



Discover 3 Levels of Sanitary Design that Affect regulatory Compliance, delivery and cost

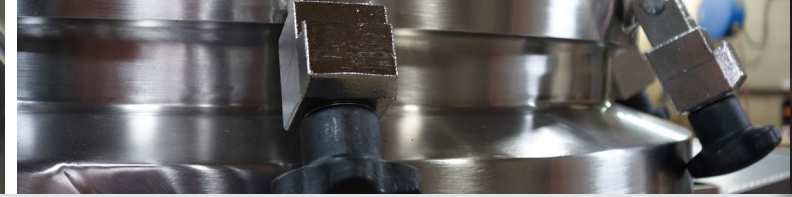
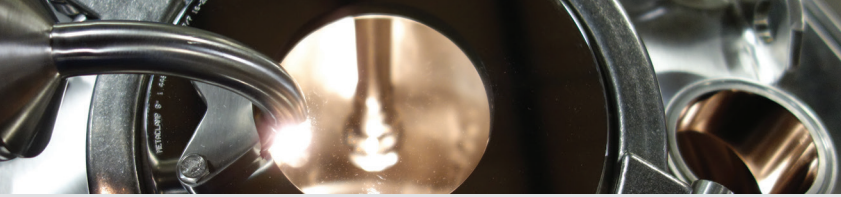
Guide to Sanitary Design for Custom Vessels in Hygienic Industries

Processors serving food or hygienic industries have varying degrees of compliance requirements for custom vessel solutions, depending on the application. When evaluating a custom vessel manufacturing partner, the qualification and discovery review starts with the vessel's sanitary requirements.




This white paper defines three sanitary levels to help guide conversations and expectations of a sanitary vessel. In this guide, basic, mid- and high-level sanitary designs are represented, offering a reference baseline for your sanitary vessel needs.

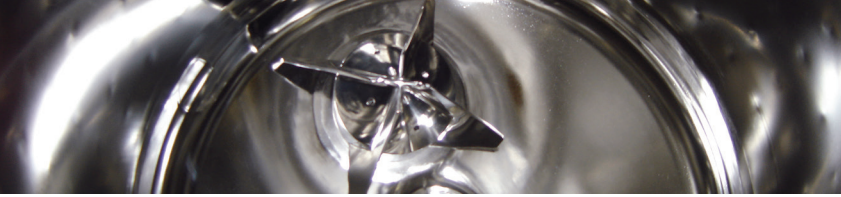
This publication serves as an educational and informational reference to include:

- Base, mid- and high-level sanitary design criteria chart
- Sanitary standards and certifications in the US, Canada and Europe
- Industry acronyms and definitions



3 LEVELS of SANITARY DESIGN

	 BASE LEVEL	 MID- LEVEL	 HIGH LEVEL
Cleanability	Manual	Cleanable Design COP (Clean Out Of Place)	Cleanable Design CIP (Clean In Place)
Welds	Continuous, crack and crevice-free welds. Some welds accomplished through automated processes.	Continuous, crack and crevice-free welds, ground flush and polished smooth to specific RA designation > 32 RA ID	Continuous, crack and crevice-free welds, ground flush and polished smooth to specific RA designation <32 RA ID
Composition / Finish	2B / Mill, 304 or 316 stainless	304 or 316 stainless, mechanically finished to >32 RA	304 or 316 stainless, mechanically finished to <32 RA
Chemical Finish	Pickle Passivated	Pickle Passivated or Nitric Passivated	Electropolished and Nitric Passivated
Typical Construction Fixtures	Threaded couplings, threaded dip tubes, ANSI flanges, Thermowells (probe measuring instrument)	Sanitary fittings, including: tri-clamp ferrules, tube connections, NA connects, flush mount outlet valves, sight glasses, orbitally welded j-tubes, dip-tubes, polished internal coils, sample ports	Electropolished sanitary fittings, including: tri-clamp ferrules, tube connections, NA connects, flush mount outlet valves, sight glasses, orbitally welded j-tubes, dip-tubes, polished internal coils, sample ports. Spray devices, control panels, external thermal jacketing
Compliance	ASME UM, ASME U, FDA, 3-A, CRN, PED, BPE	ASME UM, ASME U, FDA, 3-A, CRN, PED, BPE	ASME UM, ASME U, FDA, 3-A, CRN, PED, BPE
Types of Processes	Waste tanks, Chemical Tanks, General-Use Storage, Hydrocarbon Storage, Food-Grade Applications, Adhesives, Solvents	Material Columns, Solvent Tanks, Collection Vessels, Extraction, Expansion Chambers, Mixing Vessels, Dispensing Vessels, Filling Vessels	Process Vessels, WFI tanks, R&D Lab Equipment, Heating and Cooling Vessels, Nutsche Filters
Delivery	Depending on application, stock vessels may be used, or modified stock designs take 4-6 weeks	Dependent on Scope	Dependent on Scope



CLEANABILITY

All sanitary levels are suitable for caustic sanitation. The difference between the cleanability criteria is the degree of automation. Basic level cleaning is a manual process. The mid-level sanitary design vessel may feature removable components for cleaning, and the high-level sanitary design vessel may feature an automatic spray system.

COMPOSITION & CHEMICAL FINISH

While the base material for sanitary tank design is 304 or 316 stainless material, the mechanical and chemical finish defines each design level. The base-level sanitary design finish is pickle passivated inside and out. The mid-level sanitary design is mechanically finished to greater than 32RA and either pickle passivated or nitric passivated. High-level sanitary designs are polished to a specific RA designation lower than 32RA, and are nitric passivated and electropolished. All finishes remove free iron and clean the manufacturing processes from the material. Compliance requirements often specify the types of sanitary finishes.



These vessels in different stages of the finishing process measure 17.34 RA on the pickle passivation sample (left) and 7.92 RA after pickle passivation and electropolishing (right).

ASME	American Society of Mechanical Engineers
CIP	Clean in Place
COP	Clean out-of Place
EP	Electropolished
ID	Inside Diameter
OD	Outside Diameter
Pickled	Pickle Passivated
RA	Roughness Average (Measurement)



A hygienic industry portable vessel emerges from the electro-polishing tank at Apache Stainless Equipment Corporation.

SANITARY COMPLIANCE STANDARDS

3-A Sanitary Design Standards regulate the design criteria for processing equipment in the food and drug industries. Design details include surface finish requirements, weld quality, approved gaskets and o-rings, sanitary connections, and construction materials. A 3A certificate is proof of FDA compliance.

Apache manufactures vessels to 3-A sanitary guidelines; however, a third-party inspector is required to certify equipment.

ASME U and UM Codes are required standards by the American Society of Mechanical Engineers. The ASME standards regulate the design of boilers and pressure vessels in the United States, including evaporators, columns, heat exchangers and condensers.

Apache is an ASME manufacturer and provides full traceability to materials, procedures, welders, testing, and turn-over documentation of the vessel.

Bio Processing Equipment (BPE) is a standard within ASME that drives equipment design for the bio processing, pharmaceutical and other hygienic product industries. It covers materials, design, fabrication, inspection, testing and certification.

Apache's manufacturing practices comply with the ASME BPE standard.



Canadian Registration Number (CRN) is issued by each province or territory of Canada for the design and manufacture of boilers, pressure vessels and fittings to be shipped for use in Canada. It is important to note that each province and territory has unique application criteria for CRN.

Apache is also experienced at CRN / Canadian compliance and can facilitate design registration across all provinces.

Pressure Equipment Directives (PED) applies to the design, manufacture, and conformity of pressure vessels, with maximum pressure greater than 0.5 BAR including vessel, piping, safety, and pressure accessories that are exported for use in Europe. The qualifying vessel is marked with a CE stamp.

Apache can design and manufacture to PED standards and holds CE certifications.

ABOUT APACHE

Apache Stainless Equipment Corporation is a manufacturer of stainless equipment for a range of hygienic industries. Apache's tanks and vessels and Mepaco's food processing equipment showcase our expertise in the beverage, biotechnology, pharmaceutical, cannabinoid, food processing, and life science industries.

A dedicated quality control and compliance team directs all tests, certifications, and documents for all standards. Apache has been ASME certified for over 40 years. In addition to ASME, Apache is also accredited in many other global codes and specifications.

As a 100% employee-owned company, Apache's culture exemplifies continuous improvement, efficiency, innovation, and commitment to our customer.

DELIVERY & COST

Many general vessel needs can be met by a stock tank offering. Even with modifications to stock tanks, the price point is lower than a custom vessel solution with relatively fast availability and delivery.

Custom vessels are designed for specific processing and production requirements. The most extended lead times for a custom vessel may be the CRN or PED approval process and the availability of some special components. The required compliance criteria drive some of the costing on the vessel. However, with an experienced manufacturing partner, delivery, cost, and compliance approvals can be managed to provide the end-user with quality equipment that provides efficient and effective long-term service at high value.



These vessels in Apache's standard small vessel line are base-level sanitary design tanks.



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