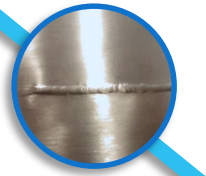
Hygienic Design & Fabrication

Bryan Downer

Learning Objectives

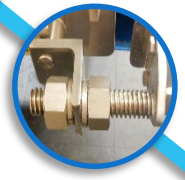
Classify permanent and non-permanent joints

Review hygienic requirements to various joint types



Review examples of unacceptable joint configurations

Describe the concept of radii



Identify hygienic requirements to various fabrication elements

Analyze hygienic design failures

Hygienic Design Process for Equipment

- Define Intended Uses & Risks
- Define Cleaning Methods
- Define Product Surfaces
- Select Approved Materials of Construction
- Design & Build to Meet Hygienic Criteria
- Third Party Verification (TPV)

Equipment cGMP: 21 CFR, Part 117.40

- Very generic – one page
- Key points:
  - Cleanable
  - No allergen cross-contact
  - No contamination
  - Facilitates cleaning and maintenance
  - Corrosion-resistant PCS
  - Non-toxic
  - Withstand intended use and cleaning
  - Seams or joints are bonded
  - NPCS must be cleanable
- Standards like 3-A provide details of how to accomplish

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§117.40 Equipment and utensils.

(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

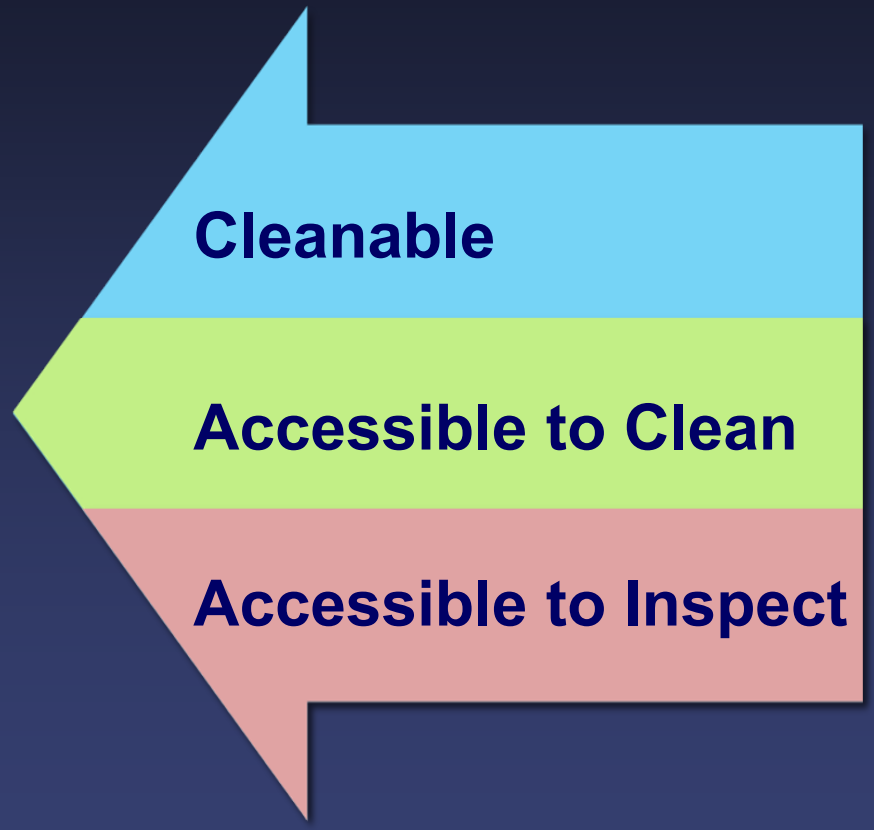
(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature- measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

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 parts may need special lifting devices
- Provide platforms, ladders, or lifts to safely clean and inspect



Equipment Intended for COP/Manual Cleaning & Inspection

- Readily accessible and inspectable when in an installed position or when removed
- Junctures between components may or may not be gasketed or sealed
- All demounted appurtenances shall be readily removable
- A mechanical lift should be provided for heavy parts removed for cleaning

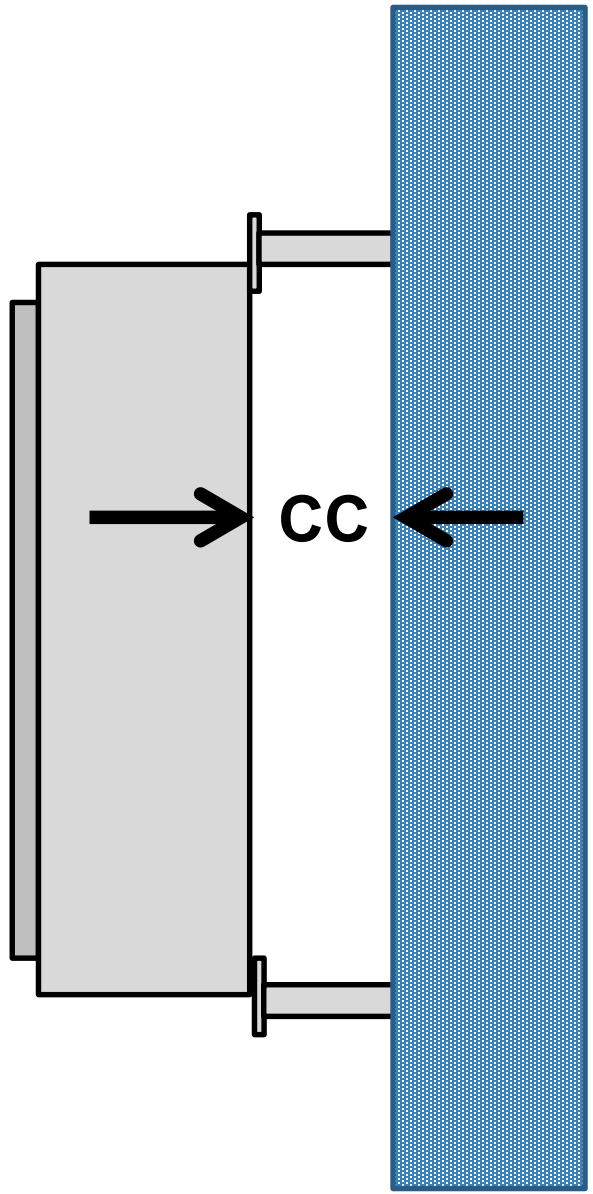
Equipment Intended for CIP Cleaning and Inspection

- PCS:
  - All PCS and non-removed appurtenance are CIP cleaned
  - Junctures between components shall be sealed or designed for manual, or COP cleaning
- All demounted appurtenances shall be readily removable
- All CIP cleaned surfaces shall be readily accessible and inspectable
- Cleanability by CIP shall be verified and documented

Cleaning Access Guidelines for Equipment

- Need access for manual cleaning
- Need clearance for hands, arms, or body
- Need clearance for cleaning tools
- Apply 12.5” rule - minimum distance from edge for cleaning access
- Clearance below and behind equipment
  - 3-A Standards – 4-6” (10-15 cm) min.
  - In practice – 12” (30 cm) min. is preferred

Depth of Reach	Cleaning Clearance (CC)
4” (10 cm)	2” (5 cm)
16” (41 cm)	4” (10 cm)
>16” (41 cm)	12” (30 cm)



Joint Design – Product Contact

Permanent Joints

- Welded – Metals
- Welded – Thermoplastics*
- Solder and Brazing*
- Interference Fits – Metal to Metal*
- Bonded Joints*

Non-Permanent Joints

- Mechanical Force Seals
- Gasketed Joints for Sanitary Fittings
- Flat Gasket must be substantially flush*
- Seals in Series

*Permitted only by specific Standards

Metal Welding

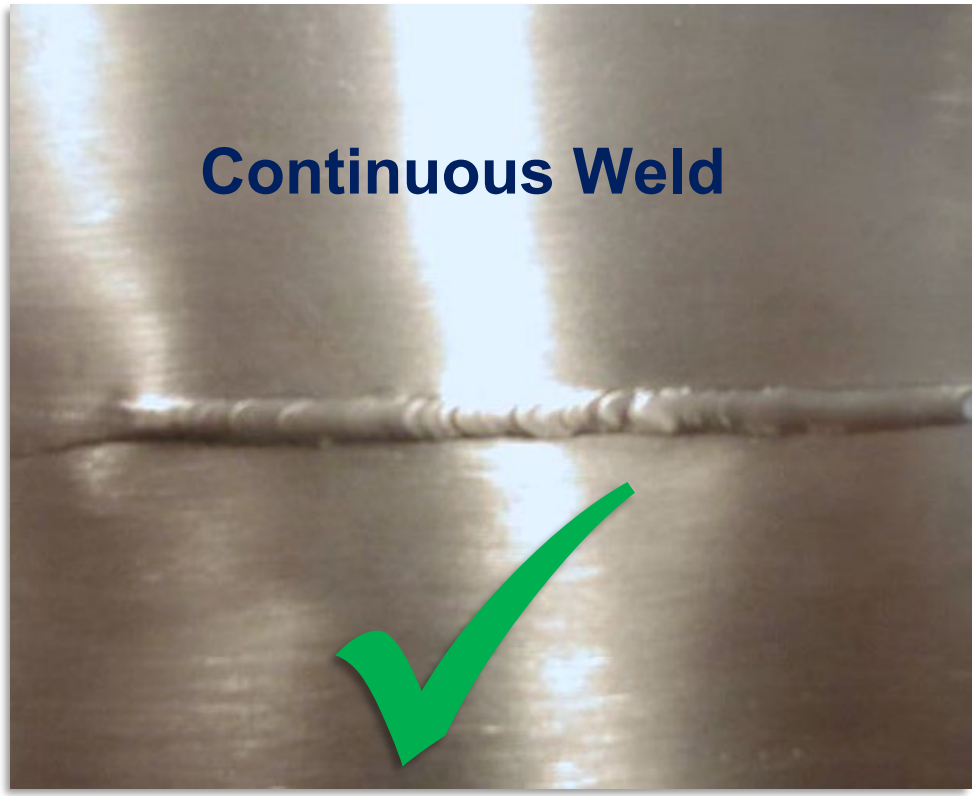
A fabrication process used to join metals together using the heat of an electrical arc. The melting point of stainless steels is 2417 ºF - 2786 ºF (1325 ºC - 1530 ºC) depending on the type of metal.

Requirements for Sanitary Welded Joints in Tanks, Vessels, and Other Equipment

- All welds shall be continuous and full penetration
- Weld interior and exterior shall be free of pits, folds, crevices, cracks, and misalignment
- As welded condition of interior welds to meet AWS/ANSI D18.3/D18.3M
- Weld finish condition shall be WF-5 per AWS/ANSI D18.3/D18.3M
- Weld final finish of PCS shall be at least as smooth as 32 µin Ra (0.8 µm Ra)

Requirements to Welded Joints

- → Continuously welded
- → Meet surface finish requirements
- → Meets Criteria of AWS D18.1,



- → Not Acceptable

TIG Weld of Tank Seam

TIG Welding with Filler Metal

Stainless Steel Filler Metals

AISI Steel	Recommended Filler Metal	Alternate Filler Metal
303, 303SE	312	309MO
304, 304L	308L	347, 309
316, 316L	316, 316L	309MO, 317
17-4 PH	630	308, 309
2205	2209	-

https://www.wmwa.net/metal-products/filler-metal-charts/

Hygienic Tubing

Sanitary Tube Welding: Autogenous Weld (No Filler Metal)

Manual

•- Flexible process

•- Lower investment

Orbital

•- Less flexible

•- More uniform process

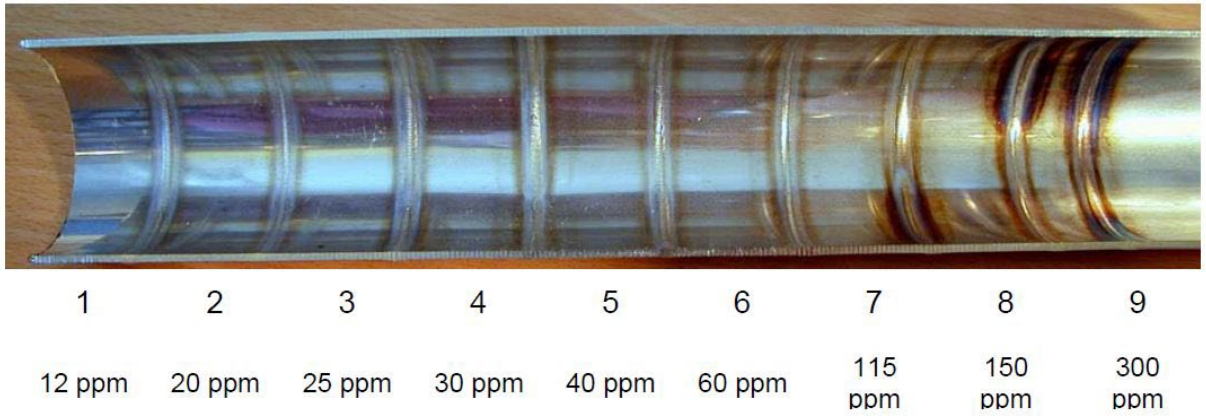
- Setup critical

- Precision parts and fit

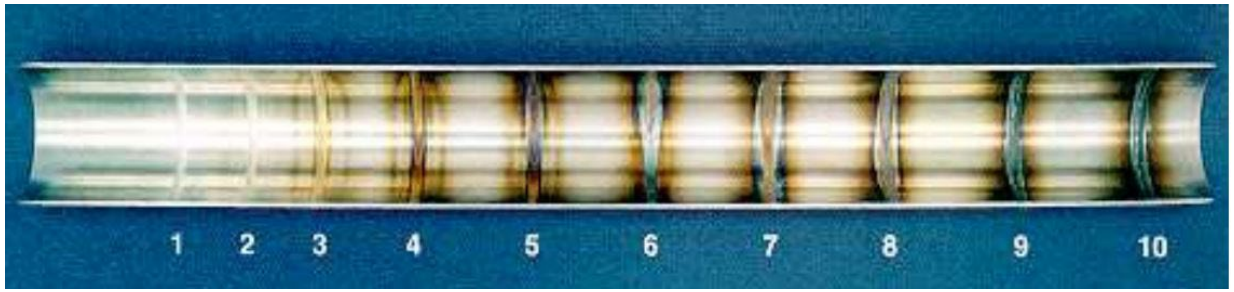
- Higher investment

Requirements for Sanitary Welded Tubing Joints

- All welds shall be continuous and full penetration
- Weld shall be free of pits, folds, laminations, crevices, cracks, and misalignment
- As welded interior surface finish per AWS/ANSI D18.1
- As welded interior discoloration shall be:
  - Weld 1, 2, or 3 as shown in AWS/ANSI D18.2 or
  - Weld 1, 2, 3, 4, or 5 as shown in EHEDG Guideline 35



EHEDG Guideline 35



AWS/ANSI D18.2

Sanitary Tubing Welding

→ Full Penetration, No Pits, Cracks, and Crevices

Manual

Orbital

Insufficient or No Backup Gas Purge

- Inert gas is used to purge oxygen from tube interior prior to welding

- Failure to remove oxygen causes an uncleanable burnt oxide deposit inside the weld

Tack Weld Not Consumed

- Excessive welder power for tack welds
- Insufficient internal gas purge
- Carbon deposit will not be consumed into the finished weld

Good Non-Purged Tack

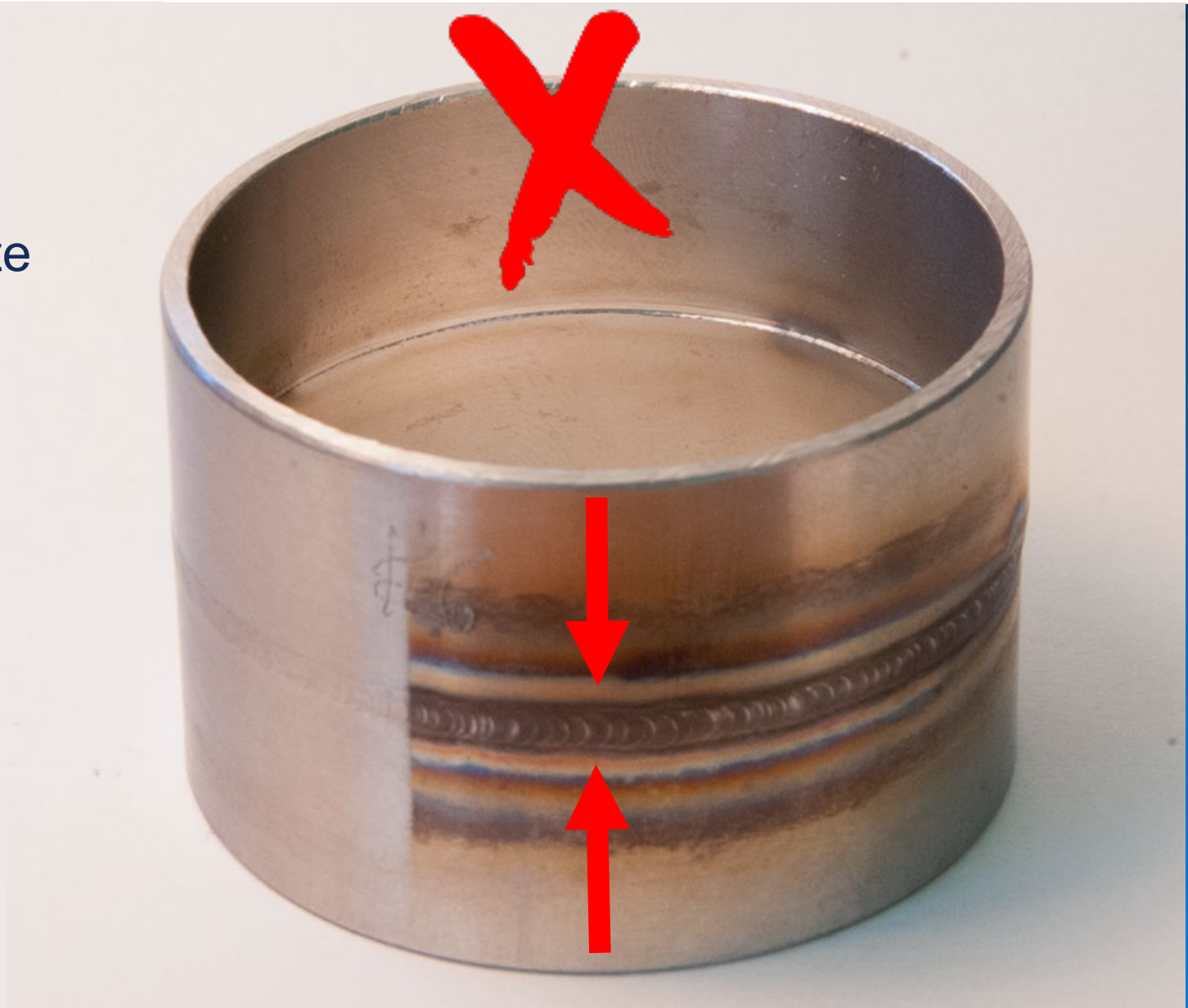
- → Lower weld heat
- → No purge gas
- → No black oxide
- → Dark discoloration is consumed with final weld

Incomplete Penetration: Off-Center Weld

- Welder meanders off the joint seam
- Uncleanable crevice

Incomplete Penetration: Narrow Weld Bead

- Weld is sealed on exterior
- Weld did not penetrate deep enough
- Uncleanable crevice



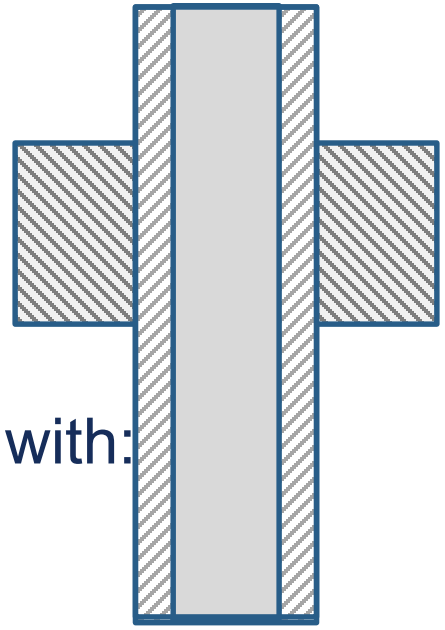
Uncleanable Pit in a Weld

Soldering and Brazing Permanent Joints

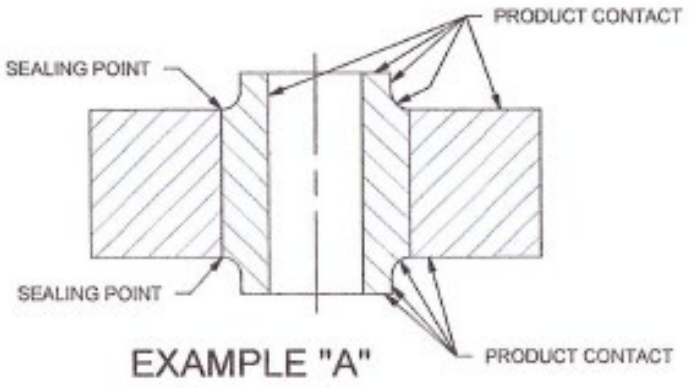
- When permitted by specific equipment 3-A Sanitary Standards of Accepted Practice
- Used for attaching components
- Visually free of surface cracks, crevices, and pits
- Smooth fully fused surface

Interference Fit – Permanent Joints

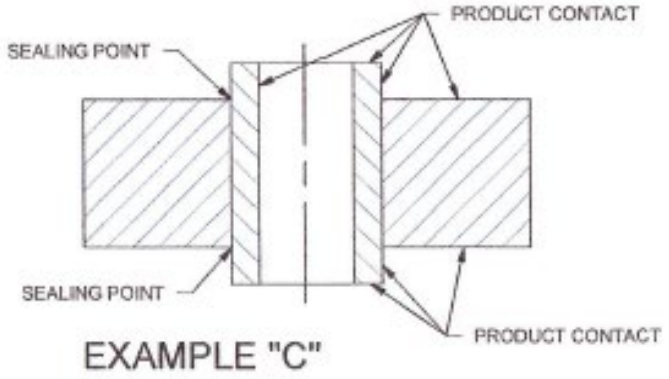
- Force or Shrink Inference Fit
- Metal to metal joints only
- Free of external shoulders and relieved area
- Interference fit dimensions per Machinery Handbook
- Tightness of Fit shall be validated for no liquid migration with:
  - EHEDG Guideline 2 Testing Procedure or
  - ASTM # E165 Pass Dye Penetrant Test or
  - Other suitable documented test method



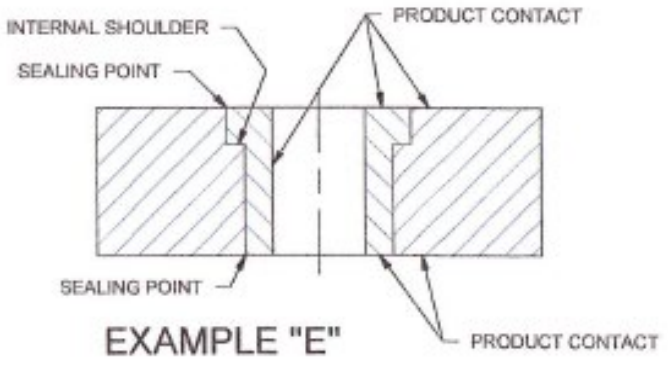
Acceptable Interference Fit Designs



EXAMPLE "A"



EXAMPLE "C"



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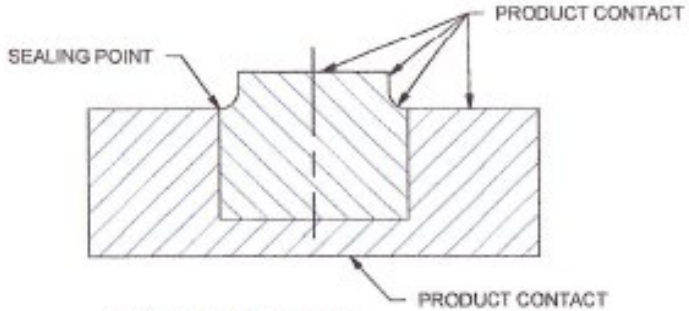
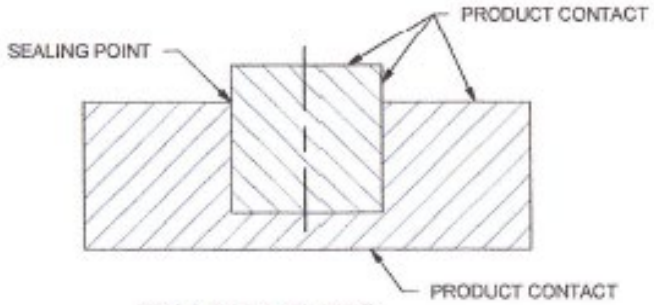


EXAMPLE "B"



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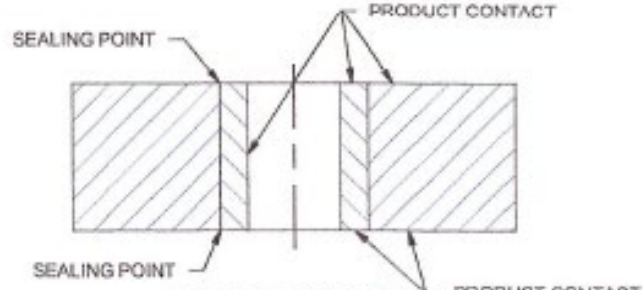
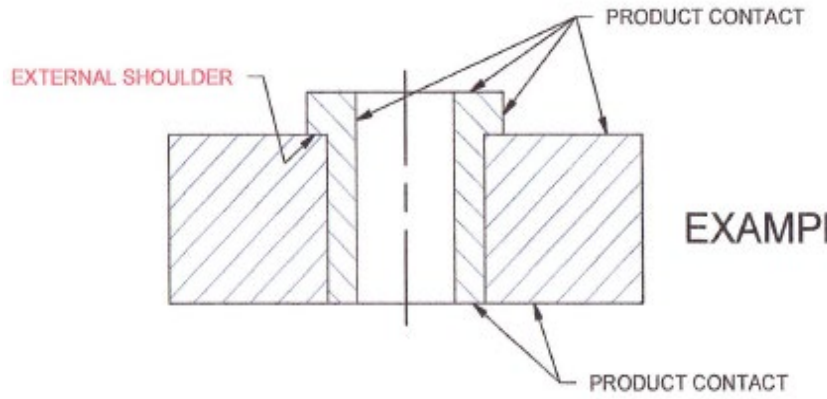


EXAMPLE "F"

ACCEPTABLE

Unacceptable Interference Fit Designs



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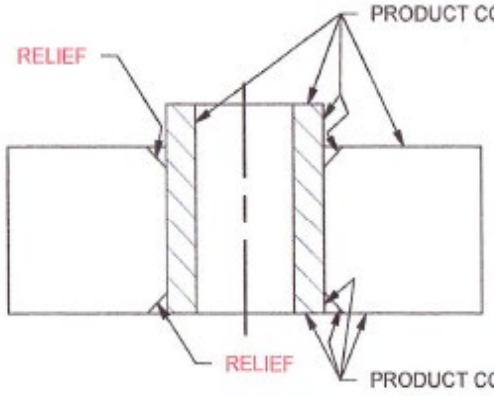
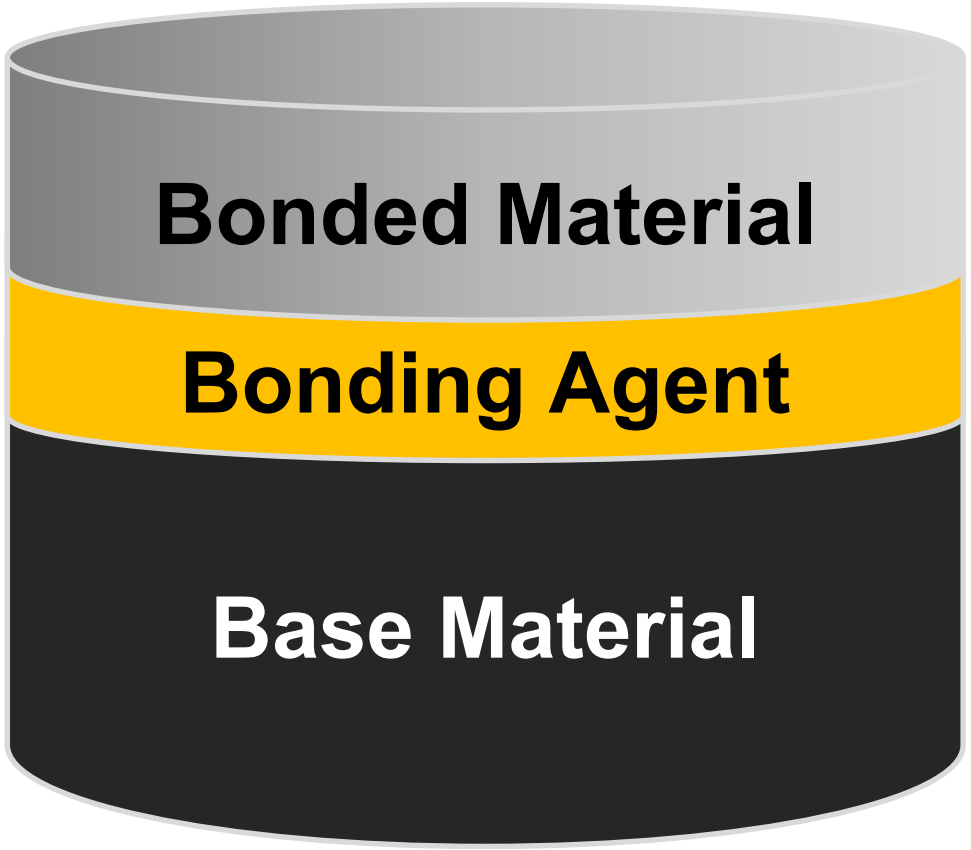


EXAMPLE "G"

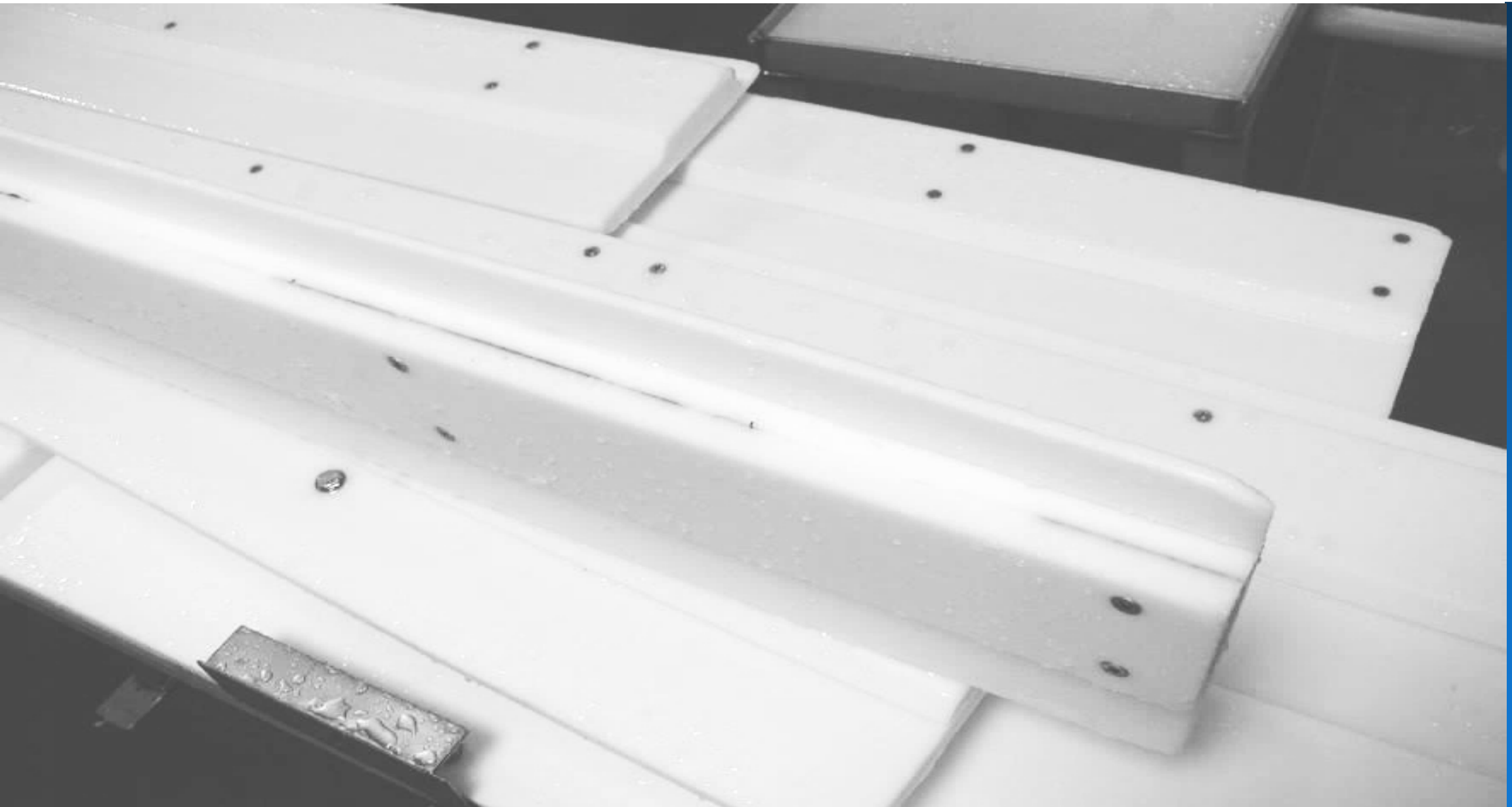
NOT ACCEPTABLE

Bonding – Permanent Joints

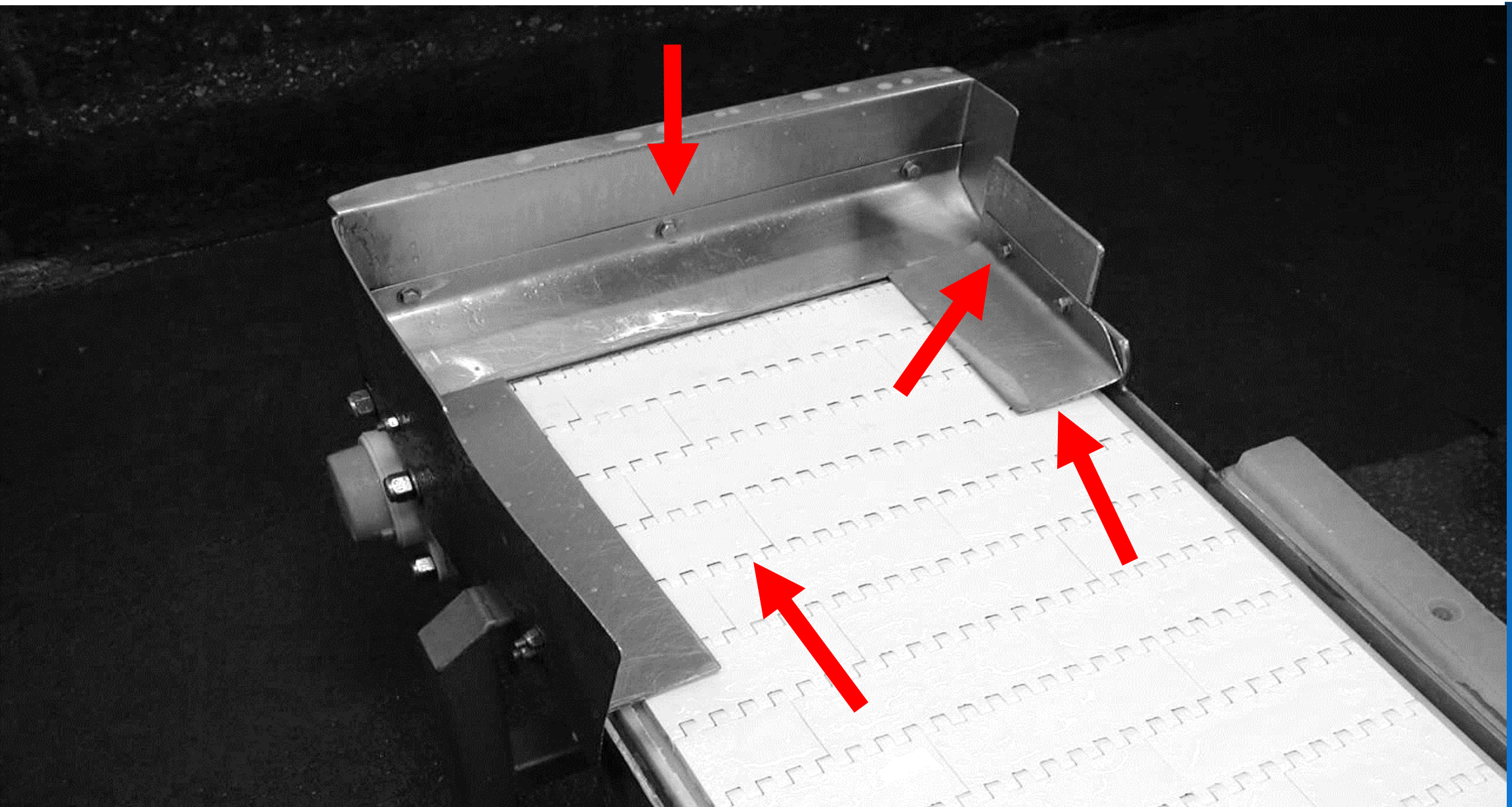
- When permitted by specific equipment 3-A Sanitary Standards or Accepted Practices
- Rubber and rubber-like materials, plastics, carbon, and ceramic seal components may be bonded
- Bond shall be continuous and mechanically sound
- Bonding material shall not separate from the base material



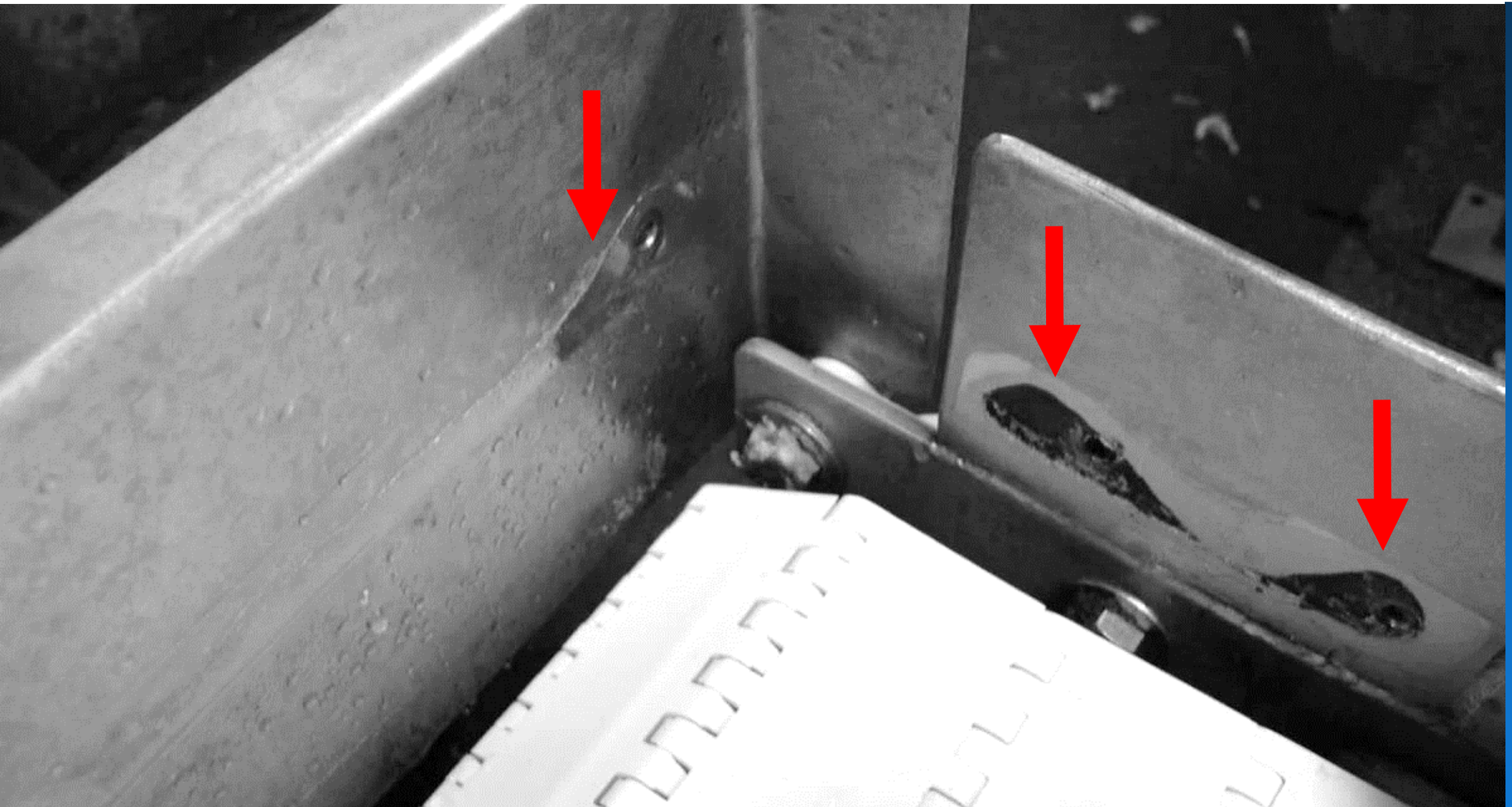
Bolted Joint Design – Hygienic Failure



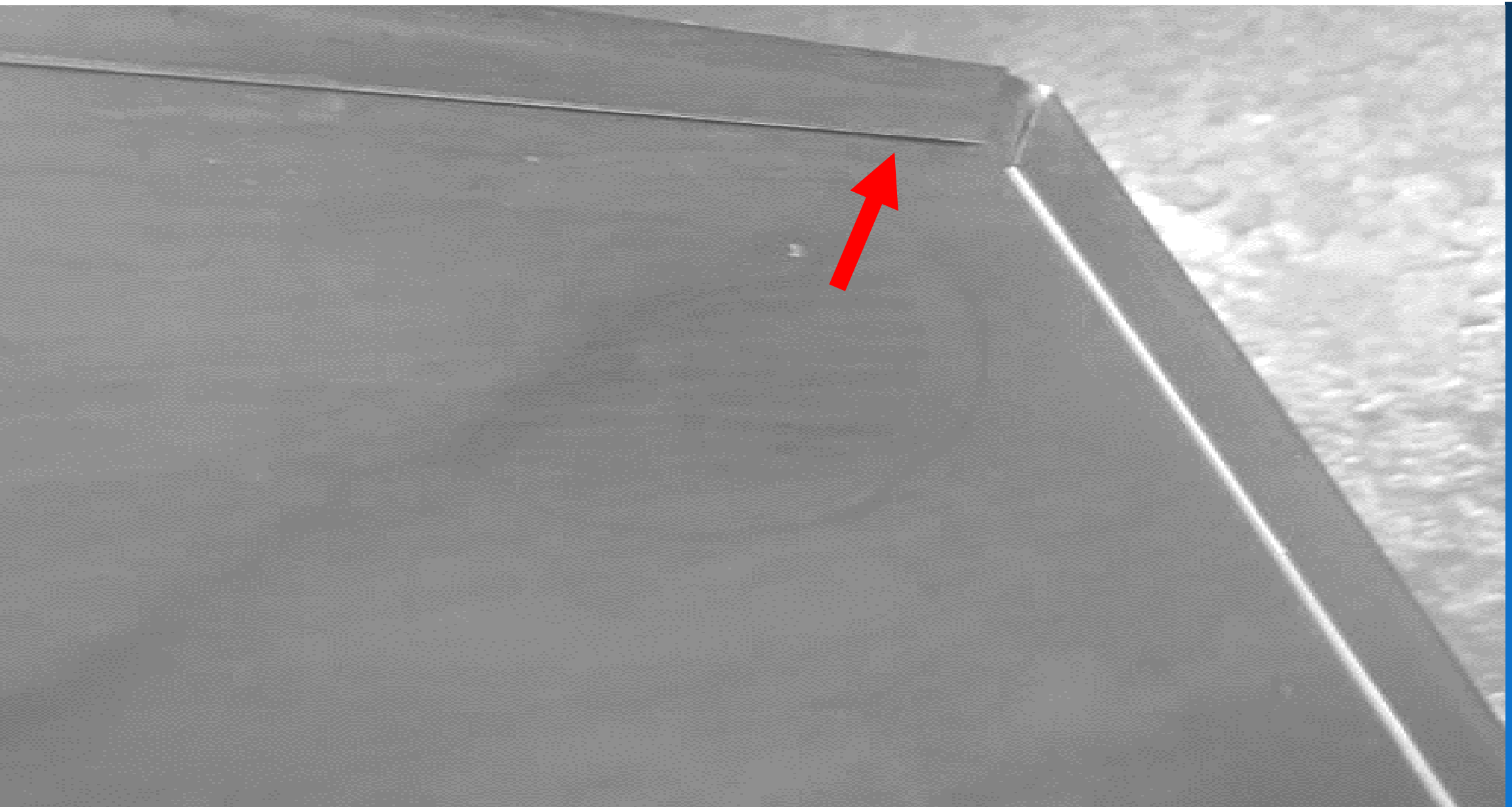
Bolted Joint Guard



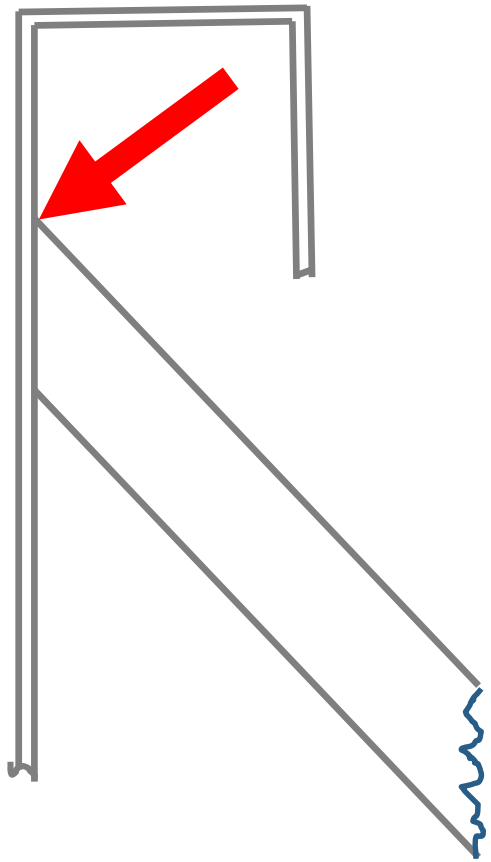
Plates Removed



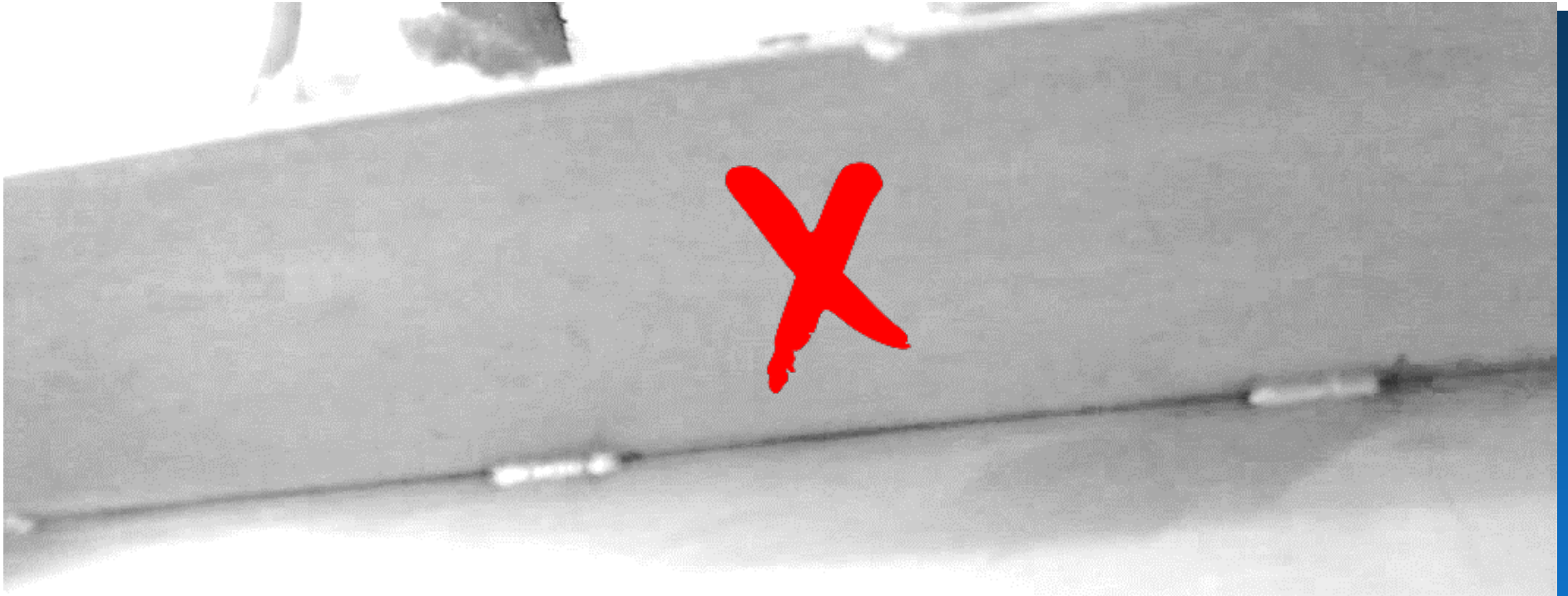
Crevice – Hygienic Failure



Inaccessible Joint for Welding Torch

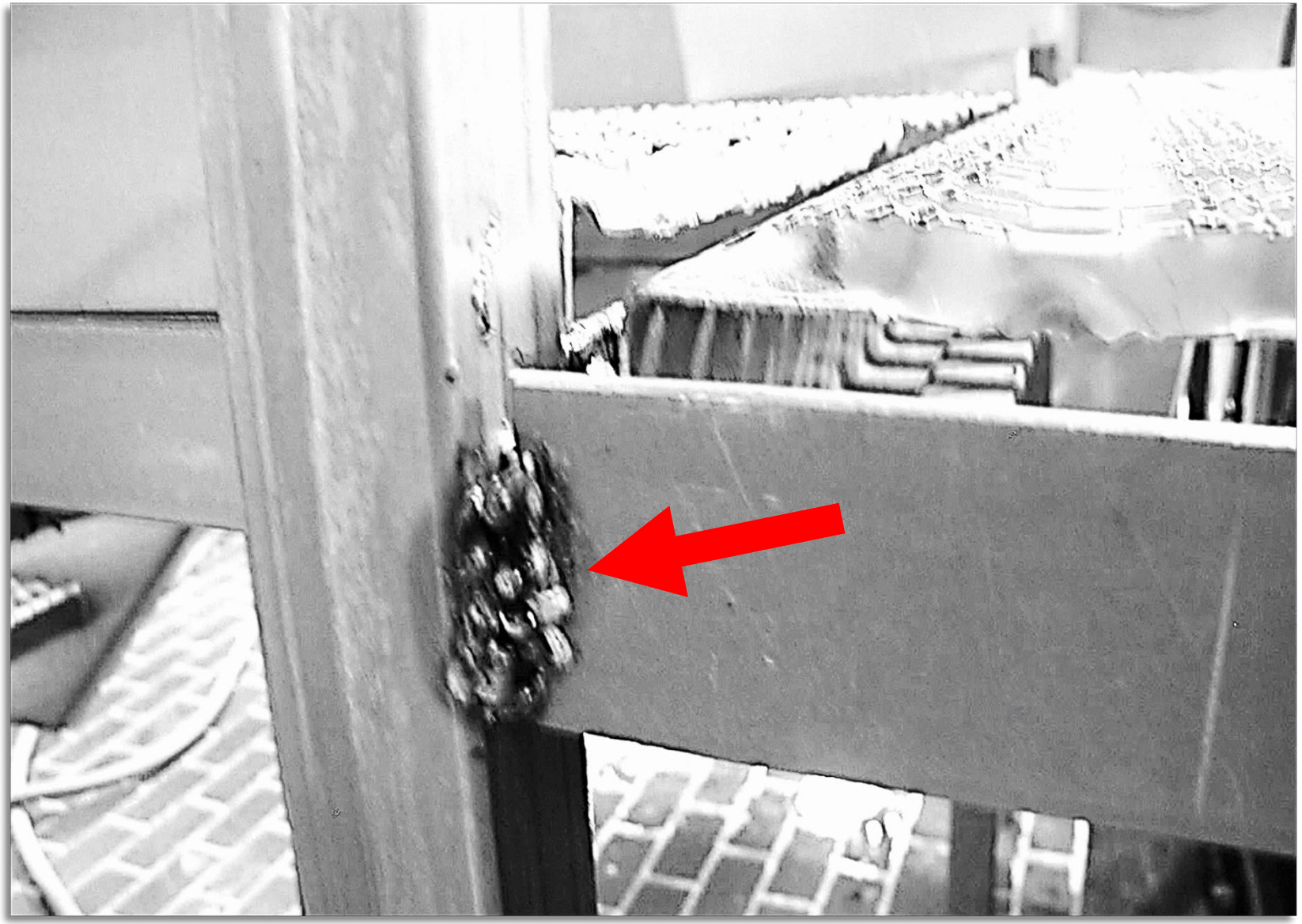


No Skip or Stich Welds



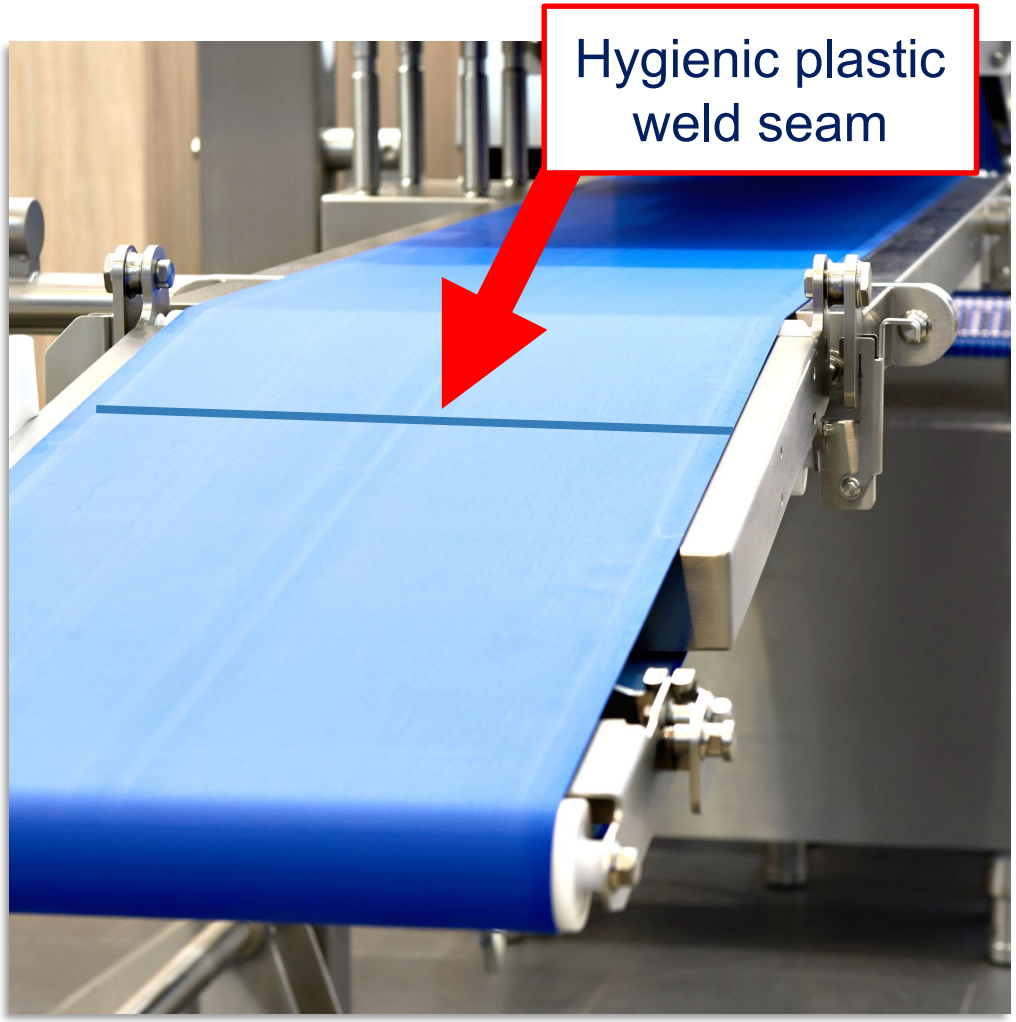
Weld Joint Hygienic Failure

Bad Weld Can Not be Cleaned



Thermoplastic – Permanent Joints

- Thermoplastics may be welded by heat, friction, solvents, or other suitable methods
- All joints shall be continuous and full penetration
- Joints interior and exterior shall be free of pits, folds, crevices, cracks, and misalignment
- Shall meet the requirements of ASTM Standard C1147-01

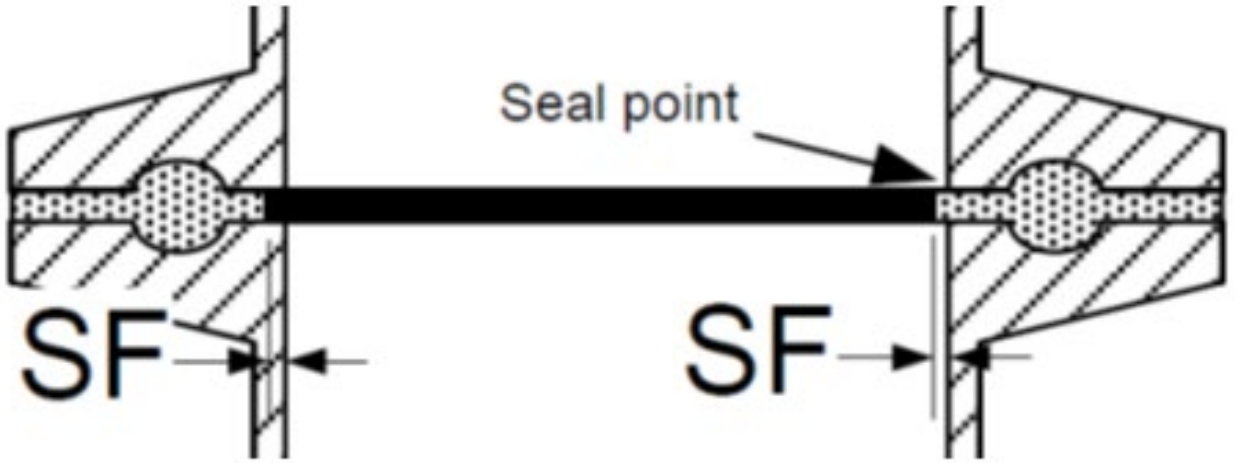


Mechanical Force Seals: Non-Permanent Joints

- When permitted by specific equipment 3-A Sanitary Standards or Accepted Practices
- Manufacturer should provide a field replacement procedure
- Validated procedure for tightness to prevent liquid penetration past the seal
- When the seal is removed, the surfaces behind the seal shall be easily cleanable and inspectable

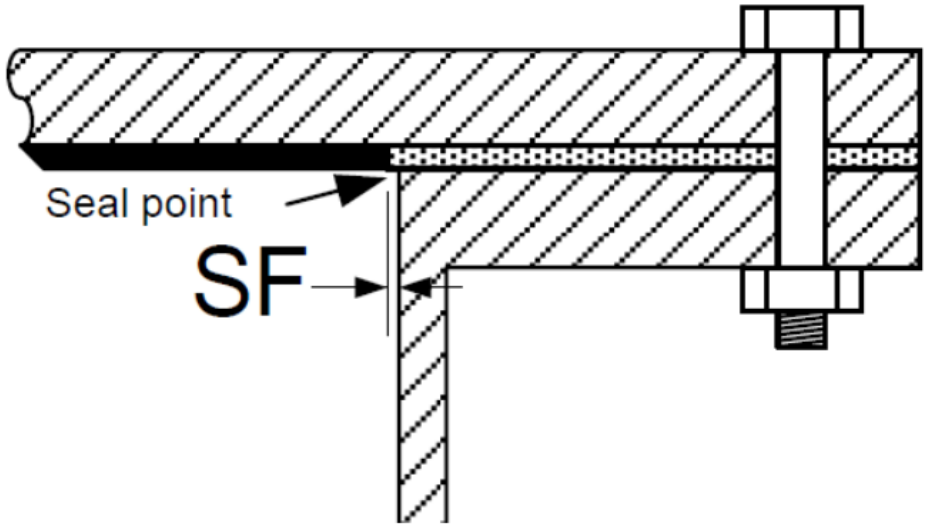
Gasketed Joints – Non-Permanent Joints

- Gasketed joints may be used for sanitary fittings and equipment components
- Interior of gasket groove shall be cleanable and inspectable when the gasket is removed



Flat Gasketed Joints – Non-Permanent Joints

- Flat gasketed joints intended for CIP cleaning shall form a substantially flush interior surface
- Substantially Flush (SF) = 1/32" (0.794 mm.) maximum

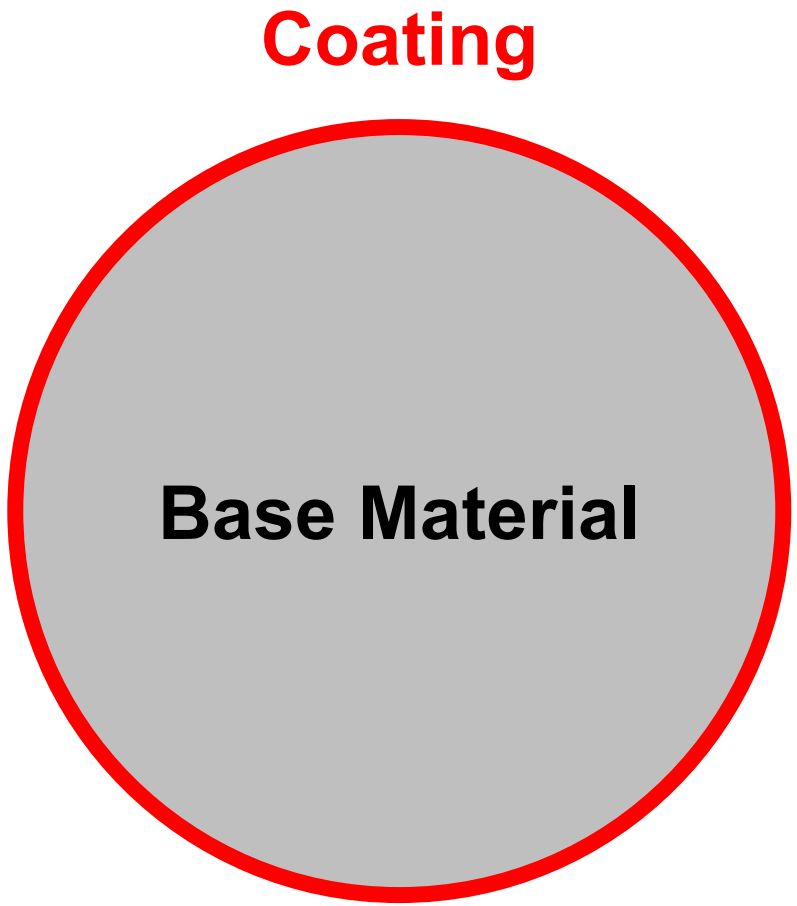


Seals in Series – Non-Permanent Joints

- Surfaces with seals in series between PCs and NPCS shall have a leakage pathway for CIP cleaning
- A minimum 1/8” (3.18 mm) diameter leakage pathway between seals shall be open to atmosphere and visually detectable
- Pathway shall be a minimum 1/8” (3.18 mm) diameter and located at the lowest point
- Leakage pathway is not required for COP cleaning

Coatings

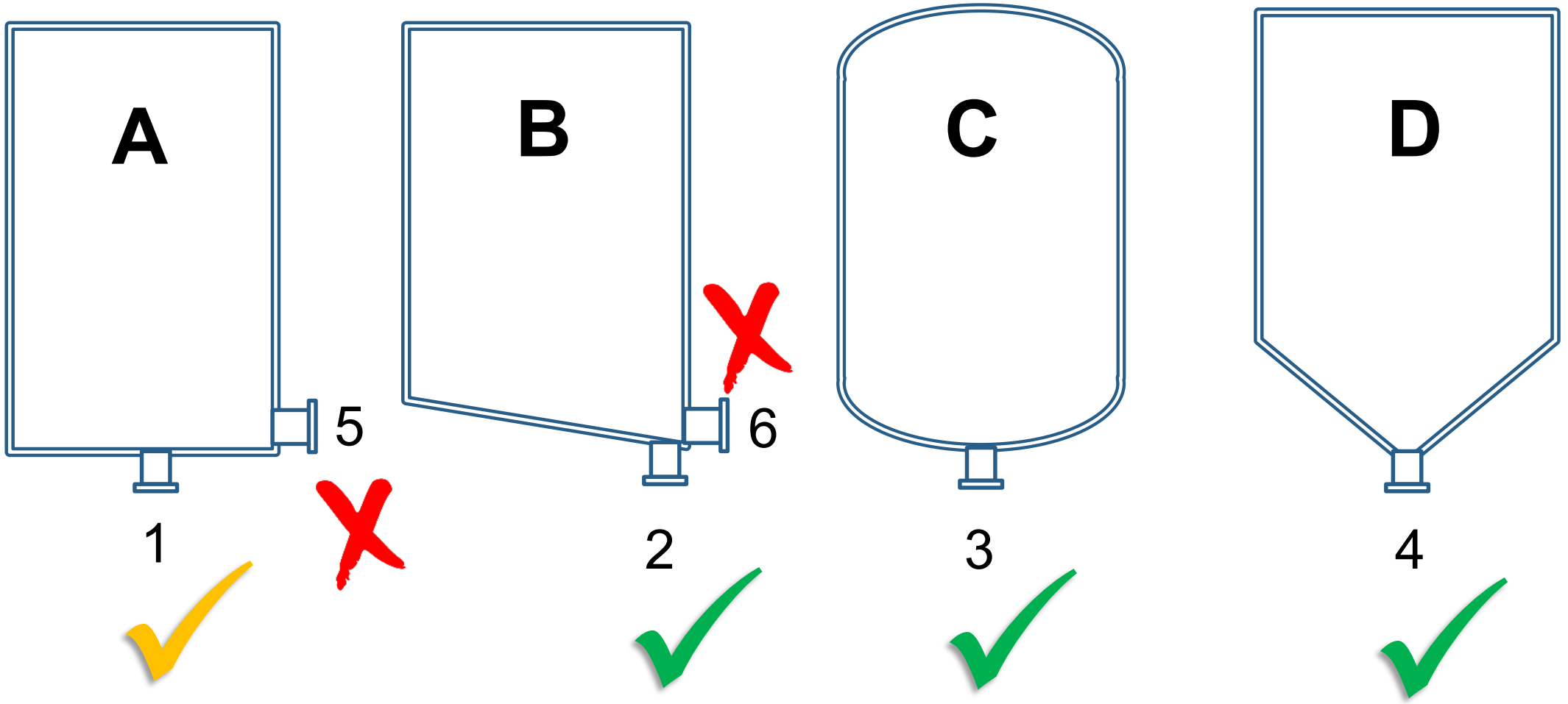
- Shall be continuous
- Free of delamination, pitting, flaking, spalling, blistering, and deformation
- Plating is a common coating for metal



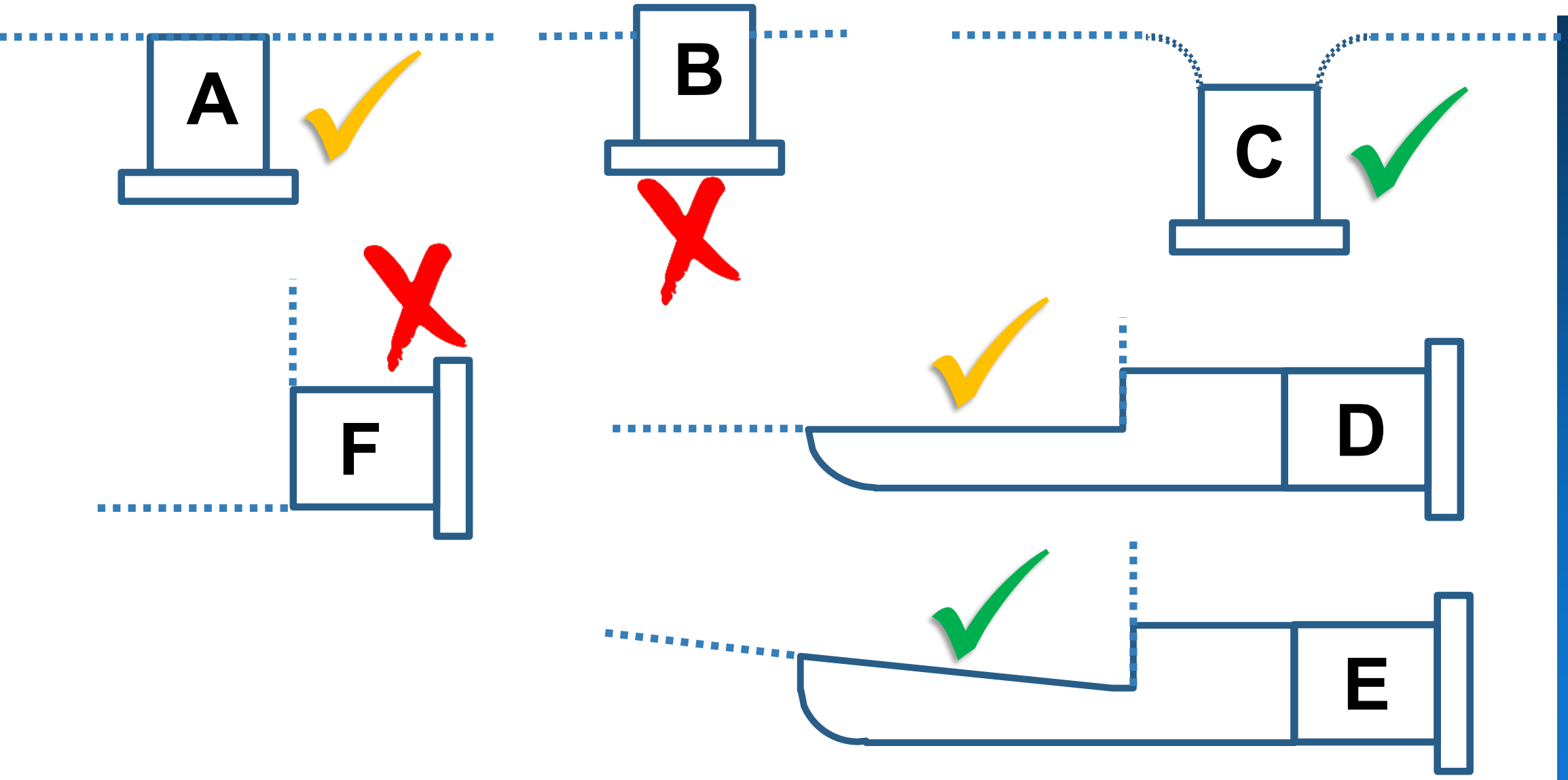
Draining

- All surfaces shall be self-draining except for typical clingage and adherence
- Solution contact surface shall be:
  - Drainable
  - Provided with sufficient drain point

Tank Drainage



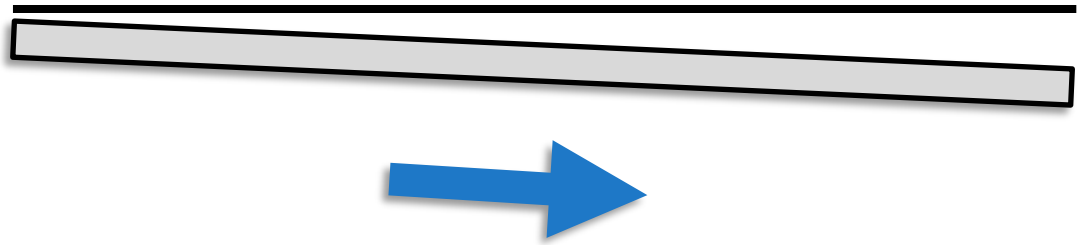
Tank Drainage Outlet Ports



Drainage of Flat Bottom Tanks & Silos

- Flat bottom tanks and silos shall slope ¾ in per ft. (63 mm. per m.)
- Flat bottoms shall be constructed so that they will not sag, buckle, or prevent complete drainage

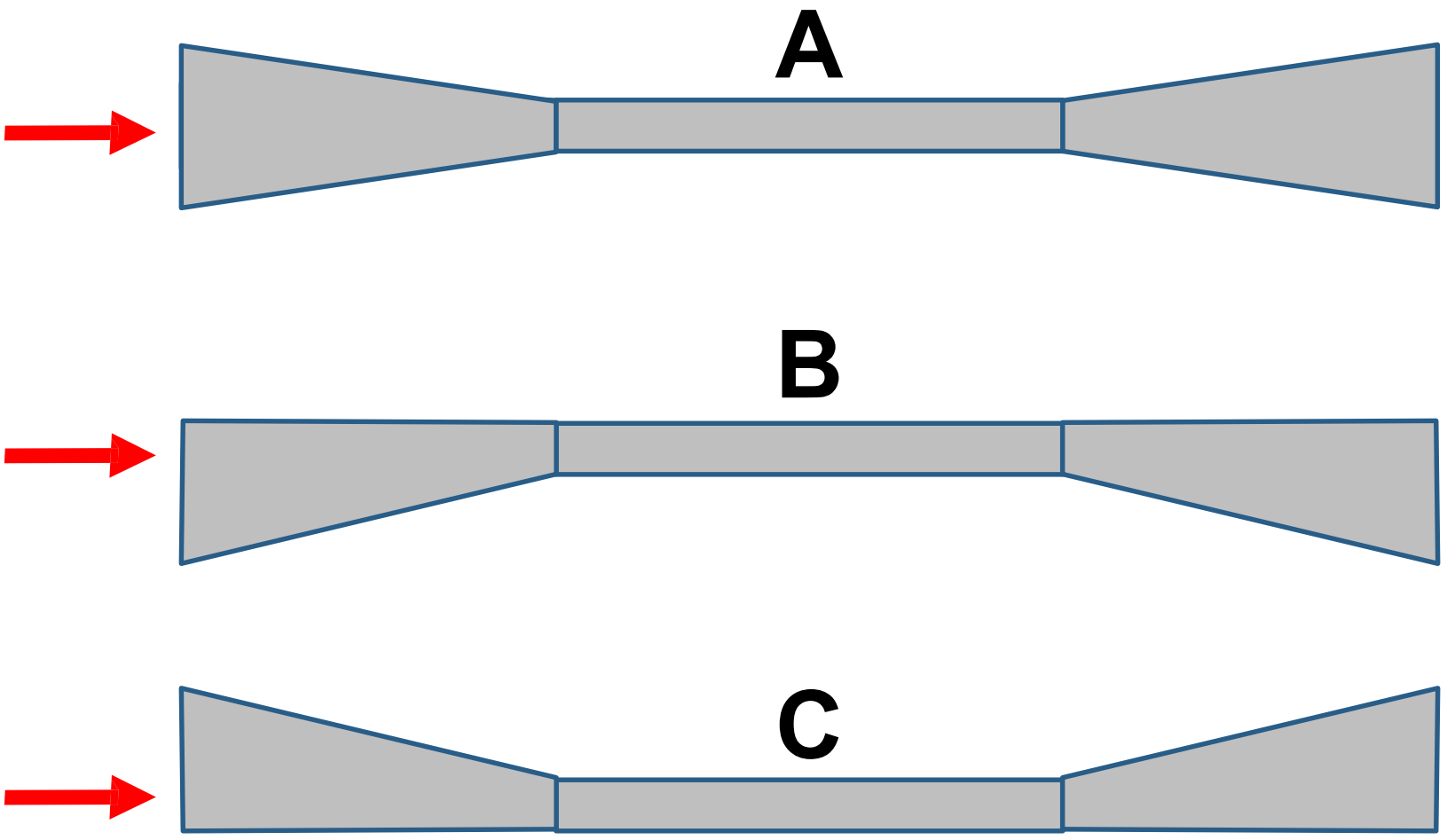
Product Tubing Slope



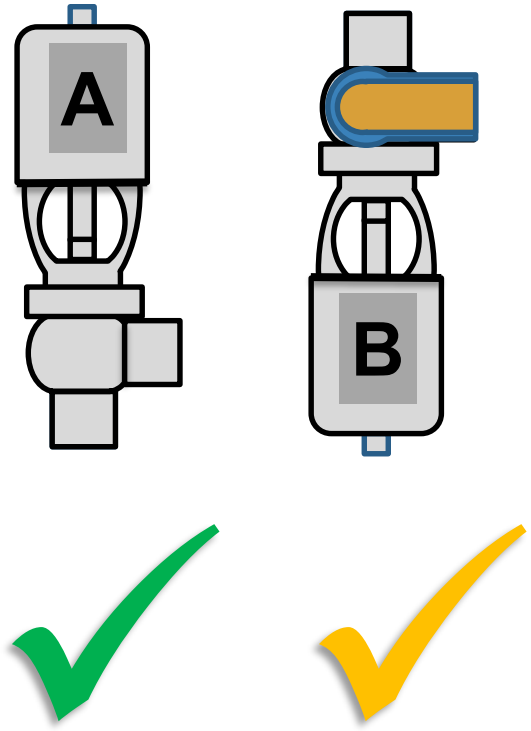
Minimum Slope

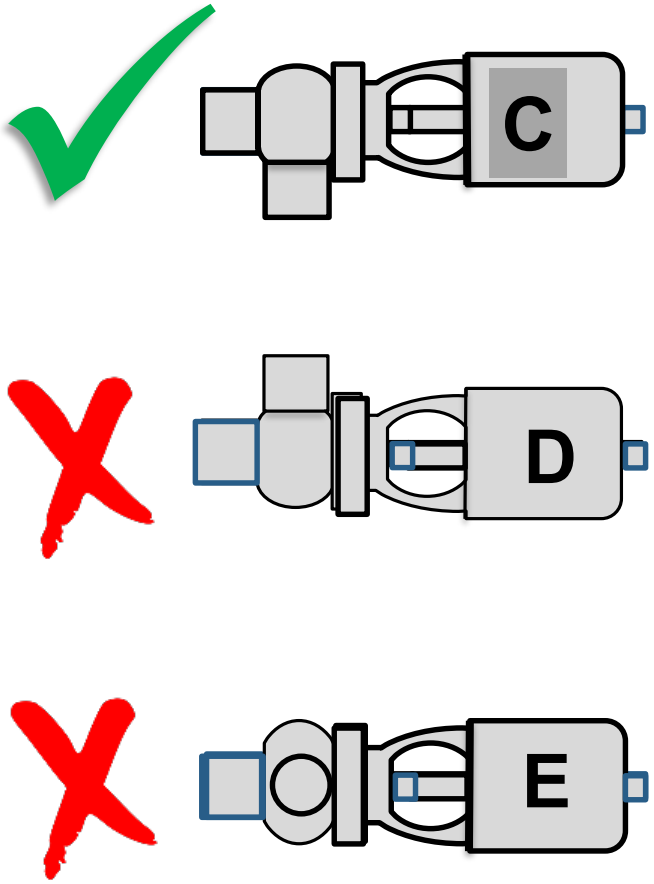
1/8 in./ft. (10.43 mm./m.)

Concentric vs. Eccentric Reducer Draining

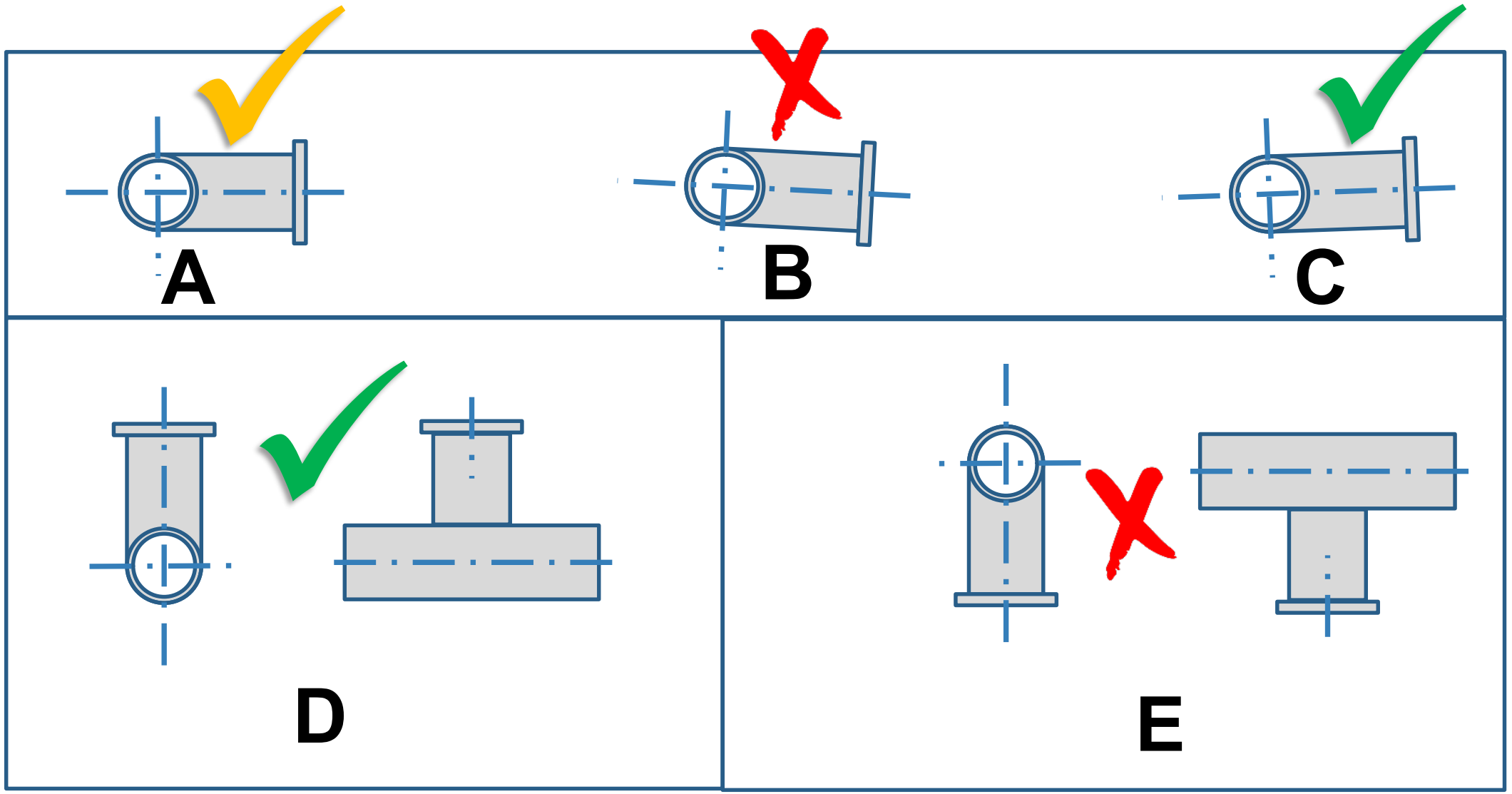


Valve Body Draining





Tee Position Drainage



Drain Pan Failure

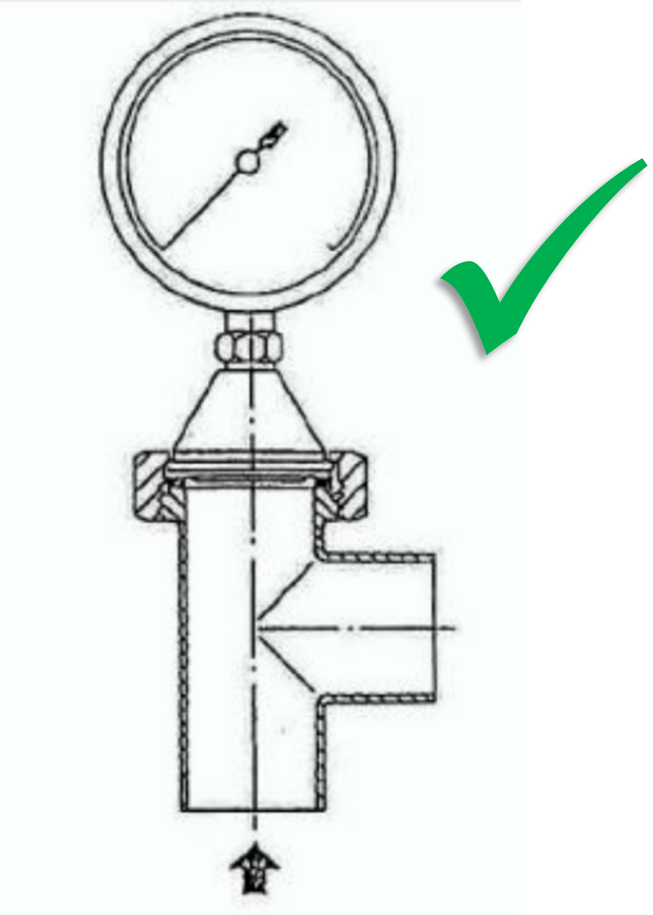
Pooling Water on Top of Cabinet

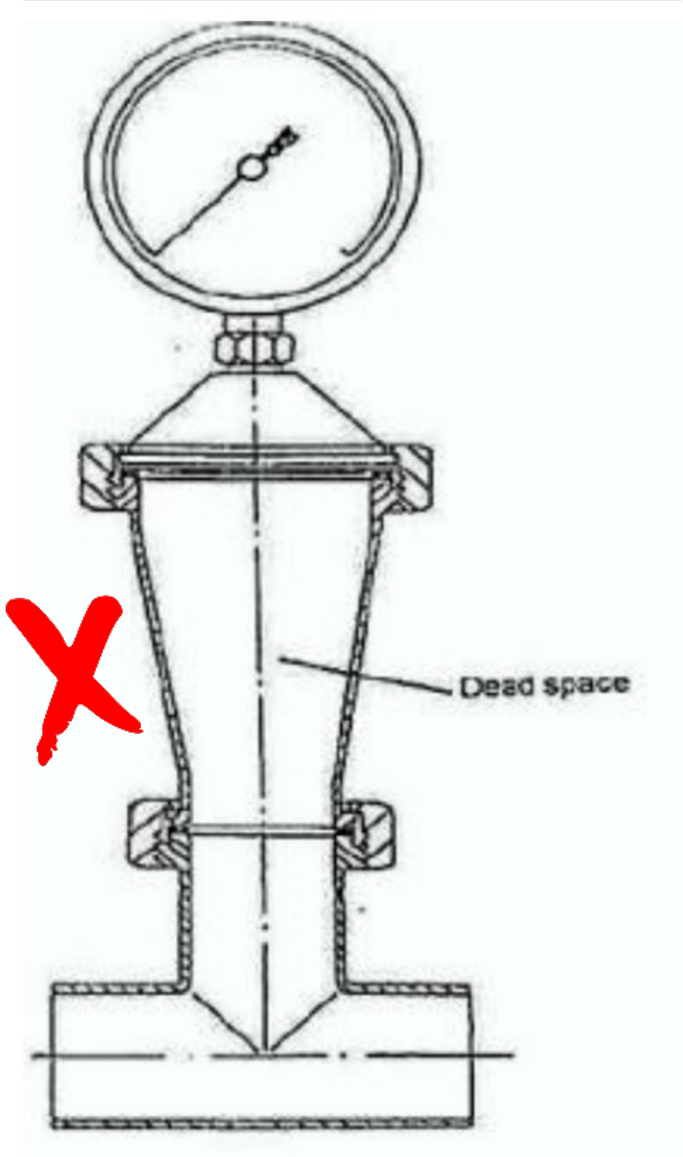
Recommend slope:
¾ in./ft. (63 mm./m.)

Dead Legs/Hollows/ Blind Spots

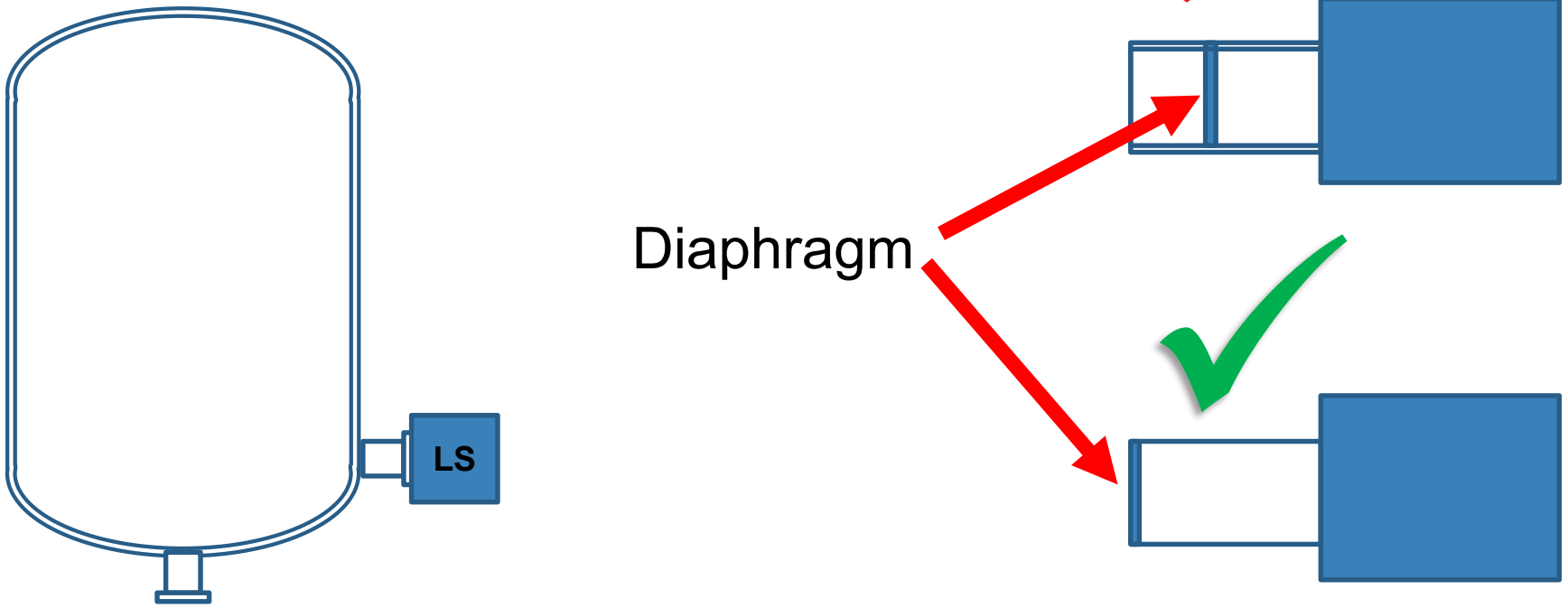
- Avoid:
  - Dead legs in hollows that may not be cleaned
  - Hollow rollers that create niches
  - Blinds spot that are hard to reach, clean, and inspect
  - Unwelded hollow frames
- Hollow components, when used, must be hermetically sealed

Dead Leg Example

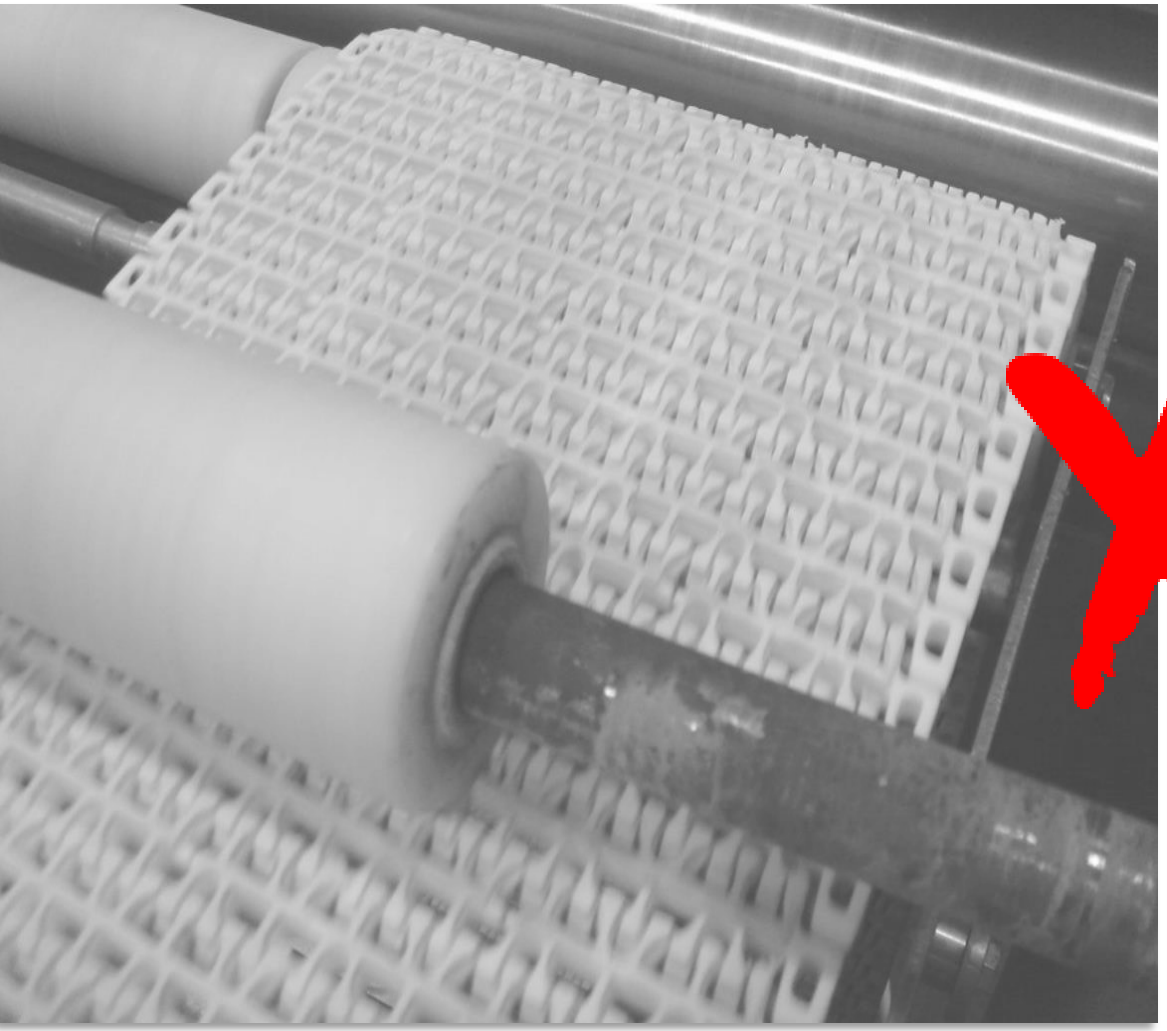




Dead Leg Example
Level Sensor on Tube

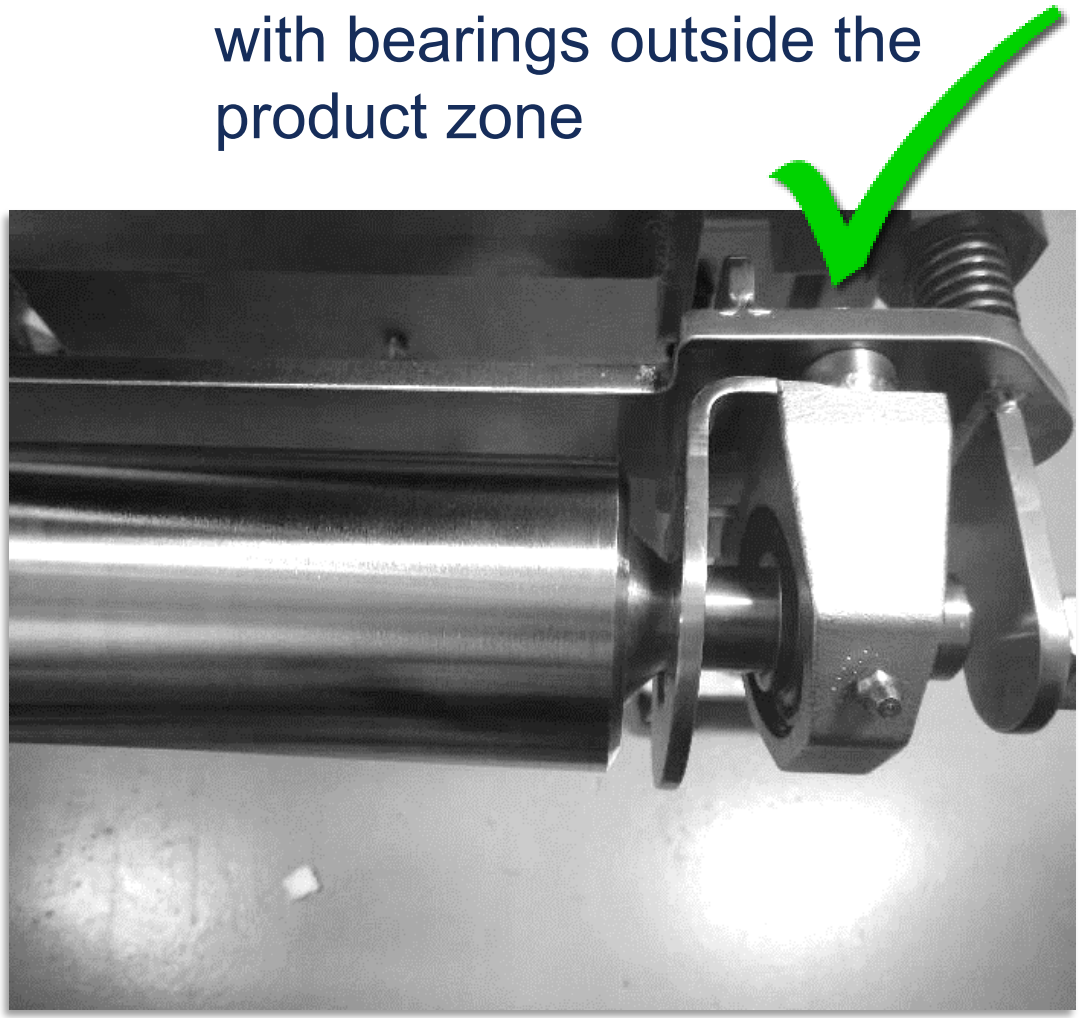


Hollow Roller Failure

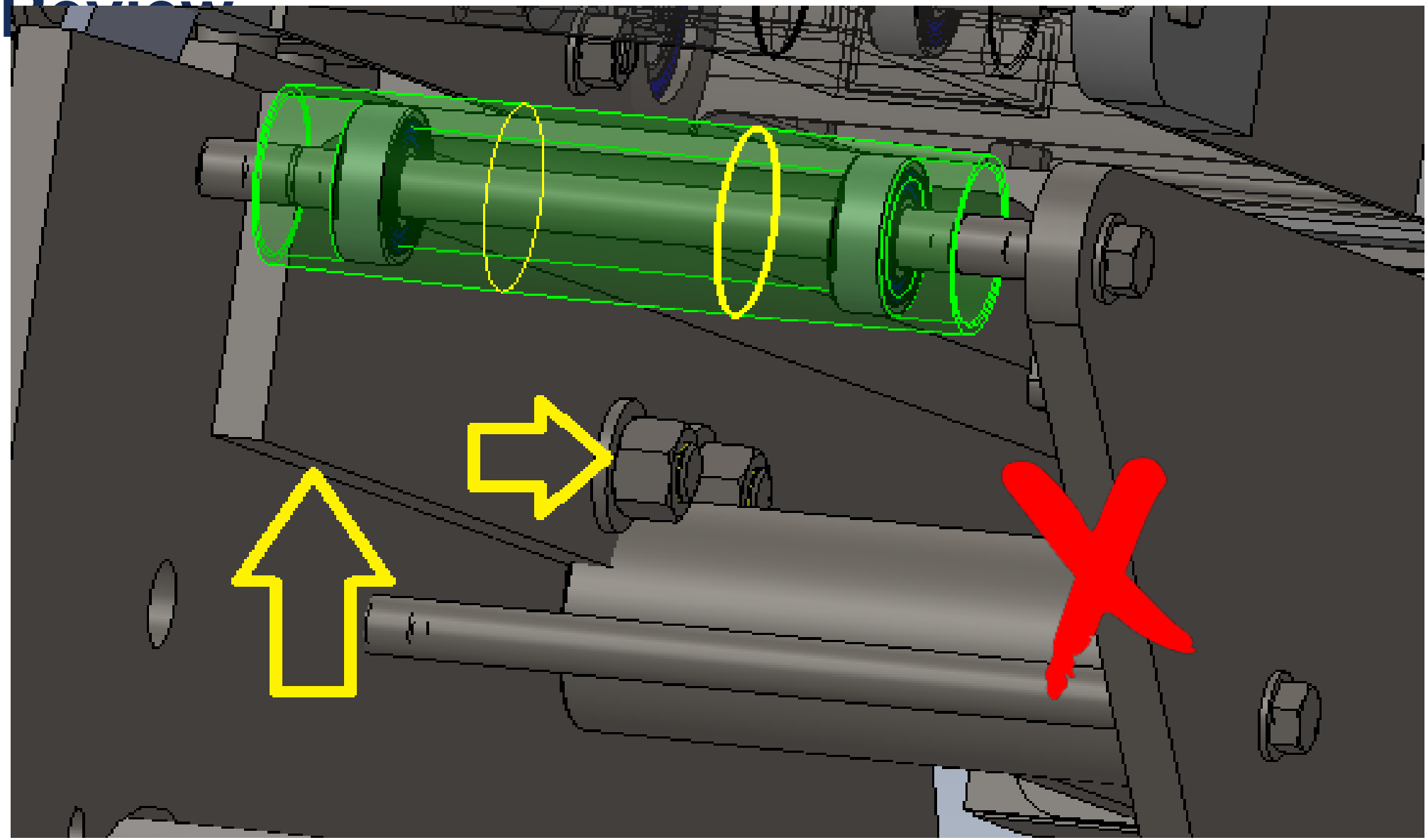


Hollow Rollers

- All rollers should be solid with bearings outside the product zone

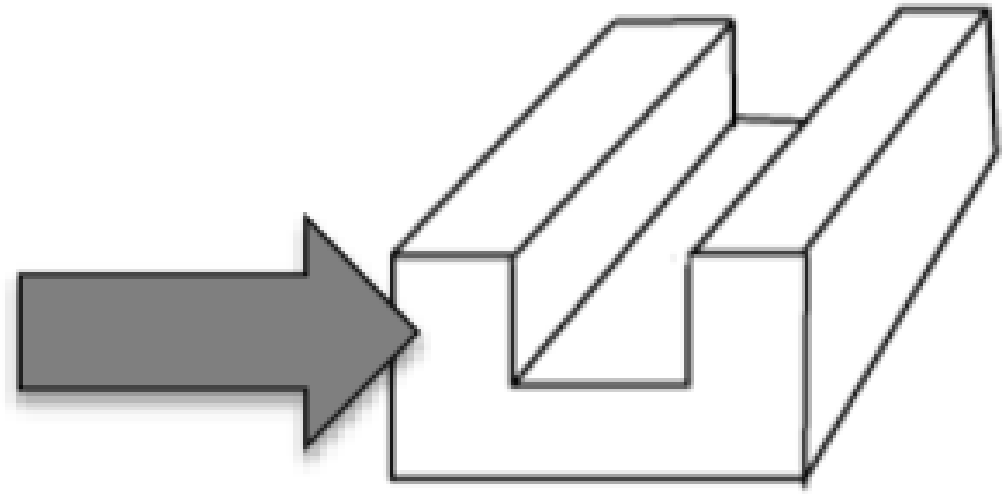


Hollow Roller Identified During Design Review



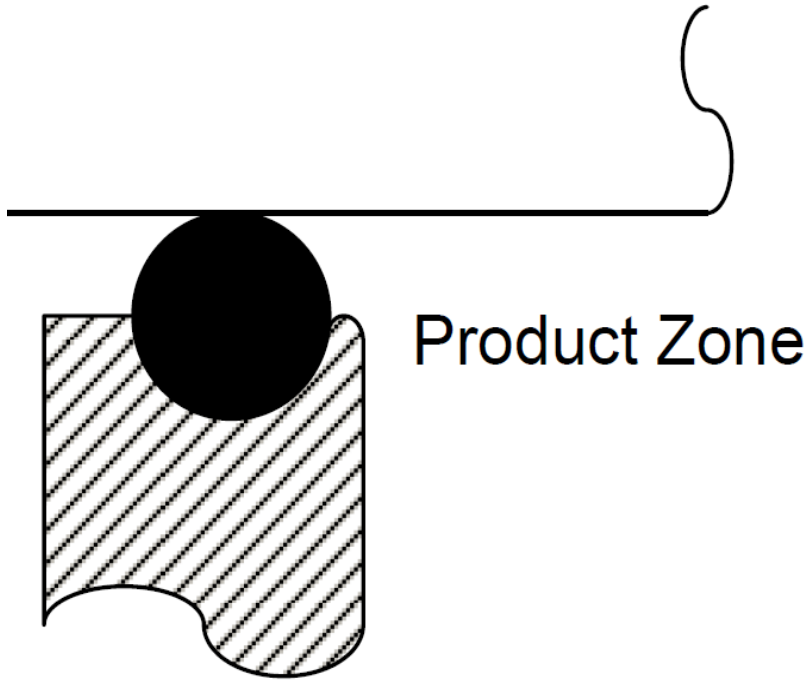
Gasket Retaining Grooves

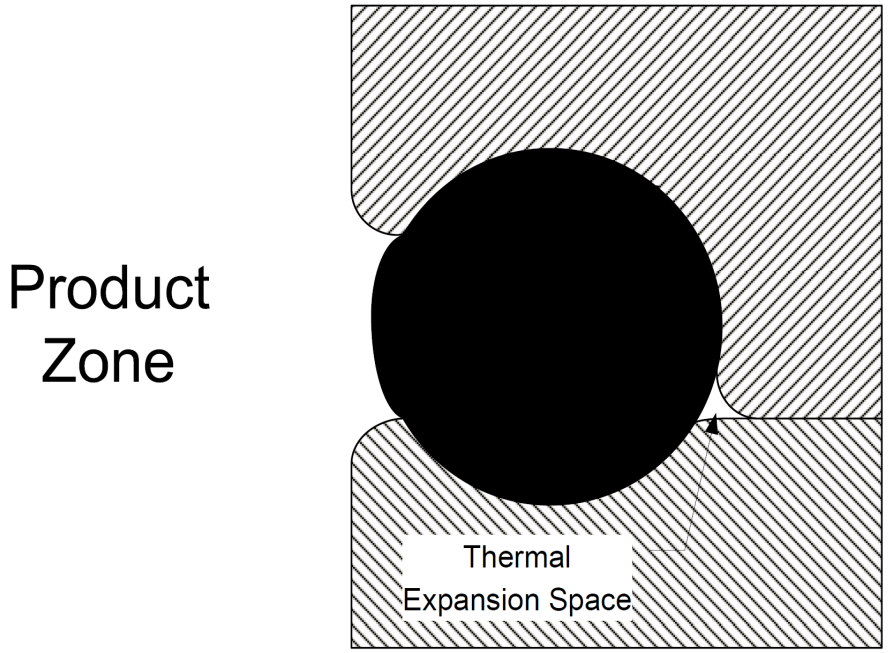
- Grooves in gaskets shall be no deeper than their width unless, they can be inverted for cleaning
- Gasket retaining grooves for removable gaskets shall not exceed ¼” in depth or be less than ¼” wide



Gaskets & O-Rings

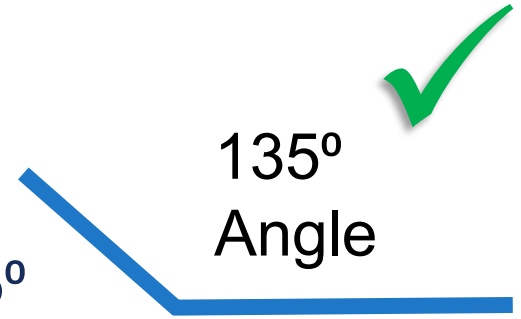
- → Removable or bonded
- → Groves no deeper than the width unless removable
- → Reference 3-A charts for groove radii

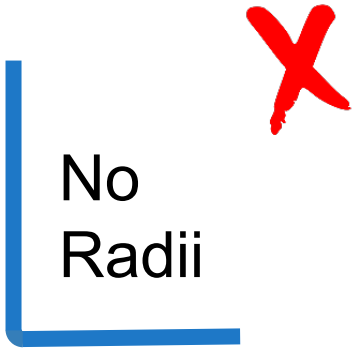


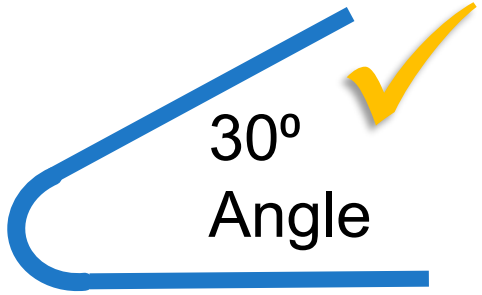


Radii

- PCS radii are required for all internal angles less than 135º
- All angles less than 135º shall have radii of at least ¼”(3.16 mm.)
- Exceptions for smaller radii are permitted in some 3-A Standards
- Some 3-A Standards require larger radii
- Exception for gaskets and O-ring groves
- Large radii are easier to clean

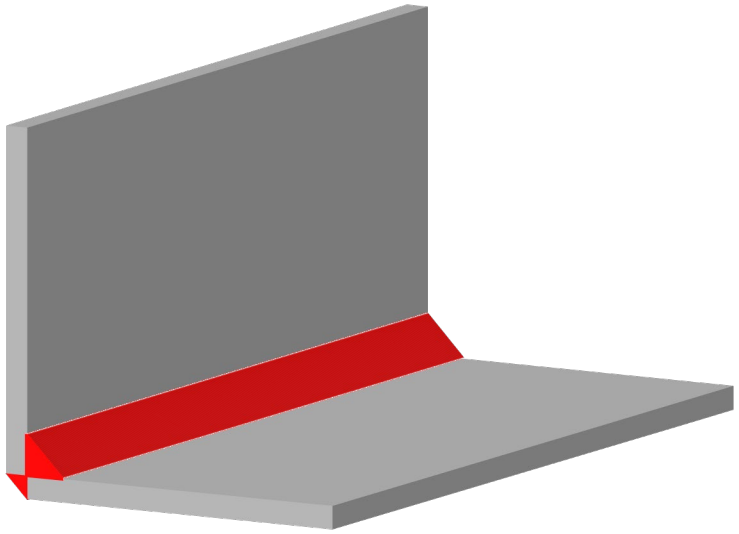




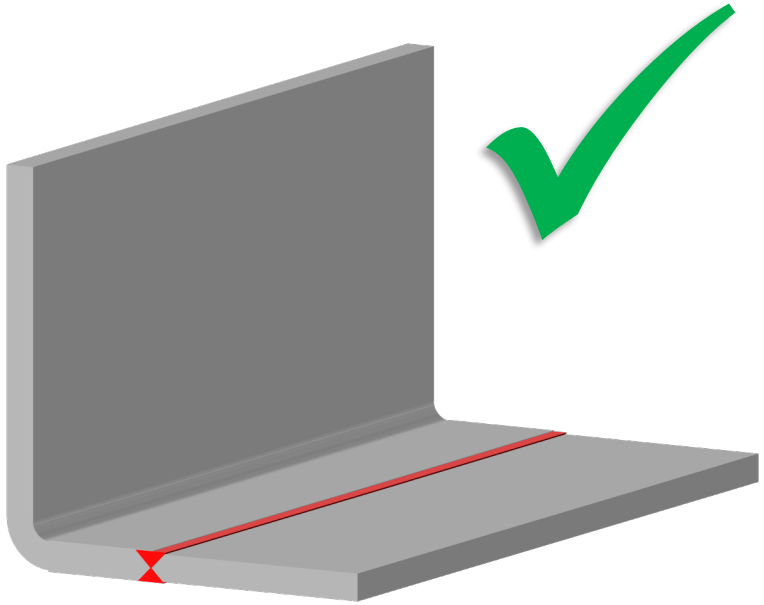


Which is easier to fit and weld?

Which is easier to grind and polish? Radii?

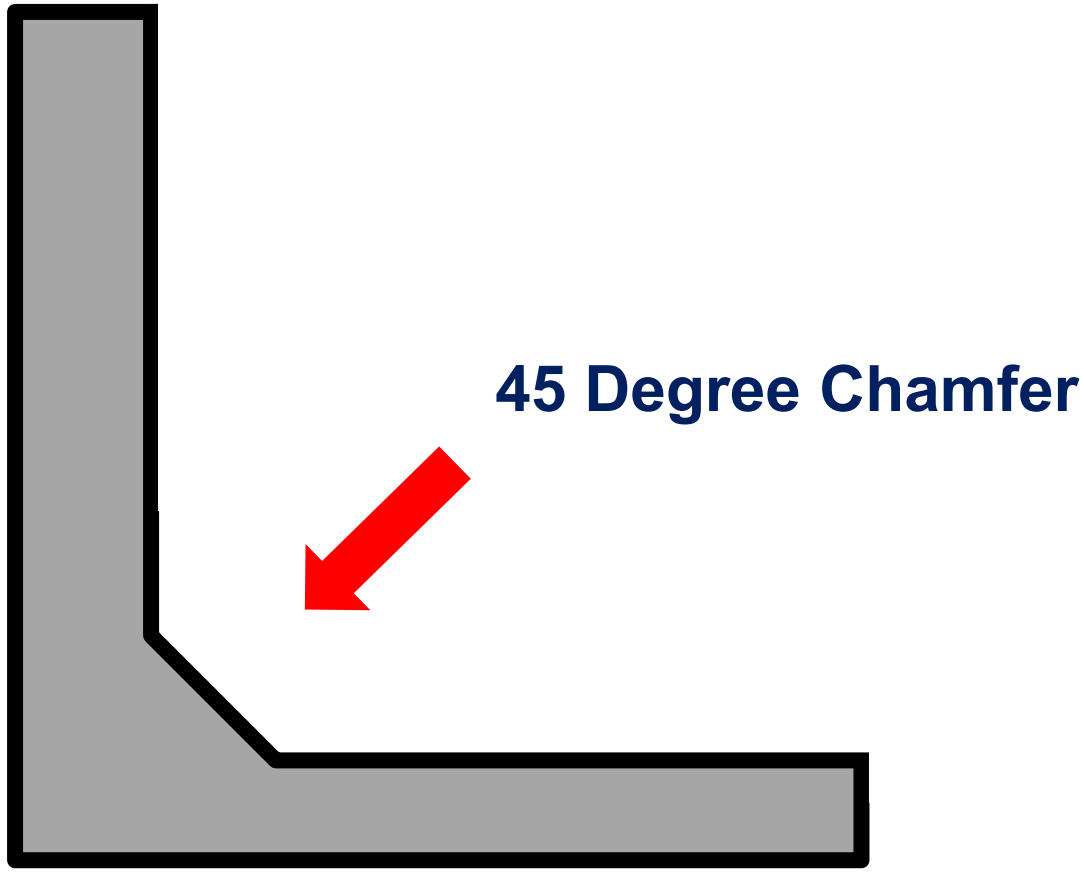


A



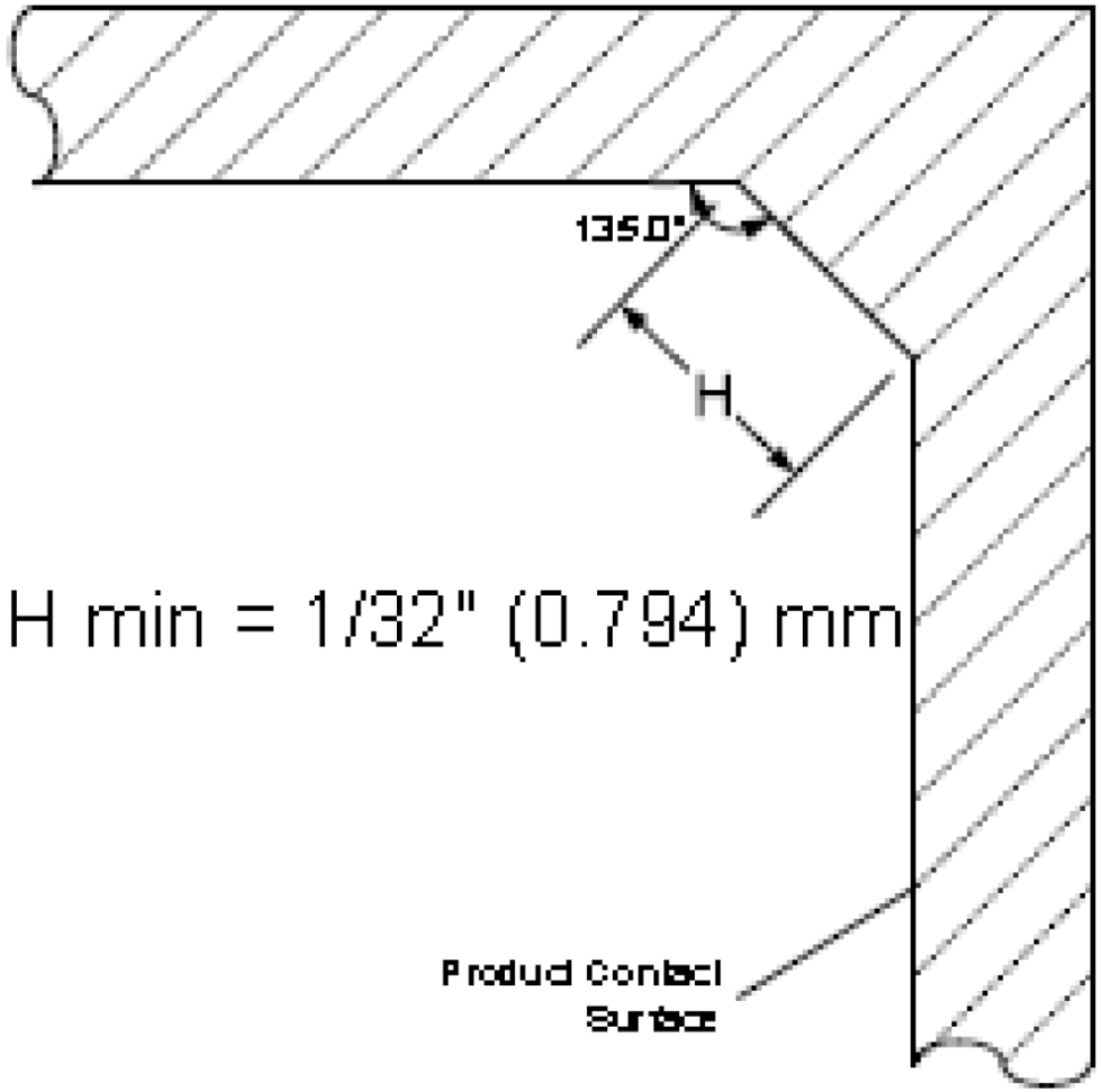
B

Is a Radius Required?



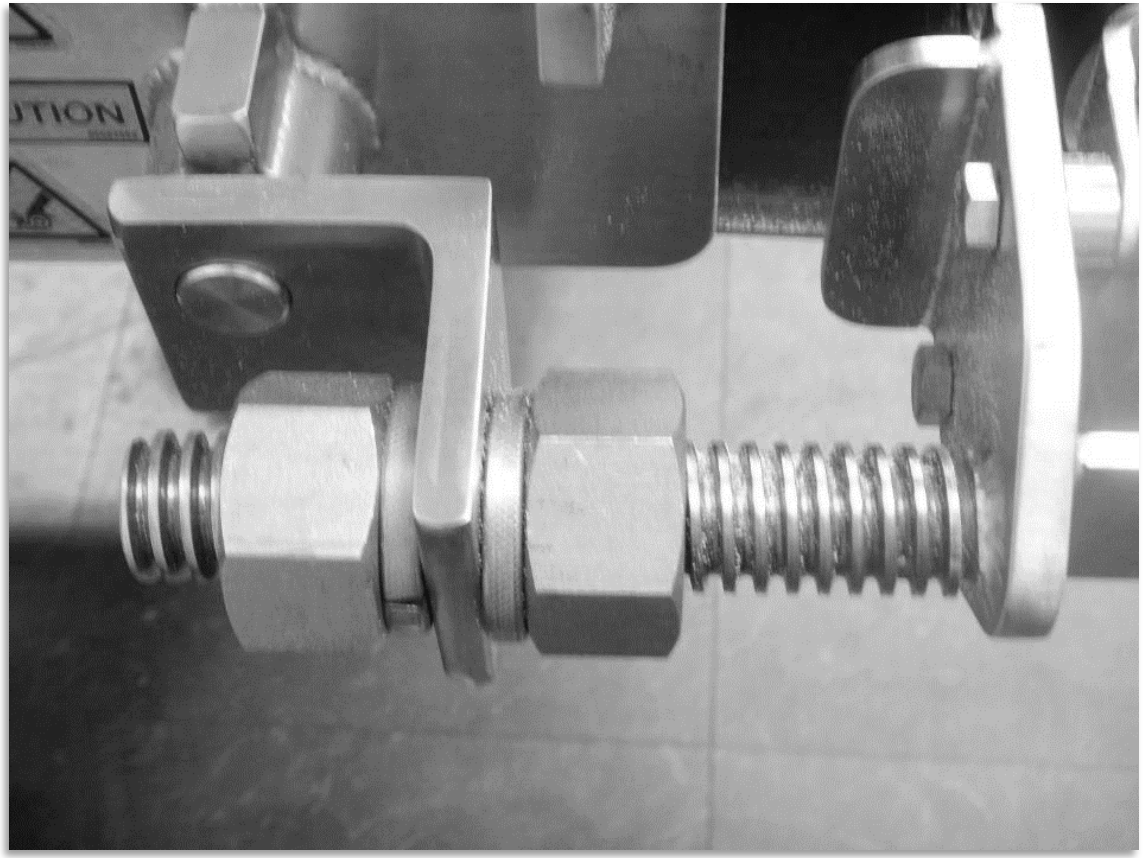
Chamfer Corner Requirements

- Machined components
- For angles between 90° and 135°



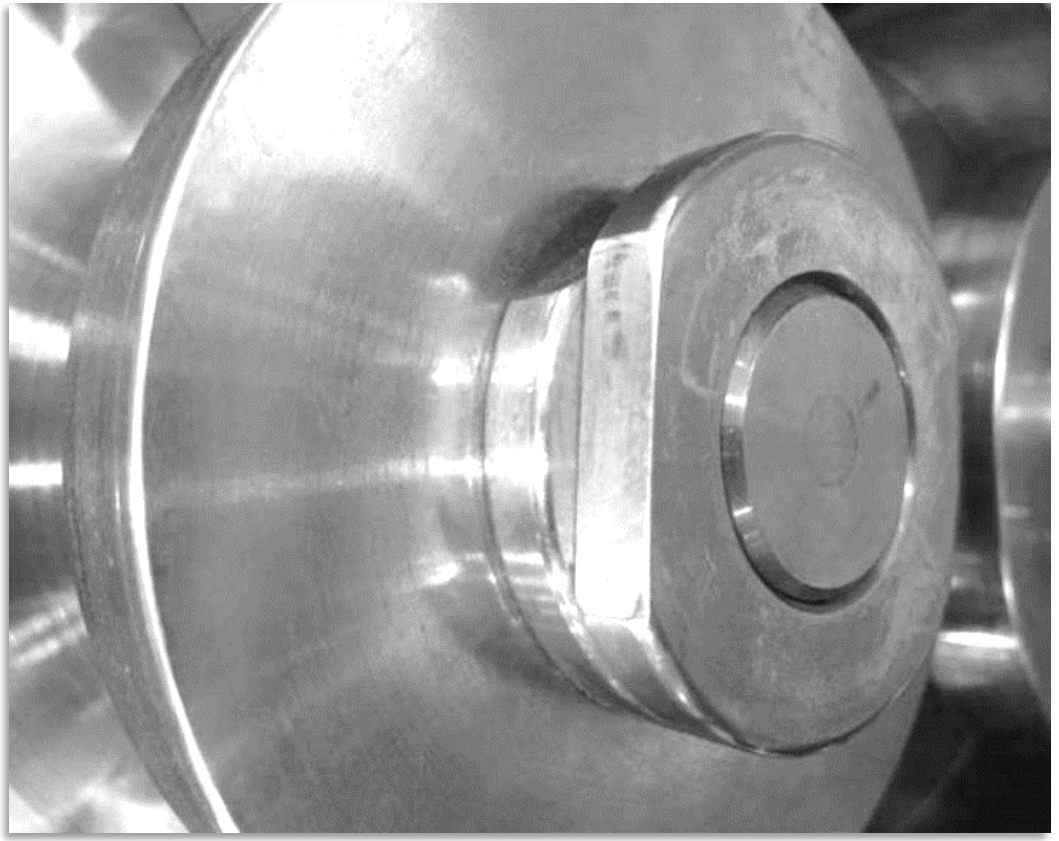
Exposed Sanitary Threads NPCS

- Sanitary designs:
  - ACME
  - Trapezoid DIN 103
  - Knuckle DIN 405
- Manual Cleaning



Exposed Threads – PCS

- Exposed threads – when permitted by 3-A Standards
  - ACME
  - Trapezoid DIN 103
  - Knuckle DIN 405
- Manual Cleaning

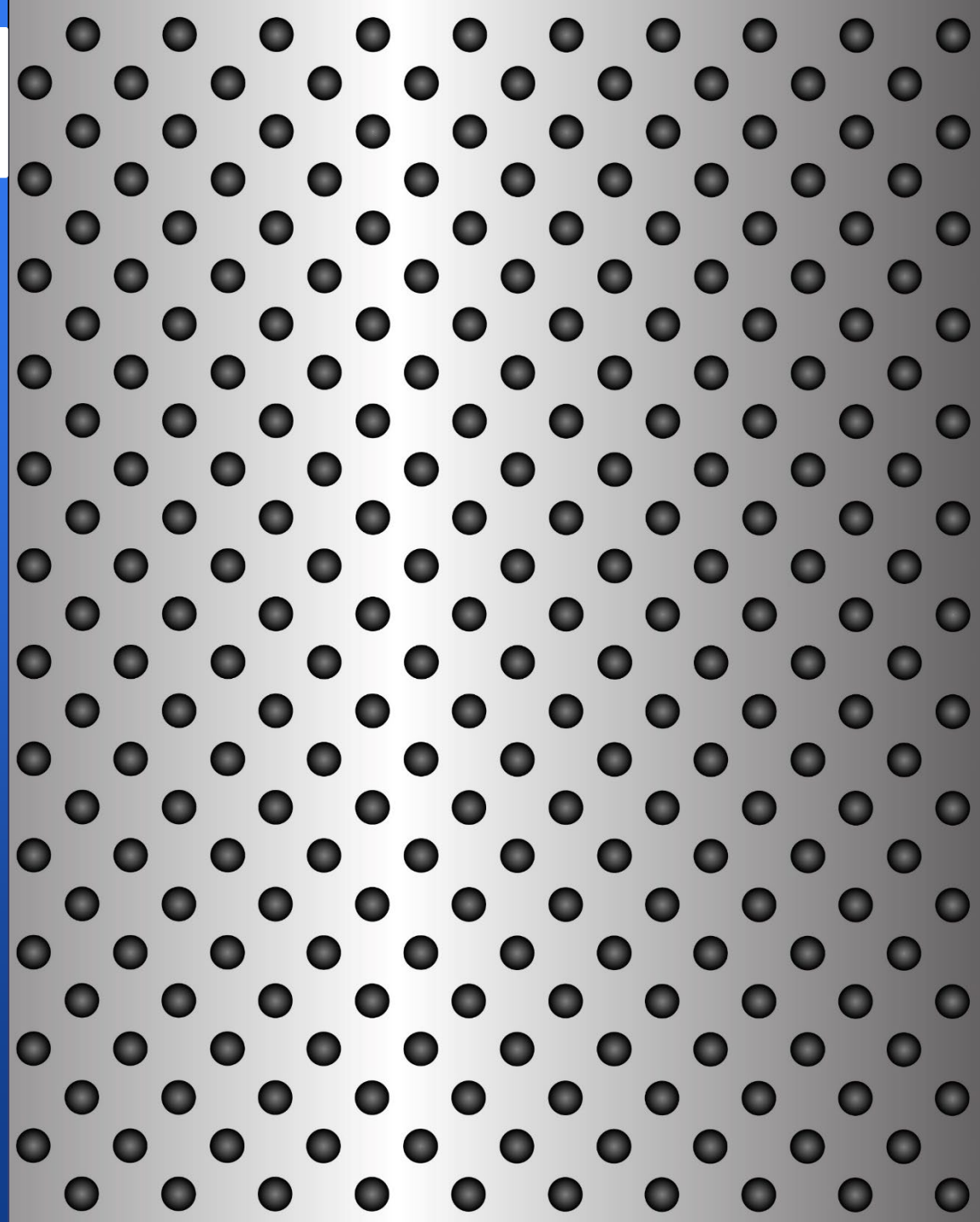


Enclosed Threads – PCS

- When permitted by 3-A Standards
- Designed for CIP
- Isolated by an O-ring or a gasket
- Seal-controlled compression by a positive stop
- Tightness shall be validated by the EHEDG Guideline 2 or an equivalent method

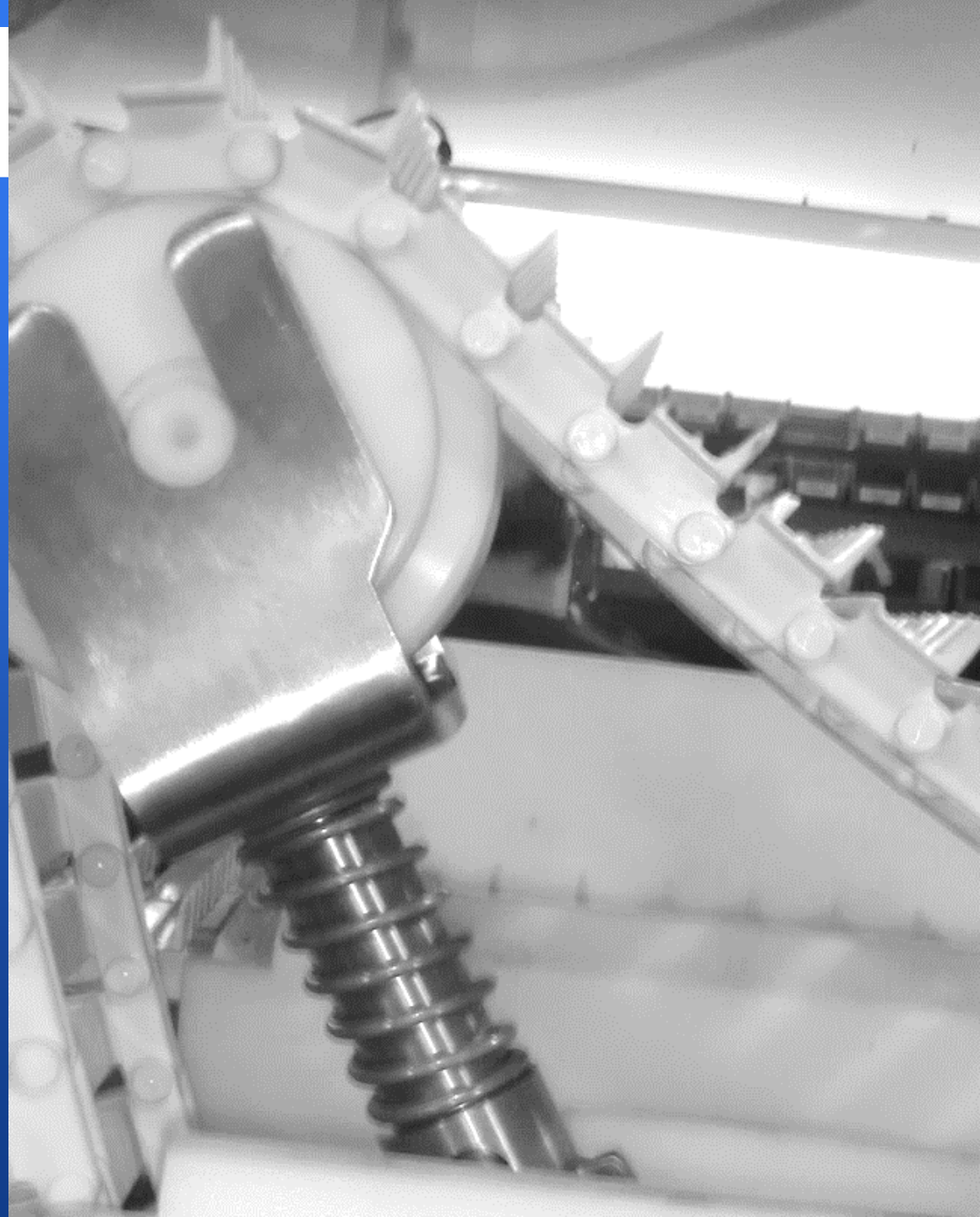
Perforated Surface

- Holes may be round, square, rectangular, or crescent shaped
- Round holes shall be at least 1/32”(0.794 mm.) in diameter
- Reference General Requirements for un-round shape dimension
- All perforations shall be free of burrs



Coil Springs

- **PCS Springs – 3-A requirements**
  - Round cross-sections
  - No flat ends for CIP applications
  - 1/32” min. space between coils under compression
  - 3/32”min. space between coils in relaxed condition for a spring with 1” outside diameter or less
- **NPCS Springs – no 3-A requirements**
  - Recommend using PCS requirement



Spring Design

Shafts

- In PCS above product level:
  - Shall prevent entrance of contaminants through opening surrounding the shaft
- In PCS below product level:
  - Shall be fitted with a sanitary seal
- Shaft keys and keyways shall not be used to drive pulleys and sprockets
- Pulleys and sprockets in PCS shall be welded to the shaft

Bearings

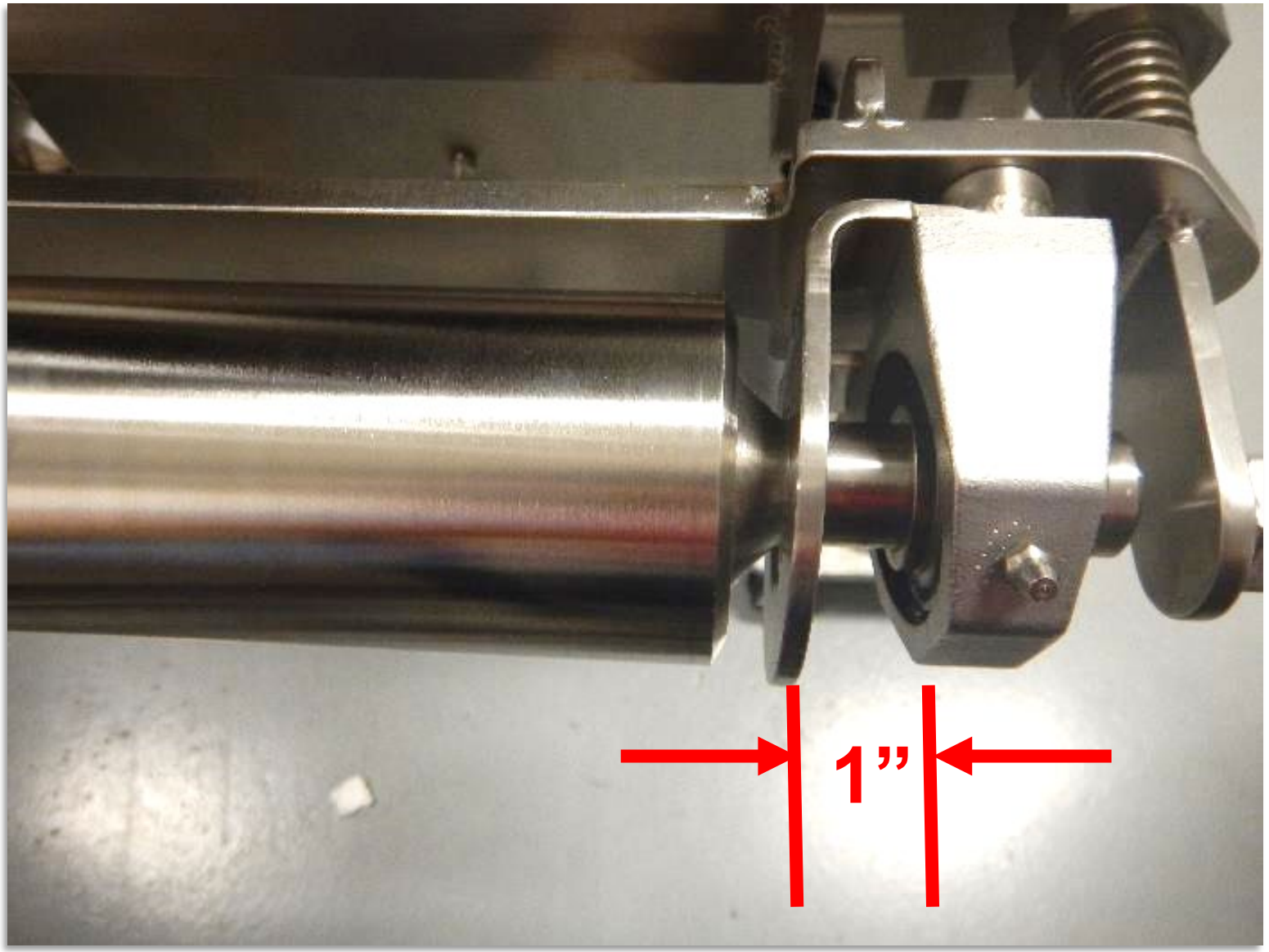
In Product Contact Zone:

- → Bearing is non-lubricated
- → Or product lubricated
- → Example is an agitator support bearing in product

Outside of Product Zone:

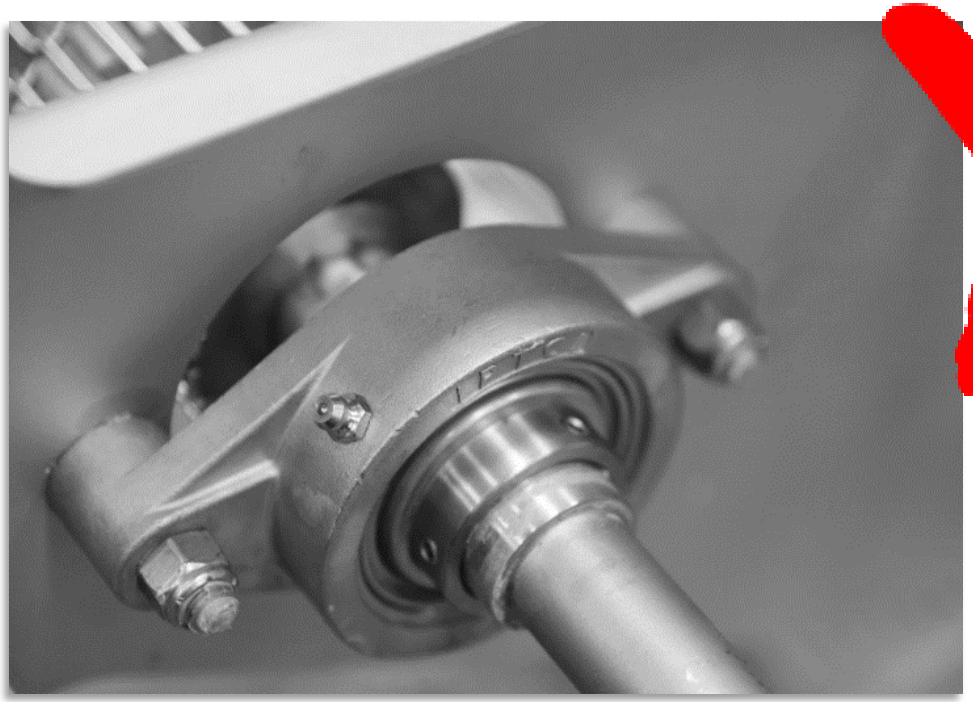
- → 1.0” (24.5 mm.) clearance
- → Bearing shall be bolted to a welded stand off

Shafts and Bearings

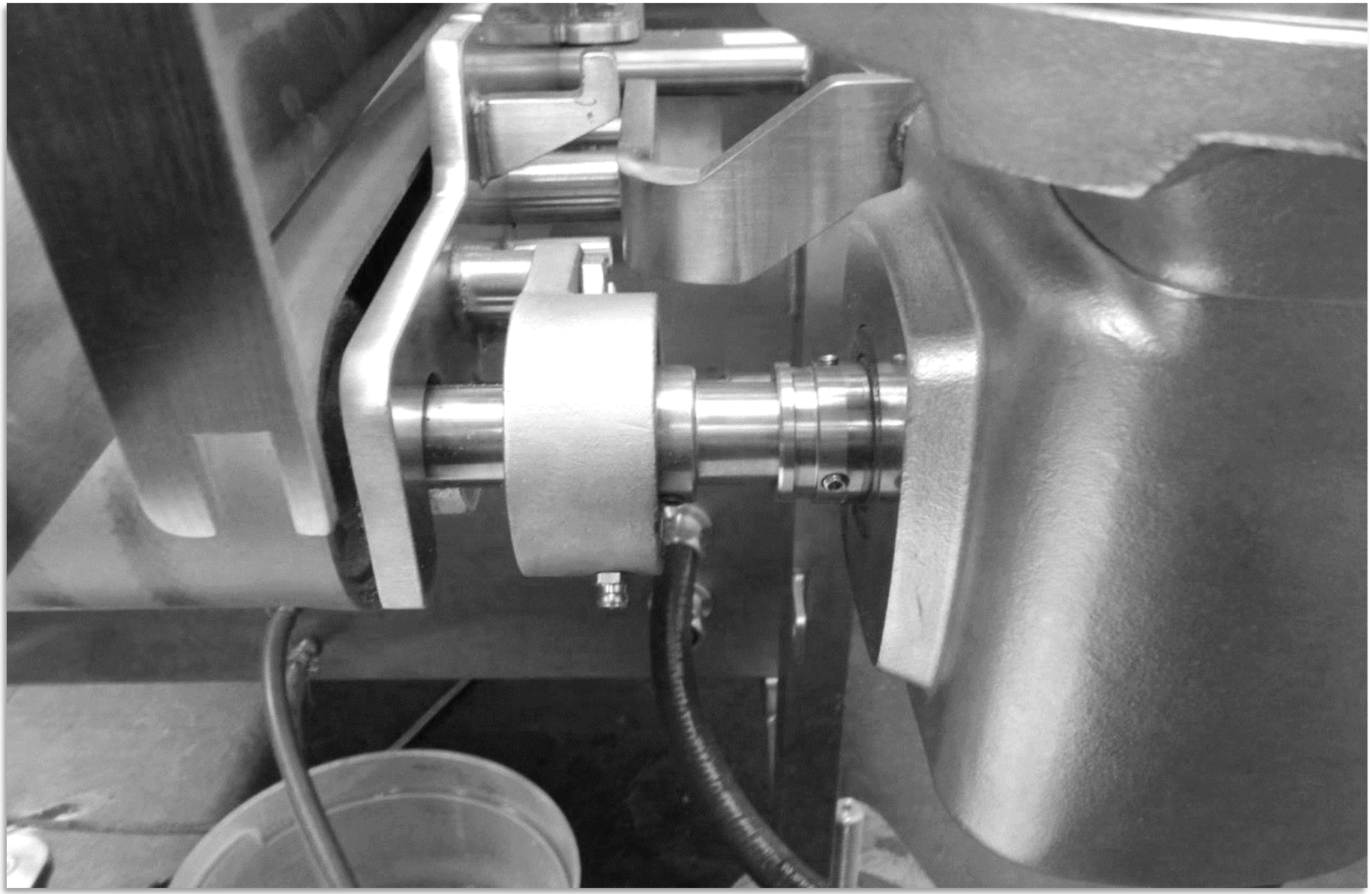


Bearing Mounting

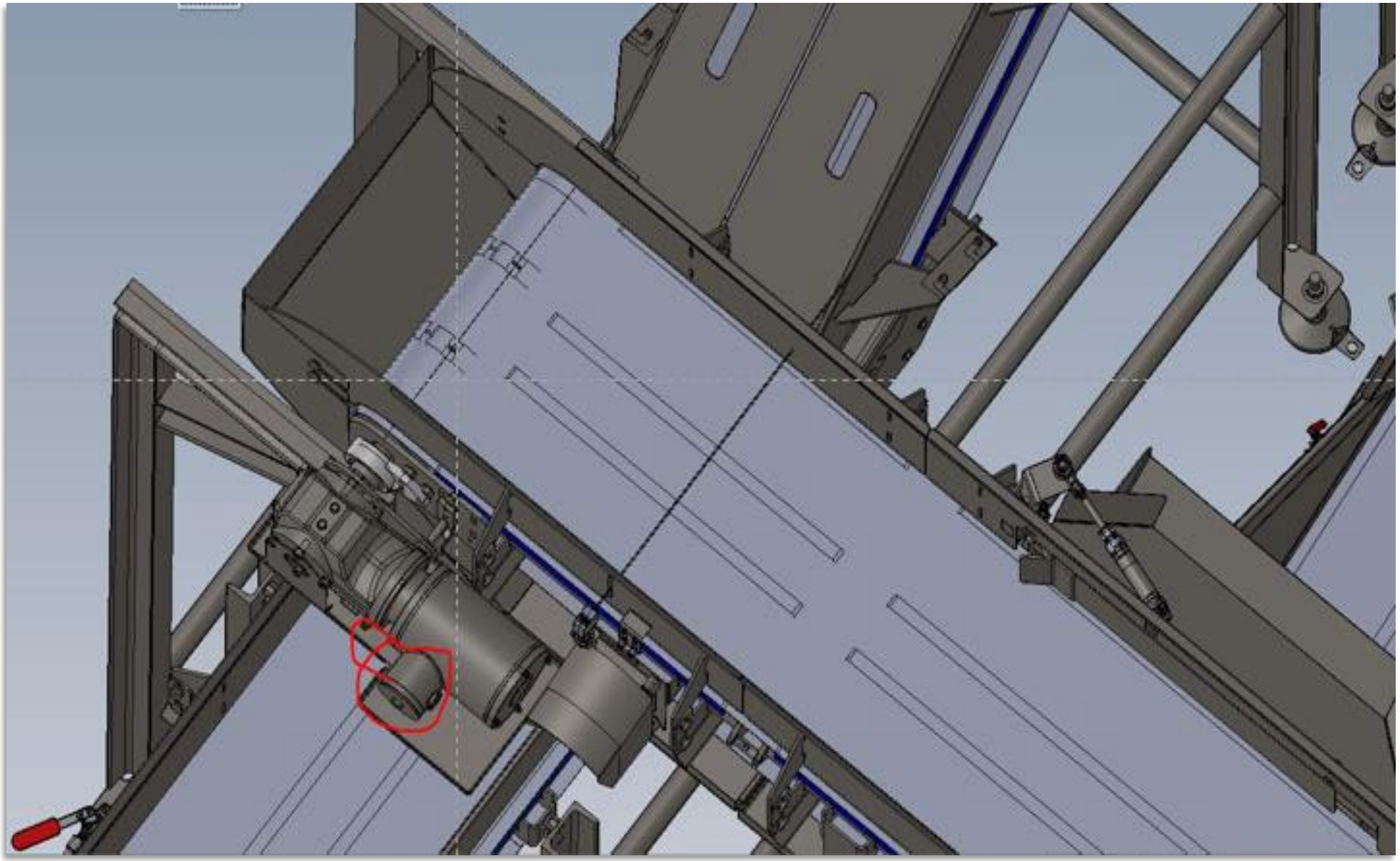
- Welded stand-offs – avoid sleeve stand-offs
- Non-corrosive
- Do not mount over the product



Oil-Filled Gearbox Mounted Outside of PCS

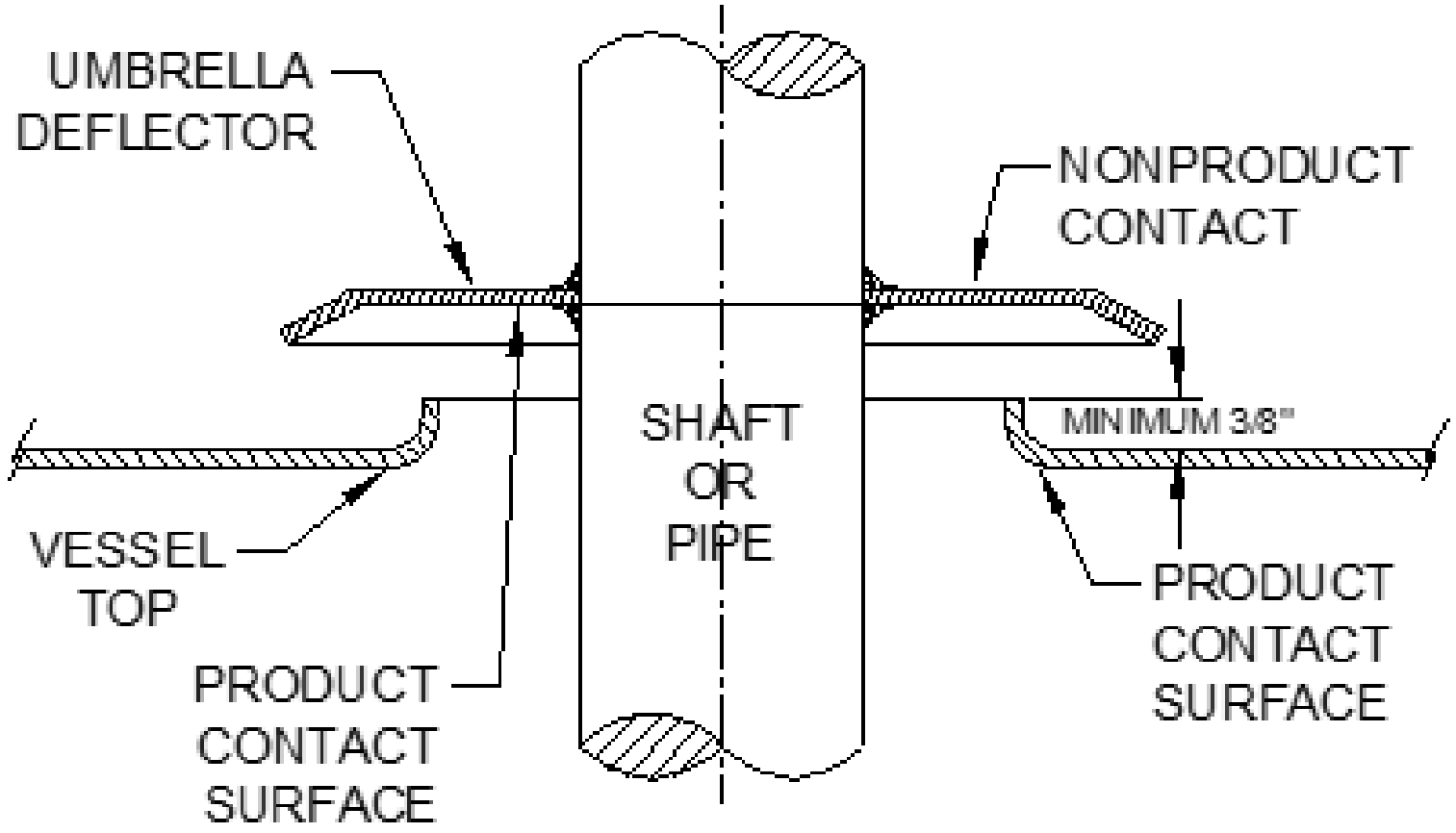


Gearbox Over Product

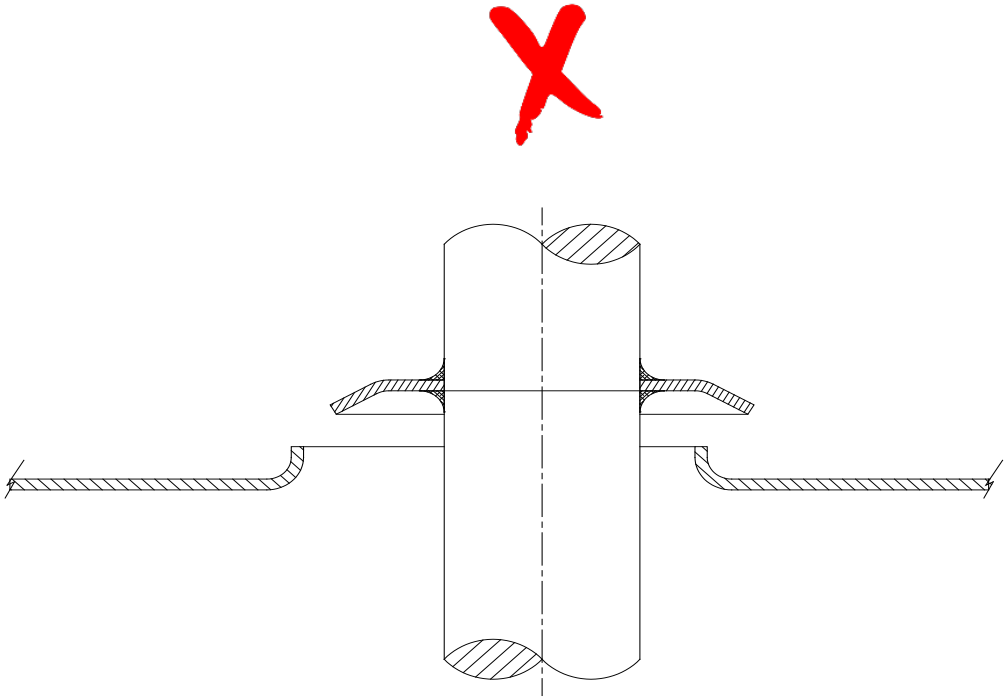


Opening and Covers

- → Minimum 3/8” flange upward
- → Umbrella Cover



Hygienic Risk?



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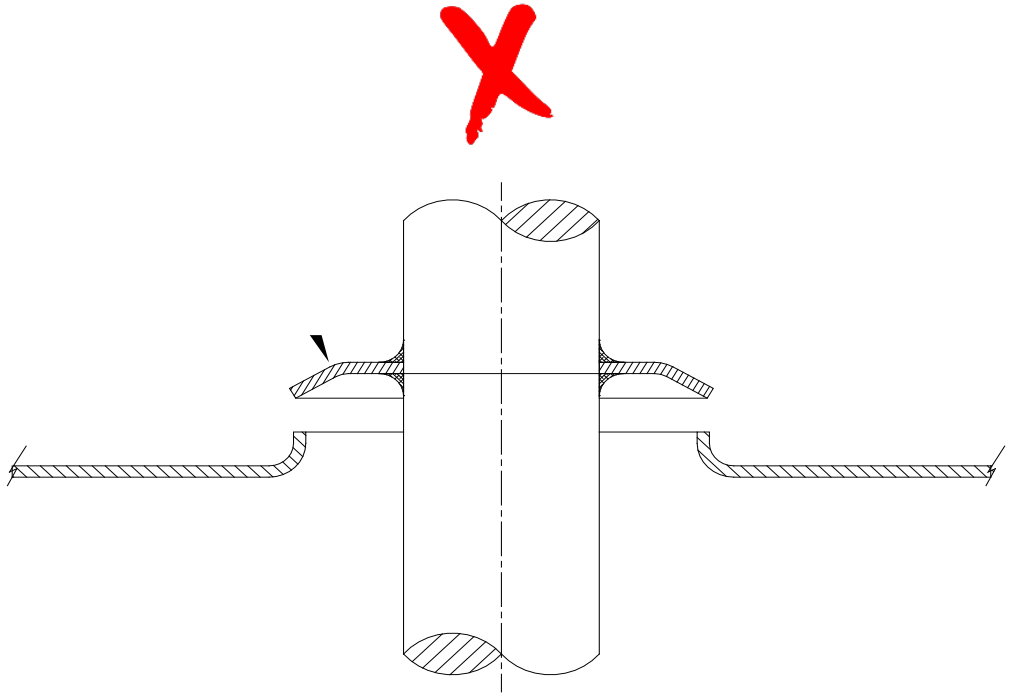
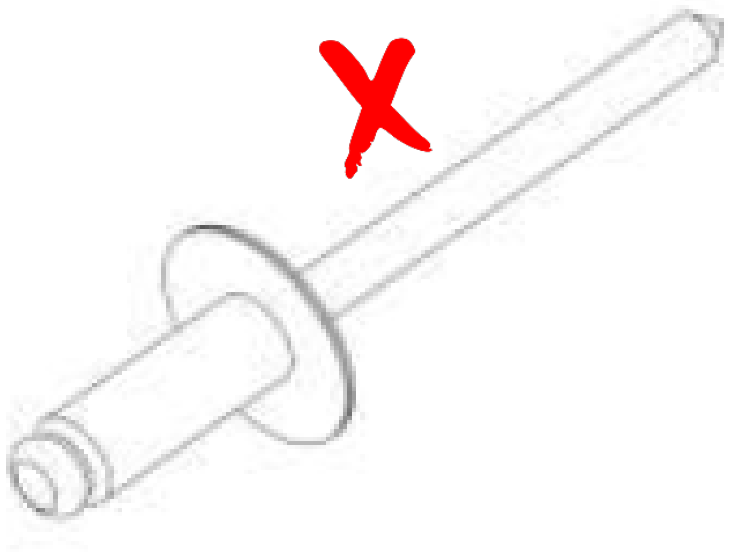


B

Fabrication of NPCS Joints

- → Continuous weld
- → Grinding and polishing not required
- → Bolting is acceptable if welding is not possible



Bolted Joints NPCS

- May be used:
  - Where welding is not possible
  - When braces or frames are hollow
- Integrity of braces or frames shall not be compromised by drilling into the hollow interiors
- If bolting is required, welded studs to the exterior or fully welded sleeves shall be employed

Recessed Socket Head Joints in NPCS

- Recessed socket head bolts shall not be used, except:
- When away from any PCS
- When shielded from any product residues
- When mounted so that the socket heads drain
- On rotating horizontal shafts

Service Piping and Lines

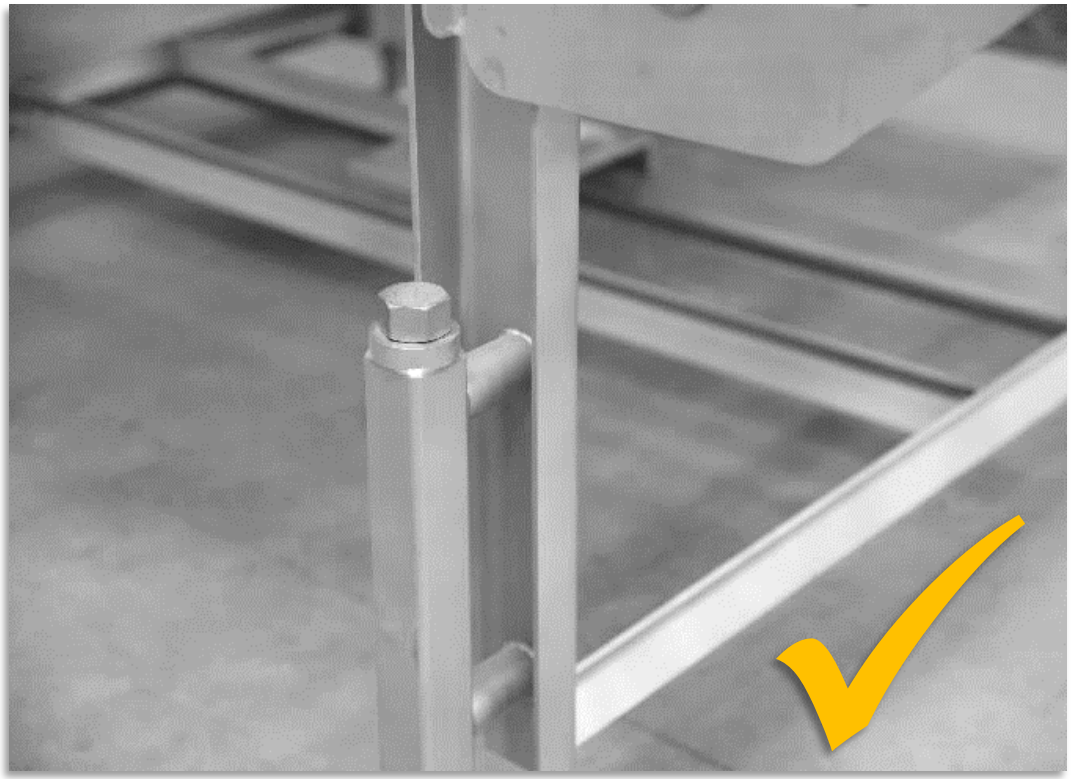
- Exposed braided coverings on cables or hoses shall not be used
- Electrical and utility connections – as remote as practical from PCS
- Electric conduit/utility pipes – at least 1” from flat surface
- Exhaust air from pneumatic equipment shall be piped away from PCS
- Components using machinery fluids shall be installed/shielded to prevent fluid ingress
- Hose clamps of the worm gear type shall not be used

Discuss Service Piping Design

Braid Hose

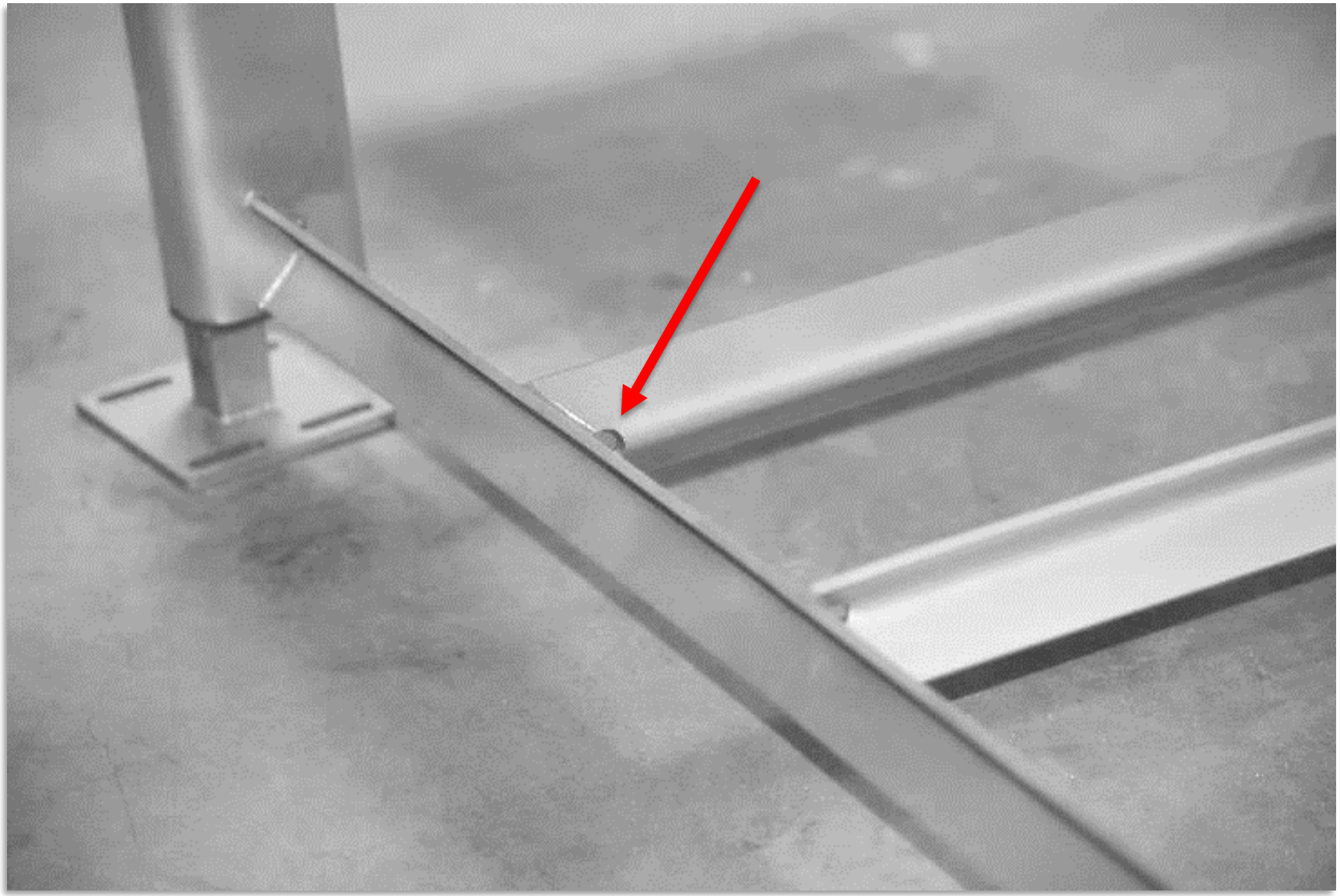
Equipment Frame Construction

Open Channel



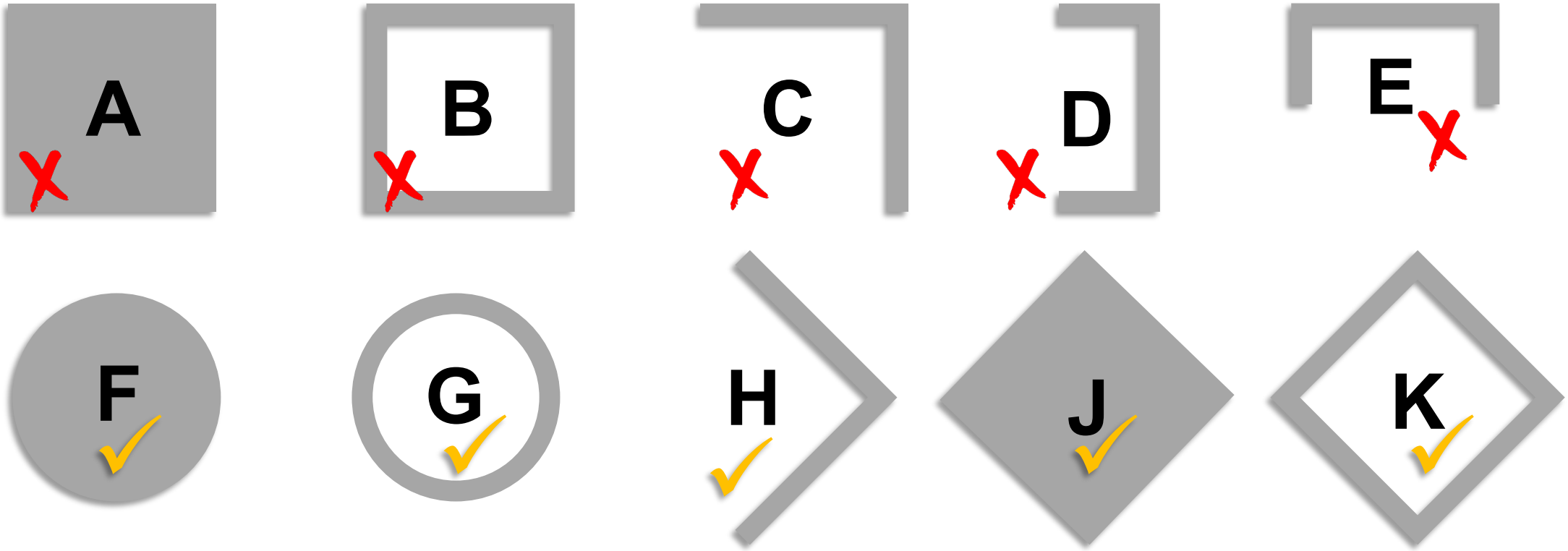
Hollow Tubing

Open Angle Frame



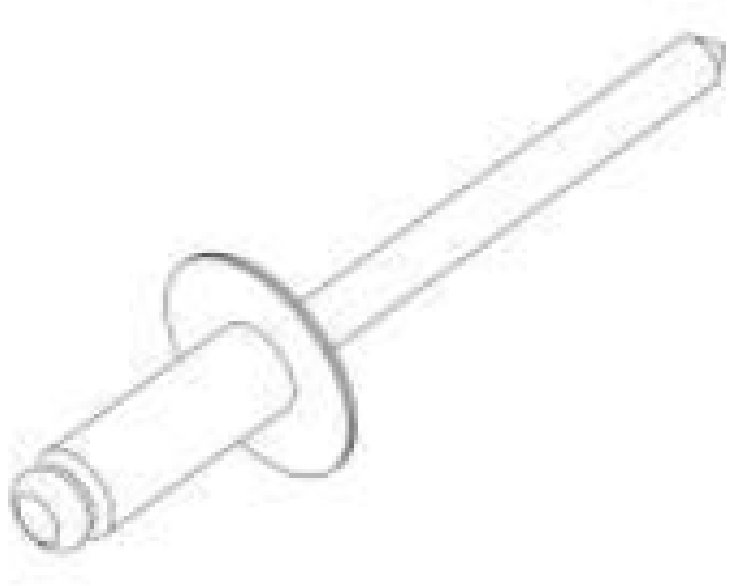
Horizontal Frames & Supports Material

- Avoid flat top and bottom surfaces on frames and supports
- All surfaces should drain
- Hollow frames must be hermetically sealed
- Frames shall not be compromised by drilling into the hollow interiors
- If bolting is required, use thread standoffs



Nameplates and Information Plates

- Nameplates shall be continuously welded or effectively sealed
- Non-metallic adhesive backed are acceptable
- Acid etched, laser etched, or embossed methods are acceptable
- All nameplates should be mounted on NPCS
- Blind rivets may be used on nameplates for motors and gearboxes



Nameplate Laser Etched Label

3-A Sanitary Practices

Farm-Based Practices

Facility-Based Environmental Practices

Facility-Based Process Practices

Farm-Based 3-A Practices

#606 Design, Fabrication, and Installation of Milking and Milk Handling

#611 Farm Milk Cooling and Storage Systems

Facility-Based Environmental 3-A Practices

#604 Supplying Air Under Pressure in Contact PCS

#610 Method of Producing Steam of Culinary Quality

#612 Plant Environmental Air Quality

Facility-Based Process 3-A Practices

- **#603** HTST Systems
- **#605** CIP & Piping Systems
- **#607** Spray Drying Systems
- **#608** Instantizing Systems
- **#610** Cross-Flow Membrane Systems

Key Cleanability Design Considerations: Summary

- → Materials of construction
- → Surface finishes
- → Joint design
- → No cracks or crevices
- → Free draining
- → No dead legs, blind spots, hollows
- → Accessibility to clean
- → Accessibility to inspect

Questions ?