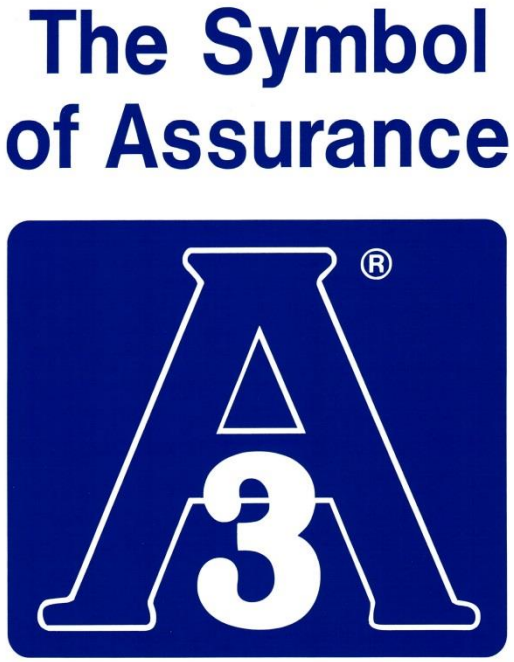
Hygienic Design Standards and Guidelines
Larry Hanson



3-A Sanitary Standards for General Requirements

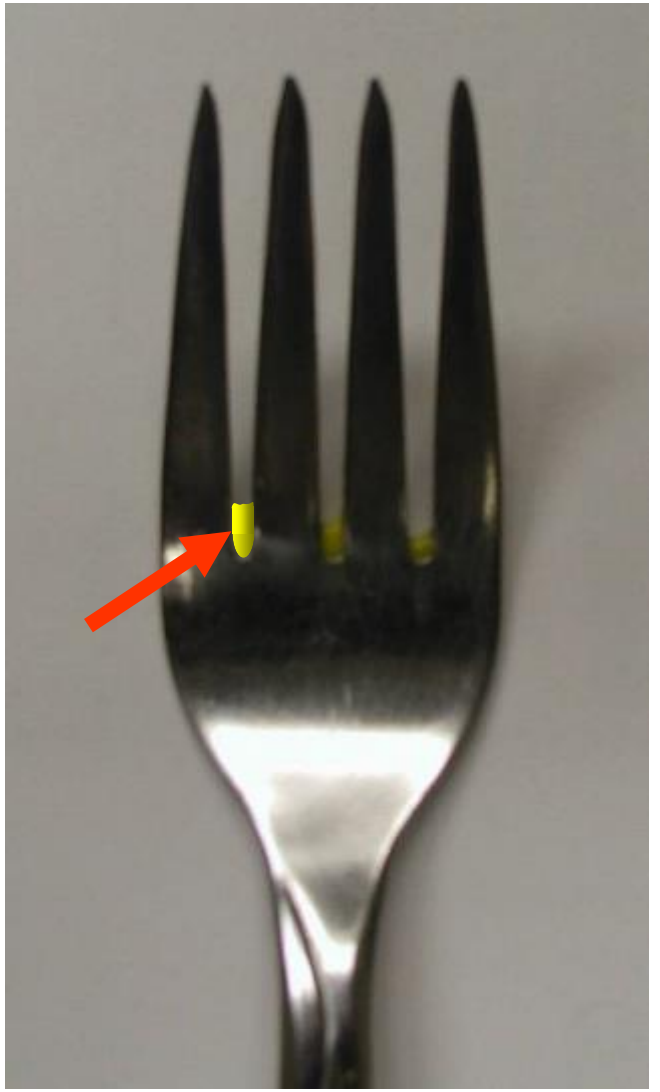
American National Standard

ANSI/3-A 00-00-2014

Key Cleanability Design Considerations

- Material of Constructions
- Surface Finishes
- Joint Design
- No Cracks or Crevices
- Free Draining
- No Dead Legs – Blind Spots - Hollows
- Accessibility to Clean
- Accessibility to Inspect

“Sanitary Design for Beginners”



HYGIENIC REQUIREMENTS: MATERIALS OF CONSTRUCTION

Physical Properties

- Inert
- Nontoxic
- Non-corrosive
- Non-reactive
- Non-contaminating
- Non-porous
- Impervious

Mechanical Properties

- Durable
- Smooth
- Free of cracks and crevices

Operational Properties

- Cleanable
- Reduced maintenance

304 Stainless Steel Meets Requirements

Metals Appendix 1

- Stainless Steels
  - Wrought 304 and 316
  - Non-Galling
  - Precipitation Hardenable
  - Duplex
  - Superaustenitic
  - Nickel-Chromium – Molybdenum Alloys
- Titaniums

304 & 316 Stainless Steel

Typical Wrought Type ASTM A240 & A270	Comparable Castings ASTM A351, A743 A744	UNS No.	Carbon	Cr	Ni	Fe	Mo
304		S30400	0.08 Max	18.2	8.2	Bal.	
	CF8	J92600	0.08 Max	18.2	8.2	Bal.	
304L		S30403	0.03 Max	18.2	8.2	Bal.	
	CF3	J92500	0.03 Max	17.2	8.2	Bal.	
316		S31600	0.08 Max	16.7	11.2	Bal.	2.2
	CF8M	J92900	0.08 Max	18.2	9.2	Bal.	2.2
316L		S31603	0.03 Max	16.7	11.2	Bal.	2.2
	CF3M	J92800	0.03 Max	17.2	9.2	Bal.	2.2

Table 1. *Wrought and Cast Stainless Steel Alloys Most Commonly Used*

Non-Galling prevents damage from moving parts wear

Other Metals

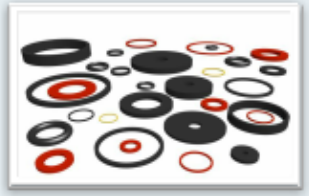
- Aluminum –
  - Limited application in 3A standards
- Brass-Bronzes
  - No acceptable 3-A applications
- Coppers
  - No acceptable 3-A applications

Non-Metals

- Plastics
- Elastomers -Rubber and Rubber like Material
- Carbon and Ceramic
- Glass
- Must meet FDA requirements
- Must not chip, crack, or have crevices

How to select and obtain approval of plastics

REGULATORY STATUS AND REQUIREMENTS



FDA

1. Title 21 of the CFR, Parts 170-199
2. Prior Sanction Letter
3. GRAS (Generally Recognized as Safe)
4. TOR (Threshold of Regulation) exemption request
5. Food Contact Surface Notification Section 409(h)(2)(C)
6. Letter of No Objection

Surface Finish

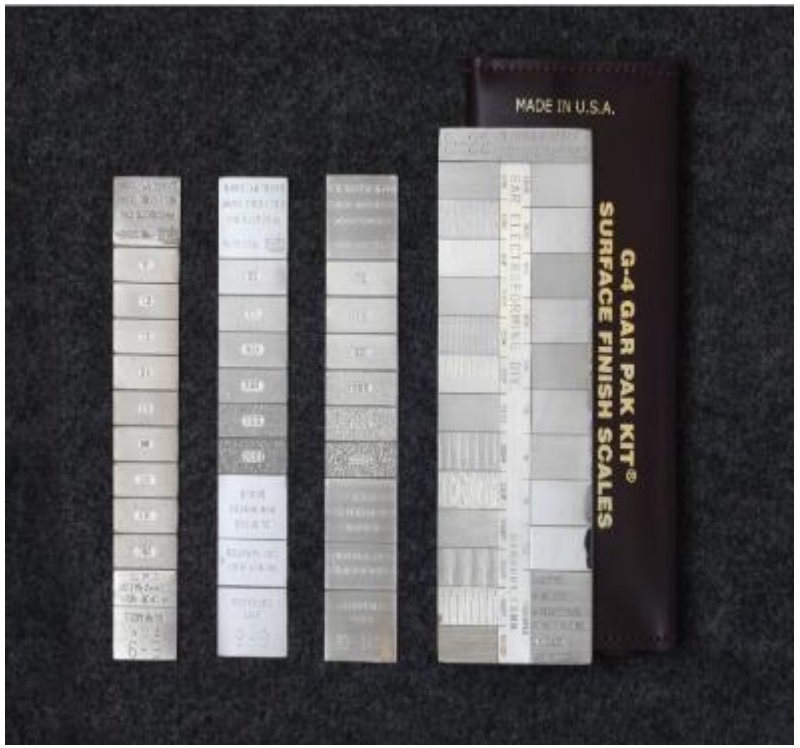
- Product Contact Surfaces
  - At least a smooth as 32 µin Ra (0.8 µm) all surfaces
  - Including welded, soldered and brazed joints
  - Free of pits, folds, cracks, crevices and misalignments
  - 2B finish is generally acceptable, but needs verification
  - Inside tubing welds shall be full pentration and meet the color criteria as specified in AWS D18.2

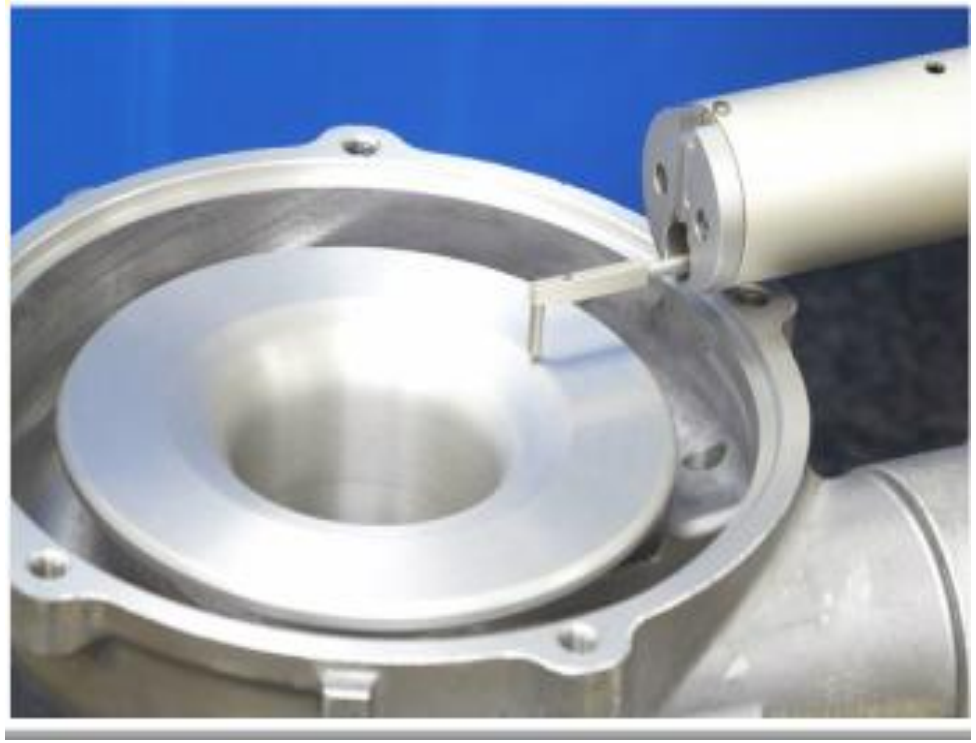
Surface Finish

- Non-Product Contact Surfaces
  - “Exposed surface shall have relatively smooth surfaces and be relatively free of pockets and crevices where soils and liquid can collect”
  - A crevice or pocket in a weld would be structural defect and would require repair
  - Welds are not required to be ground or polished.
  - Blasting or other surface treatments that reduce surface finish of the base material should not be preformed

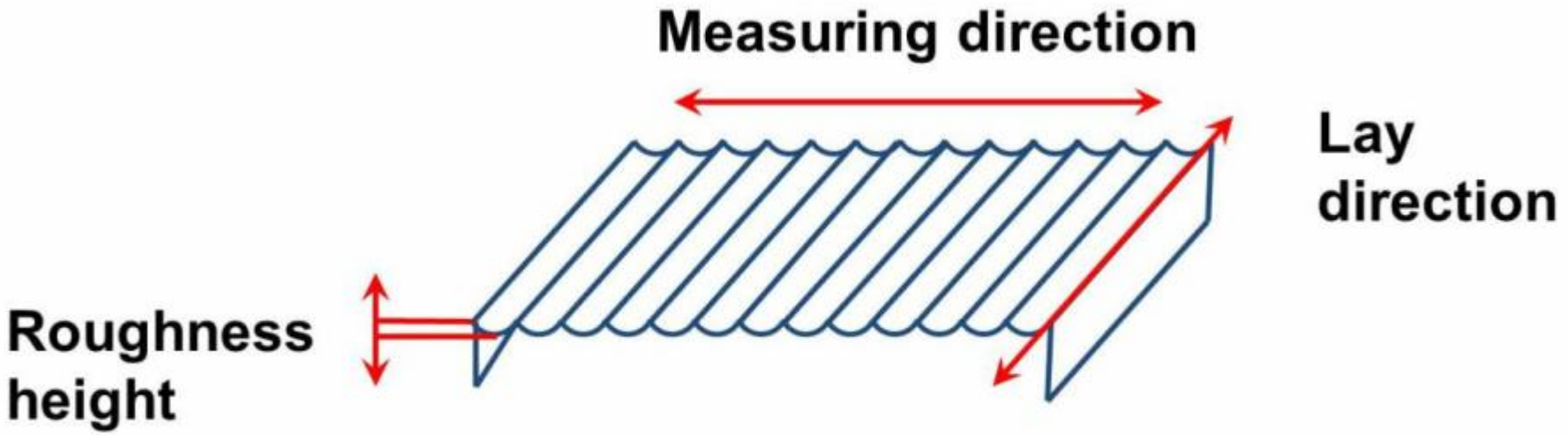
Surface Roughness Measurement

- Specify on Drawing, Specification and Proposal
- Measure with Profilometer
- Measure Across the Grain
- Optical Comparators





Measurement with Profilometer



Surface Treatments

OVERVIEW

Surface Roughness

- **Mechanical** *(grinding, polishing,ceramic bead blasting, shot peening)*
- **Chemical** *(etching, oxidation, passivation)*
- **Electropolishing**

Surface Hardness/Wear

- **Thermal** *(surface hardening laser, electron beam)*
- **Diffusion** *(carburizing, nitriding)*
- **Ion Implantation**

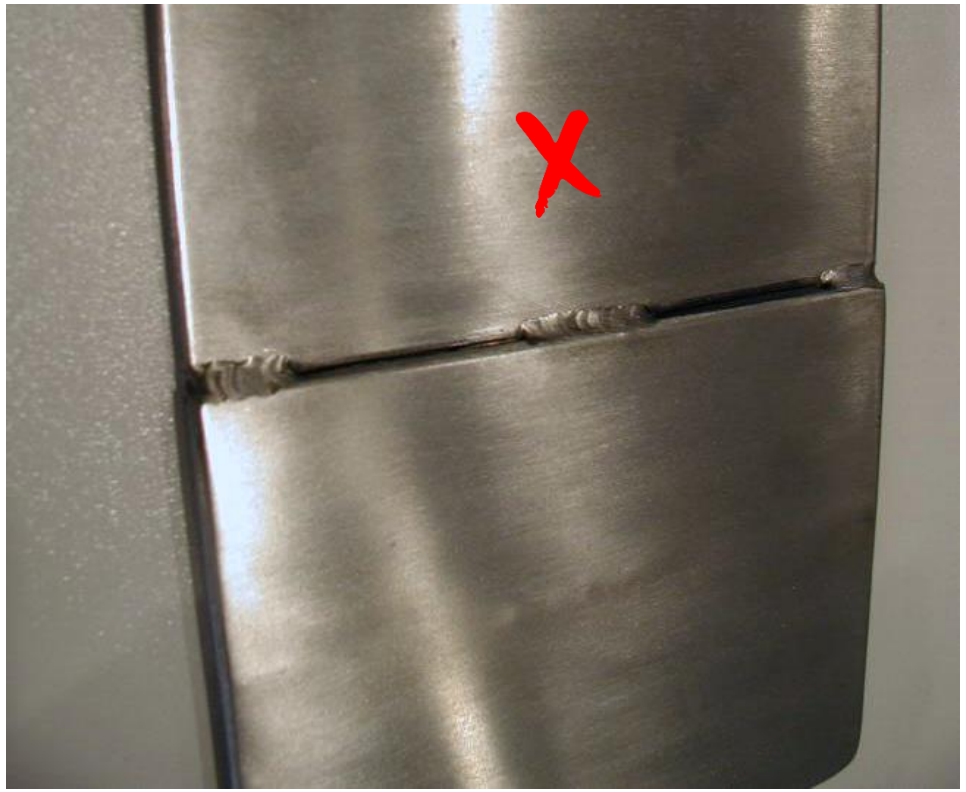
Hands on experience with surfaces finish.

Joint Design – Product Contact

- Permanent Joints
  - Welded –Metals
  - Welded –Thermoplastics (Permitted only by specific standards)
  - Solder and Brazing (Permitted only by specific standards)
  - Interference Fits –Metal to Metal
  - Bonded Joints(Permitted only by specific standards)
- Non Permanent Joints
  - Mechanical Forced Seals
  - Gasketed Joints for Sanitary Fittings
  - Flat Gasket must be substantially flush
  - Seal in Series with

Welded Joints

- Must continuously welded
- Must meet surface finish requirements stated earlier
- Meets Criteria of AWS D18.1, D18.2, and D18.3



No skip or stich welds

Sanitary Tubing Welding

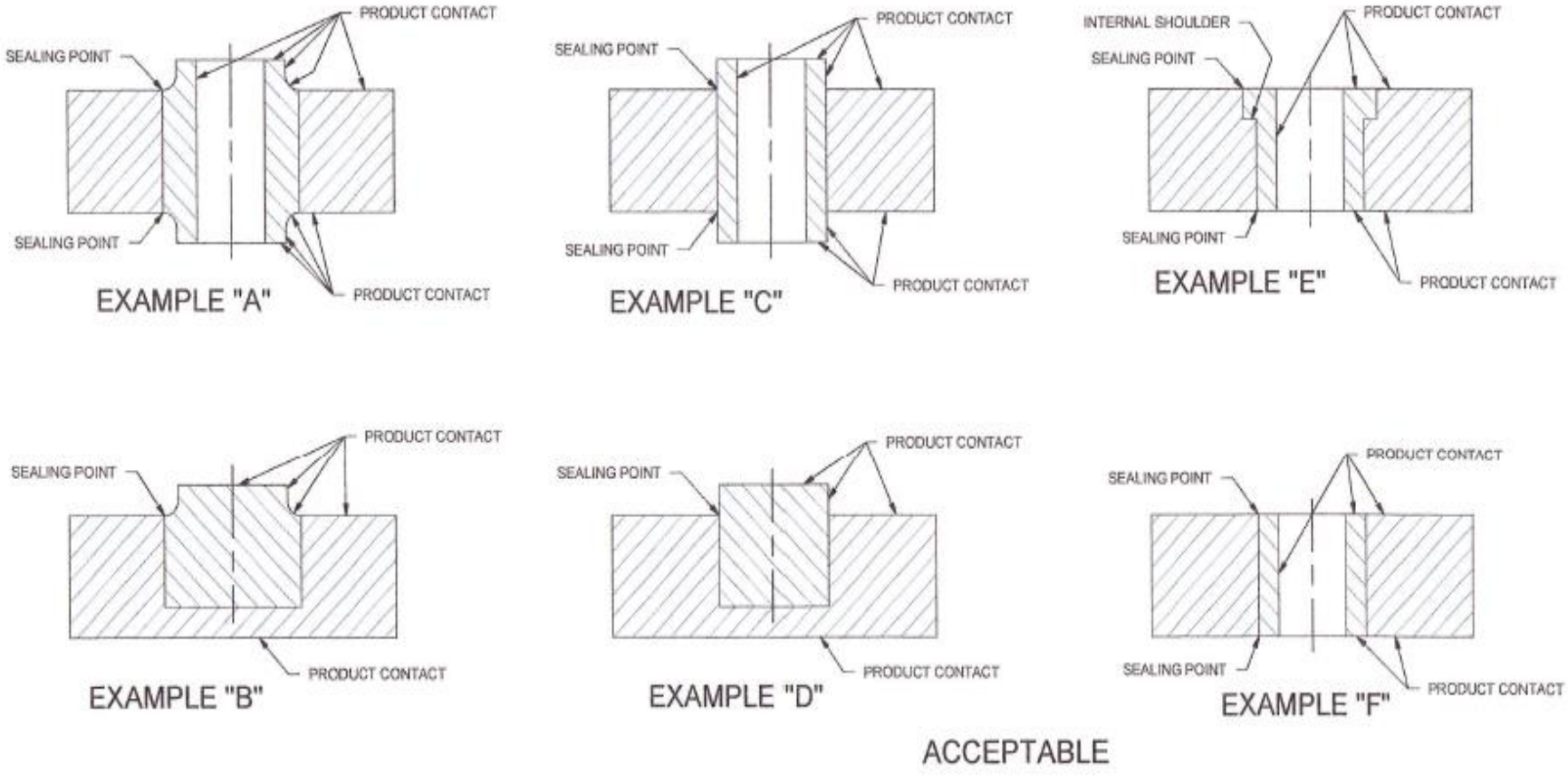
- Full Penetration
- No Pits, Cracks, and Crevices

Incomplete Weld in Hollow Tube

Interference Joints

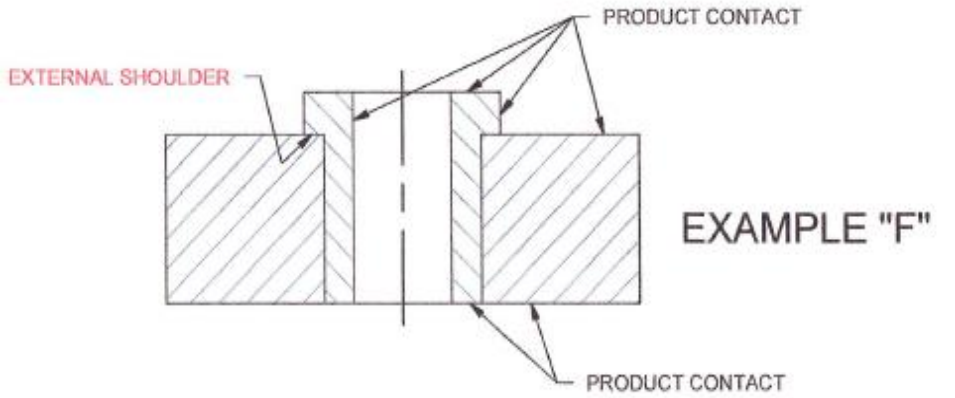
- Metal to Metal Joints Only
- Free of External Shoulders
- Free of Relieved Area
- Permitted by Specific 3-A Equipment Standards
- Tightness of Fit shall be validated no liquid migration
- EHEDG Guideline 2 Testing Procedure
- Pass Dye Penetrant Test

Acceptable – Interference Fit Designs

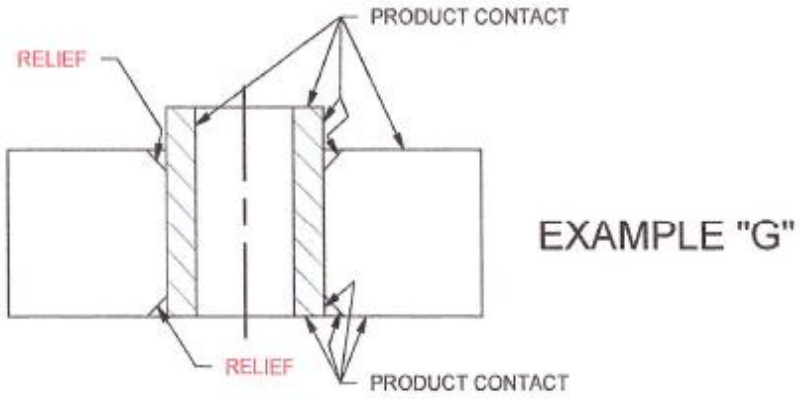


ACCEPTABLE

Un-acceptable Interference Fit Designs



EXAMPLE "F"

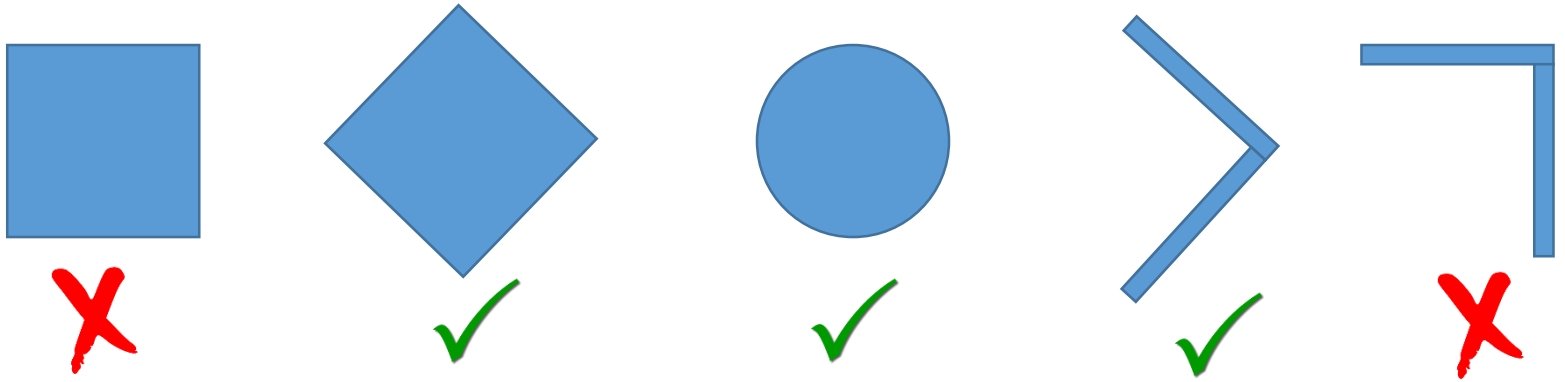


EXAMPLE "G"

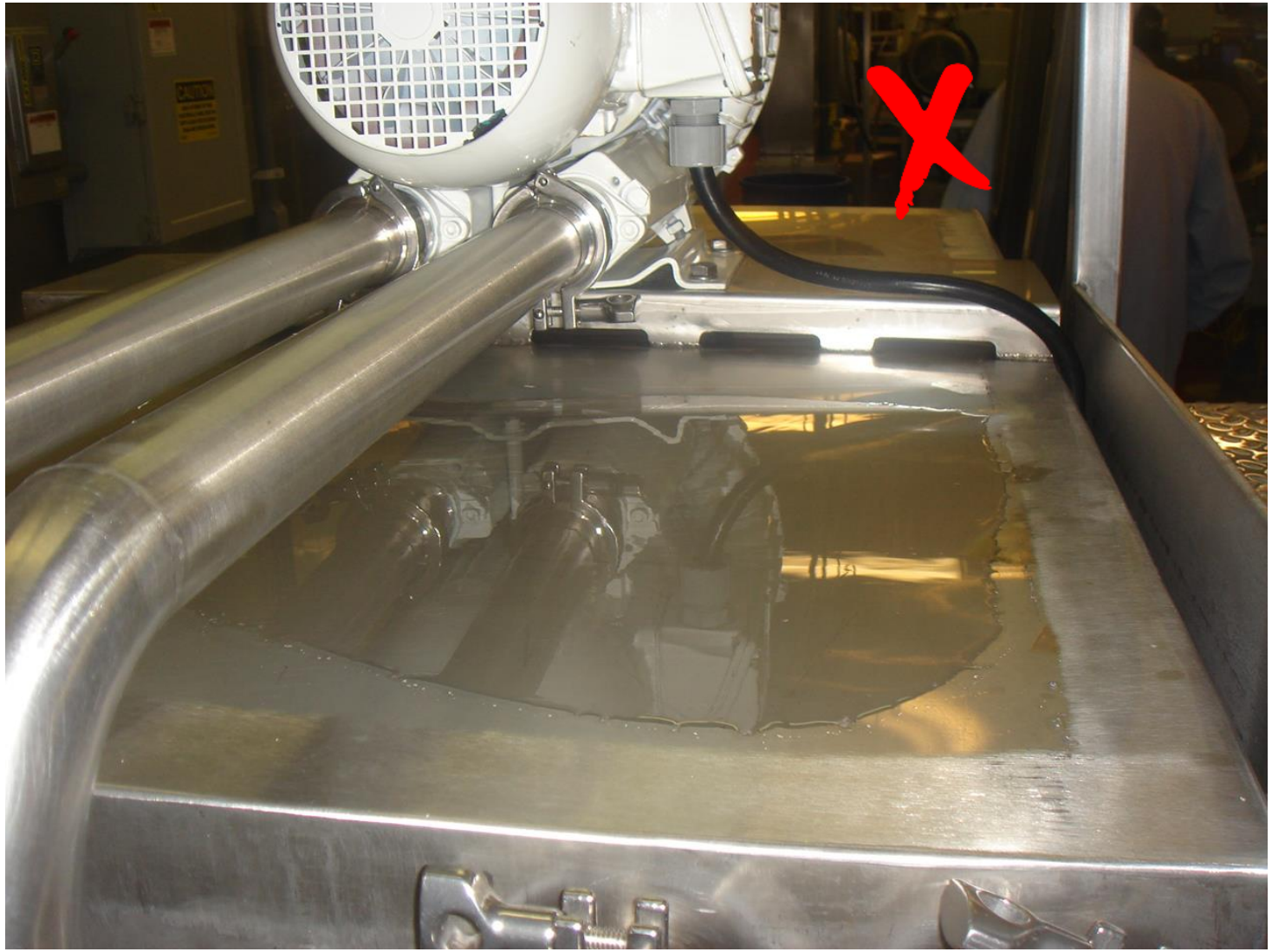
NOT ACCEPTABLE

Draining

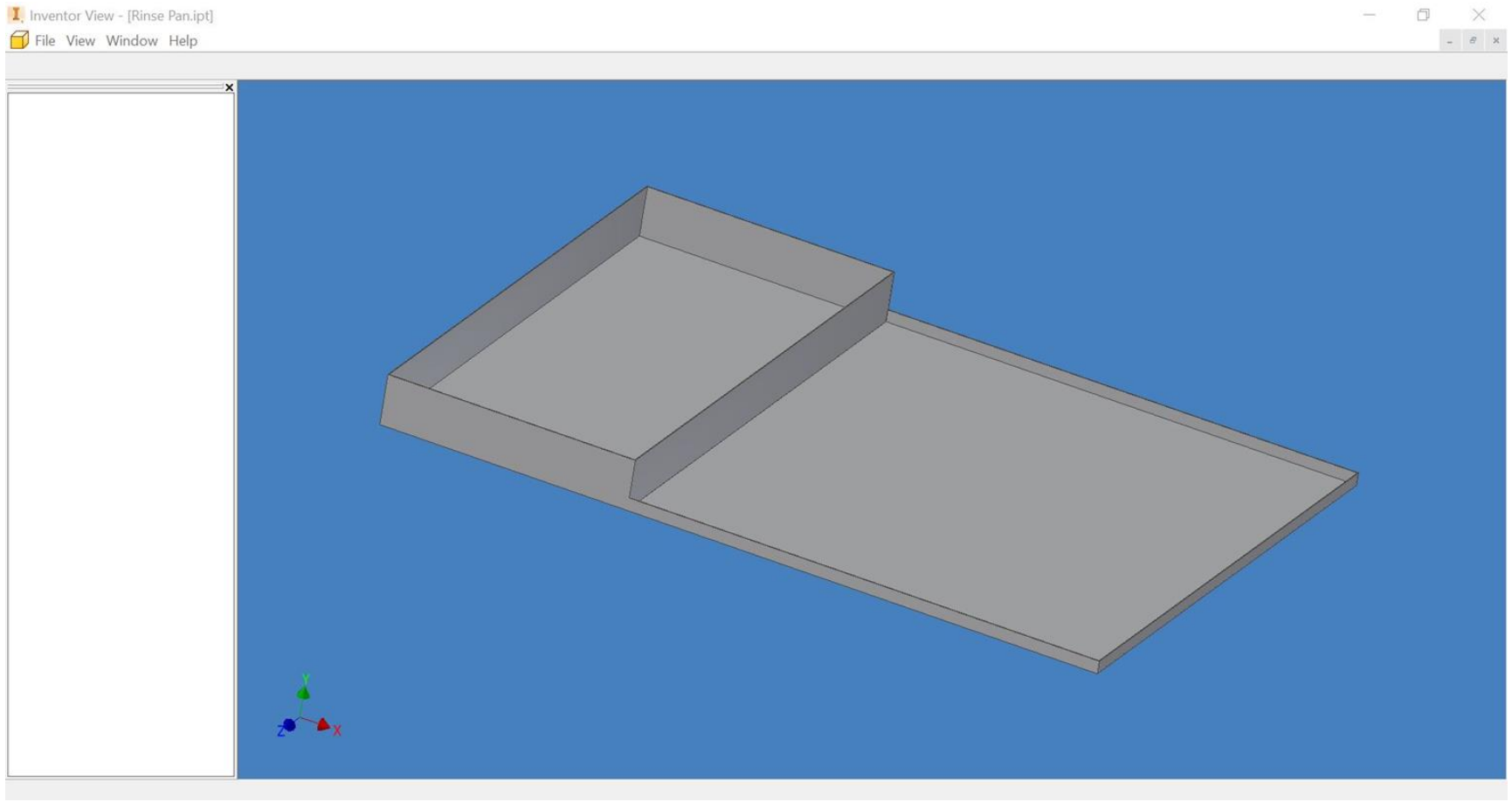
- All Product Contact Surface shall be self-draining
  - Except for typical clingage and adherence
- All Non-Product Contact Surfaces designed to minimize pooling
  - Liquids cannot drain into product or product contact surfaces
- Product and solution tubing should pitch 1/8 inch/ft minimum
- Flat surfaces should pitch ¼ inch/ft minimum



Pooling is a source of contamination in PCS and NPCS



Pans need to drain way from Product Contact surface

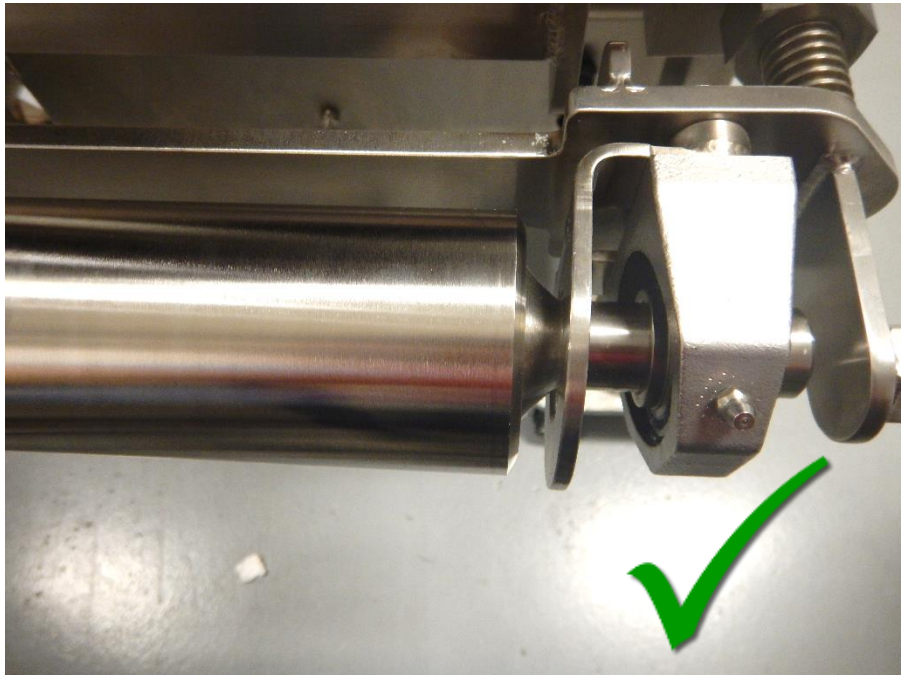


Dead Legs – Hollows - Blind spots

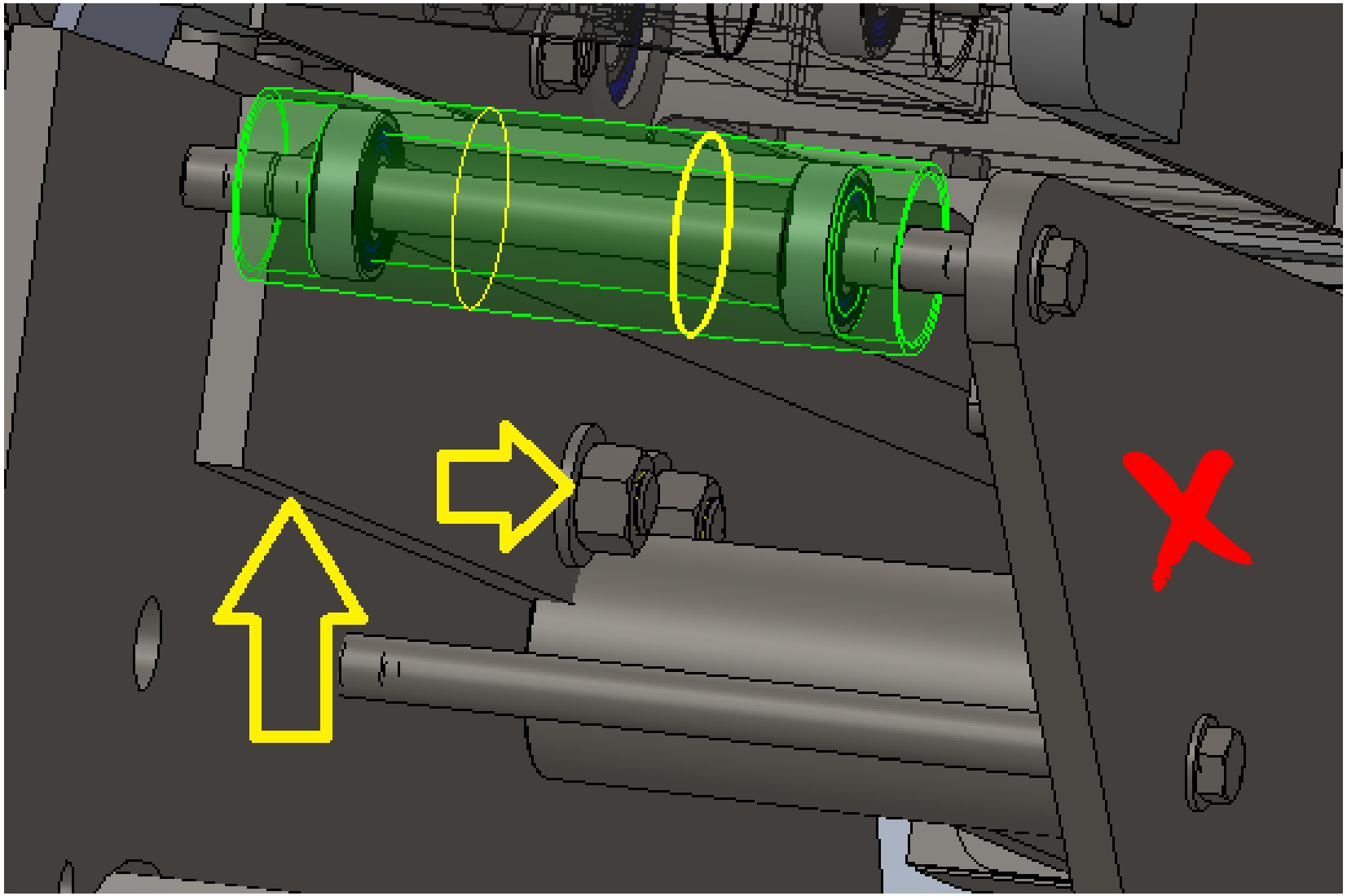
- Avoid dead legs in hollow that may not clean
- Avoid hollow roller that create niches
- Avoid hollow frame construction
- Avoid blinds spot that are hard to clean and inspect

Hollow Rollers

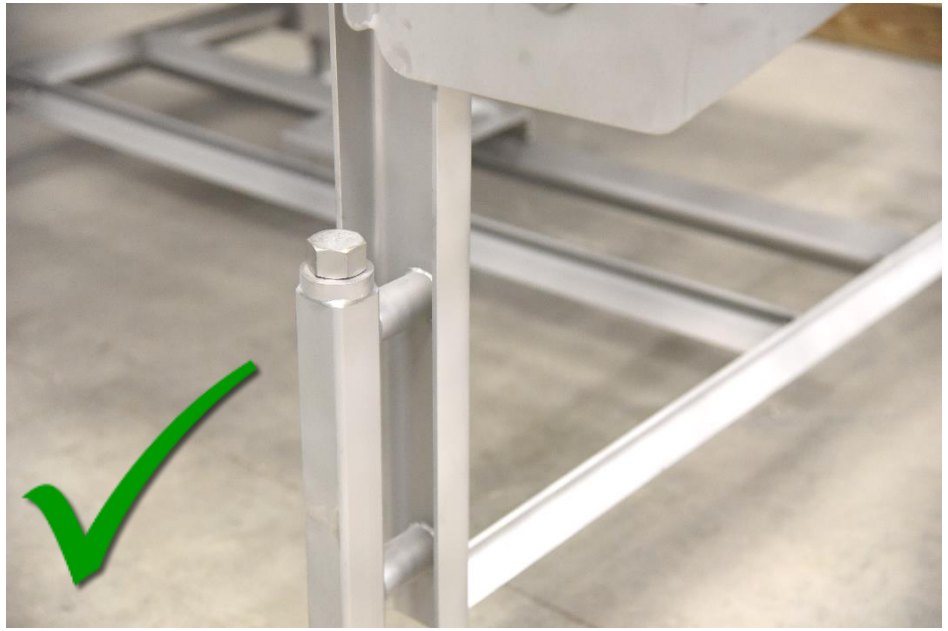
All rollers should be solid with bearings outside the product zone

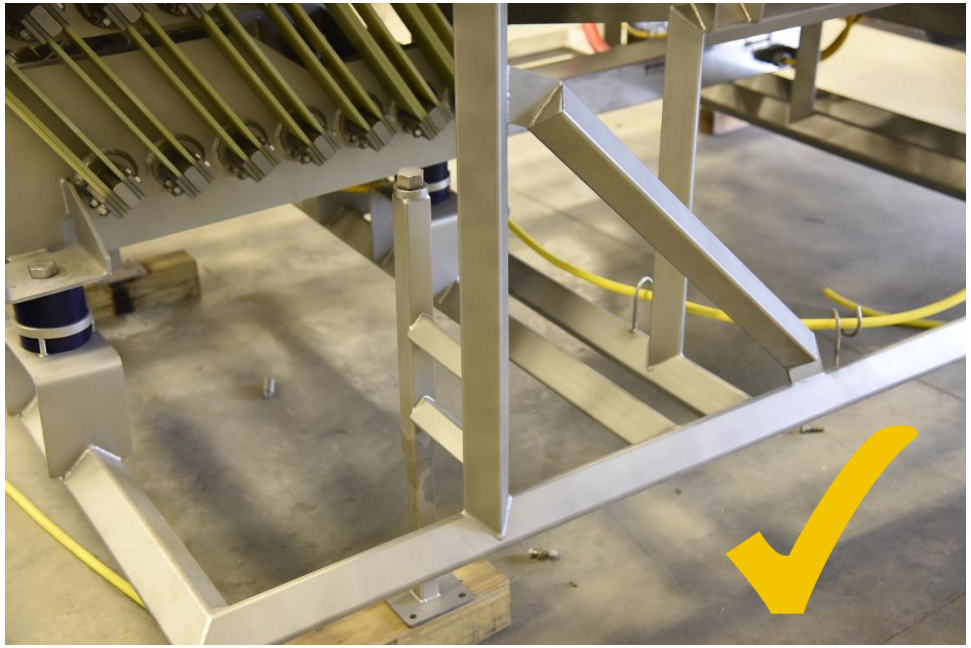


Hollow roller identified during design review

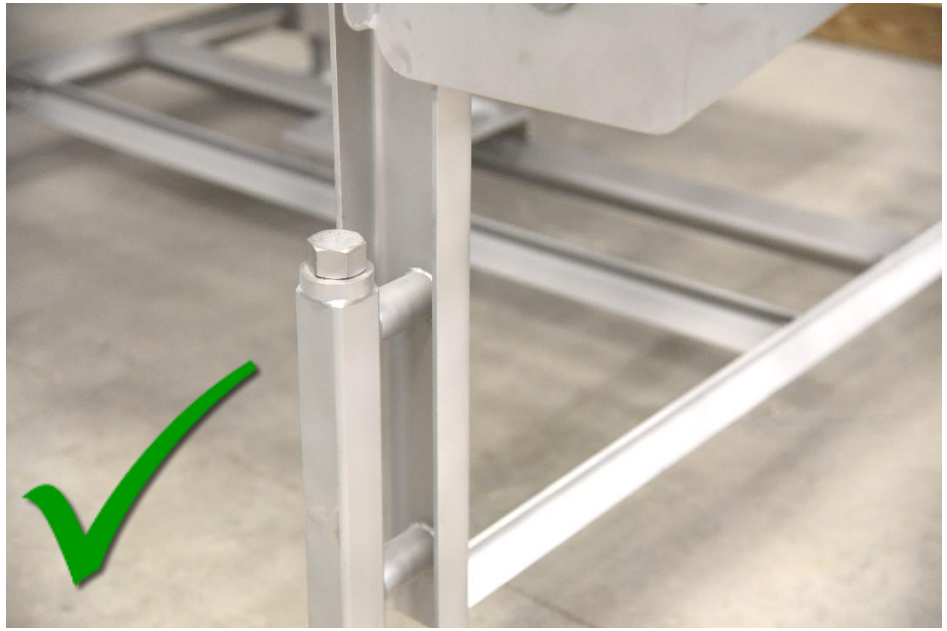


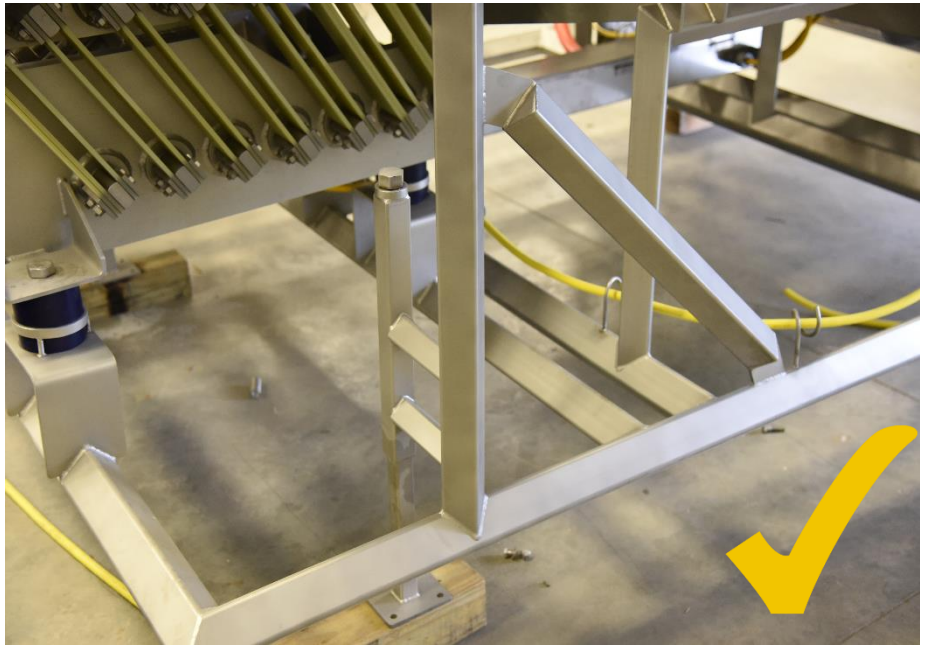
Hollow Tubing Frame

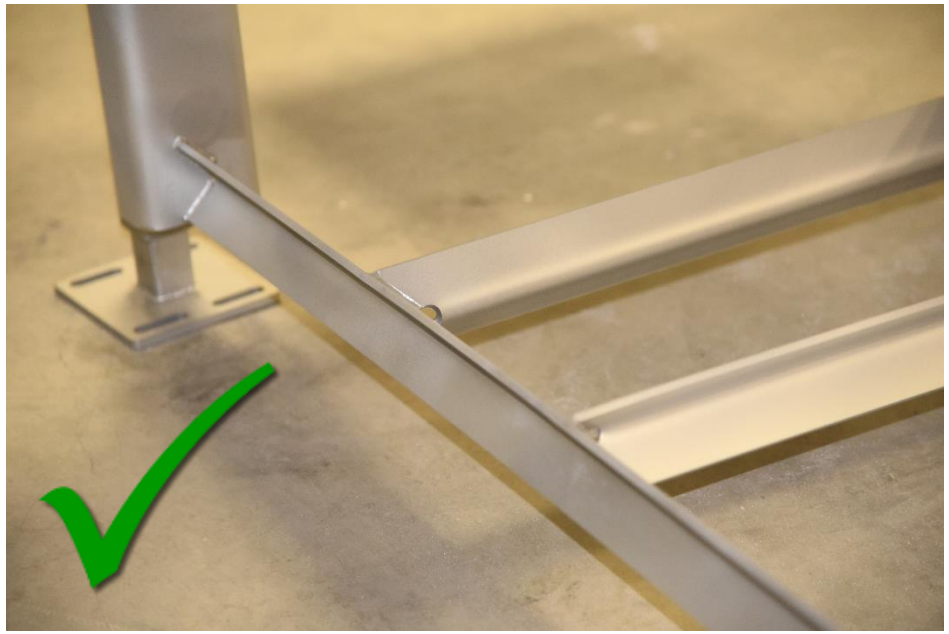




Hollow Tube Frame VS Open Angle Frame

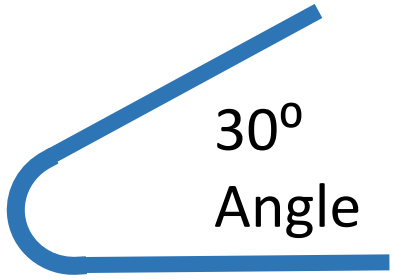


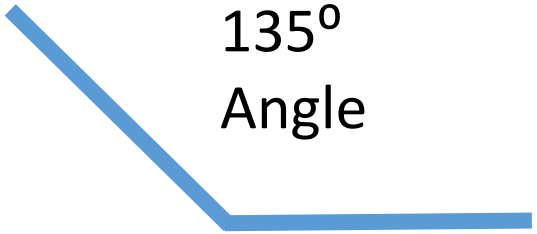




Radii

- All angle less than 135º shall have radii of at least ¼ inch
- Exception for gaskets and o-ring groves
- Large radii are easier to clean





Accessible to Clean and Inspect

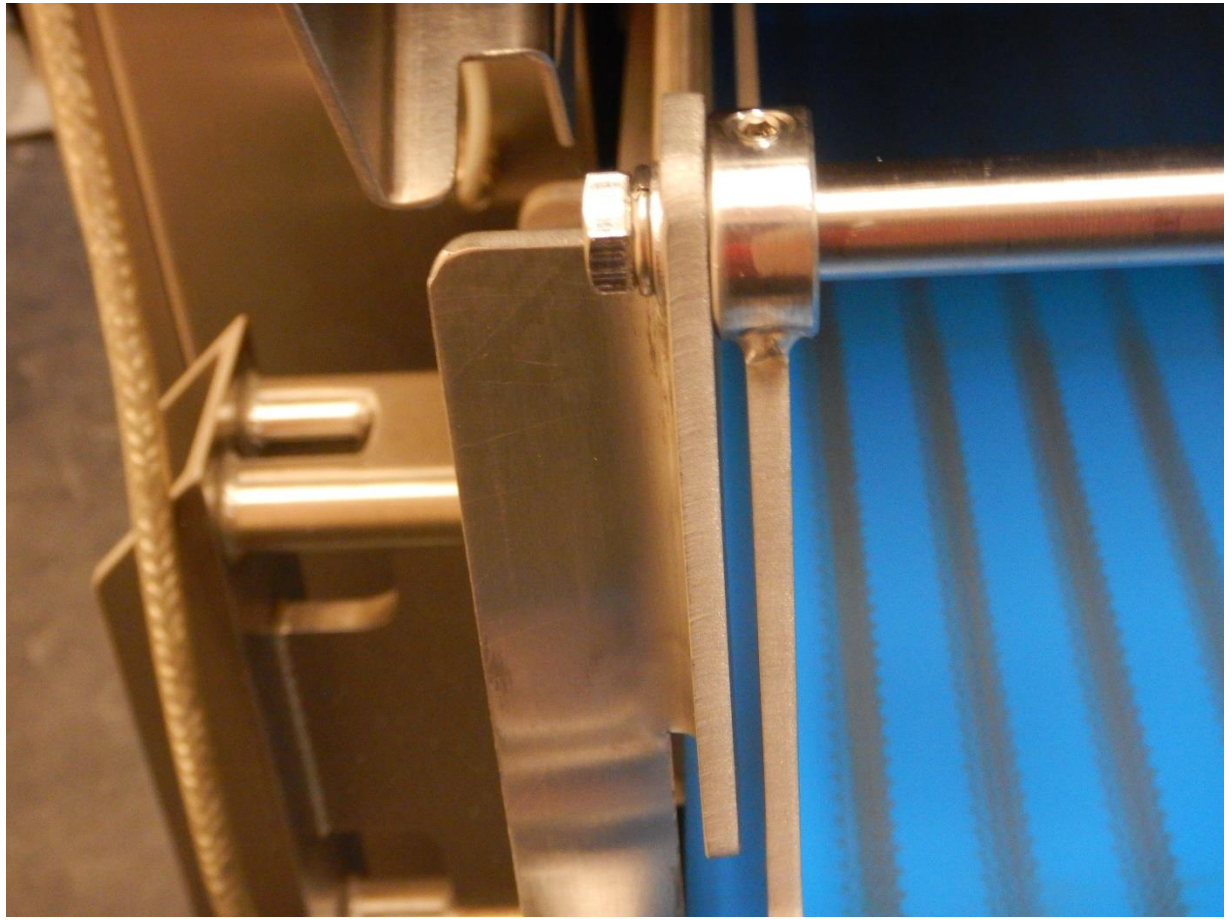
- All PCS must be readily accessible
  - In installed position
  - Or when removed
- CIP – representative surfaces are readily assessible and inspectable
- Large heavy part may need special lifting device
- Provide platforms, ladders or lifts to safely clean and inspect

Cleaning Access Guidelines

- 12” below equipment
- 36” around equipment

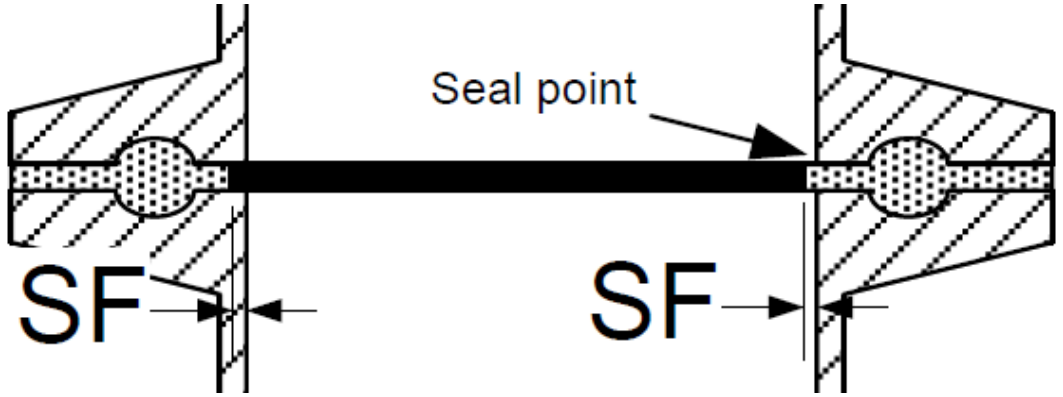
Width	Cleaning Clearance
8”	1”
24”	4”
>24”	12”

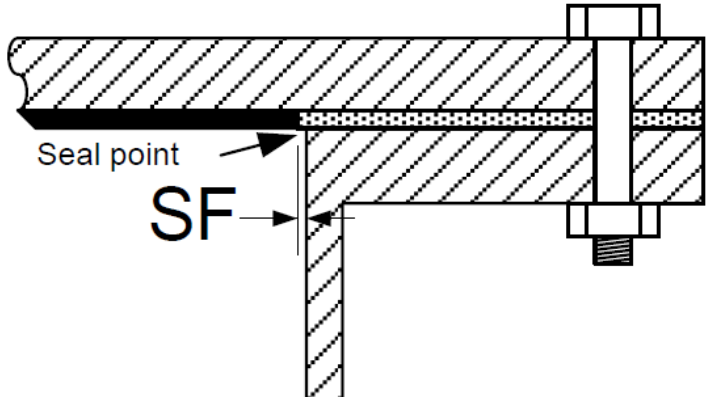
Avoid small gaps



Substantially Flush Gaskets

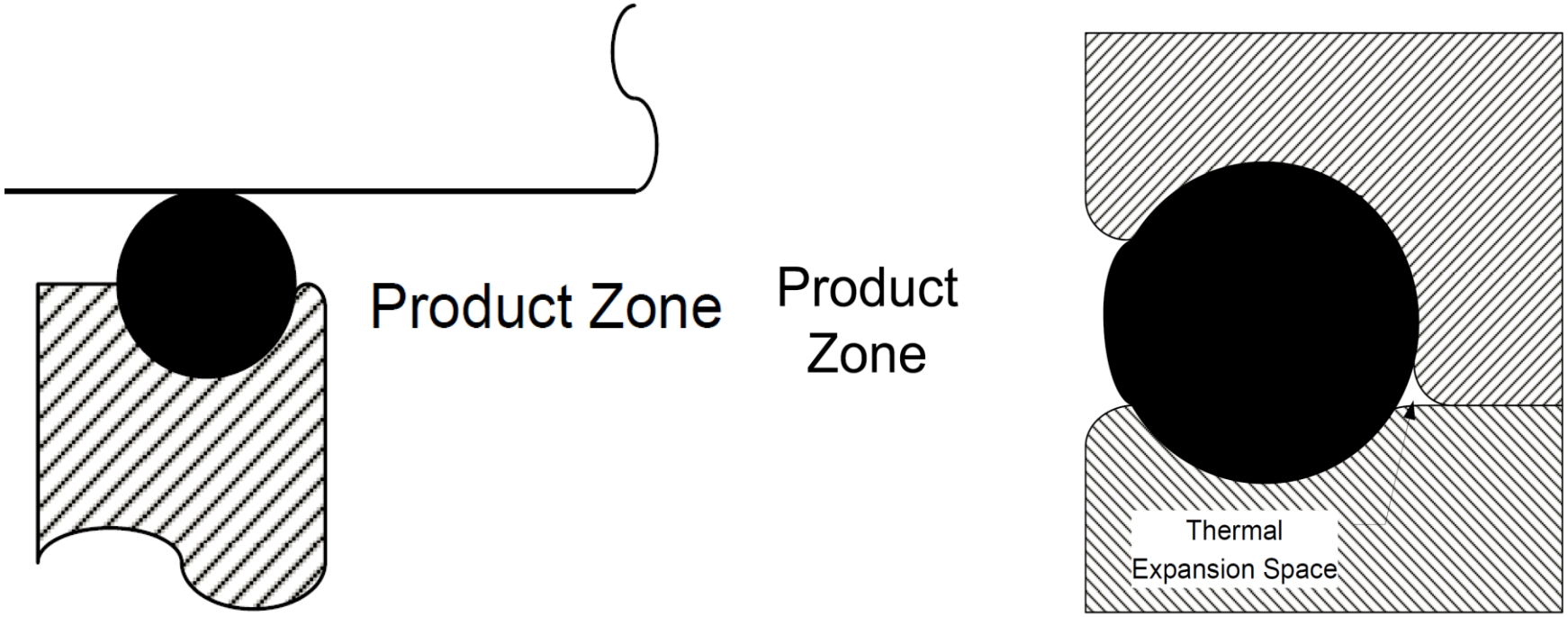
Substantially Flush (SF) = 1/32" (0.794 mm) maximum



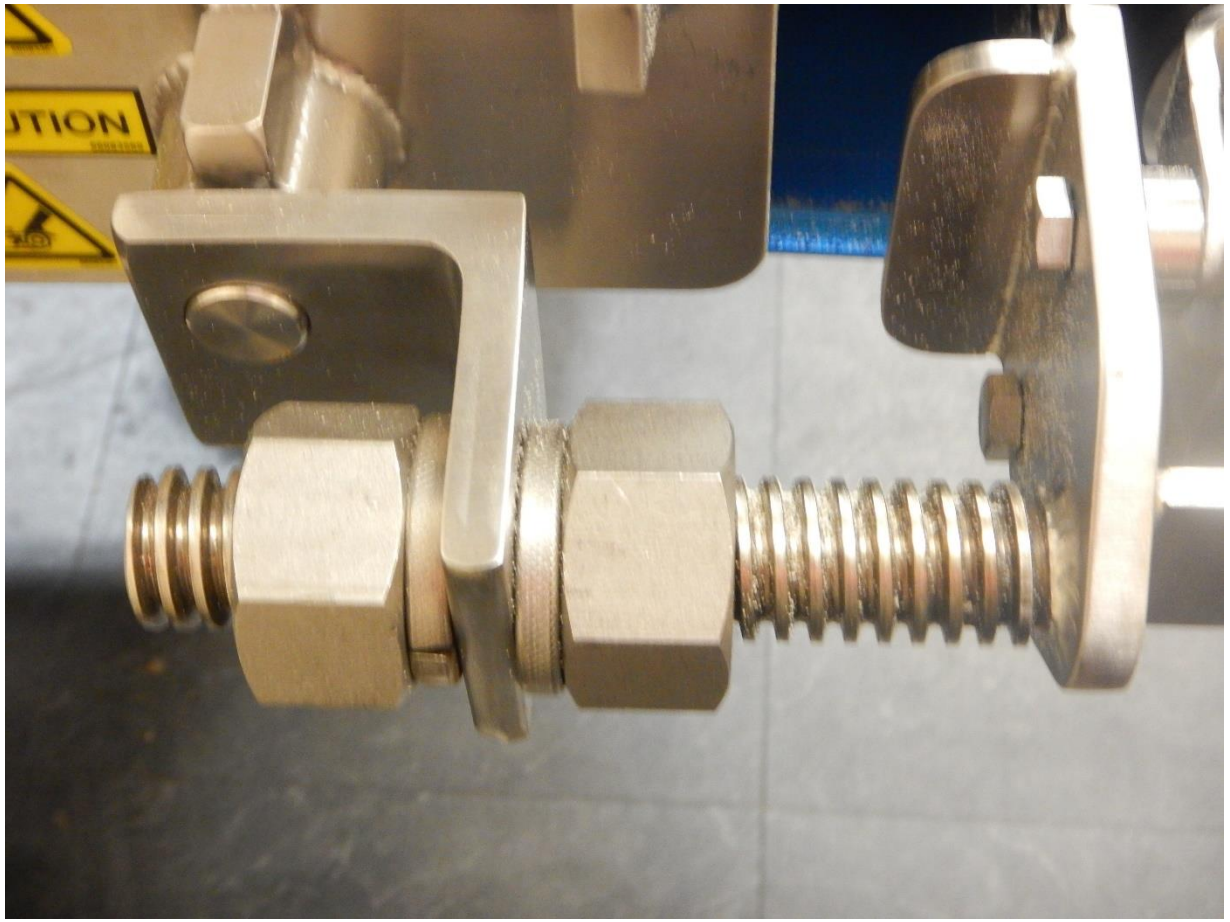


Gaskets and O-ring

- Removable or Bonded
- Groves not deeper then width unless removable
- Reference 3-A Charts for groove radii



Exposed Threads - Sanitary Acme Design



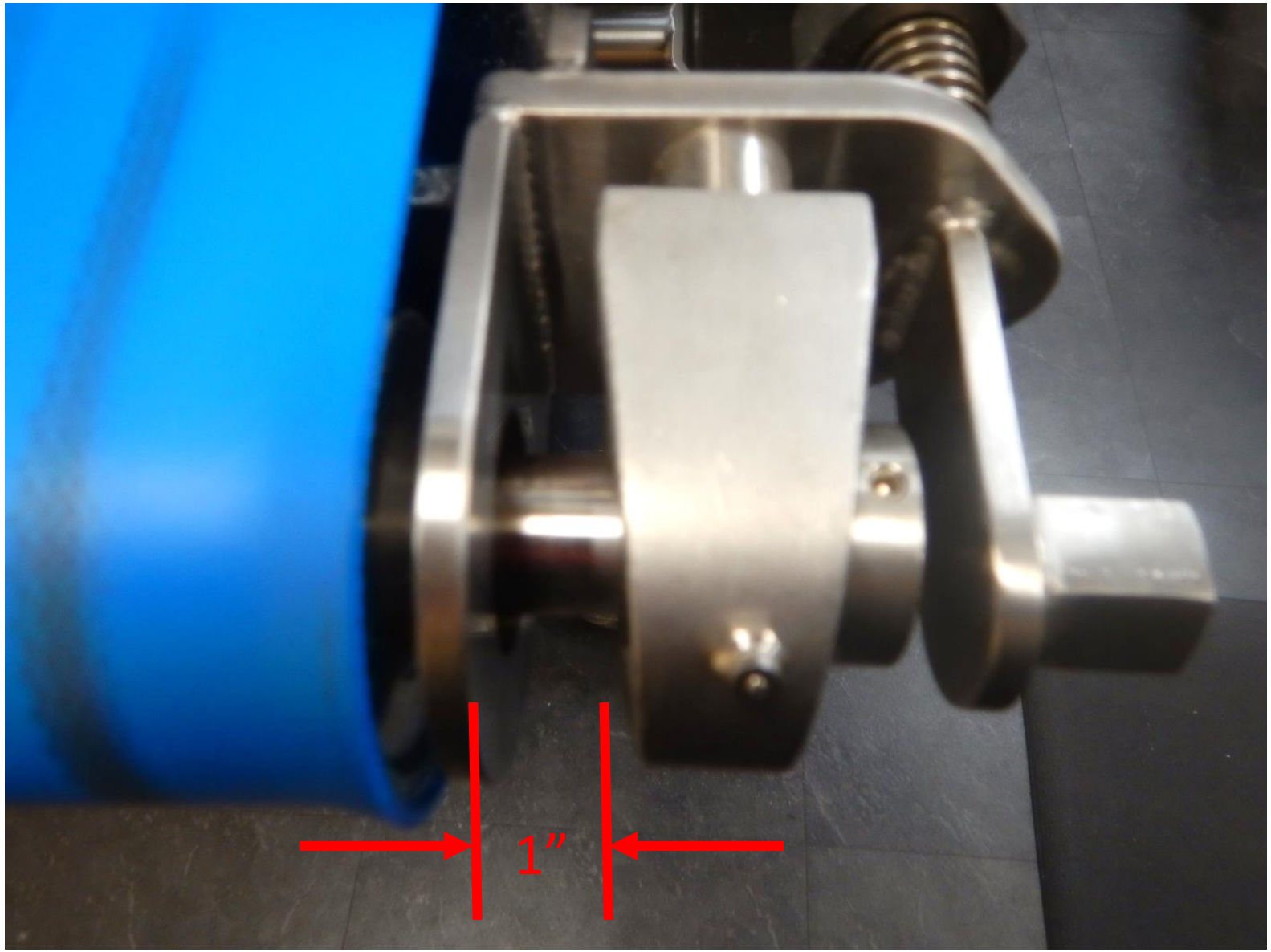
Coil Springs

- Round cross section
- No flat ends for CIP applications
- 1/32” minimum space between coils under compression
- 3/32”minimum space between coils in relaxed condition for spring with 1” outside diameter or less

Bearings and Shafts

- Bearings in product contact zone shall be non-lubricated or product lubricated.
- Bearings outside product zone need to be on stand-offs
- Shafts above product level shall be designed to prevent the entrance of contamination.

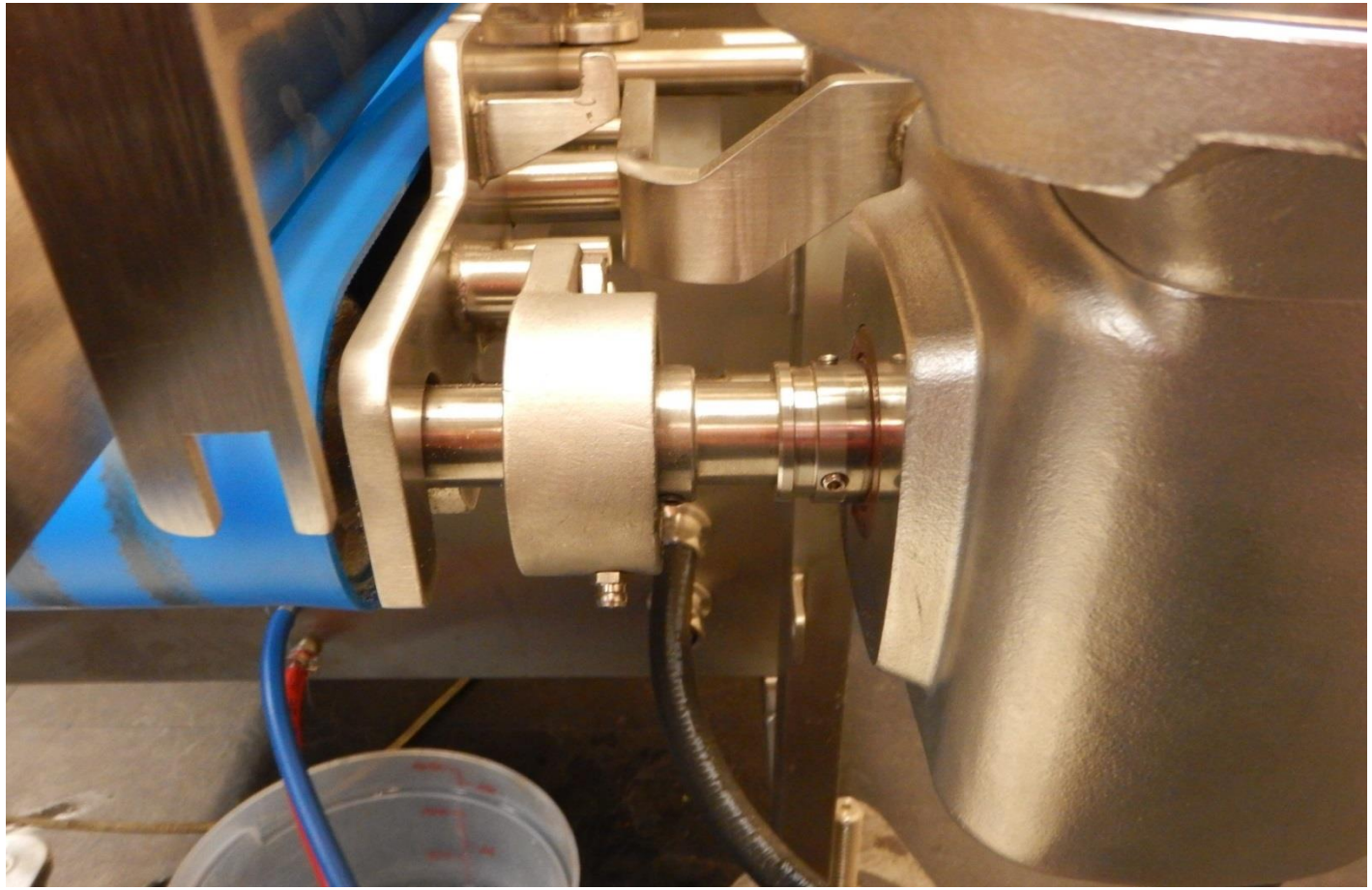
Shaft and Bearings -



Bearing Mounting

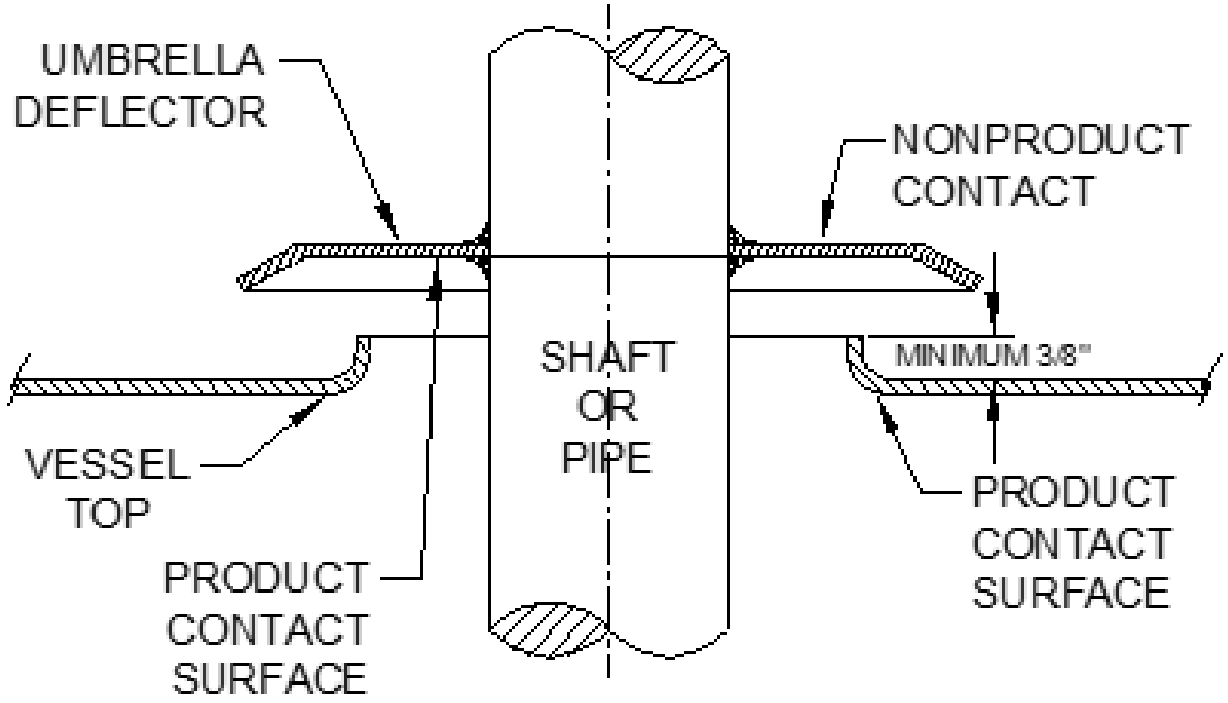
- Welded stand-off preferred
- Avoid sleeve stand-offs
- Non-corrosive
- Do not mount over product

Oil filled gearbox mount outside product contact surfaces



Opening and Covers

- Minimum 3/8 inch flange upward
- Umbrella Cover



Joints in NPCS

- Continuous Weld
- Bolted connection on welded stand-offs
- Socket head bolt must be mounted horizontal to drain
- No blind rivets

Installation and Maintenance

- Install in a hygienic condition
  - Cleaning clearances
  - Electrical washdown
  - Corrosion resistant materials
  - Free draining
  - Not over floor drains
- Maintain hygienic conditions

Questions

- ??