comply with SG-3.3.2.3.
**SD-3.16 Liquid Pressure Regulators**

(a) Regulators should be installed to be fully drainable through the outlet and/or inlet ports.

(b) There shall be no voids or crevices within the area wetted by the fluid. Regulator designs, where a portion of the valve stem penetrates the sensing diaphragm, shall be avoided unless provisions are made to avoid entrapment of foreign matter and any leakage through the interface between stem and diaphragm, especially after SIP.

(c) Due to the inherent design characteristics of self-contained regulators, manual means of override may be required to allow full drainability and drainability.

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**SD-4 PROCESS UTILITIES**

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**SD-4.1 Compendial Water Systems**

(a) Compendial water systems, such as USP Grade Water-for-Injection (PW) and Highly Purified Water (HPW), shall be designed, fabricated in such a manner as to achieve an L/d of 2 or less downstream from the primary POU valve [see Figure SD-4.1.2.1-1, illustrations (a) and (c)].

(b) Loops shall be designed to provide fully developed turbulent flow in the circulating sections and to prevent stagnation up to the weir of each point-of-use valve.

(c) Units should be completely drainable and should not contain any areas where agents used to clean, de-scale, and/or passivate the units are trapped or not easily flushed during rinsing operations.

(d) Sample valves should be integral to the design of the primary valve and should not constitute dead legs.

(e) Sample valves should be installed only as needed on the main loop.

(f) Sample valves should be installed where water is used for the process to demonstrate water quality compliance to compendial monographs.

(g) Any valve used to provide clean utility services to the POU assembly (e.g., steam or clean gas) should be fabricated in such a manner as to achieve an L/d of 2 or less downstream from the primary POU valve [see Figure SD-4.1.2.1-1, illustrations (a) and (c)].

(h) The length of tubing from POU valves to process equipment should be minimized [see Figure SD-4.1.2.1-1, illustrations (a) and (b)].

(i) If evacuating the system is not possible, appropriate venting of the primary POU valve should be accomplished to facilitate sanitation.

(j) When heat exchangers are used as POU coolers [see Figure SD-4.1.2.1-1, illustration (c)], the design shall comply with SD-2.6.

(k) Physical breaks shall be employed between hoses, drain valves, or any other component leading to drains or sinks to avoid back-siphoning into the POU assembly [see Figure SD-4.1.2.1-1, illustrations (d) and (e)]. The distance H of the physical break should be at least twice the inner diameter of the hoses, drain valves, or any other component leading to drains or sinks to avoid back-siphoning into the POU assembly. The break shall be at least 1 in. (25 mm) for hoses, drain valves, or other components with internal diameters less than or equal to 1/8 in. (13 mm) (see Figure SD-4.1.2.2-1).

(l) Tubing and other piping materials should be a minimum of 3/8 in. (19 mm) in diameter to facilitate free drainage of water after use.

(m) POU assemblies shall be drainable as indicated in SD-2.4.3.

(n) A POU may include a venturi or orifice plate, if the restriction of water flow is required. Where used, the additions of these components will require a blowdown to ensure drainability.

(o) When compendial water systems are constructed of metallic materials, the surface finish should be less than or equal to 25 μin. Rθ or 0.6 μm (see Part SF) and may be internally electropolished. All 316L-type internal surfaces shall be passivated.

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**SD-4.1.2 Compendial Water Distribution Systems**

**SD-4.1.2.1 Point-of-Use Piping Design for Compendial Water Systems.** Point-of-use (POU) can be defined as a location in a compendial water loop where water is accessed for processing, and/or sampling. Typically, the point-of-use assemblies are composed of the following elements:

(a) piping associated with a compendial water loop at the physical POU

(b) POU valves, equipment, and instruments

Additional process components and equipment may be added to satisfy application and/or system requirements and will be discussed further in this Part (see Figure SD-4.1.2.1-1).
**SD-3.17 Strainers**

**SD-3.17.1 General**
Strainers as described in this section are intended for process component and equipment protection (see Figure SD-3.17.1-1) and are not designed for bioburden control. Strainers are permitted in locations where they reduce the risk of contamination of a process (e.g., CIP return line).

**SD-3.17.2 Design and Manufacture**

a) Strainers intended for single direction flow shall have the flow direction indicated on the strainer body.

b) The strainer body should have the same surface finish as specified for the process piping or equipment in which it is being installed.

c) Surface finish achievement or measurement may not be possible for all areas of straining surfaces (e.g., strainer element holes, openings, or mesh).

d) For strainers in-line within process piping, the manufacturer should state the operating flow coefficient (Cv) when free of solid particulate loading and maximum allowable pressure drop.

e) Strainer body design features (e.g., sight glasses) shall not create a dead leg.

**SD-3.17.3 Selection, Installation, and Operation**

a) Perforated strainer elements that are free of crevices are preferred for use in permanent hygienic installations. Where perforated strainers cannot be used, the use of other types of strainers (e.g., wire mesh, wedgewire) is permitted if the risk of contamination to the process is mitigated.

b) When specifying strainer elements, the owner/user should provide strainer element hole/mesh size and allowable pressure drop at a given flow across the strainer element and body when free of solid particulate loading.

c) Strainers shall have field tagging (e.g., ID tag, engraving) to ensure external visual identification post-installation.

d) The installed strainer shall allow for removal of the element for inspection or cleaning.

e) Strainers shall be drainable when free of solid particulate loading and installed in the recommended orientation.

f) The design or installation of the strainer within the system should enable detection and removal of captured solid particulates (e.g., visual inspection or pressure differential monitoring).
Figure SD-3.17.1-1 Example Strainer Types

(a) Straight-line Strainer

(b) Gasket Strainer

GENERAL NOTE: Gasket Strainers do not have a stand-alone strainer body. When installed, the gasket strainer is integral to the hygienic piping which acts as the strainer body.
PM-4.4 SD-3.18 Chromatography Columns

PM-4.4.1 SD-3.18.1 General. This section defines typical design elements related to large-scale chromatography columns and includes columns that are intended for repeated use in processing. Although chromatography processes are not typically aseptic, design features for cleaning and/or sanitation should be considered. More information on chromatography columns can be found in Nonmandatory Appendix T.

PM-4.4.2 SD-3.18.2 Pressure-Retaining Parts. The column tube is both a product contact surface and a pressure-retaining component. Chromatography columns are vessels operating under pressure and should meet the requirements of ASME BPVC, Section VIII, as referred to in GR-1, as applicable. If the column tube is acrylic, it shall comply with ASME PVHO-1, Case 14, Low UV. The owner/user is responsible for informing the manufacturer of the normal and abnormal operating conditions to which the column may be exposed. The manufacturer is responsible for ensuring the column will operate safely under said conditions.

PM-4.4.3 SD-3.18.3 Design for Cleaning and Sanitization

PM-4.4.3.1 SD-3.18.3.1 Cleaning. Columns should be designed in accordance with SD-2.4.2 with the exception of the bed supports and flow distributor. Cleaning of chromatography columns is achieved by control of contact time and concentration of the appropriate cleaning agents.

PM-4.4.3.1.1 SD-3.18.3.1.1 Seals. All seals shall conform to Part MC.

PM-4.4.3.1.2 SD-3.18.3.1.2 Exterior Surfaces. Exterior surfaces of columns shall be nonabsorbent and compatible with cleaning agents. Columns shall be designed to allow effective removal of cleaning agents from surfaces.

PM-4.4.3.1.3 SD-3.18.3.1.3 Hygienic Connections. Hygienic connections shall conform to other Parts of this Standard.

PM-4.4.3.2 SD-3.18.3.2 Sanitization

PM-4.4.3.2.1 SD-3.18.3.2.1 Chemical Sanitization. All product contact surfaces within the system shall be compatible with the sanitization agents selected.

PM-4.4.3.2.2 SD-3.18.3.2.2 Thermal Sanitization. When thermal sanitization is used, all column product contact surfaces shall be designed to accommodate expansion and contraction during exposure and cooldown stages.

PM-4.4.4 SD-3.18.4 Column Materials. Column materials for all product contact surface wetted parts shall conform to applicable sections of Parts SD, PM, and SF.

PM-4.4.5 SD-3.18.5 Column Performance. The owner/user shall be responsible for informing the manufacturer of the conditions under which the column may be expected to operate. This shall include the methods, frequency, and duration of cleaning and sanitization procedures. In addition to the service temperature and pressure, any parameters that may affect the column performance shall be provided.

PM-4.4.5.1 SD-3.18.5.1 Service Temperature and Pressure. Columns shall be capable of withstanding thermal and pressure cycling between the rated upper and lower temperature and pressure limits.

PM-4.4.5.2 SD-3.18.5.2 Routine Maintenance. To ensure continued column performance, consideration shall be made to the accessibility of all column components for routine maintenance.

PM-4.4.6 SD-3.18.6 Compliance Conformance Requirements

PM-4.4.6.1 General Requirements. A unique identifier shall be indelibly marked on the column or the column’s support structure. The unique identifier shall enable the owner/user to identify the supplier and the supplier to identify the raw material and processing conditions used to fabricate the article.

PM-4.4.6.2 SD-3.18.6.2 A Certificate of Compliance Conformance shall be issued by the column manufacturer to certify compliance conformance to this Standard when required by the owner/user.

The Certificate of Compliance Conformance shall contain the following information:
(a) manufacturer’s name
(b) unique identifier of the column
(c) material of construction of process contact items
(d) compliance to USP <87> Class VI (or ISO 10993-5) and USP <88> (or ISO10993-6,-10, and -11)
Also see Table PM-2.2.1-1.

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When compendial water systems are constructed of polymer materials, the surface finish should be less than or equal to 25 μin. or 0.6 μm.

**SD-4.2 Clean/Pure Steam Systems**

This section is applicable to both clean and pure steam systems.

**SD-4.2.1 Clean/Pure Steam Generation**

(a) All surfaces that come into direct contact with the clean/pure steam, feed water, or condensate/blowdown produced by the units shall be constructed of 316- or 316L-type stainless steel or other material as specified by the owner/user.

(b) Connections to the clean/pure steam, feed water, or condensate/blowdown produced by the units shall be made by the use of hygienic design fittings. All fittings should be constructed to be free of dead legs and crevices.

(c) Units should be completely drainable and should not contain any areas where agents used to clean, descale, and/or passivate the units are trapped or not easily flushed during rinsing operations.

**SD-4.2.2 Clean/Pure Steam Distribution System**

(a) The distribution system shall have adequate provision to remove air during start-up and normal operations. The use of air vents installed at locations where air is likely to be trapped, such as at the ends of steam headers, can assist in this requirement.

(b) The horizontal distribution lines should be sloped in the direction of flow as indicated in SD-2.4.3. Where necessary, increases in height should be achieved by vertical risers (see Figure SD-4.2.2-1).

(c) Adequate provision should be made to allow for line expansion and to prevent sagging of the distribution lines, so that line drainage is not reduced.

(d) Distribution systems shall not be directly connected to any nonhygienic steam systems (e.g., plant steam systems).

(e) Trap legs for the collection of condensate from the steam distribution system should be of equal size to the distribution line for sizes up to 4 in. (100 mm), and one or two line sizes smaller for lines of 6 in. (150 mm) or larger. These shall be trapped at the bottom. The line size reduction can be made after the branch to the trap leg (see Figure SD-4.2.2-2).

(f) Trap legs should be installed at least every 100 ft (approximately 30 m) upstream of control and isolation valves, at the bottom of vertical risers, and at any other low points.

(g) Condensate shall be allowed to drain to and from steam traps. The use of overhead, direct-coupled, pressurized condensate return systems should be avoided (see Figure SD-4.2.2-2).

(h) Where possible, all components within the distribution system should be self-draining.

(i) Dead legs should be avoided by design of runs and the use of steam traps to remove condensate (see Figures SD-4.2.2-1 and SD-4.2.2-2).

(j) Traps and points-of-use should be routed from the top of the steam header to avoid excessive condensate load at the branch (see Figure SD-4.2.2-2).

(k) Sampling points for clean/pure steam should be located to collect representative sample(s) of the system (e.g., generator outlet, distribution header ends, critical points-of-use, autoclaves, or SIP stations).

**SD-4.2.3 Clean/Pure Steam Valves.** This paragraph covers isolation, regulation, and control valves that are part of the steam system and are subject to continuous steam service.

(a) Valves for steam service shall be designed for drainability and should have minimal fluid holdup volumes.

(b) Ball valves are an acceptable industry standard for isolation purposes on continuous steam service. Three-piece-body ball valves should be used instead of single-body designs for both cleanability and maintainability. The bore of the ball valve assembly shall match the inside diameter of the tube (see Figure SG-2.3.1.3-1).

(c) All components shall be suitable for continuous steam service at the temperatures and pressures specified by the owner/user.

(d) Requirements for operation under CIP and SIP conditions [see SG-3.3.2.3(a)(11) and SG-3.3.2.3(a)(13)] can be relaxed when agreed to by the owner/user.

(e) Secondary stem seals with telltale connections are not required for steam service.

(f) Valves shall be accessible for maintenance.
**SD-4.3 Process Gases**

**SD-4.3.1 Process Gas Distribution Systems.** For this section, a process gas distribution system is one that extends from the bulk supply source (including cylinders) to the points of use as defined by the owner/user.

(a) The installation of process gas delivery and distribution systems for use within the scope of this Standard requires appropriate selection of piping materials. All components shall be supplied or rendered both hydrocarbon free (e.g., oil free) and particulate free prior to installation and/or use.

(b) For materials of construction, the owner/user shall specify all materials. When copper is used, it should be hard drawn and installed in accordance with the current edition of NFPA 99, Chapter 5. When copper is specified in a clean room or area, the owner/user shall confirm that all planned cleaning and sanitizing agents are compatible with copper and all materials of construction. When stainless steel tubing is specified, the materials of choice are 304L-type or 316L-type alloys. Orbital welding is the recommended joining method. Inside clean rooms, the materials of choice are 304L-type or 316L-type stainless steel tubing and fittings. The owner/user and manufacturer shall agree on all joining methods, levels of inspection, and acceptance criteria for all joints prior to installation.

(c) Compression fittings may be used for valves, regulators, mass flow controllers, and other instrumentation systems at the source and/or within system boundaries.

(d) Gas systems are not designed or configured with the intent or provisions to be cleaned, passivated, or chemically treated after installation. Features such as slope, high-point vents, and low-point drains need not be incorporated into these systems.

(e) There shall be no nonvolatile residue. The system design shall ensure that gas will remain pure throughout its delivery.

(f) It is important to select appropriate prefilters and final system filters. The final point-of-use gas purity shall comply with the process requirements.

(g) Gas systems testing and sampling shall comply with 21 CFR 211 and ICH Q7 (International Conference on Harmonization, Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients).

**SD-4.4 Process Waste Systems**

This section addresses process waste systems because the reliable function of the waste system can reduce the risk of contamination to the process. By designing systems that can be cleaned and rendered safe for access and preventive maintenance, reliable operation may be achieved.

**SD-4.4.1 General.** The manufacturing of biologics generates liquid waste in various quantities that may or may not contain viable microorganisms. The liquid waste comes directly from the process fluids and may include cleaning solutions mixed with product components, buffers, or media.
The performance of process waste treatment systems may benefit from the sanitary design requirements of Part SD. The design of the process waste transfer line(s) shall prevent process waste backflow to the process system(s), reducing the risk of contamination.

The effectiveness and safety of process waste treatment systems have been shown to benefit from incorporating the design principles of Part SD. This is true of bio-inactivation systems where heat or chemical dosing is used, or where biosafety containment is required.

**SD-4.4.2 Bio-Inactivation Systems.** Depending on the type of waste, the treatment method is chosen based on effectiveness, efficiency, and jurisdictional requirements. The owner/user shall define the inactivation conditions and verify the effectiveness of the system with respect to these requirements. Bio-inactivation may be designed to be continuous or batch type and is achieved using one or more of the following methods:

(a) thermal
(b) chemical
(c) radiation

The system design should minimize fouling and buildup of solids and films. Bio-inactivation systems should be cleanable to allow safe disassembly and maintenance. Where biosafety containment is a requirement, the system shall be sanitizable.

In bio-inactivation systems, piping design features specified in SD-2 and SD-3 may help in achieving proper and repeatable operation of these process waste systems.

**SD-5 PROCESS SYSTEMS**

**SD-5.1 Bioreactors and Fermentors**

**SD-5.1.1 General.** For this section, the terms “fermentors” and “bioreactors” are interchangeable. A bioreactor or fermentor shall be defined as a vessel-based system used in the growth of microorganisms or plant, mammalian, or insect cells.

**SD-5.1.4 System Design**

**SD-5.1.4.1 Inlet Gas Assembly.** The inlet gas assembly shall be defined as a piping assembly that has the ability to deliver controlled amounts of filtered gases into a bioreactor vessel. The assembly shall include but is not limited to the items in SD-5.1.4.2 through SD-5.1.4.5.

**SD-5.1.4.2 Flow Control Devices**

(a) Flow control devices (e.g., rotameters, mass flow controllers, and modulating control valves) shall be installed outside of the sterile boundary; therefore, piping requirements within this section may not apply. However, provisions shall be included within the design to prevent instrumentation damage due to SIP procedures and backflow.

(b) Flow control devices should be sized to prevent a vacuum condition, or a provision to bypass the flow control device shall be provided to maintain positive pressure in the vessel.

**SD-5.1.4.3 Inlet Filter Assembly**

(a) For this section, an inlet filter shall be defined as a filter element installed in a housing of suitable material. The inlet filter assembly shall be defined as the filter(s) local to the bioreactor.

(b) Inlet filter assemblies shall be designed for SIP with provisions to remove entrapped air and condensate.

(c) If multiple inlet filters are used in series, then the filter assembly closest to the bioreactor shall be a sterilizing filter.

(d) Provisions shall be made for integrity testing of the inlet filter assembly in situ or out of place.

(e) If the inlet housing(s) are included in a cleaning circuit, the filter element(s) shall be removed prior to introduction of cleaning solutions.

(f) Gas filters should be installed above the bioreactor liquid level.

**SD-5.1.4.4 Gas Sparging Assemblies**

(a) Spargers shall be defined as mechanical devices normally located below an impeller used to disperse gases within a charged bioreactor. This section applies to sparge lances, wands, rings, and other devices (see Figures SD-5.1.4.4-1 through SD-5.1.4.4-4) that may be mounted in the bioreactor vessel to introduce various gas streams for process operations. Sparge device assemblies shall meet the requirements of SD-3.4.2.

(b) Spargers shall be designed for SIP with the vessel.

(c) Spargers should be designed for CIP. If the sparge element cannot be CIP’d, provisions shall be made to remove the sparge assembly from the bioreactor for replacement or cleaning out of place.

(d) The removable sparger shall be supplied with the means to ensure that the installation orientation is in compliance with design intent.

(e) If a check valve is installed in the sparge line within the sterile envelope, it shall be designed for CIP and SIP.

**SD-5.1.4.5 Inlet Gas Piping**

(a) Overlay piping is defined as piping that directs filtered gases to the vessel headspace.

(b) Inlet gas assembly piping (sparge and overlay) within the sterile envelope shall meet the requirements as defined in SD-3.1.2.

**SD-5.1.4.6 Exhaust Gas Assembly.** The exhaust gas assembly is defined as a piping assembly that maintains the integrity of the sterile boundary with respect to

conformance to
sterility and pressure. The assembly shall include but is not limited to the items in SD-5.1.4.7 through SD-5.1.4.9.

**SD-5.1.4.7 Exhaust Filter**

(a) For this section, an exhaust filter shall be defined as a filter element (as described in Nonmandatory Appendix T) installed in a housing of suitable material.

(b) Exhaust filters shall be designed for SIP. The housings shall be installed in such a way as to prevent the collection of condensate in the elements due to SIP.

(c) If redundant sterilizing-grade exhaust filters are used in series, then the filter farthest from the bioreactor shall have a maximum rating of 0.2 μm absolute. In addition, provisions shall be included for draining condensate from the piping between the filters.

(d) Consideration should be made for CIP or removal in the case of cleaning out of place.

(e) Provisions shall be made for integrity testing of the exhaust filter assembly.

(f) If the exhaust filter housing(s) are included in a cleaning circuit, the filter element(s) shall be removed prior to introduction of a cleaning solution.

(g) To prevent the exhaust filters from becoming blinded by condensate saturation during operation, the exhaust gas assembly may include exhaust condensers (Figure SD-5.1.4.7-1), exhaust heaters (Figure SD-5.1.4.7-2), or steam jacketed or electrically heat traced filter housings (Figure SD-5.1.4.7-3). These items shall be designed for SIP and CIP.

**SD-5.1.4.8 Exhaust Gas Piping**

(a) The exhaust gas assembly within the sterile envelope shall meet the requirements as defined in SD-3.1.2.

(b) The design of exhaust gas piping from the bioreactor should ensure that there is no condensate accumulation in the line downstream of the system.

**SD-5.1.4.9 Back Pressure Control Devices**

(a) If required, back pressure control devices (e.g., modulating control valves or regulators) should be installed outside of the sterile boundary.

(b) Back pressure control devices shall not hinder the bioreactor’s capability of being SIP’d and CIP’d.

(c) If a vapor-liquid separator is used in the exhaust within the sterile envelope, it shall be designed for CIP and SIP.

**SD-5.1.4.10 Feed Lines.** This section applies to bioreactor piping systems used to feed liquid ingredients (e.g., pH control reagents, antifoam reagents, media, nutrient, and inoculum). Feed lines shall be designed with the appropriate piping system to allow CIP and SIP of the bioreactor vessel and the feed line itself. CIP and SIP of the feed line may be done independently or simultaneously with the bioreactor.

**SD-5.1.4.11 Dip Tubes.** This section applies to all bioreactor port tube-extensions within the vessel.

(a) Bioreactor dip tubes shall meet the requirements of SD-3.4.2.

(b) Removable dip tubes (see Figure SD-3.4.3-1) shall be inserted through a hygienic fitting. The removable dip tube shall be supplied with the means to ensure that the installation orientation is in compliance with design intent.

(c) Bioreactor dip tubes shall be designed for CIP or cleaning out of place (COP).

**SD-5.1.4.12 Harvest Valves/Bottom Outlet Valves.** This section applies to all valves installed in the vessel bottom head.

(a) Harvest valves shall meet the requirements of SD-3.3.2.3.

(b) Bioreactor harvest valves shall be designed for SIP and CIP or COP.

**SD-5.1.4.13 Agitation Assemblies.** This section applies to mechanical agitator assemblies mounted in the bioreactor for achieving one or more mixing-related unit operations (e.g., blending, mass transfer, heat transfer, and solids suspension).

(a) Agitators shall meet the requirements of SD-3.5.

(b) Agitators with double mechanical seals (see Figure SD-2.3.2.3-2) or magnetic couplings (Figure SD-3.5.5-2) are recommended to isolate bioreactor contents from the environment.

(c) Agitator seal or magnetic coupling components shall be designed for CIP and SIP.

**SD-5.1.4.14 Mechanical Foam Breaker Assemblies.** This section applies to mechanical foam breaker assemblies that may be mounted in the bioreactor for reducing or eliminating foam accumulation in the vapor space of the bioreactor.

(a) Foam breaker assemblies shall meet the requirements of SD-3.5.

(b) Foam breakers with either double mechanical seals (Figure SD-2.3.2.3-2) or magnetic couplings (Figure SD-3.5.5-2) are recommended to isolate bioreactor contents from the environment.

(c) Foam breaker seal or magnetic coupling components shall be designed for CIP and/or SIP as appropriate.
SD-5.1.4.15 Internal Coils

(a) Internal coils should be avoided where possible.
(b) Product contact surfaces of internal coils require provisions for CIP and SIP.

SD-5.1.4.16 Baffles. Baffle assemblies shall meet the requirements of SD-3.4.

SD-5.1.4.17 Spray Devices. This section applies to sprayballs, wands, and other devices (see Figure SD-3.9.2.1-1) that may be mounted in the bioreactor vessel for distributing cleaning solution during CIP operations.
(a) Spray device assemblies shall meet the requirements of SD-3.4.2 and SD-3.9.
(b) If not removed during processing, spray device assemblies shall be designed for SIP.

SD-5.1.4.18 Instrumentation

(a) Instruments installed within the sterile envelope or boundary shall be designed for SIP. Consideration should be made in the design for instrument removal for calibration.
(b) Instruments installed within the sterile envelope or boundary shall be designed for CIP or removed for COP.
(c) Temperature-sensing elements should be installed in thermowells. Piping associated with in-line thermowells shall be sized to allow sufficient steam and condensate flow.

SD-5.1.5 Design for Bioburden Control

(a) The area within the bioreactor sterile envelope or boundary shall be designed for cleanability and bioburden control. As a minimum, the bioreactor sterile envelope or boundary shall include the following (see Figures SD-5.1.5-1 and SD-5.1.5-2):
(1) vessel internals
(2) inlet gas piping from the filter element(s) to the vessel and any installed isolation valving (If redundant sterilizing-grade filters are used in series, the inlet filter element farthest from the reactor vessel shall define the sterile boundary.)
(3) exhaust gas piping from the vessel side of the exhaust filter(s) to the vessel and any installed isolation valving (If redundant sterilizing-grade filters are used in series, the exhaust filter farthest from the reactor vessel shall define the sterile boundary.)
(4) agitation assembly including all internal surfaces of the impellers and the shaft up to the mechanical shaft seal in contact with the product
(5) feed systems from the vessel to the seat of the isolation valve nearest to the bioreactor vessel or if the feed stream is being filter sterilized, the sterilizing-grade filter element
(6) sampling system
(7) product harvesting system from the vessel to the seat of the isolation valve nearest to the bioreactor vessel
(b) A bioreactor is made up of a number of subassemblies. Process-contacting subassemblies require special design consideration for cleaning and bioburden control.
(c) The bioreactor design for cleanability and sterility shall take into consideration the biosafety level requirement for the system. A bioreactor shall be designed in accordance with a biosafety level requirement as defined by the National Institutes of Health or equivalent organization (e.g., BSL-1, BSL-2, BSL-3, or BSL-4). The biosafety level requirement should be determined based on the organism, the process, the product being produced, and the owner/user's preferences. To meet a specific biosafety level requirement, special operational considerations (e.g., steam blocks) may have to be addressed within the bioreactors' subassembly designs. If the bioreactor has been used to grow an organism that requires biohazard containment, provision shall be
made to decontaminate all surfaces that may have come in contact with the product prior to CIP, or to contain and decontaminate the fluids used for CIP.

**SD-5.1.5.1 Drainability**

(a) Inlet gas piping within the sterile envelope shall meet slope requirements as defined for GSD3 in Table SD-2.4.3.1-1.

(b) Exhaust gas piping within the sterile envelope shall meet slope requirements as defined for GSD3 in Table SD-2.4.3.1-1.

(c) All wetted surfaces of sparged devices shall be sloped to drain by gravity into the vessel.

(d) Feed line valves and piping orientation shall be designed to provide complete drainage during CIP and SIP.

(e) All wetted surfaces of dip tube(s) shall be sloped to drain by gravity into the vessel.

(f) Bottom outlet valves shall be drainable and installed in such a way as to ensure complete drainage of the bioreactor contents.

(g) Bottom-mounted agitators shall not interfere with free and complete drainage of bioreactor contents.

**SD-5.1.5.2 Cleaning**

(a) The area within the sterile envelope should be designed for CIP. For components that cannot be CIP'd, the design shall allow removal for replacement or manual cleaning out of place.

(b) If instruments will be cleaned out of place, blind caps or plugs should be provided to maintain the integrity of the bioreactor system.

(c) If CIP of the ingredient feed system is performed during active culture operations, then the design should include provisions to prevent cross-contamination between CIP solutions and product.
If dip tube(s) are cleaned in place with the vessel, both the inside and outside of the dip tube(s) shall be cleaned.

Provisions shall be included in the design to clean the product contact surfaces of impellers. Additional spray elements may be required to achieve coverage.

CIP for sparge devices that use porous material for gas distribution requires particular attention. These devices should be evaluated for CIP cleanability and should be removed from the bioreactor for external cleaning and/or replacement when CIP is not feasible.

**SD-5.1.5.4 Thermal Sanitization/Sterilization**

(a) The area within the sterile envelope should be designed for SIP. For those components or assemblies that cannot be SIP’d, the design shall allow removal for steam sterilization using an autoclave as long as additional provisions are provided for sterilizing the interface (e.g., steam block) once the components or assemblies are reconnected to the remainder of the bioreactor system. Autoclaved components or assemblies shall be capable of being steam sterilized without degradation to any of the elastomers or polymers that make up the components or assemblies.

(b) If the bioreactor is sterilized with media in the vessel, the SIP operation shall direct steam flow through the sparge device.

(c) If the bioreactor is sterilized with media in the vessel, and dip tube(s) extends below the working level of the media, the SIP operation shall direct steam flow through the dip tube into the vessel.

(d) For dip tube(s), the SIP operation shall direct or balance steam distribution to establish and maintain sterilization temperature within the tube(s) during the sterilization hold period.

(e) Special considerations for spray devices are as follows:

1. The SIP operation shall direct or balance steam distribution to establish and maintain sterilization temperature within the spray device during the sterilization hold period.
2. With the exception of a combination sparger/spray device, internal spray devices should be located above the bioreactor operating liquid level.
3. If the bioreactor is sterilized with media in the vessel, and the spray device assembly extends or is located beneath the working level of the media, the SIP operation shall direct steam flow through the device into the vessel.

SD-5.1.7 Testing. The bioreactor vessel should be pressure/vacuum and temperature rated per the owner/user’s design criteria. The vessel shall be constructed, tested, inspected, and stamped in accordance with the appropriate ASME/ANSI code.

**SD-5.2 Cell Disrupters**

**SD-5.2.4 System Design**

(a) Product contact material shall not affect product quality or integrity.

(b) The design shall incorporate non-shedding components and parts.

**SD-5.2.5 Design for Bioburden Control**

**SD-5.2.5.1 Drainability**

(a) The device shall be designed with the ability to optimize drainability.

(b) Safety rupture disks shall be oriented for drainability while maintaining system integrity and safety.

**SD-5.2.5.2 Cleaning.** The disrupter shall be designed for ease of disassembly to allow for COP.

**SD-5.3 Centrifuges**

**SD-5.3.1 General.** Centrifugation is a process used to separate suspended materials of different densities using centrifugal force. Centrifuges may be used for collection of solids such as harvest of cells, inclusion bodies of precipitated protein, or clarification of bioprocess solutions. Different types of centrifuges include disk stack centrifuges, tubular bowl centrifuges, single-use centrifuges, and ultracentrifuges.

**SD-5.3.2 Process Parameters.** The owner/user should define the following process parameters:

(a) whether the centrifuge will be used for collection of solids, for clarification, or for both

(b) whether the centrifuge is intended for open, closed, or briefly exposed operation(s)

(c) the biosafety level containment and room classification requirements of the process and system

(d) product phase (e.g., supernatant or solids)

(e) cleaning requirements (e.g., CIP or physical properties of solids (e.g., shear sensitivity, rheology)

For each parameter, the user may also define warning and alarm tolerances or limits. Additional process requirements may be defined by the owner/user.

**SD-5.3.3 Density Difference Between Solvent and Suspended Solids**

**SD-5.3.4 Viscosity and Surface Tension of Liquid**

**SD-5.3.5 Physical Properties of Solids**

For each parameter, the user may also define warning and alarm tolerances or limits. Additional process requirements may be defined by the owner/user.

**SD-5.3.6 Batch Size**

**SD-5.3.7 Process Liquid Feed Flow Rate**

**SD-5.3.8 Solids Cell Type or Particle Size and Distribution**

**SD-5.3.9 Solid Concentration [in Packed Cell Volume (PCV)]**

**SD-5.3.10 Feed Pressure**

**SD-5.3.11 Process Temperature**

**SD-5.3.12 Feed Pressure**

**SD-5.3.13 Process Temperature**

**For each parameter, the user may also define warning and alarm tolerances or limits. Additional process requirements may be defined by the owner/user.**
SD-5.2 Cell Disruptors

SD-5.2.1 General

Homogenizers and high-shear fluid processors disrupt cells by sudden cavitation, high shear or impingement of a highly pressurized process fluid.

Homogenizer systems consist of a variable-speed positive displacement pump and an adjustable orifice. The system may also include a feed pump and a cooling heat exchanger.

High-shear fluid processors are a variation of the homogenizer operating at higher pressure ranges. These include a fixed-speed positive displacement pump and a fixed orifice.

Refer to figure SD-5.2.1-1 for a typical cell disruptor process flow schematic diagram.

SD-5.2.2 System Performance Requirements

The following system performance requirements and operating parameters shall be defined:

(a) process fluid properties (e.g. cell mass concentration, shear sensitivity, density, viscosity)
(b) operating pressure range
(c) process fluid flow rate
(d) process temperature range
(e) required cell disruption efficiency

SD-5.2.3 System Design

The manufacturer shall disclose when ASME BPE non-conforming materials, connections or seals are required for product contact areas in high-pressure applications.

SD-5.2.3.1 Inlet

(a) Continuous flow and pressure shall be present to prevent damage to the cell disruptor. Pulsations or fluctuations of the process flow should be minimized.
(b) The system should be capable of priming/purging of air from the system during start-up.
(c) The system should be capable of maintaining an environment free of air entrainment during operation.
SD-5.2.3.2 Pump and Orifice

(a) The manufacturer shall disclose if seal materials in contact with process fluids do not meet the requirements of SD-2.4.1.1 (e.g., USP Section <88> Class VI).

(b) When high containment is specified, the cell disruptor shall be designed as a closed system (e.g., homogenizer with double packed cylinder seal design, containment of seal quench fluid, containment of components with the isolator).

SD-5.2.3.3 Outlet

If required by the process, the system shall be designed to remove heat generated by the cell disruptor.

SD-5.2.3.4 Instrumentation

The system should be designed to enable high pressure seal integrity monitoring (e.g., viewing through a sight glass, conductivity monitoring or turbidity monitoring).

SD-5.2.5 Design for Bioburden Control

The bioburden control strategies (e.g., CIP, COP, water rinses, SIP, hot or superheated water sanitization, chemical sanitization) for product contact surfaces shall be defined by the owner/user. The preferred mode of equipment storage (e.g., flooded or dry) shall be defined.

SD-5.2.5.1 Drainability

The design shall accommodate forced expulsion for the removal of liquid, when the system is specified to be stored dry.

SD-5.2.5.2 Cleaning

(a) The following are recommendations for cell disruptors designed for CIP:

(1) The manufacturer should recommend CIP flow rate and pressure.
(2) The equipment should be designed to enable cleaning verification/validation of all process contact surfaces.
(3) CIP bypasses should be provided parallel to flow restrictions for hydraulic balancing. Means of flow verification should be provided for cleaning circuits that employ parallel cleaning paths.
(4) The cell disruptor should be operated during cleaning, typically at the highest flow rate available.
(5) If present, seal lubrication systems should be designed to be cleaned or flushed.

(b) Portions of cell disruptors that are not designed for CIP shall be identified. Those identified portions shall be designed for disassembly and reassembly for COP and examination.

SD-5.2.4.3 Chemical Sanitization

(a) Where chemical sanitization is specified, the components within the sanitization boundary shall be designed for exposure to and removal of sanitizing agent while maintaining the sanitized state.

(b) The manufacturer should recommend the chemical sanitization flow rate and pressure.

SD-5.2.4.4 Thermal Sanitization

Where thermal sanitization is specified, the surfaces within the sanitization boundary shall be designed for SIP or for hot liquid sanitization.

SD-5.2.5 Design for Serviceability, Examination, and Operation.

The high-pressure zone shall be capable of disassembly for periodic cleaning and inspection.
**SD-5.3.3 Performance requirements.** The owner/user shall define the following system performance requirements:

(a) maximum allowable processing and cleaning/sanitization times
(b) desired purity (e.g., PCV in supernatant or % solids)

For each parameter, the user may also define warning and alarm tolerances or limits. Additional performance requirements may be defined by the owner/user.

**SD-5.3.4 Disk Stack Centrifuge.** In bioprocessing, the disk stack centrifuge is typically used as a continuous unit operation to separate cells from cell broth, cell debris or acid precipitates from liquid, or to recover inclusion bodies after homogenization of microbial cells. A disk stack centrifuge consists of a cylindrical bowl containing a stack of conical disks separated by spacers, which reduce the distance and increase the surface area for particulate settling when under centrifugal force.

**SD-5.3.4.1 Operating Capabilities and System Function.** The centrifuge shall be capable of the following functions:

**SD-5.3.4.1.1 Cleaning.** Centrifuges should be designed for CIP. Different parts within the centrifuge may have different cleaning requirements or procedures. Centrifuges that will be CIP’d shall be constructed of materials compatible with the chemistry and conditions of the cleaning process (SD-2.4.1.2). Centrifuges designed for CIP shall comply with SD-2.4.2. Additional requirements for disk stack centrifuges subject to CIP include the following:

(a) The manufacturer shall ensure that all product contact surfaces are cleanable with the CIP process. This includes adequate velocity of cleaning solutions in piping per SD-6.3.5.2. The use of instrument tees conforming with Tables DT-4.1.2-10 and DT-4.1.2-11 is recommended for instruments. However, all product contact branches (e.g., instrument tee/ports, process branches) shall be exposed to cleaning fluids during CIP.
(b) The manufacturer should design the equipment to include sample collection points that allow for representative cleaning verification/validation of all product contact branches.
(c) Spray devices shall conform with SD-3.9.
(d) The manufacturer shall recommend CIP solution supply rate and pressure requirements for effective cleaning.
(e) Due to fluctuations in flow (e.g., bowl discharge), use of recirculating CIP flow paths may require break tanks, bypass flows, and pumps that can generate suction when run dry.
(f) The centrifuge manufacturer shall identify all areas of primary and incidental product contact that require manual cleaning in addition to CIP. Centrifuges that are not designed for CIP shall be capable of disassembly and reassembly for cleaning and examination.

**SD-5.4 Filtration Systems**

**SD-5.4.4 System Design**

(a) All wetted surfaces should be accessible for cleaning and examination.
(b) The filter housing shall be designed to allow for complete venting and draining. Liquid tee-type filter housings should be installed vertically, and vent-type in-line filter housings should be installed vertically with the condensate/drain port directed downward (see Figure SD-5.4.4-1).
(c) All nozzle connections shall be of a hygienic design.
(d) Baffle plates, when used, should be cleanable and designed for SIP.
(e) The housing assembly, tube sheets, end plates, and connections should be designed to prevent bypassing of process fluid around the element.
(f) Parts forming internal crevices should be easily disassembled to enable access for cleaning.
(g) Vent filters for hot process services should be heat traced or steam jacketed. Other methods for preventing moisture accumulation in vent filters, such as vent heaters or condensers, could be considered.

**SD-5.4.4.1 Micro/Ultrafiltration Systems**

(a) Skid pumps designed for both process and CIP shall be designed to provide turbulent flow for cleaning. All process piping systems that include piping, tubing, and fluidic components shall be sloped for adequate drainage. For all low points in the system, a drain port shall be installed. A common drain port on the skid is preferred.
(b) Piping and equipment connections should be designed to prevent bypassing of process fluid around the element.
(c) Ultrafiltration cartridge with connections and covers should be drain completely.

**SD-5.3.4.1.2 Sterilization/Sanitization.** The owner/user shall inform the manufacturer of the sterilization/sanitization and storage requirements (e.g., temperature, pressure, chemistry) and storage condition (e.g., flooded or dry). The owner/user and manufacturer shall define the sterile envelope or boundary.

Centrifuges that will be SIP’d shall be designed in accordance with SD-2.3.1.1, and, in certain jurisdictions, may be considered pressure vessels (see GR-1). The manufacturer shall demonstrate saturated steam penetration across components that define the sterile boundary of the system.

Centrifuges that will be chemically sanitized shall be sanitized with an agent and process that have been proven to achieve the bioburden reduction requirements of the system.

The manufacturer should recommend the operating conditions (e.g., sanitizing agent supply flow rate, bowl speed, discharge rate) required to ensure effective chemical sanitization.
SD-5.3 Centrifuges

SD-5.3.1 General. Centrifugation is a process used to separate suspended materials of different densities using centrifugal force. Centrifuges may be used for collection of solids such as harvest of cells, inclusion bodies of precipitated protein, or for clarification of bioprocess solutions. Different types of centrifuges include disk stack centrifuges, tubular bowl centrifuges, single-use centrifuges and ultracentrifuges.

SD-5.3.4 Disk Stack Centrifuge.
In bioprocessing, the disk stack centrifuge is typically used as a continuous unit operation to separate cells from cell broth or cell debris or acid precipitates from liquid, or to recover inclusion bodies after homogenization of microbial cells.

SD-5.3.1.1 Disk Stack Centrifuge. A disk stack centrifuge consists of a cylindrical bowl containing a stack of conical disks separated by spacers, which reduce the distance and increase the surface area for particulate settling when under centrifugal force. 

SD-5.3.2 Process Parameters-System Performance Requirements.
The owner/user should design the following process parameters:
The following system performance capabilities should be defined at the beginning of design.
(a) Whether the centrifuge will be used for collection of solids, for clarification, or both
(b) Whether the centrifuge is intended for open, closed or briefly exposed operation(s)
(c) The biosafety level containment and room classification requirements of the process and system
(d) Product phase (e.g., supernatant or solids)
(e) Cleaning requirements (e.g., CIP or manual cleaning)
(f) Sanitization requirements (e.g., SIP)
(g) Batch size
(h) Process liquid feed flow rate
(i) Solids cell type or particle size and distribution
(j) Solid concentration [in packed cell volume (PCV)]
(k) Feed pressure
(l) Process temperature
(m) Density difference between solvent and suspended solids
(n) Viscosity and surface tension of liquid

For each parameter, the user may also define warning and alarm tolerances or limits. Additional process requirements may be defined by the owner/user.

(b) Product to be separated
(1) Solid concentration [e.g. in Packed Cell Volume (PCV)]
(2) Solids cell type or particle size and distribution
(3) (d) recovered product phase (e.g., supernatant, or solids), or both
(4) Density difference between solvent and suspended solids, if available
(5) Viscosity and surface tension of liquid, if available
(6) product shear sensitivity
(c) multipurpose or dedicated to a single product
(d) batch or continuous operation
(e) batch size
(f) process liquid feed flow rate
(g) process temperature
(h) description of owner/user’s processes immediately upstream and downstream of the centrifuge
(i) requirements for processing volatile flammable materials

SD-5.3.3 Performance Requirements.
The owner/user shall define the following system performance requirements:
(a) maximum allowable processing and cleaning/sanitization times
(b) desired purity (e.g., PCV in supernatant or % solids)
For each parameter, the user may also define warning and alarm tolerances or limits. Additional
performance requirements may be defined by the owner/user.

SD-5.3.2.1 Process Parameters. Additional process parameters required to confirm system
capabilities should be defined:
(a) cleaning requirements (e.g., CIP or manual cleaning)
(b) sanitization requirements (e.g., SIP)
(c) maximum allowable processing and cleaning/sanitization times
(d) requirements associated with the biosafety level containment and room classification of
the process and system
(e) required feed and discharge pressure
(f) purity criteria (e.g., solids in supernatant, turbidity, yield, based on prior product tests or
experience).

SD-5.3.4 Disk Stack Centrifuge. In bioprocessing, the disk stack centrifuge is typically used as a
continuous unit operation to separate cells from cell broth, cell debris or acid precipitates from
liquid, or to recover inclusion bodies after homogenization of microbial cells. A disk stack centrifuge
consists of a cylindrical bowl containing a stack of conical disks separated by spacers, which
reduce the distance and increase the surface area for particulate settling when under centrifugal
force.

SD-5.3.34.1 Operating Capabilities and System Function.
The centrifuge shall be capable of the following functions:
The system should be designed with an alternative liquid feed source (e.g., purified water, buffer)
for priming of the centrifuge.

SD-5.3.4 System Design.
SD-5.3.4.1 Feed
For intermittent discharge systems, the centrifuge system shall control and monitor the feed flow rate
and pressure.
SD-5.3.4.2 Bowl

(a) If a cyclone is present in intermittent solids discharge centrifuges, it shall be capable of containing and decelerating the discharged bowl contents. The cyclone should be cleanable.

(b) Nozzles at the periphery, top, or bottom of the bowl in continuous solids discharging centrifuges should allow for continuous discharge of settled contents.

(c) Process compatibility, cleaning and sanitation requirements shall be considered when selecting materials. Components in the centrifuge that are subject to high dynamic stresses (e.g., peripheral rotating components) may require high strength materials.

SD-5.3.4.3 Disk Stack

(a) Disks shall be removable for visual inspection.

(b) Disk Spacing:

(1) Spacers between disks should be drainable.

(2) Spacers should not interfere with system cleanability.

(c) The disk stack shall be designed with a material that can withstand the mechanical stresses that the centrifuge will undergo during operation.

SD-5.3.4.4 Instrumentation

(a) Instrumentation should be installed to detect a failure in the bowl discharge or flooding of the cyclone, if present.

(b) Centrifuge instrumentation shall monitor abnormal machine vibrations that may result in a safety hazard and unit failure.

(c) The system should be capable of regulating bowl speed to control the centrifugal forces that separate the product.

(d) The quality of the supernatant should be monitored through a sight glass or instruments such as a turbidity meter.

SD-5.3.4.4.1 Supernatant Outlet Pressure Control Valve

The supernatant outlet on centrifuges that are not hermetically sealed should have a pressure control valve to keep the bowl flooded.

SD-5.3.4.5 Compendial Water Separation

The compendial water system shall be isolated from potential process contamination (e.g., by use of a break tank, double block and bleed valve).

SD-5.3.4.6 Interfaces

[Reserved]

SD-5.3.5 Design for Bioburden Control

The bioburden control strategies (e.g., CIP, SIP, chemical sanitization) and associated conditions (e.g., temperature, pressure, chemistry) for product contact surfaces shall be defined.

SD-5.3.5.1 Drainability

Centrifuges that are not designed to be drainable may require additional means for liquid removal (e.g., air blow). The centrifuge shall be designed to facilitate liquid removal under dynamic bowl conditions.
The solids catcher inside the centrifuge, and the solids discharge connection to the cyclone are typically horizontal. Provisions for liquid removal from these surfaces shall be provided in accordance with SD-2.4.3.1.

SD-5.3.5.24.1.1 Cleaning. Centrifuges should be designed for CIP. Different parts within the centrifuge may have different cleaning requirements or procedures. Centrifuges that will be CIP’d shall be constructed of materials compatible with the chemistry and conditions of the cleaning process (SD-2.4.1.2). Centrifuges designed for CIP shall comply with SD-2.4.2.

SD-5.3.5.2.1 Disk Stack Centrifuges. Disk stack centrifuges should be designed for CIP. Additional requirements for disk stack centrifuges subject to CIP include the following:

(a) The manufacturer shall ensure that all product contact surfaces are cleanable with the CIP process. This includes adequate velocity of cleaning solutions in piping per SD-6.3.5.2. The use of instrument tees conforming with Tables DT-4.1.2-10 and DT-4.1.2-11 is recommended for instruments. However, all product contact branches (e.g., instrument tees/ports, process branches) shall be exposed to cleaning fluids during CIP. Product contact surfaces (e.g., bowl, hood, solids catcher, cyclone) shall be compatible with the cleaning solutions.

(b) The manufacturer should design the equipment to include sample collection points that allow for representative cleaning verification/validation of all product contact branches. Sampling points for representative cleaning verification/validation of product contact surfaces shall be defined.

(c) Spray devices shall conform with SD-3.9. The manufacturer should recommend the CIP supply flow rates, pressures, and cleaning step times required to clean the centrifuge.

(d) The manufacturer shall recommend CIP solution supply rate and pressure requirements for effective cleaning. The recovery, sampling or monitoring of the various cleaning streams shall be defined.

(e) Due to fluctuations in flow (e.g., bowl discharge), use of recirculating CIP flow paths may require break tanks, bypass flows, and pumps that can generate suction when run dry.

SD-5.3.5.2.2 Other Centrifuges.

(a) The centrifuge manufacturer shall identify all areas of primary and incidental product contact that require manual cleaning in addition to CIP. Centrifuges that are not designed for CIP shall be capable of disassembly and reassembly for cleaning and examination.

(b) Areas of primary and incidental product contact that require manual cleaning or cleaning out of place (COP) in addition to CIP shall be defined.

SD-5.3.5.35.3.4.1.2 Sterilization/Sanitization. Chemical Sanitization/Sterilization.

[Reserved]

The owner/user shall inform the manufacturer of the sterilization/sanitization and storage requirements (e.g., temperature, pressure, chemistry) and storage condition (e.g., flooded or dry). The owner/user and manufacturer shall define the sterile envelope or boundary.

Centrifuges that will be SIP’d shall be designed in accordance with SD-2.3.1.1, and, in certain jurisdictions, may be considered pressure vessels (see GR-1). The manufacturer shall demonstrate saturated steam penetration across components that define the sterile boundary of the system.

Centrifuges that will be chemically sanitized shall be sanitized with an agent and process that have been proven to achieve the bioburden reduction requirements of the system.
The system’s sterile envelope or boundary shall be defined.
The manufacturer should recommend the operating conditions (e.g., sanitizing agent supply flow rate, bowl speed, discharge rate) required to ensure effective chemical sanitization.

SD-5.3.5.4 Thermal Sanitization/Sterilization. Centrifuges subject to SIP shall be designed in accordance with SD-2.3.1.1, and, in certain jurisdictions, may be considered pressure vessels (see GR-1). Saturated steam penetration across components that define the SIP boundary of the system shall be demonstrated.

SD-5.3.5.5 Post-Use Storage. The design shall meet the sterilization/sanitization and storage requirements (e.g., temperature, pressure, chemistry) and storage condition (e.g., flooded or dry) specified for bioburden control.

SD-5.3.6 Design for Serviceability, Examination, and Operation.
[Reserved]

SD-5.3.7 Testing.
[Reserved]
**SD-5.4.5 Design for Bioburden Control.** The owner/user is responsible for defining the sanitization requirements based on the level of bioburden control required for the unit operation. All components and filter elements shall be either compatible with the selected sanitization agents and conditions or capable of being removed or isolated prior to the sanitization process while maintaining a flow path through the system.

**SD-5.4.5.2 Cleaning.**

(a) Filtration systems that are designed for CIP shall be designed in accordance with SD-2.4.2 unless otherwise agreed to by the owner/user and manufacturer.

(b) Tangential flow filtration elements may be designed for repeated use and cleaned along with the system. When multiple-use elements are cleaned in place, system design shall ensure suitable conditions (e.g., flow rates) to properly clean the filtration elements.

(c) Direct flow filtration elements are typically not reused and are not installed during the cleaning process.

**SD-5.4.5.3 Chemical Sanitization/Sterilization.** Equipment intended to be chemically sanitized shall be designed to ensure contact between process contact surfaces and the sanitization solution.

**SD-5.4.5.4 Thermal Sanitization/Sterilization.** Temperature, flow direction, and differential pressure of the thermal sanitization or sterilization process shall be defined by the owner/user. The properties of the filter elements shall be considered to confirm compatibility of the element with the exposure conditions of a thermal sanitization process.

**SD-5.5 Chromatography Systems**

For this section, the term “system” is intended to cover the chromatography piping skid, not including the associated column.

**SD-5.5.5 Design for Bioburden Control**

**SD-5.5.5.2 Cleaning.** Chromatography systems shall be designed for CIP. Systems should be designed in accordance with SD-3.1 unless otherwise agreed to by the owner/user and manufacturer.  

**SD-5.5.5.3 Chemical Sanitization/Sterilization.** Chemical sanitization processes are used to reduce bioburden. All process contact surfaces of system components shall either be compatible with the selected sanitization agents or be capable of being removed or isolated prior to the sanitization process.

**SD-5.5.5.4 Thermal Sanitization/Sterilization.** Chromatography systems may be designed for thermal sanitization. If a system is designed for thermal sanitization, components shall be designed for the specified conditions, or shall be removed or isolated prior to the sanitization process. Note that if items are removed for sanitization, they should be sanitized separately and reinstalled in a controlled environment to avoid contaminating the system.
SD-5.4 Filtration

**SD-5.4.1 General**
Filtration systems are used for the purposes of product purification, product concentration and reduction of bioburden. Filtration systems include the filter elements (see Part PM) and filter housings/holders, and may include pumps, vessels, piping, tubing, fittings, valves, and instrumentation.

The following sections describe the general design requirements for the operation, cleaning and sanitization of a multi-use filtration system.

**SD-5.4.2 System Performance Requirements**
The conditions and performance parameters under which the system will operate shall be defined. Typical items to consider include type and mode of filtration, inlet/outlet streams, operation, filtration element, system, automation, and cleaning and sanitization:

(a) **type and mode of filtration**
(b) **inlet/outlet streams**
   (1) inlet and outlet physical and chemical properties
   (2) flow rates required
   (3) pressure conditions
   (4) number of feed and outlet streams
   (5) recirculation streams for tangential flow filtration (TFF) systems
(c) **operation**
   (1) in-line dilution or formulation
   (2) diafiltration
   (3) measurement of fluid characteristics
   (4) control strategy (e.g. for TFF – transmembrane pressure (TMP) control, permeate flux control, permeate pressure control, retentate flow control)
   (5) % volume reduction and final volume
(d) **filtration element**
   (1) preparation for operation
   (2) expected pressure drop at the indicated flow rates
(c) **system**
   (1) the fluids to which the system may be exposed
   (2) acceptable holdup volumes
   (3) temperature of operating area and process fluids
   (4) room classification
(f) **automation**
   (1) control system requirements
   (2) sensors and monitors for detection of system performance
(g) **cleaning and sanitization requirements:**
   (1) methods
   (2) frequency
   (3) duration

**SD-5.4.3 Operating Capabilities and System Function**
Filtration systems shall be designed to control and monitor filtrate (or tangential and permeate flow) according to process requirements. Multi-use systems shall be designed to allow for process cleaning and sanitization.

**SD-5.4.4 System Design**
The system should be designed to promote recovery of product (e.g., drainable branches, and path-by-path air blown to recover product retained in lines and filter elements) and meet cleaning and sanitization requirements. The system should be designed to mitigate the risk of cross-over of feed solutions, which could contaminate the process.
Filtration system designs should conform to SD-3.1. Where multi-use systems are not drainable, refer to SD-2.4.3.

When required by system function, components present in direct flow and tangential flow filtration systems shall include:

(a) feed and filtrate for direct flow; permeate and retentate for tangential flow  
(b) valves  
(c) pumps  
(d) vessels (feed and filtrate collection)  
(e) instruments (process monitoring and control)  
(f) one or more filtration elements and element holders

The system design should mitigate the risk of leakage, and carryover of residual solutions to subsequent steps.

**SD-5.4.4.1 Materials**  
The process contact materials shall be compatible with process fluids, including those used for cleaning and sanitization.

**SD-5.4.4.2 Pumps**  
Pumps designed for both process and CIP shall meet the required duty points (i.e. flow rate and pressure) for each operation.

**SD-5.4.4.3 Instruments for Feedback Control of Process Liquids**  
When multiple liquids are combined, the flow rate of the feed solutions (and retentate for tangential flow systems) to the filter element should be monitored.

**SD-5.4.4.4 Multiple Connections**  
Where required, the system shall be designed to enable isolation of the filter at its connection points (e.g., for removal of the filter, to shutoff permeate, or bypass the filter element) or to control the direction of flow through the filter (e.g., “top to bottom” vs “bottom to top”).

**SD-5.4.4.5 Air Entrapment**  
The system should be designed to minimize the introduction and accumulation of air into the filter housings. The system shall be designed to relieve trapped gases from the filter housings. Sight glasses or instrumentation should be installed when required to facilitate air detection.

**SD-5.4.4.6 Filter Element Housing Design**  
(a) parts forming internal crevices should be easily disassembled to enable access for cleaning.  
(b) all wetted surfaces should be accessible for cleaning and examination.  
(c) all nozzle connections shall be of a hygienic design.  
(d) baffle plates, when used, should be cleanable and designed for SIP.  
(e) the housing assembly, end plates, and connections should be designed to prevent bypassing of process fluid around the element.  
(f) vent filters for hot liquid processes should be heat traced or steam jacketed. Other methods for preventing excessive moisture accumulation in vent filters, such as oversizing filters, vent heaters or condensers, could be considered.

**SD-5.4.5 Design for Bioburden Reduction**  
This section covers drainability, cleaning, and chemical and thermal sanitization/sterilization for the purpose of bioburden reduction.

**SD-5.4.5.1 Drainability**
Filtration systems should be designed to minimize holdup volume. Piping systems and components of filtration systems that are designed to be drainable shall be sloped to enable draining. Drain valves shall be installed at low points. Where liquid removal is required but drainability is not possible or practical, a method of forced expulsion of liquids (e.g., by air), shall be provided. Drain points shall not create dead legs. A common drain port on the skid is preferred.

Direct flow filtration housings shall include a low port drain to facilitate cleaning and removal of liquid from the system as well as filtration element changeouts. Liquid tee-style filter housings should be installed vertically for drainability. In-line vent filter housings subject to SIP should be installed vertically with the condensate/drain port directed downward (see Figure SD-5.4.4-1).

Tangential flow cartridge housings subject to CIP or SIP shall be designed with connections and covers that will allow the unit to drain.

**SD-5.4.5.2 Cleaning**
Where direct flow filtration housings are cleaned in place, provision for draining or forced expulsion of liquid shall be included to facilitate cleaning of the system. Cleaning of filtration systems is achieved using the CIP TACT principles (see SD-6.3.1)

Direct flow filtration elements are typically not reused and are not installed during the cleaning process.

Tangential flow filtration elements may be designed for multi-use and cleaned along with the system. When multi-use elements are cleaned in place, the system shall be designed to be hydraulically balanced to ensure suitable conditions (e.g., flow rates) to properly clean the filtration elements.

**SD-5.4.5.3 Chemical Sanitization/Sterilization.**
Process contact components within the system shall be exposed to the chemical solution for a specified duration. The components shall be compatible with the sanitization agents and conditions selected.

If a system subject to chemical sanitization/sterilization includes elements not compatible with the chemical conditions required, the elements shall be isolated or removed during the cleaning process without compromising the system integrity.

**SD-5.4.5.4 Thermal Sanitization/Sterilization.**
Systems shall be compatible with the thermal conditions to which the system will be exposed.

If a system subject to SIP includes elements not compatible with the thermal conditions required, the elements shall be isolated or removed during SIP without compromising the system integrity.

**SD-5.4.6 Design for Serviceability and Inspection**
Multi-use systems shall be designed to facilitate service and inspection including removal and replacement of the filter elements.

**SD-5.4.7 Testing**
Selection of filtration integrity and performance test methods should be based upon evaluation of process risks.

When the filter is used as a sterilizing or viral removal filter, provisions for integrity testing should be provided.

Acceptable testing methods include:
(a) pressure hold test to identify system leaks for direct and tangential flow systems
(b) trans-membrane test to confirm absence of membrane fouling in tangential flow filtration systems
(c) salt rejection testing to confirm system integrity in reverse osmosis applications
(d) bubble point or forward flow diffusion tests in sterilizing grade direct flow filtration systems used to verify bioburden control
(e) particle tests in viral filter systems employed to confirm specific viral removal
**SD-5.5.1 General**
Chromatography systems are used for product purification, concentration and viral load reduction. Chromatography systems include pumps, piping, valves, instrumentation and a stationary medium that is contained in a column, cartridge or capsule. The stationary medium/phase may be a membrane adsorber or resin.

The chromatography system shall not contribute to the contamination of the product. This section describes operational, cleaning and sanitization requirements of multi-use chromatography systems. This section does not address the requirements of systems intended for single-use. Chromatography systems used for analytical testing are not included in the scope of this section.

For the purposes of this section, “column” shall refer to any component (e.g., column, cartridge, capsule, membrane adsorber) housing the stationary medium.

A chromatography system may also include provisions to:
(a) assist with the packing of a column with the stationary phase.
(b) evaluate the performance of a packed column.
(c) perform in line dilution and in line formulation operations.

For the purposes of this section gradient operation refers to flow rates of two or more liquids to be adjusted such that the physical and chemical characteristics of the resulting chromatography feed solution change over time.

**SD-5.5.3 Operating Capabilities and System Function**
The chromatography system shall be capable of delivering a consistent flow of liquids through the stationary phase and mitigating the risk of introducing gas onto the column. Multi-use systems shall be designed to be cleaned and sanitized. If columns are stored, packed with stationary phase, the systems shall be capable of maintaining a flooded bacteriostatic condition.

When gradient chromatography operations are required, gradient accuracy capability shall be defined. The chromatography system should be designed to provide an elution buffer flow path that minimizes axial dispersion.
SD-5.5.5.5 Post-Use Storage. Chromatography systems are typically stored flooded with a sanitizing solution to maintain bioburden control.

SD-5.6 Lyophilizers/Freeze Dryers

SD-5.6.1 General. For the purpose of this section, the terms “lyophilizer” and “freeze dryer” may be used synonymously. This section describes the requirements for cleanability and bioburden control of lyophilizers that are used for biopharmaceutical processing. This section applies to lyophilizers in which product is loaded onto shelves. Other designs that use methods and components not described in this section should be evaluated and agreed upon by the owner/user. A lyophilizer comprises a number of interconnected components. Components with process contact surfaces and/or product contact surfaces shall be designed for cleanability and bioburden control.

Lyophilizer surfaces of components, piping, equipment, or systems that are isolated by design from both product and process fluids are not process contact surfaces nor required to be designed for cleanability or bioburden control. Examples of surfaces that are not process contact surfaces include the exterior surfaces of equipment, drain lines, vacuum lines, and systems containing hydronic or hydraulic fluids.

SD-5.6.2 Components. A lyophilizer is comprised of functional components/systems, as shown in Figure 5.6.2-1, which are designed for isolation, cleanability, and/or bioburden control. These components/systems have the potential to affect product quality and include the following:

(a) lyophilizer chamber
(b) condenser vessel
(c) lyophilizer shelves
(d) vacuum systems
(e) isolation bellows
(f) internal moving parts
(g) spray devices
(h) gas filter assemblies
(i) doors and door seals
(j) valves
(k) instruments

SD-5.6.2.1 General

(a) All components shall be rated for the applicable pressure, vacuum, temperature range, thermal shock, and exposure to sanitizing agents (e.g., vaporized hydrogen peroxide (VHP)) when applicable.

(b) Process contact surfaces made from metallic material should comply with SD-2.4.1.1 through SD-2.4.1.3.

(c) Process contact surfaces made from nonmetallic material should comply with SD-2.4.1.1, SD-2.4.1.2, SD-2.4.1.4, and Part PM.

SD-5.6.2.2 Lyophilizer Chamber

(a) The interior surfaces of the lyophilizer chamber (chamber vessel) are considered process contact surfaces.

(b) The lyophilizer chamber includes all necessary fittings and closures (e.g., doors, bellows, isolation valves). The chamber floor shall be self-draining.

(c) The surface finishes of the chamber internal surfaces (i.e., door, walls, ceiling, and floor) shall be specified by the owner/user using the designations in Table SF-2.4.1-1.

(d) Where the chamber interfaces with the clean room or isolator, the surfaces shall meet the owner/user's specified requirements.

SD-5.6.2.3 Condenser Vessel

(a) The condenser vessel, used to contain the condenser heat exchanger, is connected to the chamber vessel and may be separated by a main isolation valve.

(b) All surfaces shall be self-draining.

(c) In systems designed with backstreaming prevention (i.e., prevention of reverse flow from the vacuum pumps), the condenser vessel is downstream of the chamber. The condenser vessel surfaces are not process contact surfaces and do not have surface finish requirements.

(d) In systems not designed with backstreaming prevention, the condenser vessel surfaces are process contact surfaces. The surface finishes of the condenser vessel shall be specified by the owner/user using the designations in Table SF-2.4.1-1.

SD-5.6.2.4 Lyophilizer Shelves

(a) The flat surfaces of shelves supporting containers of product (e.g., vials containing product) are considered process contact surfaces.

(b) The flat surfaces of shelves are considered product contact surfaces if product without containers is placed directly on the shelves.

(c) Surfaces of the structural components of the shelves are considered process contact surfaces.

(d) The shelf heat transfer performance depends on shelf flatness. The loading/unloading and initial container closure performance require the shelves to be level. Therefore, shelves are not required to be sloped. Methods other than self-draining may be required to remove residual CIP liquid (e.g., collapsible shelves may be contracted to remove residual CIP liquid from shelf surfaces followed by a process that facilitates drying, such as SIP followed by a vacuum hold).

(e) The surface finishes of shelves shall be specified by the owner/user using the designations in Table SF-2.4.1-1. A rougher surface may be specified for the bottom side of the shelves by the owner/user to meet process requirements (e.g., stopper adhesion prevention).

See reorganized and revised SD-5.6 that follows.
Figure SD-5.6.2-1 Typical Lyophilizer Component Assembly

- Condenser vacuum isolation valve
- Condenser relief valve
- Condenser SIP/CIP inlet valve
- Hydraulic cylinder for moving shelves
- Vacuum system
- Condenser vessel
- Liquid ring vacuum pump
- CIP inlet
- Steam inlet
- Chamber relief valve
- Gas filter assembly
- Isolation bellows
- Chamber shelves
- Chamber vessel
- Chamber door
- CIP spray nozzles inside chamber

See reorganized and revised SD-5.6 that follows.
**SD-5.6.2.5 Vacuum Systems**

(a) The lyophilizer vacuum pumps and condenser cooler establish a pressure gradient during lyophilization from the chamber vessel through the condenser vessel resulting in single-direction flow toward the lyophilizer vacuum pumps. To maintain an environment appropriate for aseptic processing in the chamber vessel, the vacuum system shall prevent reverse flow (backstreaming).

(b) The lyophilizer vacuum pumps are not hygienic components and should be designed to be outside the sterile boundary.

(c) Where vacuum pumps for wet service (e.g., liquid ring vacuum pumps) are used to evacuate air/vapor from the chamber and condenser vessels, they should be located outside the sterile boundary.

**SD-5.6.2.6 Isolation Bellows**

(a) Isolation bellows are employed to isolate nonhygienic moving components from the lyophilizer sterile boundary.

(b) The surfaces of the bellows and its mounting connections exposed to the inside of the lyophilizer are considered process contact surfaces and should be assessed for cleanability. The bellows shall be extended during the cleaning cycle to provide access to all exposed process contact surfaces.

(c) The bellows shall be sealed at each end to isolate the inside of the lyophilizer from external conditions. Bellows may be bolted or welded into place. A bellows sealed by a bolted flange connection with an O-ring seal within the chamber vessel facilitates replacement and maintenance. The inside of the bellows may be evacuated, vented, or pressurized to facilitate retraction or extension of the bellows. The lyophilizer may be provided with a leak-test system to ensure the bellows are intact.

(d) When specified, the bellows shall be suitable for sterilization and shall allow for full penetration of the sterilizing agent at all surfaces inside the sterile boundary.

**SD-5.6.2.7 Internal Moving Parts.** The following should be considered in the design of moving parts (e.g., the raising and lowering of the shelves) within the chamber and/or condenser vessels:

(a) Nonmetallic material (e.g., PTFE, PEEK, UHMWPE) may be used for moving parts in order to reduce friction. The selection of the material should consider minimizing particle generation.

(b) Contact surfaces between moving parts shall be exposed to solutions used for cleaning and bioburden control.

(c) A bellows may be used to isolate the chamber and/or condenser from moving parts that are not of hygienic design.

**SD-5.6.2.8 Spray Devices**

(a) Spray devices are used in lyophilizers to facilitate the cleaning of surfaces inside the chamber and condenser vessels. Spray devices in the condenser vessel may also be used for directing spray at the condenser cooler to facilitate defrosting of the condenser cooler.

(b) Spray devices designed for cleaning should provide sufficient flow and force to clean flat surfaces (e.g., shelves) by direct spray. Cleaning the internal surfaces of a lyophilizer by direct spray may require a supply pressure and flow rate that are substantially higher than are typical for cleaning an empty vessel. The supply pressure and flow rate should meet the manufacturer’s recommendation for these spray devices.

(c) Both static and dynamic spray devices are acceptable for use in lyophilizers. The use and application of a particular spray device design should be agreed upon among the owner/user, lyophilizer manufacturer, and CIP system integrator. The number of spray devices may be reduced if the shelves are allowed to move during cleaning. Spraying of shelves should be designed to avoid the interference of spray streams of opposing directions.

(d) The use of threaded connections for spray devices shall only be used when agreed upon by the owner/user.

(e) Spray devices shall meet the provisions of SD-3.9.2.

(f) Spray device design, location, and orientation shall ensure appurtenances (e.g., nozzles, bellows, shelf supports, and hoses) are exposed to complete spray coverage.

**SD-5.6.2.9 Gas Filter Assemblies**

(a) For the purpose of this paragraph, the gas filter assembly is defined as those filters installed for the purpose of filtering process gases supplied to the lyophilizer. The filter assembly includes the filter media, seals, housing, and connected tubing.

(b) The last filter in the path of the gas to the lyophilizer (proximal filter) shall be part of the sterile boundary and be designed for the chosen means of bioburden reduction (e.g., SIP or VHP). The filter shall be a sterilizing-grade filter. If a redundant sterilizing filter is used, both filters shall be included within the sterile boundary.

(c) Filter assemblies that are steam in place shall be designed to

(1) limit the pressure drop across the filter to within the manufacturer’s specifications in the specified flow direction

(2) permit temperature monitoring in a location representative of the coldest location

(3) accommodate the integrity testing of the proximal filter, either in situ or out of place

(d) If CIP of the gas filter assembly is specified, provisions shall be made in the design for removal of the filter element(s) prior to the CIP. Filter elements shall be reinstalled prior to sterilization of the filter assembly.

See reorganized and revised SD-5.6 text that follows.
SD 5.6.2.11 Valves

(a) Design and selection for service shall follow the appropriate ASME BPE and Part SD specifications for valves used in hygienic design. Diaphragm valves are acceptable for hygienic fluid service.

(b) Ball valves may be used outside the sterile boundary but not inside.

(c) Butterfly valves may be used inside the sterile boundary with the option of using instrumentation with integral seals or diaphragm seals for positioning.

(d) Pressure relief devices or rupture disks of hygienic design may be used as part of the sterile boundary when piping/tubing is larger than 2 in. in diameter.

(e) The door static-seal design shall provide access for manual sanitization as the seal face under compression does not permit penetration of sterilizing agents.

(f) Compression of a single static seal to achieve a metal-to-metal contact shall be used inside the sterile boundary.

(g) Instrumentation with integral seals or diaphragm seals is preferred within the sterile boundary. The risk of using instrumentation without integral seals is considered when designing for cleaning and sterilization.

(h) Locations with product-sensing instruments (e.g., thermocouples) and wire lead-throughs should be considered when designing for cleaning and sterilization.

(i) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization. Instruments in process contact should be of hygienic design.

(j) All instruments within the sterile boundary shall comply with applicable sections of Part P1, including PI-2.2.2.

SD 5.6.2.12 Instruments

(a) All instruments shall be designed with the sterile boundary as indicated in Figure SD 5.6.3.

(b) The inside surfaces of the chamber vessel to the sealing surface on all instruments connected to the chamber and condenser vessels shall be reinstalled for sterilization.

(c) The CIP/SIP inlets to the first CIP/SIP isolation valve that is closed during the lyophilization process.

(d) The CIP/SIP inlets to the first CIP/SIP isolation valve in series are used.

(e) The CIP/SIP inlets to the first CIP/SIP isolation valve closest to the condenser vessel.

(f) The CIP/SIP inlets to the first CIP/SIP isolation valve closest to the condenser vessel.

(g) The vacuum line/gas line to the sterile gas filter. If redundant sterilizing filters in series are used, the filter farther from the chamber vessel shall be connected to the CIP/SIP inlets to the first CIP/SIP isolation valve.

(h) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(i) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(j) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(k) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(l) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(m) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(n) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(o) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(p) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(q) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(r) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(s) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(t) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(u) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(v) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(w) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(x) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(y) The CIP/SIP inlets to the first CIP/SIP isolation valve.

(z) The CIP/SIP inlets to the first CIP/SIP isolation valve.

{**Figure SD 5.6.3:**}

SD 5.6.4 Internal Connections and Fasteners

(a) Threads sealed by an O-ring or hygienic gasket are acceptable. The use of exposed threads shall be avoided.

(b) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(c) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(d) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(e) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(f) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(g) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(h) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(i) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(j) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(k) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(l) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(m) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(n) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(o) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(p) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(q) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(r) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(s) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(t) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(u) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(v) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(w) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(x) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(y) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

(z) Instrument probe surfaces and side port penetrations shall be designed for CIP and sterilization conditions.

{**Figure SD 5.6.3:**}
surfaces of exposed threads should be among those assessed for cleaning and penetration of sterilizing agents.

(b) For process contact surfaces, the use of pins, clevis rods, snap rings, and clips may be required to mount hardware inside the sterile boundary but should be minimized and only be used if agreed on by the owner/user. The surfaces of these fasteners should be among those assessed for cleaning and penetration of sterilizing agents.

c) Socket head cap screws and counterbored holes inside the sterile boundary shall only be used with the agreement of the owner/user.

SD-5.6.5 CIP of Lyophilizers

(a) Systems used to clean lyophilizers shall comply with SD-6.3.3(a), SD-6.3.3(b), and SD-6.3.3(f). Cleanability requirements of SD-2.4.2 are applicable to lyophilizers except for SD-2.4.2(b)(1), which does not apply to lyophilizer shelves.

(b) It is accepted practice to use water as the CIP fluid for cleaning water-soluble compounds. Water for injection shall be used for the final rinse in aseptic processing applications.

(c) The chamber vessel, which includes internal shelves, should be cleaned via internal spray devices designed to provide coverage of targeted surfaces. Risk to product quality should be considered when determining the required coverage. The acceptance criteria for coverage shall be agreed to by the manufacturer and owner/user. Nonmandatory Appendix M provides an acceptable procedure for spray device coverage testing.

(d) The process contact surfaces within the condenser vessel may be cleaned via internal spray devices to provide the coverage agreed on between the manufacturer and owner/user.

e) Internal liquid distribution piping shall be sloped to meet the requirements of GSD2 to facilitate gravity draining.

(f) External liquid distribution piping shall be designed with valve actions that facilitate gravity draining. The pipe slope shall meet the requirements of GSD2.

(g) The liquid level in the chamber and condenser vessels should be minimized during once-through CIP by correct sizing of the drain and by providing slope to the respective drain. A CIP drain pump may be used to assist draining of the chamber and condenser vessels.

(h) When recirculated CIP is used, the following requirements apply:

(1) Recirculated systems, including pump casing(s), shall be drainable.

(2) Recirculated systems shall be capable of removing residual chemicals and debris during the final rinse.

See reorganised and revised SD-5.6 that follows.
(i) The chamber and condenser vessels shall be self-drainable.

(ii) Process contact surfaces shall be sloped to meet the requirements of GSD3 for drainage of CIP fluids and to prevent the collection of condensate during the steaming processes.

(2) Interior surfaces of nozzles penetrating the vertical walls of the vessel shall be sloped to meet the requirements of GSD3.

(3) The floor of the vessel shall be sloped toward the drain connection to meet the requirements of GSD3, unless otherwise agreed to by the manufacturer and owner/user.

SD-5.6.6 Bioburden Reduction in Lyophilizers. Lyophilizers designed for bioburden control should consider the following:

(a) pressure or vacuum hold testing in preparation for the bioburden reduction process. Refer to SD-5.6.7.

(b) evacuation of air from the chamber and condenser vessels to reduce the potential for air to be trapped during the bioburden reduction process. Effective air evacuation may be achieved through the use of a liquid ring vacuum pump or similar.

SD-5.6.6.1 Steam-in-Place. When designing lyophilizers for steam-in-place

(a) steam should enter the lyophilizer at only one point at a time to minimize the potential to trap air or condensate. If steam needs to enter through multiple locations simultaneously, the design should create flow paths that avoid air entrapment. The design should ensure that condensate will freely flow toward low-point drains.

(b) a dual control design may be used to deliver high steam flow rates that are often required during the heating phase and to maintain tight control of temperature and pressure during the exposure phase. For example, one regulator and/or control valve may be used for the heating phase and a separate regulator and/or control valve may be used for tight control during the exposure phase.

(c) a vacuum drying phase should be used to eliminate any condensate remaining within the sterile boundary following SIP.

(d) if cooling and drying are accomplished with the introduction of a process gas with open drains, a positive pressure differential shall be maintained to preserve the sterile boundary during this operation.

(e) temperature monitored throughout the SIP cycle should include coldest (worst-case) locations. If routine monitoring of worst-case locations is not practical, the temperature of locations that have been correlated to the actual worst-case locations may be monitored instead.

(f) to minimize cold locations during SIP, horizontal penetrations should be sloped to allow condensate to drain.

SD-5.6.6.2 Hydrogen Peroxide Sterilization. When designing lyophilizers for sterilization with hydrogen peroxide gas under vacuum

(a) the system should be designed to be dried and have a surface temperature that meets the supplier’s specification for the hydrogen peroxide supply system (typically 59°F (15°C) and 176°F (80°C)) prior to the start of the sterilization process.

(b) the system should be designed to verify that the residual hydrogen peroxide levels are below the established thresholds, after the sterilization process has been completed. Threshold levels should be agreed on by the owner/user for both operator’s safety and the potential impact on the product quality.

SD-5.6.7 Leak Rate

(a) Lyophilizers designed for aseptic lyophilization processes shall be designed to meet leak-rate testing criteria as agreed to by the owner/user. The sterile boundary should be leak tested before aseptic operations begin. The leak rate is calculated as follows:

\[ Q_L = \frac{\Delta PV}{\Delta t} \]

where

- \( Q_L \) = leak rate, mbar-L/s
- \( V \) = the lyophilizer system volume subject to the vacuum, adjusted to exclude the volume occupied by internal hardware, L
- \( \Delta P \) = the absolute pressure rise during the test, mbar
- \( \Delta t \) = the test duration, sec

(b) Leak-rate testing should be performed on a clean, dry, and fully assembled and insulated system with the condenser cooler in operation to capture residual vapor. Typically, leak rates less than 0.02 mbar-L/s are acceptable for new installations. Leak-rate testing is intended to confirm vacuum integrity of the system.

(c) Leak-rate tests are performed at high vacuum conditions with an absolute pressure typically on the order of 0.01 mbar.

(d) Sufficient stabilization time will avoid misinterpretation of the vacuum leak rate due to virtual leaks. Virtual leaks are identified by a leak rate that stabilizes over time.

(e) Individual component assemblies, which are subjected to vacuum conditions, should be helium leak tested prior to final installation.

SD-5.6.8 Branch Connections

(a) The provisions of SD-3.1.2.2 are applicable to liquid-service process contact piping leading to the lyophilizer.

(b) Nozzles within the sterile boundary should be designed to allow for full exposure to the sterilizing agent.

(c) Nozzles and other appurtenances that are cleaned by liquid spraying should allow complete coverage.
SD-5.7 Solution Preparation Systems

Solution preparation systems are used for the preparation, storage, and distribution of buffer solutions, media solutions, and other reagents used in bioprocessing, formulation, and filling operations. Systems may include components for transfer and mixing of solids and liquids (e.g., agitators, in-line mixers, vacuum transfer equipment, intermediate bulk containers). The systems may also include tanks/vessels for solution preparation and for solution storage. Systems may also include components designed specifically for bioburden reduction or solution conditioning. Examples of these include filtration systems and thermal conditioning systems such as ultrahigh-temperature/high-temperature short-time (UHT/HTST) systems.

SD-5.7.1 Operating Capabilities and System Function. The owner/user shall define which process contact surfaces require cleaning and/or sanitization (e.g., vessel internals, solids transfer equipment, solution transfer lines, vent lines) and which cleaning methods (e.g., CIP, COP, water rinses) and/or sanitization methods (e.g., chemical sanitization, SIP, hot-water flush) are to be used. When a solution sterilizing-grade filter is SIP’d with the system, the sterile envelope shall include the filter membrane. In practice, this requires a design that achieves sterilization conditions across the filter membrane.

For systems that require closure, controls to achieve and maintain a functionally closed system after mixing may include

(a) equipment to achieve required bioburden reduction in prepared solutions (e.g., sterilizing-grade filters, HTST, sterilization vessels)
(b) technologies that prepare equipment for use (e.g., CIP, SIP, use of gamma-irradiated single-use components)
(c) procedures and designs to maintain control during processing and holds after bioburden reduction (e.g., system closure after sanitization, drying equipment for holds, and hold and processing time limits)

SD-5.7.2 System Design

SD-5.7.2.1 Contamination Control. Measures should be taken to contain powders that are added to mixing tanks and to contain aerosols that may be generated during solution preparation to mitigate the risk of cross-contamination between operations. The owner/user shall assess the risk of cross-contamination between operations. Controls to mitigate the risk of cross-contamination may include

(a) physical separation (e.g., separate rooms, isolators)
(b) airflow controls (e.g., dust collection systems, filtration of circulated air, flow direction)
(c) use of closed-process systems
(d) temporal separation
(e) procedural separation

The owner/user shall specify requirements for mitigation of risks from environmental contamination and growth of adventitious agents such as bacteria, fungi, and viruses in solutions during processing and hold times.

SD-5.7.3 Design for Bioburden Reduction

SD-5.7.3.1 Filters. Systems used for buffer distribution may require a filter to reduce bioburden during transfers to downstream systems, particularly when the buffer is growth-promoting or is transferred to a holding system before use.

SD-5.7.3.2 Preparation Tanks. Preparation tanks may be designed for operations that are briefly exposed to the room environment (e.g., addition of reagents through an open port) when appropriate measures are exercised for bioburden control and other particulate contamination (e.g., filtration to reduce bioburden after reagents are dissolved).

SD-5.7.3.3 Tanks for Long-Term Storage. Tanks used for long-term storage of solutions should be designed to be sterilized unless the intended solution is bactericidal or bacteriostatic.

SD-5.7.3.4 Thermal Sanitization/Sterilization. Systems used for aseptic processing shall have all surfaces that contact sterile process streams downstream of the bioburden control device capable of being sterilized. This includes interfaces between components that are sterilized separately.

SD-6 PROCESS SUPPORT SYSTEMS

SD-6.1 Cabinet Washers

SD-6.1.1 General. This section describes the requirements for washers that are designed to clean various materials and components such as glassware, drums, containers, hoses, pallets, and accessories (washable items) that are not cleaned in place. Requirements in this section are intended to be applied to cabinet washers, but may be applied to other types of washers as appropriate.

(a) Cabinet washers shall be fully automatic and should be capable of multiple cycle types for various load conditions. Cabinet washers may be designed with an integrated chemical addition system or receive cleaning solutions from a CIP system.
(b) Cabinet washers shall include racks or holding systems designed to enable repeatable exposure of washable items to cleaning solutions.
(c) The documentation requirements of GR-5 are applicable to process contact components/instruments of cabinet washers.
SD-5.6 Lyophilizers/Freeze Dryers

SD-5.6.1 General
For the purpose of this section, the terms “lyophilizer” and “freeze dryer” may be used synonymously. This section describes the requirements for cleanability and bioburden control of lyophilizers that are used for biopharmaceutical processing. This section applies to lyophilizers in which product is loaded onto shelves. Other designs that use methods and components not described in this section should be evaluated and agreed upon by the owner/user. A lyophilizer comprises a number of interconnected components. Components with process contact surfaces and/or product contact surfaces shall be designed for cleanability and bioburden control.

Lyophilizer surfaces of components, piping, equipment, or systems that are isolated by design from both product and process fluids are not process contact surfaces nor required to be designed for cleanability or bioburden control. Examples of surfaces that are not process contact surfaces include the exterior surfaces of equipment, drain lines, vacuum lines, and systems containing hydronic or hydraulic fluids.

SD-5.6.2 System Performance Requirements
The following system performance requirements shall be defined:
(a) Vacuum integrity requirements
(b) Product capacity (vial quantity or required product shelf area)
(c) Condensing capacity (liters)
(d) Minimum shelf temperature
(e) Shelf heating and cooling rate (clean dry and empty)
(f) Shelf temperature uniformity requirements
(g) Evacuation rate
(h) Minimum vacuum level

SD-5.6.3 Operating Capabilities and System Function
The lyophilizer should be capable of the following functions.
(a) Shelf and condenser temperature control
(b) Vacuum pressure control
(c) Condenser defrost
(d) Loading and unloading (when specified)
(e) Stoppering (when specified)
(f) Vacuum integrity testing
(g) Filter integrity testing
(h) Cleaning
(i) Sterilization/Sanitization

SD-5.6.4 System Design
A lyophilizer is comprised of functional components/systems, as shown in Fig. SD-5.6.1 SD-5.6.2.1, which are designed for isolation, cleanability, and/or bioburden control. These components/systems have the potential to affect product quality and include the following:
(a) Lyophilizer chamber
(b) Condenser vessel
(c) Lyophilizer shelves
(d) Vacuum systems
(e) Isolation bellows
(f) Internal moving parts
(g) Spray devices
(h) Gas filter assemblies
(i) Doors and door seals
(j) Valves
(k) Instruments
**SD-5.6.2.1 General**

(a) All components shall be specified for the applicable pressure, vacuum, temperature range, thermal shock, and exposure to sanitizing agents (e.g., vaporized hydrogen peroxide (VHP)) when applicable.

(b) Process contact surfaces made from metallic material should comply with conform to SD-2.4.1.1 through SD-2.4.1.3. Process contact surfaces made from nonmetallic material should comply with conform to SD-2.4.1.1, SD-2.4.1.2, SD-2.4.1.4, and Part PM.

**SD-5.6.2.2 Lyophilizer Chamber**

(a) The interior surfaces of the lyophilizer chamber (chamber vessel) are considered process contact surfaces.

(b) The lyophilizer chamber includes all necessary fittings and closures (e.g., doors, bellows, isolation valves). The chamber floor shall be self-draining drainable.

(c) The surface finishes of the chamber internal surfaces (i.e., door, walls, ceiling, and floor) shall be specified by the owner/user using the designations in Table SF-2.4.1.1.

(d) Where the chamber interfaces with the clean room or isolator, the surfaces shall meet the owner/user’s specified requirements.

**SD-5.6.2.3 Condenser Vessel**
(a) The condenser vessel, used to contain the condenser heat exchanger, is connected to the chamber vessel and may be separated by a main isolation valve.

(b) All surfaces shall be non-draining.

(c) In systems designed with backstreaming prevention (i.e., prevention of reverse flow from the vacuum pumps), the condenser vessel is downstream of the chamber. The condenser vessel surfaces are not process contact surfaces and do not have surface finish requirements.

(d) In systems not designed with backstreaming prevention, the condenser vessel surfaces are process contact surfaces. The surface finishes of the condenser vessel shall be specified by the owner/user using the designations in Table SF-2.4.1-1.

SD-5.6.2.4 SD-5.6.4.3 Lyophilizer Shelves
(a) The flat surfaces of shelves supporting containers of product (e.g., vials containing product) are considered process contact surfaces.

(b) The flat surfaces of shelves are considered product contact surfaces if product without containers is placed directly on the shelves.

(c) Surfaces of the structural components of the shelves are considered process contact surfaces.

(d) The shelf heat transfer performance depends on shelf flatness. The loading/unloading and initial container closure performance require the shelves to be level. Therefore, shelves are not required to be sloped and may not be drainable. Methods other than self-draining may be required to remove residual CIP liquid (e.g., collapsible shelves may be contracted to remove residual CIP liquid from shelf surfaces followed by a process that facilitates drying, such as SIP followed by a vacuum hold).

(e) The surface finishes of shelves shall be specified by the owner/user using the designations in Table SF-2.4.1-1. A rougher surface may be specified for the bottom side of the shelves by the owner/user to meet process requirements (e.g., stopper adhesion prevention).

SD-5.6.2.5 SD-5.6.4.4 Vacuum Systems
(a) The lyophilizer vacuum pumps and condenser cooler establish a pressure gradient during lyophilization from the chamber vessel through the condenser vessel resulting in single-direction flow toward the lyophilizer vacuum pumps. To maintain an environment appropriate for aseptic processing in the chamber vessel, the vacuum system shall prevent reverse flow (backstreaming).

(b) The lyophilizer vacuum pumps are not hygienic components and should be designed to be outside the sterile boundary.

(c) Where vacuum pumps for wet service (e.g., liquid ring vacuum pumps) are used to evacuate air/vapor from the chamber and condenser vessels, they should be located outside the sterile boundary.

SD-5.6.2.6 SD-5.6.4.5 Isolation Bellows
(a) Isolation bellows are employed to isolate non-hygienic moving components from the lyophilizer sterile boundary.

(b) The surfaces of the bellows and its mounting connections exposed to the inside of the lyophilizer are considered process contact surfaces and should be assessed for cleanability. The bellows shall be extended during the cleaning cycle to provide access to all exposed process contact surfaces.

(c) The bellows shall be sealed at each end to isolate the inside of the lyophilizer from external conditions. Bellows may be bolted or welded into place. A bellows sealed by a bolted flange connection with an O-ring seal within the chamber vessel facilitates replacement and maintenance. The inside of the bellows may be evacuated, vented, or pressurized to facilitate retraction or extension of the bellows. The lyophilizer may be provided with
a leak-test system to ensure the bellows are intact.

(d) When specified, the bellows shall be suitable for sterilization and shall allow for full penetration of the sterilizing agent at all surfaces inside the sterile boundary.

**SD-5.6.2.7 Internal Moving Parts.**

The following should be considered in the design of moving parts (e.g., the raising and lowering of the shelves) within the chamber and/or condenser vessels:

(a) Nonmetallic material may be used for moving parts in order to reduce friction (e.g., PTFE, PEEK, UHMWPE). The selection of the material should consider minimizing particle generation.

(b) Contact surfaces between moving parts shall be exposed to solutions used for cleaning and bioburden control.

(c) A bellows may be used to isolate the chamber and/or condenser from moving parts that are not of hygienic design.

**SD-5.6.2.8 SD-5.6.4.7 Spray Devices**

(a) Spray devices are used in lyophilizers to facilitate the cleaning of surfaces inside the chamber and condenser vessels. Spray devices in the condenser vessel may also be used for directing spray at the condenser cooler to facilitate defrosting of the condenser cooler.

(b) Spray devices designed for cleaning should provide sufficient flow and force to clean flat surfaces (e.g., shelves) by direct spray. Cleaning the internal surfaces of a lyophilizer by direct spray may require a supply pressure and flow rate that are substantially higher than are typical for cleaning an empty vessel. The supply pressure and flow rate should meet the manufacturer’s recommendation for these spray devices.

(c) Both static and dynamic spray devices are acceptable for use in lyophilizers. The use and application of a particular spray device design should be agreed upon among the owner/user, lyophilizer manufacturer, and CIP system integrator. The number of spray devices may be reduced if the shelves are allowed to move during cleaning. Spraying of shelves should be designed to avoid the interference of spray streams of opposing directions.

(d) The use of threaded connections for spray devices shall be agreed upon by the owner/user should be avoided.

(e) Spray devices shall meet the provisions of SD-3.9.2.

(f) Spray device design, location, and orientation shall ensure appurtenances (e.g., nozzles, bellows, shelf supports, and hoses) are exposed to complete spray coverage.

**SD-5.6.2.9 SD-5.6.4.8 Gas Filter Assemblies**

(a) For the purpose of this paragraph, the gas filter assembly is defined as those filters installed for the purpose of filtering process gases supplied to the lyophilizer. The filter assembly includes the filter media, seals, housing, and connected tubing.

(b) The last filter in the path of the gas to the lyophilizer (proximal filter) shall be part of the sterile boundary and be designed for the chosen means of bioburden reduction (e.g., SIP or VHP). This filter shall be a sterilizing grade filter. If a redundant sterilizing filter is used, both filters shall be included within the sterile boundary.

(c) Filter assemblies that are steamable in place shall be designed to

1. limit the pressure drop across the filter to within the manufacturer’s specifications in the specified flow direction
2. permit temperature monitoring in a location representative of the coldest location
3. accommodate the integrity testing of the proximal filter, either in situ or out of place

(d) If CIP of the gas filter assembly is specified, provisions shall be made in the design for removal of the filter element(s) prior to the CIP. Filter elements shall be reinstalled prior to sterilization of the filter assembly.
**SD-5.6.2.10** **SD-5.6.4.9** Doors and Door Seals

(a) Lyophilizer doors and door seals shall be designed to withstand vacuum, cleaning, and sterilization conditions.

(b) Lyophilizer doors shall be accessible, cleanable, and replaceable and should be capable of undergoing inspection without dismantling.

(c) For multiple-door systems, the doors shall be interlocked to allow the opening of only one door at a time during normal operation.

(d) Doors and locking hardware that interface with the clean room should not be retracted to uncontrolled space.

(e) Both sliding and swing door designs are acceptable.

(f) Door seals can be made with either static or inflatable seals. Static seal grooves that hold the seal may be on either the door or the chamber.

(g) The seal groove may be set back from the chamber flange edge to keep the seal in position during vacuum conditions.

(h) Compression of a single static seal to achieve a metal-to-metal contact is preferred to avoid a gap between door and chamber vessel.

(i) The door static seal design shall provide access for manual sanitization as the seal face under compression does not permit penetration of sterilizing agents.

(j) A combination (static and inflatable) seal design with the static seal circumscribing the inflatable seal provides for penetration of sterilizing agents across the sealing face of the inflatable seal.

(k) Door seal lubricants shall not be used in aseptic processing applications.

(l) Refer to Part **SGMC** for specifications of seals used in bioprocessing.

**SD-5.6.2.11** **SD-5.6.4.10** Valves

(a) Valve design and selection for service shall follow **SGMC** 3.3.2.3(a) and Part SD as appropriate. The application of a specific valve type for a given service should be agreed on by the manufacturer and owner/user.

(b) Hygienic valves shall be used inside the sterile boundary.

(c) Diaphragm valves are acceptable for hygienic fluid service.

(d) Butterfly valves may be used as part of the sterile boundary when piping/tubing is larger than 2in. in diameter.

(e) Ball valves may be used outside the sterile boundary to establish positive isolation.

(f) Pressure relief devices or rupture disks of hygienic design may be used as part of the sterile boundary.

(g) If the lyophilizer is designed for isolation between the chamber and condenser, the isolation valve may take the form of a mushroom valve, butterfly valve, or other proprietary valve design.

**SD-5.6.2.12** **SD-5.6.4.11** Instruments

(a) All instruments within the sterile boundary should comply with conform to all applicable sections of Part PI, including PI-2.1, PI-2.1.1(c) and (f), and PI-2.2.2.

(b) Instruments in process contact should be of hygienic design.
(c) Instrument probe surfaces and side port penetrations shall be oriented for self‐drainage: drainability.

(d) Instruments installed within the sterile boundary should be designed for CIP and sterilization. Instruments not designed for CIP should be removed for cleaning and reinstalled for sterilization.

(e) Locations with product‐sensing instruments (e.g., thermocouples and RTDs) and wire lead‐throughs should be considered when designing for cleaning and sterilization.

(f) Instrumentation with integral seals or diaphragm seals is preferred within the sterile boundary. The risk of using instrumentation without integral seals or diaphragm seals (e.g., Pirani gauges) should be assessed based on the risk to product quality as determined by the owner/user.

SD 5.6.5 Design for Bioburden Control
Lyophilizers designed for bioburden control should consider the following:

(1) pressure or vacuum hold testing in preparation for the bioburden reduction process. Refer to vacuum integrity testing para. SD 5.6.7.;

(2) evacuation of air from the chamber and condenser vessels to reduce the potential for air to be trapped during the bioburden reduction process. Effective air evacuation may be achieved through the use of a liquid ring vacuum pump or similar;

SD 5.6.3 Sterile Boundary.
(c) For the purpose of identifying areas that should be exposed to sterilizing agents, the following areas within the chamber and condenser vessels define the sterile boundary as indicated in Fig. SD 5.6.3.1:

(1) the inside surfaces of the chamber vessel to the chamber door isolation seal. 
(2) the inside surface of the condenser vessel to the condenser door isolation seal.
(3) the chamber and condenser drains to the first isolation drain valve.
(4) the vacuum pump inlet connection to the cold condenser vessel to the first isolation vacuum valve closest to the condenser vessel.
(5) the vacuum break/gas inlet line to the sterile gas filter. If redundant sterilizing filters in series are used, the sterile boundary ends at the membrane of the filter furthest from the chamber vessel.
(6) the sealing surface on all instruments connected to the chamber and condenser vessels.
(7) the exposed surface of the pressure relief valve or rupture disk.

SD 5.6.4 (d) Internal Connections and Fasteners
(1) Threads sealed by an O‐ring or hygienic gasket are acceptable. The use of exposed threads within the lyophilizer sterile boundary should be avoided. If other means of fastening are not practical, the use of exposed threads may be permitted with the agreement of the owner/user. The surfaces of exposed threads should be among those assessed for cleaning and penetration of sterilizing agents.

(2) For process contact surfaces, the use of pins, clevis rods, snap rings, and clips may be required to mount hardware inside the sterile boundary but should be minimized and agreed on by the owner/user. The surfaces of these fasteners should be among those assessed for cleaning and penetration of sterilizing agents.

(3) Socket head cap screws and counter‐bored holes inside the sterile boundary shall only be used with the agreement of the owner/user.

SD 5.6.8 (e) Branch Connections
(1) The provisions of SD 5.1.4.2 are applicable to liquid‐service process contact piping leading to the lyophilizer.
(2) Nozzles within the sterile boundary should be designed to allow for full exposure to the sterilizing agent.
(3) Nozzles and other appurtenances that are cleaned by liquid spraying should allow complete coverage.
(4) Lyophilizer internals should be designed to avoid low points where fluid can be trapped.

SD 5.6.1 Drainability

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Commented [BJ2]: Moved from SD 5.6.8 in 2019 version
6.3.3 Internal liquid distribution piping shall be sloped to meet the requirements of GSD2 to facilitate gravity draining for drainability.

6.3.4 External liquid distribution piping shall be designed with valve actions that facilitate gravity draining. The pipe slope shall meet the requirements of GSD2.

6.3.5 The liquid level in the chamber and condenser vessels should be minimized during once-through CIP by correct sizing of the drain and by providing slope to the respective drain. A CIP drain pump may be used to assist draining of the chamber and condenser vessels.

6.3.6 When recirculated CIP is used, the following requirements apply: (1) Recirculated systems shall be drainable including pump casing(s).

6.3.7 The chamber and condenser vessels shall be self-drainable.

6.3.8 Process contact surfaces shall be sloped to meet the requirements of GSD2 for drainability of CIP fluids and to prevent the collection of condensate during the steaming processes.

6.3.9 Interior surfaces of nozzles penetrating the vertical walls of the vessel shall be sloped to meet the requirements of GSD2.

6.3.10 The floor of the vessel shall be sloped toward the drain connection to meet the requirements of GSD2, unless otherwise agreed to by the manufacturer and owner/user.

SD-5.6.5 CIP of Lyophilizers
SD-5.6.5.2 Cleaning
The following requirements are for CIP of lyophilizers:

(a) Systems used to clean lyophilizers shall comply with conform to SD-6.3.3(a), SD-6.3.3(b) and SD-6.3.3(c). Cleanability requirements of SD-2.4.2 are applicable to lyophilizers except for SD-2.4.2(b)(1), which does not apply to lyophilizer shelves.

(b) It is accepted practice to use water as the CIP fluid for cleaning water-soluble compounds. Water for injection shall be used for the final rinse in aseptic processing applications.

(c) The chamber vessel, which includes internal shelves, should be cleaned via internal spray devices designed to provide coverage of targeted surfaces. Risk to product quality should be considered when determining the required coverage. The acceptance criteria for coverage shall be agreed to by the manufacturer and owner/user. Nonmandatory Appendix I provides an acceptable procedure for spray device coverage testing.

(d) The process contact surfaces within the condenser vessel may be cleaned via internal spray devices to provide coverage agreed on between the manufacturer and owner/user.

(e) Internal liquid distribution piping shall be sloped to meet the requirements of GSD2 to facilitate gravity draining.

(f) External liquid distribution piping shall be designed with valve actions that facilitate gravity draining. The pipe slope shall meet the requirements of GSD2.

(g) The liquid level in the chamber and condenser vessels should be minimized during once-through CIP by correct sizing of the drain and by providing slope to the respective drain. A CIP drain pump may be used to assist draining of the chamber and condenser vessels.

(h) When recirculated CIP is used, the following requirements apply:

(i) Recirculated systems shall be drainable including pump casing(s).

(j) Recirculated systems shall be capable of removing residual chemicals and debris during the final rinse.

(k) The chamber and condenser vessels shall be self-drainable.

(l) Process contact surfaces shall be sloped to meet the requirements of GSD2 for drainability of CIP fluids and to prevent the collection of condensate during the steaming processes.

(m) Interior surfaces of nozzles penetrating the vertical walls of the vessel shall be sloped to meet the requirements of GSD2.

(n) The floor of the vessel shall be sloped toward the drain connection to meet the requirements of GSD2, unless
that

The following requirements are for leak rate (vacuum integrity) testing thresholds, when pressure following valve phase (a) pressure or vacuum hold testing in preparation for the bioburden reduction process. Refer to leak detection para SD-5.6.7.

(b) evacuation of air from the chamber and condenser vessels to reduce the potential for air to be trapped during the bioburden reduction process. Effective air evacuation may be achieved through the use of a liquid ring vacuum pump or similar.

SD-5.6.5.3 Thermal Sanitization/Sterilization SD-5.6.6.1 steam-in-place
When designing lyophilizers for steam-in-place
(a) steam should enter the lyophilizer at only one point at a time to minimize the potential to trap air or condensate. If steam needs to enter through multiple locations simultaneously, the design should create flow paths that avoid air entrapment. The design should ensure that condensate will freely flow toward low-point drains.

(b) a dual control design may be used to deliver high steam flow rates that are often required during the heating phase and to maintain tight control of temperature and pressure during the exposure phase. For example, one regulator and control valve may be used for the heating phase and a separate regulator and control valve may be used for tight control during the exposure phase.

(c) vacuum drying phase should be used to eliminate any condensate remaining within the sterile boundary following SIP. 

(d) if cooling and drying are accomplished with the introduction of a process gas with open drains, a positive pressure differential shall be maintained to preserve the sterile boundary during this operation. 

(e) temperature monitored throughout the SIP cycle should include coldest (worst-case) locations. If routine monitoring of worst-case locations is not practical, the temperature of locations that have been correlated to the actual worst-case locations may be monitored instead.

(f) to minimize cold locations during SIP, horizontal penetrations should be sloped to allow condensate to drain.

SD-5.6.4.2 Hydrogen Peroxide Sterilization SD-5.6.5.4 Chemical Sanitization/Sterilization
When designing lyophilizers for sterilization with hydrogen peroxide gas under vacuum
(a) the system should be designed to be dried and have a surface temperature that meets the supplier’s specification for the hydrogen peroxide supply system (typically 59°F (15°C) and 176°F (80°C)] prior to the start of the sterilization process.

(b) the system should be designed to verify that the residual hydrogen peroxide levels are below the established thresholds, after the sterilization process has been completed. Threshold levels should be agreed on by the owner/user for both operator’s safety and the potential impact on the product quality.

SD-5.6.7 Testing Leak Rate
The following requirements are for leak rate (vacuum integrity) testing
(a) Lyophilizers designed for aseptic lyophilization processes shall be designed to meet leak rate testing criteria as agreed to by the owner/user. The sterile boundary should be leak tested before aseptic operations begin. The leak rate is calculated as follows:

\[ Q = \frac{\Delta P}{\Delta t} \]

where
- \( Q \) = leak rate, mbar L/s
- \( V \) = the lyophilizer system volume subject to the vacuum, adjusted to exclude the volume occupied by internal hardware, L
\( \Delta P \) = the absolute pressure rise during the test, mbar
\( \Delta t \) = the test duration, sec

(b) Leak rate testing should be performed on a clean, dry, and fully assembled and insulated system with the condenser cooler in operation to capture residual vapor. Typically, leak rates less than 0.02 mbar-L/s are acceptable for new installations. Leak rate testing is intended to confirm vacuum integrity of the system.

(c) Leak rate tests are performed at high vacuum conditions with an absolute pressure typically on the order of 0.01 mbar.

(d) Sufficient stabilization time will avoid misinterpretation of the vacuum leak rate due to virtual leaks. Virtual leaks are identified by a leak rate that stabilizes over time.

(e) Individual component assemblies, which are subjected to vacuum conditions, should be helium leak tested prior to final installation.

SD-5.6.8 Branch Connections

(a) The provisions of SD-3.1.2.2 are applicable to liquid-service process contact piping leading to the lyophilizer.

(b) Nozzles within the sterile boundary should be designed to allow for full exposure to the sterilizing agent.

(c) Nozzles and other appurtenances that are cleaned by liquid spraying should allow complete coverage.

(d) Lyophilizer internals should be designed to avoid low points where fluid can be trapped.
SD-6.1.3 Operating Capabilities and System Function

(a) Cabinet washers shall be capable of delivering cleaning solutions and of the subsequent rinsing of cleaning solutions from washed surfaces.

(b) Cabinet washers should have the ability to perform the following general phases during the cycle:

(1) prewashing
(2) washing
(3) rinsing
(4) final rinsing
(5) drying with heated filtered air
(6) cooling with filtered air

SD-6.1.3.1 Rinse Requirements

(a) The final rinse step may be performed using recirculated water integrated with drain steps or as a single-pass rinse (or series of single-pass rinses) to remove residual cleaning solutions. The final rinse water at the outlet of the washer shall meet the owner/user's acceptance criteria (e.g., conductivity, total organic carbon, cycle time).

(b) The ways of providing a single-pass rinse include:

(1) direct connection supply from a utility water system with hygienic safeguards to prevent backflow. If a direct utility connection is used, the design should mitigate the effect of variation in supply pressure (e.g., due to draw by other users) and its impact on the flow rate.

(2) use of a water break-tank. The break-tank shall be self-drainable and vented. Rinse water from the break-tank shall not contribute to the soiling or bioburden load in the cabinet.

(c) The hydraulic conditions (i.e., pressure and flow rate) for the rinsing phases shall be consistent with those established for washing phases to ensure consistent rinsing of the washable items, the chamber interior, and the complete hydraulic circuit.

SD-6.1.4 System Design

(a) Materials of Construction

(1) Process contact surfaces shall comply with the requirements of SD-2.4.1.

(2) All welded metallic process contact surfaces shall be passivated in accordance with SF-2.6.

(3) External surfaces of the washer cabinet shall be fabricated with material that is resistant to cleaning and sanitizing agents as specified by the owner/user.

(4) Process contact polymeric materials shall comply with Part SG and Part PM.

(5) Process contact metallic materials shall comply with Part MM.

(b) Surface Finish. The surface finishes for the interior surfaces of the chamber, wetted process contact tubing, and exterior surfaces exposed to cleaning solutions shall be specified by the owner/user using designations provided in Table SF-2.4.1-1. Electropolishing is not required unless specified by the owner/user.

SD-6.1.4.1 Wash Chamber

(a) The interior surfaces of the chamber are considered process contact surfaces. These surfaces, which have the potential to drip onto washed items, shall have complete spray coverage (see SD-6.1).

(b) The interior of the chamber shall comply with SD-2.4.2. Internal surfaces that may be difficult to clean (e.g., wheels, cabling, external surfaces of exposed hygienic-clamp connections) should be minimized and assessed for the risk to product quality.

(c) All internal surfaces shall be sloped for drainability with a slope agreed on between the owner/user and fabricator. Where possible, a slope of not less than 1/8 in./ft (10 mm/m) is recommended.

(d) External surfaces should be insulated to minimize heat transmission and promote cleaning and drying.

(e) Breastplates, reinforcing pads, doubler plates, poison pads, etc., which are required for welding dissimilar material to the chamber, should be of the same material as the chamber.

(f) Lubricants shall not be used where they may come in contact with cleaning solutions or washable items.

SD-6.1.4.2 Chamber Openings

(a) Nozzles that are designed to be cleaned by a spray device should have the smallest L/d ratio practical. For non-flow through nozzles, an L/d of less than 2 is recommended (see Figure SD-3.4.2-1).

(b) Sidewalls and chamber-ceiling nozzles should be flush with the interior of the chamber (see Figure SD-3.4.2-5).

(c) Blank covers shall have the same surface finish as the chamber internals.

(d) Process valves shall meet the requirements of SG-3.3.2.3.

(e) Sample valves shall meet the requirements of SD-3.11.2.1.

(f) Sight glasses on the chamber shall meet the requirements of Figure SD-3.4.6-1. Sight glasses should be designed with the smallest L/d practical and should incorporate cleanable seal designs.

SD-6.1.4.3 Washer Door and Door Seals

(a) Washer doors and door seals shall be designed to prevent wash fluid leakage during the entire wash cycle.

(b) For multiple-door systems, the doors shall be interlocked to allow the opening of only one door at a time for loading and unloading.

(c) Both sliding and swing door designs are acceptable.

(d) Doors that interface with classified clean rooms should not be retracted to an uncontrolled space.

(e) Construction of the door shall meet SD-2.4.1.

(f) The internal surface finish of the door shall be the same as specified for the chamber internal surfaces.
(g) Solid or inflatable door seals shall meet the requirements of SD-2.4.1.1 (e.g., conforming to FDA 21 CFR 177 and USP Section <88> Class VI).

(h) Refer to Part SC for specifications of seals.

**SD-6.1.4.4 Internal Components**

(a) Washer cabinet internal components include loading racks and supports, thermowells, spray manifolds, etc.

(b) Weld-in thermowells [see Figure SD-3.4.3-2, illustrations (e) and (f)] shall have the same finish as the chamber internals.

(c) Loading racks/accessories

1. The racks are designed to support the cleaning of specific washable items. The rack design should be verified to provide complete spray coverage for washable items defined by the owner/user in an arrangement for which the loading rack is designed.

2. Loading racks shall secure the washable items during the wash cycle.

3. Loading racks may be designed to distribute rinse and cleaning solutions to interior and exterior surfaces of the washable items.

4. Loading racks should have a surface finish that meets the surface finish requirements of the chamber. Surface finish verification may not be possible for all components of the loading rack.

5. The loading rack manifold fabrication shall comply with SD-3.1.2.3.

6. Loading rack design considerations should include the disassembly required for inspection and maintenance.

**SD-6.1.4.5 Air Drying, Intake, and Exhaust Systems.** Where specified by the owner/user to dry washed items, the following provisions are applicable:

(a) The air intake system shall be filtered. A prefilter and HEPA filter system are recommended to protect the washed items.

(b) The drying system shall provide heated, filtered air to the chamber, the hydraulic circuit, and in-line components.

(c) The filtered air used for drying may be supplied from a controlled or uncontrolled environment.

(d) Temperature and humidity variability of intake air should be considered in system design.

(e) The exhaust ducting should be designed to direct condensate to a drain.

**SD-6.1.4.6 Spray Systems.** Design of spray systems in cabinet washers requires the integration of manifolded spray devices in the chamber with those installed in loading racks. Spray systems in cabinet washers may use both static and dynamic spray devices that comply with SD-3.9.

(a) Loading-rack spray systems may have interchangeable spray devices to accommodate a variety of washable items in a single rack.

(b) Translational/reciprocating spray devices in the cabinet using mechanical devices (e.g., pulleys and PTFE sheathed cables) should be designed for ease of disassembly for inspection and maintenance.

(c) Mechanical devices used in the chamber shall be compatible with the process fluids and shall be cleanable.

**SD-6.1.4.7 Chemical Addition Systems.** When cleaning solutions are not provided by a CIP system, the following provisions are applicable:

(a) A number of chemicals that function as pH adjusters, emulsifying agents, and/or soil removers during the cabinet washer cycle considerations should include positive identification of each chemical delivery and connection.

(b) Concentrated chemicals may be delivered to the washer from bulk distribution systems or from local holding containers. The design of concentrated chemical delivery and storage systems should consider minimizing human contact.

(c) Design of concentrated chemical storage and distribution components should consider safety provisions enumerated in SD-6.3.4(d).

(d) The design should include monitoring of adequate bulk chemical supply (e.g., level) for the entire wash cycle.

**SD-6.1.4.8 Recirculation Pumps**

(a) The pump shall have sufficient capacity (flow rate and pressure) for all spray configurations used in the washer.

(b) Pumps shall comply with SD-3.3.2.

(c) Pump seals shall comply with Part SC.

**SD-6.1.4.9 Heat Exchangers**

(a) Heat exchangers included in cabinet washers to heat cleaning solutions, rinse water, etc., shall comply with SD-3.6.

(b) Heat exchangers using steam or a thermal liquid may include shell-and-tube, coil, or tube types.

(c) Electric heat exchangers may be direct or indirect immersion type heaters.

**SD-6.1.4.10 Instrumentation**

(a) All process contact instruments should comply with the applicable sections of Part PI.

(b) The design should enable operators to monitor process parameters without having to pass through changes in room classifications.

**SD-6.1.4.11 Interfaces.** Where the chamber interfaces with the clean room, the external surfaces shall meet the owner/user’s specified requirements.
SD-6.1.5 Design for Bioburden Control

(a) Cabinet washers shall comply with the fabrication requirements of SD-2.4.1.
(b) Tubing within the process contact boundary should be orbital-welded tubing where possible and shall comply with Part M.
(c) All wetted process contact surfaces shall be of hygienic design per the applicable sections of this Standard.

SD-6.1.5.1 Branch Connections

(a) The provisions of SD-3.1.2.2 are applicable to liquid-service process contact piping leading to the chamber and delivering cleaning solutions to the spray manifolds.
(b) Liquid-service branch connections with an L/d greater than 2 shall be provided with low-point drains that are opened between each phase of the washing cycle to avoid cross-contamination.

SD-6.1.5.2 Drainability

(a) The chamber drainability should be verified during fabrication. Verification methods and acceptance criteria for drainability shall be agreed on in advance by all the parties.
(b) Instrument probes and sidewall penetrations (see Figure SD-3.4.2-2) shall be sloped for drainability, unless the instruments used require horizontal mounting (see Figure SD-3.4.2-3).
(c) Loading racks shall be self-drainable.

SD-6.1.5.3 Cleaning

(a) The design should enable multiple chemical additions during the prewashing and washing processes.
(b) Cleaning solution temperature shall be controlled and monitored during washing and rinsing phases.
(c) The pressure and flow rates of cleaning solutions supplied to dynamic and static spray devices within the chamber and/or loading racks should be monitored.
(d) If cleaning solutions are recirculated during the cycle, the recirculation pump shall meet the requirements of SD-3.3.2.
(e) The design should provide final rinse water at an elevated temperature [e.g., >149°F (65°C)] for sanitization and improved drying efficiency.
(f) The system shall be designed to provide analytical verification of final rinse water quality (e.g., conductivity and/or total organic carbon).

SD-6.1.6 Design for Serviceability, Examination, and Operation

(a) Cabinet washers should be designed to enable access for inspection and service of components that are subject to wear and to allow periodic calibration of instruments.
(b) Mechanical components and instruments that require maintenance may be located in an unclassified space where the maintenance can be performed.
(c) The washer design considerations should include integration with the space where maintenance is performed (e.g., minimizing moisture due to condensation).
(d) Pumps should be designed and configured to enable access for removal, inspection, and maintenance.

SD-6.1.7 Testing. The test requirements shall be defined by the owner/user and agreed to by the manufacturer, and may include tests beyond those described in this section. These tests apply to newly installed systems and to modifications of existing systems (e.g., the addition of a loading rack to an existing system).

SD-6.1.7.1 Spray Device Coverage Test. Cabinet washers should be tested to confirm complete spray coverage of the specified washable items and the interior process contact surfaces of the washer chamber. The spray device coverage testing described in SD-7.1 is applicable to cabinet washers. The spray device coverage test procedure described in Nonmandatory Appendix M may be used for cabinet washers with the following additional considerations:
(a) Testing should include empty configurations (i.e., loading rack only).
(b) Testing should include racks loaded to capacity.
(c) It is acceptable to bypass the drying phase of the cycle to examine the wet conditions. If parts are dry when inspected, they should be gently rewetted with ambient or cold water to observe any residual riboflavin fluorescence.
(d) The sequence in which parts are examined should be documented to prevent false positive results due to transfer of residual riboflavin from one washable item to a clean washable item.

SD-6.1.7.2 Drainability Test. The proposed drainability test procedure in SD-7.4 for vessels may be applied to cabinet washers with the following exceptions/considerations:
(a) It is not necessary to fill the chamber with the outlet closed. The chamber should be wetted by liquid delivered through the spray system.
(b) The chamber drainability test should be performed without drain pump assistance.

SD-6.1.7.3 Cycle Performance Test. The performance test should demonstrate the ability to clean loaded items based on an initial list of washable items agreed to by the owner/user and manufacturer. The test should verify removal of residue from surfaces and that the final rinse meets the specified water quality (e.g., an acceptable compendial water requirement) at the drain within a specified period of time. The test should verify that the process contact surfaces...
within the washer are also cleaned to the same specifications used for the washable items.

**SD-6.2 Steam Sterilizers/Autoclaves**

**SD-6.2.1 General.** For this section, “autoclaves” and “steam sterilizers” shall be used synonymously. This section describes the requirements of autoclaves that are used in bioprocessing for the steam sterilization of hard, dry-wrapped, and liquid materials.

This section does not pertain to pasteurizers, ETO (ethylene oxide), VHP (vaporized hydrogen peroxide), or ClO₂ (chlorine dioxide) type sterilization equipment. The manufacturer shall define the sterile boundary of the system.

**SD-6.2.3 Operating Capabilities and System Function.** Autoclaves should be capable of multiple cycle types for various load conditions. Autoclaves shall only be used to sterilize the types of goods for which they are designed. The most common load types are specified in **SD-6.2.3.1** through **SD-6.2.3.3**.

**SD-6.2.3.1 Hard Goods Cycles.** “Hard goods” refers to goods such as metallic instruments, containers, and glassware. Effective removal of noncondensable gases is required for effective autoclaving of hard goods. Hard goods may be wrapped or unwrapped. Unwrapped goods can often be effectively autoclaved using either a single vacuum pull or gravity air displacement. These goods can sometimes be autoclaved at higher temperatures. Multiple vacuum pulse preconditioning is required for wrapped goods to ensure proper evacuation of noncondensable gases from both the autoclave chamber and autoclaved goods. Steam sterilizers used for the processing of wrapped or porous goods shall be able to pull vacuum to levels below 1 psia [69 mbar] and maintain the vacuum with a maximum leak rate of 0.1 psia·s/min [6.9 mbar·s/min]. Cooling, drying (pulse, vacuum) is an optional cycle used to dry goods at the end of the autoclave cycle. Heated pulse drying is also recommended for the drying of porous goods such as rubber stoppers. Exhaust rates and heating rates should be adjustable for pressure-sensitive materials.

**SD-6.2.3.2 Liquid Cycles.** Forced air removal preconditioning is an optional cycle used to evacuate the noncondensable gases from the autoclave chamber. Liquid cooling cycles should be provided to efficiently cool the autoclave chamber. Providing the chamber with overpressure helps prevent the liquid goods from boiling over during the cooldown phase. Liquids can also be cooled by slow-rate exhaust. Heated rates should be adjustable to help compensate for differences in heating profiles of items in mixed loads.

**SD-6.2.3.3 Air Filter Sterilization.** An independent air filter SIP sterilization cycle should be provided for the in situ sterilization of the chamber vent filters ensuring supply of sterile air for cooldown phases of autoclave loads.

**SD-6.2.4 System Design.** Materials in contact with steam shall resist corrosion from steam and steam condensate. The materials shall not affect steam quality and shall not release any substances known to be toxic or that could adulterate the product. Piping/tubing and fittings shall be pressure and vacuum tight. The piping/tubing layout should be designed to eliminate dead legs within the sterile boundary. Tubing within the sterile boundary should be orbital-welded stainless steel tubing where possible and shall comply with **Part Mj** (Table Mj-8.4-1) acceptance criteria. All process contact surfaces within the sterile boundary including tubing, chamber, and components shall be passivated. The autoclave shall be enclosed with paneling that is resistant to corrosion and is cleanable. The surface finish within the sterile boundary need not exceed 35 μin. Rₐ (0.89 μm). Electropolishing is not required for steam sterilization systems.

Elastomers shall comply with **SC-3.1.1, SC-3.1.2, and SC-3.1.3**. Elastomers shall be resistant to corrosion and to chemical and thermal degradation. Elastomers used in autoclave applications shall be capable of withstanding pressures of a minimum of 25 psig at 266°F (1.7 barg at 130°C). Seals should meet the testing requirements specified in **SD-4.2**.

**SD-6.2.4.1 Chamber.** Autoclave chambers are pressure vessels and shall be pressure and temperature rated per the owner/user’s design criteria with a minimum pressure rating of 25 psig at 266°F (1.7 barg at 130°C). The chambers shall also be vacuum rated.

For systems used in the processing of materials used in the European market, autoclaves may also be required to comply with **Pressure Equipment Directive (PED) 97/23/EC** and/or **EN 285**.

**SD-6.2.4.2 Doors.** Autoclave door(s) shall be accessible, cleanable, and replaceable, and should be capable of undergoing inspection without dismantling. The door seal shall be resistant to clean steam and clean steam condensate. The door on the nonsterile side shall be capable of reopening after closing without undergoing a cycle. The door(s) shall not be capable of opening during a sterilization cycle. The doors shall be constructed of materials that are resistant to clean steam and clean steam condensate. For multiple-door systems, the doors shall be interlocked to allow the opening of only one door at a time. The unloading (“sterile-side”) door shall remain sealed in standby mode. Refer to **Part SD** for specifications of seals used in bioprocessing.

**SD-6.2.4.3 Sterile Air/Vent Filters.** Where the sterilization cycle requires admission of air into the chamber, the air should be filtered with a sterilizing filter (0.22 µm or less). The filter element shall be replaceable.
for the steam in place of the vent filter elements should be provided.

**SD-6.2.4.4 Steam Traps.** Refer to **SD-3.12** for requirements of steam traps.

**SD-6.2.4.5 Loading Carts/Trays.** Carts and trays exposed to clean steam shall be constructed of materials resistant to clean steam and clean steam condensate. Carts, trays, and chamber shall be accessible or removable and cleanable.

**SD-6.2.4.6 Valves.** Valves and sealing materials located within the sterile boundary shall comply with **SD-3.3.2.3.** Valves within the sterile boundary are typically only exposed to clean steam service and chemical(s) used during passivation. Exposure to these conditions should be considered when selecting a valve type for this application.

**SD-6.2.4.7 Check Valves.** Provisions to prevent back-siphoning into the service feed systems should be considered.

**SD-6.2.4.8 Jacket.** The jacket shall be constructed using materials that are resistant to corrosion and degradation from steam or clean steam and clean steam condensate, as applicable.

**SD-6.2.4.9 Instrumentation.** Autoclave pressure and temperature shall be displayed at all doors. All instruments within the sterile boundary should be of hygienic design. Instruments shall be capable of being calibrated and replaced. The instrumentation shall include the following:

(a) **Temperature.** Independent temperature elements (one or two for monitoring and recording and an independent one for controlling temperature) shall be provided. The chamber temperature recording element should be located in the chamber drain. Each temperature element shall be accurate to ±0.18°F (0.1°C) with a sensor response time <5 sec. The element installation shall not affect the maximum leak rate. The temperature elements shall be temperature and clean steam resistant.

(b) **Pressure/Vacuum.** Pressure/vacuum instruments shall be provided. The pressure instruments shall monitor the chamber and jacket pressures. Provisions for recording chamber pressure during active autoclave cycles shall be included.

(c) **Date/Time.** Provisions for recording the date and time during an autoclave cycle shall be included.

(d) **Recording.** Recording may be achieved by paper or 21 CFR Part 11-compliant electronic means.

**SD-6.2.4.10 Interfaces**

(a) **Drain Temperature.** Waste to drain temperature shall comply with owner/user specifications. The owner/user shall specify discharge temperature requirements to the manufacturer.

(b) **Insulation.** External surfaces should be insulated to minimize heat transmission.

(c) **Biocontainment.** Special conditions such as bioseals may be required for autoclaves used in BSL-3 and BSL-4 applications. Please refer to the Biosafety in Microbiological and Medical Labs (BMBL) and Centers for Disease Control (CDC) guidelines for these special conditions.

**SD-6.3 CIP Systems**

**SD-6.3.1 General**

(a) The following terms are defined for this section:

(1) **CIP circuit:** the sum of paths within a process unit operation that are cleaned as part of a single CIP cycle (e.g., bioreactor, buffer hold vessel).

(2) **CIP cycle:** the executed recipe of rinses, washes, and air blows used to clean soiled equipment.

(3) **CIP path:** the specific destination contacted with cleaning solution/rinse water during a CIP cycle (e.g., spray device path, inoculum line path, addition line path). Multiple paths within a circuit may be cleaned simultaneously.

(4) **clean-in-place (CIP) system:** a system used in the preparation, distribution, delivery, and subsequent removal of cleaning solutions to soiled equipment.

(b) All in-circuit components of the CIP system (e.g., filter housings, pumps, vessels, heat exchangers, transfer panels, instrumentation, valving, piping) shall be designed to be cleanable, drainable, and of hygienic design appropriate for use in contact with process fluids per the applicable sections of this Standard.

**SD-6.3.2 System Performance Requirements**

(a) The following cleaning variables should be considered in the design of the CIP system and CIP cycle:

(1) time of exposure (contact time) to wash and rinse solutions

(2) temperature of wash and rinse solutions

(3) chemical concentration of wash solutions

(4) fluid hydraulics

(b) A CIP system should include the capability to control directly or indirectly (monitor and record if applicable) the following CIP variables:

(1) timing of CIP cycle

(2) path being cleaned (e.g., valve position indication, pressure/flow verification, manual setup verification)

(3) CIP supply temperature (or return if applicable)

(4) conductivity, volume of cleaning chemical added, or cleaning chemical concentration for wash solutions

(5) final rinse conductivity or residual cleaning chemical concentration

(6) CIP supply flow rate

(7) totalized flow (if timing not monitored)

(8) CIP supply pressure
SD-6.3.3 Operating Capabilities and System Function

(a) The CIP system shall be capable of delivering and subsequently removing cleaning solutions to soiled equipment in a verifiable and reproducible manner.

(b) The CIP system shall be capable of removing process soils to an owner/user-determined acceptance criteria.

(c) The CIP system shall be capable of removing cleaning chemicals to a verifiable amount characteristic of the final rinse solution.

(d) The CIP skid should be designed to deliver feed water, inject cleaning chemicals, heat, and supply the cleaning solution to the soiled equipment. The skid shall also be designed to remove all residual cleaning chemicals added during the cycle.

(e) The CIP distribution system shall be designed to deliver the cleaning solution to the soiled equipment. The distribution system may also return the solution to the CIP skid, if applicable.

SD-6.3.4 System Design

(a) A CIP system is a distributed system of properly integrated components.

(b) For this section, a CIP skid consists of a wash and/or rinse tank with all requisite valves, pumps, and instrumentation. Provision for separation of feed waters and wash solutions should be considered. CIP skids may be located in a fixed, centralized location or may be portable and used adjacent to the soiled equipment.

(c) The CIP system design should consider the CIP circuit volume for water consumption, location of skid in facility (if fixed), chemical consumption, waste effluent, and energy required to clean a given circuit.

(d) The design should consider hazardous operation of cycle considering choice of cleaning chemicals. Chemical segregation, spill control, addition handling, material compatibility, secondary containment, and personnel safety should be considered.

SD-6.3.4.1 Wash/Rinse Tank

(a) The wash/rinse tank(s) shall be designed and fabricated per SD-3.4. The tank(s) shall be designed for cleanliness per SD-6.3.5.3 and shall be equipped with a spray device(s) per SD-3.9.

(b) If used on wash/rinse tanks, a hydrophobic vent filter shall be designed to prevent moisture accumulation in the vent filters and shall be fabricated per SD-5.4.

SD-6.3.4.2 Heat Exchanger. Heat exchange equipment shall be designed and fabricated per SD-3.6.1.

SD-6.3.4.3 Supply Pump

(a) The CIP skid should have flow control, either via pump output or by means of flow control valves.

(b) CIP supply pumps shall be designed and fabricated per SD-3.3.2. The pump design should consider the handling of a gas/liquid mixture.

SD-6.3.4.4 Return Pump

(a) CIP return pumps (if required) shall be designed and fabricated per SD-3.3.2. Centrifugal pumps are preferred for CIP return applications. If a gas/liquid mixture is anticipated, then hygienic liquid ring pumps are recommended.

(b) When a vessel is included in the circuit, CIP return pumps should be placed as close as possible to the vessel bottom outlet and at the low point of the circuit.

(c) Provision shall be made to flush through the casing drain of CIP return pumps.

(d) CIP return pumps shall be designed to maintain hydraulic balance (supply and return flow) of the CIP circuit.

SD-6.3.4.5 CIP Return Eductors

(a) For this section, a CIP “return eductor” is defined as a device that uses a motive fluid to create a pressure differential that returns the CIP solution.

(b) Special design factors shall be considered when using CIP return eductors (e.g., vapor pressure, return line size).

SD-6.3.4.6 CIP Distribution Piping

(a) General

(1) The use and application of a particular distribution design or combination of designs is to be decided by the owner/user.

(2) The use of looped headers, transfer panels, and valve types (e.g., divert, mix-proof, multiport, zero-static, and diaphragm) should all be considered in the design of the CIP distribution system.

(b) Looped Headers (see Figure SD-6.3.4.6-1)

(1) The dimension from the looped header to the isolation valve weir or seat should conform to SD-3.1.2.2 (see Figure SD-3.1.2.2-1 for details). The use of short-outlet tees or zero-static valves should be decided by the owner/user.

(2) Future connections (if applicable) on the looped header should use capped short-outlet tees or capped installed zero-static valves.

(3) Looped header connections should be oriented horizontally when used in CIP return applications.

(4) CIP supply header design should provide for adequate velocity in parallel cleaning paths (e.g., line size reduction in loop header).

(5) The entire looped header shall be cleaned during a CIP cycle.

See reorganized and revised SD-6.3 that follows.
(c) Transfer Panels. Transfer panels shall be designed and fabricated per SD-3.7.1.

(d) Multiport Valves. For this section, a CIP distribution “multiport valve” is defined as a multiple valve assembly fabricated as a single body to minimize distances and maximize drainability [see SG-3.3.2.3(a) for details].

(e) Zero-Static Chains (see Figure SD-6.3.4.6-2). For this section, a CIP distribution “zero-static chain” is defined as a manifold of circuit-specific zero-static valves. Provision shall be made to flush the manifold in a zero-static chain.

(f) Swing Elbows and Piping Spools (see Figure SD-6.3.4.6-3). For this section, a “swing elbow” or “piping spool” is defined as a removable section of pipe used to provide a positive break between two paths. Swing elbows or piping spools shall be connected to adequately supported piping to maintain line slope and connection alignment.

(g) The distribution piping and components in a recirculated CIP circuit shall be hygienic for design and fabrication as per SD-3.1.2 and SD-2.4.3.

(h) The distribution piping and components in a once-through CIP circuit or path (not recirculated) shall be hygienic for design and fabrication as per SD-3.1.2 and SD-2.4.3 upstream of the location of cleaning performance verification.

(i) CIP supply piping should be sized to ensure that the fluid flow meets or exceeds the guidelines stated in SD-6.3.5.2 and SD-6.3.5.3.

(j) The distribution circuits shall be designed such that fluid flow will maintain a positive pressure relative to the process drain, preventing backflow.

(k) CIP return piping shall be designed to maintain hydraulic balance (supply and return flow) of the CIP circuit.

SD-6.3.7 Instrumentation. Instrumentation and controls architecture (if applicable) should be designed to communicate, monitor, and synchronize the CIP cycle, and report CIP variables.

SD-6.3.5 Design for Bioburden Control

SD-6.3.5.1 Drainability

(a) Process vessels should be cleaned via internal spray device(s) designed to consistently expose all internal surfaces to the cleaning variables described in SD-6.3.

(b) CIP return eductors shall be designed and installed to be drainable.

SD-6.3.5.2 Cleaning: CIP Flow Rate Guidelines for Process Lines

(a) For effective cleaning, the CIP flow rate shall be sufficient to ensure that the cleaning agent and rinsing solutions wet all targeted surfaces within the CIP boundary. The CIP flow rate should be greater than the process flow rate.

(b) Table SD-6.3.5.2-1 details flow rates that ensure solution contact in straight horizontal and vertical lines for line sizes up to 2 in. (50 mm) without branches, fittings, and other in-line components. These flow rates correspond to a flow velocity of 5 ft/sec (1.5 m/s), which is well into the turbulent range and typical for CIP solutions that are within the scope of this section and all line sizes referenced in Part DT.

(c) CIP flow rate requirements should be considered in conjunction with other CIP process variables (e.g., temperature, chemical concentration, and time).

(d) Air trapped in branches may inhibit full contact of cleaning agent and rinsing solution to those process contact surfaces. The flow direction, line orientation,
line size, and presence and orientation of branches, fittings, and other equipment can have a significant influence on the flow rate required to remove air. Adequate solution contact may be achieved at a flow velocity of 5 ft/sec (1.5 m/s) with 1.5 in. (38 mm) and larger short-outlet tees (Table DT-4.1.2-5). Smaller-diameter short-outlet tees and tees with longer branches may require velocities greater than 5 ft/sec (1.5 m/s) for adequate solution contact. Solution contact in branches can be enhanced in the design by

1. strategic use of zero-static valves
2. flow through branch or bleeding air from branch
3. orienting blocked branches in the horizontal position
4. use of flush-mounted instrument fittings, short-outlet tees, gauge tees, or minimum L/d "instrument cups" for small lines

Figure SD-6.3.4.6-2 Zero-Static Chain

Figure SD-6.3.4.6-3 Swing Elbow Arrangement

(5) orienting branches so the flow of the liquid entering the tee is directed toward the blocked branch.

(e) Branches with risk of incomplete solution contact should be considered worst-case locations that may require local cleaning verification.

NOTE: Factors that may mitigate the risk of insufficient cleaning due to incomplete air removal from branches include

(a) CIP flow rates higher than process flow rates are likely to wet all surfaces that were soiled.
(b) Instruments or other devices protruding into the flow path may create additional local turbulence.
(c) Condensate generated during hot washes or hot rinses as part of a CIP cycle may provide some additional rinsing of surfaces.
(d) Dynamic flow conditions during route transitions and air blows may assist wetting.

Table SD-6.3.5.2-1 Flow Rates to Achieve 5 ft/sec (1.52 m/s)

<table>
<thead>
<tr>
<th>Sanitary Tube Size</th>
<th>Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q.D. in.</td>
</tr>
<tr>
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<td>12.7</td>
</tr>
<tr>
<td>0.75</td>
<td>19.1</td>
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<td>25.4</td>
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<tr>
<td>1.50</td>
<td>38.1</td>
</tr>
<tr>
<td>2.00</td>
<td>50.8</td>
</tr>
</tbody>
</table>

SD-6.3.5.3 Cleaning: Design Guidelines for Cleaning Process Vessels

(a) Process vessels should be cleaned via internal spray device(s) designed to consistently expose all internal surfaces to the cleaning variables described in SD-6.3.
(b) The use and application of particular spray device design to satisfy these requirements shall be decided by the owner/user. Spray devices shall be designed and fabricated per SD-3.9 (also see Figure SD-3.9.2.1-1 for static spray device design considerations).
(c) Dished-head vertical vessels should have cleaning solutions delivered with the majority of flow directed toward the upper head and sidewall area at the upper knuckle radius. Cylindrical horizontal vessels should have cleaning solutions delivered with the majority of flow directed toward the lower one-third of the vessel.
1. If a static spray device is used, gravity provides a solution sheeting over the side wall and bottom head (vertical vessels) or lower surfaces (horizontal vessels).
2. If a dynamic spray device is used, the device may directly spray areas throughout the vessel or rely on sheeting action.

See reorganized and revised SD-6.3 that follows.
(3) Figure SD-3.9.2.1-2 details ranges of flow recommendations for static spray devices on vertical process vessels under typical cleaning loads. The recommendations in Figure SD-3.9.2.1-2 ensure sufficient coverage.

(d) The criteria to ensure sufficient coverage on horizontal process vessels vary with geometry and size.

(d) Spray device design and location shall ensure appurtenances such as manways, baffles, dip tubes, agitator impellers, and nozzles are contacted with cleaning solution. Some appurtenances may require additional provisions for cleaning.

(e) Spray devices only ensure coverage of the exterior of installed appurtenances and equipment. If not removed during CIP, cleaning solutions shall flow through appurtenances to clean their interior.

(f) The fluid level should be minimized in the process vessel during CIP. Proper hydraulic balance (supply and return flow) of the CIP circuit and sizing of the bottom outlet valve should be considered to minimize fluid level.

(g) Vortex formation during CIP may adversely affect the operation. The installation of a vortex breaker may be required.

(h) Vortex breaker design should be decided by the owner/user. Vortex breaker surfaces shall be sloped to eliminate pooling during CIP and positioned to not adversely affect the hydraulic balance of the CIP circuit.

(i) For process vessels equipped with an agitator, the impeller should be rotated at an appropriate speed during the CIP cycle.

SD-6.3.6 Design for Serviceability, Examination, and Operation. CIP return eductors shall be designed to be removable for examination.

SD-6.3.7 Testing. During the cleaning of process vessels, sufficient exposure shall be confirmed by coverage testing per SD-7.1 at the site of equipment manufacture and/or installation.

SD-6.4 Thermal Treatment Systems

SD-6.4.1 General

SD-6.4.1.1 Terminology. The following terms are used in this section:

average residence time: the volume of the retention tube divided by the volumetric flow rate. (Average residence time should always be greater than the required residence time.)

coil heat exchanger: a coiled tube for process liquid flow, inside a shell or a second tube containing heating/cooling medium.

cooling equipment: heat exchangers and/or a flash cooler used to cool the process liquid after the retention tube.

energy recovery heat exchange system: optional equipment that takes heat from the discharge of the retention tube and uses it to preheat the incoming process liquid. These systems may have process fluid on both sides of a heat exchanger.

heating equipment: heat exchangers and/or direct steam injection equipment. Direct steam injection refers to use of a steam injector valve (typical) or a steam infusion chamber.

high-temperature short time (HTST): processing at a combination of temperature and required residence time that is designed to achieve a desired level of bioburden reduction or viral inactivation. Treatment conditions (i.e., exposure temperatures and residence times) for HTST systems range broadly, depending on the performance goal of the system.

required residence time: the minimum exposure time required at the specified temperature to achieve desired results.

retention tube: a section of tubing used in HTST/UHT systems to retain the process liquid (typically an aqueous solution) at an elevated temperature for a specified time.

ultra-high temperature (UHT): processing at temperatures above 275°F (135°C) with rapid heating and cooling and short exposure times to achieve what is generally accepted as a sterile condition.

Thermal treatment system example configurations are shown in Figures SD-6.4.1.1-1 and SD-6.4.1.1-2.

SD-6.4.1.2 Scope and Purpose. This section addresses thermal treatment systems used in bioprocessing to reduce or eliminate viable microorganisms and viruses in a liquid under continuous flow conditions while minimizing degradation of the product or a product intermediate. Thermal systems may be designed to achieve goals that do not require sterilization of the process liquid, such as inactivation of viruses or a particular bacterial species. Bio-inactivation (waste treatment) systems (SD-4.4.2) and food pasteurization systems are not addressed in the scope of this section.

SD-6.4.2 System Performance Requirements. The following system performance capabilities shall be defined:

(a) treatment temperature range
(b) required residence time at treatment temperature
(c) process liquid flow rate
(d) discharge temperature range
(e) maximum heating surface temperature, heat transfer fluid temperature, or process liquid heating rate (°F/sec, °C/s)

Additional performance requirements may be defined by the owner/user. Additional process parameters required to confirm system capabilities, including specifying the process fluid’s incoming temperature and other properties, should be provided by the owner/user.
SD-6.3 CIP Systems

SD-6.3.1 General
This section addresses CIP systems used to clean and reduce bioburden on process contact surfaces. CIP systems include the CIP skid and the CIP distribution system. The system shall be self-cleaning and capable of distributing CIP fluids (e.g., cleaning solutions, rinse water, compressed air) to the targeted process contact surfaces of a CIP client.

(a) The following terms are defined for this section:
(1) CIP circuit: the sum of paths within a process unit operation that are cleaned as part of a single CIP cycle (e.g., bioreactor, buffer hold vessel).
(2) CIP cycle: the executed recipe of rinses, washes, and air blows used to clean soiled equipment.

(3)(a) CIP path: the specific destination route contacted with CIP fluids (cleaning solution/rinse water) during a CIP cycle (e.g., spray device path, inoculum line path, addition line path). Multiple paths within a circuit may be cleaned simultaneously or sequentially.

(b) CIP client: system or equipment (e.g., bioreactor, buffer hold vessel) targeted for cleaning by a CIP system.

(c) CIP circuit: the sum of CIP paths within CIP clients that are cleaned as part of a CIP cycle, as well as the CIP skid, CIP supply and return distribution system.

(d) CIP phase: a process-oriented action within a CIP cycle, such as a rinse, wash, or air blow, which can be subdivided into steps and transitions.

(e) CIP cycle: the executed recipe of sequential CIP phases established to provide CIP fluids to the CIP circuit, e.g., rinses, washes, and air blows.

(f) TACT: an acronym for the cleaning process parameters Time, Action, Chemistry and Temperature. The term Action refers to kinetic energy that drives breakdown and suspension of residues from the process contact surfaces.

(g) All in-circuit components of the CIP system (e.g., filter housings, pumps, vessels, heat exchangers, transfer panels, instrumentation, valving, piping) shall be designed to be cleanable, drainable, and of hygienic design appropriate for use in contact with process fluids per the applicable sections of this Standard.

SD-6.3.2 System Performance Requirements

(a) The following cleaning variables should be considered in the design of the CIP system and CIP cycle:
(1) time of exposure (contact time) to wash and rinse solutions
(2) temperature of wash and rinse solutions
(3) chemical concentration of wash solutions
(4) fluid hydraulics

(b) A CIP system should include the capability to control directly or indirectly (monitor and record if applicable) the following CIP variables:
(1) timing of CIP cycle
(2) path being cleaned (e.g., valve position indication, pressure/flow verification, manual setup verification)
(3) CIP supply temperature (or return if applicable)
(4) conductivity, volume of cleaning chemical added, or cleaning chemical concentration for wash solutions
The following technical requirements or parameters that are essential for design development shall be defined:

(a) rinse and wash duration range  
(b) flow rate and pressure ranges  
(c) cleaning agent(s) and their wash concentration ranges  
(d) rinse and wash temperature ranges  
(e) final rinse water quality (e.g., TOC, conductivity)  
(f) air blow requirements  
(g) sampling location(s)  
(h) drain limitations

Refer to SD-5 for CIP client cleaning requirements

SD-6.3.3 Operating Capabilities and System Function

(a) The CIP system shall be capable of delivering and subsequently removing cleaning solutions to soiled equipment in a verifiable and reproducible manner.

(b) The CIP system shall be capable of removing process soils to an owner/user-determined acceptance criteria.

(c) The CIP system shall be capable of removing cleaning chemicals to a verifiable amount characteristic of the final rinse solution.

(d) The CIP skid should be designed to deliver feed water, inject cleaning chemicals, heat, and supply the cleaning solution to the soiled equipment. The skid shall also be designed to remove all residual cleaning chemicals added during the cycle.

(e) The CIP distribution system shall be designed to deliver the cleaning solution to the soiled equipment. The distribution system may also return the solution to the CIP skid, if applicable.

The CIP system shall be capable of controlling:

(a) TACT  
(b) multiple water/solution feeds when required

SD-6.3.3.1 Rinse
The CIP system shall be designed with capability to provide rinse solutions at the specified flow, pressure and temperature to the CIP client.

SD-6.3.3.2 Wash
When a formulated wash step is required, the CIP system shall be designed to dose and mix cleaning agents to prepare wash solutions. The CIP system shall be capable of supplying the wash solution at the specified cleaning agent concentration and temperature.

SD-6.3.3.3 Drain
The CIP system shall be drainable. The CIP system should support the use of multiple drain paths if required (e.g., biowaste inactivation system, waste neutralization system). Where the CIP distribution or CIP client cannot be drained, provisions for a motive force such as a pump or pressurized gas (air blow) shall be included for removal of residual liquid.

SD-6.3.3.4 Air Blow
The CIP system should be designed to provide pressurized air as a motive force, if required, to assist in removing liquid from the CIP circuit. Air blows should be sequenced through the individual CIP paths of a CIP circuit.

SD-6.3.3.5 Surface Treatment Cycles
If the CIP system is designed for surface treatment (e.g., derouging or passivation cycles) of CIP clients, the CIP system should have provisions to introduce and remove associated chemicals.

SD-6.3.3.6 Self-Cleaning Cycle
If a self-cleaning cycle of the CIP skid is required (e.g., to clean the CIP skid after maintenance), the skid design should have piping that meets recirculation/cleaning requirements.

SD-6.3.4 System Design
(a) Process contacting portions of the CIP system shall be of hygienic design and fabricated as per SD-3.1.2 and SD-2.4.3.

(b) Recirculating portions of the CIP system shall be considered process contact and may be considered product contact if used to clean product contact surfaces. Risks (e.g., cross contamination and containment) associated with recirculating CIP system should be evaluated and addressed.

(c) CIP system materials of construction shall be compatible with the process and CIP fluids.

SD-6.3.4.1 CIP Skid
(a) A CIP system is a distributed system of properly integrated components.

(b) For this section, a CIP skid consists of a wash and/or rinse tank with all requisite valves, pumps, and instrumentation. Provision for separation of feed waters and wash solutions should be considered.

A CIP skid is a system that prepares, delivers, controls and monitors CIP solutions.

(a) The following parameters shall be monitored and controlled:
(1) time: rinse, wash, air blow or drain durations
(2) action: CIP supply flow rate
(3) chemistry: CIP wash solution concentration of cleaning agents (e.g., conductivity)
(4) temperature: CIP supply temperature

(b) The following parameters shall be monitored:
(1) CIP return temperature
(2) final rinse water quality (e.g., conductivity, TOC)

(c) The following parameters should be monitored:
(1) CIP supply pressure
(2) CIP return flow verification

CIP skids may be located in a fixed, centralized location or may be portable and used adjacent to the soiled equipment CIP client. When the CIP skid is installed in or moved into a cleanroom, the cleanroom classification shall be addressed both in the selections of skid surfaces and materials of construction appropriate for the environmental requirements.
The CIP skid shall be provided with a physical separation between the water supply and the CIP solutions.

(c) The CIP system design should consider the CIP circuit volume for water consumption, location of skid in facility (if fixed), chemical consumption, waste effluent, and energy required to clean a given circuit.

(d) The design should consider hazardous operation of cycle considering choice of cleaning chemicals. Chemical segregation, spill control, addition handling, material compatibility, secondary containment, and personnel safety should be considered.

SD-6.3.4.1.1 Wash/Rinse Tank Vessel(s)
(a) The wash/rinse tank(s) shall be designed and fabricated per SD-3.4. The tank(s) shall be designed for cleanability per SD-6.3.5.2.2 and shall be equipped with a spray device(s) per SD-3.9.

(b) If used on wash/rinse tanks, a hydrophobic vent filter shall be designed to prevent moisture accumulation in the vent filters and shall be fabricated per SD-5.4.

(a) A CIP system can include one or more vessels (e.g., separate wash and rinse vessels). Vessels can be used to provide a physical separation between the water supply and the CIP solutions.

(b) The rinse vessel should be sized to ensure uninterrupted delivery of rinse solution during the rinse phases of the CIP cycle.

(c) The wash vessel should be sized to provide adequate volume for the duration of the wash step. Sizing factors to consider are holdup volume for recirculation steps, total wash volume for once-through steps, and wash solution losses.

(d) Where recirculation of wash solutions is required, a no-foam inlet, tangential inlet or dip tube should be used for the return of wash solutions to the wash vessel to reduce the risk of foaming.

(e) The vessels should be provided with vortex breakers and adequate outlet sizes. Vessels should also be located close to the CIP supply pump to ensure available net positive suction head (NPSH) is greater than required NPSH. If removable vortex breakers are installed, the design shall account for the effect of vibrations and forces on the vortex breaker and vessel wall.

(f) Air entrainment in the CIP return liquid can impact CIP supply pump performance. CIP return systems using eductors or liquid ring pumps often have a high percentage of air in the CIP liquid. Wash vessels should be designed to enhance gas/liquid separation and provide adequate NPSH, as well as reduce CIP circuit volume. An example of a vessel having those features is a conical tank with a tangential inlet and cylindrical reduced diameter bottom section (i.e., tulip tank, see Figure SD-6.3.4.1-1).

(g) Vent filters on CIP skid vessels should be designed to mitigate the risk of foam or moisture blinding the filter element (e.g., heating the filter housing, bypassing the filter during filling).

(h) The CIP skid vessel used for final rinsing should be provided with a sterilizing-grade vent filter if the vessel is vented into unclassified space.
SD-6.3.4.1.2 Heat Exchanger
Heat exchange equipment shall be designed and fabricated per SD-3.6.1 Heat exchangers shall be designed to meet the full range of CIP cycle duties.

(a) CIP return pumps (if required) shall be designed and fabricated per SD-3.3.2. Centrifugal pumps are preferred for CIP return applications. If a gas/liquid mixture is anticipated, then hygienic liquid ring pumps are recommended.

(b) When a vessel is included in the circuit, CIP return pumps should be placed as close as possible to the vessel bottom outlet and at the low point of the circuit.

(c) Provision shall be made to flush through the casing drain of CIP return pumps.

(d) CIP return pumps shall be designed to maintain hydraulic balance (supply and return flow) of the CIP circuit.

SD-6.3.4.1.3 Supply Pump
(a) The CIP skid should have flow control, either via pump output or by means of flow control valves.

(b) The pump and its associated piping (e.g., partial flow diversion) shall be designed to meet all flow rate and pressure requirements for all CIP circuits.

(c) CIP supply pumps shall be designed and fabricated per SD-3.3.2. The pump design should consider the handling of a gas/liquid mixture.

SD-6.3.4.4 Return Pump
(a) CIP return pumps (if required) shall be designed and fabricated per SD-3.3.2. Centrifugal pumps are preferred for CIP return applications. If a gas/liquid mixture is anticipated, then hygienic liquid ring pumps are recommended.

(b) When a vessel is included in the circuit, CIP return pumps should be placed as close as possible to the vessel bottom outlet and at the low point of the circuit.

(c) Provision shall be made to flush through the casing drain of CIP return pumps.

(d) CIP return pumps shall be designed to maintain hydraulic balance (supply and return flow) of the CIP circuit.

SD-6.3.4.1.4 CIP Return
(a) If CIP fluids are returned to the CIP skid, motive force is required (e.g., pumps, eductors, gravity, or top pressure).

(b) CIP return sampling system should be designed for two-phase flow (i.e., liquid-gas mixtures) or vacuum conditions where applicable.

SD-6.3.4.5 SD-6.3.4.1.5 CIP Return Eductors

(a) For this section, a CIP “return eductor” is defined as a device that uses a motive fluid to create a pressure differential that returns the CIP solution.

A CIP return eductor is a venturi device that provides motive force (i.e., vacuum) to assist CIP fluids return.

(a) CIP return eductors shall be drainable.

(b) Special design factors shall be considered when using CIP return eductors include (e.g., vapor pressure, return line size, elevation, viscosity and flow rate).

(c) CIP return eductors shall be designed and installed to be drainable.

(c) When CIP return eductors are used, the potential for foaming should be considered.

D-6.3.4.6 CIP Distribution Piping

(a) General

(1) The use and application of a particular distribution design or combination of designs is to be decided by the owner/user.

(2) The use of looped headers, transfer panels, and valve types (e.g., divert, mix-proof, multiport, zero-static, and diaphragm) should all be considered in the design of the CIP distribution system.

(b) Looped Headers

(1) The dimension from the looped header to the isolation valve weir or seat should conform to SD-3.1.2.2 (see Figure SD-3.1.2.2-1 for details). The use of short-outlet tees or zero-static valves should be decided by the owner/user.

(2) Future connections (if applicable) on the looped header should use capped short-outlet tees or capped installed zero-static valves.

(3) Loop header connections should be oriented horizontally when used in CIP return applications.

(4) CIP supply header design should provide for adequate velocity in parallel cleaning paths (e.g., line size reduction in loop header).

(5) The entire looped header shall be cleaned during a CIP cycle.

(c) Transfer Panels. Transfer panels shall be designed and fabricated per SD-3.7.1.

(d) Multiport Valves. For this section, a CIP distribution “multiport valve” is defined as a multiple valve assembly fabricated as a single body to minimize distances and maximize drainability [see SG-3.3.2.3(a) for details].

(e) Zero-Static Chains (see Figure SD-6.3.4.6-2). For this section, a CIP distribution “zero-static chain” is defined as a manifold of circuit-specific zero-static valves. Provision shall be made to flush the manifold in a zero-static chain.

(f) Swing Elbows and Piping Spools (see Figure SD-6.3.4.6-3). For this section, a “swing elbow” or “piping spool” is defined as a removable section of pipe used to provide a positive break between two paths. Swing elbows or piping spools shall be connected to adequately supported piping to maintain line slope and connection alignment.
(g) The distribution piping and components in a recirculated CIP circuit shall be hygienic for design and fabrication as per SD-3.1.2 and SD-2.4.3.

(h) The distribution piping and components in a once-through CIP circuit or path (not recirculated) shall be hygienic for design and fabrication as per SD-3.1.2 and SD-2.4.3 upstream of the location of cleaning performance verification.

(i) CIP supply piping should be sized to ensure that the fluid flow meets or exceeds the guidelines stated in SD-6.3.6.2 and SD-6.3.5.3.

(j) The distribution circuits shall be designed such that fluid flow will maintain a positive pressure relative to the process drain, preventing backflow.

(k) CIP return piping shall be designed to maintain hydraulic balance (supply and return flow) of the CIP circuit.

SD-6.3.4.1.6 Chemical Delivery
The CIP skid chemical delivery does not require sanitary design. Acceptable metering methods for chemical delivery include one or more of the following:

(a) Weight

(b) Flow totalization

(c) Duration via metering pump or venturi

(d) Conductivity

Typically one method is used for delivery while a second method is used for confirmation or final control.

SD-6.3.4.1.7 Compressed Air Supply
The CIP skid may be provided with a clean compressed air supply to assist the removal of the rinse or wash solution. Compressed air shall meet the quality requirements for the application (e.g., by installing a point of use filter at the CIP skid). The supply pressure and flow rate shall meet the process requirements. Compressed air may be supplied at other locations in the CIP circuit to assist removal of rinse or wash solution.

SD-6.3.4.5 SD-6.3.4.1.8 Instrumentation.
Instrumentation and controls architecture (if applicable) should be designed to communicate, monitor, and synchronize the CIP cycle, and report CIP variables.

(a) The CIP supply flow meter shall be specified and installed to measure the flow rates of CIP liquids.

(b) To address air in the CIP return, final rinse conductivity sensors should be located to ensure proper operation in both liquid and mixed-flow conditions (e.g., by providing a drainable instrumentation cup, compensated through instrument settings).

SD-6.3.4.6.2 CIP Distribution Piping
(a) General

(1) The use and application of a particular distribution design or combination of designs is to be decided by the owner/user.

(2) The use of looped headers, transfer panels, and valve types (e.g., divert, mix-proof, multiport, zero-static, and diaphragm) should all be considered in the design of the CIP distribution system.
(b) Looped Headers (see Figure SD-6.3.4.62-1)
(1) The dimension from the looped header to the isolation valve weir or seat should conform to SD-3.1.2.2 (see Figure SD-3.1.2.2-1 for details). The use of short-outlet tees or zero-static valves should be decided by the owner/user.
(2) Future connections (if applicable) on the looped header should use capped short-outlet tees or capped installed zero-static valves.
(3) Loop header connections should be oriented horizontally when used in CIP return applications.
(4) CIP supply header design should provide for adequate velocity in parallel cleaning paths (e.g., line size reduction in loop header).
(5) The entire looped header shall be cleaned during a CIP cycle.

(c) Transfer Panels. Transfer panels shall be designed and fabricated per SD-3.7.1.

(d) Multiport Valves. For this section, a CIP distribution "multiport valve" is defined as a multiple valve assembly fabricated as a single body to minimize L/d values and enable drainability (see MC-3.3.2.3(a) for details).

(e) Zero-Static Chains (see Figure SD-6.3.4.62-2). For this section, a CIP distribution "zero-static chain" is defined as a manifold of circuit-specific zero-static valves. Provision shall be made to flush the manifold in a zero-static chain.

(f) Swing Elbows and Piping Spools (see Figure SD-6.3.4.62-3). Swing elbows or piping spools shall be connected to adequately supported piping to maintain line slope and connection alignment.

(g) Mix-proof Valves
(1) Mix-proof valves are double-seat valves with a drain path between the seats that allows for simultaneous processes in the two bodies of the valve. Mix-proof valves shall conform to the general design requirements in MC-3.3.2.3 (a) and rising steam seal valves requirements in MC-3.3.2.3 (c).
(2) If the process requires cleaning across a single seat, the valve shall be provided with individual seat lifts.
(3) Mix-proof valve arrays should be designed to accommodate draining from the leak chamber and sufficient access for maintenance of the valve internals.
(4) The mix-proof valve fitting-bound portion of looped header configurations should be installed level to avoid low points where liquid may accumulate. Pitch of the mix-proof valve array may result in liquid retention in valve bodies and should be risk assessed (see Figure SD-6.3.4.2-4).
(5) If a mix-proof valve with an exposed sliding stem is used to divert process solutions, it shall allow for cleaning of the stem surfaces prior to contacting the process fluids (e.g., by actuating the valve during CIP).

(h) The distribution piping and components in a recirculated CIP circuit shall be hygienic for design and fabrication as per SD-3.1.2 and SD-2.4.3.
(i) The distribution piping and components in a once-through CIP circuit or path (not recirculated) shall be hygienic for design and fabrication as per SD-3.1.2 and SD-2.4.3 upstream of the location of cleaning performance verification.
(i) CIP supply piping should be sized to ensure that the fluid flow meets or exceeds the guidelines stated in SD-6.3.5.2.1 and SD-6.3.5.32.2.

(ii) The distribution circuits shall be designed such that fluid flow will maintain a positive pressure relative to the process drain, preventing backflow.

(iii) CIP return piping shall be designed to maintain hydraulic balance (supply and return flow) of the CIP circuit.

Figure: SD-6.3.4.62-1 CIP Looped Header (Supply or Return)

Figure: SD-6.3.4.62-2 Zero-Static Chain

Figure: SD-6.3.4.62-3 Swing Elbow Arrangement
**SD-6.3.4.4 Return Pump**

(a) CIP return pumps (if required) shall be designed and fabricated per SD-3.3.2. Centrifugal pumps are preferred for CIP return applications. If a gas/liquid mixture is anticipated, then hygienic liquid ring pumps are recommended.

(b) When a vessel is included in the circuit, CIP return pumps should be placed as close as possible to the vessel bottom outlet and at the low point of the circuit.

(c) Provision shall be made to flush through the casing drain of CIP return pumps.

(d) CIP return pumps shall be designed to maintain hydraulic balance (supply and return flow) of the CIP circuit.

**SD-6.3.5 Design for Bioburden Control**

**SD-6.3.5.1 Drainability**

(Reserved for future content)

(b) CIP return eductors shall be designed and installed to be drainable.

**SD-6.3.5.2 Cleaning**

**SD-6.3.5.2.1 Cleaning: CIP Flow Rates Guidelines for Process Lines**

(a) The CIP system shall meet the flow rate requirements of the CIP client for each path and during each phase of the CIP cycle.

(b) For effective cleaning, the CIP flow rate and pressure shall be sufficient to ensure that the cleaning agent and rinsing solutions wet all targeted surfaces within the CIP boundary circuit. The CIP flow rate should be greater than the process flow rate.
(4)(c) Turbulent flow is required to clean targeted surfaces of the CIP client. Table SD-6.3.5.2-1 details flow rates that ensure guidelines for solution contact in straight horizontal and vertical lines for line sizes up to 2 in. (50 mm) without branches, fittings, and other in-line components. These flow rates correspond to a flow velocity of 5 ft/sec (1.5 m/s), which is well into the turbulent range and typical for CIP solutions that are within the scope of this section and all line sizes referenced in Part DT.

(4)(d) CIP flow rate requirements should be considered in conjunction with other CIP process variables (e.g., temperature, chemical concentration, and time).

(4)(e) Air trapped in branches may inhibit full contact of cleaning agent and rinsing solution to those process contact surfaces. The flow direction, line orientation, line size, and presence and orientation of branches, fittings, and other equipment can have a significant influence on the flow rate required to remove air. Adequate solution contact may be achieved at a flow velocity of 5 ft/sec (1.5 m/s) with 1.5 in. (38 mm) and larger shortoutlet tees (Table DT-4.1.2-5). Smaller-diameter shortoutlet tees and tees with longer branches may require velocities greater than 5 ft/sec (1.5 m/s) for adequate solution contact. Solution contact in branches can be enhanced in the design by
1. strategic use of zero-static valves
2. flow through branch or bleeding air from branch
3. orienting blocked branches in the horizontal position
4. use of flush-mounted instrument fittings, shortoutlet tees, gauge tees, or minimum L/d “instrument cups” for small lines
5. orienting branches so the flow of the liquid entering the tee is directed toward the blocked branch

(4)(f) Branches with risk of incomplete solution contact should be considered worst-case locations that may require local cleaning verification.

NOTE: Factors that may mitigate the risk of insufficient cleaning due to incomplete air removal from branches include
1. CIP flow rates higher than process flow rates are likely to wet all surfaces that were soiled.
2. Instruments or other devices protruding into the flow path may create additional local turbulence.
3. Condensate generated during hot washes or hot rinses as part of a CIP cycle may provide some additional rinsing of surfaces.
4. Dynamic flow conditions during route transitions and air blows may assist wetting.

Table SD-6.3.5.2-1 Flow Rates to Achieve 5 ft/sec (1.5 m/s)

<table>
<thead>
<tr>
<th>Sanitary Tube Size</th>
<th>O.D. Nominal Size, in.</th>
<th>I.D.</th>
<th>Flow Rate in gpm</th>
<th>Flow Rate Lpm</th>
</tr>
</thead>
<tbody>
<tr>
<td>½</td>
<td>0.5</td>
<td>0.370</td>
<td>9.40</td>
<td>1.7 6.3 6.4</td>
</tr>
<tr>
<td>¾</td>
<td>0.75</td>
<td>0.620</td>
<td>15.75</td>
<td>4.7 18 17.8</td>
</tr>
<tr>
<td>1</td>
<td>1.0</td>
<td>0.870</td>
<td>22.10</td>
<td>9.3 35 .2</td>
</tr>
<tr>
<td>1½</td>
<td>1.5</td>
<td>1.37</td>
<td>34.80</td>
<td>9.3 35 .2</td>
</tr>
<tr>
<td>2</td>
<td>50.80</td>
<td>1.87</td>
<td>47.50</td>
<td>43 42.8 162.0</td>
</tr>
</tbody>
</table>

SD-6.3.5.32 Cleaning: Design guidelines for cleaning CIP of pProcess vVessels
(a) Process vessels shall be designed to consistently enable exposure of the internal surfaces to the CIP liquids by spray device or flooding-cleaned via internal spray device(s) designed to consistently expose all internal surfaces to the cleaning variables described in SD-6.3.
The use and application of a particular spray device design to satisfy these requirements shall be decided by the owner/user. Spray devices shall be designed and fabricated per SD-3.9 (also see Figure SD-3.9.2.1-1 for static spray device design considerations).

Dished-head vertical vessels should have cleaning solutions delivered with the majority of flow directed toward the upper head and sidewall area at the upper knuckle radius. Cylindrical horizontal vessels should have cleaning solutions delivered with the majority of flow directed toward the upper one-third of the vessel.

1. If a static spray device is used, gravity provides a solution sheeting over the side wall and bottom head (vertical vessels) or lower surfaces (horizontal vessels).
2. If a dynamic spray device is used, the device may directly spray areas throughout the vessel or rely on sheeting action.
3. Figure SD-3.9.2.1-2 details ranges of flow recommendations for static spray devices on vertical process vessels under typical cleaning loads. The recommendations in Figure SD-3.9.2.1-2 ensure sufficient coverage.
4. The criteria to ensure sufficient coverage on horizontal process vessels vary with geometry and size.

Spray device design and location shall ensure appurtenances such as manways, baffles, dip tubes, agitator impellers, and nozzles are contacted with cleaning solution. Some appurtenances may require additional provisions for cleaning.

Spray devices only ensure coverage of the exterior of installed appurtenances and equipment. If not removed during CIP, cleaning solutions shall flow through appurtenances to clean their interior. Appurtenances that have interior surfaces not reached by the spray device coverage shall be cleaned by other CIP paths or removed and cleaned out of place.

If a vessel is cleaned with spray devices, the fluid level should be minimized in the process vessel during CIP. Proper hydraulic balance (supply and return flow) of the CIP circuit and sizing of the bottom outlet valve should be considered to minimize fluid level.

A vortex breaker should be installed to prevent vortex formation during CIP that may adversely affect the CIP operation. The installation of a vortex breaker may be required.

Vortex breaker design should be decided by the owner/user. Vortex breaker surfaces shall be sloped to eliminate pooling during CIP and positioned to not adversely affect the hydraulic balance of the CIP circuit.

For process vessels equipped with an agitator, the impeller should be rotated at an appropriate speed during the CIP cycle.

SD-6.3.6 Design for Serviceability, Examination, and Operation. CIP return eductors shall be designed to be removable for examination.

SD-6.3.7 Testing. During the cleaning of process vessels, sufficient exposure shall be confirmed by coverage testing per SD-7.1 at the site of equipment manufacture and/or after installation or both.
**SD-6.4.3 Operating Capabilities and System Function**

**SD-6.4.3.1 Priming.** The system shall be capable of a priming operation to fill the piping with liquid, remove air, and establish pressure and flow control. The thermal treatment system should be primed by the process liquid to be treated or a priming liquid (e.g., WFI), or both.

**SD-6.4.3.2 Thermal Sanitization.** The owner/user shall define the sanitization condition (e.g., time and temperature) capabilities required for the system. UHT systems shall be designed to enable sanitization. HTST systems shall be designed to enable sanitization when the treated process liquid has the potential to be compromised by the priming activities. For a functionally closed system, the owner/user shall define which components (e.g., the receiving vessel, cooling exchanger, flash chamber) must be thermally sanitized to meet the functional closure criteria.

**SD-6.4.3.3 Temperature Stabilization.** Thermal treatment systems shall be designed to stabilize the temperature of the liquid before initiating forward flow to the destination. Heating, cooling, flow rate, and back pressure control loops shall be enabled and allowed to stabilize prior to heat treatment.

If the system uses a priming liquid, such as WFI, the system shall be designed to stabilize the temperature using the priming liquid and then transition to and meet the performance requirements using the process liquid. Stabilization using the process liquid should continue until all the priming liquid has been cleared from the system, at which point the system shall initiate forward flow of the heat-treated process liquid to the destination.

**SD-6.4.3.4 Heat Treatment.** The system shall be designed to deliver heat-treated process liquid to the destination only if the performance requirements are met. If they are not met, the system shall divert the...
liquid to another destination (typically to a drain or a collection vessel). If the heat treatment conditions are not maintained, the owner/user shall specify whether the system resanitizes itself, continues diverting until the temperature and flow requirements are reestablished without resanitization, or performs a shutdown sequence.

The system shall be designed to continue heat treatment until the desired amount of liquid is treated. The owner/user shall specify whether the system flushes residual treated process liquid forward using heat-treated priming liquid to maximize recovery at the conclusion of the process batch.

**SD-6.4.3.5 Post-Use Sequence.** The owner/user shall specify whether the system shall be designed to perform a cold flush of the HTST or UHT equipment prior to cleaning to minimize soil buildup at the end of processing. The post-use sequence should finish by draining the system or promptly initiating the CIP sequence.

**SD-6.4.4 System Design**

(a) The following parameters shall be monitored and controlled by the system:

(1) heater outlet temperature
(2) cooler outlet temperature
(3) flow rate
(4) back pressure

(b) The following parameter shall be monitored by the system: retention tube outlet temperature.

(c) The owner/user shall specify whether the system shall be primed using compendial water (from a break-tank or from a backflow-protected direct water system connection) or sanitized and primed using the process liquid.

(d) The following should be considered in selection of materials used in fabrication of HTST/UHT systems:

(1) Cyclic temperature and pressure conditions may shorten the life of materials.

(2) Solutions at high temperature may accelerate the rate of metal corrosion or elastomer/polymer degradation.

(3) High-temperature operating conditions used in UHT systems may exceed the temperature ratings of typical bioprocessing equipment or components.

(e) Although UHT processing conditions are above the temperature limit specified in SD-2.3.1.1, process contact materials used for these systems shall be selected to meet the higher temperature requirements of the process.

**SD-6.4.4.1 Heat Exchangers.** Heat exchangers shall be designed to meet the performance requirements in SD-6.4.2 and the applicable design criteria of SD-3.6. Heat exchangers shall be designed to achieve fully developed turbulent flow conditions during process and CIP operations, on the process liquid contacting side(s) of the exchanger. Heat exchangers should be designed and operated such that the pressure of the treated process liquid is higher than the pressure of the utility or untreated process liquid during heat treatment to reduce the risk of process liquid contamination, unless the owner/user has assessed the risk of an alternate design. The owner/user should identify any requirements needed to minimize process fouling or enhance cleaning performance (e.g., minimum Reynolds number or velocity, maximum process contact surface temperature).

Direct energy recovery heat exchangers with process fluids on both hot and cold sides (Figure SD-6.4.1.1) shall be of hygienic design on both sides. Indirect energy recovery heat exchangers (Figure SD-6.4.1.1-2) shall be of hygienic design on the process fluid side.

The following types of heat exchangers may be used in thermal treatment systems:

(a) **Shell and Tube.** Shell-and-tube heat exchangers may be straight tube or U-tube. The effect of bypass through the bonnet drain slots and slippage between the bonnet and tube sheet shall be considered in thermal design of the heat exchanger.

(b) **Coil-in-Shell.** Coil-in-shell heat exchangers shall be installed in a self-drainable vertical orientation.

(c) **Electric.** Electric heat exchangers shall be designed to provide uniform heating (e.g., where electric current is applied directly to the process contact tube).

(d) **Tube-in-Tube.** Process liquid should flow through the inner tube. Process fluid may also flow through the outer tube in direct energy recovery heat exchangers.

(e) **Plate-and-Frame.** See cautions in SD-3.6 regarding use of plate-and-frame heat exchangers before considering use in this application.

**SD-6.4.4.2 Steam Injectors**

(a) Steam injectors shall introduce steam (typically pure steam) directly into process liquids.

(b) Steam injectors shall be installed such that single-phase flow is achieved at the desired outlet temperature. A sight glass installed downstream of the steam injector is recommended to confirm single-phase flow.

(c) Steam injectors shall be oriented to permit CIP, or designed for disassembly and cleaning out of place (COP), with agreement from the owner/user. Where the steam injection system is designed for CIP, it shall be drainable and exposed to CIP solution across the seat of the steam injection valve.

(d) Media dilution and changes in retention time due to condensate addition shall be accounted for in the system design.

**SD-6.4.4.3 Flash Chambers.** [Reserved for future content]

**SD-6.4.4.4 Pumps.** Process contact pumps used in HTST/UHT systems shall be hygienic and shall comply with SD-3.3.
$SD-6.4.4.5$ Retention Tube

(a) To account for axial dispersion in the piping, the average residence time necessary to achieve the required residence time shall be defined by the owner/user.

NOTE: The average residence time should be specified so as to meet the owner/user-defined probability that each process fluid particle is retained for the required residence time. As an example, the Taylor equation for axial dispersion in turbulent flow was used to develop Figure SD-6.4.4.5-1 which shows the theoretical additional retention tube length required for a water-like liquid treated at 216°F (102°C) for 10 sec in a 1-in. (25-mm) nominal retention tube to account for axial dispersion, assuming an insignificant number of bends. In the figure, to ensure that less than 1 particle out of 1,012 has less than the 10-sec required residence time, the retention tube length would have to increase by 24%. Actual retention tube geometry, such as the number and radii of elbows, coils, or U-bends, may impact the results.

(b) The retention tube diameter should be no larger than the main system piping diameter to minimize the residence time range due to axial dispersion.

(c) The retention tube shall be designed to enable visual inspection at its inlet and outlet. The owner/user shall specify whether inspection is required for two-phase flow during operation and/or for cleaning effectiveness.

(d) The retention tube shall be designed to maintain a consistent temperature within the tube during heat treatment (e.g., the tube should be insulated and shall not have branches or tees that could result in low local temperatures).

(e) No device shall be permitted for short-circuiting a portion of the retention tube (e.g., bypass valves) to compensate for changes in the process liquid flow rate.

(f) The retention tube shall have a continuous upward slope toward the discharge complying with Table SD-2.4.3.1-1 category GSD3 to ensure that air is purged from the retention tube during operation. It shall be drainable during cleaning and/or sterilization operations.

(g) No portion of the retention tube between the inlet and the outlet temperature sensors shall be heated.

$SD-6.4.4.6$ Flow Control. The flow rate shall be controlled and monitored to ensure proper system operation.

$SD-6.4.4.7$ Back Pressure Control. The system shall be designed to ensure that pressure downstream of the heating exchanger or steam injector is above the process fluid boiling pressure, until the treated fluid has been cooled or until it reaches a flash chamber for cooling. A pressure of at least 10 psi (0.7 bar) above the boiling pressure is recommended.
load basket or rack is used for geometrically simple parts (e.g., gaskets) and/or non-process contact surface components (e.g., clamps, tools) where repeatable orientation is not critical.

**immersion tank**: the vessel designed to hold and allow delivery of cleaning solutions in which parts are immersed.

**parts**: any component to be cleaned in the immersion washer, such as pipes, hoses, clamps, gaskets, fittings, and accessories.

**side nozzle zone**: a hydraulic circuit with nozzles or jets that encourages rotational flow within an immersion tank.

**SD-6.5.2 System Performance Requirements.**

Immersion washers shall be capable of delivering and removing cleaning solutions from surfaces of parts across multiple phases of a cleaning cycle. Immersion washers may be self-contained, or receive cleaning solutions from a CIP system. The following are typical general phases of an immersion washer cleaning cycle:

- **(a)** pre-rinse
- **(b)** wash
- **(c)** rinse
- **(d)** final rinse

The design should allow for multiple chemical additions during washing phases. The hydraulic conditions (i.e., pressure and flow rate) of all rinsing phases should be the same as for wash phases to ensure consistent rinsing of parts, immersion tank interior, and hydraulic circuit. The final rinse may be performed with recirculated final rinse water integrated with drain steps to remove residual cleaning solutions. The design should be capable of providing a final rinse phase at an elevated temperature [e.g., >149°F (65°C)] to improve air-drying efficiency.

**SD-6.5.3 Operating Capabilities and System Function**

(a) The immersion washer should control and monitor time of exposure (contact time) during wash and rinse phases.

(b) The immersion washer shall control and monitor cleaning solution temperature during all washing and rinsing phases.

(c) The immersion washer should monitor the pressure and/or flow of cleaning solutions supplied to zones within the immersion tank and/or immersion basket/rack.

(d) The immersion washer shall be designed to provide analytical verification of final rinse water quality (e.g., conductivity, TOC, number of final rinse steps).

(e) For immersion washer capabilities for chemical addition, see SD-6.1.4.7.

(f) For immersion washer recirculation pump requirements, see SD-6.1.4.8(b) and SD-6.1.4.8(c).

(g) Immersion washer pumps should have sufficient capacity (flow and/or pressure) for all zones used in the washer.

(h) For immersion washer heat exchanger requirements, see SD-6.1.4.9.

**SD-6.5.4 System Design**

(a) Immersion baskets/racks (general or designed load) should incorporate thermoplastic or thermoset material components to prevent scratching parts and/or immersion tank I.D.

(b) Materials of construction of immersion washer process contact surfaces shall adhere to the same requirements set forth in the cabinet washers section [see SD-6.1.3(a)].

(c) Materials of construction and general design of the immersion tank shall follow requirements for vessel general design (see SD-6.1.3(a)). The full vacuum service design requirement is not applicable to atmospheric immersion tanks.

(d) The surface finishes for the interior surfaces of the immersion tank, process contact tubing surfaces, and any other process contact surfaces shall be specified by the owner/user using designations provided in Table SF-2.4.1-1. Electropolishing is not required for immersion washers.

(e) The surface finish of baskets/racks, supports, thermowells, guards, and other internal tank components should meet the surface finish requirements of the tank. Surface finish verification may not be possible for all components of an immersion washer’s baskets/racks.

(f) The internal surface finish of the immersion tank cover should be the same as specified for the immersion tank internal surfaces.

**SD-6.5.4.1 Zone Design**

(a) Immersion washer design can include multiple zones to clean parts through various methods. Zone piping design shall follow SD-3.1.2.2, with the consideration that zone branch connections shall be opened between each phase to avoid carryover. All zones should be targeted during each phase to provide consistent flushing.

(b) Turbulence is critical for cleaning within an immersion washer, and zone design should provide adequate turbulence to all part surfaces. For example, tubing or similar parts that are not exposed to turbulence on the I.D. from a side nozzle zone would require an end nozzle zone or direct connection to a zone to provide adequate I.D. flow.

(c) For zones with piping manifolds within the immersion tank, baskets, and/or racks, the fabrication of the piping manifolds shall conform to the applicable sections of system piping (see SD-3.1.2.3).
SD-6.5.4.2 Tank and Cover Openings

(a) Immersion tank and cover opening design shall adhere to the same requirements used for cabinet washers (see SD-6.1.4.1).

(b) Side nozzles shall be of hygienic design (see Figure SD-6.5.4.2-1).

(c) Immersion tank covers should be used and designed to reduce operator exposure to splashing during operation as well as to minimize added humidity to the area around the immersion washer. Both sealed and nonsealed designs are permitted.

(d) Sealed (e.g., gasket or O-ring) immersion tank covers shall be designed to prevent wash fluid from leakage during the wash cycle.

(e) Nonsealed immersion tank covers should be designed to minimize wash fluid leakage during the wash cycle.

(f) Both sealed and nonsealed types should be designed to minimize wash droplet formation above the immersion tank and loaded parts.

(g) Process contact static seals used in immersion washers shall comply with the requirements of Part 2.

(h) The external surfaces (e.g., frame, immersion tank O.D.) shall meet the owner/user’s specified requirements of the installed location of the equipment.

(i) External surfaces should be insulated to minimize heat transmission.

SD-6.5.4.3 Baskets and Racks

(a) General load immersion baskets/racks should be designed to accommodate variable configurations and load items. Parts used in these baskets/racks do not require a specific orientation for self-drainability or to prevent air entrapment.

(b) Designed load immersion baskets/racks should be designed for repeatable loading and may be subject to verification, if required by the owner/user, to assure removal of entrapped air. Load items as well as the designed load immersion basket/rack shall be self-drainable.

(c) All immersion baskets/racks should be designed for disassembly required for inspection and maintenance.

SD-6.5.4.4 Interfaces. Immersion washers’ parts are loaded and unloaded in the same area/room classification. If process flow requires a separation of clean and dirty parts, an immersion washer should not be used.

SD-6.5.5 Design for Bioburden Reduction

SD-6.5.5.1 Drainability

(a) Immersion washer process contact surfaces shall adhere to SD-2.4.3.

(b) For rectangular immersion tanks sloped both to center and along the tank length, a minimum lengthwise slope designation of GSD3 (see Table SD-2.4.3.1-1) should be used to facilitate self-draining. Other surfaces sloping to drain within the tank are also recommended to have a minimum slope of GSD3.

SD-6.5.5.2 Cleaning. The interior surfaces and components of the tank as well as the baskets/racks are considered process contact surfaces and should comply with SD-2.4.2 except for SD-2.4.2(a)(4). These surfaces include the immersion tank wall I.D. above an overflow port and the immersion tank cover I.D. surfaces with the potential to drip onto cleaned parts within the immersion tank.

(a) Engraving or embossing of materials (for identification or traceability) is permitted on exterior process contact surfaces, such as the exterior of process contact tubing in the washer. Engraving or embossing
should be limited to only what is needed for unique identification or traceability.

(b) Adherence to SD-2.4.2(a)(2) for the immersion tank wall I.D. above an overflow port and immersion tank cover I.D. surfaces should be considered by the owner/user depending on the criticality of the parts being cleaned.

(c) Final rinse tank level should be higher than wash solution rinse level to promote quicker achievement of final rinse conditions.

Parts with recessed holes or cavities should not be cleaned in immersion washers. Risk of air entrapment or lack of drainability may impede exposure to and removal of cleaning solution.

SD-6.5.6 Design for Serviceability, Examination, and Operation. Immersion washers should be designed to enable access for inspection and service of components that are subject to wear, and to allow for periodic calibration of instruments.

SD-6.5.7 Testing

SD-6.5.7.1 Flow Coverage. Designed load immersion washer baskets/racks designed for repeatable loading should have flow coverage (e.g., riboflavin) testing performed for verification of liquid coverage of parts' surfaces. The spray coverage testing described in SD-7.1 is applicable to the flow coverage testing for immersion washers. If Nonmandatory Appendix M is used, it is applicable to immersion washers, with the following additional considerations:

(a) The scope of the riboflavin application and expected removal should be documented and agreed to by all parties (e.g., parts and baskets/racks only; parts, baskets/racks, and immersion tank process contact surfaces).

(b) Riboflavin may be applied while parts are loaded in the baskets/racks inside of the immersion tank, or may be applied to parts prior to loading into the basket/rack and/or immersion tank. Application prior to loading may be required for parts with limited access areas such as tubing lengths.

(c) Immersion tank filling should occur as in normal operation and to the normal operating level. As once-through rinsing is not applicable to immersion washers, a complete fill, zone(s) rinsing, and drain should be performed not less than two times. The maximum number of zone rinses (complete fill and drain) during the riboflavin testing shall not exceed the total number of phases with complete fill and drain steps during an owner/user’s normal operating wash cycle. Only the zones applicable to the components being tested should be used. Pertinent information such as zones used, time of rinse, and zone sequencing should be recorded.

(d) Riboflavin inspection may occur while parts are still loaded in the immersion tank, outside of the immersion tank, or through a combination of both. Inspection outside of the immersion tank may be needed for parts with limited access areas. Care should be taken while unloading parts from the baskets/racks and/or immersion tank to avoid false results due to transfer of residual riboflavin from other parts.

General load immersion washer baskets/racks are not subject to the same testing due to the nonrepeatable and nondenominated loading conditions and variations in parts being cleaned.

SD-6.5.7.2 Drainability. Drainability testing for immersion tanks should use methods described in SD-7.4 for vessels, with the following additional considerations:

(a) At minimum, the immersion tank should be filled to completely submerge the tank bottom.

(b) Drainability testing intended for ensuring immersion tank drainability should be performed without any baskets/racks loaded.

(c) Any outlet strainer or screen used in normal operation should be installed.

(d) Drainability testing can be performed on designed load baskets/racks and loaded parts to verify draining of surfaces on these components. The baskets/racks and parts loading information and configuration should be recorded, and the immersion tank should be filled to at minimum above the highest component of the basket/rack or loaded part.

SD-6.6 Isolator Systems

SD-6.6.1 General. Isolator systems, hereafter referred to as isolators, are used to create a controlled environment for bioprocessing and quality control testing that is isolated from operators and the background environment. This section describes the design requirements for two types of isolators, as follows:

(a) aseptic isolators, which are designed to protect the process from the environment, enable aseptic processing (e.g., cell bank processing, liquid filling of final product)

(b) containment isolators, which are designed to protect the operator environment from the process and enable safe processing of potent compounds (or other hazards) in an isolated environment.

This section does not address equipment/components used inside the isolator. Requirements of the process and process equipment enclosed by the isolator should be provided by the owner/user. This section is not applicable to restricted access barrier systems, which restrict access but do not provide environmental isolation.

SD-6.6.2 System Performance Requirements. The following system performance requirements shall be defined:

(a) environmental classification inside and outside the isolator

(b) airflow conditions as unidirectional or turbulent
(c) pressure differential target to background environment
(d) log reduction for decontamination
(e) overall cycle time limit for decontamination and aeration
(f) temperature operating ranges
(g) humidity operating ranges
(h) recirculation air, make-up air, and total exhaust air flow limitations
(i) allowable decontamination agent (e.g., vapor phase hydrogen peroxide) concentration at the end of aeration for product protection

**SD-6.6.3 Operating Capabilities and System Function**

**SD-6.6.3.1 Differential Pressure Control.** Differential pressure set points should be adjustable in the range of 0.06 in. to 0.18 in. (15 Pa to 45 Pa) of the water column. Phase transitions in the isolator system (e.g., re-dosing to aeration, aeration to production) shall be controlled without loss of pressure balance in the surrounding room specified by the owner/user.

It is permissible for the set point to be positive or negative to the surrounding room as defined by the owner/user to meet the product manufacturing requirements. The differential pressure (between the isolator interior and exterior) should be maintained within 0.02 in. (5 Pa) of water column of the set point.

**SD-6.6.3.2 Temperature and Humidity.** The isolator should be designed to monitor operational, decontamination, and aeration temperatures within the range specified by the owner/user.

Humidification requirements are application dependent and should be agreed to by the owner/user. Consideration should be given to decontamination requirements, product requirements, potential static electricity discharge, and condensation within the isolator or connected equipment (e.g., lyophilizer).

**SD-6.6.3.3 Decontamination.** Unless otherwise specified by the owner/user, the decontamination cycle shall demonstrate a five log reduction of microorganisms. The complete decontamination cycle includes leak testing, conditioning, decontamination, and aeration of residual decontamination agents. The isolator shall be designed to reduce the level of the residual decontamination agent to a concentration to be specified by the owner/user. If vapor phase hydrogen peroxide is used, the aeration shall reduce the residual vapor phase hydrogen peroxide to <1.0 ppm at the specified operating temperature for operator safety. The isolator should be designed to prevent opening during decontamination (e.g., incorporating door and window interlocks).

**SD-6.6.3.4 Venting During Aeration.** The isolator shall be designed to safely exhaust decontamination gas through a dedicated exhaust system. For example, if hydrogen peroxide gas is exhausted, a building stack or catalytic filter may be required to safely convert the hydrogen peroxide into water vapor and oxygen as it is released to the environment.

**SD-6.6.4 System Design.** Isolator systems contain bioprocessing equipment and normally do not have product contact surfaces. The owner/user shall specify

(a) surfaces required to be designed for product contact
(b) isolator designation as aseptic or containment
(c) product sensitivity to decontamination agents
(d) specific environmental requirements (e.g., inert gas blanketing)

Process contact surfaces should be impervious, nonreactive, nonadditive, and resistant to cleaning/decontaminating agents. Metallic process contact surfaces shall be fabricated with 316-type or 316L-type stainless steel by welded construction, unless otherwise approved by the owner/user. Exterior non-process contact surfaces may be fabricated with 304-type or 304L-type stainless steel by welded construction.

All equipment should be compatible (chemically resistant, nonpermeable) with cleaning and sanitization agents specified by the owner/user, e.g., sporicidal agents, peracetic acid, hydrogen peroxide gas, or 70% IPA.

Glove ports, comprising a glove and sleeve sealed into the wall or window of an isolator, shall be made with materials resistant to decontamination agents and specified sanitizing/cleaning agents (e.g., hard coated aluminum, stainless steel, UHMWPE).

Unless otherwise specified by the owner/user, process contact surfaces of metal construction should have a surface roughness of 35 μin. $R_a$ (0.89 μm) or less. Unless otherwise specified by the owner/user, the exterior (non-process contact surfaces) of metal construction should have a surface roughness compatible with the associated environmental classification. If the exterior operational environment is ISO class 8, a surface finish of 48 μin. $R_a$ (1.2 μm) or less is recommended for metal construction.

**SD-6.6.4.1 Isolator Shell.** The isolator shell (the main work chamber of the isolator), which may include windows, lights, and openings, should be designed to integrate internal equipment with ergonomic operations. The isolator shell construction should be designed to accommodate the user-specified pressure differential with limited shell deformation. Isolator shell deformation limits should accommodate openings where brittle material may be used such as glass windows and lights.

To ensure isolator shell seal integrity, tolerances for isolator shell and connection points should accommodate the potential for weld heat distortion. The shell shall be fabricated using welded construction unless otherwise specified by the owner/user.

The isolator shell construction radii of internal corners and seams should be 0.6 in. (15 mm) or greater to facilitate cleanability.
Split valves that use the same interface technology as RTPs, except that the interlock acts as a butterfly valve, may be used for liquid or solids additions into an isolator. Split valves are permitted for use in both aseptic and containment isolators.

Pass-in/pass-out holes (openings that allow the transfer of material into and/or out of isolators while in operation) shall be designed to be sealed by an external door during a decontamination cycle. The design of aseptic isolators should not permit opened doors of pass-in/pass-out holes to rest in a position above the aseptic operations. The isolator shall be designed to maintain specified pressure differentials and airflow velocities with open pass-in/pass-out holes during normal operation.

**SD-6.6.4.8 Airlock/Decontamination Chamber.** Infumation chambers, compartments, and/or doors shall be designed with locked doors, which prevent the outer door (to isolator) from being opened while the inner door (to room) is open. Both doors shall also be interlocked from opening during the decontamination cycle. The inner door shall be interlocked such that it can only be opened after a successful decontamination cycle.

**SD-6.6.4.9 Internal Components.** For piping/tubing, all wetted process contact tubing shall comply with SD-2.4.2 and shall be sloped and/or provided with an air purge to allow draining of lines per SD-2.4.3 and Nonmandatory Appendix C. Welded joints are preferred. All elastomer seals shall meet 21 CFR 177.2600 or equivalent. Gaskets and O-ring seals used to seal the isolator are not considered product contact surfaces, but should be nonsheding where exposed to the aseptic environment. Where seals are exposed to cleaning and/or decontamination processes, they are considered process contact surfaces and shall be resistant to cleaning and/or decontamination fluids. Process contact elastomers shall comply with the applicable requirements in Part PM or Part SC. The potential for seal degradation and chemical absorption and subsequent desorption should be considered in the selection of seal materials. For example, silicone and EPDM offer resistance to many cleaning and decontamination agents.

Inflatable seals and static seals are permitted. For example, inflatable seals are acceptable for doors/windows that are designed to be opened during setup and cleaning procedures. The potential for occluded areas should be considered in the design and use of inflatable seals. Inflatable seals shall have a continuous leak check, using either constant pressure or constant flow. Seals between the isolator shell and mating equipment (e.g., depyrogenation tunnel, lyophilizer) should be designed to accommodate the effects of the thermal dilation/contraction of the mating equipment. The temperature at these interfaces should be considered in the selection of seal material.

When an isolator system comprises multiple connected isolators, seals between isolators shall be designed to expose seal surfaces to decontamination agents during a decontamination cycle. Single or double seals are permitted between isolator chambers.

**SD-6.6.4.12 External Surfaces.** Exterior design requirements of SD-2.4.4.2 are applicable to isolators. The external surfaces of an aseptic isolator shall be compatible with the environmental classification to which it interfaces. The following design practices should be considered:

(a) All cables should be covered.
(b) Gaps between the isolator and other equipment, such as depyrogenation tunnels or lyophilizers, should be sealed.

**SD-6.6.5 Design for Bioburden Control**

**SD-6.6.5.1 Drainability.** Horizontal process contact surfaces of the isolator shall be self-draining. If CIP of the isolator is specified, all permanently installed internal liquid distribution piping (e.g., spray wands) should be sloped to meet the requirements of Table SD-2.4.3.1-1 category GSD2 where possible or supplied with an air purge to facilitate draining per SD-2.4.3 and Nonmandatory Appendix C.
Spray device coverage tests are not intended to demonstrate system cleanability. System cleanability is achieved through the equipment design, the spray design, knowledge of the soils, cleaning agent selection, and cleaning process parameters. Cleanability is verified using a complete CIP per protocol during cleaning validation.

**SD-7.2 Cleaning, Steaming, and Bioburden Control Testing**

Cleaning, steaming, and bioburden control testing (in addition to spray device testing) shall be as agreed to by the owner/user and manufacturer, and in accordance with accepted industry standards.

**SD-7.3 Fluid Requirements for Leak Testing**

Where leak testing is required, the following fluids shall be used:

(a) Hydrostatic testing shall use clean purified or deionized water filtered at 25 μ or better, unless otherwise agreed to by the owner/user.

(b) Pneumatic testing shall use oil-free clean dry air, nitrogen, or inert gas filtered at 25 μ or better, unless otherwise agreed to by the owner/user.

**SD-7.4 Vessel Drainability Test**

Specific steps or operations in a bioprocess may require vessels to be self-draining. Drainability test for such vessels shall be conducted as agreed to by all parties. As a proposed test procedure, the following should be considered:

(a) The vessel shall be in its intended operating orientation within a tolerance agreed to by the owner/user.

(b) The vessel shall be filled approximately to the weld seam that joins the shell to the bottom head.

(c) The outlet valve shall be opened, the vessel shall be vented to atmosphere, and the vessel shall be allowed to drain by gravity.

(d) There shall be no puddles of water left on the bottom of the vessel greater than as agreed to by the owner/user and manufacturer.

It is generally understood that residual water may be present in the form of droplets that typically do not exceed a diameter of 5 mm. Residual water droplets adhere to process surfaces due to surface tension and are not indicative of a vessel’s drainability. Observed puddles that are displaced with a 1.0-in. (25-mm) rubber dowel applied perpendicular to the puddle and re-form at the point of displacement indicate a flat or unintended low point, and that area shall be repaired to the satisfaction of the owner/user. Puddles that are displaced with a 1.0-in. (25-mm) diameter rubber dowel applied perpendicular to the puddle and do not return to the point of displacement are considered to be large droplets and do not constitute a test failure.

NOTE: Filter housings are available in several designs. In some cases, flat-bottom filter housings are specified by the owner/user based on their risk-assessed process and equipment requirements. Flat-bottom cartridge-mount filter housings, including those that will be steamed in place, are exempt from this test, and the equipment shall be installed as agreed by the manufacturer and owner/user.
SD-7.4 Vessel Drainability Test

Specific steps or operations in a bioprocess may require vessels to be **drainable self-draining**. A drainability test for such vessels shall be conducted to confirm that the vessel has been designed and manufactured without any low point other than its intended outlet(s), as agreed to by all parties. As a proposed test procedure, the following should be considered:

(a) The vessel shall be in its intended operating orientation within a tolerance agreed to by owner/user.
(b) The vessel shall be filled with water approximately to the weld seam that joins the shell to the bottom head.
(c) The outlet valve shall be opened, the vessel shall be vented to atmosphere, and the vessel shall be allowed to drain by gravity.
(d) There shall be no puddle of water left on the bottom of the vessel other than that retained due to surface tension, greater than as agreed to by the owner/user and manufacturer.

It is generally understood that residual water may be present in the form of droplets that typically do not exceed a diameter of 0.2 in. (5 mm). Residual water droplets adhere to process surfaces due to surface tension and are not indicative of a vessel’s drainability. Observed puddles that are displaced with a 1.0 in. (25 mm) rubber dowel applied perpendicular to the puddle and re-form at the point of displacement indicate a flat or unintended low point, and that area shall be repaired to the satisfaction of the owner/user. Puddles that are displaced with a 1.0 in. (25 mm) diameter rubber dowel applied perpendicular to the puddle and do not return to the point of displacement are considered to be large droplets and do not constitute a test failure.

NOTE: Filter housings are available in several designs. In some cases, flat-bottom filter housings are specified by the owner/user based on their risk-assessed process and equipment requirements. Flat-bottom cartridge-mount filter housings, including those that will be steamed in place, are exempt from this test, and the equipment shall be installed as agreed by the manufacturer and owner/user.

NOTE: This vessel drainability test is not intended for flat-bottom cartridge-mount filter housings.
CHAPTER 3
MATERIALS

PART MM
METALLIC MATERIALS

(19) MM-1 PURPOSE AND SCOPE

The purpose of this Part is to identify metallic materials considered acceptable for use in hygienic service. It identifies material specifications, grades and alloys, appropriate filler metals, and other attributes necessary for this service. It also specifies the data that must be submitted to the MM Subcommittee for any new or unlisted alloy that is proposed for inclusion in Part MM.

MM-2 ALLOY DESIGNATIONS

MM-2.1 General

This Part identifies those metallic materials of construction that have demonstrated the ability to meet welding and surface finish criteria as set forth in other parts of this Standard. It is the responsibility of the owner/user to ensure that any metallic materials selected for use from those listed in Tables MM-2.1-1 through MM-2.1-4 are appropriate for the intended application.

The guidelines and criteria listed in this Part of the Standard indicate a general acceptability for use and do not address the specifics of fabrication or requirements of any given service.

MM-3 USES OF SPECIFICATIONS

MM-3.1 General

The documents listed in MM-4.2 through MM-4.7 may contain references to codes, standards, or specifications not listed in this Part of this Standard. Such unlisted codes, standards, or specifications are to be used only in the context of the listed documents in which they are referenced. Where documents listed in MM-4.2 through MM-4.7 contain design rules that are in conflict with this Standard, the design rules of this Standard shall govern.

MM-3.2 Listed Specifications

Materials purchased to specifications listed in the appropriate sections of MM-4.2 through MM-4.7 may be used for applications governed by this Standard, provided they meet all requirements of those specifications.

Austenitic stainless steel tube shall be capable of passing the weld decay test in ASTM A249/A249M, Supplement S7 and either the intergranular corrosion test in ASTM A270/A270M, Supplement S1 or ISO 3651-2 Method B.

Fittings shall be purchased to the requirements of Part DT.

Valves shall meet the requirements of SG-3.3.2.3.

Materials used in applications governed by this Standard shall conform to a specification listed in the above paragraphs, except as provided in MM-3.3.

MM-3.3 Unlisted Specifications

Alloys in specifications not listed in MM-4.2 through MM-4.7 may be used for applications governed by this Standard provided they conform to a published specification covering composition, physical and mechanical properties, method and process of manufacture, heat treatment, and quality control, and otherwise meet the chemical composition requirements of one of the specifications listed in MM-4.2 through MM-4.7. Alloys not listed in Tables MM-2.1-1 through MM-2.1-4 may be used for applications governed by this Standard provided the following requirements are met:

(a) The applicable requirements of MM-9 are met.
(b) The specific written permission of the owner/user is obtained.

Materials listed in MM-5.2.5 are exempt from the requirements of MM-3.3.

MM-3.4 Unknown Materials

Materials of unknown origin or specification shall not be used in hygienic service.

MM-3.5 Reclaimed Materials

Reclaimed pipe/tube and other piping components may be used with owner/user authorization, provided they are properly identified as conforming to a published specification listed in MM-4.2, MM-4.3, MM-4.4, MM-4.5, or MM-
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** GENERAL NOTES **

(a) Minimum, unless range or minimum is indicated.

(b) Values listed in the Table are primary elements only and are not complete chemical compositions as listed in specific product type material specifications. Alloy composition is typically at the low end of the ranges indicated above. Refer to appropriate product type material specification for complete material composition requirements.

(c) Alloys listed between horizontal lines are not equivalent, but comparable.

** SPECIAL NOTES **

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** Superaustenitic Stainless Steels **

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N08217 1.4536
N08234 1.4547
N08926 1.4529

** Duplex Stainless Steels **

S32101 1.4626
S32205 1.4462

** GENERAL NOTES **

(a) Minimum, unless range or minimum is indicated.

(b) Values listed in the Table are primary elements only and are not complete chemical compositions as listed in specific product type material specifications. Alloy composition is typically at the low end of the ranges indicated above. Refer to appropriate product type material specification for complete material composition requirements.

(c) Alloys listed between horizontal lines are not equivalent, but comparable.

** NOTE **

(1) For cross-referencing of the UNS numbers listed above to common alloy names, refer to SAE Metals and Alloys in the Unified Numbering System, latest edition.
### Table MM-2.1-2 Wrought Nickel Alloys: Nominal Compositions (wt. %)

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<td>W: 3.0-4.5, Co: 2.5 max, Mn: 1.0 max</td>
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<td>W: 2.5-3.5, Fe: 2.0-6.0, Co: 2.5 max</td>
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**GENERAL NOTES:**
(a) Minimum, unless range or minimum is indicated.
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<td>12.5-14.5</td>
<td>...</td>
<td>W: 2.5-3.5, Fe: 2.0-6.0, Co: 2.5 max, Mn: 0.50 max</td>
</tr>
<tr>
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<td>N06022</td>
<td>...</td>
<td>0.015</td>
<td>20.0-22.5</td>
<td>Balance</td>
<td>12.5-14.5</td>
<td>...</td>
<td>W: 2.5-3.5, Fe: 2.0-6.0, Co: 2.5 max, Mn: 0.50 max</td>
</tr>
</tbody>
</table>

**GENERAL NOTES:**
(a) Minimum, unless range or minimum is indicated.
(b) Values listed in this Table are primary elements only and are not complete chemical compositions as listed in specific product type material specifications. Alloy composition is typically at the low end of the ranges indicated above. Refer to appropriate product type material specification for complete material composition requirements.
(c) Alloys listed between horizontal lines are not equivalent, but comparable.

**NOTE:**
(1) For cross-referencing of the UNS numbers listed above to common alloy names, refer to SAE Metals and Alloys in the Unified Numbering System, latest edition.
### Tubing, Piping, and Hollow Bar

<table>
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<tr>
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<th>EN</th>
<th>UNS Designation</th>
<th>EN</th>
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| MM-5.2.1.2 or MM-5.2.1.3

<table>
<thead>
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<th>Table MM-2.1-3 Stainless Steel and Nickel Alloy Cast Designations</th>
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<tr>
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<tr>
<td>J92900</td>
</tr>
<tr>
<td>J92800</td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
</tr>
</tbody>
</table>

**GENERAL NOTE:**

- (a) Minimum yield strength range is indicated.
- (b) Copper grade listed between horizontal lines are not equivalent, but comparable.

### 4.6 or to a published specification not listed in those paragraphs and otherwise meeting the minimum requirements of MM-9. When reclaiming superaustenitic or duplex stainless steel components, refer specifically to annealing to remove environmental damage.

### MM-5.2.6. Designation of Alloy and Fluid Service

The user is responsible for designating the specific alloy, from MM-2, to be used for each system having a process contact surface. The user is also responsible for identifying the appropriate fluid service category for piping or tubing, in accordance with the definitions in the current edition of ASME B16.3, Pressure Piping.

### MM-4 REFERENCED SPECIFICATIONS

#### MM-4.1 General

Standards and specifications adopted by reference in this Standard are listed by product form in this Section. It is not considered practical to identify the specific edition of each standard and specification listed in the following Sections; therefore, the most current edition is implied. Sources for procuring any of the listed material specifications are found in Nonmandatory Appendix Y.

Material manufactured in accordance with earlier editions of the referenced standards and that in all other respects conforms to this Standard will be considered to be in conformance with this Standard.

The ASME Boiler and Pressure Vessel Code (BPVC) has adopted many of the listed ASTM material specifications. Materials furnished to the latest edition of these ASME specifications are also considered to be in conformance with this Standard.

When preparing a Material Test Report (MTR), a material manufacturer may transcribe data produced by other organizations, provided he accepts responsibility for the accuracy and authenticity of the data.

#### MM-4.2 Tubing/Piping

Tubing and piping manufactured in accordance with the following specifications may be used:

<table>
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<th>UNS Designation</th>
<th>JIS Designation</th>
<th>Stainless Steel and Nickel Alloy Cast Designations</th>
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<tr>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

**GENERAL NOTE:** Alloys listed between horizontal lines are not equivalent, but comparable.
**Tubing and Hollow Bar for Seamless Stainless Steel Mechanical Tubing and Hollow Bar**

- **ASTM A511/A511M**, Standard Specification for Seamless Stainless Steel Mechanical Tubing and Hollow Bar
- **ASTM A269/A269M**, Standard Specification for Seamless and Welded Austenitic Stainless Steel Tubing for General Service
- **ASTM A270/A270M**, Specification for Seamless and Welded Austenitic and Ferritic/Austenitic Stainless Steel Sanitary Tubing
- **ASTM A511**, Standard Specification for Seamless Stainless Steel Mechanical Tubing
- **ASTM B619**, Specification for Welded Nickel and Nickel-Cobalt Alloy Pipe
- **ASTM B626**, Specification for Welded Nickel and Nickel-Cobalt Alloy Tube
- **ASTM B675**, Specification for UNS N08367 Welded Pipe
- **ASTM B676**, Specification for UNS N08367 Welded Tube
- **ASTM B819**, Standard Specification for Seamless Copper Tube

**Silicon Alloy Plate, Sheet, and Strip**

- **DIN 17751**, Tubes of wrought nickel alloys — Properties
- **EN 10216-5**, Seamless steel tubes for pressure purposes — Technical delivery conditions — Part 5: Stainless steel tubes
- **EN 10217-7**, Welded steel tubes for pressure purposes — Technical delivery conditions — Part 7: Stainless steel tubes
- **EN 10312**, Welded stainless tubes for the conveyance of water and other aqueous liquids — Technical delivery conditions
- **EN 13348**, Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum

**MM-4.3 Castings**

Castings manufactured in accordance with the following specifications may be used:

- **ASTM A351/A351M**, Specification for Castings, Austenitic, for Pressure-Containing Parts


**MM-4.4 Forgings**

Forgings in following specifications:

- **ASTM A182/A182M**, Specification for Forged or Rolled Alloy and Stainless Steel Pipe Flanges, Forged Fittings, and Valves and Parts for High-Temperature Service
- **ASTM B462**, Standard Specification for Forged or Rolled Nickel Alloy Pipe Flanges, Forged Fittings, and Valves and Parts for Corrosive High-Temperature Service

**JIS G 5121**, Corrosion-resistant cast steels for general applications

**JIS G 8214**, Stainless steel forgings for pressure vessels

**JIS G 4319**, Stainless steel blooms and billets or forgings

**JIS G 3447**, Stainless steel sanitary pipes

**JIS G 4345**, Stainless steel pipes

**JIS G 4903**, Seamless nickel-chromium-iron alloy pipes

**MM-4.5 Plate, Sheet, and Strip**

Plate, sheet, and strip manufactured in accordance with the following specifications may be used:

- **ASTM A240/A240M**, Specification for Chromium and Chromium-Nickel Stainless Steel Plate, Sheet, and Strip for Pressure Vessels and for General Applications
- **ASTM A666**, Specification for Annealed or Cold-Worked Austenitic Stainless Steel Sheet, Strip, Plate, and Flat Bar
- **ASTM B143**, Specification for Nickel-Chromium-Molybdenum Columbium Alloy (UNS N06625) and Nickel-Chromium-Molybdenum-Silicon Alloy (UNS N06219) Plate, Sheet, and Strip

MM-4.6 Hollow Products, Rod, and Bar Stock

Hollow products, rod, and bar stock manufactured in accordance with the following specifications may be used:

ASTM A276, Standard Specification for Stainless Steel Bars and Shapes

ASTM A479/A479M, Specification for Stainless Steel Bars and Shapes for Use in Boilers and Other Pressure Vessels


ASTM B691, Specification for Iron Nickel-Chromium-Molybdenum Alloys (UNS N08366 and UNS N08367) Rod, Bar, and Wire

DIN 17744, Wrought nickel alloys with molybdenum and chromium — Chemical composition

DIN 17752, Wrought nickel and nickel alloy rods and bars — Requirements and testing

EN 10088-3, Stainless steels — Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steels for general purposes

EN 10095, Heat resistant steels and nickel alloys

EN 10263-1, Steel rod, bars and wire for cold heading and cold extrusion — Part 1: General technical delivery conditions

EN 10263-5, Steel rod, bars and wire for cold heading and cold extrusion — Part 5: Technical delivery conditions for stainless steels

For austenitic stainless steels, hollow products and bar stock are acceptable for nozzles and may be used where permitted by the owner/user.

MM-4.7 Copper Alloy Fittings

Fittings manufactured in accordance with the following specifications may be used where permitted by the owner/user:

ASME B16.22, Wrought Copper and Copper Alloy Solder-Joint Pressure Fittings

ASME B16.50, Wrought Copper and Copper Alloy Brazed-Joint Pressure Fittings

5.2.1.1 Austenitic Stainless Steels

This section provides requirements and recommendations for the base metals listed in Tables MM-2.1.1 through MM-2.1.4. The use of base metal other than those listed in this section is permitted with the owner/user's written approval (see MM-3.3).

This section also recommends filler metals and consumable inserts for welding these alloys in order to produce weldments whose weld metal has corrosion resistance consistent with that of the base metal. Design for welding are provided in Part 5.2.1.1.1 Austenitic Stainless Steels

(a) Weld Ends of Process Components. Weld ends of process components manufacture

(b) Delta Ferrite.

If specific ferrite levels in austenitic stainless steels are deemed necessary to maintain certain properties, the owner/user shall specify required ferrite ranges separately for the base metal, for welds in the solution-annealed condition, and for welds left in the as-welded condition. As a general rule, material with high ratios of N/Fe show lower ferrite levels in the base metal and subsequent to welding. See Table MM-5.2.1.2 for predicted ferrite number ranges for various austenitic stainless steel product forms. These are not acceptance criteria. The listed ferrite numbers refer to as-solidified austenitic stainless steels and therefore indicate predicted ferrite levels of the respective autogenous welds with filler metal, or castings. Additional information
**MM-5.2.2 Nickel Alloys.** The nickel alloys listed in Tables MM-2.1-2 and MM-2.1-3 may be prone to precipitation of secondary phases such as mu and P. Such secondary precipitation typically occurs when the material is subjected to temperatures in the range of 1,500°F to 1,800°F (820°C to 980°C) and can create a detrimental effect on the material’s corrosion resistance. Exposure time to undesirable temperatures reached during high-temperature service, heat treatment, or joining should be minimized.

**MM-5.2.3 Castings.** When cast alloys discussed in this section solidify, microsegregation of chromium and molybdenum occurs. Segregation reduces corrosion resistance and is corrected in castings by a full solution anneal or as specified by the material specification or as recommended by the material manufacturer. All cast materials shall be supplied in the solution-annealed condition, and the solution-anneal procedure shall meet the time and temperature requirements of the product specification. Any weld repair by the casting manufacturer shall meet the requirements of the specification or shall be as specified by the owner/user.

**MM-5.2.4 Copper Alloys.** In applications allowed in Part SD and/or approved by the owner/user, copper tubing may be used for process gas distribution systems.

**MM-5.2.5 Copper Alloys.** In applications allowed in Part SD and/or approved by the owner/user, copper tubing may be used for process gas distribution systems.

**MM-5.2.6 Special Alloys.** When specified by the owner/user, alloys listed in Table MM-5.3-1 may be used for process contact surfaces in unique applications, such as original equipment manufacturer (OEM) process instrumentation, pump internals, etc. These alloys, when serving as process contact surfaces, shall meet all applicable surface finish requirements of this Standard.

**MM-5.2.7 Unlisted Alloys.** Alloys not listed in Part MM and having corrosion resistance less than that typical of UNS S30403 may be used for process contact surfaces in unique applications such as OEM instrumentation when the owner/user has determined that the proposed material is suitable for the intended service.

**MM-5.3 Filler Materials**

Filler material shall conform to a published specification. Table MM-5.3-1 lists the recommended filler metals for welding the listed austenitic, superaustenitic, and duplex stainless steels and nickel alloys.

Table MM-5.3-1 lists the recommended materials from which consumable inserts may be made for use in welding the listed superaustenitic and duplex stainless steels.

Filler materials other than those listed in Tables MM-5.3-1 and MM-5.3-2 may be used with the prior approval of the owner/user provided that:

(a) they produce weld metal having corrosion resistance equal to or greater than that of the base metal

(b) the welding procedure is qualified in accordance with Part MJ

Proprietary filler materials may be used with the prior agreement of the owner/user, provided all procedure and performance qualification requirements of Part MJ of this Standard are met.

### Table MM-5.2.2-1 Predicted Ferrite Number (FN) Ranges for Various Austenitic Stainless Steel Product Forms and Welds

<table>
<thead>
<tr>
<th>Product Form</th>
<th>Expected FN</th>
</tr>
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<tbody>
<tr>
<td>Wrought product forms with sulfur levels less than 0.005%</td>
<td>0.5 to 4</td>
</tr>
<tr>
<td>Wrought product forms with a sulfur range of 0.005% to 0.017%</td>
<td>1.0 to 6</td>
</tr>
<tr>
<td>GM/AS/BS using ER316L [Note (2)]</td>
<td>4 to 12 [Note (2)]</td>
</tr>
<tr>
<td>SMA using E316L [Notes (3), (4)]</td>
<td>4 to 10 [Note (5)]</td>
</tr>
<tr>
<td>CFMB and CF3M castings</td>
<td>5 to 15</td>
</tr>
</tbody>
</table>


NOTES:

1. EPA S.9/5.9M, Specification for Bare Stainless Steel Welding Electrodes and Rods.

2. Nitrogen pickup or weld metal dilution could result in a 3 to 4 FN loss in the as-deposited weld metal.


4. Electrodes with a restricted FN usually require a special order, or they are cryogenic temperature.

5. FN in the as-deposited weld is influenced by welding technique and is lowered by nitrogen pickup or weld metal dilution.

regarding ferrite can be found in Nonmandatory Appendix G.
Table MM-5.2.6-1 Materials for OEM Equipment

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<td></td>
<td></td>
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<tr>
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<td></td>
<td>Silver (coating)</td>
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<td>Ti — Grade 5</td>
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<td>Inconel 718 [Note (2)]</td>
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<tr>
<td>S17400</td>
<td></td>
<td>17-4 PH [Note (3)]</td>
</tr>
</tbody>
</table>

(1) Hastelloy C-2000 is a registered trademark of Haynes International, Inc.
(2) Inconel is a registered trademark of Special Metals Corp.
(3) 17-4 PH is a registered trademark of AK Steel, Cincinnati, Ohio.

MM-5.3.1 Austenitic Stainless Steels. Only the low-carbon grades of stainless steel filler metals may be used to weld these alloys.

MM-5.3.2 Superaustenitic and Duplex Stainless Steels. If a filler metal or consumable insert is used during the manufacture of process components, it should be in accordance with the filler metals or consumable inserts listed in Table MM-5.3-1 or Table MM-5.3-2, respectively. Other nickel-chromium-molybdenum filler metals or consumable inserts may be used as long as the corrosion resistance of the final weld metal meets or exceeds that of the base metal. The manufacturer shall also identify the filler metal or consumable insert as part of the documentation.

MM-5.3.3 Copper Alloys. Table MM-5.3-3 lists the filler metals to be used for brazing copper tubing.

MM-5.4 Heat Treatment

Heat treatment of process components made from the austenitic stainless steels in Table MM-2.1-1 is not addressed by this Standard.

For the listed superaustenitic and duplex stainless steels, if the filler metals or consumable inserts in Table MM-5.3-1 or Table MM-5.3-2 are used, a postweld heat treatment is not required. If those alloys are welded autogenously, postweld heat treatment is required in accordance with Table MM-5.4-1.

MM-6 MECHANICAL PROPERTIES

MM-6.1 General

The specific service environment for which the alloys in Tables MM-2.1-1 through MM-2.1-4 may be used is not within the scope of this Standard. The possibility of material deterioration in service should be considered by the owner/user. Carbide phase degradation of corrosion resistance, susceptibility to intergranular corrosion of austenitic materials, or grain boundary attack of nickel-based alloys are among those items requiring attention.

MM-6.2 Tubing/Piping

All tube or pipe used for process contact surfaces and non-process contact surfaces shall meet the mechanical property requirements of the specification to which they are manufactured.

MM-6.3 Fittings and Valves

Refer to DT-2 for strength requirements for fittings and valves.

When material is cold worked, its mechanical properties can be expected to change from those of the original heat of the raw material, not required to be the same. If they do, they shall comply with the specifications for the raw materials from which the fittings were fabricated.

MM-6.4 Toughness

Some of the materials listed in Tables MM-2.1-1 through MM-2.1-3, as well as Table MM-5.3-4, undergo a decrease in toughness when used at low temperatures, to the extent that other applicable codes may require impact tests for applications even at temperatures higher than 20°F (−7°C). It is the responsibility of the owner/user to ensure that such testing is performed and that the requirements of all applicable codes are met.

MM-6.5 Testing

Refer to DT-6 for the testing requirements for fittings and MC-4.3.1.1 for the testing requirements for valves.

MM-7 POSITIVE MATERIAL IDENTIFICATION

When positive material identification (PMI) is performed, it is limited to alloy verification. Refer to Nonmandatory Appendix W for guidance regarding procedures and data interpretation.

Table MM-5.3-2, Table MM-5.3-3, or Table MM-5.3-5

Note to editor: Paragraph being moved into MM-8.1
### Table MM-5.2-1: Filler Metals for Austenitic Stainless Steels

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<th>Base Metal Alloy (Note [1])</th>
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<th>SFA Designation</th>
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### General Note
The use of AWS/DIN filler metal is recommended for welding of UNS base metal; the use of EN filler metal is recommended for welding of EN base metal. The use of JIS filler metal is recommended for welding of JIS base metal.

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(1) Alloys listed between horizontal lines are not equivalent, but comparable.
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**Table MM-5.3-1** Filler Metals for Superaustenitic Stainless Steels

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**Table MM-5.3-2** Filler Metals for Superaustenitic Stainless Steels

GENERAL NOTE: The use of AWS/UNS filler metal is recommended for welding of UNS base metal; the use of EN filler metal is recommended for welding of EN base metal.

NOTES:
(1) Always listed between horizontal lines are not equivalent, but comparable.
(2) Filler metal designation as per ISO 3581-A
(3) Filler metal designation as per ISO 14343-A
### Table MM-5.3-1 Filler Metals (Cont’d)

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**Duplex Stainless Steels** [Note (4)]

| S32105 | E2209 | 5.4 | W39299 | .. | .. | ER2099 | 5.9 | S39209 [Note (5)] | .. | .. |
| | E2219 | W39553 | .. | .. | ER2553 | .. | S39553 | .. | .. |
| | E2293 | W39593 | .. | .. | ER2594 | .. | S32750 | .. | .. |
| | E2294 | W39594 | .. | .. | .. | .. | .. | .. | .. | .. |
| | E2295 | W39595 | .. | .. | .. | .. | .. | .. | .. | .. |
| .. | .. | .. | 22.9 % N L | 1.4462 | .. | .. | .. | 22.9 % N L | 1.4462 | .. | .. |
| | .. | .. | 22.9 % N L | 1.4501 | .. | .. | .. | 22.9 % N L | 1.4501 | .. | .. |

**Nickel Alloys**

| N10276 | EN21620-3 | 5.11 | W66012 | .. | .. | ER21620-3 | 5.14 | S06625 | .. | .. |
| | EN21620-4 | W68276 | .. | .. | EN21620-10 | W68222 | EN21620-10 | W68222 | .. | .. |
| | EN21620-10 | W68262 | EN21620-10 | W68262 | .. | .. | .. | .. | .. | Ni 6059 | 2.4607 |
| .. | .. | .. | .. | .. | .. | .. | .. | .. | .. | .. |
| N06622 | EN21620-3 | 5.11 | W66012 | .. | .. | EN21620-3 | 5.14 | S06625 | .. | .. |
| | EN21620-4 | W68276 | .. | .. | EN21620-10 | W68222 | EN21620-10 | W68222 | .. | .. |
| | EN21620-10 | W68262 | EN21620-10 | W68262 | .. | .. | .. | .. | .. | Ni 6059 | 2.4607 |
| .. | .. | .. | .. | .. | .. | .. | .. | .. | .. | .. |
| N06625 | EN21620-3 | 5.11 | W66012 | .. | .. | EN21620-3 | 5.14 | S06625 | .. | .. |
| | EN21620-4 | W68276 | .. | .. | EN21620-10 | W68222 | EN21620-10 | W68222 | .. | .. |
| | EN21620-10 | W68262 | EN21620-10 | W68262 | .. | .. | .. | .. | .. | Ni 6625 | 2.4621 |
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**Table MM-5.3-3 Filler Metals for Duplex Stainless Steels**

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GENERAL NOTE: The use of AWS/SUM filler metal is recommended for welding of UNS base metal; the use of EN filler metal is recommended for welding of EN base metal.

**NOTES:**

(1) Alloys listed between horizontal lines are not equivalent, but comparable.
(2) Any super duplex stainless steel filler metal can be used to weld duplex stainless steel.
(3) Addition of up to 5% of nitrogen to the shielding gas is recommended to aid in obtaining ferrite/austenite balance.
Table MM-5.3-1 Filler Metals (Cont’d)

GENERAL NOTE: The use of AWS/UNI filler metal is recommended for welding of UNS base metal; the use of EN filler metal is recommended for welding of EN base metal.

NOTES:
(1) Alloys listed between horizontal lines are not equivalent, but comparable.
(2) Filler metal designation as per ISO 14172.
(3) Filler metal designation as per ISO 14177A.
(4) Any super duplex stainless steel filler metal can be used to weld any duplex stainless steel.
(5) Addition of up to 5% of nitrogen to the shielding gas is recommended to aid in obtaining ferrite/austenite balance.
(6) Filler metal designation as per ISO 14343-A.

Table MM-5.3-4 Filler Metals for Nickel Alloys

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GENERAL NOTE: The use of AWS/UNS filler metal is recommended for welding of UNS base metal; the use of EN filler metal is recommended for welding of EN base metal; the use of JIS filler metal is recommended for welding of JIS base metal.

NOTES:
(1) Alloys listed between horizontal lines are not equivalent, but comparable.
### Table MM-5.3-2 Consumable Inserts for Superaustenitic and Duplex Stainless Steels

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<td>J94651</td>
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<td>J93254</td>
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<tr>
<td><strong>Duplex Stainless Steels</strong></td>
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<td>S32101</td>
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<td>J92205</td>
<td>CD3MN</td>
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</table>

**GENERAL NOTE:** The use of UNS consumable inserts is recommended for welding of UNS base metal; the use of EN consumable inserts is recommended for welding of EN base metal.

**NOTES:**
1. Alloys listed between horizontal lines are not equivalent, but comparable.
2. See MM-4 for listed rod, bar, or plate specifications from which these consumable inserts may be manufactured.
### Table MM-5.3.4-1 Brazing Filler Metals for Copper

<table>
<thead>
<tr>
<th>Base Metal [Note (1)]</th>
<th>UNS Number</th>
<th>EN Designation</th>
<th>AWS Classification</th>
<th>SFA Specification</th>
<th>UNS Designation</th>
<th>EN Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>C10200</td>
<td>...</td>
<td></td>
<td>BCuP-3</td>
<td>5.8</td>
<td>C55281</td>
<td>...</td>
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<td></td>
<td></td>
<td></td>
<td>BCuP-4</td>
<td></td>
<td>C55283</td>
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<td>BCuP-5</td>
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<td>C55284</td>
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<td></td>
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<td>BCuP-6</td>
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<td>C55280</td>
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<td></td>
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<td>BCuP-7</td>
<td></td>
<td>C55282</td>
<td>...</td>
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<td>C12000</td>
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<td>BCuP-7</td>
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<td>C55282</td>
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<tr>
<td>C12200</td>
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<td>5.8</td>
<td>C55281</td>
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<td>BCuP-7</td>
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<td>C55282</td>
<td>...</td>
</tr>
</tbody>
</table>

| ...                   | CW024A     | ...            | ...                |                   | ...             | ...           |

**GENERAL NOTE:** The use of AWS/UNS filler metal is recommended for brazing of UNS base metal; the use of EN filler metal is recommended for brazing of EN base metal.

**NOTE:**

(1) Copper grades listed between horizontal lines are not equivalent, but comparable.
**Table MM-5.4-1 Solution Anneal Heat Treatment Requirements for Superaustenitic and Duplex Stainless Steels**

<table>
<thead>
<tr>
<th>Base Metal Alloy [Note (1)]</th>
<th>Solution Anneal Temperature [Notes (2), (3), and (4)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNS Designation</td>
<td>EN Designation</td>
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<tr>
<td>S31703</td>
<td>...</td>
</tr>
<tr>
<td>N08904</td>
<td>...</td>
</tr>
<tr>
<td>S31254</td>
<td>...</td>
</tr>
<tr>
<td>N08367</td>
<td>...</td>
</tr>
<tr>
<td>N08926</td>
<td>...</td>
</tr>
</tbody>
</table>

**Duplex Stainless Steels**

<table>
<thead>
<tr>
<th>UNS Designation</th>
<th>EN Designation</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>S32101</td>
<td>...</td>
<td>1,870°F (1,020°C)</td>
</tr>
<tr>
<td>S32205</td>
<td>...</td>
<td>1,870–2,010°F (1,020–1,095°C)</td>
</tr>
</tbody>
</table>

**NOTES:**

1. Alloys listed between horizontal lines are not equivalent, but comparable.
2. Minimum solution anneal temperature unless range is specified.
3. No minimum anneal time is specified, however, very short anneal times can result in inadequate temperature to restore the corrosion resistance of autogenous welds.
4. Post-solution anneal cooling shall be achieved by a water quench or rapid cooling by other means.

**MM-8 CORROSION-RESISTANCE REQUIREMENTS**

**MM-8.1 General**

Resistance to corrosion is an essential characteristic of the materials used to fabricate the systems governed by this Standard. Corrosion testing is recommended whenever specific production performance characteristics must be determined. The owner/user shall have the final responsibility for proper material selection.

**MM-8.2 Corrosion Testing**

Corrosion testing may be performed for the following reasons:

- (a) to compare a number of alloys in a specific standard environment
- (b) to determine the compatibility of an alloy in an owner/user-defined environment

Once a particular alloy has been selected for an application, more extensive testing may be appropriate. This testing may involve the evaluation of any one of a number of process variables on material performance. These variables include, but may not be limited to, upset temperature conditions, varying concentrations of the corrosive agent or condition, cleaning chemical type and concentration, various surface finishes, welding process, and filler metal alloy. It may be appropriate to use electrochemical test methods or a standard immersion test method to evaluate the effect of the various parameters. Standard ASTM corrosion tests commonly used are discussed in Nonmandatory Appendix F.

**MM-9 MINIMUM REQUIREMENTS FOR ALLOYS IN PART MM**

**MM-9.1 General**

Metallic materials of construction shall meet the requirements of this section as a minimum.

For materials to be added to Part MM, the information in MM-9.1.1 or MM-9.1.2, as applicable, shall be provided to the ASME BPE Staff Secretary.

**MM-9.1.1 Wrought, Cast, and Welded Fabricated Applications**

(a) Listing of the alloy in an industry-recognized specification or standard including tensile strength properties.

(b) Evidence that the proposed material, in both the wrought and welded conditions, will have corrosion resistance equal to or greater than 304L stainless steel (UNS S30403) in a service environment within the scope of this Standard. Materials that will not be welded (e.g., some castings) do not require corrosion testing in the welded condition.

(c) Welded austenitic stainless steel tube shall be capable of passing the weld decay test in ASTM A249/A249M, Supplement S7 and the intergranular corrosion test in either ASTM A270/A270M, Supplement S1 or ISO 3651-2 Method B. See Nonmandatory Appendix F for additional information.

(d) Evidence that the material surface can be mechanically polished, electropolished, and or passivated to meet the applicable requirements of Part SF.

(e) Recommended welding process(es), filler metal(s), and evidence showing that the combination of base metal, filler metal(s), and recommended welding process(es) meets the applicable requirements of Parts MJ and SF. Special restrictions, exceptions, or guidance shall be noted.

**MM-9.1.2 Specialty OEM Material Applications**

(a) Listing of the alloy in an industry-recognized specification or standard. Tensile strength properties shall also be included unless the material is used only as a coating.

(b) Evidence that the proposed material, in both the wrought and welded conditions, will have corrosion resistance equal to or greater than 304L stainless steel (UNS S30403) in a service environment within the scope of this Standard. Materials that will not be welded (e.g., some castings and coatings) do not require corrosion testing in the welded condition. Sprayed or vapor deposited
coatings shall be tested over the base material used in the commercially supplied parts. See Nonmandatory Appendix F for additional information.

(c) Evidence that the material surface can be mechanically polished, electropolished, and/or passivated to meet the applicable requirements of Parts SF.

(d) For sprayed or vapor deposited coatings, a recommended spraying process(es) or vapor deposition process(es). Special restrictions, exceptions, or guidance shall be noted.

(e) For welded coatings, recommended welding process(es), filler metal(s), and evidence showing that the combination of base metal, filler metal(s), and recommended welding process(es) meets the applicable requirements of Parts M) and SF. Special restrictions, exceptions, or guidance shall be noted.
Elastomer formulations typically contain 5% to 50% filler to achieve optimum properties.

**PM-2.1.3 Other Nonmetallic Materials.** Solid single-phase nonmetallic materials can be divided into amorphous nonmetallic materials (e.g., glass, amorphous carbon) and crystalline nonmetallic materials (e.g., sintered silicon carbide, graphite).

If manufactured by heating and subsequent cooling, these materials are often referred to as ceramics. Materials may consist of a mixture of an amorphous and a crystalline phase (e.g., glass-ceramics). To improve performance, nonmetallic materials may be combined with other materials such as metals or polymers to form multiphase mixtures. Examples of such materials are metal-matrix composites such as cemented tungsten carbide with an alloyed nickel binder matrix and resin-impregnated carbon-graphites. Some of the more commonly used nonmetallic materials are listed in Table PM-2.1.3-1.

<table>
<thead>
<tr>
<th>Type of Polymer</th>
<th>Example Polymers</th>
<th>Example Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>General thermoplastics</td>
<td>Polyester (PET), Polyamide (nylon), Polycarbonate (PC), Polysulfones (PSU, PES), Polyether ether ketone (PEEK)</td>
<td>Fittings, connectors, filter housings, piping and rigid tubing, column tubes, filter media</td>
</tr>
<tr>
<td>Thermoplastic polyolefins</td>
<td>Polypropylene (PP), Ultra-low-density polyethylene (ULDPE), Low-density polyethylene (LDPE), High-density polyethylene (HDPE), Ultra-high-molecular-weight polyethylene (UHMWPE)</td>
<td>Fittings, connectors, piping and rigid tubing, filter media and capsules, bags</td>
</tr>
<tr>
<td>Thermoplastic fluoropolymers</td>
<td>Fluorinated ethylene propylene (FEP), Perfluoroalkoxy (PFA), Polytetrafluoroethylene (PTFE), Ethylene tetrafluoroethylene (ETFE), Polyvinylidene fluoride (PVDF)</td>
<td>Fittings, piping and tubing, flexible hose, filter media and capsules, diaphragms, pumps, vessel liners</td>
</tr>
<tr>
<td>Thermoplastic elastomers (TPE)</td>
<td>Blends of EPDM with polypropylene, Styrene-isobutylene-styrene block polymers, Copolymers of ethylene and octane, Ethylene-vinyl acetate copolymer (EVA)</td>
<td>Tubing, bags</td>
</tr>
</tbody>
</table>

Elastomer formulations typically contain 5% to 50% filler to achieve optimum properties.

**PM-2.2 General Requirements**

Materials shall be selected to not affect the purity or integrity of the drug product. The owner/user is responsible for the qualification of materials for the intended use. The requirements for compliance are summarized in PM-2.2.1. The requirements relate to identification, traceability, biocompatibility, and marking.

Polymeric materials exposed to process fluids and/or that have a high probability of exposure shall comply to the USP directive with regard to USP 87 (or ISO 10993-5) and USP 88 (Class VI or ISO 10993-6, -10, and -11) on biological reactivity (see PM-3.1). Examples of materials that may come into direct contact with process fluids include tubing, pipe, fittings, filters, bags, gaskets, O-rings, diaphragms, pinch tubes, and valve stem seals.

**PM-2.2.1 Certificate of Compliance.** A Certificate of Compliance shall be issued by the manufacturer to certify compliance to this Standard when required by the end-user. Additional certification documentation may be required. The Certificate of Compliance shall contain the information summarized in Table PM-2.2.1-1.
Table PM-2.2.2.1-1 Examples of Nonmetallics

<table>
<thead>
<tr>
<th>Examples of Nonmetallics</th>
<th>Types of Nonmetallic</th>
<th>Example Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glass</td>
<td>Amorphous inorganic nonmetallic material</td>
<td>Sight glasses, vessel lights, optical sensors, glass electrodes</td>
</tr>
<tr>
<td>Borosilicate</td>
<td></td>
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<tr>
<td>Soda-lime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sintered materials</td>
<td>Crystalline inorganic nonmetallic material</td>
<td>Mechanical seals, bearings, process sensors</td>
</tr>
<tr>
<td>Aluminum oxide</td>
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<tr>
<td>Silicon carbide</td>
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<tr>
<td>Silicon nitride</td>
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<tr>
<td>Tungsten carbide</td>
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<tr>
<td>Zirconium dioxide</td>
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<tr>
<td>Reaction-bonded materials</td>
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<tr>
<td>Silicon carbide</td>
<td></td>
<td>Mechanical seals</td>
</tr>
<tr>
<td>Silicon nitride</td>
<td></td>
<td></td>
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<tr>
<td>Siliconized carbon-graphite</td>
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<td>Mechanical seals</td>
</tr>
<tr>
<td>Resin-impregnated carbon-graphite</td>
<td></td>
<td>Mechanical seals</td>
</tr>
<tr>
<td>Cemented materials</td>
<td></td>
<td>Mechanical seals</td>
</tr>
<tr>
<td>Tungsten carbide with alloyed binder</td>
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<td>Tungsten carbide with nickel binder</td>
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<td>Tungsten carbide with cobalt binder</td>
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<tr>
<td>Glass</td>
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<tr>
<td>Borosilicate</td>
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<td>Soda-lime</td>
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<tr>
<td>Sintered materials</td>
<td>Crystalline inorganic nonmetallic material</td>
<td>Mechanical seals, bearings, process sensors</td>
</tr>
<tr>
<td>Aluminum oxide</td>
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<tr>
<td>Silicon carbide</td>
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<td>Silicon nitride</td>
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<tr>
<td>Tungsten carbide</td>
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<tr>
<td>Zirconium dioxide</td>
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<tr>
<td>Reaction-bonded materials</td>
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<tr>
<td>Silicon carbide</td>
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<td>Mechanical seals</td>
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<tr>
<td>Silicon nitride</td>
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<td></td>
</tr>
<tr>
<td>Siliconized carbon-graphite</td>
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<td>Mechanical seals</td>
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<tr>
<td>Resin-impregnated carbon-graphite</td>
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<td>Tungsten carbide with alloyed binder</td>
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<td>Tungsten carbide with nickel binder</td>
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<td></td>
</tr>
<tr>
<td>Tungsten carbide with cobalt binder</td>
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</tbody>
</table>

PM-2.2.2 Labeling and Marking. Manufacturers shall mark the package containing polymer components or assemblies with the manufacturer’s name, part number, and lot number or unique identifier (see Table PM-2.2.1-1) to enable the manufacturer to trace back to the raw material(s) and processing conditions used to fabricate the component/assembly. Manufacturers should mark the component/assembly itself to avoid potential loss of traceability and to aid in positive identification of components/assemblies after use.

PM-2.2.3 Change Management

PM-2.2.3.1 General. Change management requirements apply to manufacturers of polymeric or other nonmetallic process contact materials, components, and assemblies, for both single-use and multiuse applications.

PM-2.2.3.2 Change Class. Change management requirements for an owner/user to implement a change related to a material, component, or assembly is dependent on the following attributes:

(a) impact on bioprocessing product safety, efficacy, purity, identity, or strength
(b) impact to form, fit, or function of the product, which may include
   (1) formulation changes
   (2) manufacturing means, methods, or materials changes
   (3) changes to published or agreed specifications
   (4) discontinuance of a material, component, or assembly
   (5) changes in regulatory or compliance status (e.g., USP)

Table PM-2.2.3.2-1 defines four levels of change commensurate with the complexity of change and the amount of time needed for owner/users to address requirements associated with the change. Manufacturers, when selecting the level of change for notification, should consider typical owner/user regulatory constraints as well as technical, business, and supply chain practices to anticipate notification time needed by the owner/user to qualify and implement the change.

PM-2.2.3.3 Owner/User Notification. The manufacturer should provide change notification documentation to the owner/user per the timelines defined in Table PM-2.2.3.2-1. The change notification should include:

(a) identification of the manufacturer’s products affected by the change
(b) explanation of why the change is being made
(c) description of the change (current state and modified state)
(d) known potential impact to form, fit, or function and impact through the supply chain
(e) documentation and qualification data to characterize the change
### Table PM-2.2.1-1 Content Required on the Certificate of Compliance

<table>
<thead>
<tr>
<th>Requirements to Conform to ASME BPE</th>
<th>Polymeric Seals (Includes Diaphragms and Hygienic Union Seals)</th>
<th>Filters [Note (1)]</th>
<th>Chromatography Columns</th>
<th>Connectors (Includes Steam to/Through)</th>
<th>Polymeric Containers (Rigid and Flexible)</th>
<th>Other Polymeric Process Components</th>
<th>Nonmetallic Process Components</th>
<th>Single-Use Assemblies</th>
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</thead>
<tbody>
<tr>
<td>Manufacturer's name</td>
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<tr>
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<td>Compound number or unique identifier</td>
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</tr>
<tr>
<td>Cure date or date of manufacture</td>
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<td>USP &lt;87&gt; or ISO 10993-5</td>
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</tr>
</tbody>
</table>

GENERAL NOTE: For components subjected to operations such as gamma irradiation or steam, specific certification shall be provided. See Mandatory Appendix III-11.

NOTES:
1. For hygienic union seals, the intrusion category shall be provided (SG-4.2).
2. Specific lot release criteria may be required for different types of filtration elements depending on their type and application. These additional requirements should be decided by the owner/user and the supplier.
The interpretation of immersion test results is dependent on the specific application. In such cases, a different material may be more suitable for the application. The overall life of the equipment may be shortened significantly if the correct polymer is not selected. The end-user must ultimately interpret the relevance of the test results for the applicable process.

**PM-3.4 Chemical Compatibility of Thermoplastic Polymers**

Chemical concentration, temperature, and duration of exposure can all affect the property retention of thermoplastic polymers. When selecting a thermoplastic polymer for chemical contact, the user should consult the supplier for case histories and test data, where available. If further testing is required, specific fluids should be used to expose test samples for the necessary time and temperature.

**PM-3.5 Physical and Mechanical Properties of Thermoset Polymers**

Physical and mechanical properties can be characterized using many different standards (e.g., ASTM, ISO, DIN, and JIS). Typical properties include hardness, tensile strength, elongation to break, modulus, and tear strength. In some cases, abrasion resistance, compression set, specific gravity, transparency, etc., may be important. Properties may be affected by manufacturing and use conditions (e.g., temperature, pressure, physical stress). Common tests for evaluating physical and mechanical properties are listed in Nonmandatory Appendix L. Property requirements should be discussed between the owner/user and the supplier, and the owner/user shall be responsible for determining the suitability of the material for the application.

**PM-3.6 Chemical Compatibility of Thermoset Elastomers**

Chemical concentration, temperature, and duration of exposure can all affect the property retention of thermoset elastomers. When selecting a thermoset elastomer for chemical contact, the user should consult the supplier for case histories and test data, where available. If further testing is required, specific fluids should be used to expose test samples for the necessary time and temperature. Chemical compatibility is particularly important for materials that are reused. Chemical compatibility testing should be done to screen candidate materials for applications involving cleaning, storage, or exposure to potentially harsh chemicals.

**PM-3.7 Physical and Mechanical Properties of Other Nonmetallic Materials**

Physical and mechanical properties of other nonmetallic materials, such as those listed in Table PM-2.1.3-1, may be characterized using many different standards (e.g., ASTM, ISO, DIN, and JIS). Typical properties may include, but are not limited to, hardness, strength, self-lubrication, and transparency. In some cases, low friction between sliding surfaces may be important. Properties may be affected by use conditions. Material selection should be discussed between the owner/user and supplier, and the owner/user shall be responsible for determining the suitability of the material for the application.

**PM-3.8 Chemical Compatibility of Nonmetallic Materials**

Chemical composition, temperature, and duration of exposure may all affect the properties of other nonmetallic materials. When selecting nonmetallic materials, such as those listed in Table PM-2.1.3-1, the user should consult the supplier for test data, where available. If further testing is required, specific fluids should be used to expose test samples for the necessary time and temperature.

**PM-3.9 Polymeric Surface Finish**

Polymeric material contact surface classifications are found in Part SF.

**PM-4 APPLICATIONS**

**PM-4.1 Single-Use Components and Assemblies**

See Mandatory Appendix III.

**PM-4.2 Piping**

The following shall be considered in the design of polymeric rigid piping and tubing.

**PM-4.2.1 Sizing Comparisons**. Thermoplastic piping systems are available in a variety of sizing standards. Tube/pipe (e.g., Schedule 40, Schedule 80), Standard Dimensional Ratio (SDR) 11, and SDR 21 are some of the most common standards used. Table PM-4.2.1-1 is a reference that compares the outside and inside dimensions of these standards. It is important to consider these standards when performing system sizing calculations to enhance dimensional alignment of pipe/tube inner diameters to allow for sterility, cleanability, and drainability. Tube inside dimensions are critical for alignment to stainless steel systems.

**PM-4.2.2 Pressure Ratings**. Polymer piping systems have varying pressure ratings depending on material and sizing standards. Valves and mechanical connections...
such as sanitary adapters, flanges, or threads may carry pressure ratings independent of pipe and fittings. Elevated operating temperatures will decrease overall system rating. Consult material manufacturers for specific details.

PM-4.2.3 Thermal Expansion. Polymeric materials will expand and contract with changing temperature conditions. The effect of thermal expansion shall be considered and designed for in every thermoplastic system.

To compensate for thermal expansion, it is recommended to use loops, offsets, and changes in direction. By using the pipe itself to relieve the stress, the integrity of the pipe system is maintained. The use of bellows or pistons is not recommended due to the formation of pockets and gaps where liquids may be held up. The amount of thermal expansion growth in a pipe system is generally calculated by the following formula:

\[
\Delta L = 12 \times L \times \alpha \times \Delta T
\]

(U.S. Customary Units)

(2)

where

- \(L\) = length of the pipe run, ft
- \(\alpha\) = coefficient of thermal expansion, in./in./°F material and temperature dependent
- \(\Delta L\) = change in length, in.
- \(\Delta T\) = temperature change, °F

\[
\Delta L = L \times \alpha \times \Delta T
\]

(SI Units)

(3)

where

- \(L\) = length of the pipe run, mm
- \(\alpha\) = coefficient of thermal expansion, mm/m/°C material and temperature dependent
- \(\Delta L\) = change in length, mm
- \(\Delta T\) = temperature change, °C

Typical coefficients of thermal expansion at room temperature by material type are found below. Consult the manufacturer for exact coefficient values.

(U.S. Customary Units)

- PVDF: \(6.6 \times 10^{-5}\), in./in./°F
- PFA: \(7.0 \times 10^{-5}\), in./in./°F
- PP: \(8.33 \times 10^{-5}\), in./in./°F

(SI Units)

- PVDF: \(1.2 \times 10^{-5}\), mm/m/°C
- PFA: \(1.2 \times 10^{-5}\), mm/m/°C
- PP: \(1.5 \times 10^{-5}\), mm/m/°C

\(\Delta T\) is the maximum (or minimum) temperature minus the installation temperature. If the installation temperature or time of year is unknown, it is practical to increase \(\Delta T\) by 15% for safety. It is not necessary or practical to use the maximum temperature minus the minimum temperature unless it will truly be installed in one of those conditions.

PM-4.2.4 System Support Criteria

PM-4.2.4.1 Support Distances. Supports shall be placed based on the spacing requirements provided by system manufacturers. Hanging distances are based on system material as well as the specific gravity and temperature of the process media. Operating conditions of all applicable processes, including CIP and SIP, shall also be considered. Hanging criteria generally increase with system operating temperatures. The placement of hangers, guides, and anchors is critical in systems exposed to thermal cycling. Hanger locations should be identified by the system engineer and laid out to allow for expansion and contraction of the pipe over its life of operation.

PM-4.2.4.2 Hanger and Clamp Types. Avoid using hangers that place a pinpoint load on the pipe when tightened. A U-bolt hanger is not recommended for thermoplastic piping. Hangers that secure the pipe 360 deg around the pipe are preferred. Thermoplastic clamps are also recommended over metal clamps, as they are less likely to scratch the pipe in the event of movement. Clamps should be evaluated to avoid rough edges that could damage the pipe. Ideally, if a metal clamp is being used, an elastomer material should be used in between the pipe and the clamp. Refer to Part SD for exterior cleanliness.

PM-4.2.5 Connections and Fittings. Design of equipment should minimize the number of mechanical connections. Fusion welded connections should be used wherever practical. Hygienic design of connections shall comply with SD-3.1.

PM-4.3 Hose Assemblies

PM-4.3.1 General. This section defines the requirements for flexible hose assemblies intended for repeated use. Hose assemblies are defined here as a length of a flexible, polymeric element with at least one end connection securely affixed and capable of containing fluids under specified conditions (e.g., pressure and temperature).

PM-4.3.2 Hose Construction

PM-4.3.2.1 Flexible Elements. Elements may be constructed from a single, homogeneous material or multiple layers. Multilayer elements may consist of an inner contact layer surrounded by one or more additional reinforcement layers and an outer cover. Reinforcement layers may include fabric braiding, metal wire braiding, and various elastomeric materials. The liner design shall allow for drainability and cleanability as required by the end-user.
**PM-4.3.2.2 Mechanically Affixed and Reusable End Connections.** Metallic and nonmetallic end connections are attached to the flexible element by mechanical compression. The design shall ensure a seal is maintained at the end of the barb [see Figure SD-3.2.1-1, illustration (d)]. Band-style hose clamps are not recommended [see Figure SD-3.2.1-1, illustration (c)]. The fitting should be designed to minimize entrapment of liquid in the hose assembly. Dimensions and tolerances of the process connection shall be consistent with Table DT-7-1.

**PM-4.3.2.3 Flare-Through End Connections.** Flare-through end connections are connections in which the inner contact layer of the flexible element extends through the fitting and is formed into the end connector. Flare-through end connections may have integral gaskets or provisions for standard gaskets.

**PM-4.3.2.4 Molded-in-Place End Connections.** Molded-in-place end connections are secured to the flexible element by a thermal or chemical bond. Molded-in-place end connections using nonrigid materials may require additional stiffening reinforcement to achieve an adequate process connection seal. Molded-in-place end connections may include an integral gasket.

**PM-4.3.2.5 Hose Materials.** Hose assembly materials shall conform to applicable sections of SD-2.4.1.2 and PM-2.1.

(a) Biocompatibility. The biocompatibility and proper material selection shall be the responsibility of the end-user. Biocompatibility testing of candidate hose assemblies for qualification requires USP <87> (or ISO 10993-5) and USP <88> Class VI (or ISO 10993-6, -10, and -11) tests on all polymeric process contact materials. End-users may request similar testing on noncontact layers that may come in contact with the process fluid if the inner liner fails. Hose assembly suppliers shall provide, on customer request, documentation of the biocompatibility testing on final manufactured hose assembly materials. Failure of either test indicates unacceptable biocompatibility of the candidate hose assembly.

(b) Surface Finish. Surface finish of metallic end fittings shall comply with the requirements of Part SF.

(c) Particle Generation. Hose assembly designs should minimize wear that generates particles that could enter the process.

(d) Extractables. Hose assembly materials shall conform to the requirements of PM-3.2.

**PM-4.3.3 Hose Assembly Performance.** The equipment supplier shall inform the end-user of the life cycle expectancy and the methods that will ensure that the hose assembly operates within its design specification (e.g., routine maintenance).

**PM-4.3.3.1 Service Temperatures and Pressures.** Hose assemblies shall be capable of withstanding thermal and pressure cycling between the rated upper and lower temperature and pressure limits.

**PM-4.3.3.2 Nonroutine Events.** The complete procedure for nonroutine events such as passivation, derouging, and postconstruction cleaning should be supplied by the end-user. The supplier shall inform the end-user whether the hose assembly will perform as specified during these events. The end-user shall perform a risk assessment to determine if a new hose assembly is required after nonroutine events.

**PM-4.3.3.3 Cleaning Systems**

(a) Clean-in-Place (CIP). Hose assemblies shall be designed in accordance with SD-3.1. The hose assembly shall be installed to allow for drainability (see SD-3.2).

(b) Clean-out-of-Place (COP). External surfaces of hose assemblies subject to COP shall be compatible with cleaning agents and be nonabsorbent. Hose assemblies shall be designed to allow effective removal of cleaning agents from external surfaces.

**PM-4.3.3.4 Sterilizing Systems.** Hose assembly requirements shall be based on the sterilization method used. All process contact surfaces should be designed to minimize crevices. When crevices cannot be avoided, sterilization testing shall be performed to validate sterility within the system boundaries. All hose assemblies and hose assembly contact surfaces shall be designed to accommodate expansion and contraction during sterilization and cooldown stages.

**PM-4.3.4 Hose Assembly Installation.** Hose assemblies shall be installed per SD-3.2 and used in accordance with the supplier’s guidelines (e.g., bend radius). Change in hose assembly length due to pressure and temperature cycling and the potential effect on drainability should be considered by the end-user.

**PM-4.3.5 Compliance Requirements**

**PM-4.3.5.1 General Requirements.** A Certificate of Compliance shall be issued by the hose assembly supplier to certify compliance to this Standard when required by the end-user.

**PM-4.3.5.2 Certificate of Compliance.** The Certificate of Compliance shall contain the following information:

(a) manufacturer’s name

(b) part number

(c) unique identifier of the hose assembly
(d) material of construction of process contact items
(e) compliance to USP <87> (or ISO 10993-5) and USP <88> Class VI (or ISO 10993-6, -10, and -11)
(f) packaging and storage recommendations (this may be in another document)

The supplier’s name and unique identifier shall be marked on either the hose assembly itself or the package containing the hose assembly. The unique identifier shall enable the supplier to identify the raw material and processing conditions used to fabricate the article. Suppliers shall mark the hose assembly itself to avoid potential loss of traceability and to aid in positive identification of hose assemblies.

PM-4.3.5.3 Test Requirements. Conformance testing is done on initial qualification of the hose assembly. Testing is intended to show design conformance and is not required on every hose assembly. Testing shall be repeated for significant changes in raw materials or processes used to fabricate hose assemblies.

PM-4.4–Chromatography Columns

PM-4.4.1 General. This section defines typical design elements related to large-scale chromatography columns and includes columns that are intended for repeated use in processing. Although chromatography processes are not typically aseptic, design features for cleaning and/or sanitization should be considered. More information on chromatography columns can be found in Nonmandatory Appendix T.

PM-4.4.2 Pressure-Retaining Parts. The column tube is both a product contact surface and a pressure-retaining component. Chromatography columns are vessels operating under pressure and should meet the requirements of ASME BPVC, Section VIII, as referred to in GR-1, as applicable. If the column tube is acrylic, it shall comply with ASME PVHO-1, Case 14, Low UV. The owner/user is responsible for informing the manufacturer of the normal and abnormal operating conditions to which the column may be exposed. The manufacturer is responsible for ensuring the column will operate safely under said conditions.

PM-4.4.3 Design for Cleaning and Sanitization

PM-4.4.3.1 Cleaning. Columns should be designed in accordance with SD-2.4.2 with the exception of the bed supports and flow distributor. Cleaning of chromatography columns is achieved by control of contact time and concentration of the appropriate cleaning agents.

PM-4.4.3.1.1 Seals. All seals shall conform to Part SG.

PM-4.4.3.1.2 Exterior Surfaces. Exterior surfaces of columns shall be nonabsorbent and compatible with cleaning agents. Columns shall be designed to allow effective removal of cleaning agents from surfaces.

PM-4.4.3.2 Sanitization

PM-4.4.3.2.1 Chemical Sanitization. All product contact surfaces within the system shall be compatible with the sanitization agents selected.

PM-4.4.3.2.2 Thermal Sanitization. When thermal sanitization is used, all column product contact surfaces shall be designed to accommodate expansion and contraction during exposure and cooldown stages.

PM-4.4.4 Column Materials. Column materials for all product contact surface wetted parts shall conform to applicable sections of Parts SD, PM, and SF.

PM-4.4.5 Column Performance

PM-4.4.5.1 Service Temperature and Pressure. Columns shall be capable of withstanding thermal and pressure cycling between the rated upper and lower temperature and pressure limits.

PM-4.4.5.2 Routine Maintenance. To ensure continued column performance, consideration shall be made to the accessibility of all column components for routine maintenance.

PM-4.4.6 Compliance Requirements

PM-4.4.6.1 General Requirements. A unique identifier shall be indelibly marked on the column or the column’s support structure. The unique identifier shall enable the owner/user to identify the supplier and the supplier to identify the raw material and processing conditions used to fabricate the article.

PM-4.4.6.2 Certificate of Compliance. A Certificate of Compliance shall be issued by the column manufacturer under the requirements by the owner/user.

The Certificate of Compliance shall contain the following information:
(a) manufacturer’s name
(b) unique identifier of the column
(c) material of construction of process contact items
(d) compliance to USP <87> Class VI (or ISO 10993-5) and USP <88> (or ISO10993-6, -10, and -11)
Also see Table PM-2.2.1-1.
PM-4.5 Filtration Elements and Components

PM-4.5.1 General. This section defines and recommends design elements related to hygienic filtration processes. This section includes aseptic and nonaseptic processes and includes the following filtration components: housings, holders, and elements. More information on filtration elements and components may be found in Nonmandatory Appendix T.

PM-4.5.2 Filtration Formats. There are two basic modes of filtration: direct flow and tangential flow. For multiuse filters, cleaning and/or sanitization should be considered. For single-use filters, sanitization requirements shall be determined by the owner/user.

PM-4.5.3 Housing and Encapsulation. Filter housings and encapsulated components are wetted and are vessels operating under pressure. Requirements for vessels operating under pressure are found in ASME BPVC, Section VIII, as referred to in GR-1. The owner/user shall be responsible for informing the manufacturer of all expected operating conditions to which the filter housings may be exposed. The manufacturer shall be responsible for ensuring the filter housings and encapsulated components will operate safely under said conditions.

PM-4.5.3.1 Housings. Housings shall be designed in accordance with Part SD. Materials used in the construction of filtration housings shall conform to Part MM for metallic materials or Part PM for polymeric materials.

PM-4.5.3.2 Encapsulation. Encapsulated filtration elements are designed for handling purposes or in place of metallic housings. Materials used in the encapsulation of filtration elements shall conform to Part PM for polymeric materials or Part MM for metallic materials.

PM-4.5.3.2.1 Holders. Materials used in the construction of holders shall conform to Part MM for metallic materials or Part PM for polymeric materials.

PM-4.5.4 Design for Cleaning and Sanitization

PM-4.5.4.1 Cleaning. Filtration elements shall be designed in accordance with SD-3.1 and shall be compatible with the cleaning agents (to be agreed by the manufacturer and owner/user):

PM-4.5.4.1.1 Seals. All seals shall conform to Part SG.

PM-4.5.4.1.2 Exterior Surfaces. All exterior surfaces shall conform to SD-2.4.4.2.

PM-4.5.4.2 Sanitization

PM-4.5.4.2.1 Chemical Sanitization. Chemical sanitization processes are used to reduce bioburden. All product contact surfaces shall be compatible with the sanitization agents selected (to be agreed by the manufacturer and owner/user).

PM-4.5.4.2.2 Thermal Sanitization. Thermal sanitization requirements should be considered during the design process. The components shall be designed to accommodate the elevated temperatures and the expansion and contraction during exposure and cooldown stages. Special consideration should be given when designing for potential vacuum situations. Filtration elements should be tested and verified for multiple steam cycles per vendor qualification methods. Filtration elements shall conform to SD-2.3.1.

PM-4.5.5 Filtration Performance. The owner/user shall be responsible for informing the manufacturer of all the conditions under which the filter elements may be expected to operate. This shall include the methods, frequency, and duration of cleaning and sanitization procedures. In addition to the service temperature and pressure, any parameters that may affect the filtration performance shall be provided.

PM-4.5.5.1 Service Temperature and Pressure. Filtration elements shall be capable of withstanding thermal and pressure cycling between the rated upper and lower temperature and pressure limits.

PM-4.5.5.2 Routine Maintenance. To ensure continued filtration performance, consideration shall be given to the accessibility of all filtration components for routine maintenance.

PM-4.5.5.2.1 Integrity Testing and Permeability

(a) Integrity Testing. Tests may be required to ensure that the filtration elements and components are integral and meet specific process requirements. Sterilizing-grade membranes should be tested to the specific bacterial retention protocol (refer to 2004 cGMP Filtration Guideline and ASTM F838).

The following are typical integrity test procedures that may be performed:

1. Pressure decay test
2. Bubble point test
3. Diffusional flow test
4. Water intrusion test

Other integrity testing methods should be agreed on between the manufacturer and owner/user. Integrity testing may be performed either pre- or postprocess.

(b) Normalized Water Permeability. During tangential flow applications, a normalized water permeability test (NWP; see Nonmandatory Appendix T-2.5) or clean water flux test may be performed.

PM-4.5.6 Installation. Installation shall be in accordance with the manufacturer’s guidelines.

PM-4.5.7 Compliance Requirements

PM-4.5.7.1 General Requirements. A unique identifier shall be indelibly marked on the filtration element or support structure. The unique identifier shall enable the
owner/user to identify the supplier and the supplier to identify the raw material and processing conditions used to fabricate the article. A Certificate of Compliance shall be issued by the filtration element manufacturer to certify compliance to this Standard when required by the owner/user.

**PM-4.5.7.2 Certificate of Compliance.** The Certificate of Compliance shall contain the following information:

(a) manufacturer’s name
(b) date of manufacture of the element
(c) unique identifier of the element
(d) material of construction of process contact items
(e) compliance to USP <87> (or ISO 10993-5) and USP <88> Class VI (or ISO 10993-6, -10, and -11)

Other certifications of compliance should be agreed on by the manufacturer and owner/user.

**PM-4.6 Polymeric Hygienic Unions**

When using polymeric hygienic unions, several application variables should be considered to ensure optimum performance. Some variables include fluid type, process temperature, system pressure, vibration, materials of construction, sterilization method (where appropriate), cleaning methods (where appropriate), and duration of use. Pressure and temperature ratings of polymeric hygienic unions should be provided by the manufacturer.

Polymeric ferrules and clamps should be designed and manufactured to ensure proper fit-up and avoid leakage. Material of construction and the molding process impact the tolerances of polymeric ferrules; consequently, tolerances are not the same as they are for metallic ferrules. Polymeric ferrules shall meet the nominal dimensions and tolerances of Table DT-7-2 except for dimension A, which shall achieve clearance as per DT-9.4(e).

**PM-4.6.1 Multiuse**

**PM-4.6.1.1 Installation.** The manufacturer shall provide installation procedures.

**PM-4.6.1.2 Performance.** Polymeric hygienic unions shall meet the seal intrusion requirements of SG-4.2.

**PM-4.6.1.3 Cleaning.** Ferrules and clamps should be cleanable as per SD-2.4.2 and SD-3.1.2.2.

**PM-4.6.1.4 Bioburden Control.** [Reserved for future content]

**PM-4.6.1.5 Seals.** [Reserved for future content]

**PM-4.6.2 Single-Use.** For general single-use requirements, see Mandatory Appendix III.

**PM-4.6.2.1 Installation.** See PM-4.6.1.1.

**PM-4.6.2.2 Seals.** See PM-4.6.1.5.

In all locations .6 should be changed to .4
Table DT-2-1 shows the maximum allowable working pressure and temperature ratings for metallic fittings manufactured per DT-4.1 and manufactured from materials listed in Tables MM-2.1-1, MM-2.1-2 and MM-2.1-3, with the exception of automatic tube weld caps listed in Table DT-4.1-5-1.

Metallic fittings manufactured to pressure and temperature ratings that exceed Table DT-2-1 must be justified by methods accepted by ASME B31.3.

Metallic fittings listed in Table DT-4.1-5-1 (automatic tube weld cap) shall meet or exceed the pressure and temperature ratings shown in Table DT-2-1.

Special angle branch connections per DT-4.3 shall be rated per the manufacturer's pressure and temperature ratings.

### DT-2 PRESSURE RATING

Metallic fittings manufactured to this Part shall meet or exceed the pressure ratings shown in Table DT-2-1 and shall have an ambient temperature bursting strength of at least three times the 100°F (38°C) rated internal working pressure as shown in Table DT-2-1 (see also Figure DT-2-1).

Fabricated components employing welds shall be rated at 100% of the above ratings.

Valves manufactured to this Part shall be rated per the manufacturer's marked pressure and temperature recommendations.

### DT-3 WALL THICKNESS

The nominal wall thickness of the fittings and process components at the point of joining shall be the same as the tube to which they are welded. The thickness of the weld ends shall conform with the tolerances listed in Tables DT-3-1 and DT-3-2.

After fabrication and surface treatment, the wall thickness in any formed part of the fitting or process component, beyond the control portion as defined in DT-7, shall be a minimum of 65% of the nominal wall thickness. For guidelines regarding welds, refer to Part MJ. All welds shall meet the requirements of Table DT-7-8 and Figure MJ-8.4-1.

### DT-4 DIMENSIONS

Process components are designed for use with nominal outside diameter (O.D.) tubing for the sizes listed in Table DT-4-1. The dimensions are accompanied with soft metric revisions from the U.S. Customary units and are listed for reference only (see GR-6). For nominal metric size tubing and fittings, refer to the appropriate international standards.

#### DT-4.1 Fitting Dimensions

Dimensions for fittings that are governed by this Standard are grouped and categorized into tables.

All sizes shown in these tables are nominal O.D. tube sizes.

All automatic weld end fittings shall have minimum tangent lengths per Table DT-4.1-1. The tangent length, \( T_D \), is defined as the straight length measured from the welding end.

The categorized groups in DT-4.1.1 through DT-4.1.5 designate specific fitting dimensions.

- **DT-4.1.1 Elbows/Bends**. Refer to Tables DT-4.1.1-1 through DT-4.1.1-8. \( \text{DT-4.1.1-0} \)

- **DT-4.1.2 Tees/Crosses**. Refer to Tables DT-4.1.2-1 through DT-4.1.2-11. \( \text{DT-4.1.2-13} \)

- **DT-4.1.3 Reducers**. Refer to DT-4.1.3-3.

- **DT-4.1.4 Ferrules**. Refer to Table DT-4.1.4-1. Metallic ferrules are specified in Table DT-7-1. Polymeric ferrules are specified in Table DT-7-2.

- **DT-4.1.5 Caps**. Refer to Tables DT-4.1.5-1 and DT-4.1.5-2.

#### DT-4.2 Nonstandard Fitting Dimensions

Fittings not specifically described in Tables DT-4.1.1-1 through DT-4.1.5-2 may be constructed using combinations of centerline-to-end dimensions from the tables.

For tees and crosses, use Tables DT-4.1.2-4 and DT-4.1.2-8 for standard clamp leg lengths; Tables DT-4.1.2-2 and DT-4.1.2-7 for short-outlet branch clamp lengths; Table DT-4.1.2-3 for short-outlet run clamp lengths; and Table DT-4.1.2-1 for weld end lengths. Consideration shall be made for clamp clearances when fabricating fittings not depicted in Tables DT-4.1.1-1 through DT-4.1.5-2.
DT-4.3 Special Angle Fittings Dimensions

Special angle fittings can be offered if in accordance with all DT tables, with the exception of “0” (off angle) in Table DT 3.1. Fittings furnished to this Standard shall not be mitered.

DT-4.4 Valve Dimensions

The dimensions of the valve or valve fabrication shall conform to the manufacturer’s standards, or as agreed to by the purchaser and manufacturer.

Standard dimensions for valve hygienic clamp connections covered by this Standard are given in Table DT-4.4.1. All sizes shown are nominal O.D. tube sizes.

The categorized groups in DT-4.4.1 designate specific valve dimensions.

DT-4.4.1 Diaphragm Valves: Refer to Table DT-4.4.1-1. All sizes shown are nominal O.D. tube sizes.

DT-4.5 Filter Dimensions

Standard dimensions for filter components covered by this Standard are referenced in SD-3.8 and are given in Tables DT-4.5.1-1 and DT-4.5.2-1.

DT-4.5.1 Code 7 Tapered Locking Tab Retainer: Recessed. Refer to Table DT-4.5.1-1.

DT-4.5.2 Code 7 Tapered Locking Tab Retainer: External. Refer to Table DT-4.5.2-1.

DT-5 MATERIALS

Materials used in the manufacture of fittings and other process components shall conform to one of the material specifications listed in Part MM.

DT-6 TESTS

Hydrostatic testing of each fitting is not required in this Standard; however, fittings shall be capable of withstand- ing a hydrostatic test pressure of 1.5 times the pressure rating shown in Table DT-2.1 at 100°F (38°C).

DT-7 TOLERANCES

Tables DT-3.1, DT-3.2, DT-4.1, DT-4.2, DT-7.1, DT-7.1 (metallic), and DT-7.2 (polymeric) list the required tolerances for fabricated fittings and process components depicted by this Standard. Table DT-7.1 lists the required tolerances for fabricated fittings and process components.

Table DT-7 (metallic) lists the required tolerances for fabricated fittings and process components. When metallic ferrules are welded to a process component and polished, then the tolerances in Tables DT-3.1, DT-3.2, and DT-4.1 shall apply. For tubing tolerances, refer to ASTM A270.

Supplement 2. Table DT-7-3 lists the required tolerances for transfer panel connections and jumpers.

These tolerances shall apply after heat and surface treatment.

The control portion of the fitting process components (refer to Figure DT-7.1-1) length from the welding end over which tolerances for wall thickness and O.D. are maintained. The length of the control portion is fixed for all sizes at 0.75 in. (19 mm). For exceptions, see Table DT-4.1.4-1 for ferrule lengths and Table DT-4.1.5-1 for automatic tube weld caps.

DT-8 WELD ENDS

Where UNS 31603 (316L) is specified, the material of the automatic weld end shall conform to the requirements for chemical composition as prescribed in MM-5.2.1.1. For non-automatic weld ends, the chemical composition shall meet the requirements specified above. Authoritative data shall be furnished for each lot of welds and breaks. All weld end connections for valves shall have a minimum unobstructed weld end length equal to or greater than the minimum control portion as per DT-7.

DT-9 HYgienIC CLAMP UNIONS

DT-9.1 Typical Hygienic Clamp Unions

Typical hygienic clamp unions are described in SG-2.2.2.

DT-9.2 Hygienic Gaskets

Fittings and process components with hygienic clamp unions furnished to this Standard shall employ gasket materials and gasket designs that meet the requirements of Table DT-2-1 and Part 5G. Gasket seal performance in the clamp union shall be based on the principles of SG-4 and shall comply with the dimensional requirements of Figure SG-4.2-1 when the union assembly is tightened to an amount recommended by the manufacturer. Gasket width as shown in Figure SG-4.2-1 shall be a maximum of 0.05 in. in the uncompressed condition prior to installation.

DT-9.3 Connections

Connections meeting all dimensions of Table DT-7.1 are considered interchangeable. Alternative scaling designs are acceptable, provided the following are met: (a) dimensions A, B, C, and D of Table DT-7.1 (b) dimensions A and B of Table DT 9.3.1

In the case of non-flow-through connections, dimension B of Table DT 7.1 shall not apply. All connections shall meet the applicable requirements of paras. SD-3.1, SG-3.3.2.1, and SG-3.3.2.2.
**DT-9.4 Hygienic Clamps**

Hygienic clamps shall be designed and manufactured through the entire range of all union component dimensional tolerances to accomplish the following:

(a) completely retain all components in a fully sealed state to meet the requirements of DT-2
(b) maintain proper component alignment during installation and operation per SG-3.3.2.1
(c) cause the ferrules to be aligned to meet a uniform nominal gap per Figure SG-4.2-1 when filled and tightened to the proper design specifications
(d) cause the gauge and contact diameter between the ferrules and the mating surfaces of the clamp to occur at the gaging diameter (A) specified in Table DT-9.3-1 when installed and tightened to achieve the nominal gap per Figure SG-4.2-1

NOTE: As this is a nominal design condition, manufacturing tolerances of the components may use some variation in the actual gaging and contact diameter at assembly.

(e) avoid any interference with any clamp union components or itself that would prevent proper assembly when assembled with all components (see Figure DT-9.1)

**DT-10 MINIMUM EXAMINATION REQUIREMENTS**

**DT-10.1 Visual Inspection**

For fittings and process components including but not limited to, tubing, valves, pumps, filter housings, and instrumentation, each item shall be visually examined for the following criteria, as a minimum. It is not a requirement that the packaged components be removed from the original packaging; provided, the following can be verified:

(a) manufacturer’s name, logo, or trademark
(b) alloy/material type
(c) description including size and configuration
(d) heat number/code
(e) process contact surface finish designation [only one surface finish (SF) designation allowed]
(f) reference to ASME BPE
(1) ASME BPE Certificate of Authorization holders shall refer to their Certificate of Authorization holders, certified process contact component.
   (a) a number or unique identifier which provides traceability to the applicable MTR (material test report), surface test report, or other certifications. This number may be a heat number/manufacturer's code or serial number, marked on each process contact component
   (b) pressure rating for valve
   (c) valve pressure rating
   (d) no damage or other deficiencies

**DT-10.2 Documentation Verification**

Refer to Part GR for documentation verification requirements.

**DT-10.3 Physical Examination**

For this paragraph, a “lot” shall be defined as a specific combination of size, configuration, and heat number for fittings and process components including, but not limited to, tubing, valves, pumps, filter housings, and instrumentation in a single shipment.

If required by the owner/user, a percentage of each lot may be physically examined by the manufacturer, installing contractor, inspection contractor, or owner/user for the following criteria:

(a) wall thickness (for weld ends only)
(b) outside diameter (for weld ends only)
(c) surface finish (as specified)
(d) visual

When required examination reveals a defect(s), an additional 10% of that lot shall be examined for the specific defect(s). If this examination reveals another defect, an additional 10% of that lot shall be examined for the specific defect(s). If additional defects are found, perform 100% examination or reject the balance of the lot. All examined and accepted material in this lot may be retained and used.

The completed Material Examination Log shall describe all of the features listed above. The results of the examination shall be recorded on a Material Examination Log. This documentation may be one line item for the total quantity of a particular size, configuration, and heat number. The information required to be on the Material Examination Log may be in any format, written or tabular, to fit the needs of the manufacturer, installing contractor, inspection contractor, and owner/user as long as all information is included or referenced.

Refer to Forms MEL-1 and MER-1, which have been provided as a guide for the Material Examination Log (see Nonmandatory Appendix B).

**DT-11 MARKING**

**DT-11.1 Fitting Marking Information**

Except as specified in DT-11.1.1, each fitting and process component shall be permanently marked by any suitable method not injurious to the process contact surface to show the following:

(a) heat number/manufacturer’s code that is traceable to the Material Test Report for each process contact surface component
(b) material type
(c) manufacturer’s name, logo, or trademark
(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 Figure CR-1-1.

(2) Non-ASME BPE Certificate of Authorization holders shall only mark “BPE.”
(0) process contact surface designation for the appropriate BPE specification [only one surface finish (SF) designation allowed]

NOTE: All marking of a process component should be made outside of the control portion to optimize welding fit-up and identify available marking area.

(10) DT-11.1.1 Exceptions

(a) Where the size of the fitting or process component does not permit complete marking, the identification marks may be omitted in reverse of the order presented above. The process component shall be marked, at a minimum, with the items identified in Table DT-11.1.1-1.

(b) Where the process component shall have been removed due to fabrication into another component or system, the heat number or manufacturer’s code and material type shall be re-marked on the fitting or process component.

(19) DT-11.2 Valve Marking Information

Except as specified in DT-11.2.1, each valve shall be permanently marked by any suitable method not injurious to the process contact surface to show the following:

(a) heat number/manufacturer’s code that is traceable to the Material Test Report for all wetted metal component parts of the valve or valve fabrication, if more than one heat is used

(b) valve pressure

(c) material type

(d) manufacturer’s name, logo, or trademark

(e) 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 Figure CR-1-1.

(2) Non ASME BPE Certificate of Authorization holders shall only mark “BPE.”

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

NOTE: All marking of a process component should be made outside of the control portion to optimize welding fit-up and identification.

DT-11.2.1 Exceptions

(a) Where the size of the fitting or process component does not permit complete marking, the identification marks may be omitted in reverse of the order presented above. However, the heat number or manufacturer’s code, valve pressure rating, and material type shall be marked on the valve.

(b) Where the markings have been removed due to fabrication into another component or system, the heat number or manufacturer’s code and material type shall be re-marked on the valve.

DT-11.3 Modified Surfaces

When the surface finish of a process component is modified, the surface finish designation marking shall be changed to match the final surface finish designation according to Table SF-2.4.1-1. Only the final finish designation shall be indicated.

After removal of the original markings, all dimensions and tolerances shall comply with Table DT 3 1 and, as applicable, Table DT-3-2.

DT-12 PACKAGING

All end connections of fittings or process components shall be protected with end caps. Additionally, fittings shall be sealed in transparent bags or shrink wrapped. Additional packaging for process components, other than fittings, shall be as agreed to by the purchaser and manufacturer.

Table DT-2-1 Metallic Hygienic Unions: Rated Internal Working Pressure

<table>
<thead>
<tr>
<th>Temperature</th>
<th>3 in. Clamp</th>
<th>4 in. Clamp</th>
<th>6 in. Clamp</th>
</tr>
</thead>
<tbody>
<tr>
<td>°F</td>
<td>°C</td>
<td>psi</td>
<td>kPa</td>
</tr>
<tr>
<td>100</td>
<td>38</td>
<td>200</td>
<td>1 379</td>
</tr>
<tr>
<td>250</td>
<td>121</td>
<td>165</td>
<td>1 138</td>
</tr>
</tbody>
</table>

GENERAL NOTES:
(a) These pressure ratings apply to the hygienic clamp and gasket. For information on pressure ratings, see the manufacturer’s guidelines for the components.
(b) For installation practices, refer to Figure DT-2-1.

SEE TABLE DT-2-1 THAT Follows.
DT-7 TOLERANCES

DT-7.1 Fitting and Process Component Tolerances
Tables DT-3-1, DT-3-2, DT-4-1–DT-7.1-1 (metallic), and DT-7-1-2 (polymeric) list the required tolerances for fabricated fittings and process components, excluding tubing, depicted by this Standard. Table DT-7.1-1 lists the required tolerances for metallic machined hygienic clamp ferrule profiles. Table DT-7.1-2 lists the required tolerances for polymeric hygienic clamp ferrule profiles. When metallic ferrules are welded to a process component and polished, then the tolerances in Tables DT-3-1 and DT-3-2 and DT-4-1 apply. For tubing tolerances, refer to ASTM A270, Supplement 2. Table DT-7-3 lists the required tolerances for transfer panel nozzles and jumpers.

These tolerances shall apply after heat and surface treatment. The control portion of the fitting or process components (refer to C in the Table DT-3-1 illustration) is the length from the welding end over which tolerances for wall thickness and O.D. are maintained. The length of the control portion is fixed for all sizes at 0.75 in. (19 mm). For exceptions, see Table DT-4.1.4-1 for ferrule lengths and Table DT-4.1.5-1 for automatic tube weld caps.

DT-7.2 Tubing Tolerances
For tubing tolerances, refer to ASTM A270, including Supplement 2. The squareness of the tube face to outside diameter shall not exceed 0.015 in. (0.38 mm) per inch of diameter. After weld joint preparation, according to MJ-3.4, this value shall meet the requirements for dimension B of Table DT-3-1.

DT-7.3 Transfer Panel Nozzle and Jumper Tolerances
Table DT-7.3-1 lists the required tolerances for transfer panel nozzles and jumpers.
Table DT-2-1 Metallic Fittings: Rated Internal Working Pressure

<table>
<thead>
<tr>
<th>Temperature °F</th>
<th>°C</th>
<th>&lt;3 in. psig</th>
<th>kPa</th>
<th>3 in. psi</th>
<th>kPa</th>
<th>4 in. psi</th>
<th>kPa</th>
<th>6 in. psi</th>
<th>kPa</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>38</td>
<td>200</td>
<td>1379</td>
<td>200</td>
<td>1379</td>
<td>200</td>
<td>1379</td>
<td>150</td>
<td>1034</td>
</tr>
<tr>
<td>200</td>
<td>93</td>
<td>200</td>
<td>1379</td>
<td>200</td>
<td>1379</td>
<td>200</td>
<td>1379</td>
<td>150</td>
<td>1034</td>
</tr>
<tr>
<td>300</td>
<td>149</td>
<td>188</td>
<td>1293</td>
<td>188</td>
<td>1293</td>
<td>188</td>
<td>1293</td>
<td>141</td>
<td>970</td>
</tr>
<tr>
<td>400</td>
<td>204</td>
<td>170</td>
<td>1173</td>
<td>170</td>
<td>1173</td>
<td>170</td>
<td>1173</td>
<td>128</td>
<td>880</td>
</tr>
</tbody>
</table>

GENERAL NOTES:

(a) These pressure ratings apply to metallic fittings, including butt welded or hygienic clamped connections.
(b) For installation practices of hygienic clamp connections, refer to Figure DT-2-1.
(c) Manufacturer may publish higher pressure ratings, see paragraph DT-2.
Figure DT-2-1 Clamp Conditions at Installation

Acceptable

Spacing should be maintained after torquing per DT-9.4(e)

Acceptable

Spacing should be maintained after torquing per DT-9.4(e)

Acceptable

Acceptable

Not Acceptable

When clamp ends are contacting, the required load is not imparted onto the gasket per DT-9.4(e)

Not Acceptable

Not Acceptable

Not Acceptable
### Table DT-3-1 Final Tolerances for Mechanically Polished Fittings and Process Components

<table>
<thead>
<tr>
<th>Nominal Size, in.</th>
<th>O.D.</th>
<th>Wall Thickness</th>
<th>Squareness Face to Tangent, R</th>
<th>Off Angle, $\theta$</th>
<th>Equivalent Angle (for $\theta$)</th>
<th>Off Plane, $P$</th>
<th>Centerline Radius (CLR), $R$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>in.</td>
<td>mm</td>
<td>in. mm</td>
<td>in. mm</td>
<td>deg</td>
<td>in. mm</td>
<td>in. mm</td>
</tr>
<tr>
<td>¼</td>
<td>±0.005</td>
<td>±0.13</td>
<td>+0.003/−0.004</td>
<td>+0.00/−0.10</td>
<td>0.005</td>
<td>0.13</td>
<td>0.009</td>
</tr>
<tr>
<td>⅜</td>
<td>±0.005</td>
<td>±0.13</td>
<td>+0.003/−0.004</td>
<td>+0.008/−0.10</td>
<td>0.005</td>
<td>0.13</td>
<td>0.012</td>
</tr>
<tr>
<td>½</td>
<td>±0.005</td>
<td>±0.13</td>
<td>+0.005/−0.008</td>
<td>+0.13/−0.20</td>
<td>0.005</td>
<td>0.13</td>
<td>0.014</td>
</tr>
<tr>
<td>¾</td>
<td>±0.005</td>
<td>±0.13</td>
<td>+0.005/−0.008</td>
<td>+0.13/−0.20</td>
<td>0.005</td>
<td>0.13</td>
<td>0.018</td>
</tr>
<tr>
<td>1</td>
<td>±0.005</td>
<td>±0.13</td>
<td>+0.005/−0.008</td>
<td>+0.13/−0.20</td>
<td>0.008</td>
<td>0.20</td>
<td>0.025</td>
</tr>
<tr>
<td>1⅛</td>
<td>±0.008</td>
<td>±0.20</td>
<td>+0.005/−0.008</td>
<td>+0.13/−0.20</td>
<td>0.008</td>
<td>0.20</td>
<td>0.034</td>
</tr>
<tr>
<td>2</td>
<td>±0.008</td>
<td>±0.20</td>
<td>+0.005/−0.008</td>
<td>+0.13/−0.20</td>
<td>0.008</td>
<td>0.20</td>
<td>0.043</td>
</tr>
<tr>
<td>2½</td>
<td>±0.010</td>
<td>±0.25</td>
<td>+0.005/−0.008</td>
<td>+0.13/−0.20</td>
<td>0.010</td>
<td>0.25</td>
<td>0.054</td>
</tr>
<tr>
<td>3</td>
<td>±0.010</td>
<td>±0.25</td>
<td>+0.005/−0.008</td>
<td>+0.13/−0.20</td>
<td>0.016</td>
<td>0.41</td>
<td>0.063</td>
</tr>
<tr>
<td>4</td>
<td>±0.015</td>
<td>±0.38</td>
<td>+0.008/−0.010</td>
<td>+0.20/−0.25</td>
<td>0.016</td>
<td>0.41</td>
<td>0.086</td>
</tr>
<tr>
<td>6</td>
<td>±0.030</td>
<td>±0.76</td>
<td>+0.015/−0.015</td>
<td>+0.38/−0.38</td>
<td>0.030</td>
<td>0.76</td>
<td>0.135</td>
</tr>
</tbody>
</table>

**General Notes:**

(a) Tolerance on end-to-end and center-to-end dimension $E$ is ±0.050 in. (1.27 mm) for all fittings and process components depicted. For those not depicted in this standard, see manufacturer for standards.

(b) See Table DT-3-2 for electropolished wall thickness tolerances.

(c) See DT-7 (Tolerances) for control portion lengths.

(d) See Table DT-4-1 for $T$, tangent length dimensions.

(e) Tolerance for centerline radius (CLR) is ±10% of the nominal dimension ($R$).

(f) Refer to DT-7.2 for tubing tolerances.
### Table DT-3-2 Final Tolerances for Electropolished Fittings and Process Components

<table>
<thead>
<tr>
<th>Nominal Size, in.</th>
<th>Wall Thickness</th>
<th>mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>½</td>
<td>+0.003/-0.006</td>
<td>+0.000/-0.15</td>
</tr>
<tr>
<td>⅜</td>
<td>+0.003/-0.006</td>
<td>+0.008/-0.15</td>
</tr>
<tr>
<td>⅛</td>
<td>+0.005/-0.010</td>
<td>+0.13/-0.25</td>
</tr>
<tr>
<td>1</td>
<td>+0.005/-0.010</td>
<td>+0.13/-0.25</td>
</tr>
<tr>
<td>1½</td>
<td>+0.005/-0.010</td>
<td>+0.13/-0.25</td>
</tr>
<tr>
<td>2</td>
<td>+0.005/-0.010</td>
<td>+0.13/-0.25</td>
</tr>
<tr>
<td>2½</td>
<td>+0.005/-0.010</td>
<td>+0.13/-0.25</td>
</tr>
</tbody>
</table>

**GENERAL NOTE:** Refer to DT-7.2 for tubing tolerances.

### Table DT-4.1-1 Tangent Lengths

<table>
<thead>
<tr>
<th>Nominal O.D. Tube Size, In</th>
<th>Tangent, ( T_L )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>In.</td>
</tr>
<tr>
<td>½</td>
<td>1.500</td>
</tr>
<tr>
<td>⅜</td>
<td>1.500</td>
</tr>
<tr>
<td>⅛</td>
<td>1.500</td>
</tr>
<tr>
<td>1</td>
<td>1.500</td>
</tr>
<tr>
<td>1½</td>
<td>1.500</td>
</tr>
<tr>
<td>2</td>
<td>1.500</td>
</tr>
<tr>
<td>2½</td>
<td>1.500</td>
</tr>
<tr>
<td>3</td>
<td>1.750</td>
</tr>
<tr>
<td>4</td>
<td>2.000</td>
</tr>
<tr>
<td>6</td>
<td>2.500</td>
</tr>
</tbody>
</table>

**GENERAL NOTES:**
(a) Minimum tangent lengths for ferrules do not apply. See Table DT-4.1.4-1, dimensions B and C, for available length options.
(b) Minimum tangent length for ⅛ in. to ½ in. size automatic tube weld: 180 deg return bend does not conform [see Table DT-4.1.1-7, dimension B].
(c) Minimum tangent lengths for Tables DT-4.1.2-2, DT-4.1.2-3, DT-4.1.2-7, DT-4.1.3-1, and DT-4.1.3-2 do not apply.

### Table DT-4-1 Nominal O.D. Tubing Sizes

<table>
<thead>
<tr>
<th>Nominal Size, In.</th>
<th>Tube O.D.</th>
<th>Tube Wall Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>in.</td>
<td>mm</td>
</tr>
<tr>
<td>½</td>
<td>0.250</td>
<td>6.35</td>
</tr>
<tr>
<td>⅜</td>
<td>0.375</td>
<td>9.53</td>
</tr>
<tr>
<td>⅛</td>
<td>0.500</td>
<td>12.70</td>
</tr>
<tr>
<td>⅘</td>
<td>0.750</td>
<td>19.05</td>
</tr>
<tr>
<td>1</td>
<td>1.000</td>
<td>25.40</td>
</tr>
<tr>
<td>1½</td>
<td>1.500</td>
<td>38.10</td>
</tr>
<tr>
<td>2</td>
<td>2.000</td>
<td>50.80</td>
</tr>
<tr>
<td>2½</td>
<td>2.500</td>
<td>63.50</td>
</tr>
<tr>
<td>3</td>
<td>3.000</td>
<td>76.20</td>
</tr>
<tr>
<td>4</td>
<td>4.000</td>
<td>101.60</td>
</tr>
<tr>
<td>6</td>
<td>6.000</td>
<td>152.40</td>
</tr>
</tbody>
</table>

**GENERAL NOTE:** Refer to ASTM A270, Supplement 2 for tubing tolerances.

Refer to DT-7.2 for tubing tolerances.
Table DT-4.1.1-9 Automatic Tube Weld: 88-deg Elbow

<table>
<thead>
<tr>
<th>Nominal Size, in</th>
<th>A (in.)</th>
<th>A (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/4</td>
<td>2.700</td>
<td>68.58</td>
</tr>
<tr>
<td>3/8</td>
<td>2.700</td>
<td>68.58</td>
</tr>
<tr>
<td>1/2</td>
<td>3.065</td>
<td>77.85</td>
</tr>
<tr>
<td>3/4</td>
<td>3.065</td>
<td>77.85</td>
</tr>
<tr>
<td>1</td>
<td>3.050</td>
<td>77.47</td>
</tr>
<tr>
<td>1 1/2</td>
<td>3.800</td>
<td>96.52</td>
</tr>
<tr>
<td>2</td>
<td>4.810</td>
<td>122.17</td>
</tr>
<tr>
<td>2 1/2</td>
<td>5.560</td>
<td>141.22</td>
</tr>
<tr>
<td>3</td>
<td>6.310</td>
<td>160.27</td>
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<tr>
<td>4</td>
<td>8.065</td>
<td>204.85</td>
</tr>
<tr>
<td>6</td>
<td>11.580</td>
<td>294.13</td>
</tr>
</tbody>
</table>
Table DT-4.1.1-10 Automatic Tube Weld: 92-deg Elbow

<table>
<thead>
<tr>
<th>Nominal Size, in</th>
<th>A (in.)</th>
<th>A (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/4</td>
<td>2.530</td>
<td>64.26</td>
</tr>
<tr>
<td>3/8</td>
<td>2.530</td>
<td>64.26</td>
</tr>
<tr>
<td>1/2</td>
<td>2.930</td>
<td>74.42</td>
</tr>
<tr>
<td>3/4</td>
<td>2.930</td>
<td>74.42</td>
</tr>
<tr>
<td>1</td>
<td>2.950</td>
<td>74.93</td>
</tr>
<tr>
<td>1 1/2</td>
<td>3.690</td>
<td>93.73</td>
</tr>
<tr>
<td>2</td>
<td>4.690</td>
<td>119.13</td>
</tr>
<tr>
<td>2 1/2</td>
<td>5.440</td>
<td>138.18</td>
</tr>
<tr>
<td>3</td>
<td>6.190</td>
<td>157.23</td>
</tr>
<tr>
<td>4</td>
<td>7.930</td>
<td>201.42</td>
</tr>
<tr>
<td>6</td>
<td>11.410</td>
<td>289.81</td>
</tr>
</tbody>
</table>
### Table DT-4.1.2-6 Automatic Tube Weld: Reducing Tee

<table>
<thead>
<tr>
<th>Nominal Size, in.</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
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<td>73.03</td>
</tr>
<tr>
<td>$\frac{3}{4}$</td>
<td>3.125</td>
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### Table DT-4.1.2-6 Automatic Tube Weld: Reducing Tee (Cont'd)

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<th>Nominal Size, in.</th>
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</tr>
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<tr>
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<td>4.125</td>
<td>104.78</td>
</tr>
<tr>
<td>$\frac{1}{2}$</td>
<td>4.125</td>
<td>104.78</td>
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<tr>
<td>$\frac{3}{4}$</td>
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</tr>
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</table>

Insert 6"x1/2" thru 6"x2-1/2" sizes

<table>
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<th>A</th>
<th>B</th>
</tr>
</thead>
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<td>142.88</td>
</tr>
<tr>
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<td>5.625</td>
<td>142.88</td>
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<table>
<thead>
<tr>
<th>Nominal Size, in.</th>
<th>A</th>
<th>B</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\frac{1}{2}$</td>
<td>5.625</td>
<td>142.88</td>
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<tr>
<td>$\frac{3}{4}$</td>
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152
Table DT-4.1.2-8 Hygienic Clamp Joint: Reducing Tee

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<td></td>
<td>in.</td>
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<tr>
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<td>60.33</td>
</tr>
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<td>1/2</td>
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<td>63.50</td>
</tr>
<tr>
<td>2/3</td>
<td>2.500</td>
<td>63.50</td>
</tr>
<tr>
<td>5/8</td>
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<td>63.50</td>
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</tr>
<tr>
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<td>73.03</td>
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Insert 6"x1/2" thru 6"x2-1/2" sizes

- 6 1/2 7.125 180.98 5.125 130.18
- 6 3/4 7.125 180.98 5.125 130.18
- 6 1 7.125 180.98 5.125 130.18
- 6 1 1/2 7.125 180.98 5.125 130.18
- 6 2 7.125 180.98 5.375 136.53
- 6 2 1/2 7.125 180.98 5.375 136.53

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Table DT-4.1.2-12 Automatic Tube Weld: Standard-Outlet Hygienic Clamp Joint Tee

<table>
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<tr>
<td>in.</td>
<td>mm</td>
<td>in.</td>
</tr>
<tr>
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</tr>
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<td>53.98</td>
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### Table DT-4.1.2-13 Automatic Tube Weld: Standard-Outlet Hygienic Clamp Joint Reducing Tee

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</tr>
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<tr>
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### Table DT-4.4.1-1 Hygienic Clamp Joint: Weir-Style Diaphragm Valve

![Diagram of a Weir-Style Diaphragm Valve]

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<th>Nominal Size, in.</th>
<th>A, in.</th>
<th>A, mm</th>
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<tbody>
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<td>63.50</td>
</tr>
<tr>
<td>5/8 fractional</td>
<td>2.500</td>
<td>63.50</td>
</tr>
<tr>
<td>3/4 fractional</td>
<td>2.500</td>
<td>63.50</td>
</tr>
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<td>3.500</td>
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</tr>
<tr>
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<td>4.000</td>
<td>101.60</td>
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Two-Way.
<table>
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<th>Type</th>
<th>Tube Diameter, ( A )</th>
<th>L.D. Bore, ( B )</th>
<th>Flange Diameter, ( D ), E, ref.</th>
<th>Flange Thickness, ( E ), ref.</th>
<th>Groove Diameter, ( F )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td>Tolerance, ( \pm ) Dimension</td>
<td>Tolerance, ( \pm ) Dimension</td>
<td>Flange Angle, ( C ), deg</td>
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<td>6.35</td>
<td>0.005</td>
<td>0.13</td>
<td>0.180</td>
</tr>
<tr>
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<td>0.13</td>
<td>0.305</td>
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<td>12.70</td>
<td>0.005</td>
<td>0.13</td>
<td>0.370</td>
</tr>
<tr>
<td>( \frac{3}{4} )</td>
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<td>19.05</td>
<td>0.005</td>
<td>0.13</td>
<td>0.620</td>
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</tr>
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</table>

<table>
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<th>Nominal Size, in.</th>
<th>Type</th>
<th>Groove Depth, ( G )</th>
<th>Face Offset, ( H )</th>
<th>Groove Detail, ( R3 )</th>
<th>Groove Detail, ( R4 )</th>
<th>Radius, ( R2 )</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Tolerance, ( \pm ) Dimension</td>
<td>Tolerance, ( \pm ) Dimension</td>
<td>Tolerance, ( \pm ) Dimension</td>
</tr>
<tr>
<td>( \frac{1}{4} )</td>
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<td>0.005</td>
<td>0.13</td>
<td>0.301</td>
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<td>2.16</td>
<td>0.005</td>
<td>0.13</td>
<td>0.301</td>
</tr>
<tr>
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<td>A</td>
<td>0.085</td>
<td>2.16</td>
<td>0.005</td>
<td>0.13</td>
<td>0.301</td>
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<td>( \frac{3}{4} )</td>
<td>A</td>
<td>0.085</td>
<td>2.16</td>
<td>0.005</td>
<td>0.13</td>
<td>0.301</td>
</tr>
<tr>
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<td>A</td>
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<td>0.005</td>
<td>0.13</td>
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Table DT-7-2: Metallic Hygienic Clamp Ferrule Standard Dimensions and Tolerances (Cont’d)

**Type B**

<table>
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<th>Nominal Size, in.</th>
<th>Type</th>
<th>Tube Diameter, ( A )</th>
<th>L.D. Bore, ( B )</th>
<th>Flange Diameter, ( D )</th>
<th>Flange Thickness, ( E_{ref} )</th>
<th>Groove Diameter, ( F )</th>
</tr>
</thead>
<tbody>
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<td>Dimension, Tolerance, ( \pm )</td>
<td>Dimension, Tolerance, ( \pm )</td>
<td>Dimension, Tolerance, ( \pm )</td>
<td>Dimension, Tolerance, ( \pm )</td>
</tr>
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<td></td>
<td>in.</td>
<td>mm</td>
<td>in.</td>
<td>mm</td>
<td>in.</td>
</tr>
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<td>B</td>
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<td>25.40</td>
<td>0.005</td>
<td>0.13</td>
<td>0.870</td>
</tr>
<tr>
<td>1( \frac{1}{2} )</td>
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<td>0.20</td>
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</tr>
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<td>50.80</td>
<td>0.004</td>
<td>0.20</td>
<td>1.870</td>
</tr>
<tr>
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<td>63.50</td>
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<td>0.25</td>
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<th>Groove Depth, ( G )</th>
<th>Groove Detail, ( R3 )</th>
<th>Groove Detail, ( R4 )</th>
<th>Radius, ( R2 )</th>
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<td>Dimension, Tolerance, ( \pm )</td>
<td>Dimension, Tolerance, ( \pm )</td>
<td>Dimension, Tolerance, ( \pm )</td>
</tr>
<tr>
<td></td>
<td></td>
<td>in.</td>
<td>mm</td>
<td>in.</td>
<td>mm</td>
</tr>
<tr>
<td>1</td>
<td>B</td>
<td>0.063</td>
<td>1.60</td>
<td>0.005</td>
<td>0.13</td>
</tr>
<tr>
<td>1( \frac{1}{2} )</td>
<td>B</td>
<td>0.063</td>
<td>1.60</td>
<td>0.005</td>
<td>0.13</td>
</tr>
<tr>
<td>2</td>
<td>B</td>
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<td>0.005</td>
<td>0.13</td>
</tr>
</tbody>
</table>
### Table DT-7-1 Metallic Hygienic Clamp Ferrule Standard Dimensions and Tolerances (Cont’d)

<table>
<thead>
<tr>
<th>Nominal Size, in.</th>
<th>Type</th>
<th>Groove Depth, G Dimension ±</th>
<th>Face Offset, H Dimension ±</th>
<th>Groove Detail, R3 Dimension ±</th>
<th>Groove Detail, R4 Dimension ±</th>
<th>Groove Detail, A1, deg Dimension ±</th>
<th>Radius, R1, max. Dimension ±</th>
<th>Radius, R2 Maximum Dimension ±</th>
<th>Radius, R2 Minimum Dimension ±</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 1/2</td>
<td>B</td>
<td>0.063 1.60 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>46 1</td>
<td>0.063 1.60 0.031 013 N/A N/A</td>
<td>0.063 1.60 0.031 013 N/A N/A</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>B</td>
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<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>46 1</td>
<td>0.063 1.60 0.031 013 N/A N/A</td>
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<td></td>
</tr>
<tr>
<td>4</td>
<td>B</td>
<td>0.063 1.60 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>46 1</td>
<td>0.063 1.60 0.031 013 N/A N/A</td>
<td>0.063 1.60 0.031 013 N/A N/A</td>
<td></td>
</tr>
<tr>
<td>6</td>
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<td>0.063 1.60 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>0.047 1.19 0.005 013 N/A N/A</td>
<td>46 1</td>
<td>0.063 1.60 0.031 013 N/A N/A</td>
<td>0.063 1.60 0.031 013 N/A N/A</td>
<td></td>
</tr>
</tbody>
</table>

**GENERAL NOTES:**

(a) Dimensions and tolerances apply to machined finishes only.

(b) I.D. bore dimension B should be measured on the ferrule face side only.
### Table DT-7-2 Polymeric Hygienic Clamp Ferrule Standard Dimensions and Tolerances

#### Type A

![Groove Detail Diagram](Image)

<table>
<thead>
<tr>
<th>Nominal Size, in.</th>
<th>Tube Diameter, A</th>
<th>I.D. Bore, B</th>
<th>Flange Angle, C, deg</th>
<th>Flange Diameter, D</th>
<th>Flange Thickness, E, ref.</th>
<th>Groove Diameter, F</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dimension</td>
<td>Dimension</td>
<td>Tolerance, ±</td>
<td>Dimension</td>
<td>Tolerance, ±</td>
<td>Dimension</td>
</tr>
<tr>
<td></td>
<td>In.</td>
<td>mm</td>
<td>In.</td>
<td>mm</td>
<td>In.</td>
<td>mm</td>
</tr>
<tr>
<td>1/4</td>
<td>0.250</td>
<td>6.35</td>
<td>0.180</td>
<td>4.57</td>
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<td>0.25</td>
</tr>
<tr>
<td>1/8</td>
<td>0.375</td>
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<td>0.305</td>
<td>7.75</td>
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</tr>
<tr>
<td>1/4</td>
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<td>12.70</td>
<td>0.370</td>
<td>9.40</td>
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<td>0.25</td>
</tr>
<tr>
<td>3/8</td>
<td>0.750</td>
<td>19.05</td>
<td>0.620</td>
<td>15.75</td>
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<td>0.25</td>
</tr>
<tr>
<td>1</td>
<td>1.000</td>
<td>25.40</td>
<td>0.870</td>
<td>22.10</td>
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<td>0.25</td>
</tr>
</tbody>
</table>

#### Groove Details

<table>
<thead>
<tr>
<th>Nominal Size, in.</th>
<th>Groove Depth, G</th>
<th>Face Offset, H</th>
<th>Groove Detail, R3</th>
<th>Groove Detail, R4</th>
<th>Groove Detail, Groove Detail,</th>
<th>Radius, R1,</th>
<th>Radius, R2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dimension</td>
<td>Dimension</td>
<td>Tolerance, ±</td>
<td>Dimension</td>
<td>Tolerance, ±</td>
<td>Dimen.</td>
<td>Dimen.</td>
</tr>
<tr>
<td></td>
<td>In.</td>
<td>mm</td>
<td>In.</td>
<td>mm</td>
<td>In.</td>
<td>In.</td>
<td>In.</td>
</tr>
<tr>
<td>1/4</td>
<td>0.085</td>
<td>2.16</td>
<td>0.005</td>
<td>0.13</td>
<td>0.031</td>
<td>0.031</td>
<td>0.013</td>
</tr>
<tr>
<td>1/8</td>
<td>0.085</td>
<td>2.16</td>
<td>0.005</td>
<td>0.13</td>
<td>0.031</td>
<td>0.031</td>
<td>0.013</td>
</tr>
<tr>
<td>1/4</td>
<td>0.085</td>
<td>2.16</td>
<td>0.005</td>
<td>0.13</td>
<td>0.031</td>
<td>0.031</td>
<td>0.013</td>
</tr>
<tr>
<td>3/8</td>
<td>0.085</td>
<td>2.16</td>
<td>0.005</td>
<td>0.13</td>
<td>0.031</td>
<td>0.031</td>
<td>0.013</td>
</tr>
<tr>
<td>1</td>
<td>0.085</td>
<td>2.16</td>
<td>0.005</td>
<td>0.13</td>
<td>0.031</td>
<td>0.031</td>
<td>0.013</td>
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### Table DT-7-2 Polymeric Hygienic Clamp Ferrule Standard Dimensions and Tolerances (Cont’d)

#### Type B

<table>
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<th>Nominal Size, in.</th>
<th>Type</th>
<th>Tube Diameter, A</th>
<th>Flange Angle, C, deg</th>
<th>Flange Diameter, D</th>
<th>Flange Thickness, E, ref.</th>
<th>Groove Diameter, F</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Dimension</td>
<td>Tolerance, ±</td>
<td>Dimension</td>
<td>Tolerance, ±</td>
<td>Dimension</td>
</tr>
<tr>
<td></td>
<td></td>
<td>in.</td>
<td>mm</td>
<td>in.</td>
<td>mm</td>
<td>in.</td>
</tr>
<tr>
<td>1</td>
<td>B</td>
<td>1.00</td>
<td>0.670</td>
<td>0.010</td>
<td>0.25</td>
<td>20</td>
</tr>
<tr>
<td>1½</td>
<td>B</td>
<td>1.50</td>
<td>1.370</td>
<td>0.010</td>
<td>0.25</td>
<td>20</td>
</tr>
<tr>
<td>2</td>
<td>B</td>
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<td>1.870</td>
<td>0.010</td>
<td>0.25</td>
<td>20</td>
</tr>
<tr>
<td>2½</td>
<td>B</td>
<td>2.50</td>
<td>2.370</td>
<td>0.010</td>
<td>0.25</td>
<td>20</td>
</tr>
<tr>
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<td>B</td>
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<td>20</td>
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<td>101.60</td>
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<td>0.25</td>
<td>20</td>
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</table>

### Groove Depth, G

<table>
<thead>
<tr>
<th>Nominal Size, in.</th>
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<th>Dimension</th>
<th>Tolerance, ±</th>
<th>Face Offset, H</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>in.</td>
<td>mm</td>
<td>in.</td>
</tr>
<tr>
<td>1</td>
<td>B</td>
<td>0.063</td>
<td>0.600</td>
<td>0.005</td>
</tr>
<tr>
<td>1½</td>
<td>B</td>
<td>0.063</td>
<td>0.600</td>
<td>0.005</td>
</tr>
<tr>
<td>2</td>
<td>B</td>
<td>0.063</td>
<td>0.600</td>
<td>0.005</td>
</tr>
<tr>
<td>2½</td>
<td>B</td>
<td>0.063</td>
<td>0.600</td>
<td>0.005</td>
</tr>
<tr>
<td>3</td>
<td>B</td>
<td>0.063</td>
<td>0.600</td>
<td>0.005</td>
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### Groove Detail, R3

<table>
<thead>
<tr>
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<th>Tolerance, ±</th>
<th>Face Offset, H</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>in.</td>
<td>mm</td>
<td>in.</td>
</tr>
<tr>
<td>46</td>
<td>1</td>
<td>0.063</td>
<td>1.60</td>
</tr>
<tr>
<td>46</td>
<td>1</td>
<td>0.063</td>
<td>1.60</td>
</tr>
<tr>
<td>46</td>
<td>1</td>
<td>0.063</td>
<td>1.60</td>
</tr>
<tr>
<td>46</td>
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<td>0.063</td>
<td>1.60</td>
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</table>

### Groove Detail, R4

<table>
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<th>Tolerance, ±</th>
<th>Face Offset, H</th>
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</thead>
<tbody>
<tr>
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<td>in.</td>
<td>mm</td>
<td>in.</td>
</tr>
<tr>
<td>46</td>
<td>1</td>
<td>0.063</td>
<td>1.60</td>
</tr>
<tr>
<td>46</td>
<td>1</td>
<td>0.063</td>
<td>1.60</td>
</tr>
<tr>
<td>46</td>
<td>1</td>
<td>0.063</td>
<td>1.60</td>
</tr>
<tr>
<td>46</td>
<td>1</td>
<td>0.063</td>
<td>1.60</td>
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</tbody>
</table>

### Radius, R2

<table>
<thead>
<tr>
<th>Radius, R2</th>
<th>Dimension</th>
<th>Tolerance, ±</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>in.</td>
<td>mm</td>
</tr>
<tr>
<td>46</td>
<td>1</td>
<td>0.063</td>
</tr>
<tr>
<td>46</td>
<td>1</td>
<td>0.063</td>
</tr>
<tr>
<td>46</td>
<td>1</td>
<td>0.063</td>
</tr>
<tr>
<td>46</td>
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<td>0.063</td>
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</tbody>
</table>

See revised table column below.

See proposed new table graphic below.
**Type B**

Proposed new Graphic for Table DT-7-2 Type B

Revised values for "Face Offset, H" table column.
<table>
<thead>
<tr>
<th>Connection Nominal Size, in.</th>
<th>Flattening Tolerance (Tol. 1) Maximum Gap Allowed in.</th>
<th>Flattening Tolerance (Tol. 1) Maximum Gap Allowed mm</th>
<th>Centerto-Center Distance Tolerance, in. mm</th>
<th>Position Tolerance (Tol. 2) Maximum Deviation from the Design Distance between Centerlines in. mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>½</td>
<td>0.010</td>
<td>0.25</td>
<td>0.015</td>
<td>0.38</td>
</tr>
<tr>
<td>¾</td>
<td>0.010</td>
<td>0.25</td>
<td>0.015</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>0.020</td>
<td>0.51</td>
<td>0.015</td>
<td>0.38</td>
</tr>
<tr>
<td>1 ½</td>
<td>0.020</td>
<td>0.51</td>
<td>0.015</td>
<td>0.38</td>
</tr>
<tr>
<td>2</td>
<td>0.025</td>
<td>0.64</td>
<td>0.017</td>
<td>0.38</td>
</tr>
<tr>
<td>2 ½</td>
<td>0.025</td>
<td>0.64</td>
<td>0.015</td>
<td>0.38</td>
</tr>
<tr>
<td>3</td>
<td>0.030</td>
<td>0.76</td>
<td>0.015</td>
<td>0.38</td>
</tr>
<tr>
<td>4</td>
<td>0.040</td>
<td>1.02</td>
<td>0.015</td>
<td>0.38</td>
</tr>
</tbody>
</table>
Table DT-11.1.1-1

<table>
<thead>
<tr>
<th>Process Component</th>
<th>Heat Number or Unique Identifier</th>
<th>Material Type</th>
<th>Valve Pressure Rating</th>
<th>Manufacturer’s name, logo or trademark</th>
<th>Reference to this Standard (BPE)</th>
<th>Process Contact Surface Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fittings</td>
<td>Required</td>
<td>Required</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Valves</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Instrumentation</td>
<td>Required</td>
<td>...</td>
<td>Required</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

General Note: When the size of a component does not allow complete marking per DT-11.1, the above table defines the marking requirements.
PART PI
PROCESS INSTRUMENTATION

PI-1 PURPOSE AND SCOPE

The purpose of this Part is to provide requirements for process instrumentation. This Part defines the minimum requirements for the application of process contact instrumentation in hygienic systems. This Part applies to instrument components that are in contact with the process.

PI-2 PROCESS INSTRUMENTATION GENERAL REQUIREMENTS

Process instrumentation includes sensors, transmitters, analyzers, controllers, recorders, transducers, final control elements, signal converting, or conditioning devices, and supporting components (e.g., light sources and sight glasses).

Final control elements such as control valves or variable-speed pumps are covered in other Parts of this Standard.

PI-2.1 General Considerations

PI-2.1.1 Installation. All process instrumentation should be installed per the manufacturer's instructions for proper operation.

Indicating devices shall be oriented and located such that they can be easily viewed for maintenance and operation purposes. Instruments shall be located and oriented so connections can be easily made and adequate space is provided for calibration, maintenance, and replacement.

Instruments, connecting tubing, and systems shall be supported by mounting brackets as necessary to prevent potential stresses on the instrument and tubing system, and to allow for ease of removal without disturbing the adjacent components.

Remote-mounted devices (transmitters, etc.) shall be mounted with appropriate supports to a permanent structure. Ladders, handrails, guardrails, etc., shall not be acceptable mounting supports. If necessary, dedicated instrument supports shall be provided.

PI-2.1.2 Internal Design and Process Connections

(a) Sensors shall be designed in such a way that a failure will not cause contamination hazards to the process and environment.

(b) Liquid-filled elements in measuring devices should not contain materials that can potentially impact product quality.

(c) The internal volume of the liquid-filled elements should be minimized.

(d) Instruments should have integral hygienic fittings. Threaded ferrules are not acceptable to convert standard instrumentation to hygienic standards. Process connections shall be of hygienic design, per the requirements of Parts SD and SG, in order to ensure cleanliness of the system.

(e) Gauge siphons (pigtails) shall not be used. Isolation valves should be used if required by the owner/user for routine maintenance or calibration.

(f) Where required for proper operation, all instruments, valves, and in-line devices shall be permanently marked for proper installation (flow direction or orientation).

PI-2.1.3 Exterior Design. Material selection shall consider all intended uses, ambient conditions, and cleaning agents as specified by the owner/user. Sensors and transmitters shall be housed in an enclosure with an appropriate protection rating as specified by the owner/user and shall comply with Parts SD and SG.

PI-2.2 Instrumentation Categories

Process instrumentation may be broadly categorized by process installation type as in-line, insertion, at-line, and off-line devices. Process instruments within these categories share some basic installation recommendations for hygienic design and in-process performance.

PI-2.2.1 In-Line Devices. In-line process instruments are self-contained devices installed directly into the process tubing system similar to a standard fitting. Basic installation requirements for hygienic operation as found in Part SD pertain to in-line process instrumentation.

In-line devices may be installed directly in the process stream or in a bypass line to facilitate periodic services (see Figure PI-2.2.1-1). Device-specific recommendations are defined later in this Part.

PI-2.2.2 Insertion Devices. Insertion devices are instruments that are inserted directly into the process tubing system or process vessel to measure a parameter.
will optimize the flowmeter performance over the flow rate range with a pressure drop that is acceptable for both CIP/SIP and normal operating conditions.

Chemical compatibility should be established between process-wetted materials [i.e., the flow tube(s), the manifold or flow splitter, the process connections] and the process fluid and the cleaning fluid (e.g., process, CIP, SIP, and passivation).

**PI-4.1.7 Maintenance.** There are no specific maintenance requirements for a Coriolis mass flowmeter.

**PI-4.1.7.1 Seals/Gaskets.** The manufacturer shall advise the owner/user if the process connections are not fully welded to the sensor body and if use of a seal/gasket assembly that requires periodic inspection is needed.

**PI-4.1.7.2 Recalibration/Verification Schedule.** A Coriolis flowmeter properly installed and operated within the manufacturer's guidelines on clean, noncorrosive, and nonabrasive fluids is stable. The frequency of recalibration or verification of the flowmeter is governed by the criticality of the measurement and the nature of the operating conditions. The frequency of calibration verification shall be determined by the owner/user.

As the Coriolis mass flowmeter is a mass flow device, it is preferable to perform the calibration verification against a mass traceable reference. Calibration against a volume traceable reference combined with a density traceable reference may be used where applicable. Master flowmeters may be used to verify calibration of Coriolis flowmeters.

Calibration of the mass reference or a master flowmeter shall be traceable to nationally recognized standards or another standard as agreed to by the owner/user and manufacturer.

Calibration procedures can be found in ASME MFC-11.

(19) **PI-4.2 Turbine Flowmeter**

**PI-4.2.1 General.** This section provides for the hygienic design and installation requirements of turbine flowmeters specific to bioprocessing applications.

**PI-4.2.2 Components.** Turbine flowmeters typically consist of process contact and non-process contact components (see Figure PI-4.2.2-1 for examples of retaining versus non-retaining ring designs).

**PI-4.2.2.1 Process Contact Components**

(a) **Meter Housing With Bore.** The bore size shall be based on the manufacturers’ specified flow range.

(b) **Rotor Assembly.** The rotor assembly shall be a solid rotor.

(c) **Retaining Ring(s) (Optional).** The retaining ring groove and retaining ring shall not contribute to process fluid holdup.

(d) **Internal Support Hangers.** Each support hanger shall be of a solid piece construction.

(e) **Process Connections.** The turbine flowmeter shall use process connections per Part SD. Sealing gaskets shall meet the requirements of Part SG.

(f) **Flow Straightener Housing (Optional).** In a non-retaining ring design, the flow straightener housing shall be designed to keep the turbine flowmeter internals in place.

All process contact surface finishes of the turbine flowmeter shall be specified by the owner/user in accordance with the surface designations in Part SF. All process contact surface materials shall comply with the applicable sections of Part MM, Part PM, or both.

**PI-4.2.2.2 Non-process Contact Components.** The pickup shall not contact the process.

**PI-4.2.3 Installation.** The flowmeter shall be installed with a minimum straight run of 10 pipe diameters upstream of the inlet and 5 pipe diameters downstream of the outlet.

**PI-4.2.3.1 Drainability.** The installed flowmeter shall meet the drainability requirements of Part SD.

If an air purge is required to fully drain the process line, the owner/user shall consult the manufacturer for the maximum velocity to prevent over-ringing of the flowmeter. Refer to PI-4.2.4.

Turbine flowmeters shall be drainable by gravity.
Figure PI-4.2.2-1 Typical Turbine Flowmeters

(a) Retaining Ring Design

(b) Non-retaining Ring Design
Maximum process fluid velocity should be taken into consideration during air purge or clean steam sanitization to prevent over-ranging of the bearings and damaging the rotor assembly. Turbine flowmeter selection details are provided in ASME MFC-22.

These instruments use high-frequency electromagnetic signals to measure the distance between the instrument and the upper surface of the targeted process fluid directly below the instrument.

These instruments should be configured for the specific combination of vessel and process fluid to ensure measurement performance.

PI-5.1.2 Essential Components. A radar level instrument is comprised of an antenna, a process connection, and supporting electronics.

The process contact components of a radar level instrument shall meet the surface requirements as specified in Part SF and material of construction requirements as specified in Part MM or Part PM. Requirements of process contact welds are specified in Part MJ.

PI-5.1.2.1 Antenna. The antenna of a radar level instrument is available in bulb, horn, or rod construction (see Figure PI-5.1.2.1-1). The antenna is either isolated by or encapsulated in polymeric or other nonmetallic material.

PI-5.1.2.2 Process Connection. The radar level instruments and isolating seals shall use hygienic connections as per Parts SD, DT, and 5G.

PI-5.1.3 Installation. The mounting location and orientation of the antenna should be in accordance with the manufacturer’s recommendations. This is important in order to achieve the specified performance, as well as to ensure cleanliness.

PI-5.1.3.1 Drainability. To prevent any liquid holdup on the sensor’s process contact surfaces, the radar level instrument should be mounted perpendicular to the surface of the process fluid.

PI-5.1.3.2 Cleanability. Cleanability is determined by the combination of antenna design and geometry and the location of the process connection. For effective cleanability, shadowing effects, recessed areas, and annular spaces created by the installed antenna should be taken into consideration.

PI-5.1.3.3 Mounting Location. The process connection should be located on top of the vessel. For the most accurate results, the mounting location should be selected to minimize or avoid obstructions within the space below the antenna.

To ensure a reliable level measurement, the mounting location should be \( \frac{1}{4} \) to \( \frac{7}{8} \) of the vessel radius, as measured from the vessel centerline (see Figure PI-5.1.3.3-1).

The minimum detectable vessel level is given by the mounting location. To determine if the vessel is completely empty, the sensor should be pointed to the lowest section of the vessel.
Conductivity sensor components combined in one body vary depending on the sensor type (see Figure PI-8.1.2-1).

The section only provides device specific requirements related to conductivity sensors. See PI-2.1 for information on general requirements.

There are three basic types of conductivity sensors designed for specific measurement ranges: two-electrode, multielectrode, and electrodeless. Sensor-type selection is dependent on intended measurement and installation requirements. The owner/user should consult the manufacturer for final selection suitability based on the design criteria and may use PI-8.1.5 as a general reference.

Temperature impacts conductivity measurements by increasing resistance as temperature increases. All conductivity sensors shall use either an internal or external temperature sensor for compensation to express the conductivity of the solution at a standard temperature.

PI-8.1.2 Essential Components. An electrode-type sensor has wetted electrodes, between which an AC voltage is applied and the amperage measured is expressed as conductivity (see Figure PI-8.1.2-1).

An electrodeless sensor consists of a nonconductive body material encapsulating two nonwetted coils/toroids. Measurements are made of the induced current from the powered coil to the measurement coil by having the process fluid pass through the center and around the outside of the nonwetted coils (see Figure PI-8.1.2-1).

**PI-8.1.2.1 Sensor Types.** There are three typical designs of conductivity sensors.

(a) Two-Electrode. A two-electrode-type conductivity sensor generally consists of an outer shaft/body and inner electrode. Conductivity measurements are made in this interstitial space and require this area to be fully wetted.

(b) Multielectrode. A multielectrode-type conductivity sensor consists of a wetted body with inner and outer electrodes generally arranged on the same plane. Conductivity measurements are made immediately in front of and in between the electrodes and require this area to be fully wetted. A nonconductive material of construction is required between the electrodes with the sensor body generally used as the insulator.

(c) Electrodeless. An electrodeless-type conductivity sensor consists of two encapsulated coils. One coil generates a current and the second coil detects changes proportional to the conductivity of the process fluid. An electrodeless sensor requires process fluid through and around the coils for proper measurements.

**PI-8.1.3 Installation.** All conductivity sensors require full immersion of their measurement electrodes or coils into the process fluid for proper functionality. Most conductivity sensors are offered as insertion devices, with some manufacturers offering in-line options.

Electrode conductivity sensors should be installed with flow into the sensor while maintaining drainability. Figure PI-8.1.3-1 provides examples of acceptable installations.

**PI-8.1.2.2 Non-Process Contact Components**

The internal temperature sensor is an integral non-process contact component that is typical for all types of conductivity sensors.
**PI-8.1.3.1 Drainability.** Conductivity sensors shall be installed in accordance with Part SD to ensure drainability.

**PI-8.1.3.2 Cleanability.** Conductivity sensors shall be cleanable as required in Part SD.

**PI-8.1.3.3 Mounting Location.** Insertion electrode sensors perform best with process fluid flow into the sensor’s electrode(s) as shown in Figure PI-8.1.3.1. Electrodeless sensors shall be mounted with coils fully immersed in the process.

In-line installations shall ensure continuous process fluid flow around sensor electrodes or coils to maximize measurement accuracy.

**PI-8.1.3.4 Orientation.** Conductivity sensors shall be oriented to ensure electrodes or coils are fully wetted. Horizontal installations should not be top-mounted insertions to avoid air pockets or bubbles interfering with the measurement.

**PI-8.1.3.5 Immersion Length/Depth.** The owner/user shall follow the manufacturer’s recommendations regarding immersion length/depth to allow for sufficient clearance of electrodes or coil fields.

**PI-8.1.3.6 Special Consideration.** Sensor electrodes mounted too close to tube or vessel walls may cause conductivity field distortions resulting in measurement inaccuracies. The owner/user shall consult the manufacturer’s clearance requirements and recommendations (see Figure PI-8.1.3.6-1).

Conductivity sensors for purified water of WFI systems shall be installed in such a manner as to allow periodic calibration in accordance with compendial water requirements.

**PI-8.1.4 Performance.** Conductivity devices are generally required to be full of process liquid and free of air pockets. Consult the manufacturer for details.

**PI-8.1.4.1 Accuracy.** Compendial water guidelines establish a standard for the quality assessment of water based on measurements of the electrolytic conductivity. Sensors used for WFI or PW systems shall comply with this accuracy requirement.

**PI-8.1.4.2 Response Time.** Conductivity sensor response times are impacted predominately by the response time of the temperature-sensing element. All sensor types are responsive to changing conductivity levels without changes in temperature. Electrodeless
PI-8.1.3.1 Mounting Location.
Special installation considerations and process influences should be an integral part of the decision for conductivity sensor mounting locations. See PI-8.1.3.2, PI-8.1.3.3 and PI-8.1.3.4 for details.

PI-8.1.3.2 Orientation.
Conductivity sensors should not be mounted in locations or orientations that promote gas bubble collection around the sensor. Gas bubbles can affect sensor performance. Figure PI-8.1.3.2-1 provides examples of acceptable orientations. (Figure PI-8.1.3.2-1 Acceptable Orientations for Conductivity Sensors goes here)

PI-8.1.3.3 Immersion Length/Depth.
All conductivity sensors require full immersion of their measurement electrodes or coils into the process fluid for proper functionality. Conductivity sensors should be inserted to allow for sufficient clearance of electrodes and coil fields (see PI-8.1.3.4 for details).

PI-8.1.3.4 Special Installation Considerations.
(a) Sensor electrodes mounted too close to tube or vessel walls can cause conductivity field distortions resulting in measurement inaccuracies. The owner/user shall consult the manufacturer’s clearance requirements and recommendations (see Figure PI-8.1.3.4-1). (Figure PI-8.1.3.4-1 Installation Clearance Requirements goes here)

(b) Conductivity sensors shall not be located directly in the flow path of another sensor or inlet that causes a significant change in conductivity (e.g. following a glass measuring electrode pH sensor or injection port).

(c) Installation of conductivity sensors in locations where incomplete liquid mixing and reactions can occur should be avoided. Incomplete liquid mixing and reactions can result in measurements that are not representative of the average conductivity.

(d) Stagnant zones should be avoided. Stagnant zones can result in measurements that are not representative of the average conductivity and increase sensor maintenance.

See PI-8.1.4.3 for other relevant information.

PI-8.1.4 Performance.

PI-8.1.4.1 Accuracy.
In-line installations shall ensure continuous process fluid flow around sensor electrodes or coils to maximize measurement accuracy.

PI-8.1.4.2 Response Time.
Conductivity sensor response times are impacted predominately by the response time of the temperature-sensing element. Details can be found in Nonmandatory Appendix DD.

PI-8.1.4.3 Process Influences.
(a) Entrained air impacts conductivity measurements.
(b) Change of product and process temperature impact conductivity measurements. All conductivity sensors shall use either an internal or external temperature sensor for compensation, as required.

PI-8.1.4.4 Ambient Influences.
Electro-magnetic interferences that affect conductivity sensor performance should be avoided.

PI-8.1.5 Selection.
Conductivity sensors shall be selected based on process conditions and specific performance requirements (e.g. conductivity range and chemical compatibility). Guidance for application based sensor selection can be found in Nonmandatory Appendix DD.
PI-8.1.3.2-1 Acceptable Orientations for Conductivity Sensors

**PI-8.1.3.2-1 Acceptable Orientations for Conductivity Sensors**

- Flow
- Slope

**Figure PI-8.1.3.2-1 Acceptable Installations for Conductivity Sensors**

- Flow

**PI-8.1.3.4-1**

- Sensors are slower to respond in processes with changing temperatures due to the nonconductive nature of the coils’ encapsulating material.

**PI-8.1.4.3 Process Influences.** Temperature changes impact conductivity measurements of a process fluid. All conductivity sensors shall use either an internal or external temperature sensor for compensation as required.

**PI-8.1.4.4 Ambient Influences.** Not applicable.

**PI-8.1.5 Selection.** Sensor selection shall be based on the anticipated conductivity range of the process. The following may be used as a general selection reference:

(a) Two-electrode sensors should be selected for WFI systems, PW systems, or other process fluids that have low conductivity ranges. These sensors are most suitable for systems ranging from 0.02 μS/cm to 10 000 μS/cm.

(b) Multielectrode (more than two) sensors should be selected for process fluids that have medium to high conductivities, such as those found on CIP or chromatography systems. These sensors are most suitable for systems ranging from 0.01 μS/cm to 800 μS/cm.

(c) Electrodeless (inductive or toroidal) sensors should be selected for process fluids that have the highest conductivity. These sensors are most suitable for systems ranging from 0.1 mS/cm to 2 000 mS/cm.

**PI-8.1.6 Maintenance**

**PI-8.1.6.1 Calibration/Verification Schedule.** Sensors used in WFI or PW systems shall be calibrated in accordance with compendial water requirements.

**PI-8.2 pH — Glass Measuring Electrode**

**PI-8.2.1 General.** This section provides the requirements for installation and operation of ion-selective pH sensors specific to bioprocessing and pharmaceutical device-specific requirements for pH sensors incorporating a glass measuring electrode.
**PI-8.2.2 Components.** Commonly used pH sensor technologies incorporate four major components

(a) an ion-selective electrode (measuring electrode)

(b) an electrolyte-filled reference electrode

(c) a liquid interface (reference junction)

(d) an internal or external temperature sensor (temperature compensator)

Typical pH sensor construction combines all four of these components into one body, referred to as a combination pH sensor (see Figure PI-8.2.2-1).

Other components that compose a complete sensor assembly may include elastomeric seals and gaskets, polymeric- and/or metallic-based components, holders, and hygienic clamp connections.

**PI-8.2.3 Installation.** All pH sensors require insertion of the measuring electrode and reference junction into the process fluid for proper functionality. Most pH sensors are offered as insertion devices. Figure PI-8.2.3-1 provides examples of acceptable installations. The owner/user should consult with the sensor manufacturer to determine other installation options.

**PI-8.2.3.1 Drainability.** When installed, pH sensor assemblies shall be drainable in accordance with Part SQ.

**PI-8.2.3.2 Cleanability.** The owner/user should consult with the sensor manufacturer regarding suitability of the sensor for the intended use and sterilization/sanitization methods.

**PI-8.2.3.3 Mounting Location.** Sensor mounting location affects sensor performance. The following process-specific issues should be considered when specifying the location and use of a pH sensor:

(a) The point of addition of acid and/or base to the process solution should be considered when locating a pH sensor. Sufficient distance and/or time is required to ensure complete liquid mixing and reaction.

(b) Locating sensors in areas prone to flashing, cavitation, or siphoning or where the sensor may not be in constant contact with liquid should be avoided.

(c) Maintenance of pH sensors should be considered when selecting sensor location.

The owner/user should consult with the sensor manufacturer for mounting recommendations.

**PI-8.2.3.4 Orientation.** pH sensors should be installed in horizontal tubing, up-flow tubing, appropriately designed flow cells, and vessels. Most pH sensor technologies exhibit optimal performance when installed at 15 deg or more from the horizontal (see Figure PI-8.2.3.4-1).

pH sensors can be sensitive to flow profile. Orientation should be kept consistent in order to produce repeatable results.

The owner/user should follow the sensor manufacturer's installation orientation recommendations for optimal measurement reliability.

**PI-8.2.3.5 Insertion Length/Depth.** The sensor shall be inserted far enough into the tube or vessel so that the sensor measuring electrode and reference junction are always in contact with the process fluid. Unprotected sensor exposure should be limited to help prevent inadvertent breakage. Maximum recommended insertion of an unprotected sensor from the holder is less than or equal to 0.25 in. (6.3 mm) as measured from the reference junction (see Figure PI-8.2.3.5-1).

The owner/user should consult with the sensor manufacturer for appropriate sensor design and sensor holder selection.

**PI-8.2.3.6 Special Considerations.** The measuring electrode and reference junction should be kept wet at all times whether in service or in storage. Extended periods without liquid contact will permanently affect sensor performance.

pH sensors are consumable devices and require periodic replacement. The owner/user should consider sensor accessibility during installation planning.

The owner/user should consult with the sensor manufacturer for specific storage, handling, and rewetting recommendations.
PI-8.2.2 Components
pH sensors typically include a measuring electrode, a reference electrode, a reference junction, and an internal temperature sensor, combined in one body (see Figure PI-8.2.2-1).
The measuring electrode and reference junction are process contact components. The reference electrode and internal temperature sensor are non-process contact components. *(Insert Figure: PI-8.2.2-1 pH Sensor Components)*

PI-8.2.3 Installation
Criteria described in PI-8.2.3.1 through PI-8.2.3.5 should be taken into consideration for pH sensor installation.

PI-8.2.3.1 Cleanability
pH sensors shall be selected to be compatible with cleaning procedures. Some cleaning procedures will not effectively clean the sensor, and will affect sensor performance.

PI-8.2.3.2 Mounting Location
Special installation considerations and process influences should be an integral part of the decision for sensor mounting location. See PI-8.2.3.5 and PI-8.2.4.2 for details.

PI-8.2.3.3 Orientation
pH sensors that have air bubbles in the measuring electrode or reference electrode shall be installed at a minimum angle of 15° from the horizontal (see Figure PI-8.2.3.3-1). *(Insert Figure: PI-8.2.3.3-1 Mounting Orientations)*

PI-8.2.3.4 Insertion Length/Depth
pH sensors should be inserted only as far as needed to ensure the measuring electrode and reference junction are submerged into the process liquid.

PI-8.2.3.5 Special Installation Considerations
Installation of pH sensors in locations where incomplete liquid mixing and reactions may occur should be avoided. Incomplete liquid mixing and reactions can result in measurements that are not representative of the average pH.

PI-8.2.4 Performance
pH sensor performance can be influenced by the conditions described in PI-8.2.4.1 through PI-8.2.4.4.

PI-8.2.4.1 Response Time
pH sensor response time is affected by sensor design and process conditions. Sensor selection shall take into account process conditions and required response times.

PI-8.2.4.2 Process Influences
(a) High process liquid velocity should be avoided. Process liquid velocity in excess of 8 ft/sec (2.4 m/sec) can cause excessive measurement noise and physical damage to the pH sensor.
(b) Pressure fluctuations should be avoided. Pressure fluctuations can cause measurement instability.
(c) Stagnant zones should be avoided. Stagnant zones can result in measurements that are not representative of the average pH and increase sensor maintenance.

PI-8.2.4.3 Ambient Influences
Electro-magnetic interference that affects pH sensor performance should be avoided.

PI-8.2.4.4 Special Performance Considerations
(a) pH sensors shall be kept hydrated at all times to ensure design performance as sensors will be non-responsive if allowed to dry out.
(b) After any process stability upset (e.g. cleaning), the reference electrode shall be allowed recovery time. Recovery times after an upset can vary depending on upset conditions and sensor design. pH sensor readings will drift during recovery.
(c) After recovery from a process stability upset, pH sensors should be checked for appropriate span, response, offset, and stability. Sensors that do not meet performance requirements shall be re-calibrated or replaced.

PI-8.2.5 Selection
pH sensors shall be selected based on the process conditions and specified performance requirements (e.g., measuring electrodes shall be compatible with design pH ranges).
Figure PI-8.2.3-1 Accepted pH Sensor Installations

(a) Horizontal Flow

(b) Upward Flow

(c) Vessel Installation
PI-8.2.3.3-1 Accepted Mounting Orientations

**Figure PI-8.2.3.4-1 Accepted Mounting Orientations**

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**PI-8.2.4 Performance.** pH sensor performance will degrade over time. The rate of degradation is application, maintenance, and installation dependent. Critical factors that affect performance and the frequency of replacement are:

(a) changes in span and response (measuring electrode function)
(b) changes in offset and stability (reference electrode function)
(c) temperature compensator response
(d) installation (insertion length, location, and orientation)
(e) maintenance schedules and methods
(f) postmaintenance sensor recovery time

pH sensors are sensitive to coating and/or plugging of the measuring electrode and reference function. After cleaning, sensors should be calibrated.

The owner/user should contact the sensor manufacturer for recommendations based on documented owner/user performance requirements.

**PI-8.2.4.1 Accuracy.** Published pH sensor accuracy can be affected by calibration (standardization) methods, maintenance procedures and frequencies, cleaning methods, process conditions, sensor design, installation, and sensor age and condition, as well as the ambient conditions.

**PI-8.2.4.2 Response Time.** pH sensor response time is affected by sensor design, sensor age and condition, and process temperature. As a sensor ages or process fluid temperature decreases, sensor response time will become slower.

**PI-8.2.4.3 Process Influences.** pH sensors are sensitive to process influences that include, but are not limited to, process fluid velocity, process fluid temperature, high pH, and high ionic strength.

Process fluid velocity in excess of 8 ft/sec (2.4 m/s) can cause excessive signal noise and physical damage.

As process fluid temperature increases, response time becomes faster but sensor life may be adversely affected.

High pH (over 12 pH) will tend to decrease sensor life.

High ionic strength chemicals such as those used in CIP systems can decrease sensor life.

The owner/user should discuss process conditions with the sensor manufacturer to minimize potentially negative process influences.

**PI-8.2.4.4 Ambient Influences.** pH sensors, in combination with other loop components (electronics and cables), can be affected by electrical noise, electromagnetic/radio-frequency interference (EMI/RFI), ground loops, close coupling of sensors with other instruments or equipment, and external washdown environments.
The owner/user should consult with the sensor manufacturer to match the complete loop with ambient conditions.

**PI-8.2.5 Selection.** The owner/user should consult with the manufacturer to determine sensor applicability and loop component (mounting hardware, cable, and electronics) compatibility.

**PI-8.2.6 Maintenance.** Maintenance schedules and methods shall be established by the owner/user based on owner/user historical experience and sensor manufacturer recommendations.

**PI-8.2.6.1 Calibration/Verification Schedule.** pH sensors should be calibrated using multipoint and/or single-point methods.

A multipoint calibration adjusts both the sensor span (measuring electrode) and sensor offset (reference electrode). A single-point calibration, often referred to as standardization, only adjusts the sensor offset.

pH sensor span, offset, response time, and stability can be affected by coating and/or plugging of the measuring electrode and reference junction. Operators should perform a calibration or standardization after each cleaning or sterilization cycle.

The owner/user should consult with the sensor manufacturer to establish procedures based on sensor design, owner/user expectations, instrument historical performance, and process design.

**PI-9 OPTICAL**

**PI-9.1 Optical Devices**

**PI-9.1.1 General.** Optical devices are used to measure various process characteristics parameters including color, turbidity, concentration, percent suspended solids, optical density, particle and cell size/shape, cell density, and cell viability. Applications include filtration, chromatography, cell culture fermentation, and water systems.

**PI-9.1.2 Components**

**PI-9.1.2.1 Light Source(s).** Optical devices include a light source(s) such as visible (VIS), ultraviolet (UV), near infrared (NIR), or infrared (IR), which is transmitted into the process fluid.

**PI-9.1.2.2 Sensor.** Sensor types include photo detectors, photomultipliers, and CCD (charge-coupled device) imaging chips. The system can involve various optical components to focus, filter, and enhance the light beam either one-dimensionally or multidimensionally.

**PI-9.1.2.3 Sight Glass.** Sight glasses are one of the key components of an optical device. Process fluid-contacting components of the sight glass assembly shall comply with Parts MM and PM.

(a) When glass is used as a sight glass for viewing (viewport), a glass fused to a metal hermetic compression seal shall be used. The fused glass shall be circular in shape within the metal frame.
(b) Bubbles in the fused sight glass are acceptable but the size and quantity should be kept to a minimum. Bubbles shall not be present on the glass surface.

c) The seal point of the glass fused to metal sight glass is at the surface. The surface of the sight glass shall be integral, continuous, and free of defects such as crevices and pits.

d) Cracked glass shall not be used.

e) Sight glasses shall be marked with the glass type, maximum pressure, and temperature rating as per Part DT.

(f) Typical sight glass mountings are shown in Figure SD-3.4.6-1.

PI-9.1.3 Installation. The measuring probe should be installed past the boundary layer. Seals used for installation of viewport sight glass shall meet the requirements of Part 5G.

PI-9.1.3.1 Drainability. Optical devices shall be installed in accordance with Part SD to ensure drainability.

PI-9.1.3.2 Cleanability. Process fluid-contacting surfaces of optical devices shall be cleanable as required per Part SD.

PI-9.1.3.3 Mounting Location. Optical devices shall be mounted in a pipe or vessel where a representative measurement can be made.

A light or combined light and sight glass for viewing shall be mounted as shown in Figure PI-9.1.3.3-1.

PI-9.1.3.4 Orientation. The preferred mounting of in-line optical devices is in the vertical section of tubing to avoid particle segregation. The probe should be in constant contact with the process fluid.

PI-9.1.3.5 Insertion Length. For tube diameters less than 1 in. (25 mm), experimental test data should be used to assess performance.

For in-line installation of tube diameters ranging from 1 in. (25 mm) to 4 in. (100 mm), optical probes should be mounted a minimum \( L_{\text{min}} \) of 0.3 in. (8 mm) away from any interior tube wall (reference Figure PI-9.1.3.5-1).

For vessels and tubing in excess of 4 in. (100 mm) diameter, optical probes should be mounted where the glass measurement surface is a minimum \( L_{\text{min}} \) of 1.5 in. (38 mm) from any interior tube wall (reference Figure PI-9.1.3.5-2).

PI-9.1.3.6 Special Considerations. Special care should be taken for process fluids that are adversely impacted by temperature to avoid high temperatures on the process side of the sight glass or optical window caused by the optical devices. Testing of the optical device at the maximum operating wattage of the probe or probes should not result in still water within 0.5 in. (13 mm) of the probe rising more than 2°F (1°C) in 1 hr.

For light sources used for viewing only, a thermal switch, timer, momentary switch, IR filter, or some other suitable means should be considered to control overheating.

PI-9.1.4 Performance. In-line optical devices generally require the tube to be full of liquid and free of air pockets. Certain optical devices can tolerate the presence of some air bubbles. The owner/user should consult with the optical device manufacturer for guidance.

PI-9.1.4.1 Accuracy. Optical devices are inherently accurate and repeatable but dependent on device-specific calibration.

PI-9.1.4.2 Response Time. Optical sensing elements provide instantaneous readings with no delays due to process conditions such as temperature or flow. The owner/user should consult the manufacturer if a specific response time is required.

PI-9.1.4.3 Process Influences. Velocity and particulate content in the process fluid may impact the cleaning frequency requirement of the optical device.

PI-9.1.4.4 Ambient Influences. Some optical sensing electronics have limited process and ambient temperature ranges. The owner/user should consult the manufacturer to ensure the selection is compatible with the temperature conditions.

PI-9.1.5 Selection. Optical device sensing technologies vary based on the intended application and suitable measurement ranges. The owner/user shall determine the desired measurement range and unit of measurement before selecting the optical device and associated technology.
Figure PI-9.1.3.3-1 Vessel Light Glass Design and Mounting

(Accepted)

(a) Hygienic Full-Flange Light Glass on Hygienic Clamp Pad

(b) Hygienic Clamp Light on Hygienic Clamp Pad

(c) Hygienic Clamp Light

(d) Fiber-Optic Light on Hygienic Clamp

(e) Typical Vessel Light Glass Mounting Tangent to Tank Head
Figure PI-9.1.3.5-1 In-Line Insertion Length

Figure PI-9.1.3.5-2 Insertion Probe Length

$L_{\text{min}} = \text{minimum recommended distance from interior tube wall}$
PART SG
SEALING COMPONENTS FOR MULTI-USE

MC

**SG-1 PURPOSE AND SCOPE**

The purpose of this Part is to provide the requirements for the sealing components of seals, valves, and fittings used in the bioprocessing industry. These sealing components create or maintain process boundaries between system components and/or subassemblies to ensure process system integrity. This Part defines the design of seals, valves, and fittings. This Part also enables equipment manufacturers, system designers, and owner/users to specify the required seal, valve, and fitting type and performance for specific applications. It is not the intent of this Part to inhibit the development or use of new technologies.

MC

**SG-2 SEALING COMPONENT TYPES**

**MC SG-2.1 General**

Sealing components used in bioprocessing equipment take a variety of forms based on their function within the system and the process boundaries to the atmosphere and other systems, which they must maintain. The following sections define the main types of sealing components and their acceptability for use in the bioprocessing industry. For this section, seals are divided into static and dynamic seals. All acceptable seals shall meet the design criteria, materials, and performance characteristics contained in this Standard.

MC

**SG-2.2 Static Seals**

**MC SG-2.2.1 General.** A static seal is characterized by the absence of relative motion between sealing surfaces, or between the sealing surface and a mating surface, after initial installation. Small amounts of movement that might be caused by thermal expansion, vibration, bolt stretch, or seal response to fluid pressure do not alter the static definition.

**MC SG-2.2.2 Hygienic Unions.** Hygienic unions provide connections between process components (e.g., pipe fittings, tank fittings, instruments, and hoses) to ensure the process integrity is maintained. They include seals between two ferrules.

The geometry of the most common hygienic union is governed by Table DT-7-1 and is shown in Figures SG-2.2.2-1 and SG-2.2.2-2. Other geometries for the opposing ferrules are also used in the industry and are controlled by relevant industry standards [e.g., ISO 2852, DIN 11864 (-1, -2, -3, O-rings)]. (See Figures SG-2.2.2-3 and SG-2.2.2-4.)

Other hygienic unions and cross-sectional geometries shall meet all of the requirements of this Standard, except for the ferrule dimensions.

Nonhygienic connections shown in Figure SG-2.2.2-5 are not recommended (e.g., threaded fittings exposed to process fluid).

**MC SG-2.2.3 O-Ring Seals.** An O-ring is a ring seal with a circular cross section (a toroid), designed to be seated in a groove and compressed during assembly. O-rings are most often used as static seals. These are used extensively in hygienic applications and can seal both radially and axially opposed faces. Common static O-ring applications include sealing fasteners, shaft couplings, and pump and filtration components.

Other ring seal geometries of varying cross sections (e.g., manway gaskets) may be used in hygienic applications. However, significant differences may exist in their performance (e.g., pressure and cleanability), and they should be evaluated accordingly.


For use in bioprocessing applications, O-rings and their mating surfaces shall meet the requirements of this Standard.

**MC SG-2.2.4 Other Static Seals.** Other static seals used in bioprocessing applications shall meet the requirements of this Standard (e.g., flat gaskets, L-cups, U-cups, stoppers, septums, and bioseals).
Figure SG-2.2.2-1 Hygienic Union per Table DT-7-1

(a) Typical Hygienic Clamp Union — 1 in. and Smaller (Type A) per Table DT-7-1 (Accepted)

(b) Typical Hygienic Clamp Union — 1 in. (Type B) per Table DT-7-1 (Accepted)

(c) Typical Hygienic Clamp Union — 1.5 in. and Larger (Type B) per Table DT-7-1 (Accepted)

Figure SG-2.2.2-2 Hygienic Clamp Union per Table DT-7-1

Symmetric ferrules
Gasket
Clamp

(Accepted)

Figure SG-2.2.2-3 Hygienic Union per DIN 11864

(Accepted)
Figure SG-2.2.2-4 Hygienic Clamp Union per DIN 11864

Asymmetric ferrules

O-ring

Clamp

(Accepted)
Figure SG-2.2.2-5 Nonhygienic Connections
(Not Accepted for Hygienic Service)

(a) Roll-On Fitting

(b) Compression Fitting

(c) Threaded Joint

(d) Flanged Joint

(e) Bevel Seat

(f) Nozzle Detail

(g) Socket Joint
Inflatable static seals are static seals where gas is supplied to the inner part of the seal, providing a pillow barrier between the process and the atmosphere. They are commonly used in large process components, and in connections to support structures.

**SG-2.3 Dynamic Seals**

A dynamic seal is characterized by the movement of the seal surface and a mating surface after initial installation.

**SG-2.3.1 Valves**

**SG-2.3.1.1 General.** Valves are process components that provide dynamic seals within the process. They also provide seals between the process and the atmosphere.

**SG-2.3.1.2 Diaphragm Valves**

(a) *Weir Diaphragm Valve, Weir Diaphragm Tank Bottom Valve.* The diaphragm seal is a flexible membrane that forms positive closure when compressed against the weir (see Figure SG-2.3.1.2-1). The diaphragm is a product/process contact seal creating both static (atmospheric) and dynamic (differential) seals.

(b) *Radial Diaphragm Valve, Radial Diaphragm Tank Bottom Valve.* The diaphragm seal is a flexible membrane that forms positive closure when compressed against a radial seat (see Figure SG-2.3.1.2-2). The diaphragm is typically a product/process contact seal creating both static (atmospheric) and dynamic (differential) seals. However, in some designs static seals may be used between body components.

(c) *Weirless Diaphragm Valve.* The diaphragm seal is a flexible membrane that modulates flow across a weirless valve body and also forms positive closure when compressed against the weirless valve body (see Figure SG-2.3.1.2-3). The diaphragm is a product contact seal creating both atmospheric and differential seals.

(d) *Linear Control Valve.* A sliding seal (such as an O-ring) or nonsliding seal (such as a diaphragm) is used to seal a linear stem (see Figure SG-2.3.1.2-4). For closure, the linear control valve may use a soft seal such as an O-ring or diaphragm or a metal-to-metal seal/seat.

(e) *Regulator Valve.* A control diaphragm is a flexible membrane that typically is used as a pressure barrier and also forms a static seal to the atmosphere. A plug-type dynamic seal may be used for closure. Static seals are used between body components. To regulate the flow, the operating diaphragm responds to pressure to control the regulating plug and functions as a static seal around its perimeter (see Figure SG-2.3.1.2-5).

**SG-2.3.1.3 Ball Valve and Ball Tank Bottom Valve.** The seat/seal functions as a dynamic seal against the rotating ball. Static seals are used between body components. A dynamic seal is used on a rotary stem (see Figure SG-2.3.1.3-1).

**SG-2.3.1.4 Rising Stem Single, Double-Seat Mix-Proof, and Needle Valves.** Plug(s) are used to close flow against seat(s). Dynamic seal(s) are used on linear stem(s). Static seals are used between body components (see Figure SG-2.3.1.4-1).

**SG-2.3.1.5 Butterfly Valves.** The seat/seal creates a dynamic seal when the disk is rotated into the closed position (see Figure SG-2.3.1.5-1). The seat/seal also forms the primary stem seal to prevent leakage through the stem journal.

**SG-2.3.1.6 Thermostatic Steam Trap.** The valve seat is closed by a plug attached to a dynamic bellows seal. The body cavity for a serviceable steam trap is typically sealed by a static seal (see Figure SD-3.1.2.2-1).

**SG-2.3.1.7 Back Pressure Control Valve.** A nonsliding seal (such as a diaphragm) is used to seal a linear stem. For closure, the valve may use a soft seal, such as an O-ring or diaphragm, or a metal-to-metal seal/seat (see Figure SG-2.3.1.7-1). To regulate the flow, the operating diaphragm responds to pressure to control the regulating plug and functions as a static seal around its perimeter.

**SG-2.3.1.8 Pinch Valve.** Pinch valves use a flexible tube or sleeve that forms a differential seal when closed (see Figure SG-2.3.1.8-1).

**SG-2.3.1.9 Check, Pressure Relief, and Safety Pressure Relief Valves**

(a) A check valve is a unidirectional flow device (see Figure SG-2.3.1.9-1). When the application requires drainage, a check valve may include provisions for drainage, such as flats, drain holes, or a drain port.

(b) A pressure relief valve is a type of valve that relieves pressure in a system in order to protect against mechanical damage of equipment. An override device may be used to allow flow through the valve for the purpose of cleaning. Pressure relief valves allow bypassing of the overpressured fluid back into the process line or a safe location (e.g., from a pump discharge back to the pump suction).

(c) A safety pressure relief valve is a type of valve used to relieve the pressure in a system or vessel, caused by a process upset, instrument or equipment failure, or fire. Its purpose is to protect people and equipment from a potential explosion or leak. The flow is one-directional. In case of overpressure, the fluid is discharged to a safe location outside the pressurized system.
Figure SG-2.3.1.2-1 Weir Valves

(a) Weir Diaphragm Valve
(b) Weir Diaphragm Tank Bottom Valve

Figure SG-2.3.1.2-2 Radial Valves

(a) Radial Diaphragm Tank Bottom Valve
(b) Radial Diaphragm Valve
(c) Bellows Radial Diaphragm Tank Bottom Valve
(d) In-Line Radial Diaphragm Valve
Figure SG-2.3.1.2-5 Regulator Valve

Figure SG-2.3.1.3-1 Ball Valves

(a) Ball Tank Bottom Valve

(b) Ball Valve
Figure SG-2.3.1.4-1 Rising Stem Single, Double-Seat Mix-Proof, and Needle Valves

(a) Rising Stem Single Valve  (b) Double-Seat Mix-Proof Valve  (c) Needle Valve

Figure SG-2.3.1.5-1 Butterfly Valve

Figure SG-2.3.1.7-1 Back Pressure Control Valve
Figure SG-2.3.1.8-1 Pinch Valve

(a) Pinch Valve Open

(b) Pinch Valve Closed
Figure SG-2.3.1.9-1 Pressure Relief and Check Valves

(a) Spring-Type Check Valve

(b) Poppet-Type Check Valve (Vertical Configuration) [Note (1)]

(c) Poppet-Type Check Valve (Horizontal Configuration) [Note (1)]

NOTE: (1) Gray color represents backflow blocked by the poppet.
### SG-2.3.1.10 Plug Valves
The plug-body valve or plug-seal valve functions as a dynamic seal against the rotating plug (see Figure SG-2.3.1.10-1).

### SG-2.3.2 Mechanical Seals

#### SG-2.3.2.1 General

(a) An end face mechanical seal is a device that controls leakage of fluids by compressing a sealing element between two rotating ring members perpendicular to the fluid pressure. It maintains the contact between the wearing seal faces.

(b) Selection of the proper seal for the specific equipment and application is the responsibility of the owner/user. The owner/user shall consult the equipment supplier/manufacturer.

#### SG-2.3.2.2 Single Mechanical Seals

(a) Single mechanical seals are seal arrangements in which there is only one mechanical seal per seal chamber.

(b) Single mechanical seals offer simplicity and an observable leakage path to the atmosphere.

(c) Single mechanical seals weep fluid across the face in the direction from high pressure to low pressure.

(d) Single Mechanical Seals for Pumps

1. The process fluid provides lubrication and cooling for the faces. A single seal operating in dry or vacuum conditions will result in seal failure.

2. Not all process fluids will provide adequate lubrication and cooling. In this case an alternative seal design or flush plan shall be considered.

3. A typical single seal for pumps is illustrated in Figure SG-2.3.2.2-1.

(e) Single Mechanical Seals for Top-Mounted Agitators

1. Single mechanical seals for top-mounted agitators operate in the head space of the vessel typically exposed to the gas phase of the process fluid.

2. Top-mounted agitator single seals may contain a debris well to catch wear material from dry contacting faces.

3. A typical single seal design for top-mounted agitators is illustrated in Figure SG-2.3.2.2-2.

#### SG-2.3.2.3 Dual Mechanical Seals

(a) Dual Pressurized Mechanical Seals

1. Dual pressurized mechanical seals consist of an inboard mechanical seal and an outboard mechanical seal. Barrier fluid is injected between these two seals. The inboard mechanical seal has process contact, and the outboard mechanical seal has atmospheric contact.

2. Pressurized barrier fluid means the barrier fluid pressure is higher than the process pressure acting on the inboard mechanical seal.

(3) Dual pressurized mechanical seals offer absolute separation of process and atmosphere.

(4) The pressurized barrier fluid will weep into the process and will weep into the atmosphere.

(5) The owner/user shall arrange for a pressurized barrier fluid to be introduced between the inboard seal and the outboard seal to ensure a positive barrier exists between the process and the atmosphere. A liquid barrier fluid such as water also cools and lubricates the dual mechanical seal. Gas barrier fluid such as air provides a barrier between the atmosphere and process only and does not provide cooling or lubrication to the seal faces.

(6) Providing barrier fluid flow and pressure at an appropriate temperature is the responsibility of the owner/user and shall be based on the recommendation of the equipment manufacturer.

7. A typical dual pressurized mechanical seal is illustrated in Figure SG-2.3.2.3-1 for pumps and Figure SG-2.3.2.3-2 for top-entry agitators.

(b) Dual Unpressurized Mechanical Seals

1. Dual unpressurized mechanical seals consist of an inboard mechanical seal and an outboard mechanical seal. Buffer fluid is injected between these two seals. The inboard mechanical seal has process contact, and the outboard mechanical seal has atmospheric contact.

2. Unpressurized buffer fluid means the buffer fluid pressure is lower than the process pressure acting on the inboard mechanical seal. The highest pressure in the sealing system is the process pressure on the inboard side of the inboard seal. The lowest pressure of the system is the atmosphere pressure on the outboard seal.

3. Dual unpressurized mechanical seals offer absolute separation of the atmosphere from the process but do not provide absolute separation of the process from the atmosphere.

4. Process fluid will weep into the unpressurized buffer fluid, and the buffer fluid will in turn weep into the atmosphere along with dilute process fluid.

5. The owner/user shall arrange for an unpressurized buffer fluid to be introduced and the outboard seal to be pressurized. The atmosphere pressure and the traces of process fluid will penetrate the outboard seal faces.

(6) Providing buffer fluid flow and pressure at an appropriate temperature is the responsibility of the owner/user and shall be based on the recommendation of the equipment manufacturer.

7. A typical dual unpressurized mechanical seal is illustrated in Figure SG-2.3.2.3-3.
SG-2.3.2.4 Flush Plans. A flush plan describes how the end face mechanical seal is lubricated and cooled. The flush plan numbers directly reflect plans that were developed by the American Petroleum Institute (API 682), were subsequently approved by the American National Standards Institute (ASME B73 series), and are global standard shorthand for seal support systems. If properly implemented to the requirements of this Standard, all of the following flush plans are acceptable for use in the bioprocessing industry. The numbering system used below is also recognized and used by the Fluid Sealing Association (FSA) and the European Sealing Association (ESA as a group associated with FSA). ISO 21049, API 682, and ISO 13709 also contain important information about support systems for mechanical seals.

(a) Flush Plan 01. Internal seal chamber circulation for single seal from pump discharge. A high-pressure discharge of the process fluid flows to the low-pressure seal chamber. The flow of process fluid cools and lubricates the seal faces. See Figure SG-2.3.2.4-1.

(b) Flush Plan 02. Dead-ended seal chamber with no other sources of flush for single seal. The ambient conditions of the seal chamber are satisfactory for the process fluid to remain a coolant and lubricant for the seal faces. See Figure SG-2.3.2.4-2.

(c) Flush Plan 03. Dead-ended seal chamber with circulation between the seal chamber and the pump created by the design of the sealing chamber. The flow of process fluid cools and lubricates the seal faces and may prevent the accumulation of solids in the seal chamber. See Figure SG-2.3.2.4-3.

(d) Flush Plan 11. Seal flush from pump discharge for single seal. Often uses an orifice, but the flush line itself may be considered an orifice. A high-pressure discharge of the process fluid flows to the low-pressure seal chamber. The flow of process fluid cools and lubricates the seal faces. See Figure SG-2.3.2.4-4.

(e) Flush Plan 32. Seal flush from external source. This plan is used for single seals. A fluid that is compatible with the process is injected into the seal cavity to cool and lubricate the seal. Plan 32 flush fluid will go into the process. See Figure SG-2.3.2.4-5.

(f) Flush Plan 52. This plan is for unpressurized dual seals only. Unpressurized buffer fluid circulates through a reservoir. The buffer fluid is at a pressure less than the process side of the inboard seal. This plan offers protection from product entering the atmosphere and, when used under vacuum conditions, from the atmosphere entering the seal chamber. See Figures SG-2.3.2.4-6 and SG-2.3.2.4-7.

(g) Flush Plan BPE52. Flow and pressure are taken from the pump discharge and injected between the dual seals. The seal cavity is vented to low-pressure point. This flush plan is used exclusively for dual unpressurized seals. See Figure SG-2.3.2.4-8.

(h) Flush Plan 53. This plan is for pressurized dual seals only. Pressurized barrier fluid is circulated through a reservoir where the barrier fluid is cooled then returned to the seal cavity. Circulation must be provided by a pumping device located in the dual-seal design. This arrangement ensures that the atmosphere and pumped process fluid cannot cross-contaminate. The barrier fluid shall be compatible with the product. See Figures SG-2.3.2.4-9 and SG-2.3.2.4-10.

(i) Flush Plan 54. This plan is for dual pressurized seals only. Pressurized barrier fluid is circulated through the dual-seal cavity from an external source. The source of flow and pressure is undefined in this flush plan. The barrier fluid pressure between the inboard and outboard seals shall be higher than the process pressure acting on the inboard seal. The barrier fluid shall be compatible with the process fluid. See Figures SG-2.3.2.4-11 and SG-2.3.2.4-12.

(j) Flush Plan 55. This plan is for unpressurized dual seals only. Unpressurized buffer fluid is circulated through the dual-seal cavity from an external source. The source of flow and pressure is undefined in this flush plan. The buffer fluid is at a pressure less than the process side of the seal protection from the process fluid entering the atmosphere and, when used under vacuum conditions, from the atmosphere entering the seal chamber. See Figures SG-2.3.2.4-13 and SG-2.3.2.4-14.

(k) Flush Plan 74. This plan is for gas-pressurized dual seals only. The barrier fluid pressure between the inboard and outboard seals shall be higher than the process pressure acting on the inboard seal. The barrier fluid shall be compatible with the process fluid. See Figures SG-2.3.2.4-15 and SG-2.3.2.4-16.

SG-2.3.3 Other Dynamic Seals

SG-2.3.3.1 Reciprocating Seals. Reciprocating seals exhibit axial movement between the inner and outer elements, as in a plunger or a piston and a cylinder. The seal, usually an O-ring, slides along the sealingsurface.

SG-2.3.3.2 Oscillating Seals. Oscillating seals have angular movement around an arc, as in a valve handle. The seal, usually an O-ring, slides between the inner and outer elements and has limited or no longitudinal movement.
Figure SG-2.3.2.4-6 Flush Plan 52 for Pump

Figure SG-2.3.2.4-7 Flush Plan 52 for Top-Entry Agitator

Figure SG-2.3.2.4-8 Flush Plan BPE52 for Pump

Figure SG-2.3.2.4-9 Flush Plan 53 for Pump

Figure SG-2.3.2.4-10 Flush Plan 53 for Top-Entry Agitator
Figure SG-2.3.2.4-11 Flush Plan 54 for Pump

Figure SG-2.3.2.4-12 Flush Plan 54 for Top-Entry Agitator

Figure SG-2.3.2.4-13 Flush Plan 55 for Pump

Figure SG-2.3.2.4-14 Flush Plan 55 for Top-Entry Agitator

Figure SG-2.3.2.4-15 Flush Plan 74 for Pump

Figure SG-2.3.2.4-16 Flush Plan 74 for Top-Entry Agitator
MC-3 SEALING COMPONENTS GENERAL DESIGN REQUIREMENTS (GENERAL PROVISIONS)

SG-3.1 Seal Design Conditions
The equipment supplier/manufacturer shall be informed of all the conditions which may be expected to operate in addition to the service temperature and pressure parameters that may affect the sealing components. Form S-1 Application Data Sheet shall be provided to the equipment supplier/manufacturers to ensure that the sealing components will be able to meet the system requirements of SD-2.4.2.

SG-3.1.1 Service Temperature
The number of allowable thermal cycles may be lower than that stated by the manufacturer. Sealing components shall be accessible for a duration of at least 100 hours.

SG-3.1.2 Service Pressure
The maximum permissible usage pressure meets the maximum permissible pressure and acceptance level furnished by the seal supplier.

SG-3.1.3 Bioburden
Bioburden includes viruses, bacteria, yeast, mold, and parts thereof.

SG-3.1.4 Cavitation Resistance
The seal shall be designed so as to minimize damage by cavitation.

MC-3.2 System Requirements
Sealing components designed for CIP shall meet the requirements of SD-2.4.2. Sealing components designed for SIP shall be able to withstand continuous exposure to saturated steam at a minimum temperature of 266°F (130°C; representing 24.5 psig/1.70 bar under saturated steam conditions) for a duration of at least 100 hours. Sealing components shall be accessible for maintenance.

SG-3.2 System Requirements
All systems require cleaning and sterilization of seals on a regular basis. This is necessary to ensure elimination of any bacterial growth, which could harm the seal, future products, or the environment. The methods of cleaning are listed in SG-3.2.1 through SG-3.2.3.

SG-3.3 Seal Construction
MC-3.3.1 Materials

(a) Biocompatibility. Biocompatibility testing shall be performed per PM-3.1. Qualification testing of final manufactured seals shall be conducted as the materials combination tested. Representative testing shall be materials or otherwise specified by the materials manufacturer.

(b) Process Conditions
The testing shall be valid for all similar seals represented by the unique combination of the materials and manufacturing processes used in the test article. Biocompatibility testing shall be repeated for significant changes in raw materials or manufacturing processes. Otherwise, biocompatibility testing is used on initial qualification of the material and process by the seal supplier/manufacturer.

MC-3.1 Process Conditions
The equipment supplier/manufacturer shall provide documentation stating the recommended operational limits of the sealing components and maintain appropriate data (e.g., test results, calculations) supporting these limits. The equipment supplier/manufacturer should provide available information regarding allowable number of thermal cycles. The equipment supplier/manufacturer should provide available information regarding the component's life cycle performance and the methodology used in its determination (e.g., test protocol). Nonmandatory Appendix K provides guidelines for determining whether the seal will be able to perform as specified after passivation or whether a new seal is required before the start of operation.
selection shall be governed by Part PM and reference Form S-1, Application Data Sheet. It is unlikely that any single seal material can withstand all conditions present in the facility. Material selection should be done in concert with the seal supplier/manufacturer to ensure that seal performance is maximized for each location within a process. However, material selection remains the responsibility of the owner/user.

(c) Permeation Resistance. Seal permeation shall be included in seal leakage criteria and is not addressed as an individual topic.

(d) Surface Finish

(1) Seals shall be free of molding imperfections or burrs within the system boundary and on sealing surfaces.

(2) Seals shall be free of foreign matter on surfaces within the system boundary and on sealing surfaces.

(3) Surfaces to be sealed shall meet specifications provided by the seal supplier/manufacturer based on performance and the requirements in Part SF.

(4) Molded seals and components shall have molding flash removed to prevent contact with the process stream.

(e) Particle Generation. Seal designs should minimize wear that generates particles that could enter the process stream.

(f) Lubrication. When required to facilitate installation, seals may be lubricated with an acceptable lubricant that is compatible with the seal material and process. The supplier/manufacturer shall advise the owner/user of special lubrication requirements. The selection of accepted lubricant is the responsibility of the owner/user.

SG-3.3.2 Design

SG-3.3.2.1 General

(a) Crevices. A smooth, contoured, pocketless interior surface shall be created when seals are placed between the seal contact surfaces. All recessed seal contact surfaces shall avoid sharp corners and be easily cleanable with the seal removed. All seal and seal contact surfaces shall be designed to minimize cracks or crevices that might harbor system media.

(b) Dead Spaces. Dead spaces are defined here as a void in the process contact surface(s) portion of the structure not completely occupied by a seal and are usually required to allow for thermal expansion of the seal material. These should be avoided. All seal and seal contact surfaces shall be designed so that the system is self-draining when seals are properly installed.

SG-3.3.2.2 Static Seals

(a) Static Seal General Design Requirements. SG-2.2 lists some standards describing the design of hygienic unions, O-rings, and other static seals. Figures SG-2.2.2-1 through SG-2.2.2-4 illustrate typical static hygienic and O-ring connections. Figure SG-2.2.2-5 illustrates unacceptable connections. In addition, the following general requirements apply to all hygienic static seals:

(1) Gaskets and O-ring seals shall seal and meet the cleanability and bioburden control requirements of the application. Fittings should be selected or designed to consider the gasket or O-ring geometry, materials of construction, and seal performance under operating conditions.

(2) Static seals should be self-aligning and self-positioning.

(b) Hygienic Unions. Most common hygienic union geometries used in bioprocessing are listed in SG-2.2.2. All hygienic unions shall comply with the general design requirements in this Part, the material requirements of Parts MM and PM, and the surface finish requirements of Part SF. Intrusion categories of hygienic seals are defined in SG-4.2 and illustrated in Figure SG-4.2-1.

(c) O-Ring Seals

(1) General O-Ring and Gland Design Criteria. An O-ring is a seal with a circular cross section (a toroid), designed to be seated in a groove and compressed during assembly. These are most often used in static sealing performance during bioprocessing production, performance during other processes, typically CIP and bioburden control processes, shall be considered in the design of a hygienic O-ring seal. The following design criteria should be evaluated:

(-a) seal performance under all process conditions

(-b) proximity of the sealing point to the bulk fluid flow for CIP and bioburden control processes

(-c) consistent location of the sealing point and exposed surfaces under all relevant process conditions

(-d) ability to handle the effects of thermal expansion and chemical swell

(-e) drainability

Often designs that target specific criteria sacrifice others. For example, installation of O-rings in tight grooves to improve cleanability often causes problems due to the thermal expansion of elastomers being significantly greater than the thermal expansion of stainless steel or other nonmetallic materials.

The owner/user should consult with the seal designer to optimize the design for an application. The owner/user should determine whether an O-ring seal provides adequate overall performance for a specific application.

Some examples of O-ring groove designs are shown in Figure SG-3.3.2.2-1.

(2) O-Ring/Gland Sizing (Fill). Proper gland design and appropriate O-ring selection are critical for proper sealing. O-ring selection includes the proper sizing and proper material selection for the process environment. An O-ring gland shall include sufficient room for
thermal expansion and chemical swell to prevent seal material extrusion and damage. Seal designs that compress in multiple directions require extra caution.

3 O-Ring Stretch (Elastomeric O-Rings). It is suggested that O-ring stretch during installation be limited. The designer should consider the maximum amount of allowable stretch to prevent O-ring breakage during part assembly. When located in position for use, the O-ring stretch should not exceed 5%. Similarly, the O-ring diameter should not be too large for a groove, which would cause the ring to buckle. Overstretching or oversizing an O-ring can lead to premature seal failure.

4 O-Ring Compression (Squeeze). Proper O-ring compression is critical to proper sealing. At ambient temperature, O-ring compression is frequently in the range of 10% to 25%; however, this can vary greatly depending on materials, conditions, and applications (e.g., static vs. dynamic). O-ring compression over 30% should generally be avoided. Relative O-ring compression can increase during heating due to thermal expansion. Factors to consider for O-ring compression include chemical swell, temperature change, elastomer hardness, etc. Caution should be taken when substituting elastomeric seals for nonelastomeric seals or vice versa. A nonelastomeric seal may require a crush groove, and direct substitution of an elastomer into such a groove may result in premature seal failure.

5 O-Ring Thermal Expansion. O-ring thermal expansion is dependent on the particular material and formulation. The O-ring supplier/manufacturer can provide information on the material’s coefficient of thermal expansion (CTE) characteristics.

6 Hygienic O-ring connections are available (see Figures SG-2.2.2-3 and SG-2.2.2-4) in threaded, flanged, or clamped styles. The O-ring connections shall be manufactured to a hygienic standard (e.g., DIN 11864 parts 1 to 3) or shall be accepted as a hygienic connection by a recognized independent organization [e.g., the European Hygienic Engineering and Design Group (EHEDG)]. O-ring connections shall comply with this paragraph and SD-3.1.1. The construction of the fitting shall be such that excessive deformation of the seal will not be caused as a result of overtightening the connection.

7 O-Rings Fabricated From Molded or Extruded Section Using Vulcanized Molded Joints

(a) O-Rings. Fully molded O-rings should be used, wherever possible.

(b) Vulcanized Bonded Joints. When the fully molded seal diameters are not available, O-rings fabricated from molded section using molded vulcanized joints can be fitted as long as the following parameters are kept:

1 Materials. All bonded joint seal materials shall be compliant with SG-3.3.1 and any additional requirements specified by the owner/user. The vulcanized bonded joint should consist of either an unvulcanized portion of the seal material or a compatible material where this gives an improved joint. In both cases, the joining material shall meet the same requirements as the seal material.

2 Joint Integrity. The joint integrity shall meet the strength requirements of the application. A vulcanized O-ring should contain only one joint. Where tooling availability limits seal diameter, extra joints can be included by prior arrangement with the owner/user.

3 Excessive Material and Tool Marks. All excessive joint material shall be removed. The surface finish and any residual material, tool marks, or reductions in cross-sectional tolerances should not be at a level that compromises seal performance and cleanliness.

(c) Adhesive-Bonded Joints. Adhesive bonded joints should be avoided and their use shall be agreed upon between the supplier/manufacturer and the owner/user.

(d) Other Static Seals

1 Flat Gaskets. All flat gasket general design requirements in this requirements of Part PM, and the segments of Parts SD and SF.

2 Inflatable Seals. Inflatable seals shall comply with the general design requirements of this Standard.

SG-3.3.2.3 Valves

(a) General

1 Process flow valves should optimize drainability and prevent pooling when installed in their proper drain orientation.

2 When possible, welding valves into the process line is the preferred method of installation to minimize the use of seals.

3 All process contact surfaces of components designed for CIP/SIP shall be easily accessible by CIP fluids and SIP steam.

4 Valve surfaces that may become process contact surfaces if a component (e.g., diaphragm) fails in service shall be readily accessible for examination, maintenance, and cleaning.

5 Cavity fillers shall not be used.

6 The metallic fluid-contact surfaces of the valve, including the body cavity, shall comply with the applicable requirements in Part SF.
(6) The internal geometry of cluster, block, and multiport valves should be designed to minimize the conditions that contribute to a dead leg and optimize drainability when installed.

(7) The internal volume of the valve should be kept to a minimum while meeting other requirements of the process design.

(8) Any crevices (e.g., between mating parts of a valve) should be minimized in areas in contact with the process.

(9) Any guiding of valve trim and operating mechanisms should be minimized in areas in contact with the process.

(10) Valves intended for CIP/SIP/sanitization shall be capable of being opened as required during those processes.

(11) Valves not capable of CIP shall be able to be disassembled for cleaning/steaming.

(12) The valve design should enable immediate process side and environment. The area between a valve should be fitted with a leakage detection port to indicate primary seal leakage.

(13) Pneumatically controlled valves shall be designed to prevent air transfer from the actuator to the process.

(14) All seals and seals shall comply with the requirements of this Standard, or as agreed on between the supplier/manufacturer and owner/user.

(15) The owner/user should refer to Form S-1, Application Data Sheet, when communicating process conditions to the supplier/manufacturer. The valve supplier/manufacturer shall recommend material for the intended service and pressure and comply with the URS (User Requirement Specification), but material selection is the responsibility of the owner/user.

(16) See Form S-1, Application Data Sheet, to communicate process conditions to the supplier/manufacturer.

(b) Diaphragm Valves

(1) Diaphragm valves use nonsliding seals and are the preferred valve for bioprocessing fluid applications.

(2) Two-way, weir-style diaphragm valve bodies shall be permanently marked on both sides of the body to show optimum drain position. Orientation of welded and machine multiple-port bodies shall be included on submittal drawings. Other types of diaphragm valves should be installed to the manufacturer's recommendations.

(3) Point-of-use (POU) valves should be designed with the seal at or below the lowest point in the tube to facilitate draining.

(4) Diaphragms should be marked in accordance with Section 12.3 of MSS-SP-88.

(5) Weirless diaphragm valves use nonsliding seals. The installation angle is not critical due to the elimination of the weir in the body design; however, the valve should be installed to the manufacturer's recommendations.

(c) Rising Stem Seal Valves. Rising stem seal valves use sliding and nonsliding seals (see Figure 6C.3.2.3-1). Suitable designs are available for fluid utility applications such as clean steam and CIP as well as for product. The owner/user shall define the degree of suitability of the design for the application.

(1) Seals for rising stem valves are classified as follows:

(a) Primary Rising Stem Seals. Primary rising stem seals serve as pressure barriers for process fluids. Such seals shall be exposed for cleaning and shall meet the pressure and temperature requirements of the specified material outlined in this Standard and the aseptic and bioburden control requirements specified by the owner/user. In addition, they shall meet all of the general requirements for seals outlined in this section. Primary sealing can be provided in different ways.

(b) Nonsliding sealing such as bellows and diaphragms eliminate contamination risk by preventing the product/process contact surface(s) portion of the stem from contacting the atmosphere. When the primary stem seal is a nonsliding seal, a secondary stem seal is not required.

(2) Sliding seals such as lip-seals and O-rings can be used for the reciprocating stem between process fluid and atmosphere. Single sliding stem seals can be used for fluid utility applications such as clean steam and CIP. If sliding seals are to be used as the primary seal for product contact applications, there should be a secondary stem seal to facilitate cleaning and sanitization behind the primary sliding seal.

(b) Secondary Rising Stem Seals. Secondary seals serve as the sealing between atmosphere and a steam disinfection chamber (e.g., steam barrier or disinfection means barrier). These seals shall be designed to serve as pressure-sanitizing fluid. Such seals shall meet the pressure and temperature requirements of the specified material outlined in Part 6C of this Standard. Secondary stem seals are typically sliding seals (e.g., O-rings or lip-seals).

(2) Wherever elastomeric or polymeric seals are retained under static compression, adjoining metal surfaces shall be machined to a roughness specified by the seal manufacturer to ensure required performance, and shall meet the requirements of Part SF, if the fluid is exposed to the system fluid under the normal course of system operation.

(3) Primary stem O-ring seals shall be fitted in grooves located as close to the valve body cavity as possible to meet bioburden control requirements.

(4) When made from metal, static seals shall meet the surface finish requirements for the valve housing interior on the side facing the process fluid.

(d) Regulator Valves. When using regulator valves, a means of override is normally required to allow drainability and drainability of the valve.
(e) Ball Valves. Ball valves (Figure SG-3.3.1.3-1) are not recommended for product contact streams. The owner/user should determine whether a ball valve is acceptable for other process contact applications. Applications where ball valves are typically acceptable include liquid and gas utility and process support applications, such as clean steam. The valve bore I.D., including ball and body, shall match the I.D. of the connecting tubing to allow self-draining. Cavity fillers shall not be used.

(f) Butterfly Valves. Butterfly valves use sliding seals. Butterfly valves are commonly used for powder and vacuum applications. The valve should be installed per the manufacturer’s recommendations to allow self-draining.

(g) Steam Traps (Thermostatic). A thermostatic steam trap shall be designed to minimize the risk of soil attachment to the process fluid surfaces. The bellows should have a low subcool to prevent the backup of condensate into the process equipment and clean steam system. Steam traps shall be installed with an uninsulated section upstream of the trap to facilitate proper steam trap function (see Figure SD-3.12-1).

(h) Back Pressure Control Valves. Back pressure control valves shall be designed to allow free draining through the outlet or inlet port. Crevices created by a pierced diaphragm or soft seat plug shall be minimized.

(i) Pinch Valves. When using pinch valves, care shall be taken to prevent permanent deformation of the flexible tube or sleeve that restricts the flow or affects drainability.

(j) Check Valves. Check valves may use sliding and/or nonsliding seals. A check valve, clack valve, nonreturn valve, or one-way valve is a valve that allows fluid flow in one direction. Check valves using an exposed coil spring shall be of a design to prevent the coil spring from full compression creating an enclosure.

(k) Plug Valves. Rotating plug valves use sliding seals and are not preferred in product contact applications. Plug valves are suitable for liquid and gas utility applications such as clean steam and CIP. The plug valve uses a ¼-turn cylindrical plug with O-ring seals to provide straight-through flow. The plug I.D. does not always match the I.D. of the tubing; therefore, self-drainability of the valve is limited.

SG-3.3.2.4 End Face Mechanical Seal General Design Requirements

(a) General

(1) Mechanical seal hardware used to mount the mechanical seal to equipment shall be consistent with nonpooling and drainability requirements of Part SD.

(2) Springs and drive mechanisms (e.g., pins) shall not be located in the process fluid.

(3) When applicable, the seal should be designed in accordance with this Standard for CIP and/or SIP.

(4) Surface requirements for the process side of the mechanical seal shall be consistent with the requirements of Part SF.

(5) Process-side hardware radii shall meet the requirements of SD-2.4.2.
(6) Secondary seals are used in static and dynamic positions. The dynamic position in a typical mechanical seal is where the secondary seal is in contact with the spring-loaded seal face. The dynamic secondary seal accommodates motion during operation and face movement as the primary faces wear. The secondary seal shall be located and designed to be accessible to fluid flow and is driven by requirements of Part SD.

(7) Secondary seal material should be selected to minimize compression set on all phases of operation, which may include CIP and/or SIP.

(8) Materials of construction shall meet Part PM for polymers or other nonmetals and Part MM for metal components. The owner/user is responsible for selection of appropriate materials in consultation with the equipment supplier/manufacturer.

(9) Form S-1, Application Data Sheet, should be filled out with appropriate information to make a correct seal selection.

(10) Assembly lubrication will be specified by the owner/user in consultation with the equipment manufacturer. The owner/user will determine compatibility of the lubricant with the process. The equipment supplier/manufacturer will determine the compatibility of the lubricant with the seal components.

(b) Single Mechanical Seal

(1) Single mechanical seals are applied for their simplicity, observable leakage path to the atmosphere, and no requirement for maintenance.

(2) Single mechanical seals protect the process boundary at the seal’s secondary seals and at the seal’s primary face.

(3) When operating in pressurized process fluid, single mechanical seals will wick fluid to the atmosphere. If a process upset occurs, the seal will serve as a vacuum in the equipment, then wicking the fluid into the process fluid.

(4) Single liquid mechanical seals are applied when the process fluid has desirable lubricating characteristics to support the rubbing of the primary seal faces.

(a) Fluids that have desirable lubricating characteristics do not include fluids that change state, are in gaseous phase, precipitate solids, and cause thin film bonding, congealing, solidification, or crystallization between the seal faces.

(b) An example of a possible desirable lubricant is pure steam condensate at 100°F (38°C).

(5) Single dry contacting gas seals will operate in a gaseous phase environment.

(c) Dual Pressurized Mechanical Seal

(1) Dual mechanical seals are preferred to prevent process fluid from weeping to atmosphere and to prevent atmosphere from weeping into the process.

(2) Dual mechanical seals protect the process boundary with a pressurized barrier fluid.

(3) Dual pressurized seals are used when the process fluid does not have desirable lubricating characteristics.

(4) Dual pressurized seals shall be designed for liquid or gas barrier fluid. Dual pressurized seals cannot be designed for gas and liquid lubrication.

(5) Dual pressurized gas barrier seals can be contacting or noncontacting face design.

(6) A barrier fluid compatible with the process fluid and atmosphere shall be specified by the owner/user. The owner/user should consult with the equipment supplier/manufacturer to determine suitability of the barrier fluid for the dual pressurized mechanical seal.

(7) The owner/user should provide Form S-1, Application Data Sheet, so the supplier/manufacturer can recommend pressure, flow rate, and temperature of the barrier fluid.

(d) Dual Unpressurized Mechanical Seal

(1) Dual unpressurized mechanical seals are preferred to prevent dilution of the process fluid by the buffer fluid weeping across the inboard faces. The buffer fluid will prevent atmosphere from entering the process fluid. The process fluid will weep into the buffer fluid that may weep to the atmosphere.

(2) Dual unpressurized mechanical seals protect the process boundary with an unpressurized buffer fluid.

(3) Dual unpressurized seals are used when the process fluid has desirable lubricating characteristics.

(4) Dual unpressurized seals shall be designed for liquid or gas buffer fluid. Dual unpressurized seals cannot be designed for gas and liquid lubrication.

(5) Dual unpressurized gas buffer seals can be contacting or noncontacting face design.

(6) A buffer fluid and atmosphere should be specified by the owner/user. The owner/user should consult with the equipment supplier to determine suitability of the buffer fluid for the dual unpressurized mechanical seal.

(7) The owner/user should provide Form S-1, Application Data Sheet, so the supplier/manufacturer can recommend pressure, flow rate, and temperature of the buffer fluid.

SG-3.4 Compliance Requirements for Sealing Elements

MC

SG-3.4.1 General Requirements. A Certificate of Compliance shall be issued by the seal manufacturer to certify compliance to this Standard when required by the owner/user. Additional agreements may be required; refer to SD 24.1. At a minimum, seals exposed to process contact fluids and/or that have a high probability of exposure will comply with the United States Pharmacopeia (USP) directive with regard to USP <87> (or ISO 10993-5) and USP <88> Class VI (or ISO 10993-6, -10, and -11) on biological reactivity (see Part PM for additional details). Examples of seals coming in direct....
contact with a process stream include gaskets, O-rings, diaphragms, pinch tubes, and valve stem seals.

**SG-3.4.2 Certificate of Compliance.** See PM-2.2.1.

**SG-3.4.3 Test Requirements.** Conformance testing is done on initial qualification of the hygienic union. Testing is intended to show design conformance and is not required on every seal. Testing shall be repeated for significant changes in raw materials or processes used to fabricate seals. The seal manufacturer shall provide, on request of the owner/user, a certificate of design conformance that the sealed union meets the intrusion requirements of SG-4.2. The intrusion value is defined as the measured quantity that provides the maximum radial distance from the fitting I.D. to the point of maximum intrusion under the manufacturer's specified conditions (e.g., torque, fitting design, clamp design). The point of maximum intrusion/recess shall be measured using a method that does not cause deformation of the components being measured.

**SG-3.4.4 Additional Requirements.** [Reserved for future content]

**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.

**SG-3.6 Other Seal Requirements**

[Reserved for future content]

**SG-4 SEAL PERFORMANCE REQUIREMENTS**

**SG-4.1 General Requirements**

Seals form an integral part of process systems and maintain static and/or dynamic system boundaries while being exposed to chemical, thermal, and mechanical (hydraulic and pneumatic) conditions in both cyclic and continuous modes of operation. On exposure to operating conditions, the seal shall not swell, shed, crack, erode, or otherwise deteriorate to an extent that it impacts the product or process during its expected lifetime. The seal shall not add to nor remove from the process or product to which it is exposed beyond an acceptable level (see PM-3). Following exposure to the process conditions, the seal shall be capable of being inspected, serviced, and/or replaced. Specific seal performance criteria shall be established by the owner/user in consultation with the seal supplier/manufacturer. Form S-1, Application Data Sheet, may be used to communicate expected process conditions.

Any given seal is not designed to perform in all possible operating conditions.

Parameters for evaluating the performance of a seal include leak rate, sealing location, dimensional stability, material stability (including shedding), and serviceability. The requirements for each of the parameters depend on the seal type and application. To predict how a seal will perform in service it shall be evaluated (e.g., testing, past performance). Standardized performance test conditions and methods permit a consistent approach to gathering data used to evaluate seal performance. When evaluating performance test data, the owner/user should consider if the test parameters are relevant to the conditions expected in the application. Performance data should be considered when determining the appropriate service interval for the desired application.

**SG-4.2 Static Seal Performance**

Static seals shall meet the general performance requirements of SG-4.1.

On initial installation, a hygienic static seal shall provide a substantially flush interface with the hygienic clamp ferrules. Hygienic seals shall meet and be designated by one of the following intrusion categories when tested by the seal manufacturers:

(a) *Intrusion Category I.* Seals having a maximum intrusion/recess of 0.025 in. (0.6 mm).

(b) *Intrusion Category II.* Seals having a maximum intrusion/recess of 0.008 in. (0.2 mm).

The purpose of a flush interface is to minimize the entrapment of material in a dead space that can lead to microbial growth and contamination (see Figure SG-4.2-1). Excessive intrusion into the process stream may lead to erosion of elastomeric seals, thereby contaminating the process stream. The amount of intrusion depends on the dimensional control of the seal, the hygienic clamp ferrule dimensions [see Table DT-7-1 and Figure SG-2.2.2-1, illustrations (a) through (c)], the amount of torque applied to the flange, the material properties of the seal, the application of steam, and the surface of the seal (wet or dry) during installation.

Testing parameters used to identify the desired performance should be based on the intended operating conditions. Nonmandatory Appendix K identifies standard process test conditions (SPTC) and a method for performing testing to gather data used to evaluate the appropriate level (e.g., 10, 100, or 500) of the seal for the given service life. Performance data are collected at 10-, 100-, and/or 500-cycle intervals. The 10-cycle
interval is intended to provide data for short durations (e.g., single-use or inspect-between-use applications). The 100- and 500-cycle intervals are intended to provide data on the service life of the seals (e.g., multiple-use applications) that are not routinely inspected.

**MC**

**SG-4.3 Dynamic Seal Performance**

**SG-4.3.1 Valve Seal Performance.** Valve seal performance is acceptable when the seal maintains the system boundaries and design flow characteristics for which it was intended (e.g., static and/or dynamic). A valve seal shall operate through the desired range of motion against differential pressure. It shall be hygienic and meet the cleanliness requirements stated in **3.3.2.3.** A valve seal shall meet these performance conditions following exposure to operating conditions in both cyclic and continuous modes of operation.

Performance data shall be collected at intervals that reflect the use mode (e.g., discrete/open/closed or modulating), operation (e.g., continuous or cyclic), and intended service life (e.g., continuous hours of exposure or number of cycles) of the valve seal.

Testing parameters shall be based on the operating conditions of the intended application. **Nonmandatory Appendix K** identifies standard process test conditions and a method for conducting performance tests of seals in simulated process conditions. For valve seal testing, the method identified in **Nonmandatory Appendix K** requires modification to reflect a specific use mode and intended operation of a valve seal. **Form S-1,** Application Data Sheet, identifies a number of operational conditions (e.g., chemistry, temperature, pressure) to consider when developing nonstandard performance tests.

**MC**

**SG-4.3.1.1 New Valve Seal Performance.** The valve manufacturer shall test each valve assembly as part of the production process or shall validate the design and manufacturing process. One-hundred percent leak testing is not required for validated manufacturing processes.

When EN 12266-1 is specified below, use leakage rate A when evaluating seat leakage performance. For control valves, other leakage rates may be used with agreement by the owner/user.

(a) For diaphragm valves, the following requirements shall apply:

(1) seat leakage rates per MSS-SP-88, EN 12266-1, or ANSI/FCI Standard 70-2, Class VI

(2) shell leakage rates per MSS-SP-88 category C or EN 12266-1

(b) For ball valves, the requirements of MSS-SP-72, MSS-SP-110, or EN 12266-1 shall apply.

(c) For rising stem, mix-proof, and needle valves, the requirements of EN 12266-1 shall apply. For seat tightness, Test P12 of EN 12266-1, use the globe valve test method.

(d) For butterfly valves, the requirements of MSS-SP-67 or EN 12266-1 shall apply.

(e) For pinch valves, the requirements of EN 12266-1 shall apply. For seat tightness, Test P12 of EN 12266-1, use the diaphragm valve test method.

(f) For plug valves, the requirements of EN 12266-1 shall apply.

**SG-4.3.2 Mechanical Seal Performance.** Mechanical seal performance may be characterized by leakage rate, service life, cleanliness, particle shedding, suitability for application, and heat generation. Acceptable values for each of these characteristics may vary widely, so it is strongly advised that the mechanical seal’s various characteristics and the ramifications of each to the service are understood.

**Nonmandatory Appendix K-2.1** provides important information about mechanical seal performance. It provides exceptions to normal seal performance that are commonly found in the industry. Familiarity with these will help the reader understand the impact that design, installation, and operation have on mechanical seal performance. Also included in **Nonmandatory Appendix K-2.1** are outlines for various methods of testing seal integrity.

**SG-4.3.2.1 New Mechanical Seal Performance.** There are four key points between procurement and operation of a new mechanical seal where the seal might be evaluated for performance. The four key points are manufacturing, installation, assembly, and use.
(a) **Point of Manufacture.** Mechanical seal manufacturers have performance requirements for new seals. The manufacturer's tests should be accepted. If special performance requirements are necessary, those special requirements shall be specified.

If the mechanical seal manufacturer alters the design, material, or manufacturing technique of a mechanical seal in service, it is the responsibility of the mechanical seal manufacturer to inform all relevant parties that changes have occurred. Specific information may be requested from the seal manufacturer to support the premise that seal performance has not been altered.

(b) **Point of Seal Installation.** The mechanical seal will be installed in a piece of equipment. An original equipment manufacturer (OEM) will typically have its own test to verify the performance of the mechanical seal. The test of the OEM should be accepted. A review of the OEM test procedure may be requested. The OEM should consult with its seal supplier/manufacturer for seal performance issues and questions.

Contractors may install a new seal in a piece of equipment. The seal performance test may be reviewed with the installation contractor.

If unique conditions exist where special performance requirements are necessary, it is the customer’s responsibility to specify the additional requirements. An acceptable performance test may be developed.

If the OEM alters the design, material, or manufacturing technique of a mechanical seal in service, or is informed by the seal manufacturer that the design, material, or manufacturing technique has been altered, it is the responsibility of the OEM to inform all relevant parties that changes have occurred.

(c) **Point of Systems Assembly.** The equipment that contains the seal is installed in a system. The system’s supplier/manufacturer will have standard test procedures for testing the system integrity. The test procedures of the system’s supplier/manufacturer should be accepted. A review of the test procedure may be requested. The system assembler should consult with the OEM/manufacturer for seal performance issues and questions.

If the system assembler alters the design, material, or manufacturing technique of a mechanical seal in service, or is informed by the OEM that the design, material, or manufacturing technique has been altered, it is the responsibility of the system assembler to inform all relevant parties that changes have occurred.

(d) **Point of Use.** Once the system is delivered to the destination. It is the owner/user’s responsibility to determine if the mechanical seals meet performance requirements. The owner/user should consult with the system designer/manufacturer/vendor for seal performance issues and questions.

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**MC SG-4.3.2.2 Installed Seals.** Original point-of-use performance requirements shall be used to determine if the seal is suitable for continued use. Refurbished seals shall be held to the original point-of-use performance requirements. It is the owner/user's responsibility to monitor equipment for failure.

**MC SG-5 SEAL APPLICATIONS**

**MC SG-5.1 General Considerations**

This section provides guidance for selecting sealing components for common applications. Each component is recommended for its suitability for the particular application, and the selection reflects current common industry practice.

Every component has its own limited process capabilities and service life for each application in which it is used. Application characteristics such as size, speed, pressure, temperature, cycles, and cycle time help define an application envelope and will determine the suitability of a particular component. Appropriate component selection requires understanding of the application requirements and component capabilities.

In order to use the component selection guidance in this section

(a) The owner/user shall collect the required application data (e.g., **Form S-1**, Application Data Sheet).

(b) If the owner/user's application data fall inside the component's application envelope, then the guidance provided is valid.

(c) If the owner/user's application data fall outside the component's application envelope, then the owner/user should consult with the vendor to find the appropriate component.

Sections describing each seal type may list additional characteristics of the system and equipment necessary to ensure proper application of that component.

Seals shall be accessible for maintenance.

**MC SG-5.1.1 Static Seals.** Static seals used in all applications shall

(a) meet the specific design requirements of MC SG-3.3.2.2.

(b) meet the requirements of Part PM unless otherwise agreed to by the seal/equipment supplier and owner/user.

(c) meet the operational requirements of the application envelope as defined in the relevant section of MC SG-5.

Static seal performance (chemical resistance, physical properties, and maintenance considerations) varies significantly with both material class (e.g., EPDM, FKM, PTFE) and each supplier’s formulation and manufacturing choices. The owner/user should consult with the seal/equipment supplier to determine which material(s) have the best balance of properties for their specific static application and expectations for service life.
Application-specific static seals selection guidance is provided in Nonmandatory Appendix AA to assist the discussion between supplier and owner/user.

Hygienic union fitting details (e.g., torque settings, choice of clamping mechanism, and alignment) significantly affect the performance and longevity of static sealing components and should be considered (see also ASME B31.3). For example, overtightening of these clamps may damage seals or cause excessive intrusion (see SG-4.2).

SG-5.2 Process Systems

[Reserved for future content]

SG-5.3 Compendial Ambient/Hot-Water Distribution Systems

The application and selection of sealing components are based on compendial water at temperatures between 68°F and 185°F (20°C and 85°C) and pressures greater than 0 psig (0 barg) up to 87 psig (6 barg). Systems may be exposed to hot-water sanitization and/or intermittent steam at up to 266°F (130°C).

These systems are typically constructed of metallic materials.

Sealing components used in compendial water systems should be selected based on requirements for long-term seal reliability in a continuous-duty cycle.

(a) Most compendial water systems are sanitized with hot water (self-sanitizing). When systems are steam-sanitized, the owner/user should consult with the static seal manufacturer to determine the appropriate materials/fittings based on operational requirements.

(b) Seals used in systems that are periodically heated for sanitization should be selected to accommodate thermal cycling.

SG-5.3.1 Valves for Compendial Water

SG-5.3.1.1 Seals for Compendial Water. A polymer seal material is acceptable provided that the manufacturer rates the seal material for the pressure and temperature limits and the material is compatible with the service stated in SG-5.3.

SG-5.3.1.2 Valve Types for Compendial Water

(a) Valves shall meet the general design requirements of SG-3.3.2.3(a).

(b) Diaphragm valves, which have nonsliding seals, as designated in SG-2.3.1.2(a), SG-2.3.1.2(b), and SG-2.3.1.2(c), are preferred.

(c) Other valve types with nonsliding seals are acceptable (e.g., pinch valves designated in SG-2.3.1.8; bellows seals like those shown in Figure SG-2.3.1.2-2, illustration (c); membrane or diaphragm seals like those shown in Figure SG-2.3.1.2-4, illustrations (b) and (c), Figure SG-2.3.1.2-5, or Figure SG-2.3.1.4-1, illustration (a)).

(d) Valves with sliding seals in process contact are not acceptable (e.g., ball, butterfly, or plug valves) unless the design enables maintaining both sides of the sliding seal in a clean and sanitized condition or the valves are used in a continuously self-sanitizing system.

(e) Valves with nonsliding and sliding seals are acceptable if only the nonsliding seal is in process contact (e.g., needle, control, or rising stem valves with O-ring seals).

SG-5.3.2 Single Mechanical Seals for Compendial Water per SG-3.3.2.4(a) and SG-3.3.2.4(b)

SG-5.3.2.1 Additional Application Conditions Relevant to Mechanical Seals. The fluid in contact with the mechanical seal is process compendial water during operation. The corrosive component is compendial water.

SG-5.3.2.2 Additional Equipment Characteristics Relevant to Mechanical Seals. The selections shown in SG-5.3.2.3 and SG-5.3.2.4 apply only for equipment with

(a) shaft sizes: ≤2 in. (50 mm)

(b) shaft speed: 0 RPM to 3,600 RPM

(c) radial runout: <0.002 in. (0.05 mm) total indicator reading (TIR)

(d) perpendicularity of mounting flange: <0.002 in. (0.05 mm) TIR to shaft

(e) axial movement: <0.005 in. (0.13 mm)

SG-5.3.2.3 Materials of Construction. Materials of construction shall comply with Part MM and/or Part PM, as appropriate.

There are two sets of conditions that should be considered for material selection in compendial water due to the tribological characteristics of the seal face pair

(a) operating 68°F to 160°F (20°C to 71°C), steam at 266°F (130°C) and 0 RPM, and 0 psig to 87 psig (0 barg to 6 barg)

(b) operating 68°F to 185°F (20°C to 85°C), steam at 266°F (130°C) and 0 RPM, and 0 psig to 87 psig (0 barg to 6 barg)

SG-5.3.2.4 Flush Plans. Flush Plan numbers 01, 02, 03, and 11, as defined in SG-2.3.2.4, are recommended.

Compendial water is the seal face lubricant.

SG-5.4 Pure Steam Distribution Systems

The application and selection of sealing components is based on pure steam with pressures to 45 psig (3.1 bar), at 292°F (145°C) (saturated steam) in high-pressure distribution areas, and 25 psig (1.7 bar), at 267°F (130°C) (saturated steam) in low-pressure distribution areas.

Seals used in service conditions beyond these limits require special consideration.

Sealing components used in pure steam distribution systems should be selected based on requirements for long-term seal reliability in a continuous-duty cycle.
Pure steam systems should be designed to provide access for examination and replacement of sealing components as many seal types used with pure steam lines may leak after thermal cycling.

**SG-5.4.1 Static Seal Recommendations for Pure Steam Distribution Systems.** Static seals used for pure steam applications should be selected (see Nonmandatory Appendix AA) for their ability to

(a) resist pure steam

(b) withstand continuous high temperatures

(c) minimize retightening

Hardware for use with static seals in pure steam systems should be selected to accommodate creep (cold flow) when plastic seals (e.g., PTFE or PTFE composites) are used.

**SG-5.4.2 Valves for Pure Steam Distribution Systems**

**SG-5.4.2.1 Valve Seals.** A polymeric seal material is acceptable provided that the manufacturer rates the seal material for the pressure and temperature limits and the service conditions stated in SG-5.4.

**SG-5.4.2.2 Valve Types**

(a) Valves shall meet the general design requirements of SG-3.3.2.3(a) and SD-4.2.3. Valve design and materials of construction shall be rated for the pressure and temperature ranges of the service stated in SG-5.4.

(b) Valve types with nonsliding or sliding seals are acceptable (e.g., diaphragm, ball, rising stem, steam trap, pressure control, check, pressure relief, and plug valves).

**SG-5.5 CIP**

[Reserved for future content]
CHAPTER 5
FABRICATION, ASSEMBLY, AND ERECTION

PART MJ
MATERIALS JOINING

MJ-1 PURPOSE AND SCOPE

The purpose of this Part is to provide requirements for the joining of metallic and polymeric materials. This includes joining methods, welding procedure and performance qualifications, examination, inspection, testing, and acceptance criteria.

MJ-2 MATERIALS

MJ-2.1 Base Metals

MJ-2.1.1 Stainless Steels

(a) Austenitic Stainless Steels. Only the austenitic stainless steel grades listed in Table MM-2.1-1 or Table MM-2.1-3 may be used for welded components, except as permitted in MM-5.1.

Weld ends that are to be autogenously welded (without filler metal or consumable inserts) shall meet the requirements of MM-5.2.1.

However, a process component or tube of one of the above alloys with a sulfur content either below the lower limit or above the upper limit for sulfur in MM-5.2.1.1 may be used in a welded connection, provided all of the following conditions are met:

(1) Use of the process component or tube is agreed to by the owner/user.

(2) All welds on the component or tube are internally inspected and meet the requirements of MJ-8.4.

(b) Superaustenitic Stainless Steels. Only the superaustenitic stainless steel grades listed in Table MM-2.1-1 or Table MM-2.1-3 may be used for welded components, except as permitted in MM-5.1.

The superaustenitic stainless steels are prone to the precipitation of undesirable secondary intermetallic phases such as sigma and chi. The cautions of MM-5.2.3 shall be considered when welding superaustenitic stainless steels.

(c) Duplex Stainless Steels. Only the duplex stainless steel grades listed in Table MM-2.1-1 or Table MM-2.1-3 may be used for welded components, except as permitted in MM-5.1. The cautions of MM-5.2.3 shall be considered when welding duplex stainless steels.

MJ-2.1.2 Nickel Alloys. Only the nickel alloys listed in Table MM-2.1-2 or Table MM-2.1-3 may be used for welded components, except as permitted in MM-5.1.

MJ-2.1.3 Copper Alloys. Only the copper alloys listed in Table MM-2.1-4 may be used for brazed systems.

MJ-2.1.4 Other Metals. Other metals (e.g., titanium, tantalum, palladium, or gold, as used in instrumentation) may be joined, when specified by the owner/user.

MJ-2.2 Filler Metals

MJ-2.2.1 Stainless Steels. When filler metals are used, the matching filler metals listed in Tables MM-5.3-1 and MM-5.3-2 shall be used, except that higher alloy filler metals may be used when specified by the owner/user.

Austenitic stainless steel grades may be welded with or without filler metals. See MM-5.3 and MM-5.3.1 for further instructions.

Superaustenitic stainless steels may be welded with or without filler metals or consumable inserts. When welded autogenously (without filler metal or consumable inserts), postweld heat treatment in accordance with MM-5.4 is required. See MM-5.3.2 for further instructions.

Duplex stainless steels may be welded with or without filler metals or consumable inserts. When welded autogenously, postweld heat treatment in accordance with MM-5.4 is required. Welding of duplex stainless steels generally results in an increase in the amount of ferrite in the microstructure, and, as a result, appropriate welding procedures should be selected. The balance of austenite and ferrite in the weld metal shall be maintained so that there is no less than 30% of the lesser phase. See MM-5.3, MM-5.3.2 and MM-5.3.3 for further instructions.

MJ-2.2.2 Nickel Alloys. When filler metals are used, the matching filler metals listed in Tables MM-5.3-1 and MM-5.3-2 shall be used, except that higher alloy filler metals may be used when specified by the owner/user.
MJ-3.1 JOINT DESIGN AND PREPARATION

MJ-3.1.1 General

All butt joints in which one or both weld faces are process contact surfaces shall have continuous complete weld joint penetration. This requirement exists for welds made from either one side or both sides of the weld joint. All weld joints shall have the process contact surfaces properly purged or protected for the prevention of discoloration or contamination. External attachments (e.g., lift lugs, dimple jackets, or ladder clips) shall have any discoloration of the process contact surface removed.

Welds attaching any connection that passes through the wall of a tank or vessel, or a branch connection on a pipe or tube system, in which one or both sides of the weld joint is a process contact surface, shall be either joined with a full penetration groove weld [similar to Figure SD-3.4.2-2, illustration (a)], or have at least one telltale hole provided if double fillet welded only [similar to Figure 3.4.2-2, illustration (b)]. A telltale hole is required on all lap, tee, corner, or edge joints that have one or both welds as a process contact surface and are not attached by full penetration welds. The weld joint shall be prepared by means compatible with hygienic service. The weld joint shall be properly cleaned within 1/2 in. (13 mm) on the inside and outside surfaces, where accessible, prior to welding. Fillet welds, groove welds, or a combination of both may be used.

MJ-3.5 Tube-Attachment Welds

(a) Tube-attachment welds are those that
(1) make branch connections other than those used to fabricate the fittings described in Part DT
(2) attach tubes to other product forms
(3) attach nozzles to transfer panels
(4) attach a tube to any part of a hygienic system

(b) Tube-attachment welds not governed by this section include
(1) those governed by MJ-8.4
(2) tube-to-tubesheet welds that are governed by ASME BPVC, Section VIII, in addition to the visual examination requirements of Part SF and MJ-8.2

These welds may be performed manually, by machine, or by an automatic welding process. Joint designs shall comply with MJ-3.1. The weld joints for complete penetration welds shall be prepared by means compatible with hygienic service. The weld joints shall be properly cleaned within 1/2 in. (13 mm) on the inside and outside surfaces, where accessible, prior to welding. Fillet welds, groove welds, or a combination of both may be used.

MJ-3.6 Brazed Joints

Joint design shall comply with the latest edition of NFPA 99.

Socket welding is not permitted in process stream systems or where CIP or SIP requirements are defined.

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a change in the weld head type from open head to closed head or vice versa.

(k) a change from single-pass to multipass welding or vice versa, when using filler wire.

In addition, either the original ASME BPVC, Section IX qualification coupon or another tube-to-tube weld coupon made by that same welding operator shall be visually examined and shall meet all the requirements of Table MJ-8.4-1.

Any change in the variables listed in (a) through (k) requires welding of a new test coupon, for which only visual examination in accordance with Table MJ-8.4-1 is required. Compliance with the variables in this paragraph shall be documented.

MJ-6.4 Brazing

Brazer performance qualifications, for piping systems, shall be in accordance with NFPA 99 and shall be made under an internal purge and exhibit full joint penetration.

MJ-7 EXAMINATION, INSPECTION, AND TESTING

Owner/user, inspection contractor, and/or engineer shall agree to the types of examinations, inspections, and testing unless otherwise specified in the applicable code.

MJ-7.1 Examination Procedures

MJ-7.1.3 Tubing. Examination procedures for tubing systems shall be in accordance with ASME B31.3.

MJ-7.1.4 Tube Attachments. Examination procedures for tubing systems shall be performed in accordance with ASME B31.3.

MJ-7.1.5 Brazing. Examination procedures for brazed systems shall be in accordance with NFPA 99.

MJ-7.2 Personnel Requirements

MJ-7.2.1 Pressure Vessels and Tanks. Personnel performing examinations of pressure vessels and tanks designed to ASME BPVC, Section VIII shall meet the requirements of the appropriate section of that Code.

All inspectors shall be qualified in accordance with GR-4.

All Inspectors' Delegates shall meet the requirements of GR-4.2.

MJ-7.2.2 Piping. All examiners, inspectors, and Inspectors' Delegates shall be qualified in accordance with GR-4.

MJ-7.2.3 Tubing. All examiners, inspectors, and Inspectors' Delegates shall be qualified in accordance with GR-4.

MJ-7.2.4 Tube Attachments. All examiners, inspectors, and Inspectors' Delegates shall be qualified in accordance with GR-4.

MJ-7.2.5 Copper Tubing/Piping. All examiners, inspectors, and Inspectors' Delegates shall be qualified in accordance with GR-4.

MJ-7.2.6 Examination Personnel Eye Examination Requirements. Personnel performing examinations shall have eye examinations as follows:

(a) 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.

(b) 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.
such as cracks, voids, porosity, or joint misalignment that will promote contamination of the process fluid. All welding procedures shall be qualified to MJ-5.

**MJ-8.2 Pressure Vessel and Tank Welds**

Weld acceptance criteria for pressure vessels and tanks shall be in accordance with ASME BPVC, Section VIII, with the additional requirements of Table MJ-8.2-1.

**MJ-8.3 Piping Welds**

Weld acceptance criteria for piping shall be in accordance with the specified fluid service of ASME B31.3. The additional requirements of Table MJ-8.3-1 shall apply. See SD-3.1.1 for cautionary information if using pipe instead of tube for hygienic systems.

**MJ-8.4 Tubing Welds**

Weld acceptance criteria (including borescopic acceptance criteria) for tubing and components shall be in accordance with Table MJ-8.4-1. This includes welds on components but not longitudinal welds on tubes manufactured in accordance with a recognized standard. Welds performed in the fabrication of extruded branch outlets (such as tees) and reducers are exempt from the misalignment criteria.

Preproduction sample welds, when required, shall be submitted by the contractor to the owner/user to establish weld quality. The owner/user, contractor, and inspection contractor shall agree to the number and type of sample welds.

During construction, sample welds shall be made on a regular basis to verify that the equipment is operating properly and that the purging setup is adequate to prevent discoloration beyond the level agreed on by the owner/user and contractor. The owner/user and contractor shall agree to the frequency of sample welds. It is strongly recommended that these sample welds be made at the beginning of each work shift, whenever the purge source bottle is changed, and when the automatic or machine welding equipment is changed (such as when the orbital tube weld head is changed).

The sample welds described in the preceding paragraphs, and any associated welding machine printed records (e.g., welding parameter printouts directly from the welding machine or downloaded from a welding machine), if any, may be disposed of after written acceptance of the coupons by the owner, the owner’s representative, or the inspector.

**MJ-8.4.1 Sample Welds.** Sample welds for tubing shall meet all the acceptance criteria of Table MJ-8.4-1. An internal bead width of 1.0 to 2.5 times the nominal wall thickness is required.

**MJ-8.4.2 Rewelding.** Rewelding (reflow) may be attempted one time only for the following defects:

(a) incomplete penetration (lack of penetration)
(b) incomplete fusion (lack of fusion)
(c) un Consumed tack welds that can be inspected on the process contact side

All rewelds shall either totally consume the original weld or overlap the original weld with no base metal between the welds.

**MJ-8.5 Tube-Attachment Welds**

The acceptance criteria for tube-attachment welds shall be in accordance with Table MJ-8.5-1 (see also Figure MJ-8.5-1).

**MJ-8.5.1 Sample Welds.** Sample welds are not required for tube-attachment welds or seal welds.

**MJ-8.5.2 Rewelding.** Rewelding is allowed, except for welds that are process contact surfaces, for which the restrictions of MJ-8.4.2 apply.

**MJ-8.6 Brazed Joints**

Brazed joint acceptance criteria shall be in accordance with NFPA 99.

**MJ-9 JOINING OF POLYMERIC MATERIALS**

**MJ-9.1 General**

Polymeric materials are described in Part PM. All joining techniques may not be available for all polymeric materials, nor are all methods acceptable for all processes. The selection of materials of construction and joining techniques is based on application requirements.

**MJ-9.2 Weld Joint Design and Preparation**

The weld surfaces to be joined shall be properly aligned. This may include planing or facing of the components. The weld surfaces shall be protected against adverse environmental influences, including excessive moisture, extreme temperature conditions, excessive drafts, and contamination sources (e.g., dirt, dust, oil, foreign material shavings).

**MJ-9.2.1 Tubing and Piping.** Joint designs for tubing, piping, and fittings shall be square butt joints. Joining surfaces shall have ends prepared by molding, cutting, machining, or facing to provide a square end that meets requirements for the applicable welding procedure specification (WPS).
<table>
<thead>
<tr>
<th>Discontinuities</th>
<th>Welds on Process Contact Surfaces</th>
<th>Welds on Non-Process Contact Surfaces</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Welds Left in the As-Welded Condition</td>
<td>Prior to Postweld Finishing</td>
</tr>
<tr>
<td>Cracks</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Lack of fusion</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Incomplete</td>
<td>None on process</td>
<td>None on process</td>
</tr>
<tr>
<td>Porosity</td>
<td>None open to the surface; otherwise, see Note (1)</td>
<td>acceptance criteria for pits/porosity</td>
</tr>
<tr>
<td>Inclusions</td>
<td>None open to the surface; otherwise, see Note (1)</td>
<td>See Note (1)</td>
</tr>
<tr>
<td>Undercut</td>
<td>None</td>
<td>See Note (1)</td>
</tr>
<tr>
<td>Groove weld concavity</td>
<td>See Note (1)</td>
<td>See Note (1)</td>
</tr>
<tr>
<td>Fillet weld convexity</td>
<td>$\frac{1}{16}$ in. (1.5 mm) max.</td>
<td>Per applicable design and fabrication code</td>
</tr>
<tr>
<td>Discoloration (heat-affected zone) and weld bead</td>
<td>Heat-affected zone (HAZ) may be permitted to have light straw to light blue color (see Figures M8.4-2 and M8.4-3). Any discoloration present must be tightly adhering to the surface such that normal operations will not remove it. In any case, the HAZ shall have no evidence of rust, free iron, or sugaring. See Note (3).</td>
<td>N/A</td>
</tr>
<tr>
<td>Discoloration (weld bead)</td>
<td>None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (3).</td>
<td>N/A</td>
</tr>
<tr>
<td>Oxide island</td>
<td>Oxide islands are permitted as long as they are adherent to the surface. Reflective color of oxide island is not cause for rejection. Alloy types are identified in Tables MM-2.1-1, MM-2.1-2, and MM-2.1-3.</td>
<td>N/A</td>
</tr>
<tr>
<td>Reinforcement</td>
<td>See Note (1)</td>
<td>See Note (1)</td>
</tr>
<tr>
<td>Tack welds</td>
<td>See Note (1)</td>
<td>N/A</td>
</tr>
<tr>
<td>Arc strikes</td>
<td>None</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Discoloration of light straw to light blue color is permitted (see Figures MJ-8.4-2 and MJ-8.4-3). Acceptable discoloration levels beyond that shall be established between the owner/user and contractor.
### Table MJ-8.2-1 Visual Examination Acceptance Criteria for Welds on Metallic Pressure Vessels and Tanks (Cont’d)

<table>
<thead>
<tr>
<th>Discontinuities</th>
<th>Welds Left in the As-Welded Condition</th>
<th>Prior to Postweld Finishing</th>
<th>After Postweld Finishing</th>
<th>Welds Left in the As-Welded Condition</th>
<th>After Postweld Finishing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overlap</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Weld bead width</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Minimum fillet weld size</td>
<td>See Note (1)</td>
<td>See Note (1)</td>
<td>See Note (1)</td>
<td>See Note (1)</td>
<td>See Note (1)</td>
</tr>
<tr>
<td>Misalignment (mismatch)</td>
<td>See Note (1)</td>
<td>See Note (1)</td>
<td>See Note (1)</td>
<td>See Note (1)</td>
<td>See Note (1)</td>
</tr>
</tbody>
</table>

**NOTES:**
(1) The limits of ASME BPVC, Section VIII shall apply.
(2) Does not apply to insulation sheathing and similar welds.
(3) Welds on pressure vessels or tanks that have been in service may require unique criteria.

### Table MJ-8.3-1 Visual Examination Acceptance Criteria for Welds on Metallic Pipe

<table>
<thead>
<tr>
<th>Discontinuities</th>
<th>Welds Left in the As-Welded Condition</th>
<th>Prior to Postweld Finishing</th>
<th>After Postweld Finishing</th>
<th>Welds Left in the As-Welded Condition</th>
<th>After Postweld Finishing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cracks</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Lack of fusion</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Incomplete penetration</td>
<td>None</td>
<td>None on process contact side; otherwise, see Note (1)</td>
<td>None on process contact side; otherwise, see Note (1)</td>
<td>See Notes (1) and (2)</td>
<td>See Notes (1) and (2)</td>
</tr>
<tr>
<td>Porosity</td>
<td>None open to the surface; otherwise, see Note (1)</td>
<td>See Note (1)</td>
<td>See Table SF-2.2-1 for acceptance criteria for pits/porosity</td>
<td>None open to the surface; otherwise,</td>
<td>None open to the surface; otherwise,</td>
</tr>
</tbody>
</table>

**Discoloration of light straw to light blue color is permitted. Acceptable discoloration levels beyond that shall be established between the owner/user and contractor. The color photos in Figure MJ-8.4-3, PFI Standard ES-50, or AWS D18.2 may be used as a guide.**

- **Undercut**
  - N/A [see Note (3)]
- **Concavity**
  - See Note (1)
  - See Note (1)
- **Fillet weld convexity**
  - $\frac{1}{16}$ in. (1.5 mm) max.
  - See Note (1)
  - $\frac{1}{32}$ in. (0.8 mm) max
- **Discoloration (heat-affected zone)**
  - Heat-affected zone (HAZ) may be permitted to have light straw to light blue color (see Figures MJ-8.4-2 and MJ-8.4-3). Any discoloration present must be tightly adhering to the surface such that normal operations will not remove it. In any case, the HAZ shall have no evidence of rust, free iron, or sugaring. See Note (3).
  - HAZ may be permitted to have light straw to light blue color (see Figures MJ-8.4-2 and MJ-8.4-3). Any discoloration present must be tightly adhering to the surface such that normal operations will not remove it. In any case, the HAZ shall have no evidence of rust, free iron, or sugaring. See Note (3).
**Table MJ-8.3-1 Visual Examination Acceptance Criteria for Welds on Metallic Pipe (Cont’d)**

<table>
<thead>
<tr>
<th>Discontinuities</th>
<th>Welds Left in the As-Welded Condition</th>
<th>Prior to Postweld Finishing</th>
<th>After Postweld Finishing</th>
<th>Welds Left in the As-Welded Condition</th>
<th>After Postweld Finishing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discoloration (weld bead)</td>
<td>None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (3).</td>
<td>N/A [see Note (3)]</td>
<td>None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (3).</td>
<td>Per customer specification</td>
<td>Per customer specification</td>
</tr>
<tr>
<td>Oxide island</td>
<td>Oxide islands are permitted as long as they are adherent to the surface. Reflective color of oxide islands is not cause for rejection. Alloy types are identified in Tables MM-2.1-1, MM-2.1-2, and MM-2.1-3.</td>
<td>N/A</td>
<td>None allowed</td>
<td>Oxide islands permitted</td>
<td>Oxide islands permitted</td>
</tr>
</tbody>
</table>

**Reinforcement** | See Note (1) | See Note (1) | 1/32 in. (0.8 mm) max. | See Note (1) | See Note (1) |
**Tack welds** | Must be fully consumed by final weld bead | Must be fully consumed by final weld bead | Must be fully consumed by final weld bead | Per customer specification | Per customer specification |
**Arc strikes** | None | None | None | None | None |
**Overlap** | None | None | None | None | None |
**Weld bead width** | N/A | N/A | N/A | N/A | N/A |
**Minimum fillet weld size** | See Note (1) | See Note (1) | See Note (1) | See Note (1) | See Note (1) |
**Misalignment (mismatch)** | See Notes (1) and (4) | See Notes (1) and (4) | See Notes (1) and (4) | See Notes (1) and (4) | See Notes (1) and (4) |

**NOTES:**
(1) The limits of ASME B31.3 shall apply.
(2) Does not apply to insulation sheathing and similar welds.
(3) Special surface preparation may be needed to meet the criteria. Welds on piping that has been in service may require unique criteria.
(4) It is recognized that the I.D. misalignment is more relevant to hygienic design than O.D. misalignment. However, not all connections facilitate ready measurement of I.D. misalignment. For situations where compliance with O.D. misalignment criteria results in an I.D. misalignment that could affect drainability or cleanability, see Nonmandatory Appendix C for further details.

**Table MJ-8.4-1 Visual Examination Acceptance Criteria for Groove Welds on Metallic Tube-to-Tube Butt Joints**

<table>
<thead>
<tr>
<th>Discontinuities</th>
<th>Welds on Process Contact Surfaces</th>
<th>Welds on Non-Process Contact Surfaces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cracks</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Lack of fusion</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Incomplete penetration</td>
<td>None [see Figure MJ-8.4-1, illustration (g)]</td>
<td>None [see Figure MJ-8.4-1, illustration (g)]</td>
</tr>
<tr>
<td>Porosity</td>
<td>None open to the surface; otherwise, see Note (1). If postweld finishing is performed, see Table SF-2.2-1 for acceptance criteria for pits/porosity.</td>
<td>None open to the surface; otherwise, see Note (1)</td>
</tr>
<tr>
<td>Inclusions [metallic (e.g., tungsten) or nonmetallic]</td>
<td>None open to the surface; otherwise, see Note (1)</td>
<td>See Note (1)</td>
</tr>
<tr>
<td>Undercut</td>
<td>None</td>
<td>See Note (1)</td>
</tr>
<tr>
<td>Concavity</td>
<td>10% (T_w) max. [see Figure MJ-8.4-1, illustration (d)]. However, O.D. and I.D. concavity shall be such that the wall thickness is not reduced below the minimum thickness required in DT-3 [see Note (2)].</td>
<td>10% (T_w) max. [see Figure MJ-8.4-1, illustration (c)] over entire circumference with up to 15% (T_w) permitted over a maximum of 25% of the circumference [see Note (2)]</td>
</tr>
</tbody>
</table>
Table MJ-8.4-1 Visual Examination Acceptance Criteria for Groove Welds on Metallic Tube-to-Tube Butt Joints (Cont'd)

<table>
<thead>
<tr>
<th>Discontinuities</th>
<th>Welds on Process Contact Surfaces</th>
<th>Welds on Non-Process Contact Surfaces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Convexity</td>
<td>10% (T_w) max. [see Figure MJ-8.4-1, illustration (f)] [see Note (2)]</td>
<td>0.015 in. (0.38 mm) max. [see Figure MJ-8.4-1, illustration (e)] [see Note (2)]</td>
</tr>
<tr>
<td>Discoloration (heat-affected zone)</td>
<td>Heat-affected zone (HAZ) may be permitted to have light straw to light blue color [see Figures MJ-8.4-2 and MJ-8.4-3]. Any discoloration present must be tightly adhering to the surface such that normal operations will not remove it. In any case, the HAZ shall have no evidence of rust, free iron, or sugaring. See Note (3)</td>
<td></td>
</tr>
<tr>
<td>Discoloration (weld bead)</td>
<td>None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (3)</td>
<td></td>
</tr>
<tr>
<td>Discoloration (weld bead)</td>
<td>Discoloration level shall be agreed on between the owner/user and contractor. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user. See Note (3)</td>
<td></td>
</tr>
<tr>
<td>Reinforcement</td>
<td>See convexity</td>
<td>See convexity</td>
</tr>
<tr>
<td>Tack welds</td>
<td>Must be fully consumed by final weld bead [see Note (4)]</td>
<td>Same as process contact side</td>
</tr>
<tr>
<td>Arc strikes</td>
<td>None [see Note (5)]</td>
<td>None</td>
</tr>
<tr>
<td>Overlap</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Weld bead width</td>
<td>No limit provided that complete joint penetration is achieved</td>
<td></td>
</tr>
<tr>
<td>Minimum throat</td>
<td>N/A [see Note (6)]</td>
<td>N/A [see Note (6)]</td>
</tr>
<tr>
<td>Misalignment (mismatch) [Notes (6), (7), and (8)]</td>
<td>15% (T_w) max. [see Figure MJ-8.4-1, illustration (b)], except that 4-in. tube may have a maximum of 0.015 in. (0.38 mm) misalignment on the O.D. and 6-in. tube may have a maximum of 0.030 in. (0.76 mm) misalignment on the O.D. Figure MJ-8.4-1, illustration (b) does not apply to 4-in. and 6-in. tube [see Notes (2) and (6)].</td>
<td></td>
</tr>
<tr>
<td>Oxide island</td>
<td>Oxide islands are permitted as long as they are adherent to the surface. Reflective color of oxide island is not cause for rejection. Alloy types are identified in Tables MM-2.1-1, MM-2.1-2, and MM-2.1-3.</td>
<td></td>
</tr>
<tr>
<td>Oxide island</td>
<td>Oxide islands permitted</td>
<td></td>
</tr>
</tbody>
</table>

GENERAL NOTE: Includes all product forms (e.g., tube, fittings, castings, forgings, and bar) whose final dimensions meet Part DT requirements.

NOTES:
(1) The limits of ASME B31.3 shall apply.
(2) \(T_w\) is the nominal wall thickness of the thinner of the two members being joined. Weld metal shall blend smoothly into base metal.
(3) Welds on tubing that has been in service may require unique criteria.
(4) Any weld that shows unconsumed tack welds on the non-process contact surface shall be examined on the process contact surface; otherwise it is rejected. If the weld cannot be examined on the process contact surface, rewelding per MJ-8.4.2 is not allowed. Rewelding per MJ-8.4.2 is allowed if the weld can be examined on the process contact surface after rewelding.
(5) Arc strikes on the non-process contact surface may be removed by mechanical polishing as long as the minimum design wall thickness is not compromised.
(6) Note that misalignment is controlled on the O.D. and is based on allowable O.D. dimensions and tolerances of fittings and tubing. The owner/user is cautioned that this can result in greater I.D. misalignment because this also takes into consideration the wall thickness dimensions and tolerances of fittings and tubing. However, there are no specified I.D. misalignment acceptance criteria.
(7) It is recognized that the I.D. misalignment is more relevant to hygienic design than O.D. misalignment. However, not all connections facilitate ready measurement of I.D. misalignment. For situations where compliance with I.D. misalignment criteria results in an I.D. misalignment that could affect drainability or cleanability, see Nonmandatory Appendix C for further details.
(8) Misalignment criteria do not apply in the fabrication of extruded branch outlets (such as tees) and reducers.
MJ-9.3 Joining Processes and Procedures

Tube and pipe systems composed of polymeric materials are joined by a variety of heat fusion welding methods, including beadless fusion, noncontact infrared (IR) fusion, contact butt fusion, and socket fusion. Fusion does not require solvents or glue to join material, and nothing is added or changed chemically between the two components being joined. Other joining methods may be used when agreed on by the owner/user. Joining of polymeric material being welded must be performed in accordance with a documented WPS that is qualified in accordance with MJ-9.4. The owner/user, contractor, and manufacturer shall agree that the welding process selected will provide the desired results.

MJ-9.3.1 Beadless Welding. Beadless welding (a material-dependent process) shall be used where drainability is required (see Figure MJ-9.7.1-1) (reference SD-2.4.3).

MJ-9.3.1.1 Records. Weld equipment should monitor and record critical weld parameters such as heat, cool time, and temperature. If the equipment does not have monitoring or recording capabilities, weld data shall be recorded in welding protocols or on data carriers.

MJ-9.3.2 Noncontact IR and Contact Butt Fusion Welding. Noncontact infrared and contact butt fusion are not suitable joining processes for systems requiring drainability. Either may be acceptable for single-use applications. Refer to the WPS or manufacturer’s written procedures.

MJ-9.3.3 Socket Fusion Welding. Socket fusion is not suitable for systems requiring drainability. Socket fusion may be acceptable for single-use applications where approved by the owner/user for the intended service. Refer to the WPS or manufacturer’s written procedures.

MJ-9.4 Procedure Qualifications

Welding procedures shall be qualified in accordance with AWS B2.4. A WPS shall be provided for each polymeric material and process being used. Environmental condition recommendations shall be included in the WPS.

MJ-9.5 Performance Qualifications

Welder and welding operator performance qualifications shall be in accordance with AWS B2.4. The quality of polymeric weld joints depends on the qualification of the welders and welding operators, the suitability of the equipment used, environmental influences, and adherence to the applicable WPS. Welders and welding operators shall be trained and possess a valid qualification certificate from the manufacturer for the process and material being welded.

MJ-9.6 Examination, Inspection, and Testing

Examination, inspection, and testing criteria and methods are dictated by material type and joining method. The owner/user, inspection contractor, and/or engineer shall agree to the types of examinations, inspections, and testing unless otherwise specified in the applicable code.

MJ-9.6.1 Examination Procedures. Written visual examination procedures shall be used.

MJ-9.6.2 Personnel Requirements

MJ-9.6.2.1 Personnel Qualifications. All examiners, inspectors, and Inspectors’ Delegates shall be qualified in accordance with GR-4 and shall be trained and possess a valid qualification certificate from the manufacturer for the process and material being welded.

MJ-9.6.2.2 Examination Personnel Eye Examination Requirements. Personel performing examinations shall have eye examinations as follows:

(a) 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.

(b) 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.

MJ-9.6.3 Examination, Inspection, and Testing Requirements

MJ-9.6.3.1 Examination. Examinations shall be performed in accordance with the provisions of the specified fluid service in ASME B31.3.

The external surfaces of all welds shall be visually examined. If ASME B31.3, High Purity Fluid Service (Chapter X), is specified, radiographic, ultrasonic, or in-process examination is not required unless specified by the owner/user. Preproduction sample Welds, when required, shall be submitted by the contractor to the owner/user to establish weld quality. The owner/user, contractor, and inspection contractor shall agree to the number and type of sample Welds. During construction, sample Welds shall be made on a regular basis to verify that the equipment is operating properly and that the setup is adequate to prevent discoloration beyond the level agreed on by
Figure MJ-8.4-1 Acceptable and Unacceptable Weld Profiles for Groove Welds on Metallic Tube-to-Tube Butt Joints

(a) Acceptable Weld Profile

(b) Misalignment (Mismatch)

(c) O.D. Concavity

(d) I.D. Concavity (Suckback)

(e) O.D. Convexity

(f) I.D. Convexity

(g) Incomplete Penetration

Unacceptable

Editor please remove

15% $T_w$ max. [for < 4 in. (100 mm) O.D.]

10% $T_w$ max.

0.015 in. (0.38 mm) max.
Figure MJ-8.4-2 Discoloration Acceptance Criteria for Welds and Heat-Affected Zones on Electropolished UNS S31603 Tubing

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 N 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.
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 N 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.
Figure MJ-8.4-4 Acceptable and Unacceptable Metallic Weld bead Width and Meander on Non-Process Contact Surfaces of Groove Welds on Tube-to-Tube Butt Joints

(a) Acceptable Weld bead

(b) Excessive Weld bead Width Variation

(c) Excessive Weld bead Meander

GENERAL NOTE:
Applies only to non-process contact surfaces and only if weld on process contact surface cannot be examined.
### Table MJ-8.5-1 Visual Examination Acceptance Criteria for Metallic Tube-Attachment Welds

<table>
<thead>
<tr>
<th>Discontinuities</th>
<th>Groove Welds [Note (1)]</th>
<th>Fillet Welds</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Welds on Process Contact Surfaces</td>
<td>Welds on Non-Process Contact Surfaces</td>
</tr>
<tr>
<td>Cracks</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Lack of fusion</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Incomplete penetration</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Porosity</td>
<td>None open to the surface; otherwise, see Note (3). If postweld finishing is performed, see Table SF-2.2-1 for acceptance criteria for pits/porosity.</td>
<td>None open to the surface; otherwise, see Note (3)</td>
</tr>
<tr>
<td>Inclusions [metallic (e.g., tungsten) or nonmetallic]</td>
<td>None open to the surface</td>
<td>None open to the surface</td>
</tr>
<tr>
<td>Undercut</td>
<td>None</td>
<td>See Note (3)</td>
</tr>
<tr>
<td>Concavity</td>
<td>10% $T_w$ max. [see Figure MJ-8.4-1, illustrations (c) and (d)]. However, O.D. and I.D. concavity shall be such that the wall thickness is not reduced below the minimum thickness required in DT-3 [see Note (6)].</td>
<td>10% $T_w$ [see Figure MJ-8.4-1, illustrations (c) and (d)] over entire circumference with up to 15% $T_w$ permitted over a maximum of 25% of the circumference [see Note (6)]</td>
</tr>
<tr>
<td>Convexity</td>
<td>10% $T_w$ max. 0.015 in. (0.38 mm) max. and Note (3)</td>
<td>10% $T_w$ max. [see Figure MJ-8.5-1, illustration (b) and Note (6)]</td>
</tr>
<tr>
<td>Discoloration (heat-affected zone) and weld bead</td>
<td>Discoloration level shall be agreed on between the owner/user and contractor. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user. See Note (7)</td>
<td>HAZ may be permitted to have light straw to light blue color (see Figures MJ-8.4-2 and MJ-8.4-3). Any discoloration present must be tightly adhering to the surface such that normal operations will not remove it. In any case, the HAZ shall have no evidence of rust, free iron, or sugaring. See Note (7)</td>
</tr>
<tr>
<td>Discoloration (weld bead)</td>
<td>None allowed. This criterion does not apply to oxide islands visible on weld bead. See Note (7)</td>
<td>Discoloration level shall be agreed on between the owner/user and contractor. Postweld conditioning may be allowed to meet discoloration requirements at the discretion of the owner/user. This criterion</td>
</tr>
</tbody>
</table>
the owner/user and contractor. The owner/user and contractor shall agree to the frequency of sample welds. It is strongly recommended that these sample welds be made at the beginning of each work shift and when changing the welder and/or welding operator (as applicable) and welding equipment.

The sample welds described in the preceding paragraphs, and any associated welding machine printed records (e.g., welding parameter printouts directly from the welding machine or downloaded from a welding machine), if any, may be disposed of after written acceptance of the coupons by the owner, the owner's representative, or the inspector.

MJ-9.6.3.2 Inspection. The owner/user, inspection contractor, and/or engineer shall agree to the minimum percentage of process contact welds to be selected for borescopic or direct visual inspection, and they shall inform the installation contractor. The inspection contractor shall submit an inspection plan to ensure that welds meet the acceptance criteria of this Part. This plan shall include borescopic or direct visual inspection of the process contact surfaces or visual inspection with light illumination of the weld cross sections on at least 20% of the welds in each system installed. A representative sample of each welder's and/or welding operator's (as applicable) work shall be included. There shall also be a plan for inspecting a representative sample of each welder's and/or welding operator's (as applicable) first shift of production. A procedure shall be submitted for inspecting blind welds. The random selection of accessible welds to be inspected shall be up to the owner/user's inspector's discretion.

Weld acceptance criteria for beadless welds shall be in accordance with Table MJ-9.7.1-1 (see also Fig. MJ-9.7.1-1).

The examination required for compliance with ASME B31.3 may be included in the minimum inspection percentage, provided those examinations were direct visual or borescopic and of the process contact surface.

MJ-9.6.3.3 Testing. Hydrostatic leak testing shall be performed in accordance with the specified fluid service requirements in ASME B31.3. Hydrostatic leak testing shall never exceed the manufacturer's rating of the system installed.

The use of pneumatic testing is not recommended on these systems.

MJ-9.6.4 Records. See GR-5.

MJ-9.7 Weld Acceptance Criteria

Common visual acceptance criteria include complete bonding of joining surface, straight and aligned joints, and exclusion of dirt and foreign substances in the weld zone.

MJ-9.7.1 Acceptance Criteria for Beadless Welds. An acceptable beadless weld is shown in Figure MJ-9.7.1-1, illustration (a). Weld acceptance criteria shall be in accordance with the following:

(a) Cracks and Crevices. Any crack or crevice would generally indicate lack of full penetration welds. Internal or external cracks or crevices shall not be permitted in the weld zone [see Figure MJ-9.7.1-1, illustration (b)].

(b) Pits and Pores. Pits and pores shall not be present in the weld zone on the interior surface [see Figure MJ-9.7.1-1, illustration (c)].
Voids or microbubbles in the weld zone are the result of molten material shrinking as it cools, leaving small voids, usually in the center of the weld, due to volume displacement. They are not uncommon in beadless welding, and their presence alone is not reason for rejection.

1. The maximum single void diameter shall be 10% of nominal wall thickness.
2. The maximum total for all void diameters in a given cross-sectional examination shall be 10% of nominal wall thickness [see Figure MJ-9.7.1-1, illustration (d)].

- **Fit-Up and Mismatch:** Components shall be aligned so as to prevent holdup that would contribute to contamination of the process fluid. The maximum misalignment is 10% of nominal wall thickness [see Figure MJ-9.7.1-1, illustration (e)]. It is not recommended to join components of different wall thicknesses.

- **Inclusions:** Any dark, visible inclusion(s) or speck(s) on the process contact surface of the weld zone are considered foreign materials and are not acceptable [see Figure MJ-9.7.1-1, illustration (f)].

- **Discoloration:** Slight discoloration in the weld zone is not uncommon in beadless welding. Slight discoloration would include up to a light “straw” color in the weld zone. Dark color on the surface or at the weld interface could indicate improper cleaning or joint preparation and is rejectable [see Figure MJ-9.7.1-1, illustration (g)].
### Table MJ-9.7.1-1 Visual Examination Acceptance Criteria for Polymeric Pipe Beadless Welds

<table>
<thead>
<tr>
<th>Discontinuities</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cracks and Crevices</td>
<td>None [see Fig. MJ-9.7.1-1, illustration (b)]</td>
</tr>
<tr>
<td>Pits and Pores</td>
<td>None [see Fig. MJ-9.7.1-1, illustration (c)]</td>
</tr>
<tr>
<td>Voids (Microbubbles) [Note (1)]</td>
<td>Single void diameter 10% Tw max. or total of all void diameters in a given cross-sectional examination 10% Tw max. [see Fig. MJ-9.7.1-1, illustration (d)]</td>
</tr>
<tr>
<td>Fit-Up and Mismatch [Note (2)]</td>
<td>10% Tw max. [see Fig. MJ-9.7.1-1, illustration (e)]</td>
</tr>
<tr>
<td>Inclusions [Note (3)]</td>
<td>Visible inclusion(s) or speck(s) unacceptable [see Fig. MJ-9.7.1-1, illustration (f)]</td>
</tr>
<tr>
<td>Discoloration</td>
<td>Weld zone may be permitted to have light straw color. Dark color on the surface or at the weld interface is unacceptable. [see Fig. MJ-9.7.1-1, illustration (g)]</td>
</tr>
<tr>
<td>Concavity</td>
<td>10% Tw max. for I.D. concavity [see Fig. MJ-9.7.1-1, illustration (h)]</td>
</tr>
</tbody>
</table>

#### NOTES:

1. Voids or microbubbles in the weld zone are the result of molten material shrinking as it cools, leaving small voids, usually in the center of the weld, due to volume displacement. They are not uncommon in beadless welding, and their presence alone is not reason for rejection.
2. Components shall be aligned to prevent holdup that would contaminate the process fluid. It is not recommended to join components of different wall thicknesses.
3. Slight discoloration in the weld zone is not uncommon in beadless welding.
Concavity. Maximum inside diameter (I.D.) concavity shall be limited to 10% of the nominal wall thickness [see Figure MJ-9.7.1-1, illustration (h)].

**MJ-9.7.2 Acceptance Criteria for Nonbeadless Welds.** Acceptance criteria for nonbeadless welds in piping shall be in accordance with AWS G1.10M or DVS 2202-1.

**MJ-9.7.3 Acceptance Criteria for Sample Welds.** Sample welds shall meet all the acceptance criteria of MJ-9.7.1.

**MJ-9.7.4 Rewelding.** Rewelding is not allowed.

**MJ-9.8 Documentation Requirements**

The following documentation shall be presented to the owner/user or their designee, as a minimum:

(a) *Welding Documentation.* Welding procedure specifications (WPSs) used, their procedure qualification records (PQRs), and welder performance qualifications (WPQs)/performance qualification test records (PQTRs) and/or welding operator performance qualifications (WOPQs).

(b) *Weld Maps.* When required by the owner/user, weld maps of bioprocessing components, weld inspection logs of bioprocessing components (including type and date of inspection), and welder and/or welding operator identification of each weld shall be provided either on the weld map or on the inspection log.

Fusion equipment that electronically stores welding histories and serializes welds should be used. Welding history shall be turned over, in printed or electronic format, to the owner/user on completion of work and as part of the installation qualification (IQ) process.

(c) *Materials.* All molded fittings, molded valves, and extruded piping shall be intrinsically identified to provide, as a minimum, material of construction, lot number, and date of production to ensure traceability. Certificates of Compliance shall be provided for molded/extruded components not individually labeled.

(d) *Testing Records.* Other records (e.g., pressure test, surface finish) shall be provided as required by the owner/user.

**MJ-10 DOCUMENTATION REQUIREMENTS**

The requirements for metallic materials and weld documentation are listed in GR-5. For polymeric materials, see MJ-9.8.

**MJ-11 PASSIVATION**

Refer to SF-2.4.
PART SF
PROCESS CONTACT SURFACE FINISHES

SF-1 PURPOSE AND SCOPE

The purpose of this Part is to provide process contact surface finish acceptance criteria for metallic and polymeric materials.

SF-2 METALLIC APPLICATIONS

SF-2.1 Applicable Systems

This Part shall be applicable to all systems designated by the owner/user or representative thereof.

Process contact surface requirements shall apply to all accessible and inaccessible areas of the systems that directly or indirectly come in contact with the designated product.

These systems shall include, but are not limited to, one or more of the following:

(a) USP water-for-injection (WFI)
(b) USP purified water
(c) USP pure steam
(d) other product/process contact surface systems

SF-2.2 Acceptance Criteria

Acceptance criteria, for common austenitic stainless steels as per Table MM-2.1-1, are listed in Tables SF-2.2-1 and SF-2.2-2. Acceptance criteria for other alloys as described in Part MM may differ and should be mutually agreed on by both the owner/user and supplier prior to ordering material. Visual comparison charts or samples may be used to define acceptable and/or unacceptable process contact surfaces.

SF-2.3 Examination Techniques Employed in the Classification of Process Contact Surface Finishes

SF-2.3.1 General. Process contact surface finish examinations shall be made by one or more of the following methods:

(a) visual examination
   (1) direct visual examination
   (2) remote visual examination (e.g., videoscopes, borescopes)

(b) liquid penetrant testing

(c) surface roughness measurement device (profilometer)

Acceptance criteria for metallic process contact surface finishes are shown in Table SF-2.2-1.

Acceptance criteria for electropolished metallic process contact surface finishes shall meet requirements shown in Table SF-2.2-2 in addition to those shown in Table SF-2.2-1.

SF-2.3.2 Direct Visual Examination. Direct visual examinations should be performed with a light source having a color temperature between 5,000 K and 6,500 K. Illumination should be at least 500 lux at the surface to be examined. Personnel performing direct visual examinations shall meet the eye examination requirements of MJ-7.2.6. The size, shape, and contour of many process components (piping, vessels, valves, etc.) may limit the accessibility of direct visual examinations; however, direct visual examinations should be conducted with the eye at a distance of not more than 24 in. (600 mm) from the surface at an angle of not less than 30 deg.

SF-2.3.3 Remote Visual Examination. In some cases where areas subject to examination are inaccessible for direct visual examination, remote visual examination may be used. Such examination systems shall have a resolution capability at least equivalent to that obtainable by direct visual examination. Remote visual examination systems using cameras need particular attention paid to the following specific features:

(a) The observed colors may differ significantly from the actual colors due to the combined electronic data handling of camera, monitor, and software.

(b) Magnification level of viewed areas or objects should be verified. See ASTM A1015, para. 7, Calibration, for reference.

(c) Illumination typically is self-adjusted by the camera by changing readout time. Illumination requirements for direct visual examinations do not apply.

SF-2.4 Surface Condition

The process contact surfaces of metallic materials listed in Tables MM-2.1-1, MM-2.1-2, and MM-2.1-3 shall be cleaned prior to being placed into service. The process contact surfaces of stainless steels listed in Tables MM-2.1-1 and MM-2.1-3 should be passivated after cleaning. Refer to Nonmandatory Appendix E for cleaning and passivating guidelines. Passivation of electropolished surfaces is not required unless the process contact surface has been
### Anomaly or Indication

<table>
<thead>
<tr>
<th>Anomaly or Indication</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pits/porosity</td>
<td>If diameter &lt; 0.020 in. (0.51 mm) and bottom is shiny, [Notes (1) and (2)]. Pits &lt; 0.003 in. (0.08 mm) diameter are irrelevant and acceptable.</td>
</tr>
<tr>
<td>Cluster of pits/porosity</td>
<td>No more than 4 pits per 0.5 in. (13 mm) × 0.5 in. (13 mm) inspection window. The cumulative total diameter of all relevant pits shall not exceed 0.040 in. (1.02 mm).</td>
</tr>
<tr>
<td>Dents</td>
<td>None accepted [Note (3)]</td>
</tr>
<tr>
<td>Finishing marks</td>
<td>If Ra max. is met</td>
</tr>
<tr>
<td>Welds</td>
<td>Welds used in the as-welded condition shall meet the requirements of MJ-8. Welds finished after welding shall be flush with the base metal and concavity and convexity shall meet the requirements of MJ-8. Such finishing shall meet the Ra requirements of Table SF-2.4.1-1.</td>
</tr>
<tr>
<td>Nicks</td>
<td>None accepted</td>
</tr>
<tr>
<td>Scratches</td>
<td>For tubing, if cumulative length is &lt; 12.0 in. (305 mm) per 20 ft (6.1 m) tube length or prorated and if depth is &lt; 0.003 in. (0.08 mm) For fittings, valves, and other process components, if cumulative length is &lt; 0.25 in. (6.4 mm), depth &lt; 0.003 in. (0.08 mm), and Ra max. is met For vessels, if length &lt; 0.50 in. (13 mm) at 0.003 in. (0.08 mm) depth and if &lt; 3 per inspection window [Note (4)]</td>
</tr>
<tr>
<td>Surface cracks</td>
<td>None accepted</td>
</tr>
<tr>
<td>Surface inclusions</td>
<td>If Ra max. is met</td>
</tr>
<tr>
<td>Surface roughness (Ra)</td>
<td>See Table SF-2.4.1-1</td>
</tr>
<tr>
<td>Weld slag</td>
<td>For tubing, up to 3 per 20 ft (6.1 m) length or prorated, if &lt; 75% of the width of the weld bead For fittings, valves, vessels, and other process components, none accepted (as welded shall meet the requirements of MJ-8 and Table MJ-8.4-1)</td>
</tr>
<tr>
<td>Blistering</td>
<td>None accepted</td>
</tr>
</tbody>
</table>

GENERAL NOTE: This table covers surface finishes that are mechanically polished or any other finishing method that meets the Ra max. requirements.

NOTES:
1. Black bottom pit of any depth is not acceptable.
2. Pits in superaustenitic and nickel alloys may exceed this value. Acceptance criteria for pit size shall be established by agreement between owner/user and supplier. All other pit criteria remain the same.
3. For vessels, dents in the area covered by and resulting from welding dimple heat transfer jackets are acceptable.
4. An inspection window is defined as an area 4 in. × 4 in. (100 mm × 100 mm).
altered (e.g., welded or mechanically polished) or exposed to external contamination after electropolishing. Specific passivation requirements shall be defined in the engineering design documents and/or specifications and shall be in accordance with SF-2.6.

**SF-2.4.1 Surface Finishing.** Process contact surfaces shall be finished using mechanical polishing, cold working, machining, or electropolishing in conformance with applicable sections of this Part. Electropolished surfaces may have variances in luster that are acceptable, if the surface roughness values meet the requirements in Table SF-2.4.1-1. Mechanical buffing as a final polishing finish is unacceptable. All surfaces shall be clean. Cleanliness applies to finished components/equipment as produced and packaged by the manufacturer. Subsequent shipping, storage, handling, and/or installation may affect the cleanliness, and it will become a contractual issue between owner/user and manufacturer/service provider.

**SF-2.5 Electropolishing Procedure Qualification**

Electropolishing service providers shall maintain and implement a quality assurance/control program for their electropolishing procedures. They shall also qualify their electropolishing method(s) in accordance with a written procedure. This procedure shall specify acceptable ranges of the electropolishing essential variables.

Nonmandatory Appendix H has been provided as a guide.
Flash electropolishing shall not be acceptable. Spot electropolishing shall be acceptable if it meets the requirements in this section.

**SF-2.6 Passivation Procedure**

Passivation for this Part shall be limited to newly installed or newly modified sections of systems and components. Passivation shall be performed in accordance with an approved quality assurance/control program. The passivation method(s) including procedures for initial water flushing, chemical cleaning and degreasing, passivation, and final rinse(s) shall be qualified in accordance with a written procedure and documentation package. This procedure shall specify the acceptable ranges of the passivation essential variables. Nonmandatory Appendix E has been provided as a guide to passivation practices and evaluation of passivated surfaces. Spot passivation is permitted. The pickling process shall not be accepted as a substitute for passivation. There is no universally accepted nondestructive test for the presence of a passive layer.

For passivated process contact surfaces, the acceptance criteria in Table SF-2.6-1 apply in addition to Table SF-2.2-1 and/or Table SF-2.2-2, as applicable. Tests to ensure the presence of a passive layer shall be agreed to between the owner/user and contractor.

**SF-2.7 Normative References**

The following standards contain provisions that, through reference, specify terms, definitions, and parameters for the determination of surface texture (roughness, waviness, and primary profile) by profiling methods.

ASME BPE-2019
Publisher: The American Society of Mechanical Engineers (ASME), Two Park Avenue, New York, NY 10016-5990 (www.asme.org)
SF-2.8 Rouge and Stainless Steel

Rouge is a naturally occurring phenomenon in existing stainless steel high-purity process systems (including water or pure steam). The degree to which it forms depends on

(a) the stainless steel material used for each component within the system

(b) how the system was fabricated (e.g., welding, surface finish, passivation treatment)

(c) what process conditions the system is exposed to (e.g., water purity, process chemicals, temperatures, pressures, mechanical stresses, flow velocities, and concentration of dissolved gases, such as oxygen or carbon dioxide)

(d) how the system is maintained

The presence of rouge in a system needs to be evaluated against its potential to affect the product, process, and/or long-term operation of the system. Nonmandatory Appendix D provides the methods to measure rouge in a system both in the process solution and on the actual process contact surface. It also suggests various fabrication and operation practices to minimize rouge formation and methods/techniques for its remediation. See the definition of rouge in GR-8.

For more information, refer to the ISPE Water and Steam Systems Baseline® Pharmaceutical Engineering Guide.

SF-3 POLYMERIC APPLICATIONS

SF-3.1 Applicable Systems

This section shall be applicable to all systems designated by the owner/user or representative thereof.

Process contact surface requirements shall apply to all accessible and inaccessible areas of the systems that directly or indirectly come in contact with the designated product.

These systems shall include process systems and clean utilities.

SF-3.2 Materials

The preferred materials of construction for these systems shall be as described in PM-2.

SF-3.3 Examination Techniques Employed in the Classification of Process Contact Surface Finishes

Process contact surface finish examinations shall be made by one or more of the following methods:

(a) visual examination

(1) direct visual examination (e.g., illumination through pipe/tube wall)

(2) remote visual examination (e.g., videoscopes, borescopes)

(b) surface roughness measurement device: profilometer or other surface measurement devices

Acceptance criteria of polymeric process contact surface finishes are shown in Table SF-3.3-1.

Visual examination shall be performed under adequate room lighting. Additional lighting shall be used when appropriate to illuminate blind or darkened areas and to clarify questionable areas.

The same techniques shall be used for both examinations and inspections.
Table SF-3.4.1 Acceptance Criteria for Polymeric Process Contact Surface Finishes

<table>
<thead>
<tr>
<th>Anomaly or Indication</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scratches</td>
<td>For rigid tubing/piping, if cumulative length is &lt;12.0 in. (305 mm) per 20 ft (6.1 m) tube/pipe length or prorated and if depth &lt;0.003 in. (0.08 mm) For other process components, surface finish must be agreed on by supplier and owner/user</td>
</tr>
</tbody>
</table>

Surface cracks
None accepted

Surface inclusions
None accepted

Surface roughness, $R_a$
See Table SF-3.4-1

GENERAL NOTE: All process contact surface finishes shall be defined by the owner/user and supplier using the criteria described in SF-1.

SF-3.4 Surface Condition

The following surface finishes of polymeric materials are available:

(a) piping/tubing and fittings
   (1) as molded
   (2) as extruded
   (3) as machined
   (4) as fabricated from molded, extruded, or machined components

(b) sheet, rod, and block
   (1) as molded
   (2) as extruded
   (3) as machined after molding or extrusion

These are generally used terms and may not be applicable in all cases. The final criteria shall be determined by the $R_a$ values shown in Table SF-3.4-1.

Table SF-3.4-1 $R_a$ Readings for Polymeric Process Contact Surfaces

<table>
<thead>
<tr>
<th>Surface Designation</th>
<th>$R_a$ max. $\mu$m</th>
</tr>
</thead>
<tbody>
<tr>
<td>SFP0</td>
<td>No finish requirement</td>
</tr>
<tr>
<td>SFP1</td>
<td>15 0.38</td>
</tr>
<tr>
<td>SFP2</td>
<td>25 0.64</td>
</tr>
<tr>
<td>SFP3</td>
<td>30 0.76</td>
</tr>
<tr>
<td>SFP4</td>
<td>40 1.01</td>
</tr>
<tr>
<td>SFP5</td>
<td>50 1.27</td>
</tr>
<tr>
<td>SFP6</td>
<td>60 1.52</td>
</tr>
</tbody>
</table>

GENERAL NOTES:
(a) No single $R_a$ reading shall exceed the $R_a$ max. value in this table.
(b) Other $R_a$ readings are available if agreed on between owner/user and supplier, not to exceed values in this table.
CHAPTER 6
CERTIFICATION

PART CR
CERTIFICATION REQUIREMENTS

CR-1 PURPOSE AND SCOPE

Part CR and ASME CA-1, Conformity Assessment Requirements, together establish requirements for organizations providing components in accordance with the BPE Standard to obtain a Certificate of Authorization and the ASME Certification Mark (see Figure CR-1-1). This is a voluntary certification program.

NOTE: Administrative requirements pertaining to the obtaining of an ASME Certificate of Authorization for the application of the ASME Certification Mark on BPE components in Part CR have been relocated to ASME CA-1.

In Part CR, the term “components” shall be limited to tubing and fittings.

CR-2 GENERAL

(a) An organization providing components meeting the requirements of this Standard is issued a Certificate of Authorization and the ASME Certification Mark on successful completion of a survey and approval by ASME. Certificate Holders maintain certification through audits and renew certification of an existing certificate number through a renewal survey. All surveys and audits are performed by ASME to determine the adequacy of the quality management system and to verify the organization’s knowledge, understanding, and capabilities of providing a component in conformance with the BPE Standard under the organization’s Quality Management System (QMS) (see Nonmandatory Appendix Z).

(b) ASME BPE certification means that the capability to fulfill requirements of this Standard by the organization has been reviewed and accepted by ASME. The organization is responsible for ensuring that the products stamped with the ASME Certification Mark and BPE Designator meet the requirements on which the certification is based.

CR-2.1 ASME BPE Certificate Holders

(a) An ASME BPE Certificate Holder has a Quality Management System that has been reviewed and accepted by ASME and has demonstrated its capability to fulfill the requirements of this Standard for the scope of work identified on the Certificate of Authorization. The Certificate Holder is authorized under a valid Certificate of Authorization to mark components, and/or documentation traceable to the components, in conformity with this Standard with the ASME Certification Mark.

(b) Certificate Holders are issued a certificate number to be used to attest to the validity of their certification on data reports and/or certificates of conformance.

(c) Written references indicating that an organization is a Certificate Holder are not valid without reference to the certificate number.

CR-2.2 ASME BPE Certificate Holder’s Responsibilities

The responsibilities of the Certificate Holder include the following:

(a) obtaining a BPE Certificate of Authorization.

(b) compliance with the latest edition of ASME CA-1 as applicable to the BPE Certification Program.

(c) compliance with all requirements of this Standard, as applicable, for the scope of work identified on the BPE Certificate of Authorization.

(d) establishing and maintaining a Quality Management System under Part CR of this Standard.

(e) documenting the QMS.
filing a control copy of the QMS manual with ASME. The QMS manual shall provide a detailed description of the items and services that are being provided under the company’s ASME BPE Certificate of Authorization.

(g) preparing procedures, work instructions, forms, and other implementing documents used under the QMS.

(h) ensuring that the BPE Designator is used in conjunction with the ASME Certification Mark.

(i) qualifying suppliers of subcontracted work.

(j) qualifying and certifying a Certified Individual.

CR-2.3 Certification Designator

The BPE Certification Designator shall be the responsibility of the Certificate Holder. The Certification Designator shall consist of the uppercase letters “BPE” and shall be of a design having similar proportions to that shown in Figure CR-1-1. The Certification Designator shall be legible and located immediately underneath the ASME Certification Mark.

CR-2.4 Quality Management System

The applicant shall establish and maintain an effective QMS as addressed in Nonmandatory Appendix Z. The QMS shall contain all of the elements in Nonmandatory Appendix Z.

CR-2.4.1 Requirements for Designated Oversight. The use of the ASME Certification Mark and BPE Designator shall be documented with data reports or certificates of conformance, or both, that are signed by a responsible representative of the Certificate Holder who is authorized to perform the designated oversight activities (i.e., a Certified Individual).

CR-2.4.1.1 Duties of the Certified Individual. The Certified Individual shall

(a) verify that each item, or lot of items, to which the ASME Certification Mark and BPE Designator is applied conforms with the applicable requirements of the ASME BPE Standard

(b) sign the appropriate data report or certificate of conformance or both prior to release of control of the item

CR-2.4.1.2 Requirements for the Certified Individual

(a) The Certified Individual shall be an employee of the Certificate Holder and shall be qualified and certified by the Certificate Holder. Qualifications shall include the following as a minimum:

(1) knowledge of the applicable requirements of the ASME BPE Standard for the application of the ASME Certification Mark

(2) knowledge of the Certificate Holder’s QMS

(3) training commensurate with the scope, complexity, or special nature of the activities to which oversight is to be provided

(b) The Certificate Holder shall maintain a record of the qualifications and training of the Certified Individual.
CHAPTER 2
CERTIFICATION

PART CR
CERTIFICATION REQUIREMENTS

CR-1 PURPOSE AND SCOPE

Part CR establishes the requirements for an organization manufacturing components in accordance with the BPE Standard to certify the components under an ASME Certificate of Authorization or an ASME Quality System Certificate. The type of certificate issued is based on the type of components manufactured, as identified in Table CR-1-1.

Application of the ASME Single Certification Mark with the “BPE” certification designator (see Figure CR-1-1) to components or documentation that fulfill the requirements of the BPE Standard is granted by the ASME under a Certificate of Authorization.

An ASME Quality System Certificate is issued to a manufacturer to identify the acceptance of its Quality Management System (QMS) by the ASME. That manufacturer may then issue a Certificate of Conformance, bearing its Certificate number, with components that fulfill the requirements of the BPE Standard.

Both programs are voluntary certification programs; however, organizations seeking to apply the ASME Single Certification Mark or issue the Certificate of Conformance shall comply with the requirements of Part CR.

In Part CR, the term “components” shall be limited to those listed in Table CR-1-1.

Figure CR-1-1 The ASME Single Certification Mark with the BPE Certification Designator
Table CR-1-1 Types of ASME BPE Certificates

<table>
<thead>
<tr>
<th>Component</th>
<th>Certificate of Authorization</th>
<th>Quality System Certificate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metallic Fittings</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Metallic Tubing</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Polymeric Static Seals</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

CR-2 GENERAL

(a) To obtain, maintain, and renew an ASME Certificate, applicants and Certificate Holders shall comply with the conformity assessment requirements addressed in ASME CA-1. An ASME BPE Certificate Holder shall have a QMS in conformance with Nonmandatory Appendix Z. The essential controls of the QMS ensuring the components’ conformance with the BPE Standard shall be documented in a QMS Manual. Decisions to issue, renew, suspend, withhold or withdraw an ASME Certificate are made by the ASME based upon surveys, audits, and investigations conducted by an ASME team. A listing of ASME BPE Certificate Holders can be found on the ASME website.

(b) ASME surveys are conducted by an ASME team to evaluate the capability of an organization to manufacture components in conformance with the requirements of its QMS and the BPE Standard. Surveys are conducted as part of the ASME decision process for the issuance or renewal of an ASME Certificate. ASME Certificates are issued and renewed with an expiration date by which time the Certificate Holders shall have their QMS Manual and its implementation surveyed by ASME. During the term of the ASME Certificate, Certificate Holders are subject to a planned audit program by the ASME. Additional audits may be conducted based upon the results of past surveys and audits or complaints.

(c) Certificate Holders who manufacture components under a Certificate of Authorization shall provide designated oversight of their activities and the proper utilization of the ASME Single Certification Mark. This shall be performed by a Certified Individual (CI). The Certified Individual shall be an employee of the Certificate Holder and shall be qualified and certified by the Certificate Holder. The Certificate Holder’s qualification and certification program for the Certified Individual shall be subject to evaluation at the time of the ASME survey.

(d) Certificate Holders who manufacture components under a Quality System Certificate are not required to use a Certified Individual to provide designated oversight of their activities.

CR-2.1 ASME BPE Certificate Holders

(a) An ASME BPE Certificate Holder shall have a QMS that has been reviewed and accepted by ASME and shall have demonstrated their capability to fulfill the requirements of the BPE Standard for the scope of work identified on the ASME Certificate.
(b) ASME BPE Certificate Holders shall be issued a Certificate number to be used to attest to the validity of their certification statements on data reports, Certificates of Conformance, or both.

(c) Written references indicating that an organization is an ASME BPE Certificate Holder shall not be valid without reference to the Certificate number.

(d) ASME BPE Certificate Holders shall be authorized under a valid Certificate of Authorization to mark components, documentation, or both, traceable to the components, with the ASME Single Certification Mark with the BPE certification designator and their Certificate number, as appropriate.

CR-2.2 ASME BPE Certificate Holder’s Responsibilities

CR-2.2.1 All Certificate Holders shall be responsible for:

(a) obtaining an ASME BPE Certificate issued by the ASME in accordance with Table CR-1-1.

(b) conforming with the latest edition of ASME CA-1 as applicable to the ASME BPE Certification Program.

(c) conforming with all requirements of the BPE Standard, as applicable, for the scope of work identified on the ASME BPE Certificate.

(d) establishing and maintaining an effective QMS under Part CR of this Standard.

(e) documenting the QMS as follows:

(1) The QMS Manual shall provide a detailed description of the items and services that are being provided under the company’s ASME BPE Certificate and address the essential controls for each element identified in Nonmandatory Appendix Z.

(2) The Certificate Holder shall prepare procedures, work instructions, forms, and other implementing documents specified by the QMS.

(f) filing a controlled copy of the QMS Manual with ASME.

(g) qualifying and approving suppliers of subcontracted work.

CR-2.2.2 Organizations manufacturing components under an ASME BPE Certificate of Authorization are also responsible for the following:

(a) ensuring that the BPE certification designator is used in conjunction with the ASME Single Certification Mark. The BPE certification designator shall be the responsibility of the Certificate Holder. The BPE certification designator shall consist of the uppercase letters “BPE” and shall be of a design having similar proportions to that shown in Figure CR-1-1. The BPE certification designator shall be legible and located immediately beneath the ASME Single Certification Mark.
(b) establishing and defining competency requirements for the qualification and certification of a Certified Individual.

(c) establishing and defining the duties for the Certified Individual.

(d) providing authorization for the Certified Individual to perform duties that protect the integrity of the ASME Single Certification Mark with the BPE certification designator.

(e) providing authorization for the Certified Individual to notify ASME when the ASME Single Certification Mark with the BPE certification designator is being inappropriately controlled or misused.

CR-2.2.3 All Certificate Holders shall be responsible for proper use of ASME markings, i.e., the ASME Single Certification Mark, “ASME,” or the ASME Certificate number. These markings shall certify conformance with the BPE Standard and shall clearly indicate by stampings, labels, nameplates, data reports, or Certificates of Conformance, that the component is certified by the name of the Certificate Holder as it appears on the ASME BPE Certificate.

CR-2.3 Certified Individual Requirements Under A Certificate of Authorization

Certificate Holders performing work under a Certificate of Authorization shall have a Certified Individual providing designated oversight of the proper utilization of the ASME Single Certification Mark with the BPE certification designator.

CR-2.3.1 Competency Requirements. The Certificate Holder shall establish and define the competency requirements for an individual to qualify and be certified as a Certified Individual.

(a) At a minimum, the competency requirements shall require the individual to:

(1) be an employee of the Certificate Holder with authorization to ensure the ASME Single Certification Mark with the BPE certification designator is not misused and to contact ASME on matters concerning the integrity of the Mark.

(2) have knowledge of the applicable requirements of the BPE Standard for the application of the ASME Single Certification Mark with the BPE certification designator.

(3) have knowledge of the Certificate Holder’s QMS.

(4) have training commensurate with the scope, complexity, or special nature of the activities to which oversight is to be provided.

(b) The individual meeting the established competency requirements under the Certificate Holder’s qualification and certification program shall be certified by the Certificate Holder to be able to perform the duties of a Certified Individual.

(c) The Certificate Holder shall maintain a record of the qualifications and training of the Certified Individual.

CR-2.3.2 Duties of the Certified Individual.
The duties of the Certified Individual shall include, but are not limited to:

(a) verifying that each component to which the ASME Single Certification Mark with the BPE certification designator is applied conforms with both the QMS on file with ASME and the applicable requirements of the BPE Standard. Verification activities include, but are not limited to, ensuring the component is manufactured in accordance with:

(1) the scope of the ASME Certificate of Authorization

(2) a valid and current ASME Certificate of Authorization,

(3) the QMS Manual on file with the ASME.

(b) signing the appropriate data report or Certificate of Conformance or both, prior to release of the BPE component. The signature shall attest to the component being in conformance with the BPE Standard.

(c) terminating the application of the ASME Single Certification Mark with the BPE certification designator on components that do not conform with the QMS or the BPE Standard.

(d) notifying the ASME when the QMS, or any portion thereof, is not being effectively implemented.

(e) being present during ASME surveys, audits, and investigations.
SU-1 GENERAL

The purpose of this part is to define the requirements that are applicable and unique to the use and manufacturing of single-use components and assemblies.

SU-2 GENERAL GUIDELINES

Single-use components and assemblies are intended for one-time use and may be referred to as disposables. Single-use components and assemblies are unique from multiuse components and assemblies as they are not intended for SIP and CIP cycles. In this Part, "component" is defined as an individual unit, and "assembly" is defined as the combination of two or more individual components. This Part addresses the methods for identifying, inspecting, packaging, joining, biocompatibility, and sterilization applicable to single-use components and assemblies.

SU-3 INTEGRITY

Integrity of single-use components and assemblies shall be maintained throughout the life cycle of the product (i.e., packaging, shipping, set up, assembly and use). A compromise in the integrity of single-use components and assemblies that may result in loss of material, microbial ingress, or impact to operator safety should be mitigated.

SU-3.1 Maintenance of Integrity

Maintenance of system integrity is paramount to both bioburden control and maintaining a sterile envelope. Qualification of design, manufacturing, testing and distribution should be conducted by the suppliers of single-use components and assemblies. Leak detection tests should be conducted, commensurate with the level of risk for the intended use of the single-use component or assembly. Monitoring throughout the product life cycle should be performed to deliver reliability of performance. Owner/user shall ensure that single-use component or assembly system integrity is appropriately considered during design and maintained during installation and use.

SU-3.3 Common Leak Test Methods

The decision to implement a leak test should be based on an overall risk mitigation strategy. Nonmandatory Appendix XX describes common leak test methods utilized for single-use components and assemblies. The specific test methods used during the life cycle shall be selected based on sensitivity, suitability and practicality of the method.

SU-4 BIOCOMPATIBILITY

The biocompatibility of single-use components and assemblies shall be considered carefully due to the potential for large product contact areas and long contact times. Many of these components and assemblies are composed of multiple materials or multilayer structures, and the primary concern is how the process interacts with the contact surfaces. The design of the component and assembly shall not compromise the integrity, safety, or efficacy of the process fluid. The focus of evaluations should be on the material of construction of the process contact surface, but it is preferred to evaluate the complete component and assembly. At a minimum, the process contact surface shall conform to the following tests:

(a) biological reactivity, in vitro (cytotoxicity, i.e., USP <87>)
(b) biological reactivity, in vivo (i.e., USP <88>) or equivalent per recognized compendia.

Additionally, the user should consider protein adsorption, preservative absorption, leaching of low-molecular weight compounds, endotoxins, and the presence of animal derived ingredients in single-use components and assemblies.

SU-5 EXTRACTABLES AND LEACHABLES

SU-5.1 General

Testing of process equipment/components made of polymeric materials for extractables and leachables should be done to identify chemical substances that could migrate into the process fluid, potentially affecting the process or altering the final product. Some examples of chemical substances identified in this testing include oligomers, monomers, curing (cros-
linking) agents, catalysts, antioxidants, initiators, dyes, pigments, plasticizers, and mold release agents. The data generated may be used to make risk-based decisions of the potential impact that any identified substances may have on the final drug product and may aid in the selection of equipment/components. PM-3.2 provides information on extractables and leachables from polymeric materials. Nonmandatory Appendix P-4 provides an overview of bioprocessing equipment/component evaluation related to extractables and leachables characterization.

SU-6 IDENTIFICATION

Single-use components and assemblies shall be designed and packaged to provide lot traceability. The traceability shall enable the owner/user to identify the raw material(s), processing conditions critical to support the manufacturer’s specifications, and the date of manufacture.

SU-6.1 Labeling

The primary packaging of single-use components and assemblies shall be labeled with the following information:

(a) manufacturer
(b) part identifier
(c) lot identifier

Additional information for the label may be requested by the owner/user.

SU-7 CERTIFICATE OF CONFORMANCE

The single-use component or assembly manufacturer shall issue a Certificate of Conformance that contains the following information:

(a) manufacturer
(b) part identifier
(c) lot identifier
(d) date of manufacture and/or expiration date
(e) conformance information

Additional information for the Certificate of Conformance may be requested by the owner/user.

SU-8 INSPECTION AND PACKAGING

The packaging of single-use components and assemblies shall mitigate the risk of bioburden, particulate, or other contaminants (see SU-10 and Nonmandatory Appendix P-2). Inspection shall be performed to confirm the quality of the packaging and that the contents meet the specified criteria.

SU-8.1 Inspection

Single-use components and assemblies shall be inspected for the presence of particulates or other contaminants before primary packaging. This inspection shall take place in a controlled environment in accordance with the intended use of the final component or assembly.

SU-8.2 Packaging

The purpose of packaging of single-use components and assemblies is to control the potential introduction of bioburden, particulates, or other contaminants. The packaging shall not adulterate the component and assembly. Primary packaging shall take place in a controlled environment at a level suitable for the final use of the component or assembly. The packaging of single-use components and assemblies shall be labeled according to SU-5.1.

SU-9 STERILIZATION (BIOBURDEN CONTROL)

Single-use assemblies and components shall be compatible with the intended sterilization method. Common sterilization methods include autoclaving and gamma irradiation. Autoclaving is generally performed by the owner/user. Gamma irradiation is generally contracted to a third party by the manufacturer. The owner/user shall determine the appropriate method and level of documentation required for the given application.

SU-9.1 Gamma Irradiation

Single-use assemblies that will be gamma irradiated shall be manufactured in a controlled environment. The maximum recommended gamma irradiation dose should be specified by the manufacturer of the single-use assembly or component. When establishing a maximum dose, the manufacturer should consider the effects on physical and mechanical properties (e.g., appearance, tensile) and chemical characteristics of the materials used (e.g., leachable/extractable effects). The
supplier shall provide lot-specific certification of processing to the owner/user. The degrees of validation are the following:

(a) validated sterility assurance level per a recognized standard (e.g., ISO 11137)
(b) gamma irradiated to the specified dose range. No validation of the effectiveness is conducted.

SU-10 SHELF LIFE, STORAGE, AND EXPIRATION DATE

The shelf life of a single-use component or assembly is the duration under specified storage conditions from the date of manufacture to the last date the product can be placed in service and remain suitable for its intended use. The expiration date is the date after which the shelf life has been exceeded. The manufacturer shall, on request, provide methodology used to determine shelf life or expiration date such as aging tests, stability tests, or other industry standards.

(a) Non-sterilized Components and Assemblies. The manufacturer shall provide an expiration date (preferred) or the manufacturing date and shelf life, plus storage requirements and any special handling requirements. Shelf life shall be based on raw material, component, and/or assembly data.
(b) Sterilized Components and Assemblies. The manufacturer shall provide expiration dates, storage requirements, and any special handling requirements. Shelf life shall be based on raw material, component and/or assembly data, sterilization method, and package integrity. Package integrity testing shall be performed per a relevant standard (e.g., ISO 11607). See SU-7.2.

SU-11 PARTICULATES

Single-use components and assemblies should be free of loose, non-embedded, and solid particulates as seen by direct visual observation without magnification. Particulates greater than or equal to 100 μm are considered to be visible. The TAPPI Size Estimation Chart may be used for reference. Particulates of less than 100 μm, considered to be sub-visible, should be minimized.

SU-11.1 General

Particulates may unintentionally be present on surfaces of the single-use article and may impact the manufacturing process or product. Particulate sources include machines, materials, methods, environment, and people. More information and characteristics of particulates may be found in Nonmandatory Appendix O-2.

SU-11.2 Particulate Monitoring Program

The supplier shall have an established risk-based particulate-monitoring program. The program should include testing, trending analysis, particulate characterization, and analysis of particulate quantity and size.

SU-11.3 Mitigation Techniques

The materials, design, manufacturing operations, environment, and product use should be considered for their impact on particulate generation and control. The level of observation and particulate control should be appropriate for the degree of risk for the particular application (e.g., fill/finish).

SU-11.3.1 Suppliers

Suppliers shall implement controls to ensure their single-use products meet established particulate criteria. Typical controls include:

(a) proper use and maintenance of manufacturing equipment
(b) utilization of controlled environments for the manufacturing and assembly process such as a classified clean room or clean zone
(c) appropriate packaging; see SU-7
(d) training of manufacturing personnel on particulate control practices
(e) product inspection and documentation of batch records
(f) establishment of a particulate investigation process

SU-11.3.2 Owner/User

Owner/users should implement controls to ensure their use of single-use products meet established particulate criteria. Typical controls include:
(a) procedures to determine risk associated with particulate matter
(b) supplier quality agreements
(c) required incoming inspection documentation
(d) training of personnel in best practices for the handling and use of single-use products
(e) establishment of a particulate investigation process.
CHAPTER 8 PROCESS COMPONENTS FOR SINGLE-USE

PART SC COMPONENTS FOR SINGLE-USE

SC-1 STEAM-THROUGH AND STEAM-TO CONNECTORS

Steam-through and steam-to connectors are designed to connect single-use systems to multiuse (metallic) systems. Steam-through and steam-to connections shall

(a) form a hygienic clamp union, meeting the requirements of Parts DT and MC
(b) maintain a seal (MC-4)
(c) be drainable (Part SD)
(d) be sterilizable (SU-8)
(e) be compatible with SIP, post sterilization (e.g., gamma irradiation) at 266°F (130°C) for 1 hr exposed surfaces
(f) meet the biocompatibility requirements of PM-3.1
(g) meet the Certificate of Conformance requirements of Table PM-2.2.1-1.

SC-2 ASEPTIC CONNECTORS

Aseptic connectors allow single-use assemblies to be joined while maintaining a sterile process contact surface before, during and after connection, without regard to the manufacturing environment.

SC-2.1 Manufacturer Responsibilities

The manufacturer shall

(a) Conduct microbial ingress testing to qualify that a sterile fluid path post-connection is not compromised.
(b) Define whether the connectors are dry connectors or wet connectors.
   1. Dry means liquid cannot be in the connector. Pinch clamps or another suitable technique must be used to isolate the liquid from the connector prior to use.
   2. Wet means the connection can be made with liquid in the connector.
(c) Provide product specifications including, but not limited to:
   1. Temperature ratings
   2. Pressure ratings
   3. Sterilization method compatibility (e.g., gamma, autoclave)
   4. Product flow path cleanliness (particulates, endotoxins, bioburden)
   5. Flow rates
(d) Define gender of the connector halves
   1. Unique male and female halves.
   2. Genderless, where each half is identical.
(e) Define whether the connection is designed for one-time connection or multiple connections.
   1. Connectors designed for a one-time connection shall incorporate an irreversible locking mechanism, unless it is specifically designed for aseptic disconnect
   2. Connectors designed for multiple connections and disconnections shall have the maximum number of connections specified
(f) Provide assembly instructions to ensure proper connection.

SC-2.2 Owner/User Responsibilities

The owner/user should:

(a) Review the manufacturer’s specifications against the service requirements for all applicable process and sterilization conditions.
(b) Ensure the connection will be performed to a qualified procedure by a properly trained operator to maintain system integrity.

SC-3 FLEXIBLE BIOPROCESS CONTAINERS (BAGS)

Flexible bioprocessing containers, also referred to as single-use bags, are available as 2D or 3D format, in different configurations and volume capacities. These bags are utilized in assemblies for preparation, storage, sampling, transfer, and transport of bioprocess fluids or powders. The bags have connection ports and are used in conjunction with tubing or tubing manifolds to allow for filling, dispensing, sampling, and other process functions. This section provides requirements on materials of construction and qualification.

SC-3.1 Materials

Multi-layer films are often used to manufacture single-use bags. The manufacturer should identify the material of construction of all film and tie layers of the bag. For bags intended for process contact, the manufacturer shall identify all materials (e.g. primary materials, tie layers, and additives) that have the potential to adulterate the bag contents.
**SC-3.2 Qualifications**

The manufacturer shall provide the operating temperature and pressure limits of the single-use bag. The manufacturer shall specify appropriate sterilization methods, including range of exposure, post-sterilization shelf life and other limitations. The manufacturer should provide handling and safe use procedures, including hanging restrictions, filling limitations and secondary containment recommendations.

**SC-4 POLYMERIC HYGIENIC UNIONS**

See PM-4.4.
PART SJ JOINING METHODS FOR SINGLE-USE

SJ-1 GENERAL

The joining of components may be performed in many ways for single-use applications. Examples of these joining techniques include, but are not limited to, welding, heat sealing, over-molding, solvent bonding, mechanical connections, and adhesives. With any of these methods, the procedure for the joining of polymers, components, or assemblies shall be controlled to ensure repeatable results. The joint shall not leak, shall meet the pressure requirements for the intended use, and shall maintain the integrity of the component or assembly's contact surface.

SJ-2 MECHANICAL HOSE BARB CONNECTIONS

This section applies to the mechanical joining of single-use assemblies using a hose barb, flexible tubing and a retention device, commonly referred to as a hose barb connection. Flexible hose assemblies intended for repeated use are addressed in PM-4.3.2 and SD-3.2. Refer to Nonmandatory Appendix YY Single-use Mechanical Hose Barb Design Recommendations for additional design considerations.

SJ-2.1 Operating Conditions

The owner/user should define the operating temperature range, operating pressure range, and sterilization method (if applicable) for the intended use of the hose barb connection.

SJ-2.2 Assembly

Manual assembly of single-use hose barb connections shall follow documented standard operating procedures. Assembly equipment (e.g., tubing stretchers, fitting inserters, retention devices, and application tools) shall be maintained in a state of calibration. Fluids used to aid in the insertion of a hose barb into flexible tubing shall be identified by chemical type and meet the requirements of PM-2.1.

SJ-2.3 Qualification

Single-use hose barb connections shall be qualified by the supplier to ensure they meet performance criteria as stated in their specification. The supplier shall have an established testing program to substantiate performance of the mechanical connection. The testing should reference at least one of the following:

(a) Pressure testing: Reference ASTM D1599, ISO1402
(b) Leak testing
   i. pneumatic: Reference ASTM E515
   ii. vacuum: Reference ASTM D4991
   iii. hydraulic: Reference ASTME1003
(c) Tracer gas testing: Reference ASTM E499.

SJ-3 THERMAL WELDING OF THERMOPLASTIC ELASTOMER TUBING

Thermoplastic elastomer (TPE) tubing is used as part of single-use assemblies when there is a need to join or separate the assembly from the single-use system or other process equipment without the use of mechanical fittings. Welding of rigid thermoplastic tubing and piping is addressed in MJ-9.

SJ-3.1 Specifications

Thermal welding shall be performed using the procedure provided by the welding equipment manufacturer. Tubing material, dimensions (e.g., inner and outer diameters), and tubing pre-welding sterilization shall be compatible with the capabilities of the welding equipment.

SJ-3.2 Design Parameter

TPE tube welding equipment for closed processing shall be designed to

(a) fuse two integral tubing assemblies and maintain an aseptic flow path during the welding process to form one closed system
(b) maintain the flow and pressure characteristics of the assembly after fusing.

SJ-3.3 Acceptance Criteria

The weld shall be evaluated to confirm it is leak free and meets the owner/user’s acceptance criteria. Acceptance criteria may include

(a) tolerance requirements for tube to tube alignment
(b) presence of bubbles, gaps, contaminants or foreign material, and internal flash or occlusion of tubing lumen.
MANDATORY APPENDIX III
SINGLE-USE COMPONENTS AND ASSEMBLIES

III-1 GENERAL

The purpose of this Appendix is to define the requirements that are applicable and unique to the use and manufacturing of single-use components and assemblies.

III-2 GENERAL GUIDELINES

Single-use components and assemblies are intended for one-time use and may be referred to as disposables. Single-use components and assemblies are unique from multiuse components and assemblies as they are not intended for SIP and CIP cycles. In this Appendix, "component" is defined as an individual unit, and "assembly" is defined as the combination of two or more individual components. This Appendix addresses the methods for identifying, inspecting, packaging, joining, biocompatibility, and sterilization applicable to single-use components and assemblies.

III-3 MATERIALS

III-3.1 Polymeric Materials

See Part PM.

III-4 BIOCOMPATIBILITY

The biocompatibility of single-use components and assemblies shall be considered carefully due to the potential for large product contact areas and long contact times. Many of these components and assemblies are composed of multiple materials or multilayer structures, and the primary concern is how the process interacts with the contact surfaces. The design of the component and assembly shall not compromise the integrity, safety, or efficacy of the process fluid. The focus of evaluations should be on the material of construction of the process contact surface, but it is preferred to evaluate the complete component and assembly. At a minimum, the process contact surface shall comply with the following tests:

(a) biological reactivity, in vitro (cytotoxicity, i.e., USP <87>)
(b) biological reactivity, in vivo (i.e., USP <88>), or equivalent per recognized compendia agreed to by the owner/user and manufacturer.

Additionally, the user should consider protein adsorption, preservative absorption, leaching of low-molecular-weight compounds, endotoxins, and the presence of animal-derived compounds in single-use components and assemblies.

III-5 EXTRACTABLES AND LEACHABLES

III-5.1 General

Testing of process equipment/components made of polymeric materials for extractables and leachables should be done to identify chemical substances that could migrate into the process fluid, potentially affecting the process or altering the final product. Some examples of chemical substances identified in this testing include oligomers, monomers, curing (cross-linking) agents, catalysts; antioxidants, initiators, dyes, pigments, plasticizers, and mold release agents. The data generated may be used to make risk-based decisions of the potential impact that any identified substances may have on the final drug product and may aid in the selection of equipment/components. PM-3.2 provides information on extractables and leachables from polymeric materials. Nonmandatory Appendix P-4 provides an overview of bioprocessing equipment/component evaluation related to extractables and leachables characterization.

III-6 COMPONENTS

III-6.1 Polymeric Hygienic Unions

See PM-4.6.

III-6.2 Steam-Through and Steam-To Connections

III-6.2.1 General Requirements. Steam-through and steam-to connectors are designed to connect single-use systems to multiuse (metallic) systems. Steam-through and steam-to connections shall

(a) form a hygienic clamp union, meeting the requirements of Parts DT and SG,
(b) maintain a seal (SG-4)
(c) be self-draining (Part SD)
(d) be sterilizable per III-11
(e) be compatible with SIP, poststerilization (e.g., gamma irradiation) at 266°F (130°C) for 1 hr (exposed surfaces)
III-7 JOINING METHODS

The joining of components may be performed in many ways for single-use applications. Examples of these joining techniques include, but are not limited to, welding, heat sealing, overmolding, solvent bonding, mechanical connections, and adhesives. With any of these methods, the procedure for the joining of polymers, components, or assemblies shall be controlled to ensure repeatable results. The joint shall not leak, shall meet the pressure requirements for the intended use, and shall maintain the integrity of the component or assembly’s contact surface.

III-7.1 Mechanical Hose Barb Connections

This section applies to the mechanical joining of single-use assemblies using a hose barb, flexible tubing and a retention device, commonly referred to as a hose barb connection. Flexible hose assemblies intended for repeated use are addressed in PM-4.3.2 and SD-3.2.

III-7.1.1 Operating Conditions. The owner/user should define the operating temperature range, operating pressure range, and sterilization method (if applicable) for the intended use of the hose barb connection.

III-7.1.2 Assembly. Manual assembly of single-use hose barb connections shall follow documented standard operating procedures. Assembly equipment (e.g., tubing stretchers, fitting inserters, retention devices, and application tools) shall be maintained in a state of calibration. Fluids used to aid in the insertion of a hose barb into flexible tubing shall be identified by chemical type and meet the requirements of PM-2.1.

III-7.1.3 Qualification. Single-use hose barb connections shall be qualified by the supplier to ensure they meet performance criteria as stated in their specification. The supplier should have an established testing program to substantiate performance of the mechanical connection.

III-7.2 Thermal Welding of Thermoplastic Elastomer Tubing

Thermoplastic elastomer (TPE) tubing is used as part of single-use assemblies when there is a need to join or separate the assembly from the single-use system or other process equipment without the use of mechanical fittings. Welding of rigid thermoplastic tubing and piping is addressed in MJ-9.

III-7.2.1 Specifications. Thermal welding shall be performed using the procedure provided by the welding equipment manufacturer. Tubing material, dimensions (e.g., inner and outer diameters), and tubing pre-welding sterilization shall be compatible with the capabilities of the welding equipment.

III-7.2.2 Acceptance Criteria. The weld shall be evaluated to confirm it is leak free and meets the owner/user’s acceptance criteria. Acceptance criteria may include:

(a) tolerance requirements for tube to tube alignment
(b) presence of bubbles, gaps, contaminants or foreign material, and internal flash or occlusion of tubing lumen

III-8 IDENTIFICATION

Single-use components and assemblies shall be designed and packaged to provide lot traceability. The traceability shall enable the owner/user to identify the raw material(s), processing conditions critical to support the manufacturer’s specifications, and the date of manufacture.

III-8.1 Labeling

The primary packaging of single-use components and assemblies shall be labeled with the following information:

(a) manufacturer
(b) part identifier
(c) lot identifier
Additional information may be included on the label on agreement between the manufacturer and owner/user.

III-9 CERTIFICATE OF COMPLIANCE

The single-use component or assembly manufacturer shall issue a Certificate of Compliance that contains the following information:

(a) manufacturer
(b) part identifier
(c) lot identifier
(d) date of manufacture and/or expiration date
(e) compliance information

Additional information may be included in the Certificate of Compliance on agreement between the manufacturer and the owner/user.

III-10 INSPECTION AND PACKAGING

The packaging of single-use components and assemblies shall be performed to help control the potential introduction of bioburden, particulate, or other contaminants to the component, assembly, or the owner/user’s system (see III-13 and Nonmandatory Appendix P-2). Inspection shall be performed to confirm the quality of the packaging and that the contents meet the specified criteria between the supplier and owner/user.
III-10.1 Inspection

Single-use components and assemblies shall be inspected for the presence of particulates or other contaminants before primary packaging as agreed on by the manufacturer and owner/user. This inspection shall take place in a controlled environment in accordance with the intended use of the final component or assembly.

III-10.2 Packaging

The purpose of packaging of single-use components and assemblies is to control the potential introduction of bioburden, particulates, or other contaminants. The packaging shall not adulterate the component and assembly. Primary packaging shall take place in a controlled environment at a level suitable for the final use of the component or assembly. The packaging of single-use components and assemblies shall be labeled according to III-8.1.

III-11 STERILIZATION (BIOBURDEN CONTROL)

Single-use assemblies and components shall be compatible with the intended sterilization method. Common sterilization methods include autoclaving and gamma irradiation. Autoclaving is generally performed by the owner/user. Gamma irradiation is generally contracted to a third party by the manufacturer. The owner/user shall determine the appropriate method and level of documentation required for the given application.

III-11.1 Gamma Irradiation

Single-use assemblies that will be gamma irradiated shall be manufactured in a controlled environment. The maximum recommended gamma irradiation dose should be specified by the manufacturer of the single-use assembly or component. When establishing a maximum dose, the manufacturer should consider the effects on physical and mechanical properties (e.g., appearance, tensile) and chemical characteristics of the materials used (e.g., leachable/extractable effects). The supplier shall provide lot-specific certification of processing to the owner/user. The degrees of validation are the following:

(a) validated sterility assurance level per a recognized standard (e.g., ISO 11137);
(b) gamma irradiated to the specified dose range. No validation of the effectiveness is conducted.

III-12 SHELF LIFE, STORAGE, AND EXPIRATION DATE

The shelf life of a single-use component or assembly is the duration under specified storage conditions from the date of manufacture to the last date the product can be placed in service and remain suitable for its intended use. The expiration date is the date after which the shelf life has been exceeded. The manufacturer shall, on request, provide methodology used to determine shelf life or expiration date such as aging tests, stability tests, or other industry standards.

(a) Nonsterilized Components and Assemblies. The manufacturer shall provide an expiration date (preferred) or the manufacturing date and shelf life, plus storage requirements and any special handling requirements. Shelf life shall be based on raw material, component, and/or assembly data.

(b) Sterilized Components and Assemblies. The manufacturer shall provide expiration dates, storage requirements, and any special handling requirements. Shelf life shall be based on raw material, component and/or assembly data, sterilization method, and package integrity. Package integrity testing shall be performed per a relevant standard (e.g., ISO 11607). See III-10.2.

III-13 PARTICULATES

Single-use components and assemblies should be free of loose, non-embedded, and solid particulates as seen by direct visual observation without magnification. Particulates greater than or equal to 100 μ are considered to be visible. The TAPPI Size Estimation Chart may be used for reference. Particulates less than 100 μ are considered to be subvisible and should be minimized.

III-13.1 General

Particulates may unintentionally be present on surfaces of the single-use article and may impact the manufacturing process and/or product. Particulate sources include machines, materials, methods, environment, and people. More information and characteristics of particulates may be found in Nonmandatory Appendix O-2.

III-13.2 Mitigation Techniques

The materials, design, manufacturing operations, environment, and product use should be considered for their impact on particulate generation and control. A program should be established to characterize, quantify, control, and minimize particulates, as applicable. The level of observation and particulate control should be appropriate for the degree of risk for the particular application (e.g., fill/finish).

III-13.2.1 Suppliers. Suppliers shall implement controls to ensure their single-use product can meet their established particulate criteria. Typical controls include

(a) proper use and maintenance of manufacturing equipment
(b) utilization of controlled environments for the manufacturing and assembly process such as a classified clean room or clean zone
(c) appropriate packaging; see III-10
III-13.2.2 Owner/User. Owner/users should implement controls to ensure their use of single-use products can meet their established particulate criteria. Typical controls include

(a) procedures to determine risk associated with particulate matter
(b) supplier quality agreements
(c) required incoming inspection documentation
(d) training of personnel in best practices for the handling and use of single-use products
(e) establishment of a particulate investigation process

(d) training of manufacturing personnel on particulate control practices
(e) product inspection and documentation of batch records
(f) establishment of a particulate investigation process
# MANDATORY APPENDIX IV
## NOMENCLATURE

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
<th>Units [Note (1)]</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Distance of the annular space between the O.D. of a dip tube or shaft and the I.D. of a nozzle neck</td>
<td>in., mm</td>
<td>Figure SD-3.4.3-1</td>
</tr>
<tr>
<td>D</td>
<td>Outside diameter of tube or pipe</td>
<td>in., mm</td>
<td>…</td>
</tr>
<tr>
<td>d</td>
<td>Inside diameter</td>
<td>in., mm</td>
<td>Figure SD-4.1.2.2-1</td>
</tr>
<tr>
<td>dh</td>
<td>I.D. of the extension or leg of tubing or fitting</td>
<td>in., mm</td>
<td>SD-3.1.2.2</td>
</tr>
<tr>
<td>H</td>
<td>Height</td>
<td>in., mm</td>
<td>Figure SD-4.1.2.2-1</td>
</tr>
<tr>
<td>L</td>
<td>Length</td>
<td>in., ft mm, m</td>
<td>PM-4.2.3, Table SD-3.1.2.2-1, Table SD-3.1.2.2-2, Figure SD-3.1.2.2-1</td>
</tr>
<tr>
<td>Lmin</td>
<td>Minimum length or distance</td>
<td>in., mm</td>
<td>Figure PI-9.1.3.5-1, Figure PI-9.1.3.5-2</td>
</tr>
<tr>
<td>L/A</td>
<td>Ratio of the nozzle neck length divided by the distance of the annular space between the O.D. of a dip tube or shaft and the I.D. of a nozzle neck</td>
<td>…</td>
<td>Figure SD-3.4.3-1</td>
</tr>
<tr>
<td>L/d</td>
<td>Dead leg determination</td>
<td>…</td>
<td>Table SD-3.1.2.2-1, Table SD-3.1.2.2-2, Figure SD-3.1.2.2-1, Figure SD-3.4.2-1</td>
</tr>
<tr>
<td>Q</td>
<td>Flow rate</td>
<td>gpm, lpm</td>
<td>…</td>
</tr>
<tr>
<td>QL</td>
<td>Leak rate</td>
<td>mbar–L/s</td>
<td>SD-5.6.7, eq. (1)</td>
</tr>
<tr>
<td>R</td>
<td>Radius</td>
<td>in., mm</td>
<td>Table DT-4.5.1-1, Table DT-4.5.2-1, Figure PI-8.1.3.6-1</td>
</tr>
<tr>
<td>Ra</td>
<td>Roughness average</td>
<td>μin., μm</td>
<td>Table SF-2.2-1, Table SF-2.2-2, Table SF-2.4.1-1</td>
</tr>
</tbody>
</table>

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SD-6.3.5.2.1
NONMANDATORY APPENDIX C
SLOPE MEASUREMENT AND JOINT MISALIGNMENT

C-1 GENERAL

(a) Slope measurement shall be made with a digital level or a digital protractor. The instrument used should be capable of displaying slope in degrees, percent, and in./ft (mm/m).

(b) Refer to the owner’s manual for the proper procedure to perform the self-calibration routine. This must be performed immediately prior to use.

(c) Slope measurements shall only be made under the following conditions:
   (1) before insulation has been installed
   (2) after hangers/pipe supports have been installed, adjusted, and fixed in place
   (3) before the introduction of any fluids, such as liquids or process gases (pure oxygen, nitrogen, steam, etc.)
   (4) when the system is at ambient pressure and temperature

(d) For piping or tubing systems, slope measurements shall be made at the following locations:
   (1) between hangers/pipe supports
   (2) at each change in direction
   (3) at any other location deemed necessary by the inspector, such as between welds or any apparent change in slope

(e) Slope should be measured only on runs that are approximately horizontal.

(f) Slope measurements may be made on either the top or bottom of the tubing/piping.

(g) For slope measurements made on skids or modules, ensure that the base is level in all directions. Then, make sure that all slope measurements are made relative to the base.

(h) Slope shall be verified after the fabricator has completed, or corrected, the piping installation and set the slope.

C-2 JOINT MISALIGNMENT

In order to meet O.D. misalignment criteria in this Standard, the accumulated tolerances in piping, tubing, and fittings may result in a welded joint with an I.D. misalignment. Should this occur, the owner/user, installation contractor, and inspection contractor shall apply good engineering judgment to determine the best solution for the application considering flow, orientation, and drainability.

The orientation of the piping, tubing, or fittings should be considered prior to final disposition of the weld joint prior to welding.

(a) Vertical Orientation

   (1) Misalignment should be uniformly distributed around the circumference.

   (2) Direction of flow should be considered when assembling the components.

(b) Horizontal Orientation. Horizontal Orientation. Misalignment should be oriented to maximize drainability, normally accomplished by minimizing the I.D. misalignment at the bottom.
Electrochemical cleaning is an alternative method of rouge removal that uses phosphoric acid and applied direct current where the process contact surface is anodic. As a cathode is moved over the process contact surface to be cleaned, rouge is readily removed. This process is very effective in removing all three classes of rouge but is limited to accessible parts of a system and is primarily performed on the product contact surfaces in vessels.

For specific Class I rouge remediation processes, refer to Table D-4.1-1.

**D-4.2 Class II Rouge Remediation**

Class II rouge consists mostly of hematite or ferric iron oxide with some amount of chromium and nickel oxides as well as small carbon content. It is removed with chemistries that are very similar to the above processes with the addition of oxalic acid, which improves the effectiveness in removal of this type of rouge. All of the above chemistries remove the rouge without damage to the surface finish with the exception of oxalic acid, which may etch the surface depending on conditions and concentration processed. Class II rouges are more difficult to remove than Class I and may require additional time, even though these processes are often run at slightly higher temperatures and increased concentrations.

For specific Class II rouge remediation processes, refer to Table D-4.1-1.

**D-4.3 Class III Rouge Remediation**

Class III rouge is much more difficult to remove compared to Class I and Class II rouge, due to both its chemical composition difference and its structural difference. These high-temperature deposits form magnetite iron oxide with some substitution of chromium, nickel, or silica in the compound structure. Significant amounts of carbon are generally present in these deposits due to reduction of organics present in the water, which sometimes produces the “smut” or black film that may form during derouging. The chemistries used to remove Class III rouge are very aggressive and will affect the surface finish to some degree. Phosphoric acid-based derouging systems are generally only effective on very light accumulation of the rouge. The strong organic acid blends with formic and oxalic acid are effective on some of these high-temperature rouges, and, being less aggressive, they produce much less potential for etching of the surface finish.

Citric and nitric blends with hydrofluoric acid or ammonium bifluoride will remove these Class III rouges more quickly but will definitely etch the surface wherever the base metal is subjected to the derouging fluid. The amount of etching or increase in surface finish roughness is dependent on process conditions, chemical concentration, and variability of the rouge thickness and level of surface finish roughness initially. The condition of use for these processes is highly variable in both temperature and time required to effectively remove all of the rouge and leave the surface prepared for cleaning and passivation. The less-aggressive chemistries are used at higher temperatures [140°F to 176°F (60°C to 80°C)] and require longer contact time (8 hr to 48-plus hr); the nitric acid-based fluoride solutions are often used at lower temperatures [ambient to 104°F (40°C)], while the citric acid-based fluoride solutions are used at higher temperatures and shorter contact times (2 hr to 24 hr).

For specific Class III rouge remediation processes, refer to Table D-4.1-1.

**D-4.4 Remediation Variables**

The times and temperatures given in D-4.1 through D-4.3 are in direct relation to the percent by weight of the base reactant(s). A change in a formulation will change the corresponding requirements. Different application methods include fluid circulation, gelled applications for welds or surfaces, and spraying methods for vessels and equipment. Rinsing of the surface after processing as well as proper waste disposal planning is critical to the derouging process. The waste fluids generated by these processes can be classified as hazardous due to chemical constituents or heavy metals content.

Rouge can effectively be removed from process contact surfaces to reduce the potential for oxide particulate generation into the process fluids. These derouging processes are required prior to proper cleaning and passivation of the stainless steel surface for restoration of the passive layer after corrosion. Analytical testing of utility fluids may be useful in identifying the level of particulate generation and levels of metal oxides contained in these fluids as corrosion degrades the surface.
### Table D-2-1 Considerations That Affect the Amount of Rouge Formation During the Fabrication of a System

<table>
<thead>
<tr>
<th>Variables</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category 3 — Strong Influence on the Formation of Rouge [Note (1)]</strong></td>
<td></td>
</tr>
<tr>
<td>Alloy selection</td>
<td>Selection of the proper alloy (e.g., 316L-type or 6 moly-type stainless steel) should address the corrosive effects of the process conditions. For example, low-carbon stainless steel (316L-type) has better corrosion resistance than higher-carbon stainless steels (316-type). Beneficial alloys can mitigate premature or accelerated corrosion. Higher nickel content will enhance corrosion resistance.</td>
</tr>
<tr>
<td>Mechanical polishing/buffing</td>
<td>Striations from cold working techniques may include residual grinding/polishing debris in lapping inclusions. Cumulative increase of interior area due to surface finish inconsistency proportionally exposes more alloy to the mechanisms of corrosion and burden of passivation.</td>
</tr>
<tr>
<td>Electropolishing</td>
<td>Minimizes the exposure area of the alloy to oxidizing fluids or halides and minimizes the origins for micropitting by corrosion mechanisms.</td>
</tr>
<tr>
<td>Passivation</td>
<td>Impedes or retards corrosive development of stainless steel surfaces. The effectiveness of passivation methods in terms of depth and enhancement of surface alloy ratios (i.e., chrome to iron) determines the eventual propensity of the alloy to corrode and the rate of corrosion.</td>
</tr>
<tr>
<td>Alloy composition (% molybdenum, chromium, nickel, etc.)</td>
<td>The microstructure quality affects precipitation of impurities at grain boundaries. Migration of impurities to the alloy surface can either support corrosion cells or seed downstream corrosion. Weld joints on tubing and other components with dissimilar sulfur concentrations may result in lack of penetration due to weld pool shift. The resulting crevice may become a corrosion initiation site.</td>
</tr>
<tr>
<td>Welding, welding conditions, purging, etc.</td>
<td>Improper welds can result in chromium-depleted heat-affected zones (HAZs) and other conditions that reduce corrosion resistance. Weld discontinuities create opportunities to trap fluid-borne impurities. Cracks resulting from poor welds will create breaches in the passive layer and form active corrosion cells. Proper purging prevents weld contamination by heat tint oxides and the concurrent loss of corrosion resistance. Passivation cannot reverse the effects of improper purging.</td>
</tr>
<tr>
<td>Product form and fabrication methods</td>
<td>The ferrite content can be greatly affected by the forming process (e.g., a forging will typically have much lower ferrite percentages than a casting). Barstock endgrain voids at the surface can enhance the potential of the alloy to pit and corrode. Minimization of differences in sulfur content will enhance the potential for successful welding.</td>
</tr>
</tbody>
</table>

| **Category 2 — Moderate Influence on the Formation of Rouge [Note (1)]** |                                                                                                                                                                                                             |
| Installation/storage environment               | Unidentified corrosion due to the storage or installation environment, including carbon steel contamination, scratching, exposure to chemical contaminants, stagnated condensation or liquids, etc., may warrant a derouging step prior to passivation. Failure to detect instances of corrosion will marginalize the effect of a normal passivation. |
| Expansion and modifications to an established system | Oxide formations in newly commissioned systems can form at different rates than in older systems and initially generate migratory Class I rouge. Where oxide films exist in established systems, they are likely to be more stable, producing less migratory iron or chrome oxides. Because the newer system can generate and distribute lightly held Class I migratory hematite forms throughout the system, the corrosion origin and cause can be difficult to identify. |

NOTE: (1) There is well-established industry data supporting this, and it needs to be considered.
Table D-2-2 Considerations That Affect the Amount of Rouge Formation During the Operation of a System

<table>
<thead>
<tr>
<th>Variables</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corrosive process fluid (bleach, halides, etc.)</td>
<td>Corrosion cell inceptions at breaches in the passive layer, as in chloride corrosion cells, will progressively catalyze the corrosion mechanism. This has a very strong influence for applications such as high-salt buffer tanks, etc.</td>
</tr>
<tr>
<td>High shear/velocity environment (pump-impeller, sprayball, tees, etc.)</td>
<td>High shear/velocity or impellers or impingement spots on vessel walls. In pure steam systems, high-velocity sections can scour tubing walls, either preventing sustained buildup of stable magnetite layers or sloughing off fragments from developing oxide formations that are then transported downstream for possible corrosion seeding.</td>
</tr>
<tr>
<td>Gaseous phase composition, including dissolved gases (O₂ and CO₂)</td>
<td>For monographed fluids (PW, WFI, and pure steam), the constituency of dissolved gases is generally believed to have an influence on rouge formation when within established conductivity and total organic carbon (TOC) limits in systems that have an adequate passive layer. It is possible for impurities to migrate across distillation and pure steam generation processes as dissolved gases. A variety of analytic spectrometry methods are available to identify these species. (Refer to Tables D-3.1-1 and D-3.2-1.)</td>
</tr>
<tr>
<td>Application, process media (pure steam, WFI, buffer, media, CIP, etc.), frequency of operation</td>
<td>The nature of the oxide formation, potential for corrosion, remedial methods, and period of formation are greatly influenced by the application as noted in the other impact descriptions (temperature, corrosive process, etc.). In steam-in-place (SIP) systems, velocity, temperature, and trapping can have impacts on the composition and locations of rouge formations and migratory deposits. Adequately designed systems can minimize this impact. Poorly trapped pure steam headers, regularly exposed to pressure gradients, can introduce corrosion mechanisms and products through steam condensate. Long hold periods in high-salt buffer tanks and the effectiveness of the tank agitation can promote or accelerate rouge formation. SIP following inadequate CIP can create corrosion mechanisms and further aggravate removal methods.</td>
</tr>
<tr>
<td>System CIP, cleaning methods</td>
<td>Exposure to CIP cycles and the specific chemical cleaning solutions strongly affects the potential for rouge occurrence. System sections exposed to a cyclic CIP regime will be less likely to form or collect rouge. Significant factors include whether there is an acid or hot acid CIP cycle in the CIP recipe. The duration and temperature of the acid cycle can be important. Acid cycles with mild concentrations (e.g., 2% to 20% phosphoric acid) have been shown to maintain and restore passive layers.</td>
</tr>
<tr>
<td>Redox potential</td>
<td>The use of ozone to sanitize purified water or WFI systems has also demonstrated beneficial effects in impeding alloy corrosion.</td>
</tr>
<tr>
<td>Maintenance of the system</td>
<td>System components such as worn pure steam regulator plug seats, improper or misaligned gaskets, worn regulator and valve diaphragms, pump impellers (with worn tips), and eroded or cracked heat exchanger tube returns are believed to be sources of Class I rouge.</td>
</tr>
<tr>
<td>Stagnant flow areas</td>
<td>A moving oxidizing fluid can maintain the passive layer. (Studies with nitrogen-blanketed WFI storage tanks have shown negative effects on passive layers as a result of minimizing oxygen in the fluid.) Liquid condensate that is not immediately removed from a pure steam conduit or that collects from improper valve sequencing can concentrate and transport surface oxidation products or steam contained solubles. These can concentrate and deposit at a branch terminus such as a vessel sprayball, dip tube, etc. These deposits are typically lightly held forms of hematite. Though easily removed, they can be difficult to remove in large vessels and appear to go against the common stipulation of “visually clean.”</td>
</tr>
<tr>
<td>Pressure gradients</td>
<td>Pure steam systems only. Pressure changes in the distribution system will affect the amount of steam condensate as well as the quality of the steam. If system sections are exposed to pressure ranges, condensate that is not effectively removed from horizontal sections can be revalorized at higher pressures, which will lower the steam quality and transport any impurities borne in the steam condensate.</td>
</tr>
<tr>
<td>System age</td>
<td>This depends on how the system has been maintained in regard to frequency of passivation or derouging, CIP exposure, and formation of stable oxide layers. New systems have been observed to generate disproportionate amounts of Class I rouge formations in contrast to established systems. In pure steam systems, although oxide formations become stable with</td>
</tr>
</tbody>
</table>

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Table D-2-2 Considerations That Affect the Amount of Rouge Formation During the Operation of a System (Cont’d)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>age, they can also thicken and be prone to particle sloughing in high-velocity sections. It should be noted that system time in use can have both beneficial and negative effects in regard to rouge formation and that regular system monitoring is important in identification of incipient corrosion.</td>
</tr>
</tbody>
</table>

NOTE: There is well-established industry data supporting this, and it needs to be considered.

Table D-3.1-1 Process Fluid Analyses for the Identification of Mobile Constituents of Rouge

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Test Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultra trace inorganic analysis (by ICP/MS)</td>
<td>Concentrations of trace metals in process solutions including pure water/steam are directly analyzed by inductively coupled plasma mass spectrometry (ICP/MS).</td>
</tr>
<tr>
<td>Standard particulate analysis (via light)</td>
<td>A liquid sample is subjected to a laser light, which scatters on contact with particles. The scattered light is collected, processed, segregated by channel, and displayed as a specific count for each size range analyzed.</td>
</tr>
<tr>
<td>Ultra trace analysis (by SEM/EDX)</td>
<td>Fluids are filtered via vacuum filtration, and particles are collected on a fine-pore filter medium. The particles are then analyzed by scanning electron microscopy for size, composition, and topographical features.</td>
</tr>
<tr>
<td>Fourier transform infrared spectroscopy (FTIR)</td>
<td>Organic analysis of liquid samples or extracts from wipe samples. Used to identify possible organic films or deposits.</td>
</tr>
</tbody>
</table>

Pros

- Noninvasive sample acquisition
- Highly quantitative information
- Provides strong ability to trend data

Cons

- Baseline must be determined for each system analyzed.
- Potentially noninvasive sample acquisition
- Allows for organic identification of elastomers or alternate organic contaminants

Shall

- Provides highly detailed physical observation and elemental composition data for mobile particulates
- Organic contaminants must be profiled in a specific target compound library.
<table>
<thead>
<tr>
<th>Type of Test</th>
<th>Test Description</th>
<th>Test Criteria</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scanning auger microanalysis</td>
<td>Surface metal elemental composition analysis. Provides for detailed analysis.</td>
<td>Highly accurate method for the identification and quantification of the surface metal composition. Used to determine the depth and compositional analysis of the surface including the passive layer.</td>
<td>Highly accurate method for the identification and quantification of the surface metal composition. Used to determine the depth and compositional analysis of the passive layer. Provides excellent elemental analysis of the top surface layers, including which oxide(s) are present.</td>
<td>Invasive and destructive test. Requires periodic removal of solid samples (e.g., coupons).</td>
</tr>
<tr>
<td>Small spot electron spectroscopy</td>
<td>Provides excellent elemental analysis of the top surface layers, including which oxide(s) are present.</td>
<td>Highly accurate method for the identification and quantification of the surface metal composition. Used to determine the depth and compositional analysis of the surface including the passive layer.</td>
<td>Highly accurate method for the identification and quantification of the surface metal composition. Used to determine the depth and compositional analysis of the passive layer. Provides excellent elemental analysis of the top surface layers, including which oxide(s) are present.</td>
<td>Invasive and destructive test. Requires periodic removal of solid samples (e.g., coupons).</td>
</tr>
<tr>
<td>Reflection grade ellipsometry</td>
<td>Multicolor interferometry using light and its diffractive properties to assess surface conditions.</td>
<td>Nondestructive analysis. Known diffractive characteristics of elements could provide for qualitative analysis of surface chemistry properties.</td>
<td>Nondestructive analysis. Known diffractive characteristics of elements could provide for qualitative analysis of surface chemistry properties.</td>
<td>Invasive test. Requires periodic removal of solid samples (e.g., coupons).</td>
</tr>
<tr>
<td>Electrochemical impedance spectrometry</td>
<td>The analysis of electrochemical noise in order to quantify the state of corrosion of a metallic surface.</td>
<td>Noninvasive, real-time quantification of metallic corrosion. Provides strong ability to trend data.</td>
<td>Noninvasive, real-time quantification of metallic corrosion. Provides strong ability to trend data.</td>
<td>Field qualification of this method is still ongoing.</td>
</tr>
</tbody>
</table>
### Table D-4.1-1 Rouge Remediation Processes Summary

**Derouging Processes: Specific**

<table>
<thead>
<tr>
<th>Class of Rouge</th>
<th>Description</th>
<th>Comments</th>
<th>Chemistry</th>
<th>Conditions of Process</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class I</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Removal</td>
<td>Phosphoric acid</td>
<td>Effective at removing iron oxides without etching the process contact surface</td>
<td>5% to 25% phosphoric acid</td>
<td>2 hr to 12 hr at 40°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Citric acid with intensifiers</td>
<td>Effective at removing iron oxides without etching the process contact surface</td>
<td>3% to 10% citric acid with additional organic acids</td>
<td>2 hr to 12 hr at 40°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Phosphoric acid blends</td>
<td>Can be used at a variety of temperatures and conditions</td>
<td>phosphoric acid blends</td>
<td>2 hr to 12 hr at 40°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Sodium hydrosulfite (i.e., sodium dithionite)</td>
<td>Effective at removing iron oxides without etching the surface but may generate sulfide fumes</td>
<td>Up to 10% sodium hydrosulfite</td>
<td>2 hr to 12 hr at 40°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Electrochemical cleaning</td>
<td>Useful in removing stubborn rouge without risk of etching the process contact surface</td>
<td>25% to 85% phosphoric acid</td>
<td>1 min/ft²</td>
</tr>
<tr>
<td><strong>Class II</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Removal</td>
<td>Phosphoric acid</td>
<td>Effective at removing iron oxides without etching the surface</td>
<td>5% to 25% phosphoric acid</td>
<td>2 hr to 24 hr at 40°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Citric acid with organic acids</td>
<td>Effective at removing iron oxides without etching the surface</td>
<td>5% to 10% citric acid with additional organic acids</td>
<td>2 hr to 24 hr at 40°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Phosphoric acid blends</td>
<td>Can be used at a variety of temperatures and conditions</td>
<td>phosphoric acid blends</td>
<td>2 hr to 24 hr at 40°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Oxalic acid</td>
<td>Effective at removing iron oxides; may etch electropolished surfaces</td>
<td>25% to 80% oxalic acid</td>
<td>8 hr to 48+ hr at 60°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Electrochemical cleaning</td>
<td>Useful in removing stubborn rouge without risk of etching the process contact surface</td>
<td>25% to 85% phosphoric acid</td>
<td>1 min/ft²</td>
</tr>
<tr>
<td></td>
<td>Sodium hydrosulfite (i.e., sodium dithionite)</td>
<td>Effective at removing iron oxides without etching the surface but may generate sulfide fumes</td>
<td>Up to 10% sodium hydrosulfite</td>
<td>2 hr to 12 hr at 40°C to 80°C</td>
</tr>
<tr>
<td><strong>Class III</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Removal</td>
<td>Phosphoric acid blends</td>
<td>Can be used at a variety of temperatures and conditions</td>
<td>phosphoric acid blends</td>
<td>8 hr to 48+ hr at 60°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Oxalic acid</td>
<td>May etch metallic surfaces</td>
<td>10% to 20% oxalic acid</td>
<td>8 hr to 48+ hr at 60°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Citric acid with organic acids</td>
<td>May etch metallic surfaces</td>
<td>5% to 10% citric acid with additional organic acids</td>
<td>8 hr to 48+ hr at 60°C to 80°C</td>
</tr>
<tr>
<td></td>
<td>Citric acid with intensifiers</td>
<td>Will etch metallic surfaces</td>
<td>5% to 10% citric acid with additional organic acids and fluorides</td>
<td>8 hr to 48+ hr at 60°C to 80°C</td>
</tr>
</tbody>
</table>
### Table D-4.1-1 Rouge Remediation Processes Summary (Cont’d)

<table>
<thead>
<tr>
<th>Class of Rouge</th>
<th>Description [Notes (1), (2)]</th>
<th>Comments [Notes (3), (4)]</th>
<th>Chemistry Notes (5)</th>
<th>Conditions of Process [Notes (6), (7)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitric/HF or nitric/ammonium bifluoride</td>
<td>Will etch metallic surfaces</td>
<td></td>
<td></td>
<td>1 hr to 24 hr at ambient to 40°C</td>
</tr>
<tr>
<td>Electrochemical cleaning</td>
<td>Useful in removing stubborn rouge without risk of etching the process contact surface</td>
<td></td>
<td></td>
<td>Limited to accessible parts of systems, primarily vessels. Process times are approximately 1 min/ft².</td>
</tr>
</tbody>
</table>

**NOTES:**
1. All of these derouging processes should be followed with a cleaning and passivation process of the treated surface.
2. Application methods include fluid circulation, gelled applications for welds or process contact surfaces, and spraying methods for vessels and equipment.
3. These derouging processes may produce hazardous wastes based on metals content and local and state regulations.
4. Oily or loose black residue due to carbon buildup may be present on the process contact surfaces after derouging and may require special cleaning procedures to remove.
5. Chemical percentages are based on weight percent.
6. The time and correlating temperatures given above are in direct relation to the percent by weight of the base reactant(s). A change in a formulation will change those corresponding requirements.
7. A deionized water rinse shall immediately follow each of the above chemical treatments.
E-1 GENERAL

This Appendix provides basic information and offers guidelines for owner/users, equipment manufacturers, and service providers for newly manufactured or installed systems in accordance with the requirements of GR-1. This Appendix covers the preparation and execution of procedures associated with the initial water flushing, chemical cleaning and degreasing, passivation, and final rinse(s) of specialized systems, as well as bioprocessing equipment after assembly, erection, or modification. These procedures will apply to UNS S30400, UNS S30403, UNS S31600, and UNS S31603 stainless steels. Superaustenitic stainless steels and nickel alloys may require a modified procedure.

This Appendix defines a method for qualifying the passivation process used for system and process component surfaces.

This Appendix provides information on passivation procedures and testing of the surface resulting from various passivation procedures.

E-2 PURPOSE OF PASSIVATION TREATMENTS

Passivation, or the forming of a passive layer on the surface of stainless steel alloys, is a naturally occurring phenomenon on a clean surface when oxygen is present. The passive layer may be augmented by chemical treatment of the stainless steel surface.

A critical prerequisite in preparation for chemical passivation processes is a cleaning procedure. This procedure includes all operations necessary for the removal of surface contaminants (oil, grease, etc.) from the metal to allow the chemical passivation to be most effective. The purpose of the final chemical passivation process is to enhance the passive layer and provide an alloy surface free of free iron or other contaminants, allowing the alloy to be in the most corrosion-resistant state.

For improved corrosion resistance in the standard stainless steel grades (e.g., UNS S31603), the passivation treatment is most beneficial and important. With superaustenitic stainless steels and nickel alloys, passivation is less critical, provided the surfaces are clean and free of contaminants. At the owner/user’s option, passivation may be performed to remove any free iron on process contact surfaces and to facilitate the formation of the passive layer.

In a discussion on passivation, it should be realized that the best passivation treatment or any surface treatment only puts the alloy in its most corrosion-resistant state for a particular environment. In other words, there are inherent corrosion-resistance limitations for any alloy, and the best passivation treatment does not replace the need for a more corrosion-resistant material for certain applications.

E-2.1 Why Passivation Is Necessary

Although stainless steel components may be clean and the passive layer intact prior to installation, welding destroys the passive film on the weld bead and the heat-affected zone (HAZ) of the weld. The distribution of elements across the weld and HAZ, including chromium, iron, and oxygen, are disturbed when the metal is melted so that the concentration of iron is elevated, while chromium, which is normally of higher percentage than iron in the passive layer, is reduced.

Discoloration and contamination (especially free iron) introduced during fabrication may also compromise corrosion resistance unless removed. Passivation after welding, by removing free iron, helps to restore the passive layer. It does not remove discoloration. Removal of discoloration requires a more aggressive acid than the usual nitric or citric acids used for passivation. Since the only postweld treatment normally used for installed piping systems is passivation, welding procedures that minimize discoloration are specified (see Part M) of this Standard.

Fabrication, cutting, bending, etc., can result in contamination that leads to loss of corrosion resistance. Examples are embedded iron, heat tint, welding flux from covered electrodes, arc strikes, and painting/markings. Exposure to carbon steel or iron is particularly detrimental. By removing contamination, especially free iron, a passivation treatment can help to restore the natural passivity of stainless steel that is damaged by fabrication.

E-2.2 When Passivation Is Necessary

(a) after welding and fabrication
(b) after welding of new components into a system
E-3 PASSIVATION PROCEDURE (SEE SF-2.6)

E-3.1 Procedure Description

The passivation provider shall obtain welded and nonwelded sample component(s) or coupons from each passivation method used (e.g., circulation, spot, bath) for the purpose of demonstrating that the procedure is capable of providing the required surface characteristics, namely, cleanliness, surface chemistry, and corrosion resistance.

The passivation process used on the qualification component(s) or coupons shall be reproducible in the system for which it is intended.

The procedure description and qualification document shall be available for review by the owner/user or his designee. The owner/user shall be responsible for verifying that the passivation procedure to be used on their system or components has been qualified.

E-3.2 Procedure Qualification

The passivation provider shall develop a passivation procedure for each method used. The procedure shall be developed to ensure that essential variables used to obtain the qualification samples can effectively remove free iron and meet the requirements of Table E-3.2-1.

Procedure qualification, as a minimum, shall include the following:

(a) Process Description. The following steps shall be described as a minimum (Table E-3.2-2 may be used as a guide):

1. prepassivation survey and preparation
2. flushing
3. cleaning
4. passivation
5. final rinsing
6. verification

(b) Essential Variables (Conditions Under Which the Samples Were Processed). The following essential variables shall remain within the designated range:

1. process time
2. temperature of solution during process
3. general chemistry of process fluids
4. process endpoint determination
5. conductivity of final deionized rinse water

(c) Procedure Qualification Coupon Testing

Table E-3.2-1 Minimum Surface Requirements for Process Qualification Samples

<table>
<thead>
<tr>
<th>Material</th>
<th>Test Method</th>
<th>Cr/Fe Ratio</th>
<th>Oxide Depth</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNS S31600 or UNS S31603</td>
<td>AES</td>
<td>1.0 or greater</td>
<td>15 Å, min.</td>
</tr>
<tr>
<td>UNS S31600 or UNS S31603</td>
<td>GD-OES</td>
<td>1.0 or greater</td>
<td>15 Å, min.</td>
</tr>
<tr>
<td>UNS S31600 or UNS S31603</td>
<td>XPS/ESCA</td>
<td>1.3 or greater</td>
<td>15 Å, min.</td>
</tr>
</tbody>
</table>

GENERAL NOTES:

(a) AES/ESCA readings of metal oxides typically obtain higher values than readings of metals.
(b) Additional alternative testing methods for cleanliness and passivation are shown in Table E-5-1.

(1) AES (auger electron spectroscopy) testing at the weld, including the worst discoloration area in the weld and heat-affected zone, and on the base metal to meet the requirements of Table E-3.2-1

(2) GD-OES (glow discharge–optical electron spectroscopy) testing at the weld, including the worst discoloration area in the weld and heat-affected zone, and on the base metal to meet the requirements of Table E-3.2-1

(3) XPS (X-ray photoelectron spectroscopy), also known as ESCA (electron spectroscopy for chemical analysis), testing at the weld, including the worst discoloration area in the weld and heat-affected zone, and on the base metal to meet the requirements of Table E-3.2-1

Qualification of method shall be supported by documentation for each procedure. The actual values of the essential variables and coupon testing listed above shall be documented and maintained as part of the procedure.

E-3.3 Procedure Documentation Requirements

The passivation provider shall generate and provide the following documentation, as a minimum:

(a) process descriptions
(b) essential variables
(c) ESCA/XPS or AES or GD-OES testing for each procedure qualification sample produced

E-4 PASSIVATION QUALITY CONTROL

E-4.1 Quality Control Surveillance

Quality control surveillance to ensure the written and qualified passivation procedure has been followed is essential. A thorough rinse with deionized or owner/user-approved water should follow the chemical treatment. It is good practice to continue rinsing until, as determined by conductivity analysis, the ionic contaminants, process chemicals, and by-products have been removed. This document shall be available for review by the owner/user or his designee.

(a) Written documentation that all requirements of the qualified procedure have been followed.
(b) Final rinse shall meet pre-established conductivity (quality) requirements.
<table>
<thead>
<tr>
<th>Process Type</th>
<th>Process Description [Notes (1), (2)]</th>
<th>Comments [Note (3)]</th>
<th>Conditions of Process [Notes (4), (5)]</th>
<th>Chemistry [Note (6)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-cleaning</td>
<td>Water flushing/filteration process</td>
<td>Removes debris prior to the passivation process</td>
<td>Ambient temperature for 5 min to 30 min per section; generally includes filtration of fluids</td>
<td>DI water</td>
</tr>
<tr>
<td></td>
<td>High-velocity water flushing process</td>
<td>Removes debris prior to the passivation process. Chlorides in water are detrimental to austenitic stainless steels</td>
<td>Ambient temperature for 15 min to 60 min per section</td>
<td>DI water (recommended)</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Phosphate cleaners</td>
<td>Removes light organic deposits. Can leave phosphate surface contamination</td>
<td>1 hr to 4 hr at heated conditions depending on the solution and contamination level</td>
<td>Blends of sodium phosphates [monosodium phosphate (MSP), disodium phosphate (DSP), trisodium phosphate (TSP)] and surfactants</td>
</tr>
<tr>
<td></td>
<td>Alkaline cleaners</td>
<td>Can be selected for specific organic contaminate</td>
<td>Effective at removal of heavy organic contamination or degreasing</td>
<td>Blends of nonphosphate detergents, buffers, and surfactants</td>
</tr>
<tr>
<td></td>
<td>Isopropyl alcohol (IPA)</td>
<td>Effective as a degreaser. Volatile. Highly flammable and sensitive to static discharge</td>
<td>Hand swab or wipe at ambient conditions</td>
<td>70% to 99%</td>
</tr>
<tr>
<td>Passivation</td>
<td>Nitric acid</td>
<td>Proven method under ASTM A380/A967. Can be processed at ambient conditions depending on formulation</td>
<td>30 min to 90 min at ambient temperature or higher, depending on concentration used</td>
<td>10% to 40% nitric acid</td>
</tr>
<tr>
<td></td>
<td>Phosphoric acid</td>
<td>Effective at removing iron oxides in addition to free iron</td>
<td>1 hr to 4 hr at heated conditions</td>
<td>5% to 25% phosphoric acid</td>
</tr>
<tr>
<td></td>
<td>Citric acid</td>
<td>Specific for free iron removal. Should be processed at elevated temperatures. Takes longer to process than mineral acid systems. Meets or exceeds ASTM A967</td>
<td>3% to 10% citric acid with various chelants, buffers, and surfactants</td>
<td>10% citric acid</td>
</tr>
</tbody>
</table>
E-4.2 Certificate of Passivation Compliance

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:

(a) customer's name
(b) description of system or component(s)
(c) vendor 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

E-5 EVALUATION OF CLEANED AND PASSIVATED SURFACES

There are no universally accepted tests to ensure that a component or system has been passivated or is in a passive condition. If the system/component has received the proper chemical passivation treatment, the documentation generated during the process (listed in E-4.2) should provide assurance that the components or system has received the specified treatment. As a guide to owner/users and others, to help determine whether an acceptable surface has been achieved following a particular cleaning or chemical passivation procedure, Table E-5-1 has been developed.

E-5.1 Acceptance Criteria for Cleaned and/or Passivated Process Contact Surfaces (See Table SF-2.6-1)

Table E-5-1 may be used as a guide for acceptance criteria for cleaned and/or passivated components or systems. This matrix is a simplified compilation of testing methodologies that an owner/user may want to use in selecting a test or as a means to interpret a proposal from a testing company.

The matrix is divided into groups of four types of testing methods

(a) gross inspection of cleaned and passivated parts per ASTM A380/A967 (Pass/Fail)
(b) precision inspection of cleaned and passivated parts under ASTM A380/A967 (Pass/Fail)
(c) electrochemical field and bench tests
(d) surface chemical analysis tests

Groups 1 and 2 of Table E-5-1 reflect the two main divisions in ASTM A380 and ASTM A967. The most obvious type of examination of these methods is visual. The
## Table E-5-1 Test Matrix for Evaluation of Cleaned and/or Passivated Surfaces

<table>
<thead>
<tr>
<th>Type of Test</th>
<th>Test Description</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Gross Inspection of Cleaned and/or Passivated Parts per ASTM A380/A967 (Pass/Fail)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visual examination [CT (test for cleanliness), RT (test for the presence of rouge)]</td>
<td>Bench or field test. Visual examination is the direct or remote visual examination of, in this case, a passivated metallic surface.</td>
<td>Can be performed with minimal preparation and equipment.</td>
<td>Not quantitative. Subjective interpretation of findings.</td>
</tr>
<tr>
<td>Wipe test ASTM A380 (CT, RT)</td>
<td>This test is useful for testing surfaces that cannot be readily accessed for direct visual examination.</td>
<td>Useful for testing surfaces that cannot be readily accessed for direct visual examination.</td>
<td>Not quantitative. Difficult to inspect hard-to-reach areas of large tube diameters.</td>
</tr>
<tr>
<td>Residual pattern test ASTM A380 (CT)</td>
<td>After finishing the cleaned surface per ASTM A380, the presence of stains or water spots indicates the presence of contaminants.</td>
<td>A simple test with rapid results</td>
<td>Not quantitative. Not very sensitive.</td>
</tr>
<tr>
<td>Water-break test ASTM A380 and ASTM A967 Practice B (PT)</td>
<td>The water-break test is performed by withdrawing the surface to be tested, in a vertical position, from a container overflowing with water.</td>
<td>General cleanliness of surface is easily determined. Useful in detecting hydrophobic contamination.</td>
<td>Not quantitative. This test identifies the presence of retained oils and greases. The test is not applicable on all surfaces including, but not limited to, electropolished surfaces.</td>
</tr>
<tr>
<td>High-humidity test ASTM A380 and ASTM A967 Practice B (PT)</td>
<td>Bench test. Sample coupon is immersed or swabbed with acetone or methyl alcohol then dried in an inert atmosphere. The coupon is then subjected to 97% humidity at 100°F for 24 hr or more.</td>
<td>Staining is evidence of free iron, which is detected through visual examination. Identifies possible pitting corrosion sites or embedded iron.</td>
<td>Not quantitative. Not used for installed tubing. Sample coupons are used, but does not prove complete coverage. Lengthy test Containment cabinet required.</td>
</tr>
<tr>
<td>Salt spray test ASTM A967 Practice C (PT)</td>
<td>Bench or field test. This test is conducted in accordance with ASTM B117 subject to the test area to a 5% solution of 3% to 7% salt water, with a final rinse prior to inspection, using DI-quality water or better.</td>
<td>Not quantitative. Longer-term testing is required to test for passive film quality or corrosion resistance. However, exposures over about 24 hr may show light staining resulting from differences in microfinish texture.</td>
<td>Not quantitative. Longer-term testing is required to test for passive film quality or corrosion resistance. However, exposures over about 24 hr may show light staining resulting from differences in microfinish texture.</td>
</tr>
<tr>
<td>Solvent ring test ASTM A380 (CT)</td>
<td>Bench test. Place a single drop of high-purity solvent on the surface to be evaluated, stir briefly, then transfer to a clean quartz microscope slide and allow the drop to evaporate. If foreign material has been dissolved by the solvent, a distinct ring will be formed on the outer edge of the drop as it evaporates.</td>
<td>Good test for organic contamination on the test surface and.</td>
<td>Not quantitative.</td>
</tr>
</tbody>
</table>

### 2. Precision Inspection of Cleaned and/or Passivated Parts Under ASTM A380/A967 (Pass/Fail)
### Table E-5-1 Test Matrix for Evaluation of Cleaned and/or Passivated Surfaces (Cont'd)

<table>
<thead>
<tr>
<th>Type of Test</th>
<th>Test Description</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. Precision Inspection of Cleaned and/or Passivated Parts Under ASTM A380/A967 (Pass/Fail) (Cont'd)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black light inspection</td>
<td>Bench test. This test requires the absence of white light. Suitable for detecting certain oil films and other transparent films that are not detectable under white light. Good test for organic contamination on surface.</td>
<td>Not quantitative. Not practical when testing for passivation</td>
<td></td>
</tr>
<tr>
<td>ASTM A380 (CT)</td>
<td>Test for presence of hydrophobic films. This test is more sensitive than the waterbreak test.</td>
<td>Not quantitative. Requires direct visual examination</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bench test. This test is conducted in accordance with ASTM F21 using DI-quality water or better.</td>
<td>Identification of free iron contamination on surface. Very sensitive test.</td>
<td>Not quantitative. This test will only identify free iron on the surface and will not directly measure the improvements of the passive oxide layer. This is a very sensitive test and must be performed by personnel familiar with its limitations. Either a sacrificial coupon is used for this test, or the test area is cleaned as described in the respective ASTM practice or specification. Safety and disposal issues exist with the test chemical. Easy to get a false-positive result.</td>
</tr>
<tr>
<td>Atomizer test</td>
<td>ASTM A380 (CT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bench test. This test is conducted in accordance with ASTM F21 using DI-quality water or better. A variation of the water-break test, this test uses an atomized spray, rather than a simple spray or dip to wet the surface.</td>
<td>Test for presence of hydrophobic films. This test is more sensitive than the waterbreak test.</td>
<td></td>
</tr>
<tr>
<td>Ferroxyl test for free iron</td>
<td>Bench or field test. Apply a freshly prepared solution of DI-quality water or better, nitric acid, and potassium ferricyanide to the coupon using an atomizer having no iron or steel parts. After 15 sec a blue stain is evidence of surface iron. Remove solution from the surface as soon as possible after testing, per ASTM A380 or ASTM A967. Test nonsystem coupons only.</td>
<td>Identification of free iron contamination on surface. Very sensitive test.</td>
<td>Not quantitative. Embedded iron is detected, but difficult to detect small discrete iron particles.</td>
</tr>
<tr>
<td>ASTM A380/potassium ferricyanide-nitric acid ASTM A967 Practice E (PT)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Copper sulfate test</td>
<td>Bench test. Prepare a 250-cm³ solution consisting of 1 cm³ of sulfuric acid (s.g. 1.84), 4 g copper sulfate, and the balance in DI-quality water or better. Apply this to a coupon using a swab. Keep the surface to be tested wet for a period of 6 min with additional applications as needed.</td>
<td>Identification of free iron contamination on surface. Very effective in detecting smeared iron deposits.</td>
<td>Not quantitative. Embedded iron is detected, but difficult to detect small discrete iron particles.</td>
</tr>
<tr>
<td>ASTM A380/ASTM A967 Practice D (PT)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cyclic polarization measurements</td>
<td>This technique uses cyclic polarization measurements similar to the ASTM G61 test method to measure the critical pitting potential (CPP). The more noble (more positive) the CPP, the more passive the stainless steel surface. Similar results may be obtained with the ASTM G150 test that measures critical pitting temperature (CPT).</td>
<td>This test method provides a direct measurement of the critical pitting potential of a stainless steel surface. The measured CPP provides a quantitative measurement of the level of passivation. The test equipment is relatively inexpensive.</td>
<td>The method requires a potentiostat and corrosion software package to make the measurements. To ensure reliable results, operators should be trained in electrochemical test techniques.</td>
</tr>
</tbody>
</table>

---

**Group**

Suitable for detecting certain oil films and other transparent films that are not detectable under white light. Good test for organic contamination on surface.

Not quantitative. Not practical when testing for passivation.

Requires direct visual examination.

Identification of free iron contamination on the test surface. Is effective in detecting smeared iron deposits.

Identification of free iron contamination on the test surface. Very sensitive test.

Not quantitative. This test will only identify free iron on the surface and will not directly measure the improvements of the passive oxide layer. This is a very sensitive test and must be performed by personnel familiar with its limitations. Either a sacrificial coupon is used for this test, or the test area is cleaned as described in the respective ASTM practice and/or specification. Safety and disposal issues exist with the test chemical. Easy to get a false-positive result.

Not quantitative. Embedded iron is detected, but difficult to detect small discrete iron particles.

Identification of free iron contamination on the test surface. Very effective in detecting smeared iron deposits.

The method requires a potentiostat and corrosion software package to make the measurements. To ensure reliable results, operators should be trained in electrochemical test techniques.

The method requires a potentiostat and corrosion software package to make the measurements. To ensure reliable results, operators should be trained in electrochemical test techniques.

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<table>
<thead>
<tr>
<th>Type of Test</th>
<th>Test Description</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electrochemical Field and Bench Tests (Cont'd)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electrochemical pen (ec-pen) (PT)</td>
<td>The result is based on preset values. Being the size and shape of a writing instrument, the ec-pen makes electrolytic contact when placed on the test surface. Capillary action causes electrolyte to flow from the reservoir to the surface through a porous polymer body while preventing the electrolyte from leaking out of the pen. There is a stable electrode inside the pen mechanism. By simply positioning the ec-pen on the sample surface, electrolytic contact is established and electrochemical characterization is possible. The measured area is typically 1.5 mm².</td>
<td>Easy to handle, short sample preparation time, real-time results, and the possibility to run experiments on virtually any size object with various surface geometries. The ec-pen is a portable instrument for the measurement of corrosion potential suitable for field use.</td>
<td>This test does not quantify the passive layer, but instead provides a pass-fail indication of passivity. The local test area needs to be cleaned and repassivated after testing.</td>
</tr>
<tr>
<td>Koslow test kit 2026/3036 (PT)</td>
<td>Similar to the ec-pen, in that it measures the corrosion potential of the metal surface, the Koslow 2026/3036 consists of a meter, a probe, and an interconnecting cable. An electrical charge is first applied to the test piece, after which a moist pad is placed on the surface of the same test piece. The probe is pressed into the moist pad to complete the circuit. Within a couple of seconds the cell voltage result appears on the digital meter.</td>
<td>Measures corrosion potential at the surface</td>
<td>User sensitive</td>
</tr>
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</table>

**4. Surface Chemical Analysis Tests**

<table>
<thead>
<tr>
<th>Method</th>
<th>Test</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auger electron spectroscopy (AES) (PT, RT)</td>
<td>Secondary and auger electrons, which are ejected from the surface of the test coupon, are analyzed by means of AES. The Auger electrons are analyzed as a function of energy, are used to identify the elements present. Elemental composition of the surface to a depth of 2 Å to 20 Å is determined and can be used in depth profiling applications.</td>
<td>Provides quantitative analysis using a scanning primary beam, secondary electron images yield information related to surface topography. Auger electrons, when analyzed as a function of energy, are used to identify the elements present. Elemental composition of the surface to a depth of 2 Å to 20 Å is determined and can be used in depth profiling applications.</td>
<td>The specimen chamber must be maintained at ultra-high vacuum (UHV). The specimen shall electrically conductive. Instrument is not readily available. Expertise is needed for data interpretation.</td>
</tr>
</tbody>
</table>

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examiner shall look for a clean surface free of oxides, scale, weld discoloration/heat tint, stains, dirt, oil, grease, or any deposits that could prevent the chemical passivation solution from reaching the metal surface.

The test results from ASTM A967, which are exclusively for passivation, are all based on visual detection of staining or discoloration indicative of the presence of free iron. These test results are subjective and nonquantifiable. However, for some applications this may be all that is required. The visual acceptance criteria in ASTM A380 and ASTM A967 apply.

Groups 3 and 4 of Table E-5-1 reflect two distinct methods of quantitative testing. These tests are not contained in either of the ASTM standards. These tests are designed to provide a more quantifiable analysis of a passivated surface. The electrochemical field and bench tests in Group 3 in Table E-5-1, with the exception of cyclic polarization, are suitable for field tests such as those used for postpassivation testing of installed piping systems and passivated welded surfaces.

Passivation is capable of dramatically increasing the chromium-to-iron (Cr/Fe) ratio on the surface of 316L-type stainless steel when properly applied. One measurement of the degree of enhancement of the layer following a chemical passivation treatment is the Cr/Fe ratio as determined by AES, GD-OES, or ESCA. The procedure is not readily adapted to field use but may be useful in developing the passivation procedure.

A Cr/Fe acceptance ratio, regardless of test method, should be 1.0 or greater (see Table E-3.2-1); because of variability in accuracy, identical results obtained with the different test methods are not expected. The surface chemical analysis tests in Group 4 in Table E-5-1 include methods for evaluation of the thickness and chemical state of the passive layer on stainless steel. Cyclic polarization measurements (Group 3 in Table E-5-1) may also be used to provide a quantitative evaluation of the level of passivation. Cyclic polarization as well as the methodologies in Group 4 in Table E-5-1 might be applied to sacrificial coupons placed in systems subject to the complete passivation process.
NONMANDATORY APPENDIX F
CORROSION TESTING

F-1 GENERAL

Corrosion testing may be used to determine whether the material manufacturer has used the appropriate processing variables during the fabrication of the raw product form. These variables include those primarily related to thermomechanical processing and heat treatment. The material can be evaluated based on weight loss or electrochemical response, or it can be measured by destructive testing techniques such as toughness testing. The standard ASTM tests that are commonly used are shown in Table F-1-1. However, there is no guarantee that a tested alloy will be appropriate for a specific environment even if it performs well in an industry-accepted test.

It is often appropriate to test a number of candidate alloys in a specific environment. Ideally the test selected should reflect the corrosion mode anticipated in production. These corrosion modes include general corrosion, crevice corrosion, pitting corrosion, and stress corrosion cracking.

F-2 CORROSION TESTS

For general corrosion, the most commonly used test method is ASTM G31, Standard Practice for Laboratory Immersion Corrosion Testing of Metals.

To rank materials based on their resistance to localized corrosion, such as pitting corrosion, the two most commonly used electrochemical methods are ASTM G61, Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements for Localized Corrosion, and ASTM G150, Standard Test Method for Electrochemical Critical Pitting Temperature Testing of Stainless Steels.

Other methods used to screen for more specific metallurgical problems such as the presence of sigma phase, chromium carbides, or improper heat treatment are described in Table F-1-1.

F-3 PITTING RESISTANCE EQUIVALENT (PRE) NUMBER

Where testing is not possible or desired, owner/users may use the PRE number as a guide to rank a material's corrosion resistance. Relative PRE number values for some wrought stainless steel and nickel alloys are shown in Table F-3-1. Notice that although different equations are used to calculate the PRE number for the two different alloy systems [see Table F-3-1, Notes (1) and (2)], the numbers may still be used to compare alloys for ranking purposes.

Since the PRE numbers are calculated based on composition, the listed values in Table F-3-1 are based on nominal composition only and are not representative of the ranges of PRE numbers that could result from the compositional ranges permitted by the applicable material specification. The values listed in Table F-3-1 are not representative of values that may be obtained by compositions specified by the owner/user. The owner/user is cautioned that PRE numbers should be developed from the specific composition of the heat intended for use in order to accurately rank or estimate the alloy's resistance to pitting. Consideration should be given to other factors that might reduce the corrosion resistance such as

(a) improper heat treatment
(b) surface finish and quality
(c) deleterious second phases
(d) welding
<table>
<thead>
<tr>
<th>ASTM Standard</th>
<th>Purpose of Test</th>
<th>Data Obtained</th>
<th>Typical Alloys Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ASTM A262</strong></td>
<td>Practice A (oxalic acid test)</td>
<td>Qualitative test to determine susceptibility to intergranular attack associated with chromium carbide precipitates. Tests the effectiveness of final heat treatment. Used to screen specimens intended for testing in Practices B, C, and E</td>
<td>Comparative, visual examination of microstructure after testing only</td>
</tr>
<tr>
<td>Practice B (ferric sulfate–sulfuric acid test)</td>
<td>Quantitative test measuring weight loss due to intergranular corrosion associated with chromium carbide precipitates. Also tests for sigma phase in 321-type alloys. Tests the effectiveness of final heat treatment</td>
<td>Report weight loss only</td>
<td>Austenitic stainless steels</td>
</tr>
<tr>
<td>Practice C (nitric acid test)</td>
<td>Quantitative test measuring weight loss due to intergranular corrosion associated with chromium carbide precipitates. Also tests for sigma phase in 316, 316L, 317, 321-, and 347-type alloys. Tests the effectiveness of final heat treatment</td>
<td>Report weight loss only</td>
<td>Austenitic stainless steels</td>
</tr>
<tr>
<td>Practice E (copper–copper sulfate–sulfuric acid test)</td>
<td>Qualitative test to determine susceptibility to intergranular attack associated with chromium carbide precipitates. Tests the effectiveness of final heat treatment</td>
<td>Pass or fail</td>
<td>Austenitic stainless steels</td>
</tr>
<tr>
<td><strong>ASTM A923</strong></td>
<td>Method A (sodium hydroxide etch test)</td>
<td>Detection of the presence of detrimental intermetallic phases. Used to screen specimens intended for testing in Method B and Method C</td>
<td>Visual examination. Pretest for subsequent methods</td>
</tr>
<tr>
<td>Method B (Charpy impact test)</td>
<td>Used to test toughness characteristics that may result from processing irregularities</td>
<td>Impact toughness energy</td>
<td>Duplex stainless steels</td>
</tr>
<tr>
<td>Method C (ferric chloride test)</td>
<td>Detects a loss of corrosion resistance associated with a local depletion of chromium, as a result of the precipitation of chromium-rich and possibly molybdenum-rich phases</td>
<td>Report weight loss only</td>
<td>Duplex stainless steels</td>
</tr>
<tr>
<td><strong>ASTM G48</strong></td>
<td>Methods A and B (ferric chloride test)</td>
<td>Resistance to pitting and/or crevice corrosion</td>
<td>Report weight loss</td>
</tr>
<tr>
<td>Methods C and D (ferric chloride test)</td>
<td>Resistance to pitting and/or crevice corrosion. Define the minimum temperature at which pitting or crevice corrosion initiates. Test the effects of alloying elements, final heat treatment, and surface finish of final product.</td>
<td>Report critical temperature</td>
<td>Ni-based and Cr-bearing alloys</td>
</tr>
<tr>
<td>Methods E and F (ferric chloride test)</td>
<td>Resistance to pitting and/or crevice corrosion. Define the minimum temperature at which pitting or crevice corrosion initiates. Test the effects of alloying elements, final heat treatment, and surface finish of final product.</td>
<td>Report critical temperature</td>
<td>Stainless steels</td>
</tr>
<tr>
<td><strong>ASTM G28</strong></td>
<td>Method A</td>
<td>Tests the susceptibility to intergranular attack associated with composition and processing</td>
<td>Report weight loss only</td>
</tr>
<tr>
<td>Method B</td>
<td>Tests the susceptibility to intergranular attack associated with composition and processing, specifically subsequent heat treatments</td>
<td>Report weight loss only</td>
<td>Ni-based alloys</td>
</tr>
</tbody>
</table>
### Table F-3-1 PRE Numbers for Some Alloys

<table>
<thead>
<tr>
<th>UNS or EN Designation</th>
<th>PRE Number</th>
</tr>
</thead>
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<td><strong>Austenitic Stainless Steels</strong> [Note (1)]</td>
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</tr>
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<td><strong>6% Mo Super austenitic Stainless Steels</strong></td>
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<td><strong>Nickel-based Alloys</strong> [Note (2)]</td>
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**GENERAL NOTE:** The above are industry-accepted formulas. Other formulas may be used at the owner's discretion.

**NOTES:**
1. For stainless steels: PRE Number = %Cr + 3.3 [(%Mo + 0.5(1/6 c)) + (1/6 N)].
2. For nickel alloys: PRE Number = %Cr + 1.5 [(%Mo + %W) + (%Nb)].

---

### Table MM-2.1-1 and Nickel Alloys as per Table MM-2.1-2

<table>
<thead>
<tr>
<th>UNS Number</th>
<th>EN Designation</th>
<th>JIS Designation</th>
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<td>...</td>
<td>NW5022</td>
<td>46</td>
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</tbody>
</table>

**GENERAL NOTE:** Alloys listed between horizontal lines are not equivalent, but comparable.

**NOTES:**
1. Calculation of PRE numbers is based on typical analyses for the respective alloys.
2. For stainless steels: PRE Number = %Cr + 3.3 [(%Mo + 0.5(1/6 c)) + (1/6 N)].
3. For nickel alloys: PRE Number = %Cr + 1.5 [(%Mo + %W) + (%Nb)].
NONMANDATORY APPENDIX K
STANDARD PROCESS TEST CONDITIONS (SPTC) FOR SEAL PERFORMANCE EVALUATION

K-1 SEALING COMPONENT PERFORMANCE EVALUATION

K-1.1 Material and Component Testing

Standard process test conditions are presented here in order to assess sealing components (hygienic union seal materials and diaphragm valve component seals). Typical steam operating parameters are presented in K-1.2.1. A simulated clean in place (CIP) and steam in place (SIP) test cycle is presented in K-1.2.2. Other process considerations are presented in K-1.2.3. Any specific process conditions that fall outside the design of this standard test should be evaluated separately.

The specific material composition(s) used in the test article shall be evaluated against the process conditions to which it may be exposed, including routine sterilization and cleaning. For diaphragm valve testing, the test article should reflect the specific valve configuration to be used in the anticipated application. Other conditions or process parameters/chemicals, such as allowable extreme process upset conditions and nonroutine treatments (e.g., passivation, derouging), should also be considered.

Form S-1, Application Data Sheet, defines a number of operational conditions (e.g., chemistry, temperature, pressure) to consider when developing nonstandard performance tests.

Before testing

(a) verify that the material/component’s service temperature and pressure rating meet the desired process conditions, including sterilization and cleaning.

(b) verify that the material/component is compatible with the intended process and cleaning chemicals at the routine concentrations used, including consideration for extreme allowable process conditions, per Part PM.

K-1.1.1 Test Article Requirements

(a) The following information, at a minimum, shall be included in test reports:

- seal type
- seal size
- sample size
- maximum rated pressure of valve or seal
- for valves only
- actuator model number and spring pressure

(b) air pressure supplied to actuator
(c) valve type
(d) valve size
(e) valve model number

(b) Test samples shall be representative of a certain model or product range of seals and shall be chosen randomly from those fabricated with the standard manufacturing process. Any modifications that may impact performance shall be included in the test report, e.g., travel stops. Knowledge of factors that impact material performance may help determine the minimum selection criteria of samples. Appropriate study design or supporting data are required to support all conclusions. Any differences or factors that impact material performance across the commercial product range shall be addressed. This includes, but is not limited to, seal materials of construction, size, shape, and manufacturing process.

K-1.2 Exposure Testing

Sections K-1.2.1 and K-1.2.2 present two example test cycles that can be performed on test articles. Simulated SIP testing in K-1.2.1 incorporates a typical steam sanitization cycle. K-1.2.2 provides simulated CIP and SIP testing and additional information for valve cycling. Components can be evaluated with either or both of these tests based on application requirements. Actuation requirements in K-1.2.1 and K-1.2.2 apply to valve testing only.

K-1.2.1 Simulated Steam-in-Place Testing. Expose the material to multiple SIP cycles to establish a life expectancy for the application and configuration. The testing cycles should occur without intervention (e.g., retorquing of clamps or fasteners), beyond initial installation procedures. All deviations identified during the test program should be documented and analyzed, including their impact on the test results and conclusions.

The cycle will consist of the following:

(a) Initial Installation and Preparation. This typically includes assembly, cleaning, performance verification (typically includes a thermal exposure cycle to allow the seals to set), seating of seals, and retorquing of valve clamps and fasteners, etc., per the manufacturer’s procedures.
(b) Initial Performance Evaluation. Verify the initial performance of the sealing component per K-1.2.4.

(c) Steam-in-Place. Expose the system to a simulated SIP with saturated USP pure steam or equivalent (e.g., steam generated from DI/RO water or equivalent).

1. System Temperature. Above 266°F (130°C).
2. System Pressure. Saturated steam pressure.
3. Test System Volume. A fixed volume of less than 2.6 gal (10 L) is recommended.
4. Test Exposure Time. Minimum of one continuous hour greater than 266°F (130°C).

1. System Temperature. Ambient, as close to 77°F (25°C) as possible.
2. System Pressure. 0 psig to 45 psig (0 bar to 3.1 bar).
3. Cool-Down Target. Until the system reaches 77°F (25°C).

(e) Performance Evaluation. Assess the performance of the sealing component at appropriate intervals (e.g., initial, 10, 100, 500 cycles and final) per K-1.2.4.

(f) Repeat Steps. Repeat steps in paras. (c) and (d).

(g) Final Performance Evaluation. Assess the performance of the sealing component at the completion of testing per K-1.2.4.

K-1.2.2 Simulated Combined CIP and SIP Testing

Exposure of the system to multiple CIP and SIP cycles to determine relative performance. Because this cycle is designed to assess material degradation, actual performance in service may differ. The testing cycles should occur without intervention (e.g., retorquing of clamps or fasteners) beyond initial installation procedures. All deviations identified during the test program should be documented and analyzed, including their impact on the test results and conclusions.

The cycle will consist of the following:

(a) Initial Installation and Preparation. This typically includes assembly, cleaning, performance verification (routine includes a steaming cycle), seating of seals, and retorquing of valve clamps and fasteners, etc., per the manufacturer's procedures.

(b) Initial Performance Evaluation. Verify the initial performance of the sealing component per K-1.2.4.

(c) DI/RO Water Rinse — 5 min

1. System Temperature. ≤104°F (≤40°C)
2. System Pressure. 72.5 psig ± 7.3 psig (5 bar ± 0.5 bar)
3. Actuations. 15 (10 sec open, 10 sec closed)
4. Chemical Wash 1 — 30 min

1. System Temperature. 176°F ± 9°F (80°C ± 5°C)
2. System Pressure. 72.5 psig ± 7.3 psig (5 bar ± 0.5 bar)
3. Actuations. 30 (5 sec closed, 55 sec open)

K-1.2.3 Other Process Testing Considerations

K-1.2.3.1 Vacuum. The ability of the system to hold vacuum should be considered for routine process equipment, where applicable. Specific applications that require vacuum, such as autoclave and lyophilizers, shall require the addition of a vacuum hold test requirement.

K-1.2.3.2 Additional Cleaning Chemicals. Additional integrated CIP test exposures should also be considered as part of the testing cycles. Specific cleaning chemicals and concentrations are determined by the process applications. Some systems, such as CIP systems, may be exposed to multiple cleaners. In addition to those listed in K-1.2.2, other cleaning agents such as sodium hypochlorite (0.67N, 0.67M, 0.5% w/w) should be assessed as required.

K-1.2.4 Performance Testing and Acceptance Criteria. Test the sealing components to evaluate their ability to maintain the component's integrity before, during, and after exposure (e.g., initial, 10, 100, 500
Appendix.

Evaluation Test for Valve Diaphragms, per This Requirements for Hygienic Performance of Diaphragms

K-1.3 Test Acceptance Criteria

(6) Check for presence of any residual material or debris that may have transferred to the surrounding environment or may have been shed from the components.

(7) The components shall be examined for any visible degradation of the diaphragm material or any other changes that may affect its performance.

(8) Post-exposure testing should be performed to confirm the integrity of the primary sealing point and to document any observed changes.

(9) If the diaphragm has failed or the test has failed, the test shall be repeated.

K-2.1 Mechanical Seal Performance Evaluation

K-2.1.1 General Requirements for Performance

(1) The mechanical seal shall be designed to provide an effective seal between the component and the mating surfaces.

(2) The seal faces shall be made of a durable, non-corrosive material.

(3) The seal faces shall be designed to allow for easy removal and replacement.

(4) The seal faces shall be designed to provide a uniform load distribution.

(5) The seal faces shall be designed to allow for easy adjustment.

K-2.2 Valve Diaphragms

K-2.2.1 General Requirements for Performance

(1) The valve diaphragm shall be designed to provide an effective seal between the component and the mating surfaces.

(2) The diaphragm shall be made of a durable, non-corrosive material.

(3) The diaphragm shall be designed to allow for easy removal and replacement.

(4) The diaphragm shall be designed to provide a uniform load distribution.

(5) The diaphragm shall be designed to allow for easy adjustment.

K-1.3.2 Test Acceptance Criteria

(1) The test shall be performed at the component design pressure and ambient temperature.

(2) The test shall be performed for one hour or as required at 90 psig (shell) or at the component design pressure, whichever is less, using a suitable soiling media (e.g. color dye, UV fluorescent solution).

(3) Assessment to be made and photographically recorded on dismantling of the components.

(4) Post-exposure testing should be performed to confirm the integrity of the primary sealing point and to document any observed changes.

(5) If the diaphragm has failed or the test has failed, the test shall be repeated.

EN 12296-1-1

(1) For all sealing components, post exposure testing should be performed at the component design pressure and ambient temperature for one hour or as required at 90 psig (shell) or at the component design pressure, whichever is less, using a suitable soiling media (e.g. color dye, UV fluorescent solution).

(2) Post-exposure testing should be performed to confirm the integrity of the primary sealing point and to document any observed changes.

(3) If the diaphragm has failed or the test has failed, the test shall be repeated.

EN 12296-1-2

(1) For all sealing components, post exposure testing should be performed at the component design pressure and ambient temperature for one hour or as required at 90 psig (shell) or at the component design pressure, whichever is less, using a suitable soiling media (e.g. color dye, UV fluorescent solution).

(2) Post-exposure testing should be performed to confirm the integrity of the primary sealing point and to document any observed changes.

(3) If the diaphragm has failed or the test has failed, the test shall be repeated.

EN 12296-1-3

(1) For all sealing components, post exposure testing should be performed at the component design pressure and ambient temperature for one hour or as required at 90 psig (shell) or at the component design pressure, whichever is less, using a suitable soiling media (e.g. color dye, UV fluorescent solution).

(2) Post-exposure testing should be performed to confirm the integrity of the primary sealing point and to document any observed changes.

(3) If the diaphragm has failed or the test has failed, the test shall be repeated.

EN 12296-1-4
To procure JIS specifications, contact JIS at https://www.jsa.or.jp/en/

**NONMANDATORY APPENDIX Y**

**PROCUREMENT SOURCES**

To procure ASTM specifications, contact ASTM International at www.astm.org.
To procure ASME specifications, contact ASME at www.asme.org.
To procure DIN specifications, contact DIN at www.din.de.
EN specifications may be obtained from any of the following member organizations:

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<thead>
<tr>
<th>Country</th>
<th>Country Standards Development Organization</th>
<th>Website</th>
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<tr>
<td>Austria</td>
<td>Austrian Standards Institute (ASI)</td>
<td><a href="http://www.austrian-standards.at">www.austrian-standards.at</a></td>
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<td>Belgium</td>
<td>Bureau de Normalisation/Bureau voor Normalisatie (NBN)</td>
<td><a href="http://www.nbn.be">www.nbn.be</a></td>
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<td><a href="http://www.evs.ee">www.evs.ee</a></td>
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<td><a href="http://www.sfs.fi">www.sfs.fi</a></td>
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<td><a href="http://www.din.de">www.din.de</a></td>
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<td>Greece</td>
<td>National Quality Infrastructure System (NQIS/ELOT)</td>
<td><a href="http://www.elot.gr">www.elot.gr</a></td>
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<td>Hungarian Standards Institute (MSZT)</td>
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<td><a href="http://www.stadlar.is">www.stadlar.is</a></td>
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<td><a href="http://www.unms.sk">www.unms.sk</a></td>
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NONMANDATORY APPENDIX Z
QUALITY MANAGEMENT SYSTEM

Z-1 SCOPE AND PURPOSE

This Appendix identifies the elements that shall be addressed in a Quality Management System (QMS) for ASME BPE component manufacturers. These elements identify the procedures, describe the processes, and list the resources necessary to implement the QMS. The QMS shall identify and describe the authority of the individuals responsible for ensuring that the quality activities necessary for the manufacture of ASME BPE-compliant components is done in a consistent and controlled manner. These activities shall ensure that the requirements of the ASME BPE Standard are met through quality planning, quality control, quality assurance, and quality improvement.

A QMS established by a manufacturer that intends to meet the requirements of the ASME BPE Standard shall be suitable for the types of components being manufactured and the types of activities performed in the manufacture of those components.

Z-2 GENERAL

The manufacturer shall establish and maintain a QMS that ensures compliance with all applicable requirements of the current ASME BPE Standard. Upon the issuance of a revised ASME BPE Standard, the certificate holder shall review his QMS and, where required, revise it to be in conformance with the revised Standard. Implementation of the revised QMS shall be within 6 months of the date of issue of the revised Standard.

Z-3 QUALITY MANAGEMENT SYSTEM MANUAL

The QMS shall be documented in a written QMS manual. There is no specific format or particular arrangement required for the manual, as long as all applicable elements have been addressed and the various topics are arranged in a logical and easy-to-interpret manner. The elements identified in Z-3.1 through Z-3.15, as applicable to the manufacturer’s scope of work, shall be addressed in the manual. The manual shall be ASME’s guide for surveying and auditing the manufacturer’s activities and documentation for conformance to its QMS. The manual shall be an auditable document that identifies the controls and processes used to ensure that the activities performed in the manufacture of ASME BPE components will be in conformance with the ASME BPE Standard. The manual shall not be a reiteration of the ASME BPE Standard, but shall, instead, describe or identify what, when, where, and how processes are conducted.

Z-3.1 Quality Management System

(a) Management personnel shall establish objectives for measuring effective implementation of the QMS and are responsible for obtaining the desired results. A policy statement indicating management authority and responsibility shall be included.

(b) A description of the components being manufactured in accordance with the ASME BPE Standard shall be provided.

(c) The authority and duties of those responsible for implementing the QMS shall be clearly established. Individuals performing quality assurance and quality control functions shall not be under the direct supervision of those in charge of areas being evaluated. They shall also have sufficient and well-defined responsibility, authority, and organizational freedom to

(1) identify quality-related problems
(2) initiate, recommend, and provide solutions to quality-related problems
(3) verify implementation of those solutions
(4) assure that further processing, delivery, or use of a suspect material or product is halted until proper disposition of any potentially nonconforming, deficient, or unsatisfactory condition has occurred

(d) Activities required to be performed by qualified personnel shall be identified. Minimum qualifications for such personnel shall be established. Controls shall be established to ensure that only those personnel who have the specified qualifications are permitted to perform those activities.

(e) Auditing activities shall be performed by trained and qualified auditors. The qualification, experience, and training requirements for auditors shall be specified in the QMS manual. Auditing competence includes, at a minimum, demonstrated knowledge and understanding of

(1) the ASME BPE Standard
(2) applicable regulations
(3) the QMS program
Z-3.3 Drawings, Design Calculations, and Specification Control

Controls shall be established to ensure that only the latest applicable drawings, design calculations, specifications, instructions, and authorized changes thereto are used for manufacturing, examination, inspection, and testing.

Z-3.4 Material Control

Personnel may, however, perform both quality and production functions as long as the organizational structure establishes clear segregation of duties between production and quality control activities.

(a) The QMS manual shall include an organization chart that shows the structure of functional groups, their responsibilities, levels of authority, lines of communication and identify within each group by job title the individuals involved with activities affecting quality. The purpose of this chart is to identify and associate the various organizational groups with the function for which they are responsible. The organization may modify this chart as necessary to suit changes in its scope of activities as long as those changes are reflected in the QMS manual.

(b) Quality assurance and quality control activities shall be performed by personnel whose functions are sufficiently independent of cost and schedule and independent of departments responsible for production or service processes.

(c) Specific personnel shall be designated for each of the following functions as appropriate to the scope of work performed by the organization:

1. Design
2. Purchasing/procurement
3. Contract review
4. Document control
5. Material control
6. Manufacturing/production
7. Quality control/assurance
8. Examination/inspection

A manufacturer may perform either examination functions or both examination and inspection functions. However, the individuals performing the final examination to assess the component’s conformance to the ASME BPE Standard shall be independent of all departments responsible for production or service activities. Examination personnel may be responsible to production management only if a third-party inspection agency is performing the final evaluation for conformance to the ASME BPE Standard.

(d) Maintenance of equipment

Z-3.5 Examination, Inspection, and Testing Program

Provisions shall be in place to establish acceptance criteria for the examinations, inspections, and testing necessary to prove conformance with the requirements of the ASME BPE Standard. In addition, the type and extent of examinations, inspections, and testing shall be specified as well as the step(s) during the manufacturing sequence at which these activities are to be performed.

Unless otherwise specified in the ASME BPE Standard, examinations, inspections, and testing shall be conducted at frequencies (extent) specified in the applicable referenced product specification(s), but not less than 10%.

Z-3.6 Control of Special Processes

Special processes shall be identified and performed as a controlled activity. Special processes include, but are not limited to:

(a) Material Joining. Measures shall be established to ensure that all joining processes are performed by qualified personnel using qualified procedure specifications. The qualification of personnel and procedure specifications shall be in accordance with the ASME BPE Standard.

(b) Heat Treatment. Measures shall be established to ensure that heat treatment of components conforms to the requirements of the ASME BPE Standard.

(c) Nondestructive Examination (NDE). Measures shall be established to ensure that NDE is performed by personnel whose qualifications meet the requirements of the ASME BPE Standard. These measures shall also ensure responsibilities, except as allowed by Z-3.2(b).
that all NDE activities are conducted in accordance with procedures as specified in the ASME BPE Standard.

(e) Approving suppliers through surveys and audits. Surveys and audits shall be documented and conducted by qualified lead auditors and auditors using a checklist. The frequency of the surveys and audits shall be commensurate with the schedule of production or procurement, but shall be at a minimum, commensurate with the surveys and audits conducted by ASME performed on BPE Certificate Holders.

Z-3.8 Control of Outsourced Items and Services

(a) Controls shall be established to ensure that outsourced items and services meet the specified requirements of the ASME BPE Standard. Provisions shall be established for the qualification and approval of suppliers and for the correction or elimination of nonconformances in outsourced items and services.

(b) The method used to qualify, approve, and monitor the performance of suppliers shall be described.

(1) For outsourced items supplied by an ASME BPE Certificate Holder, the method employed shall be based on the following:

(-a) a review of the certificate's scope and/or the QMS manual to determine the Certificate Holder's capability of supplying the item.

(-b) receipt of the supplied item with documentation certifying that the work was performed in accordance with the ASME Certificate of Authorization with the certificate number identified.

(2) For items and services supplied by an organization that does not hold an ASME BPE Certificate of Authorization, the method employed shall be based upon one or more of the following:

(-a) The supplier's history of providing items or services that conform to specified requirements or that perform satisfactorily in service. This can be based on past performance or a current third-party certification from a recognized accreditation body. Additionally, when qualification and approval are based upon third-party certification, the scope of that certification must be verified to be appropriate for the item or service being supplied.

(-b) Verification upon receipt inspection that the item or service conforms to specified requirements. Inspections shall be performed by qualified personnel using an inspection plan that details the characteristics to be inspected, the method of inspection, and the acceptability criteria. The results of the inspection shall be documented.

(-c) Verification during fabrication that the item or service performs satisfactorily in service. When adequate service performance cannot be verified through inspection activities on the completed component, hold points shall be established to evaluate the conformity of the supplied item or service. Work shall not proceed until the inspector has verified that the work performed is in conformance with the specified requirements.

(d) On-site surveillance of the supplier by a qualified technical expert or an auditor to verify the conformance of the supplied item or service.

(c) Controls shall be established for the segregation of outsourced items that are determined to be nonconforming.

Z-3.9 Control of Measurement and Test Equipment

Controls shall be established for the calibration of examination, measuring, and test equipment used in quality control activities.

(a) Procedures.

Procedures shall be established to ensure that measuring and testing devices used to verify compliance of outsourced items that are determined to be nonconforming.

(b) Calibration.

Calibration shall be conducted using a review of the certificate's scope and/or the QMS manual to determine the Certificate Holder's capability of supplying the item.

(c) Control measures shall include

(-a) receipt of the supplied item with documentation certifying that the work was performed in accordance with the ASME Certificate of Authorization with the certificate number identified.

(1) When the supplier is an ASME BPE Certificate Holder and the supplied items bear the ASME Certification Mark, the method employed shall be one of the following:

(-a) Calibration. Calibration shall be conducted using samples having documented traceability to the primary standard where such standards exist. If no primary standard exists, the standard or basis for calibration shall be documented.

These periodic checks shall be documented.

(add comma)

(-b) Out-of-Tolerance Devices

(1) When a device fails to calibrate during a planned periodic calibration, provisions shall be established to ensure that appropriate corrective action shall be taken. These provisions shall include a method for reviewing all measurements or tests performed with that device since the last successful periodic calibration to determine if applicable requirements have been met.

(2) When a device fails to calibrate during a periodic check, provisions need only address measurements or tests performed since the last successful periodic check. The method and frequency used for the periodic check are described in calibration procedures.

Editor Note: It appears that (c) is indented too far.
Z-3.10 Nonconformances and Corrective Actions

(a) Items and services that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall address identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, as well as the notification of affected organizations.

(b) Measures shall be established to ensure that conditions that do not conform to specified requirements, such as failures, malfunctions, deviations, defective material and equipment, nonconformances, and other quality system deficiencies, are identified, reported to appropriate levels of management, and promptly corrected. These measures shall also ensure that the root cause(s) responsible for these nonconformances be determined and corrected.

(c) The identification of conditions causing recurring nonconformances, the cause of these conditions, and the corrective action taken shall be documented and reported to appropriate levels of management.

Z-3.11 Storage, Shipping, Handling, and Packaging

Controls shall be established for the cleaning, preservation, packaging, storage, and shipping of finished components.

Z-3.12 Control of Documents and Record Retention

(a) Provisions shall be established to ensure that documents that are to be maintained throughout the design and manufacture of the component are identified. A minimum retention period of 3 yr from the date the component is shipped shall be established.

(b) These provisions shall also require that manufacturer's Data Reports, MTRs, and C of Cs shall be retained for a minimum period of 5 yr from the date the component is shipped.

(c) Document retention requirements shall extend to records of personnel training, qualification, and certification, for which the minimum retention time shall be 5 yr after their employment ceases. For personnel providing outsourced services in accordance with Z-3.1(f), provisions shall be established for the certificate holder to have access to their personnel records, as needed.

Z-3.13 Sample Forms

The use of forms shall be described in the QMS manual. Typical examples, referred to as “exhibits” shall be included and marked “Sample.” These samples should be completed in a manner typical of that expected for actual production documents.

Z-3.14 Internal Audits

Requirements shall be established for internal audits. Those requirements should address the following, as a minimum:

(a) The frequency of internal audits shall be specified. These audits shall be conducted in accordance with a written procedure by qualified auditors not having direct responsibility for the areas being audited. All elements in the QMS shall be internally audited at least once during each certification period.

(b) Audit results shall be documented by auditing personnel and reviewed by management having responsibility over the areas being audited. This documentation shall bear the signatures of the responsible management personnel.

(c) Corrective actions taken in response to deficiencies or nonconformances shall be documented. Follow-up actions shall be required after corrective actions have been taken to ensure the problem has been corrected. These follow-up actions may include a re-audit of deficient areas.

Z-3.15 Management Performance Assessments

Management personnel with assigned responsibility shall review the organization's QMS at least annually to ensure its continued suitability, adequacy, and effectiveness. The input from management review shall include information on the results of audits, process performance and product conformity, the status of preventive and corrective actions, and customer feedback, as appropriate.
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Chemical [Note (2)]</th>
<th>Maintenance</th>
<th>Physical/Mechanical Properties</th>
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<td>fluorination ~66%</td>
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<tr>
<td>Type 2: medium</td>
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<td>fluorination ~68%</td>
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<tr>
<td>Type 2: high</td>
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<tr>
<td>fluorination ~70%</td>
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</table>

- Preferred
- Acceptable
- Unacceptable
++ Best
+ Good
- Caution

GENERAL NOTE: Relative importance to this application [see SG-5.3] is defined as follows:

C = critical
I = important
S = secondary (importance depends on owner/user specifics)
Table AA-1-1 Static Seals for Use in Compendial Water Systems (SG-2.2.1)
Recommendations are for Static Seals Located Within the Compendial Water Envelope (SG-5.3) (Cont'd)

NOTES:
(1) Comments made here are generally true with compounds in this class currently available. Different compounds within a class vary between seal suppliers. Different compound numbers from a particular supplier may also vary. Communication between user and supplier is recommended to find the balance of properties needed for the owner/user.
(2) Passivation chemicals are occasionally used in compendial water systems. Consult with supplier.
## NONMANDATORY APPENDIX CC
### EXAMINATION, INSPECTION, AND CROSS REFERENCES

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<td>Visual examination acceptance criteria for welds on metallic pressure vessels and tanks</td>
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NONMANDATORY APPENDIX EE
VESSEL FLANGE, AGITATOR AND MECHANICAL SEAL DESIGN
FOR BOTTOM-MOUNT AGITATORS

EE-1 PURPOSE
This Appendix provides guidance for selected vessel, agitator, and dual mechanical seal features to ensure the mechanical integrity and hygienic performance of the assembled components.

EE-2 SCOPE
This appendix addresses the integrated design of vessel mounting flanges, dual mechanical seal assembly housings and agitator assemblies for bottom, centerline-mounted agitators in vertical cylindrical vessels. Information is provided for a limited range of equipment sizes based on a specified range of shaft sizes (nominal 0.75 in. (19 mm) – 4 in. (100 mm) diameter) for multi-use agitators and vessels. Alternate component designs which are not shown but that address the functionality described below may be acceptable. Single-use applications are not addressed.

EE-3 COMPONENT DESIGN
The design of each of the three listed components is dependent on the others as shown in Figures EE-3-1 (direct-mount agitator) and EE-3-2 (pedestal-mount agitator). The direct-mount agitator configuration is common for agitators with smaller shaft sizes; for this design, the agitator drive must be removed from the vessel to replace the mechanical seal. The pedestal-mount agitator configuration is common for larger shaft sizes; this design provides the ability to replace the seal without removing the agitator drive.
EE-3.1 Agitator Assembly

The agitator assembly typically consists of a motor, gearbox, mechanical seal, shaft, and impeller(s). As noted above, the motor with or without gearbox may either be mounted directly to the mechanical seal and vessel as shown in Figure EE-3-1 or may be attached to a pedestal which is, in turn, mounted to the vessel as shown in Figure EE-3-2. Direct-mount units may incorporate either a one-piece shaft as shown or a multi-piece shaft with in-tank coupling(s) as described in SD-3.5.2. Pedestal-mount units may include in-tank coupling(s) and, as shown, may include a shaft coupling within the pedestal to allow for installation and replacement of the seal assembly without disassembly of the agitator drive and pedestal.

Design of the agitator assembly shall meet the concentricity requirements for the components as specified by their manufacturers to limit runout at the seal faces. Registered pilot fits (see Figure EE-3.1-1 for direct-mount agitator example) or other appropriate methods (e.g., locating pins, installation tools, work instructions) shall be used to center the shaft and ensure concentricity.

EE-3.2 Dual Mechanical Seal Assembly

Dual mechanical seals are commonly used for bottom-mount agitator applications. The seal assembly may either be mounted directly to the vessel flange or it may be mounted in a pedestal that is attached to the vessel flange.

Figure EE-3.2-1 illustrates construction details for a typical dual mechanical seal assembly. Inner and outer seal face pairs provide the dynamic seal between the rotating agitator shaft and the stationary housing. O-ring seals provide the static seal between the vessel flange and seal housing, agitator shaft and rotating portion of the seal assembly, and between the seal faces and their support assemblies (the latter O-rings are not shown for clarity). Inlet and outlet ports provide pure steam and condensate or other appropriate fluid for seal sterilization and lubrication, respectively. A port outboard of the outer seal allows for detection of fluid leakage that may indicate seal failure.

Design of the static O-ring seals in the mechanical seal assembly shall be per MC-3.3.2.2(c). Seal assembly design shall locate the O-ring between the seal housing and the inner corner of the vessel flange bore in a manner to allow for adequate flushing to remove process residues. Figure EE-3.2-2 illustrates proper location of this O-ring, together with dimensional considerations for design of the O-ring groove and associated flange features. Manufacturing tolerances, materials and exposure conditions should be considered to ensure performance. In particular,

(a) O-ring selection and groove design shall provide 10-15% radial compression to ensure proper O-ring function.
(b) O-ring groove height L should be selected to provide at least minimal axial compression.
(c) Design L/L1 ratio should be selected to yield a value within the indicated range considering manufacturing tolerances.
(d) Sufficient void volume (5-10%) should be provided in the groove to accommodate O-ring thermal expansion during SIP and material swell, if any, due to chemical exposure.

This guidance presumes the use of Part PM-conforming (e.g., USP Class VI, ADI-free) EPDM and FKM O-ring elastomers with 70-75 durometer hardness. FFKM, if used, has a higher coefficient of thermal expansion which should be considered.
EE-3.3 Vessel Mounting Flange

Pad-style flanges are commonly used to mount the agitator and seal assemblies to the vessel. Flange thickness is dictated by code requirements for pressure vessel design and its integration into the vessel head should address agitator static and dynamic forces (e.g., vertical downward load, torque, bending moment).

Seal housing outside diameter and thus vessel mounting flange inside diameter (bore) are a function of the shaft diameter and seal design. A seal housing may be designed to accommodate a range of shaft diameters; the flange bore sizes given in Table EE-3.3-1 reflect this functionality.

Table EE-3.3-1  Vessel Flange Bore per Shaft Diameter

<table>
<thead>
<tr>
<th>Nominal Shaft Dia, in.</th>
<th>Flange Bore, in.</th>
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<tr>
<td>⅞</td>
<td>4.50</td>
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<tr>
<td>1</td>
<td>4.50</td>
</tr>
<tr>
<td>1¼</td>
<td>4.50</td>
</tr>
<tr>
<td>1½</td>
<td>4.50</td>
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<tr>
<td>1¾</td>
<td>5.50</td>
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<tr>
<td>2</td>
<td>5.50</td>
</tr>
<tr>
<td>2¼</td>
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<td>2½</td>
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<td>2¾</td>
<td>8.00</td>
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<td>3¾</td>
<td>8.00</td>
</tr>
<tr>
<td>4</td>
<td>8.00</td>
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</table>

Flange bore may be a constant diameter along its entire length or may be piloted as shown in Figure EE-3.3-1 to facilitate seal installation. Piloted construction should employ gradual transitions at changes in bore diameter to reduce the potential for O-ring damage or improper installation.

As-built tolerances (post welding) for flange thickness, bore, face flatness and face perpendicularity parameters as shown in Figure EE-3.3-2 shall meet the requirements in Table EE-3.3-2 to ensure proper installation and function of the seal and agitator.
Table EE-3.3-2  Vessel Flange Fabrication Tolerance Guidelines

<table>
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<tr>
<td>Flange thickness</td>
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<tr>
<td>Flange bore</td>
<td>± 0.001 in.</td>
</tr>
<tr>
<td>Flange face flatness</td>
<td>± 0.002 in.</td>
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<tr>
<td>Flange face-to-bore perpendicularity</td>
<td>± 0.005 in.</td>
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</table>

The agitator mounting flange design shall not create areas where bioburden may be retained nor impede the ability of the equipment to drain.

Vessel pad flanges may also be incorporated in vessel bottom fabrications that include other features (e.g., drain assemblies, instrumentation ports) as appropriate to achieve performance and mechanical design objectives.
Figure EE-3-1  Direct-Mount Agitator

Figure EE-3-2  Pedestal-Mount Agitator
**Figure EE-3.1-1** Registered Fit to Ensure Concentricity: Seal Housing-to-Drive Pilot

**Figure EE-3.2-1** Dual Mechanical Seal Assembly
Figure EE-3.2-2 Seal Assembly to Flange O-Ring Detail

T: Select to achieve
10-15% compression
L/L1: 3-4
L: Select to achieve
90-95% groove fill
T/R: ~10

Figure EE-3.3-1 Vessel Flange With Piloted Bore
Figure EE-3.3-2 Vessel Flange Tolerance Parameters
Nonmandatory Appendix FF
Leak Test Methods for Single-use Components and Assemblies

See Tables FF-1 and FF-2.
<p>| Type of Test                  | Test Description                                                                 | Advantages                                                                 | Disadvantages                                                                                                                                                                                                 | Reference                                                                                           | Typical Defect Size Limit of Detection | Typical Test Time | Typical Test User                                                                 |
|------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------|-------------------|====================================================================================|
| Helium tracer gas            | Assembly or component is placed in a vacuum chamber, followed by chamber evacuation. The helium tracer gas is then admitted to inside of the assembly. Any leaks will be detected via a mass spectrometer with a helium sensor. | High sensitivity; correlation to microbial challenge is possible             | Specialized equipment required; not suitable for complex systems; complicated handling and maintenance; impacted by material gas permeability; pre-use only                                                                 | ASTM F2391: Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas | ≥2 µm                   | 5-15 minutes (for assembly); &lt;1 minute (for connectors) | Assembly manufacturer; component manufacturer |
| Pressure decay with restraining plates | Bag body is placed between two plates and connected to a pressurized air supply, inflated to a defined pressure, and monitored for pressure drop over a defined time. Pass/fail results are based on specified pressure decay rates. | Tests entire assembly; correlation to aerosol microbial challenge is possible; | Specialized equipment required; pre-use only                                                                                                                                                                  | ASTM F2095: Standard Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates | ≥50 µm                  | 10 minutes          | Assembly manufacturer; component manufacturer                                        |
| Volume-dosed flow measurement | Assembly is installed at point of use, connected to a forward flow tester, inflated to a defined pressure, and pressure is maintained while monitoring flow of air. Pass/fail results are based on specified air flow rates. | Tests entire assembly; correlation to aerosol microbial challenge is possible | Specialized equipment required, pre-use only, may require a filter post-gamma irradiation; limited volume range; leaks may be occluded by the assembly support hardware walls                                                                 | ASTM E2930: Standard practice for pressure decay leak test method                                        | ≥30 µm                  | 15 minutes          | Assembly manufacturer; owner/user                                                      |
| Pressure decay without restraining plates | Assembly or component is connected to a pressurized air supply, inflated to a defined pressure, and monitored for pressure drop over a defined time. Pass/fail results are based on specified pressure decay rates. | Simple handling and operation; test can also be performed in situ.          | Sensitivity limited by assembly pressure tolerance; pre-use only (post-use possible with limitations); may require a filter post-gamma irradiation; sensitivity declines as volume increases, larger bag volumes require a large workspace; significant risk of damage during testing | ASTM F2095: Standard Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates | ≥50 µm                  | 15-30 minutes (does not include filling time)                                     | Assembly manufacturer; component manufacturer; owner/user |
| Visual inspection            | Visual inspection is conducted for the assembly or component                        | No specialized equipment required                                           | Requires skilled operators; lack of clear pass/fail criteria; defects in folds or seams of assembly may not be visible                                                                                       | ASME BPVC, Section V, Article 9 (Visual Examination)                                                  | ≥100 µm                 | 5 minutes           | Assembly manufacturer; component manufacturer; owner/user                             |</p>
<table>
<thead>
<tr>
<th>Type of Test</th>
<th>Test Description</th>
<th>Advantages</th>
<th>Disadvantages</th>
<th>Reference</th>
<th>Typical Defect Size Limit of Detection</th>
<th>Typical Test Time</th>
<th>Typical Test User</th>
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<tr>
<td>Microbial challenge</td>
<td>Microbial challenge testing by liquid immersion involves immersing a media-filled</td>
<td>Correlation of physical test method sensitivity to microbial ingress barriers; complicated set up;</td>
<td>Difficult to test large assemblies; high cost; typically</td>
<td>ASTM E3251: Standard Test Method for Microbial Ingress Testing on Single-Use Systems</td>
<td>&gt;2 um</td>
<td>180 minutes immersion (for</td>
<td>Assembly manufacturer; component</td>
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<tr>
<td>liquid Immersion</td>
<td>assembly unit into a liquid concentration of microorganisms for a specified       probabilistic method</td>
<td>qualitative</td>
<td></td>
<td></td>
<td>assembly); shorter times for small components; several days incubation</td>
<td>manufacturer; component</td>
<td>manufacturer</td>
</tr>
<tr>
<td></td>
<td>period of time, removing the unit, incubating the unit and examining the unit for</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>microbial growth.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Microbial challenge</td>
<td>Microbial challenge testing by aerosol involves placing a media-filled assembly   Correlation of physical test method sensitivity to microbial ingress barriers; complicated set up; probabilistic method; typically qualitative</td>
<td></td>
<td></td>
<td>ASTM E3251: Standard Test Method for Microbial Ingress Testing on Single-Use Systems</td>
<td>&gt; 2µm</td>
<td>60 minutes aerosol chamber; several days incubation</td>
<td>Assembly manufacturer; component</td>
</tr>
<tr>
<td>aerosol</td>
<td>unit into a specially designed aerosolization chamber, charging the atmosphere</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>within the chamber with a nebulized cloud or aerosol of microorganisms for a</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>specified period of time, incubating the unit and examining the unit for</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>microbial growth.</td>
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</tr>
<tr>
<td>Seal Strength</td>
<td>This test method measures the force required to separate a test strip of material  Quantitative</td>
<td>Limited usefulness for owner/user</td>
<td></td>
<td>ASTM F88: Standard Test Method for Seal Strength of Flexible Barrier Materials</td>
<td>N/A</td>
<td>15 minutes</td>
<td>Assembly manufacturer</td>
</tr>
<tr>
<td></td>
<td>containing the seal. It also identifies the mode of specimen failure.</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Burst test</td>
<td>Assembly is subjected to progressively greater internal pressures (air or fluid)  Inexpensive; quantitative</td>
<td>Limited usefulness for owner/user</td>
<td></td>
<td>ISO 7241-2: Hydraulic fluid power -- Quick-action couplings - Part 2: Test methods (Section 21); ASTM D1599: Standard Test Method for Resistance to Short-Time Hydraulic Pressure of Plastic Pipe, Tubing, and Fittings; ISO 1402: Rubber and plastics hoses and hose assemblies - Hydrostatic testing</td>
<td>N/A</td>
<td>15 minutes</td>
<td>Design team; component manufacturer</td>
</tr>
<tr>
<td></td>
<td>until it fails.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Tensile (Pull-off)</td>
<td>Assembly is subjected to progressively greater tensile stresses until it fails.   Quantitative</td>
<td>Specialized equipment required; limited usefulness for owner/user</td>
<td></td>
<td>Manufacturer-defined method</td>
<td>N/A</td>
<td>15 minutes</td>
<td>Design team; component manufacturer; failure investigators</td>
</tr>
<tr>
<td>Methylene blue leak</td>
<td>Assembly is filled with methylene blue solution, outside inspected for evidence   Inexpensive; identifies exact leak location</td>
<td>Qualitative; limited usefulness for owner/user</td>
<td></td>
<td>ASTM F1929: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration</td>
<td>N/A</td>
<td>15 minutes</td>
<td>Failure investigators</td>
</tr>
<tr>
<td>test</td>
<td>of leaks.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soap leak location</td>
<td>Assembly is pressurized with air, followed by spraying the outside with a soap   Inexpensive; identifies exact leak location</td>
<td>Qualitative; limited usefulness for owner/user</td>
<td></td>
<td>ASTM E515: Standard Practice for Leaks Using Bubble Emission Techniques (Section 1.2.2 - Liquid Application Technique)</td>
<td>N/A</td>
<td>15 minutes</td>
<td>Failure investigators</td>
</tr>
<tr>
<td></td>
<td>solution, with bubbles indicating leak locations.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immersion leak</td>
<td>Assembly is partially inflated with air, with sections or entire assembly         Inexpensive; identifies exact leak location</td>
<td>Difficult to test large assemblies; qualitative; limited usefulness for owner/user</td>
<td></td>
<td>ASTM E515: Standard Practice for Leaks Using Bubble Emission Techniques (Section 1.2.1 - Immersion Technique)</td>
<td>N/A</td>
<td>15 minutes</td>
<td>Failure investigators</td>
</tr>
<tr>
<td>location</td>
<td>immersed in a water tank, while escaping air bubbles indicate leak locations.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GG-1 Terminology

This section explains common terminology for hose barb design variables for single-use hose barb components.

Terminology:

(a) **Hose Barb**: The feature of a single-use component which allows the attachment of flexible tubing.

(b) **Mono-Barb Design**: Hose barb that features a single ridge.

(c) **Multi-Barb Design**: Hose barb that features 2 or more ridges.

(d) **Tip**: The end of the hose barb that is inserted into flexible tubing.

(e) **Barb Section**: The ridged section of a hose barb from the tip to the shaft.

(f) **Shaft**: The section between the end of the barb section and the body of the component.

Dimensional Considerations:

Refer to Figure GG-1.1.

(a) The length of the shaft typically determines the allowable insertion length past the barb section for the flexible tubing.

(b) The overall length of the hose barb is measured from the tip of the barb section to the termination of the shaft section into the body of the component.

(c) The major OD typically determines the maximum expansion of the flexible tubing relative to its nominal inner diameter.

(d) The taper angle is often constant (as shown), however, alternative designs exist wherein this is variable.

(e) The ID is the smallest measured inner diameter of the hose barb.

(f) The minor OD is measured at the tip of the hose barb.

(g) The linear tip length is not present in some hose barb designs.
GG-2 Design Guidance

Mechanical hose barb connections and performance vary widely depending on individual component selection. Refer to requirements for mechanical hose barb connections in SJ-2. General design guidance follows:

(a) Hose Barb and Tubing Interface Considerations:
(1) The hose barb should be selected based on the nominal tubing dimensions (ID and wall thickness) and material characteristics (e.g., hardness) of the tubing to ensure performance and ease of assembly. Tubing must be allowed to elastically return to a smaller diameter around the shaft behind the major OD of the barb to seal the connection.
(2) The major OD of the barb should exceed the inner diameter of the tubing by a minimum of 10%.
(3) Excessive oversizing of a hose barb relative to the inner diameter of the tubing should be avoided as overstretching can cause deformation or potential damage of the tubing.

(b) Retention Device Considerations:
(1) The primary function of a retention device is to prevent disengagement of the tubing from the hose barb.
(2) The retention device should be selected with consideration of the hose barb and tubing geometry.
   (-a) The retention device should be sized to provide adequate compressive force to the tubing, without damaging the component or deforming the tubing to the point of compromising the seal.
   (-b) The shaft length and taper should dimensionally accommodate the retention device such that the appropriate radial compressive force can be produced.
   (-c) The retention device should be selected such that assembly will not be hindered by interference.
(3) Retention device compatibility with the associated sterilization method should be evaluated.

(4) Table GG-2.1 below provides general guidance for thermoplastic elastomer (TPE) and silicone tubing materials commonly employed in single-use assemblies.

Table GG-2.1 – Typical Retention Devices by Tubing Type and Operating Pressure

<table>
<thead>
<tr>
<th>Retention Device Type</th>
<th>Unreinforced 50-65 Shore A Tubing</th>
<th>Unreinforced Tubing &gt; 65 Shore A</th>
<th>Reinforced Tubing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cable Ties</td>
<td>Operating pressure ≤ 10 psi (0.7 bar)</td>
<td>Evaluation recommended</td>
<td>Evaluation recommended</td>
</tr>
<tr>
<td>Polymeric press-fit retention devices</td>
<td>Operating Pressure ≤ Tubing rating</td>
<td>Operating pressure ≤ Tubing rating</td>
<td>Operating pressure ≤ Tubing rating</td>
</tr>
<tr>
<td>Metallic clamp type retention devices</td>
<td>Evaluation recommended</td>
<td>Operating pressure ≤ Tubing rating</td>
<td>Operating pressure ≤ Tubing rating</td>
</tr>
</tbody>
</table>