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, duplex stainless steels (e.g., 316-type and 316L-type alloys), 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 21CFR 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-2.4.1.4 Transparent Materials

(a) Transparent materials (e.g., glass, polymer) that are used in viewing ports shall be rated for the applicable pressure, temperature range, and thermal shock.

(b) Internally coated glass shall only be used if the coating complies with FDA regulations or another regulatory authority’s regulations and is approved by the owner/user.

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) shall 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.

(3) Fasteners or threads shall not be exposed to the process, steam, or cleaning fluids. The use of threads within the process requires owner/user agreement. Bolted attachments should be eliminated whenever possible.

(4) No engraving or embossing of materials (for identification or traceability reasons) should be made on the process contact side. When markings are required on process contact surfaces, other methods of identification shall be used.

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

(1) Internal horizontal surfaces should be minimized.

(2) The equipment shall be drainable and free of areas where liquids may be retained and where soil or contaminants could collect. The equipment shall be free of areas of low flow and velocity or impact where soil or contaminants could collect.

(3) Design of corners and radii should meet the following requirements: All internal angles of 135 deg or less on surfaces shall have the maximum radius possible for ease of cleanability. Where possible, these surfaces shall have radii of not less than \( \frac{1}{8} \) in. (3.2 mm) except where required for functional reasons, such as the bonnet/body connection. For special cases, the radii may be reduced to \( \frac{1}{16} \) in. (1.6 mm) when agreed to by the owner/user. When the \( \frac{1}{16} \) in. (1.6 mm) radii cannot be achieved for essential functional reasons such as flat
Table MM-5.2.1.2-1 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>
</thead>
<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>GMW/GTAW using E316L [Note (1)]</td>
<td>4 to 12 [Note (2)]</td>
</tr>
<tr>
<td>SMAW using ER316L [Notes (3), (4)]</td>
<td>4 to 10 [Note (5)]</td>
</tr>
<tr>
<td>CF8M and CF3M castings</td>
<td>5 to 15</td>
</tr>
</tbody>
</table>


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 service temperatures.
5. FN in the as-deposited weld is influenced by welding technique and is lowered by nitrogen pickup or weld metal dilution.

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 1040°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.

Owners/users are cautioned that any service temperature, heat treatment, or joining procedure that exposes these materials to these temperatures 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 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, must 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.

MM-5.3.1 Austenitic Stainless Steels. Only the low-carbon grades of stainless steel filler metals may be used to weld these alloys.
## 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><strong>Alloy selection</strong></td>
<td>Selection of the proper alloy [e.g., 316L stainless steel (S31603), 6 moly (N08367), etc.] should address the corrosive effects of the process conditions. For example, low-carbon stainless steel (316L) has better corrosion resistance than the higher-carbon stainless steels (316). Beneficial alloys can mitigate premature or accelerated corrosion. Higher nickel content will enhance corrosion resistance.</td>
</tr>
<tr>
<td><strong>Mechanical polishing/buffing</strong></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><strong>Electropolishing</strong></td>
<td>Minimizes the exposure area of the native alloy to oxidizing fluids or halides and minimizes the origins for micropitting by various mechanisms, including halide and stress corrosion cracking. Surface occlusions from passivation fluids are minimized by the smooth, more even finish.</td>
</tr>
<tr>
<td><strong>Passivation</strong></td>
<td>Impedes or retards corrosive developments 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 an alloy to corrode and the rates of corrosion.</td>
</tr>
<tr>
<td><strong>Alloy composition</strong> (% 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/or 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><strong>Welding, welding conditions, purging, etc.</strong></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><strong>Product form and fabrication methods</strong></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)**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Installation/storage environment</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Expansion and modifications to an established system</strong></td>
<td>Oxide formations in newly commissioned systems can form at different rates than 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.</td>
</tr>
</tbody>
</table>

**NOTE:**

(1) There is well-established industry data supporting this, and it needs to be considered.
E-1 GENERAL

This Nonmandatory Appendix provides basic information and offers guidelines for owners/users, equipment manufacturers, and service providers for newly manufactured or installed systems in accordance with the requirements of GR-1. This Nonmandatory 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, S30403, S31600, and S31503 stainless steels. Superaustenitic stainless steels and nickel alloys may require a modified procedure.

This Nonmandatory Appendix defines a method for qualifying the passivation process used for system and process component surfaces.

This Nonmandatory 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 the 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 MJ 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, painting/markings, etc. 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
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 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.
### Table H-3.3-1  Minimum Surface Requirements for Process Qualification Samples

<table>
<thead>
<tr>
<th>Material</th>
<th>Cr/Fe Ratio</th>
<th>Depth [Note (1)]</th>
<th>Surface Photo [Note (2)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNS S31600 (316 SS); UNS S31603 (316L SS)</td>
<td>1 to 1 or greater</td>
<td>15 Å minimum</td>
<td>150X</td>
</tr>
</tbody>
</table>

**NOTES:**
1. Test method: X-ray photoelectron spectroscopy (XPS/ESCA) analysis.
2. Scanning electron microscopy (SEM).