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 for use 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.

(19) 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 (19)

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-5.2.6 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 (19)

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-

(19)

Table MM-2.1-1 Wrought Stainless Steels: Nominal Compositions (wt. %)

UNS Number [Note (1)]	EN Designation	C	Mn	N	Cr	Ni	Mo	Cu
Austenitic Stainless Steels								
S30400	...	0.07	2.00	0.10	17.5–19.5	8.0–10.5	...	...
...	1.4301	0.07	2.00	0.10	17.5–19.5	8.0–10.5	...	...
S30403	...	0.030	2.00	0.10	17.5–19.5	8.0–12.0	...	...
...	1.4307	0.030	2.00	0.10	17.5–19.5	8.0–10.5	...	...
...	1.4306	0.030	2.00	0.10	18.0–20.0	10.0–13.0	...	...
S31600	...	0.08	2.00	0.10	16.0–18.0	10.0–14.0	2.00–3.00	...
...	1.4401	0.07	2.00	0.10	16.5–18.5	10.0–13.0	2.00–2.50	...
S31603	...	0.030	2.00	0.10	16.0–18.0	10.0–14.0	2.00–3.00	...
...	1.4404	0.030	2.00	0.10	16.5–18.5	10.0–14.5	2.00–2.50	...
...	1.4435	0.030	2.00	0.10	17.0–19.0	12.5–15.0	2.50–3.00	...
Superaustenitic Stainless Steels								
S31703	...	0.030	2.00	0.10	18.0–20.0	11.0–15.0	3.0–4.0	...
...	1.4438	0.030	2.00	0.10	17.5–19.5	13.0–17.0	3.0–4.0	...
N08904	...	0.020	2.00	0.10	19.0–23.0	23.0–28.0	4.0–5.0	1.0–2.0
...	1.4539	0.020	2.00	0.15	19.0–21.0	24.0–26.0	4.0–5.0	1.20–2.00
N08367	...	0.030	2.00	0.18–0.25	20.0–22.0	23.5–25.5	6.0–7.0	0.75
S31254	...	0.020	1.00	0.18–0.25	19.5–20.5	17.5–18.5	6.0–6.5	0.50–1.00
...	1.4547	0.020	1.00	0.18–0.25	19.5–20.5	17.5–18.5	6.0–7.0	0.50–1.00
N08926	...	0.020	2.00	0.15–0.25	19.0–21.0	24.0–26.0	6.0–7.0	0.5–1.5
...	1.4529	0.020	1.00	0.15–0.25	19.0–21.0	24.0–26.0	6.0–7.0	0.50–1.50
Duplex Stainless Steels								
S32101	...	0.040	4.00–6.00	0.20–0.25	21.0–22.0	1.35–1.70	0.10–0.80	0.10–0.80
...	1.4162	0.04	4.0–6.0	0.20–0.25	21.0–22.0	1.35–1.70	0.10–0.80	0.10–0.80
S32205	...	0.030	2.00	0.14–0.20	22.0–23.0	4.5–6.5	3.0–3.5	...
...	1.4462	0.030	2.00	0.10–0.22	21.0–23.0	4.5–6.5	2.50–3.5	...

GENERAL NOTES:

(a) Maximum, 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.

Table MM-2.1-2 Wrought Nickel Alloys: Nominal Compositions (wt. %)

UNS Designation [Note (1)]	EN Number	C	Cr	Ni	Mo	Cu	Other
N06625	...	0.10	20.0–23.0	58.0 min	8.00–10.0	...	Fe: 5.0 max., (Nb + Ta): 3.15–4.15
...	2.4856	0.03–0.10	20.0–23.0	58.0 min	8.0–10.0	0.5	Fe: 5.0 max., (Nb + Ta): 3.15–4.15, Ti: 0.40 max.
N10276	...	0.01	14.5–16.5	Balance	15.0–17.0	...	W: 3.0–4.5
...	2.4819	0.01	14.5–16.5	Balance	15.0–17.0	0.5	W: 3.0–4.5 Co: 2.5 max., Mn: 1.0 max.
N06022	...	0.015	20.0–22.5	Balance	12.5–14.5	...	W: 2.5–3.5
...	2.4602	0.01	20.0–22.5	Balance	12.5–14.5	...	W: 2.5–3.5 Fe: 2.0–6.0, Co: 2.5 max.

GENERAL NOTES:

(a) Maximum, 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.

Table MM-2.1-3 Stainless Steel and Nickel Alloy Cast Designations

			Approximate Wrought Equivalent	
UNS Designation	ACI Designation	EN Designation	UNS Designation	EN Designation
Austenitic Stainless Steels				
J92600	CF8	...	S30400	...
...	...	1.4308	...	1.4301
J92500	CF3	...	S30403	...
...	...	1.4309	...	1.4307
...	...	...	...	1.4306
J92900	CF8M	...	S31600	...
...	...	1.4408	...	1.4401
J92800	CF3M	...	S31603	...
...	...	1.4409	...	1.4404
...	...	...	...	1.4435
Superaustenitic Stainless Steels				
J92999	CG3M	...	S31703	...
...	...	1.4412	...	1.4438
J94651	CN3MN	...	N08367	...
J93254	CK3MCuN	...	S31254	...
...	...	1.4557	...	1.4547
Duplex Stainless Steels				
J92205	CD3MN	...	S32205	...
...	...	1.4470	...	1.4462
Nickel-Based Alloys				
N26625	CW6MC	...	N06625	...
...	...	...	...	2.4856
N30002	CW12MW	...	N10276	...
...	...	...	...	2.4819
N26455	CW2M	...	N10276	...
...	...	...	...	2.4610
...	...	...	...	2.4819
N30107	CW6M	...	N10276	...
...	...	...	...	2.4819
N26002	CX2MW	...	N26022	...
...	...	...	...	2.4602

GENERAL NOTE:
Alloys listed between horizontal lines are not equivalent, but comparable.

Table MM-2.1-4 Wrought Copper: Nominal Compositions (wt. %) (Cleaned for Oxygen Service)

UNS Number	EN Designation	Cu + Ag	P	O
C10200	...	99.95	...	0.00010 max.
C12000	...	99.90	0.008–0.012	...
C12200	...	99.90	0.015–0.040	...
...	CW024A	99.90	0.015–0.040	...

GENERAL NOTES:
(a) Minimum, unless range or maximum is indicated.
(b) Copper grades 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 MM-5.2.2 or MM-5.2.3, respectively.

MM-3.6 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 B31.3, Process 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 Part. It is not considered practical to identify the specific edition of each standard and specification listed in the following listing; 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:

ASTM A213/A213M, Specification for Seamless Ferritic and Austenitic Alloy — Steel Boiler, Superheater, and Heat-Exchanger Tubes
ASTM A249/A249M, Specification for Welded Austenitic Steel Boiler, Superheater, Heat-Exchanger, and Condenser Tubes
ASTM A269, 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 A312/312M, Specification for Seamless, Welded, and Heavily Cold Worked Austenitic Stainless Steel Pipes
ASTM A511, Standard Specification for Seamless Stainless Steel Mechanical Tubing
ASTM A789/A789M, Standard Specification for Seamless and Welded Ferritic/Austenitic Stainless Steel Tubing for General Service
ASTM A790/A790M, Standard Specification for Seamless and Welded Ferritic/Austenitic Stainless Pipe
ASTM B619, Specification for Welded Nickel and Nickel-Cobalt Alloy Pipe
ASTM B622, Standard Specification for Seamless Nickel and Nickel-Cobalt Alloy Pipe and Tube
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 B690, Specification for Iron-Nickel-Chromium-Molybdenum Alloys (UNS N08366 and UNS N08367) Seamless Pipe and Tube
ASTM B819, Standard Specification for Seamless Copper Tube for Medical Gas Systems
DIN 17744, Wrought nickel alloys with molybdenum and chromium — Chemical composition
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 steel 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
ASTM A494/A494M, Standard Specification for Castings, Nickel and Nickel Alloy
ASTM A743/A743M, Specification for Castings, Iron-Chromium, Iron-Chromium-Nickel, Corrosion Resistant, for General Application
ASTM A744/A744M, Standard Specification for Castings, Iron-Chromium-Nickel, Corrosion Resistant, for Severe Service
ASTM A890/A890M, Specification for Castings, Iron-Chromium-Nickel-Molybdenum Corrosion-Resistant, Duplex (Austenitic/Ferritic) for General Application
ASTM A995/A995M, Standard Specification for Castings, Austenitic-Ferritic (Duplex) Stainless Steel, for Pressure-Containing Parts
EN 10213, Steel castings for pressure purposes
EN 10283, Corrosion resistant steel castings

MM-4.4 Forgings

Forgings manufactured in accordance with the following specifications may be used:

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, Specification for Forged or Rolled UNS N06030, UNS N06022, UNS N06035, UNS N06200, UNS N06059, UNS N06686, UNS N08020, UNS N08024, UNS N08026, UNS N08367, UNS N10276, UNS N10665, UNS N10675, UNS N10629, UNS N08031, UNS N06045, UNS N06025, and UNS R20033 Alloy Pipe Flanges, Forged Fittings, and Valves and Parts for Corrosive High-Temperature Service
ASTM B564, Specification for Nickel Alloy Forgings
EN 10222-5, Steel forgings for pressure purposes — Part 5: Martensitic, austenitic, and austenitic-ferritic stainless steels
EN 10250-4, Open die steel forgings for general engineering purposes — Part 4: Stainless steels

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 B443, Specification for Nickel-Chromium-Molybdenum-Columbium Alloy (UNS N06625) and Nickel-Chromium-Molybdenum-Silicon Alloy (UNS N06219) Plate, Sheet, and Strip

ASTM B575, Specification for Low-Carbon Nickel-Chromium-Molybdenum, Low-Carbon Nickel-Chromium-Molybdenum-Copper, Low-Carbon Nickel-Chromium-Molybdenum-Tantalum, and Low-Carbon Nickel-Chromium-Molybdenum-Tungsten Alloy Plate, Sheet, and Strip
ASTM B688, Specification for Chromium-Nickel-Molybdenum-Iron (UNS N08366 and UNS N08367) Plate, Sheet, and Strip
DIN 17744, Wrought nickel alloys with molybdenum and chromium — Chemical composition
DIN 17750, Strip and sheet of nickel and wrought nickel alloys — Properties
EN 10028-1, Flat products made of steels for pressure purposes — Part 1: General requirements
EN 10028-7, Flat products made of steels for pressure purposes — Part 7: Stainless steels
EN 10088-2, Stainless steels — Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes
EN 10095, Heat resistant steels and nickel alloys

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 B574, Specification for Low-Carbon Nickel-Chromium-Molybdenum, Low-Carbon Nickel-Molybdenum-Chromium-Tantalum, Low-Carbon Nickel-Chromium-Molybdenum-Copper, and Low-Carbon Nickel-Chromium-Molybdenum-Tungsten Alloy Rod
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
EN 10272, Stainless steel bars for pressure purposes

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 Braze-Joint Pressure Fittings

MM-5 BASE METALS AND FILLER MATERIALS

MM-5.1 General

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 metals 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. Details necessary for welding are provided in Part MJ.

MM-5.2 Base Metals

MM-5.2.1 Austenitic Stainless Steels

MM-5.2.1.1 Weld Ends. Weld ends that are to be autogenously welded shall have a sulfur content between 0.005 wt. % and 0.017 wt. % [see also MJ-2.1.1(a)]. This requirement applies to the austenitic stainless steels listed in Tables MM-2.1-1 and MM-2.1-3. This requirement does not apply to materials used in the construction of process components, only to the weld ends of process components in their final form.

MM-5.2.1.2 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 Ni to Cr show lower ferrite levels in the base metal and subsequent to welding. See Table MM-5.2.1.2-1 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, welds with filler metal, or castings. Additional information

(19) **Table MM-5.2.1.2-1 Predicted Ferrite Number (FN) Ranges for Various Austenitic Stainless Steel Product Forms and Welds**

Product Form	Expected FN
Wrought product forms with sulfur levels less than 0.005%	0.5 to 4
Wrought product forms with a sulfur range of 0.005% to 0.017%	1.0 to 6
GMAW/GTAW using ER316L [Note (1)]	4 to 12 [Note (2)]
SMAW using E316L [Notes (3), (4)]	4 to 10 [Note (5)]
CF8M and CF3M castings	5 to 15

GENERAL NOTE: FN ranges determined from D. J. Kotecki and T. A. Siewart, "WRC-1992 Constitution Diagram for Stainless Steel Weld Metals: A Modification of the WRC-1988 Diagram," *Welding Journal* 71(5), p. 171-s, 1992.

NOTES:
(1) SFA 5.9/5.9M, Specification for Bare Stainless Steel Welding Electrodes and Rods.
(2) Nitrogen pickup or weld metal dilution could result in a 3 FN to 4 FN loss in the as-deposited weld metal.
(3) SFA 5.4/5.4M, Specification for Stainless Steel Electrodes for Shielded Metal Arc Welding.
(4) Electrodes with a restricted FN usually require a special order, with the exception of 2 FN maximum product for cryogenic temperatures.
(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.

(19) **MM-5.2.2 Superaustenitic Stainless Steels.** The superaustenitic stainless steels in Tables MM-2.1-1 and MM-2.1-3 are prone to the precipitation of undesirable secondary intermetallic phases such as sigma and chi. This precipitation typically occurs in the range of 1,000°F to 1,900°F (540°C to 1 040°C). This is a concern during welding and other thermomechanical processes, including solution annealing. It is, therefore, desirable to keep exposure time within this temperature range to a minimum.

Exposure time to undesirable temperatures reached during high-temperature service, heat treatment, or a joining procedure should be minimized. The material manufacturer should be consulted for specific instructions regarding heat treatment.

(19) **MM-5.2.3 Duplex Stainless Steels.** The corrosion resistance and mechanical properties of duplex stainless steels are based on having roughly equal amounts of ferrite and austenite in the microstructure at room temperature.

The listed duplex stainless steel, UNS S32205, may be prone to the precipitation of undesirable secondary intermetallic phases such as sigma and chi. This precipitation occurs continually in the range of 1,200°F to 1,830°F (650°C to 1 000°C). Exposure time to undesirable temperatures reached during high-temperature service, heat treatment, or a joining procedure should be minimized. The material manufacturer should be consulted for specific instructions regarding heat treatment.

MM-5.2.4 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 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-5.2.5 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-5.2.6-1 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-5.3-2 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.

(19) **Table MM-5.2.6-1 Materials for OEM Equipment**

UNS Number	EN Designation	Common Name
...	...	Platinum (coating)
...	...	Gold (coating)
...	...	Silver (coating)
R50250	...	Ti — Grade 1
...	3.7025	...
R50400	...	Ti — Grade 2
...	3.7026	...
R56400	...	Ti — Grade 5
...	3.7164	...
R52400	...	Ti — Grade 7
R56320	...	Ti — Grade 9
R53400	...	Ti — Grade 12
N06200	...	Hastelloy C-2000 [Note (1)]
N06600	...	Inconel 600 [Note (2)]
N07718	...	Inconel 718 [Note (2)]
...	2.4668	...
S17400	...	17-4 PH [Note (3)]
...	1.4542	...

GENERAL NOTE: Alloys listed between horizontal lines are not equivalent, but comparable.

NOTES:
(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-5.3.3-1 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. MTRs for fittings are therefore not required to list mechanical properties; however, 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-5.2.6-1, 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 SG-4.3.1.1 for the testing requirements for valves.

MM-7 POSITIVE MATERIAL IDENTIFICATION (19)

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.

(19)

Table MM-5.3-1 Filler Metals

Base Metal Alloy [Note (1)]		Filler Metal									
		SMAW					GTAW/GMAW/SAW/PAW				
UNS Designation	EN Designation	AWS Classification	SFA Specification	UNS Designation	ISO 14343-A Designation	EN Designation	AWS Classification	SFA Specification	UNS Designation	ISO 14343-A Designation	EN Designation
Austenitic Stainless Steels											
S30400	...	E308-15	5.4	W30810	...	...	ER308	5.9	S30880	...	...
		E308-16		W30810			ER308L		S30883		
		E308-17		W30810			ER308Si		S30881		
							ER308LSi		S30888		
...	1.4301	...	...	...	19 9 L	1.4316	...	...	...	19 9 L Si	1.4316
					19 9 Nb	1.4551				19 9 Nb Si	1.4551
S30403	...	E308L-15	5.4	W30813	...	...	ER308L	5.9	S30883	...	...
		E308L-16		W30813			ER308LSi		S30888		
		E308L-17		W30813							
...	1.4307	...	...	...	19 9 L	1.4316	...	...	...	19 9 L Si	1.4316
					19 9 Nb	1.4551				19 9 Nb Si	1.4551
...	1.4306	...	...	...	19 9 L	1.4316	...	...	...	19 9 L Si	1.4316
					19 9 Nb	1.4551				19 9 Nb Si	1.4551
S31600	...	E316-15	5.4	W31610	...	...	ER316L	5.9	S31683	...	...
		E316-16		W31610			ER316LSi		S31688		
		E316-17		W31610							
...	1.4401	...	...	...	19 12 3 L	1.4430	...	...	...	19 12 3 L Si	1.4430
					19 12 3 Nb	1.4576				19 12 3 Nb Si	1.4576
					20 25 5 Cu N L	1.4519				20 25 5 Cu L	1.4519
S31603	...	E316L-15	5.4	W31613	...	...	ER316L	5.9	S31683	...	...
		E316L-16		W31613			ER316LSi		S31688		
		E316L-17		W31613							
...	1.4404	...	...	...	19 12 3 L	1.4430	...	...	...	19 12 3 L Si	1.4430
					19 12 3 Nb	1.4576				19 12 3 Nb Si	1.4576
										20 25 5 Cu L	1.4519
...	1.4435	...	...	...	19 12 3 L	1.4430	...	...	...	19 12 3 L Si	1.4430
					19 12 3 Nb	1.4576				19 12 3 Nb Si	1.4576
					18 16 5 N L	1.4440				18 16 5 N L	1.4440
					20 16 3 Mn N L	1.4455				20 16 3 Mn L	1.4455
					20 25 5 Cu N L	1.4519				20 25 5 Cu L	1.4519

Table MM-5.3-1 Filler Metals (Cont'd)

Base Metal Alloy [Note (1)]		Filler Metal									
		SMAW					GTAW/GMAW/SAW/PAW				
UNS Designation	EN Designation	AWS Classification	SFA Specification	UNS Designation	ISO 14343-A Designation	EN Designation	AWS Classification	SFA Specification	UNS Designation	ISO 14343-A Designation	EN Designation
Superaustenitic Stainless Steels											
S31703	...	E317L-15	5.4	W31713	...	...	ER317L	5.9	S31783	...	...
		E317L-16		W31713							
		E317L-17		W31713							
...	1.4438	...	...	...	18 16 5 N L	1.4440	...	...	...	18 16 5 N L	1.4440
					20 25 5 Cu N L	1.4519				20 25 5 Cu L	1.4519
N08904	...	ENiCrMo-3	5.11	W86112	...	...	ERNiCrMo-3	5.14	N06625	...	...
		ENiCrMo-4		W80276			ERNiCrMo-4		N10276		
		ENiCrMo-10		W86022			ERNiCrMo-10		N06022		
...	1.4539	...	...	...	20 25 5 Cu N L	1.4519	...	...	...	20 25 5 Cu N L	1.4519
					Ni 6625 [Note (2)]	2.4621				Ni 6625 [Note (3)]	2.4831
Base Metal Alloy [Note (1)]		Filler Metal									
		SMAW					GTAW/GMAW/SAW/PAW				
UNS Designation	EN Designation	AWS Classification	SFA Specification	UNS Designation	ISO 14172 Designation	EN Designation	AWS Classification	SFA Specification	UNS Designation	ISO 18274 Designation	EN Designation
S31254	...	ENiCrMo-3	5.11	W86112	...	...	ERNiCrMo-3	5.14	N06625	...	...
		ENiCrMo-4		W80276			ERNiCrMo-4		N10276		
		ENiCrMo-10		W86022			ERNiCrMo-10		N06022		
...	1.4547	...	...	...	Ni 6059	2.4609	...	...	...	Ni 6082	2.4806
					Ni 6625	2.4621				Ni 6625	2.4831
N08367	...	ENiCrMo-3	5.11	W86112	...	...	ERNiCrMo-3	5.14	N06625	...	...
		ENiCrMo-4		W80276			ERNiCrMo-4		N10276		
		ENiCrMo-10		W86022			ERNiCrMo-10		N06022		
N08926	...	ENiCrMo-3	5.11	W86112	...	...	ERNiCrMo-3	5.14	N06625	...	...
		ENiCrMo-4		W80276			ERNiCrMo-4		N10276		
		ENiCrMo-10		W86022			ERNiCrMo-10		N06022		
...	1.4529	...	...	...	Ni 6059	2.4609	...	...	...	Ni 6059	2.4607
					Ni 6625	2.4621				Ni 6625	2.4831

Table MM-5.3-1 Filler Metals (Cont'd)

Base Metal Alloy [Note (1)]		Filler Metal									
		SMAW					GTAW/GMAW/SAW/PAW				
UNS Designation	EN Designation	AWS Classification	SFA Specification	UNS Designation	ISO 14172 Designation	EN Designation	AWS Classification	SFA Specification	UNS Designation	ISO 18274 Designation	EN Designation
Duplex Stainless Steels [Note (4)]											
S32101	...	E2209	5.4	W39209		...	ER2209	5.9	S39209		...
		E2553		W39553			ER2307 [Note (5)]		S82371		
		E2593		W39593			ER2553		S39553		
		E2594		W39594			ER2594		S32750		
		E2595		W39595							
...	1.4162	...	...	...	22 9 3 N L [Note (6)]	1.4462	...	...	...	22 9 3 N L [Note (6)]	1.4462
					23 7 N L [Note (6)]	1.4362				23 7 N L [Note (6)]	1.4362
					25 9 4 N L [Note (6)]	1.4501				25 9 4 N L [Note (6)]	1.4501
S32205	...	E2209	5.4	W39209	...	...	ER2209	5.9	S39209 [Note (5)]	...	...
		E2553		W39553			ER2553		S39553		
		E2593		W39593			ER2594		S32750		
		E2594		W39594							
		E2595		W39595							
...	1.4462	...	...	...	22 9 3 N L [Note (6)]	1.4462	...	...	...	22 9 3 N L [Notes (5), (6)]	1.4462
					22 9 4 N L [Note (6)]	1.4501				22 9 4 N L [Note (6)]	1.4501
Nickel Alloys											
N10276	...	ENiCrMo-3	5.11	W86112	...	...	ERNiCrMo-3	5.14	N06625	...	...
		ENiCrMo-4		W80276			ERNiCrMo-4		N10276		
		ENiCrMo-10		W86022			ERNiCrMo-10		N06022		
...	2.4819	...	...	...	Ni 6059	2.4609	...	...	...	Ni 6059	2.4607
N06022	...	ENiCrMo-3	5.11	W86112	...	...	ERNiCrMo-3	5.14	N06625	...	...
		ENiCrMo-4		W80276			ERNiCrMo-4		N10276		
		ENiCrMo-10		W86022			ERNiCrMo-10		N06022		
...	2.4602	...	...	...	Ni 6059	2.4609	...	...	...	Ni 6059	2.4607
N06625	...	ENiCrMo-3	5.11	W86112	...	...	ERNiCrMo-3	5.14	N06625	...	...
		ENiCrMo-4		W80276			ERNiCrMo-4		N10276		
		ENiCrMo-10		W86022			ERNiCrMo-10		N06022		
...	2.4856	...	...	...	Ni 6625	2.4621	...	...	...	Ni 6625	2.4831

Table MM-5.3-1 Filler Metals (Cont'd)

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) 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 18274.
(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.

(19) **Table MM-5.3-2 Consumable Inserts for Superaustenitic and Duplex Stainless Steels**

Base Metal Alloy [Note (1)]			Insert Alloy [Note (2)]	
UNS Designation	**ACI Designation**	**EN Designation**	**UNS Designation**	**EN Designation**
Superaustenitic Stainless Steels				
N08904	...	...	N06625 N06022 N10276	...
...	...	1.4539	...	2.4856 2.4602 2.4819
N08367	...	...	N06625 N06022 N10276	...
N08926	...	...	N06625 N06022 N10276	...
...	...	1.4529	...	2.4856 2.4602 2.4819
S31254	...	...	N06625 N06022 N10276	...
...	...	1.4547	...	2.4856 2.4602 2.4819
J94651	CN3MN	...	N06625 N06022 N10276	...
J93254	CK3MCuN	...	N06625 N06022 N10276	...
...	...	1.4557	...	2.4856 2.4602 2.4819
Duplex Stainless Steels				
S32101	...	...	S32205 S32750 N06625 N06022 N10276	...
...	...	1.4162	...	2.4602 2.4819
S32205	...	...	N06022 N10276	...
...	...	1.4462	...	2.4602 2.4819
J92205	CD3MN	...	N06022 N10276	...
...	...	1.4470	...	2.4602 2.4819

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-5.3.3-1 Brazing Filler Metals for Copper

Base Metal [Note (1)]		Filler Metal			
UNS Number	EN Designation	AWS Classification	SFA Specification	UNS Designation	EN Designation
C10200	...	BCuP-3	5.8	C55281	...
		BCuP-4		C55283	...
		BCuP-5		C55284	...
		BCuP-6		C55280	...
		BCuP-7		C55282	...
C12000	...	BCuP-3	5.8	C55281	...
		BCuP-4		C55283	...
		BCuP-5		C55284	...
		BCuP-6		C55280	...
		BCuP-7		C55282	...
C12200	...	BCuP-3	5.8	C55281	...
		BCuP-4		C55283	...
		BCuP-5		C55284	...
		BCuP-6		C55280	...
		BCuP-7		C55282	...
...	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.

(19) **Table MM-5.4-1 Solution Anneal Heat Treatment Requirements for Superaustenitic and Duplex Stainless Steels**

Base Metal Alloy [Note (1)]		
UNS Designation	EN Designation	Solution Anneal Temperature [Notes (2), (3), and (4)]
Superaustenitic Stainless Steels		
S31703	...	1,900°F (1 040°C)
...	1.4438	
N08904	...	2,000°F (1 095°C)
...	1.4539	
S31254	...	2,100°F (1 150°C)
...	1.4547	
N08367	...	2,025°F (1 105°C)
N08926	...	2,010°F (1 100°C)
...	1.4529	
Duplex Stainless Steels		
S32101	...	1,870°F (1 020°C)
...	1.4162	
S32205	...	1,870–2,010°F (1 020–1 100°C)
...	1.4462	

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 time at 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.

(19) 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 (19)

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 Part 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 MJ and SF. Special restrictions, exceptions, or guidance shall be noted.

PART PM
POLYMERIC AND OTHER NONMETALLIC MATERIALS

(19) ## PM-1 PURPOSE AND SCOPE

The purpose of this Part is to provide the basis for selecting and using polymeric and other nonmetallic materials.

This Part describes the types of polymeric and other nonmetallic materials and identifies different ways to characterize materials.

PM-2 MATERIALS

Polymeric and nonmetallic materials have found widespread use in bioprocessing equipment because of their broad range of physical and chemical properties, their ability to be formed into complex shapes, and their biocompatibility. Polymeric materials may be used in a range of applications including static and dynamic seals, hoses, pumps, tubing, barrier coatings, diaphragms, valves, and filters. The choice of material class depends on the design requirements and material performance, both as installed and during use.

For in-depth discussion and guidance on polymeric and nonmetallic materials, see Nonmandatory Appendix O.

PM-2.1 Materials of Construction

Materials of construction shall be selected to maintain the purity and integrity of the product/process fluid. It is the owner/user's responsibility to select the appropriate materials of construction for the conditions of use. Materials should be compatible with the stated processing conditions, cleaning solutions (where appropriate), and sterilizing conditions (where appropriate), etc., as specified by the owner/user. The following sections outline the major classes of polymeric and nonmetallic materials and their requirements for use in bioprocessing equipment.

PM-2.1.1 Thermoplastic Polymers. Thermoplastic polymers will melt and flow to form desired shapes when sufficiently heated. They can be melt-processed into a wide variety of shapes by molding, extruding, thermoforming, etc., and can be re-formed and shaped with heat and/or pressure.

Thermoplastic materials are often used for fittings, tubing, piping, diaphragms, seals, liners for vessels, column tubes, filter media and capsules, etc. Examples of thermoplastic polymers are shown in Table PM-2.1.1-1.

Some thermoplastics, such as thermoplastic elastomers, combine an elastomer such as ethylene propylene diene monomer (EPDM) with a plastic such as polypropylene, giving the resulting thermoplastic compound properties of flex endurance and sealability so it can be used for tubing, seals, diaphragms, etc. Thermoplastic elastomers (TPE) combine the features of melt processability and flexibility.

Many polymeric materials are described in ASTM standards that detail their composition and mechanical properties. It is the owner/user's responsibility to select materials that are appropriate for their applications.

Filler materials may be used to enhance the properties of thermoplastic polymers. Fillers may be carbon based, inorganic, metallic, organometallic, etc., as needed for performance.

Additives for thermoplastic polymers may be used to aid in thermal stability, flexibility, gamma stability, extrudate performance, crystallization control, oxidative stability, mold release, plasticization, and adhesion. Additives may be used in the bulk of the polymer as well as the surface, as required.

PM-2.1.2 Thermoset Polymers. Thermosets are polymers that, in their final state after processing, are rendered substantially insoluble and infusible. Fully processed thermosets cannot be resoftened or re-formed by exposure to heat. Exposure to excessive heat will cause degradation.

Thermoset polymers are processed from a liquid or malleable state and are converted to the solid state by irreversible curing with heat, catalysis, or other means. Chemical cross-links are formed between polymer chains during the curing process. This results in an interconnected polymer network with the cross-link junctions restricting flow of the polymer when exposed to thermal or mechanical stresses.

Thermoset polymers can be classified into either thermoset elastomers or thermoset resins, with the elastomers being more common. Thermoset elastomers are often elastic and soft materials and are used for seals, gaskets, tubing, diaphragms, hoses, etc. Examples of thermoset polymers are shown in Table PM-2.1.2-1.

Most thermoset polymeric materials contain reinforcing fillers and other additives to meet required use conditions. Fillers may be carbon based, inorganic, metallic, organometallic, etc., as needed for performance.

Table PM-2.1.1-1 Common Thermoplastic Polymers and Applications

Type of Polymer	Example Polymers	Example Applications
General thermoplastics	Polyester (PET) Polyamide (nylon) Polycarbonate (PC) Polysulfones (PSU, PES) Polyether ether ketone (PEEK)	Fittings, connectors, filter housings, piping and rigid tubing, column tubes, filter media
Thermoplastic polyolefins	Polypropylene (PP) Ultra-low-density polyethylene (ULDPE) Low-density polyethylene (LDPE) High-density polyethylene (HDPE) Ultra-high-molecular-weight polyethylene (UHMWPE)	Fittings, connectors, piping and rigid tubing, filter media and capsules, bags
Thermoplastic fluoropolymers	Fluorinated ethylene propylene (FEP) Perfluoroalkoxy (PFA) Polytetrafluoroethylene (PTFE) Ethylene tetrafluoroethylene (ETFE) Polyvinylidiene fluoride (PVDF)	Fittings, piping and tubing, flexible hose, filter media and capsules, diaphragms, pumps, vessel liners
Thermoplastic elastomers (TPE)	Blends of EPDM with polypropylene Styrene-isobutylene-styrene block polymers Copolymers of ethylene and octane Ethylene-vinyl acetate copolymer (EVA)	Tubing, bags

Table PM-2.1.2-1 Common Thermoset Polymers and Applications

Type of Polymer	Example Polymers	Example Applications
Thermoset elastomers	Ethylene propylene diene (EPDM) Ethylene propylene rubber (EPR) Silicone (VMQ) Fluoroelastomers (FKM) Perfluoroelastomer (FFKM)	Tubing, seals, gaskets, diaphragms, and hoses
Rigid thermosets	Fiber-reinforced polymer (FRP/GRP) composites	Tanks and pipes

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.

PM-2.2 General Requirements (19)

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-2.1.3-1 Examples of Nonmetallics

Examples of Nonmetallics	Types of Nonmetallic	Example Applications
Glass Borosilicate Soda-lime	Amorphous inorganic nonmetallic material	Sight glasses, vessel lights, optical sensors, glass electrodes
Sintered materials Aluminum oxide Silicon carbide Silicon nitride Tungsten carbide Zirconium dioxide	Crystalline inorganic nonmetallic material	Mechanical seals, bearings, process sensors
Reaction-bonded materials Silicon carbide Silicon nitride	Multiphase mixture of crystalline silicon carbide or nitride and silicon	Mechanical seals
Siliconized carbon-graphite	Multiphase mixture of crystalline silicon carbide, carbon, and graphite	Mechanical seals
Resin-impregnated carbon-graphite	Multiphase mixture of carbon, graphite, organic resin, and potential inorganic nonmetallic additives	Mechanical seals
Cemented materials Tungsten carbide with alloyed binder Tungsten carbide with nickel binder Tungsten carbide with cobalt binder	Crystalline inorganic nonmetallic in a metallic matrix	Mechanical seals, bearings

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.

(19) **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 Classifications. The magnitude of qualification and regulatory filing 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

(19) **Table PM-2.2.1-1 Content Required on the Certificate of Compliance**

Requirements to Conform to ASME BPE	Applications									
	Polymeric Seals (Includes Diaphragms and Hygienic Union Seals) [Note (1)]	Hoses	Tubing	Filters [Note (2)]	Chromato-graphy Columns	Connectors (Includes Steam to/ Through)	Polymeric Containers (Rigid and Flexible)	Other Polymeric Process Components	Nonmetallic Process Components	Single-Use Assemblies
Manufacturer's name	X	X	X	X	X	X	X	X	X	X
Manufacturer's contact information	X	X	X	X	X	X	X	X	X	X
Part number	X	X	X	X	X	X	X	X	X	X
Lot number or unique identifier or serial number	X	X	X	X	X	X	X	X	X	X
Material(s) of construction (process contact)	X	X	X	...	X	X	X	X	X	...
Compound number or unique identifier	X	...	X	...	...	...	...	X	X	...
Cure date or date of manufacture	X	...	X	X	X	...	X	X	...	X
USP <87> or ISO 10993-5	X	X	X	X	X	X	X	X	X	X
USP <88> Class VI or ISO 10993-6, -10, -11	X	X	X	X	X	X	X	X	...	X

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.

(19) **Table PM-2.2.3.2-1 Change Levels and Minimum Change Notification Requirements**

Change Level	Description	Typical Examples, Not Representative of All Changes	Notification Requirement	
			Preliminary Change Notification Prior to Change Notification	Change Notification Prior to Change Implementation
Level 3	A change that requires a minimum of 6 months for the end user to plan and a minimum of 12 months for the owner/user to implement	Change impacting leachables and extractables profiles	6 months minimum required	12 months minimum required
Level 2	A change that requires a minimum of 3 months to plan and a minimum of 6 months for the owner/user to implement	Revision to a product specification, change in part number	3 months minimum recommended	6 months minimum required
Level 1	A change that requires a minimum of 3 months for the owner/user to implement	Change in labeling, change in document format (e.g., C of C), editorial update of analytical method	None required	3 months minimum required
Level 0	A change that is not expected to impact the attributes in PM-2.2.3.2	Certain non–process contact changes (e.g., change in carton supplier)	Notification not required	Notification not required
Emergency	An emergency change occurs when the manufacturer does not have prior knowledge that they will be impacted by a change	Force majeure, act of God	The change notification should be expedited to the greatest extent possible appropriate for the level of change	The change notification should be expedited to the greatest extent possible appropriate for the level of change

(f) change level per Table PM-2.2.3.2-1

In the event of a Level 3 change, the manufacturer should provide preliminary change notification documentation to the owner/user as defined in Table PM-2.2.3.2-1. Preliminary change notification provides advanced warning to the owner/user prior to release of required change notification documentation (e.g., documentation and qualification data) that may not be available at the time of preliminary change notification. A plan for implementation with anticipated timelines should be included in the preliminary notification. Change notification shall include the documentation and qualification data to characterize the plan.

PM-2.2.3.4 Manufacturer's Responsibilities. The manufacturer shall have procedures and documentation that effectively manage changes both internally and throughout the supply chain and defines requirements for owner/user notification. The manufacturer shall maintain a record of notification and change implementation. Manufacturers should establish a single point of contact for change communication.

PM-2.2.3.5 Owner/User Responsibilities. The owner/user should provide a single point of contact for change communication. The method of receiving communication should be electronic (e.g., an e-mail address such as change@companyx.com). The owner/user should acknowledge receipt of the communication to the manufacturer's single point of contact and evaluate the change notification for impact to their processes.

PM-3 PROPERTIES AND PERFORMANCE

Materials should be selected to retain their functional properties and to minimize their impact on the process fluid. Materials should be selected to not affect the purity and integrity of the drug product. This section outlines the requirements for biocompatibility, extractables/leachables, physical properties, and chemical compatibility. Each of the following sections should be considered for the application.

PM-3.1 Biocompatibility

"Biocompatibility" is defined here as the ability of a substance or material to be in contact with living matter such as bacteria or mammalian cells without interfering in any way with its metabolism or ability to live and procreate. Polymer materials shall be biocompatible with the system fluid to ensure that the system fluid is not adversely affected by the polymer material. The

biocompatibility and the proper material selection shall be the responsibility of the system user.

Biocompatibility testing of candidate components for qualification requires both in vivo (animal testing) and in vitro (testing in glass) tests. In vivo testing is described in the United States Pharmacopeia (USP) in Chapter <88> (or ISO 10993-6, -10, and -11) and involves intramuscular implantation, intracutaneous injection, and systemic toxicity testing. In vitro testing is described in the United States Pharmacopeia in Chapter <87> (or ISO 10993-5) and is used to place extract from candidate polymers in direct contact with living cells (typically mouse cells) for a prescribed period of time. The amount of cell lysing (death) shall be recorded and reported for the particular polymer material.

Material manufacturers shall provide, on customer request, documentation (test report) of the in vivo USP <88> Class VI and in vitro USP <87> testing on final manufactured parts. Failure of either test indicates unacceptable biocompatibility of candidate material. Such failures are often attributed to leachables from cured elastomeric seals extractables and may include catalyst residues, cross-linking agents, process aids, plasticizers, etc.

(19) PM-3.2 Extractables and Leachables

PM-3.2.1 Extractables. Extractables are chemical substances that can be removed from polymeric materials using appropriate solvents (e.g., polar and nonpolar). Extraction studies are conducted under conditions that exceed typical bioprocess manufacturing or storage conditions (e.g., higher temperature, pH, or concentration or longer exposure time) and are used to generate an extractables profile for a given polymeric material. Manufacturers should provide extractables profile data for polymeric materials used in equipment/components on request by the owner/user. The extractables profile generated may vary depending on both the extraction conditions and the extraction fluids used in the study. Depending on the purpose of the study, one or more of the extraction studies described in PM-3.2.1.1 or PM-3.2.1.2 should be done to generate an extractables profile.

PM-3.2.1.1 Polymeric Material Specific Extraction Study. This study is done to generate an extractables profile that characterizes the total content of soluble chemical substances contained in the polymeric material. The extraction solvent(s) and conditions shall be appropriate for the particular polymeric material being tested. Nonmandatory Appendix P-2 identifies recommended conditions for a polymeric material specific extraction study.

PM-3.2.1.2 Extraction Study in Bioprocess Model Solutions. This study is done to generate an extractables profile under conditions that exceed those typically found in bioprocessing applications. The model solutions and extraction conditions should be selected based on the intended use of the equipment/component. This study generates an extractables profile that may be used to predict potential leachables. Nonmandatory Appendix P-3 identifies recommended conditions for an extraction study in bioprocess model solutions.

PM-3.2.2 Leachables. Leachables, typically a subset of extractables, are chemical substances that migrate into the drug product from process equipment or its container under normal conditions of use and/or storage. Leachables may also be created as a result of chemical reactions with other leachables and/or ingredients in the process fluid or drug product. Leachables studies conducted in process and of the final product shall be the responsibility of the owner/user.

PM-3.2.3 Sample Preparation. Extraction studies shall include careful sample preparation appropriate to the test article and analytical techniques to be used.

The size of the sample should be determined in consideration of the material, test equipment, analytical test sensitivity, and the sample available for testing.

Any tool used for sample preparation shall not adulterate the sample.

Prior to extraction, test samples should be exposed to the same pretreatment process (under worst-case conditions) that the material would see when used as intended.

PM-3.2.4 Documentation. Documentation of results shall include the extraction method(s), analytical technique(s) protocol, sample surface area (or weight) to volume ratio, and extraction time and temperature. Relative limits of detection should be reported.

PM-3.2.5 Risk Assessment. The owner/user should consider supplier data, relevant standards, regulatory guidance, and industry recommendations as listed in Nonmandatory Appendix P, when performing a risk assessment.

The results of the risk assessment should determine the suitability of the equipment/component for its intended use.

PM-3.3 Physical and Mechanical Properties of Thermoplastic Polymers

The physical and mechanical properties of thermoplastics are important to better understand how fluid exposure could affect the polymer's strength, stiffness, inertness, durability, barrier properties, etc. Physical and mechanical properties can be characterized using many different standards (e.g., ASTM, ISO, DIN, and JIS). Typical properties include tensile strength, elongation to break, modulus, and, in some cases, seam strength, weld strength, coefficient of friction, compression set, tensile set, hardness, specific gravity, and transparency.

Common useful tests for evaluating thermoplastic performance are listed in Nonmandatory Appendix L.

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 (19)

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

Table PM-4.2.1-1 Size Comparison of Common Thermoplastic Sizing Standards

Nominal Size System	SS Tube				Sch 40				Sch 80				SDR 11				SDR 21			
	O.D.		I.D.		O.D.		I.D.		O.D.		I.D.		O.D.		I.D.		O.D.		I.D.	
	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm	in.	mm
½	0.5	12.7	0.37	9.4	0.84	21.3	0.61	15.4	0.84	21.3	0.53	13.4	0.79	20	0.59	16.2	0.79	20	0.64	16.2
¾	0.75	19.1	0.62	15.7	1.05	26.7	0.81	20.6	1.05	26.7	0.74	18.8	0.98	25	0.77	20.4	0.98	25	0.83	21.2
1	1	25.4	0.87	22.1	1.32	33.4	1.03	26.2	1.32	33.4	0.94	23.7	1.26	32	1.02	24.2	1.26	32	1.07	27.2
1¼	...	...	...	...	1.66	42.2	1.36	34.6	1.66	42.2	1.26	31.9	1.57	40	1.28	32.6	1.57	40	1.38	35.2
1½	1.5	38.1	1.37	34.8	1.9	48.3	1.59	40.4	1.9	48.3	1.48	37.5	1.97	50	1.61	40.8	1.97	50	1.73	44
2	2	50.8	1.87	47.5	2.38	60.3	2.05	52	2.38	60.3	1.91	48.6	2.48	63	2.02	51.4	2.48	63	2.24	57
2½	2.5	63.5	2.37	60.2	2.88	73	2.45	62.1	2.88	73	2.29	58.1	2.95	75	2.41	61.4	2.95	75	2.67	67.8
3	3	76.2	2.87	72.9	3.5	88.9	3.04	77.3	3.5	88.9	2.86	72.7	3.54	90	2.9	73.6	3.54	90	3.07	81.4
4	4	102	3.84	97.5	4.5	114	3	76.1	4.5	114	3.79	96.2	4.33	110	3.54	90	4.33	110	3.8	99.4
6	6	152	5.78	147	6.63	168	6.03	153	6.63	168	5.71	145	6.3	160	5.14	131	6.3	160	5.69	145

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:

(U.S. Customary Units)

$$\Delta L = 12 \times L \times \alpha \times \Delta T \quad (2)$$

where

L = length of the pipe run, ft
α = coefficient of thermal expansion, in./in./°F material and temperature dependent
ΔL = change in length, in.
ΔT = temperature change, °F

(SI Units)

$$\Delta L = L \times \alpha \times \Delta T \quad (3)$$

where

L = length of the pipe run, mm
α = coefficient of thermal expansion, mm/m/°C material and temperature dependent
ΔL = change in length, mm
ΔT = 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 6.6×10^{-5}, in./in./°F
PFA 7.0×10^{-5}, in./in./°F
PP 8.33×10^{-5}, in./in./°F

(SI Units)

PVDF 1.2×10^{-5}, mm/m/°C
PFA 1.2×10^{-5}, mm/m/°C
PP 1.5×10^{-5}, mm/m/°C

ΔT 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 ΔT 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 cleanability.

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 should be informed of all the conditions under which the hose assembly may be expected to operate. This should include the methods, frequency, and length of cleaning and sterilization procedures. In addition to the service temperature and pressure, any parameters that may affect the hose assembly performance should be provided. The equipment supplier should 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 should inform the end-user whether the hose assembly will perform as specified during these events. The end-user should 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 process 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-4.4.3.1.3 Hygienic Connections. Hygienic connections shall conform to other Parts of this Standard.

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. 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 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 to certify compliance to this Standard when required 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.

(19) ## 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 (19) 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 require- (19) ments, 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.