3-A SSI For Beginners and the Basics of Sanitary Design

3-A Sanitary Standards, Inc.

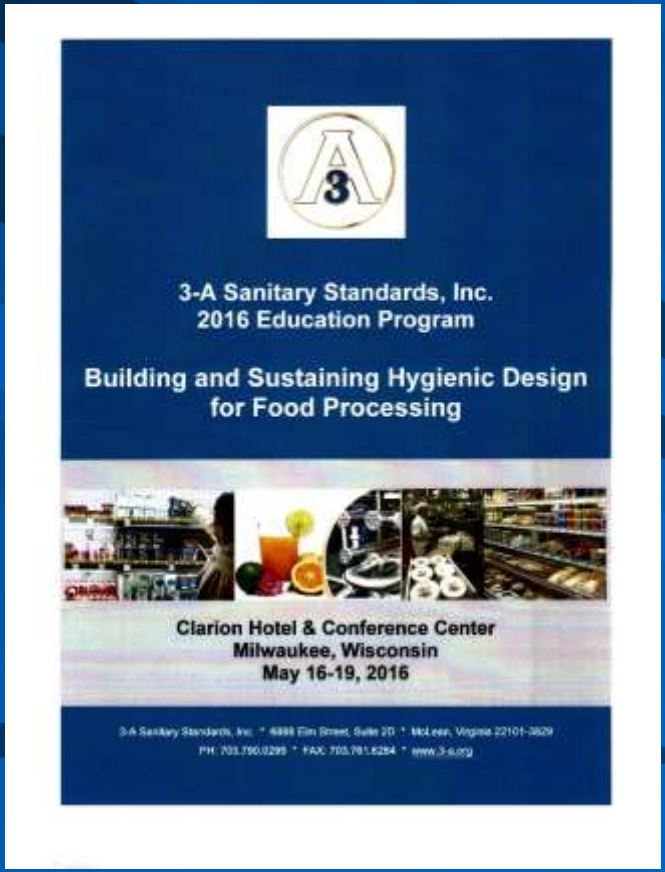
May 16, 2016

Welcome!

Carl Buell, Chair, 3-A SSI

Special Welcome!

Student Travel Award Recipients



Student Travel Award Recipients

- George Kwabena Afari, University of Georgia
- Gabriela-Alejandra Arteaga-Arredondo, Texas Tech
- Ilan-Alexander Arvelo-Yagua, Texas Tech
- Darvin-Abel Cuellar-Milian, Texas Tech
- Andrea English, Texas Tech
- Mengyuan Fan, Ohio State University
- Efran Tash, University of California, Davis

3-A SSI Executive Director

Tim Rugh

The Schedule

- Overview of 3-A SSI
- Basics Part 1

  Refreshment Break
- Basics Part 2
- Wrap Up

And Now…

3-A SSI For Beginners

3-A SSI For Beginners

- History and Structure
- Key Activities

What is 3-A Sanitary Standards, Inc.?

- Not-for-profit 501 (c) (3) corporation
- Represents three stakeholder groups with a long history of collaboration on sanitary equipment design
  - Regulatory Sanitarians
  - Processors (Users)
  - Fabricators

Brief History of 3-A SSI

1920
First Standard

1944 USPH
Participation

1956
New Symbol

2002
3-A SSI

Standards Writing
FPSA

Publishing
IAFP

3A Symbol
Council

Before 2002

After 2002

Standards Writing-Publishing-TPV-Symbol Training-Education-Harmonization

3-A Sanitary Standards Inc.

Who Leads 3-A SSI?

- 5 Original Founding Member Organizations (2 representatives of each)
  - International Dairy Foods Association (IDFA)
  - Food Processing Suppliers Association (FPSA)
  - International Association for Food Protection (IAFP)
  - American Dairy Products Institute (ADPI)
  - 3-A Symbol Administrative Council (now dissolved)
- Chair of the 3-A Steering Committee
- One USDA and one FDA representative

3-A SSI Board of Directors

Officers

- Chair, Carl Buell, Leprino Foods
- Vice Chair, Ronald Schmidt, University of Florida
- Secretary, Ken Anderson, Harold Wainess Associates
- Treasurer, Dan Meyer, ADPI

Directors

- John T. Allan, IDFA
- Lou Beaudette, Admix, Inc.
- Warren S. Clark, Jr., Consultant
- Lyle Clem, ESC, 3-A Steering Committee
- Larry Hanson, CIP Concepts, LLC
- Robert F. Hennes, Chief, FDA/CFSAN-Milk Safety Branch
- Dave Kedzierski, Cabot Cheese
- Helen Piotter, Dean Foods
- F. Tracy Schonrock, TPV Coordinating Committee
- David Seckman, FPSA
- Bjorn Sorensen, Dairy Industry Consultants
- Ken Vorgert, USDA/AMS, Dairy Grading Branch

The ‘New’ 3-A SSI

Primary Activities

- Standards Writing and Publishing
- Industry Education and Training
- 3-A Symbol Licensing Program
- Harmonization and Liaison With Other Organizations

The 3-A SSI Committees

- Communications & Education
- Finance Committee
- TPV Coordinating Committee
- Interpretations Committee
- 3-A Steering Committee

What is the 3-A Symbol?

- A registered mark used to show the conformity of equipment designed and manufactured to a 3-A Sanitary Standard
- Available for use on a voluntary basis subject to licensing requirements of 3-A SSI

Use of the 3-A Symbol

- Since introduction of the mark in 1956, use of the mark was based on self-certification
- 3-A SSI was created to implement a new Third Party Verification (TPV) inspection program for all users of the mark

Why a New TPV Requirement?

- TPV brings added assurance that equipment showing the 3-A Symbol fully conforms to the applicable 3-A Sanitary Standard.

The TPV Program in Brief

- Verification of compliance must be done by an independent credentialed authority – a Certified Conformance Evaluator (CCE)
- TPV certification performed via agreement between CCE and Symbol holder
- Scope of TPV program and CCE credentialing set by 3-A SSI

TPV Inspection Sites

- Argentina
- Australia
- Austria
- Belgium
- Brazil
- Canada
- China
- Denmark
- England
- Finland
- France
- Germany
- India
- Israel
- Italy
- Japan
- Korea
- Mexico
- Netherlands
- New Zealand
- Poland
- Portugal
- Russia
- Spain
- Sweden
- Switzerland
- Taiwan
- Thailand

TPV Inspection Services

- Required for 3-A Symbol licensing
- Necessary for other voluntary certificate programs:
  - Replacement Parts & System Component Qualification Certificate
  - 3-A Process Certification

The Role of 3-A in Commerce

USDA – General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service

All new, replacement or modified equipment and all processing systems, cleaning systems, utensils, or replacement parts shall comply with the most current, appropriate 3-A Sanitary Standards or 3-A Accepted Practices.

Grade "A"

Pasteurized

Milk

Ordinance

(Includes provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" PMO)

2013 Revision

U.S. Department of Health and Human Services

Public Health Service

Food and Drug Administration

PMO 2013 Revision, Section 7
ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT

- **NOTE:** 3-A Sanitary Standards and Accepted Practices for dairy equipment are developed by 3-A SSI. 3-A SSI is comprised of equipment fabricators, processors, and regulatory sanitarians, which include State milk regulatory officials, USDA Agricultural Marketing Service Dairy Programs, the USPHS/FDA CFSAN/MST, academic representatives and others.
- Equipment manufactured in conformity with 3-A Sanitary Standards and Accepted Practices complies with the sanitary design and construction standards of this *Ordinance*. For equipment not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices may be used by Regulatory Agencies as guidance in determining compliance with this Section.

How Does 3-A SSI Develop Documents?

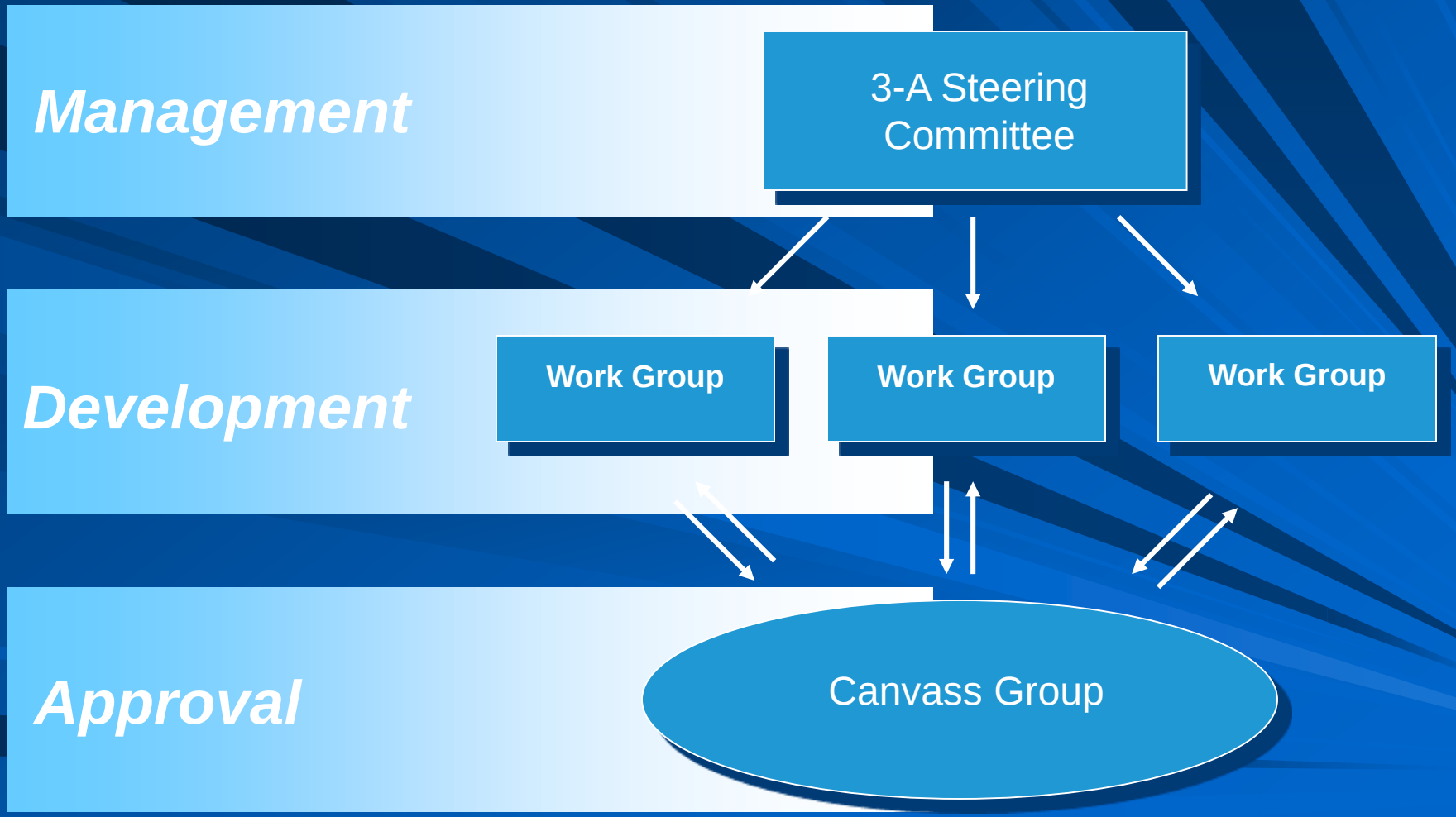
Consensus Process Overview

The Consensus Process

3-A SSI is an ANSI-accredited Standards Developer Organization (SDO)

- 3-A Sanitary Standards
- 3-A Accepted Practices

Consensus Process - Overview



Basics of Sanitary Design
Dennis Glick

Basics of Sanitary Design

Dennis Glick
USDA
Equipment Review Specialist

What is Hygienic Design?

Design process or set of design principles to manage hazards and reduce food safety risks in food processing equipment, processes and facilities.

IMPACT OF HYGENIC DESIGN ON THE FOOD INDUSTRY AND PUBLIC HEALTH AGENCIES

- Reduces hazardous risk
- Improves food safety
- Improves product quality
- Extends shelf life
- Faster, easier and more reliable cleaning
- Lowers cost of cleaning

DEFINITION: HAZARD

- A physical, chemical, biological, allergen or radiological agent that is likely to cause illness or injury in the absence of its control.

EXAMPLES OF HOW 3-A MANAGES PHYSICAL HAZARDS

1. Materials of Construction
   - Corrosion resistant material vs. rust of carbon steel
   - Risks of paint and coatings
   - Glass breakage and brittle materials risk
   - Rubber and plastic compatibility

2. Fasteners Elimination or Reduction

EXAMPLES OF HOW 3-A MANAGES CHEMICAL HAZARDS

1. Lubricated bearings
   - Must be mounted outside product zone
2. Gear boxes
   - Must be mounted outside product zone
3. Cleaning solutions
   - Free draining and no pools

EXAMPLES OF HOW 3-A MANAGES BIOLOGICAL HAZARDS

To reduce harborage points and keep microorganisms out, 3-A SSI requires:

- Elimination of cracks and crevices
- Elimination of ungasketed bolted construction
- No absorbent materials
- Cleanable material surface finishes

EQUIPMENT DESIGN

HYGIENIC EQUIPMENT DESIGN

- Materials of Construction
- Surface Finishes
- Joints
- Drainability
- Cleaning and Inspectability
- Dead Ends
- Gaskets, Gasket Retaining Grooves, O-rings and Seals
- Radii
- Threads
- Springs
- Shafts and Bearings

FACILITY DESIGN

Illustration by Chris Gash

FACILITY DESIGN

Grounds and Buildings

- Materials of Construction
- Surface Finishes
- Permanent Joints

Process Flow

- Products, people, air

Product Contact Utilities

- Water, air, steam, gases

Facility Utilities

- Water, steam, air, HVAC

GROUNDS AND BUILDING CONSTRUCTION

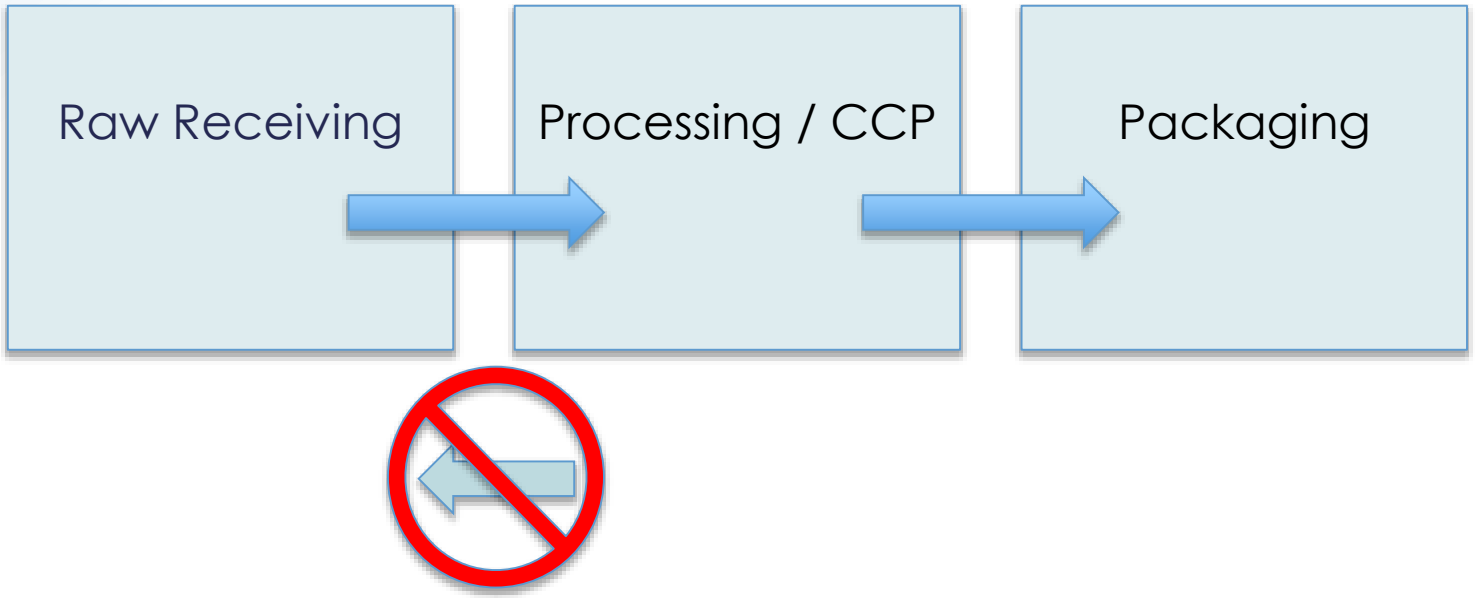
- Eliminate harborage areas
- Graded landscape
- Maintain walls and doors

INTERIOR CONSTRUCTION

- Impervious floors, walls and ceiling materials
- No cracks, crevices or unsealed joints
- Smooth and cleanable surfaces
- Adequate space for maintenance and cleaning
- No dead spaces or uninspectable areas.
- Sloped floors with proper drainage.

PROCESS FLOW MANAGEMENT

- Manage traffic flow
- Isolate exposed product areas
- Isolate raw processing areas



PROCESS FLOW PRACTICES

RAW AND READY TO EAT SHOULD HAVE:

- Separate process rooms
- Separate ventilation systems
- Separate personnel
- Separate break rooms, toilets

All traffic flow should be restricted from the Raw areas into the RTE areas.

PRODUCT CONTACT UTILITIES

Utilities that come in contact with product should be contamination-free, clean and safe.

Requirements:

- Process water
- Compressed Air in Contact With Product or product contact surfaces ***(3-A Accepted Practice 604-05)***
- Culinary steam ***(3-A Accepted Practice 609-03)***

SANITATION UTILITIES

Adequate sources of utilities are available for the sanitation process:

- Potable water
- Source of hot water
- Proper ventilation and condensation management
- Floor drainage system

CLEANING

CLEANING METHODS

- Manual Dry Cleaning
- Manual Wet Cleaning
- COP (Clean out of Place)
- CIP (Clean in Place)

MANUAL

- CLEANING TOOLS AND METHODS MANIPULATED BY HAND.
- CAN BE WET OR DRY
- PARTIALLY DISASSEMBLED OR COMPLETELY REMOVED **(COP)**
- COP MAY OR MAY NOT INCLUDE A TANK.

CIP (CLEAN IN PLACE)

- CIRCULATING, SPRAYING OR FLOWING CHEMICAL SOLUTIONS AND WATER RINSES ONTO AND OVER THE SURFACES TO BE CLEANED.
- CLEANED ACHIEVED WITHOUT REMOVAL.

TYPES OF SOIL

- FATS > CAUSTICS
- SOLIDS > ACIDS
- PROTEINS > CHLORINATED CLEANER

REGULATORY AGENCIES

- City and County Public Health Officials
- State Public Health Officials
- Federal Agencies
  - FDA - Food and Drug Administration
  - USDA - U.S. Department of Agriculture
  - FSIS - USDA Food Safety and Inspection Service

HYGIENIC DESIGN STANDARDS

3A SSI (Sanitary Standards, Inc)

- Food Equipment Standards and Practices

EHEDG (European Hygienic Engineering & Design Group)

- Hygienic Design and Testing Guidelines

NSF International

- Hygienic Equipment Standards

AMI (American Meat Institute)

- Ten Principles of Sanitary Design

BISSC (Baking Industry Sanitary Standards Committee)

- Sanitary Baking Equipment Standards

ASME - BPE (Bioprocessing Engineering)

- Hygienic Bio-Pharmaceutical Standards

THIRD PARTY AUDITS AND CERTIFICATIONS: HYGIENIC EQUIPMENT FABRICATORS

Third Party Audits provide:

- Unbiased verification that hygienic equipment are designed and fabricated to hygienic standards
- Industry experts
- Hygienic Experts

THIRD PARTY AUDITS AND CERTIFICATIONS: HYGIENIC EQUIPMENT FABRICATORS

3-A SSI Third Party Verification (TPV) Program:

- Certified Conformance Evaluator (CCE) evaluates equipment for compliance to a designated 3-A standard
- A 3-A Symbol can be attached to equipment that has passed a CCE evaluation
- Re-evaluation is required every 5 years

THIRD PARTY AUDITS AND CERTIFICATIONS: HYGIENIC EQUIPMENT FABRICATORS (CONTINUED)

EHEDG Certification and Testing Program:

- Certify and test to EHEDG guidelines
- Tests for: cleanability
- EHEDG logo

QUESTIONS?

SESSION 2 OVERVIEW

3-A Sanitary Standard for General Requirements
American National Standard

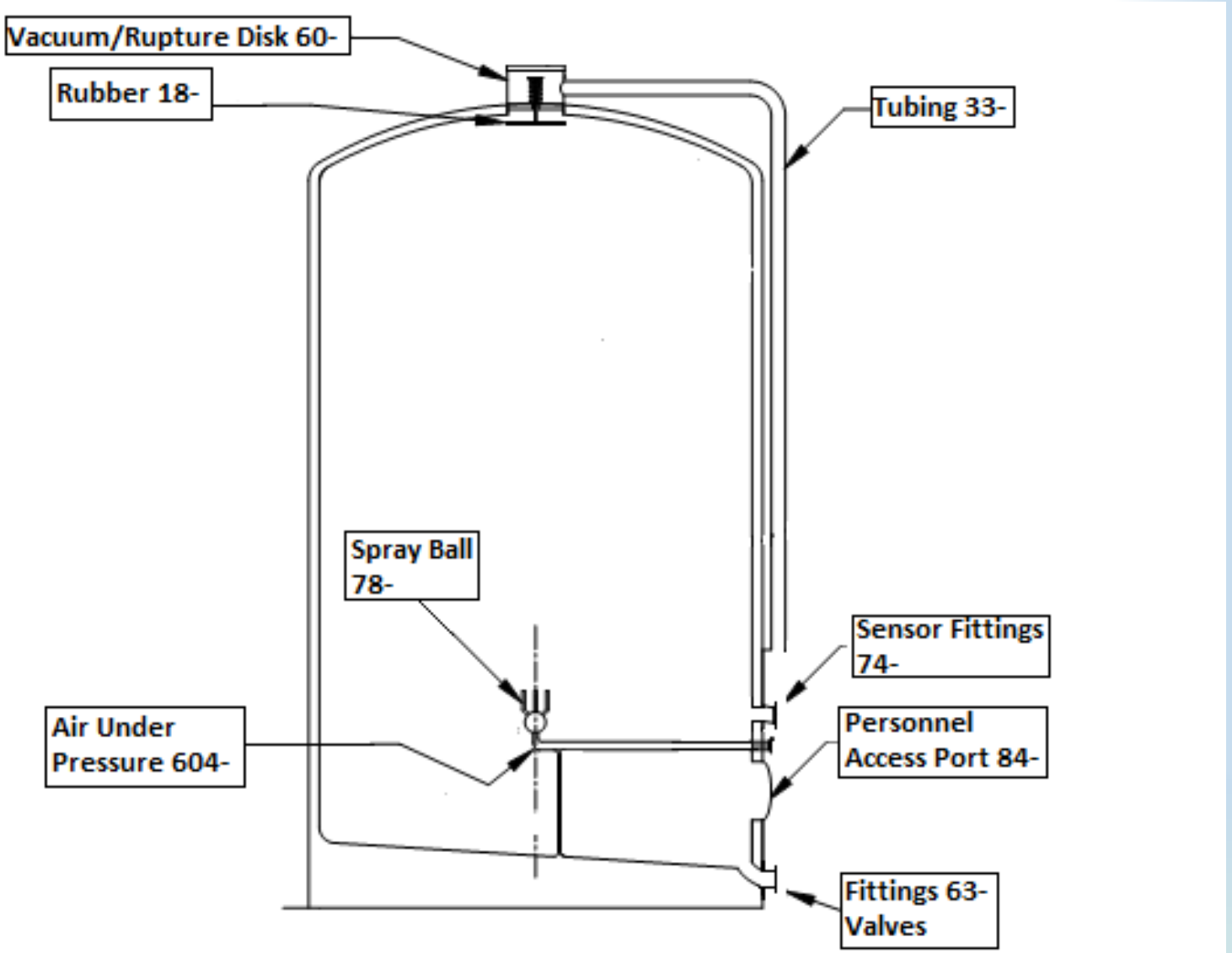
ANSI/3-A 00-00-2014

What is a 3A Standard?

- **3-A Sanitary Standards specify the criteria for the design and fabrication of a specific type of equipment that comes into contact with food.**

Accepted Practice?

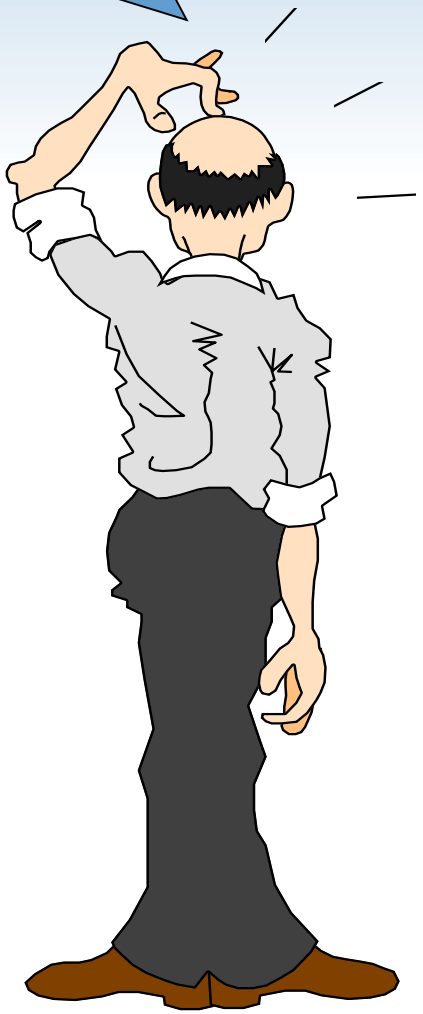
- **3-A Accepted Practices specify the criteria for the design, fabrication and installation of systems that come into contact with food.**


Vacuum/Rupture Disk 60-
Rubber 18-
Tubing 33-
Spray Ball 78-
Sensor Fittings 74-
Air Under Pressure 604-
Personnel Access Port 84-
Fittings 63- Valves

THERE ARE THREE TYPES OF SURFACES ON EQUIPMENT.

- PRODUCT CONTACT
- NON PRODUCT CONTACT
- SOLUTION CONTACT

WHAT IS PRODUCT CONTACT?



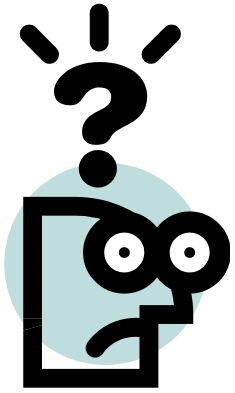
***Product Contact Surfaces*:**

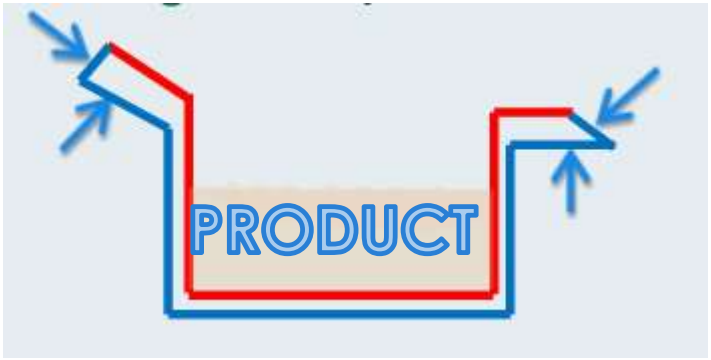
Shall mean all surfaces which are exposed to the product, surfaces from which liquids may drain, drop, or be drawn into the product or into the container, and surfaces that touch the product contact surfaces of the container.


PRODUCT

Nonproduct Contact Surfaces:

Shall mean all other exposed surfaces.





SOLUTION CONTACT:

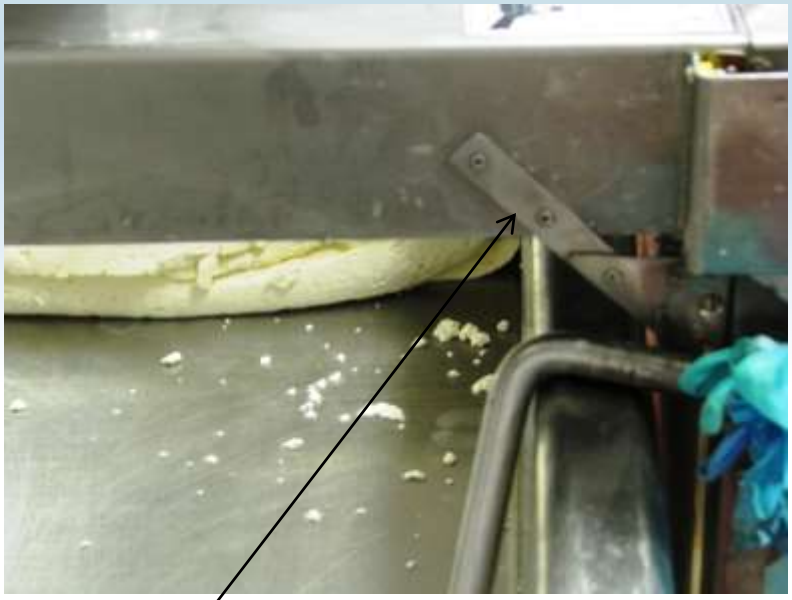
All interior surface of the equipment or system, including the associate piping that are used for supplying and recirculating cleaning and /or sanitizing solutions, except those used to supply concentrated cleaning and sanitizing chemicals from the bulk storage to the point of chemical addition.

SOLUTION CONTACT:

Solution Contact surfaces are considered to be Product Contact Surfaces except as listed as otherwise.


LOCATED OVER OPEN FILLED BAGS
SHIELD REQUIRED


RAISED EDGES OF DRIP SHIELD
UNDERSIDE POLISHED TO A 32 Ra.



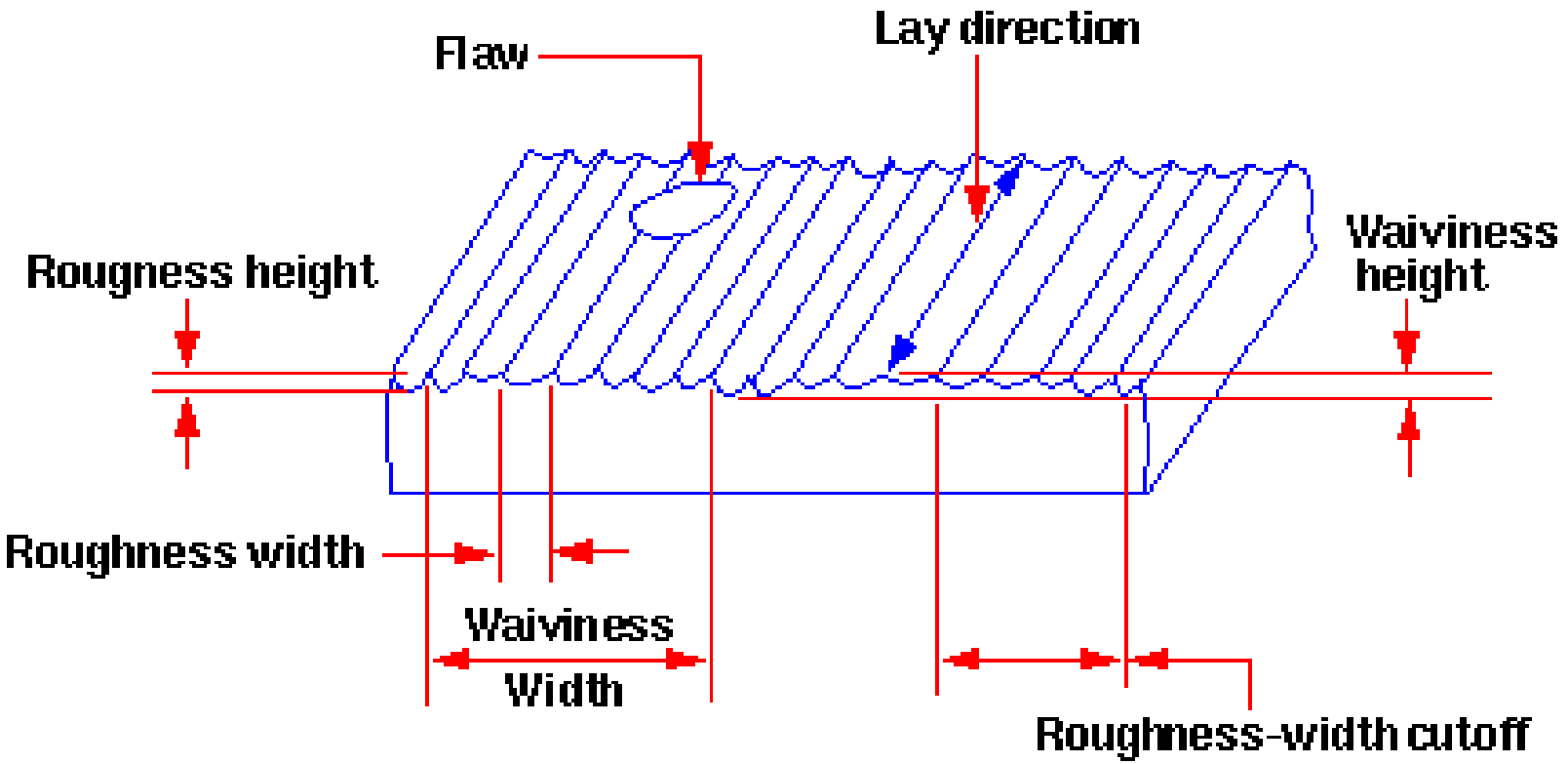
1.POP RIVETS
2.WELDS NOT GROUND AND POLISHED

MATERIALS OF CONSTRUCTION

- 300 SERIES STAINLESS *(Except 301 and 302)*
- OTHER METALS MAY BE USED IF TESTED AND ARE CORROSION RESISTANT AS 300 SERIES.
- 302 AND 400 SERIES MAY BE USED FOR SPECIFIC APPLICATIONS. *(Must be stated.)*
- PLASTICS *(By Application)*
- RUBBER AND RUBBER LIKE. *(By Application)*
- *6 METHODS OF VALIDATING RUBBER AND PLASTIC*

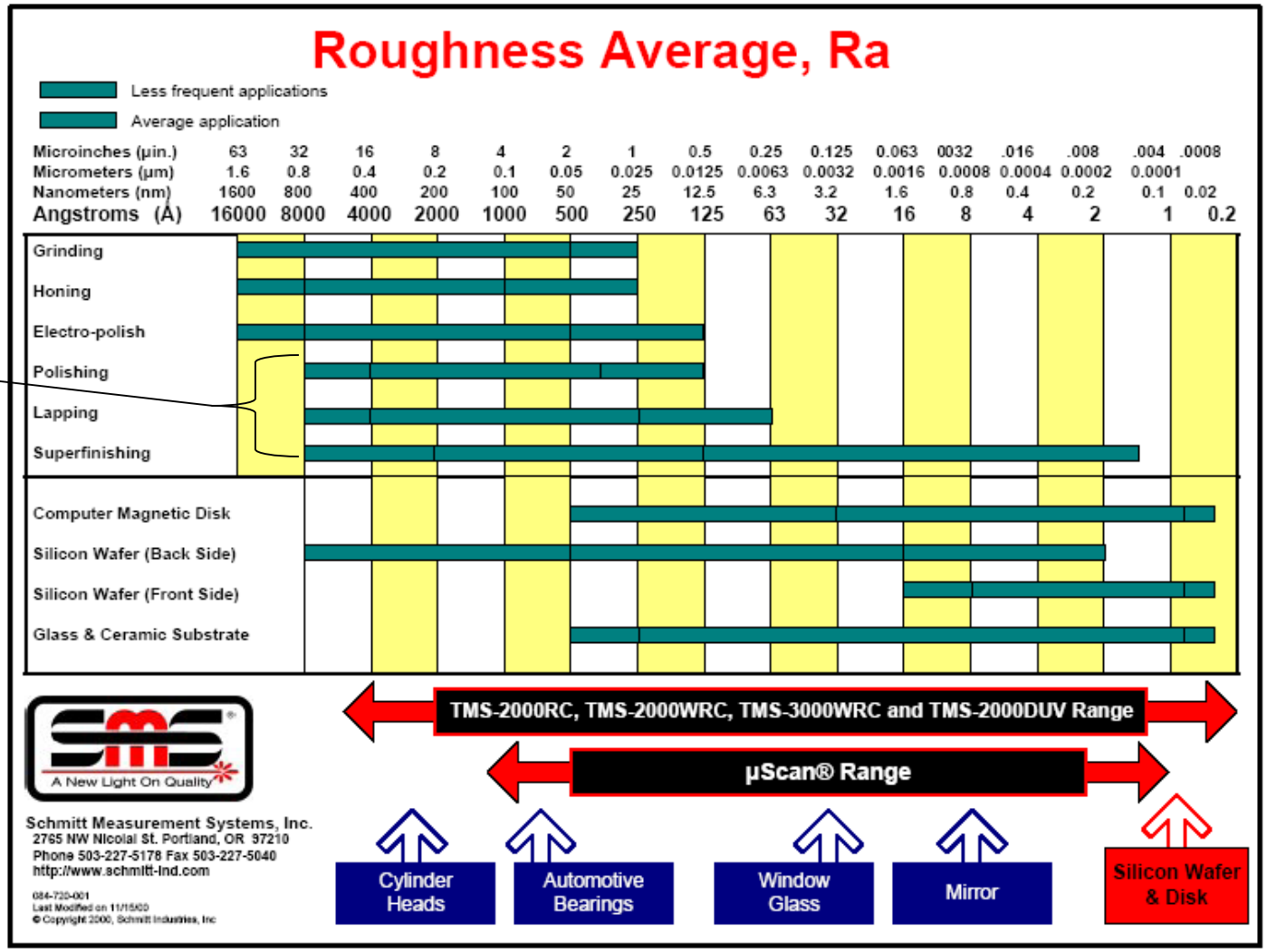
SURFACE FINISH FOR PRODUCT CONTACT:

- 32 µin Ra (0,8 µm Ra)
- Grinding and Polishing.
- #2B Sheet Mill Finish
- Less Than 32 µin Ra (0,8 µm Ra)
- *(Must be free of imperfections)*
- Shot Peening
- *(Specific to Standard)*

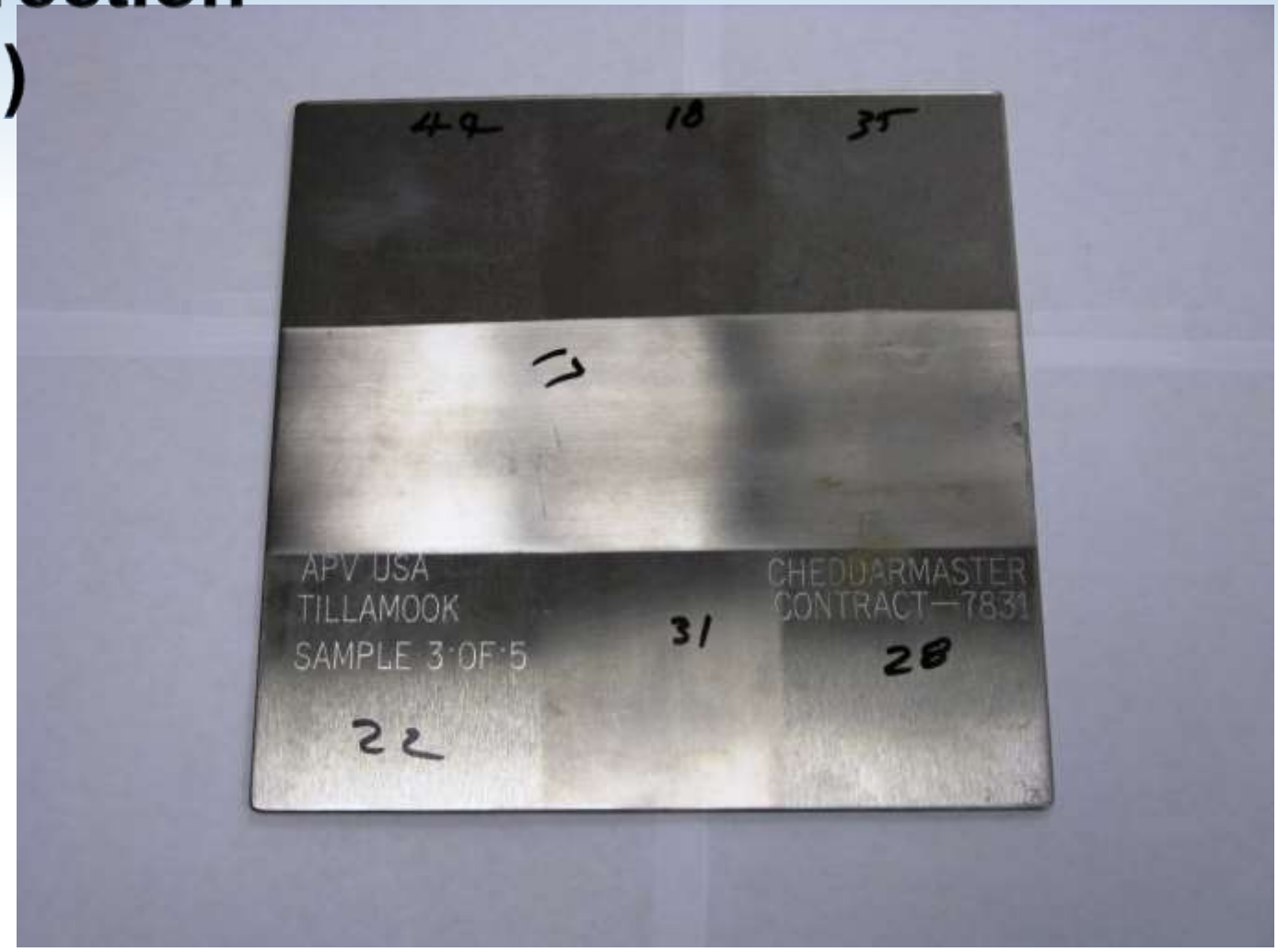


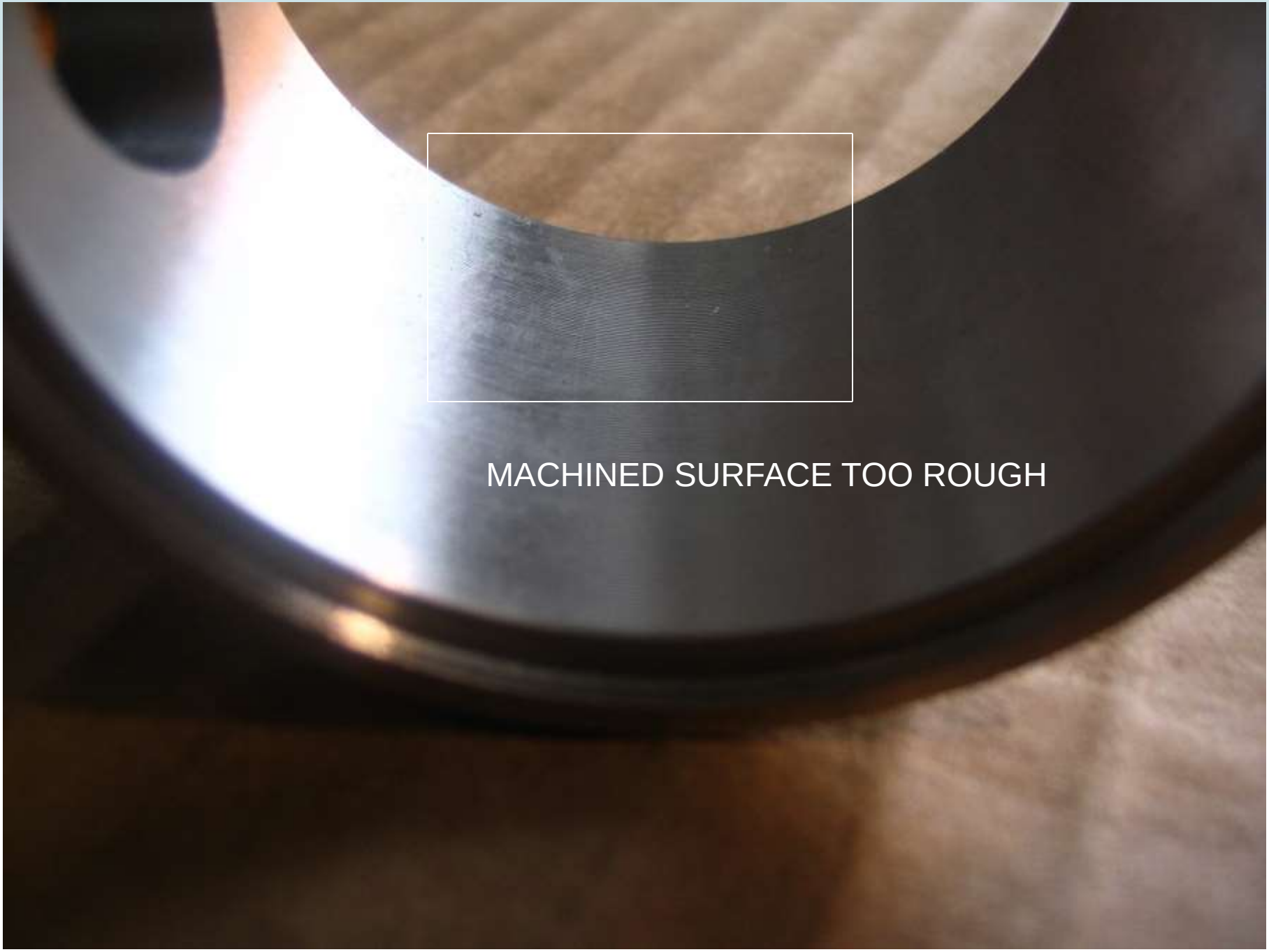
Surface characteristics (Courtesy, ANSI B46.1 - 1962)

32 µin is where polishing starts



A roughness tester must run against the lay direction (grain)




MACHINED SURFACE TOO ROUGH

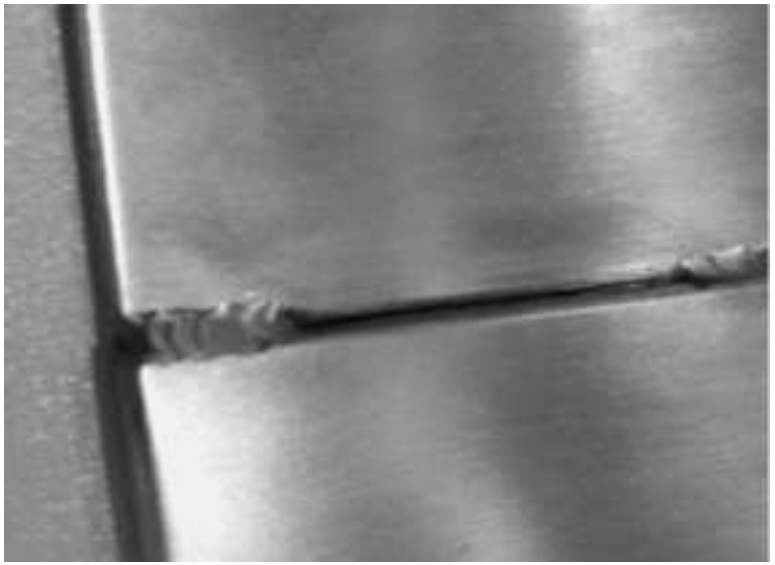
PERMANENT JOINTS

- CONTINUOUS WELDS.
- INTERFERENCE FITS
- BONDED JOINTS
- SOLDERING OR BRAZING

WELDED JOINTS

- IMPROPERLY GAS PURGED. NOT ACCEPTABLE.

- SKIP WELDS NOT ACCEPTABLE



NON PERMANENT JOINTS

- THREADED OR CLAMPED CONSTRUCTION
- MAY BE GASKETED
- MANUAL DISASSEMBLY OR CLEAN IN PLACE.
- FLAT GASKETS INTENDED FOR CIP SHALL BE SUBTANTIALLY FLUSH. (+/- 1/32 INCH (0.8 MM)

CLEANING AND INSPECTABLITLY

- COP SURFACES SHALL BE DESIGNED TO BE READILY ACCESSABLE AND INSPECTABLE.
- EITHER INSTALLED OR REMOVED
- **IF YOU CANNOT SEE IT, YOU CANNOT CLEAN IT!**
- CIP SURFACES SHALL BE DESIGNED TO BE READILY ACCESSABLE AND INSPECTABLE.
- IN SOME CASES,ONCE DOCUMENTED, ONLY REPRESENTATIVE SURFACES NEED BE ACCESSABLE AND INSPECTABLE.

DRAINING

- Surfaces must be self-draining except for typical clingage or adherence.
- The degree of pitch will be specific to the standard.

DEAD ENDS

- **SHALL NOT EXCEED 2 X THE NOMINAL DIAMETER OF THE TUBING.**
- **SHALL NOT EXCEED 5 INCHES. (127 mm)**

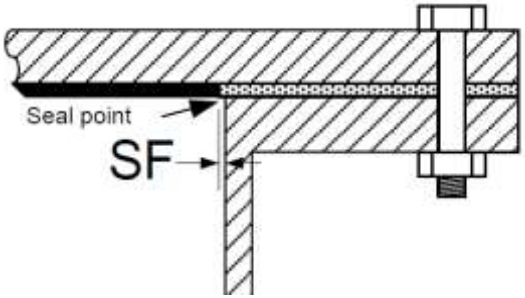

O-RINGS
AND
GASKETS

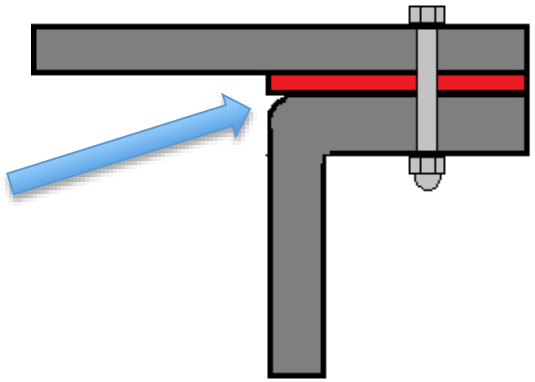
O-RINGS AND GASKETS

- LOCATION
- LOCATION
- LOCATION

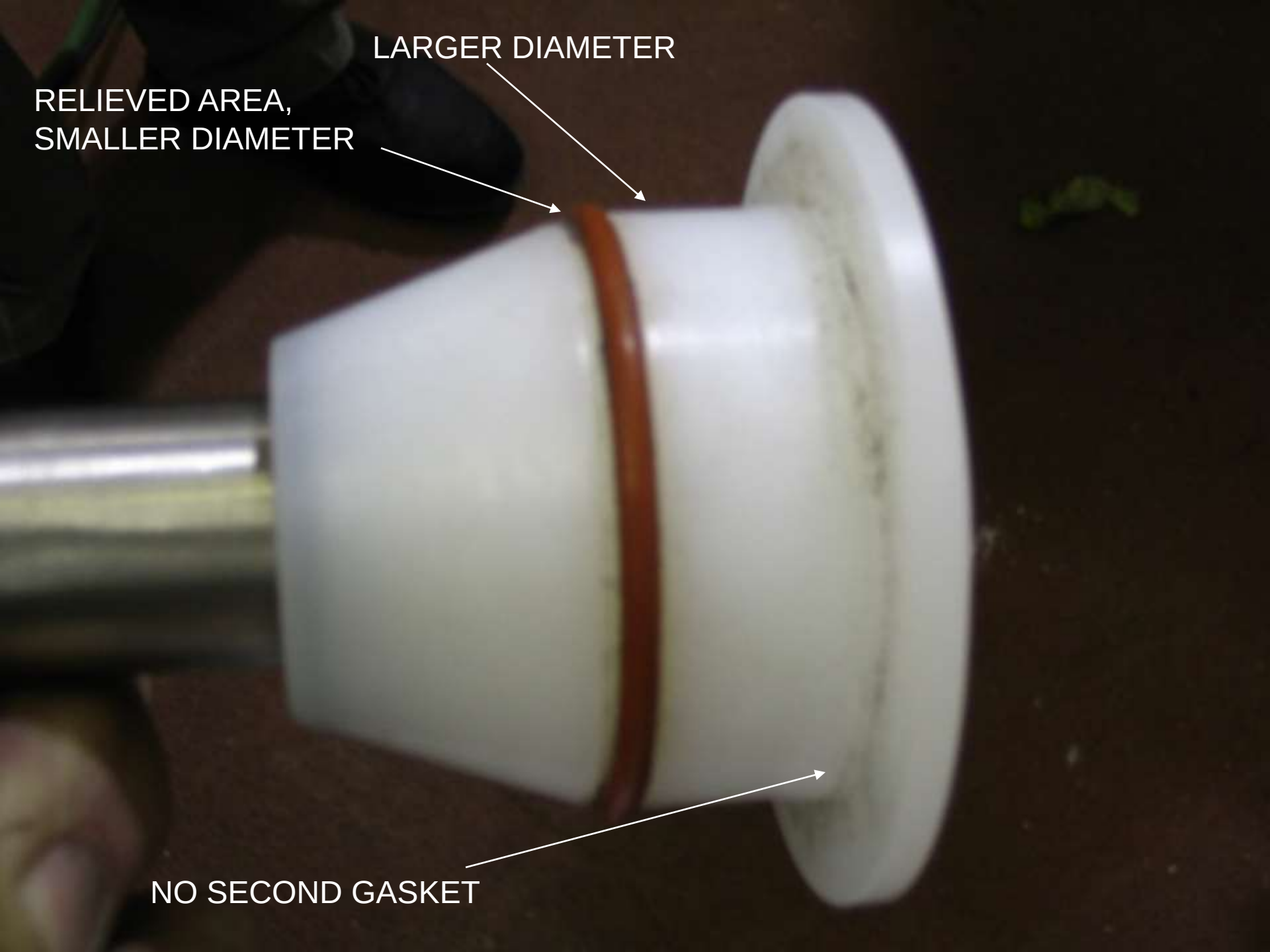
GASKETED JOINTS INTENDED FOR CIP.

- SHALL BE PARTIALLY EXPOSED TO THE CLEANING SOLUTIONS.
- FLAT GASKET SEALING SURFACES SHALL BE SUBSTANTIALLY FLUSH WITH THE PRODUCT CONTACT SURFACES.
- TIGHT PINCH SEAL (270° ANGLE)






O-RINGS PARTIALLY
EXPOSED

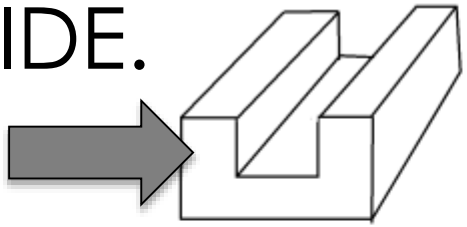

LARGER DIAMETER
RELIEVED AREA,
SMALLER DIAMETER
NO SECOND GASKET


RECESSED O-RING
IS SATISFACTORY
FOR MANUAL
CLEANING

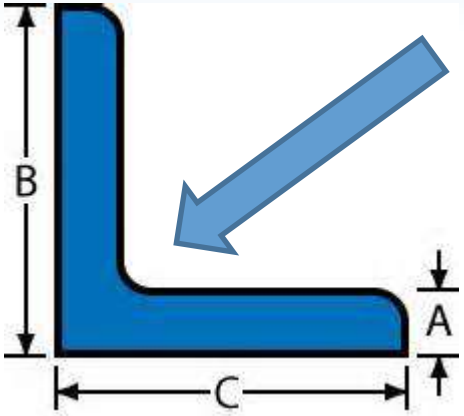
GASKET RETAINING GROOVES

- GROOVE 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 INCH IN DEPTH OR BE LESS THAN ¼ INCH WIDE.

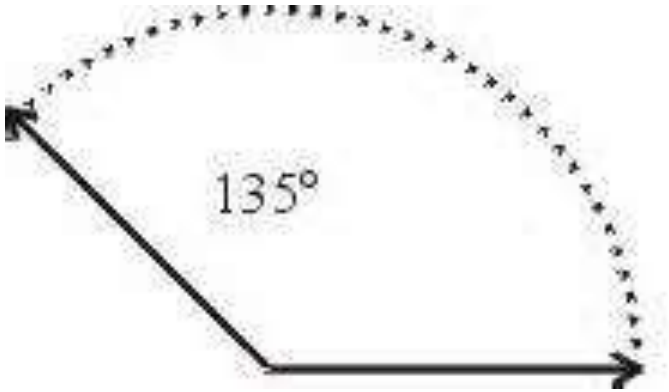


RADII

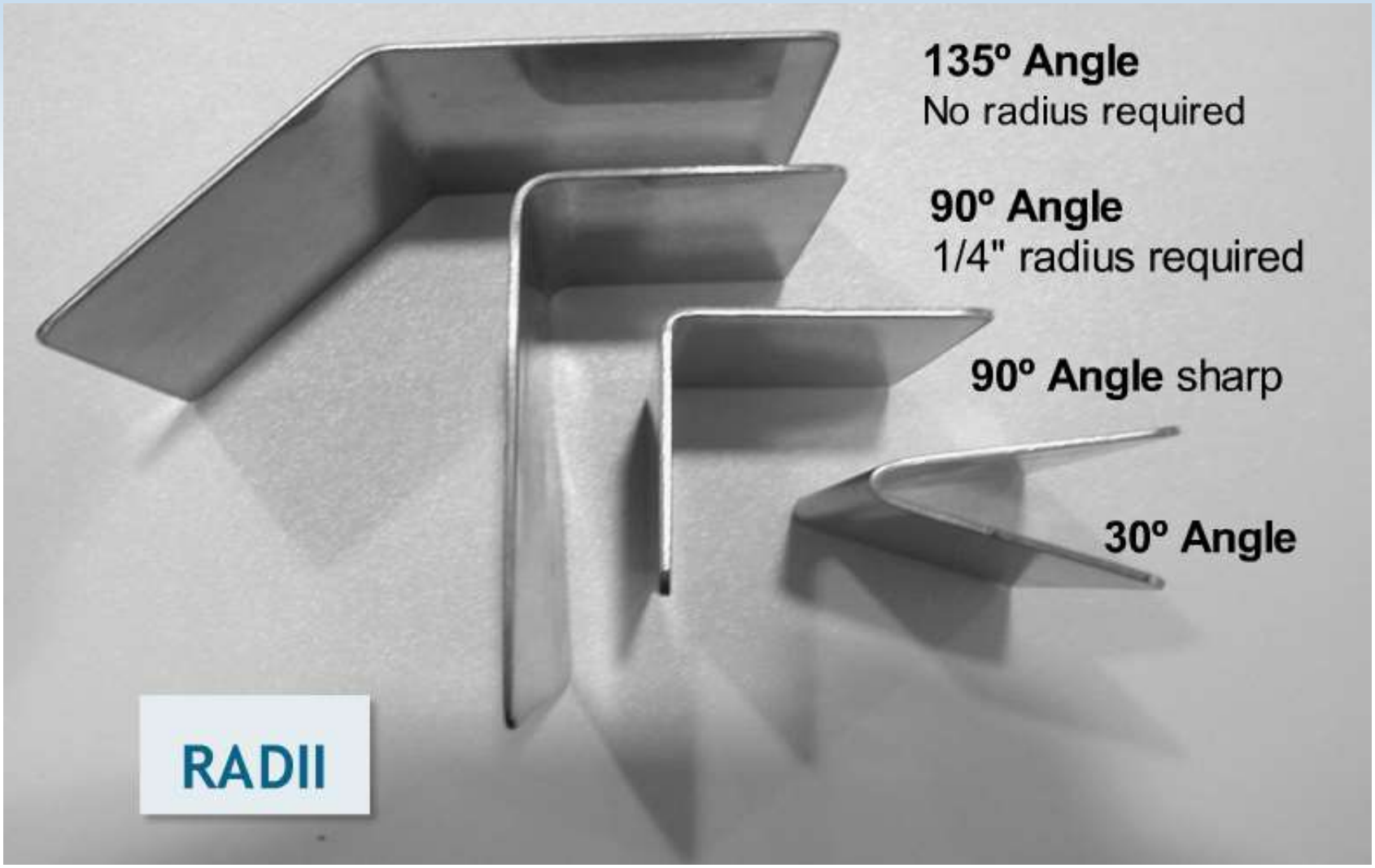


WHEN ARE THEY REQUIRED?

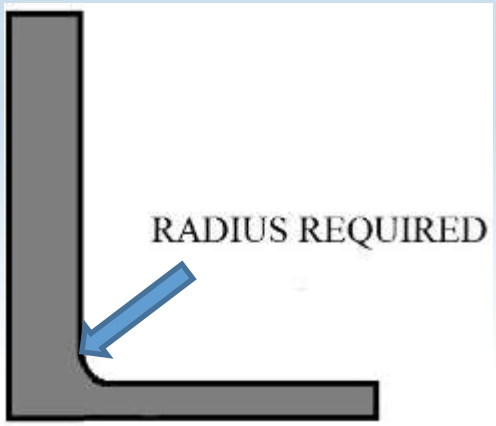
RADII ARE REQUIRE FOR ALL INTERNAL ANGLES LOCATED IN PRODUCT CONTACT LESS THAN 135 DEGREES.



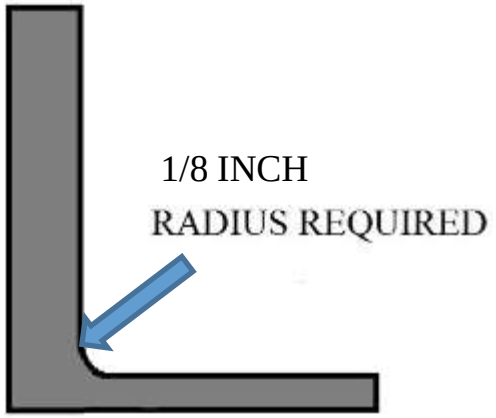
RADII


135° Angle
No radius required
90° Angle
1/4" radius required
90° Angle sharp
30° Angle
RADII

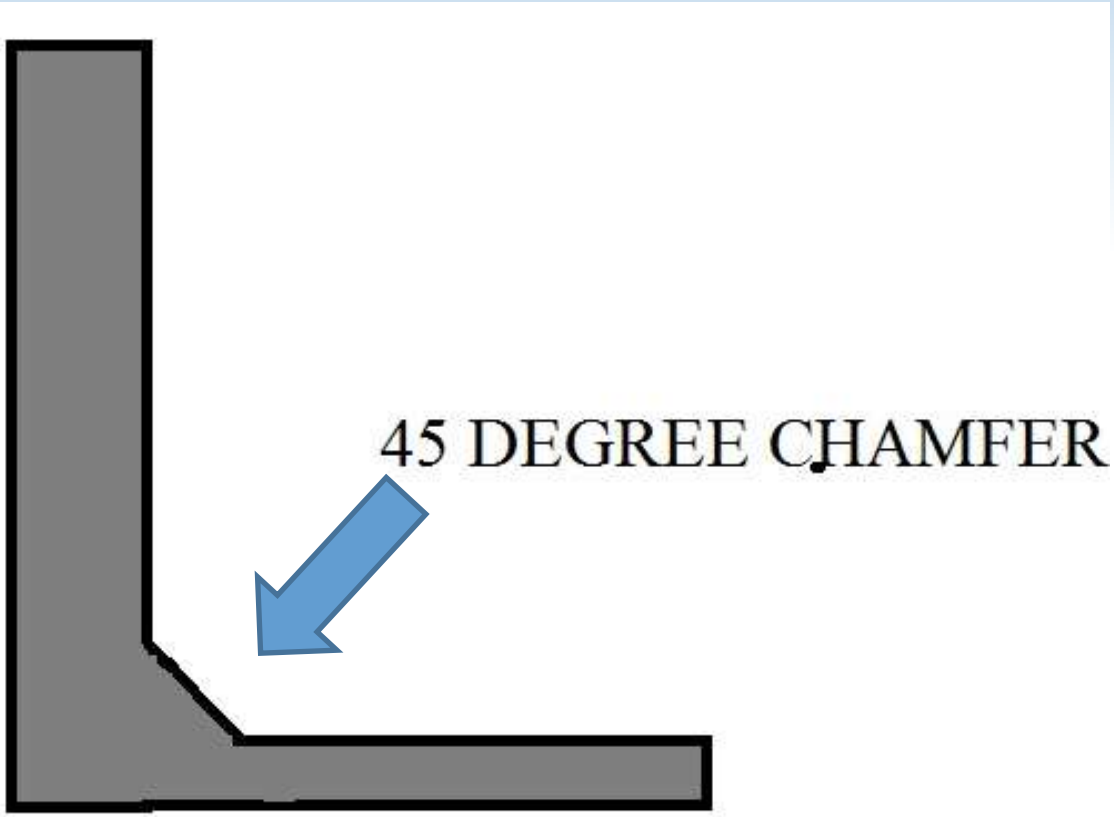
ALL INTERNAL ANGLES LESS THAN 135 DEGREES SHALL HAVE AT LEAST A 1/4 INCH (6.35 MM RADIUS



IF THE INTERNAL ANGLE IS CREATED BY WELDING AND THE THINNER OF THE TWO MATERIALS IS 3/16 INCH (4.76 MM) OR LESS, 1/8 INCH (3.18 MM) RADII ARE SATISFACTORY.

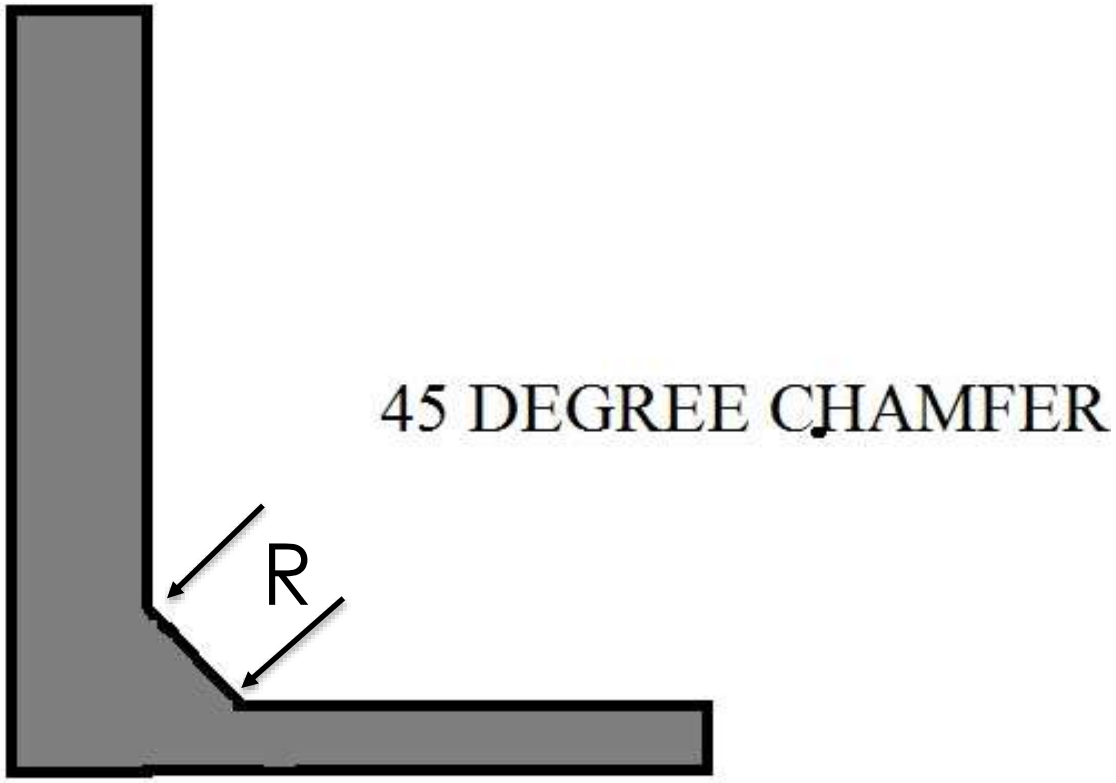


IS A RADIUS REQUIRED HERE?



NO

THE HYPOTENUSE DIMENSION SHALL EQUAL THE MINIMUM RADIUS REQUIREMENT.

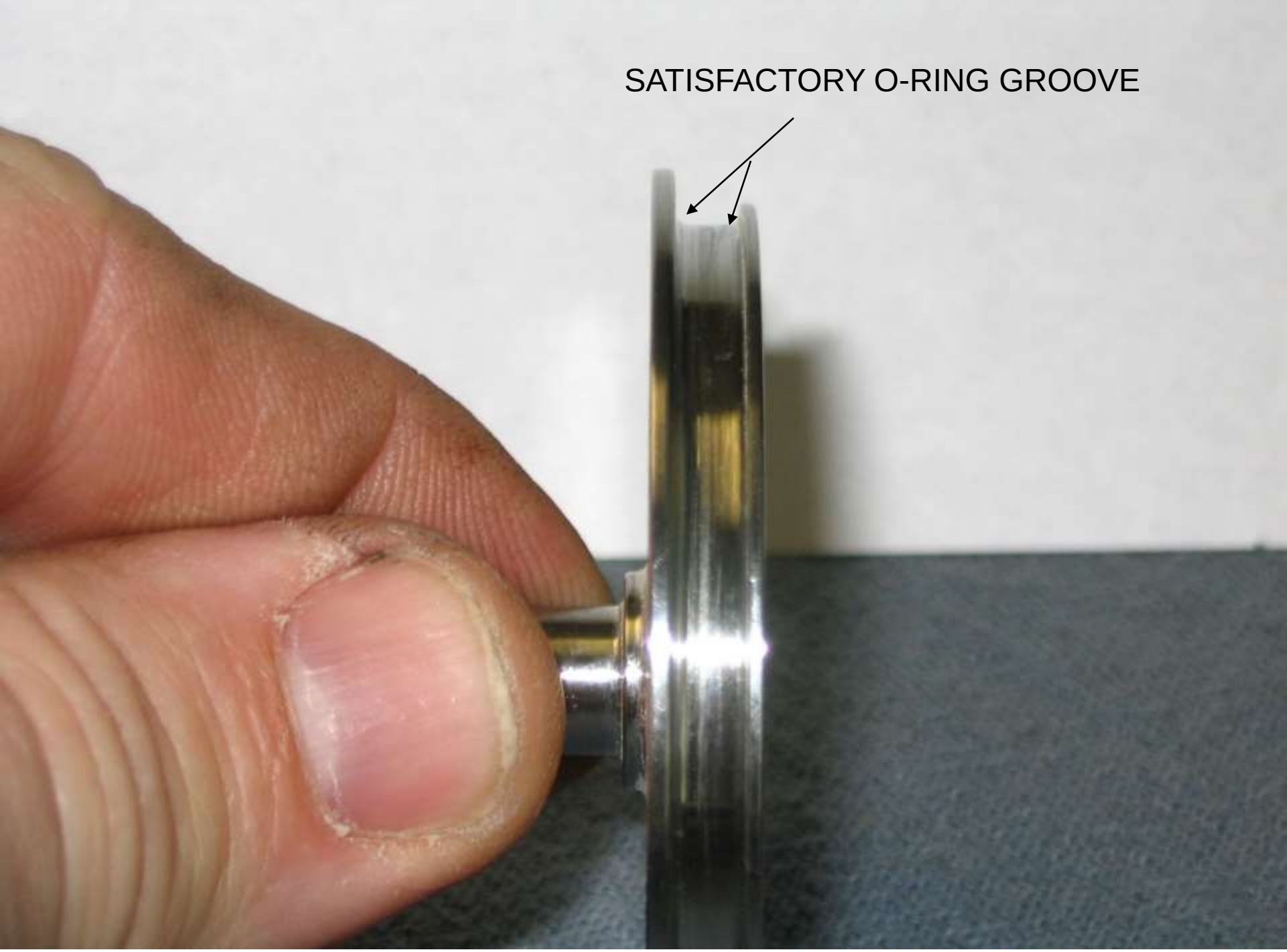


O-RINGS AND GASKET GROOVES

- GASKET GROOVES SHALL HAVE AT LEAST 1/8 INCH RADII.
- O-RING GROOVE RADIUS IS BASED[1] ON NOMINAL DIAMETER OF THE O-RING.

Groove Radii Dimensions for Standard O-Rings			
O-Ring Cross Section, Nominal (AS 568)	O-Ring Cross Section, Actual (AS 568)	O-Ring Cross Section, Actual (ISO 3601-1)	Minimum Groove Radius
1/16 in.	0.073 in.	1.85 mm	0.0160 in. (0.406 mm)
3/32 in.	0.106 in.	2.69 mm	0.0301 in. (0.787 mm)
1/8 in.	0.143 in.	3.63 mm	0.0310 in. (0.787 mm)
3/16 in.	0.215 in.	5.46 mm	0.0620 in. (1.575 mm)
1/4 in.	0.281 in.	7.14 mm	0.0940 in. (2.39 mm)


NO RADIUS IN O-RING GROOVE


SATISFACTORY O-RING GROOVE

EXCEPTIONS

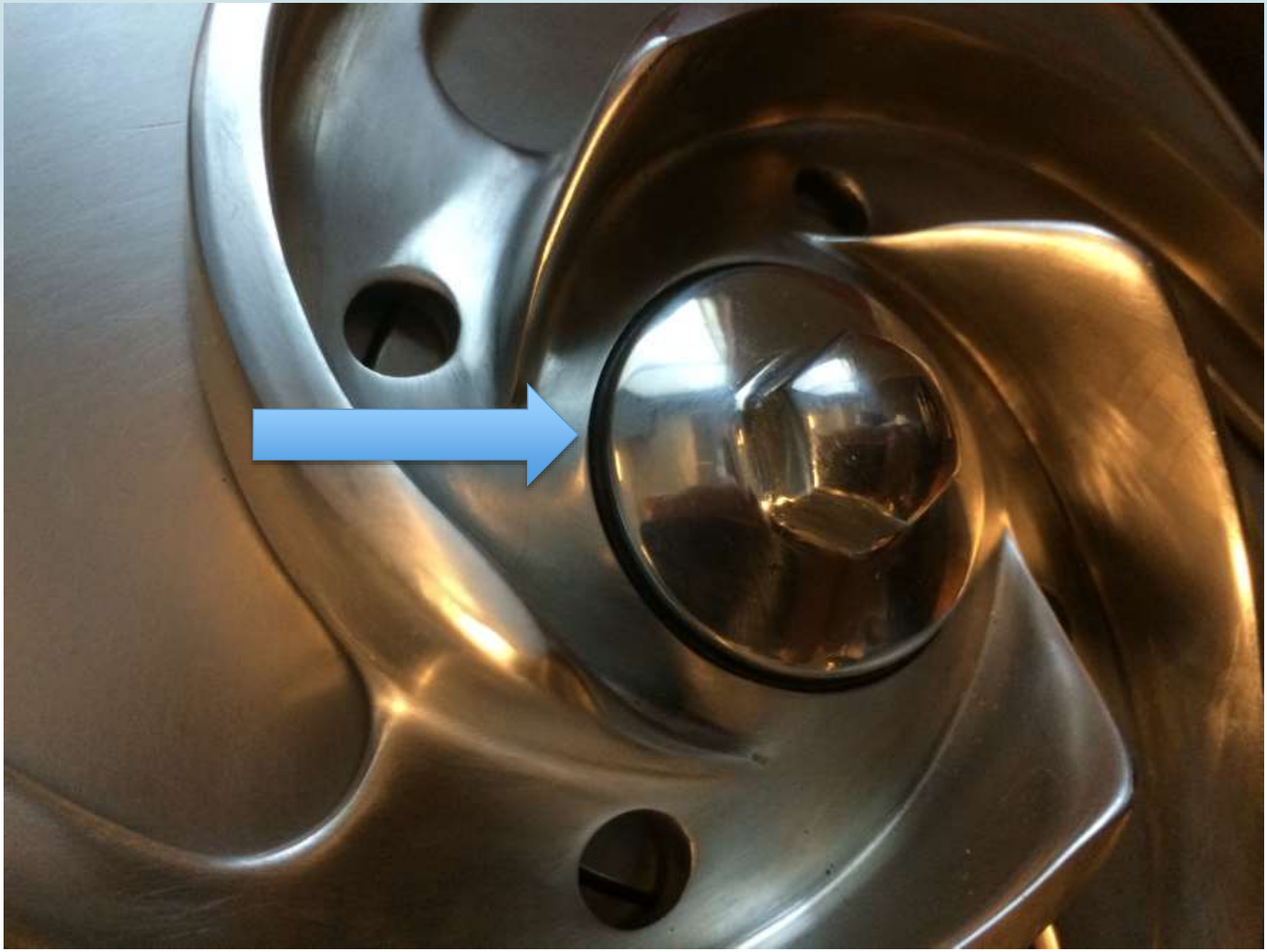
- **THERE ARE NO MINIMUM RADIUS REQUIRMENT FOR THE PRODUCT CONTACT JUNCTURES OF FLAT SEALING SURFACES.**
- **GASKET GROOVES OF BONDED GASKETS.**

THREADS

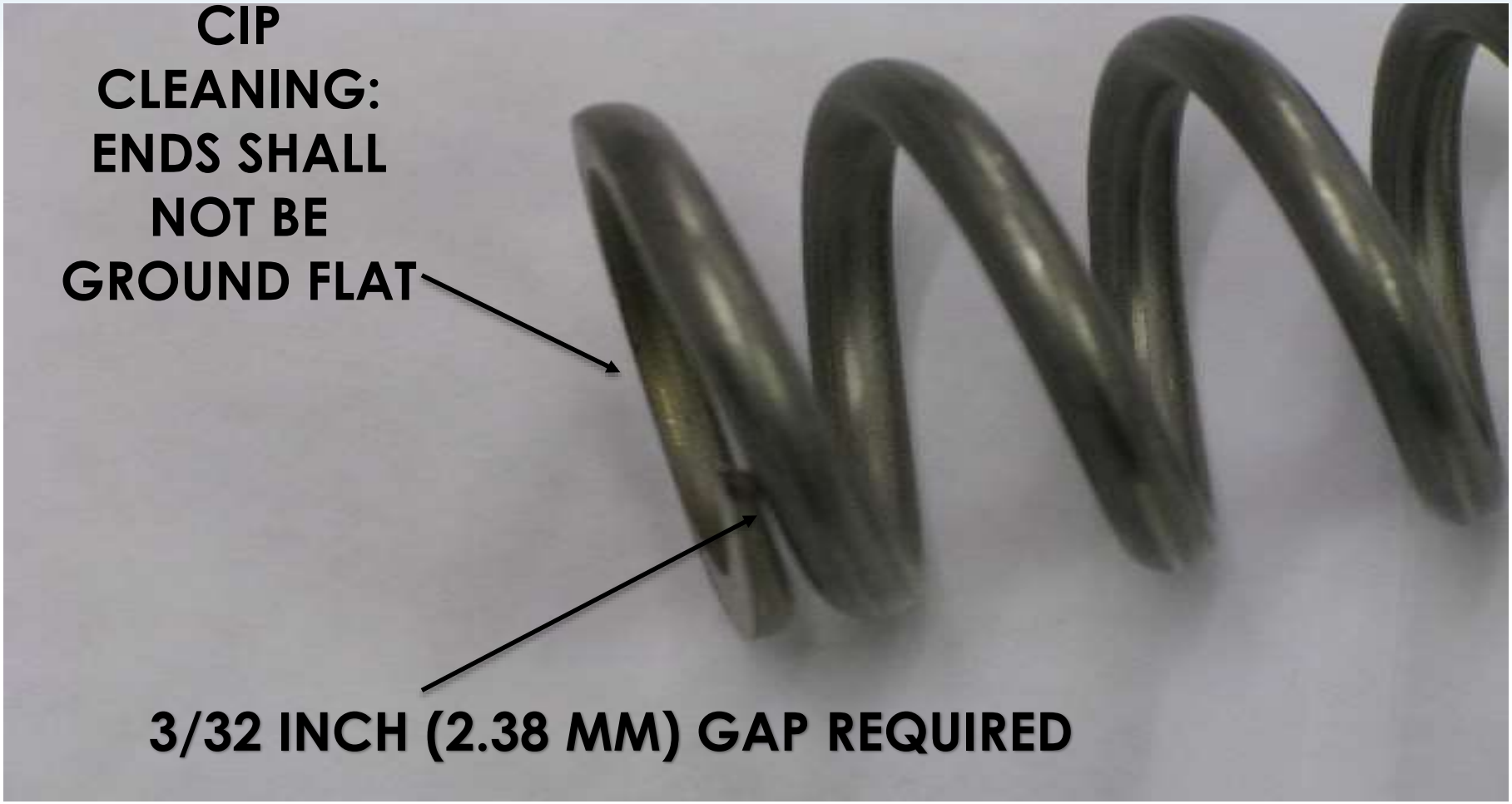
- Exposed Threads when permitted by the Standard.
  - ACME
  - Trapezoid DIN103
  - Knuckle DIN 405
  - Manual cleaning

THREADS

- ENCLOSED THREADS WHEN PERMITTED BY THE STANDARD.
  - DESIGNED FOR CIP
  - ISOLATED BY O-RING OR GASKET
  - SEAL CONTROLLED COMPRESSION BY A POSITIVE STOP
  - TIGHTNESS SHALL BE VALIDATED BY EHEDG GUIDELINE 2.



COIL SPRINGS



SHAFTS

- PREVENT ENTRANCE OF CONTAMINATES IF THE SHAFT PASSES THROUGH ABOVE PRODUCT
- IF LOCATED BELOW PRODUCT LEVEL SHALL BE FITTED WITH A SANITARY SEAL

BEARINGS

- BEARINGS HAVING PRODUCT CONTACT SURFACE SHALL BE OF A NON LUBRICATED TYPE OR PRODUCT – LUBRICATED
- NORMALLY, A CLEARANCE OF 1 INCH (25.4 MM) IS REQUIRED BETWEEN BEARING AND PRODUCT CONTACT SURFACES.

QUESTIONS?