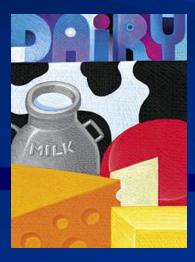
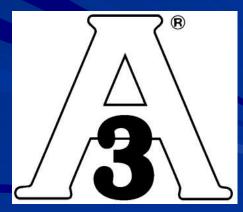
# 3-A SSI For Beginners and the Basics of Sanitary Design

#### 3-A Sanitary Standards, Inc. May 14, 2012





## Welcome!



#### Welcome!



#### The 100 Most Influential People in the World



Special Welcome! Student Travel Award Recipients Ron Schmidt, Chair, 3-A SSI



### **Student Travel Award Recipients**

Breanne Harlan, Cal Poly San Luis Obispo

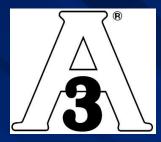
Esmond Nyarko, University of Vermont

## Program Welcome! Larry Hanson Chair, 3-A SSI Communications & Education Committee





The Schedule
Overview of 3-A SSI
Basics Part 1 Break
Basics Part 2
Wrap Up



### And Now...

# **3-A SSI For Beginners**



# **3-A SSI For Beginners**

History and StructureKey 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



# **Brief History of 3-A SSI**

1920 First Standard 1944 USPH Participation

1956 New Symbol 2002 3A-SSI



# Before 2002 After 2002

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

3A Sanitary Standards Inc.

#### The 3-A SSI Stakeholders

Regulatory Sanitarians
 Processors (Users)
 Fabricators

#### 3-A Sanitary Standards, Inc.

#### **The 3-A SSI Structure**

As a non-profit corporation, 3-A SSI is governed by Articles of Incorporation and Bylaws

- Decision making authority is vested in the Board of Directors
- Dedicated, independent staff

#### **The 3-A SSI Board of Directors**

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 Chair of the P3-A Steering Committee **One USDA and one FDA representative** 

### **3-A SSI Board of Directors**

#### Officers

- Chair, Ron Schmidt, University of Florida
- Vice Chair, Dan Meyer, ADPI
- Secretary, Carl Buell, Leprino Foods
- Treasurer, Lou Beaudette, Admix, Inc.

Directors
Ken Anderson, IAFP
Warren S. Clark, Jr., 3-A Administrative Symbol Council (retired)
Ray Dyke, Agri-Mark, Inc.

Jon Gardner, IDFA

#### **3-A SSI Board of Directors**

- Larry Hanson, Johnsonville Sausage, LLC
- Robert Hennes, FDA/CFSAN – Milk Safety Branch
- Paul Hoblitzell, Eli Lilly Co., P3-A Steering Committee

 Ken Vorgert, USDA/AMS Dairy Grading Branch
 Lyle Clem, 3-A Steering Committee
 Tracy Schonrock, TPV Coordinating Committee
 David Seckman, FPSA

#### The 3-A SSI Staff

Oversees organization activities:

- Standards Writing and Publishing
- Industry Education and Training
- Administration of 3-A Symbol Licensing Program
- Harmonization and Liaison

#### **Mission Objectives**

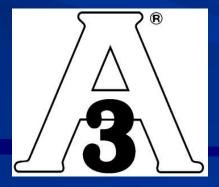
- To advance the regulatory goals of USDA, FDA, regional and local agencies through a credible third party verification program for food processing equipment and systems.
- To promote recognition and adoption of 3-A sanitary design criteria worldwide.
- To administer a modern, effective, and efficient consensus process to develop national standards.
- To advance the application of 3-A Sanitary Standards in the processing of all comestible products.
- To maintain a sound, progressive and respected organization to serve the evolving interests of all stakeholders in sanitary equipment design and advance the goal of public health.

#### **The 3-A SSI Committees**

Communications & Education
Finance Committee
TPV Coordinating Committee
Interpretations Committee
3-A Steering Committee
P3-A Steering Committee

### What is the 3-A Symbol?

The 3-A Symbol is a licensed mark used to show the conformity of equipment designed and manufactured to a 3-A Sanitary Standard.



### **Use of the 3-A Symbol**

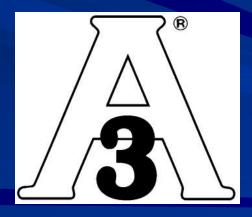
Since introduction of the mark in 1956, use of the mark was based on selfcertification.

3-A SSI was created to implement a new Third Party Verification (TPV) inspection program for all users of the mark.



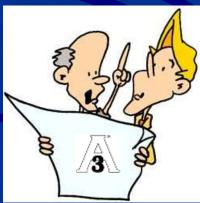
# Why a New TPV Requirement?

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 <u>credentialed</u> 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.



### How a TPV is Done

- The Symbol Holder or applicant contracts with a CCE to do a TPV.
- The CCE reviews drawings, bills of material, <u>material certificates</u>, and compares to the 3-A Sanitary Standard.
- The CCE inspects an actual piece of finished equipment—checks radii, surface finish, welds, etc.
- The CCE inspects the fabrication plant on site visit is required.
- The CCE reviews EDTCF, Quality program, instruction manuals, etc.

#### How a TPV is Done

The CCE issues a report and certificate of the TPV with 4 copies:

- One to the 3-A SSI Office
- Two to the Fabricator, one to send to 3-A
   SSI and the other for their file.
- One for the CCE files
- The TPV Report follows the language of the standards.
- The TPV is good for 5 years unless significant design changes or Report of Alleged Nonconformance.

#### **Qualifications of a CCE**

Must meet specific criteria for education and work experience.

- Must have high professional integrity.
- Must pass comprehensive written exam.
- Must undergo special CCE orientation and ongoing training.





## **TPV Inspection Sites**

Argentina Austria Belgium Brazil Canada China Denmark England Finland France Germany Israel Italy

Japan Korea Mexico Netherlands New Zealand Poland Portugal 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 **P3-A Symbol authorization** 

#### The Role of 3-A SSI 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.

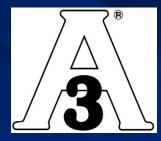
### The Role of 3-A SSI in Commerce

USPHS/FDA Pasteurized Milk Ordinance (PMO)

Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance.



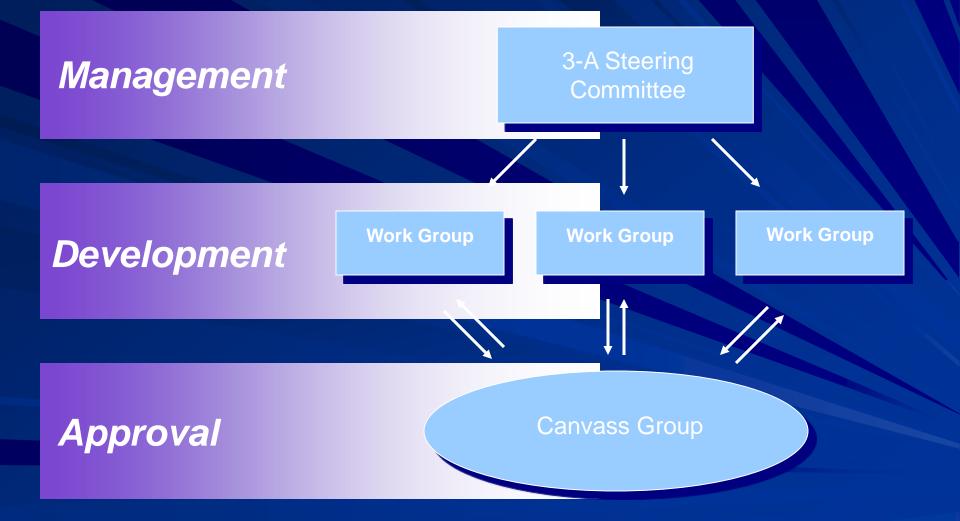
### The Consensus Process How Does 3-A SSI Develop Documents?



#### The Consensus Process 3-A SSI is an ANSI-accredited Standards Developer Organization (SDO)

3-A Sanitary Standards
 3-A Accepted Practices
 P3-A Standards

### **Consensus Process - Overview**



# Basics of Sanitary Design Part 1



### What is a 3-A Sanitary Standard?

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



# **3-A Sanitary Standards**

Vessels
Fillers
Valves and Fittings
Pumps and Mixers
Heat Exchangers
Gonveyors and Feeders Instruments Concentrating Equipment Farm/Raw Milk Cheese and Butter Equipment Materials and **Materials Testing** 

## What is a 3-A Accepted Practice?

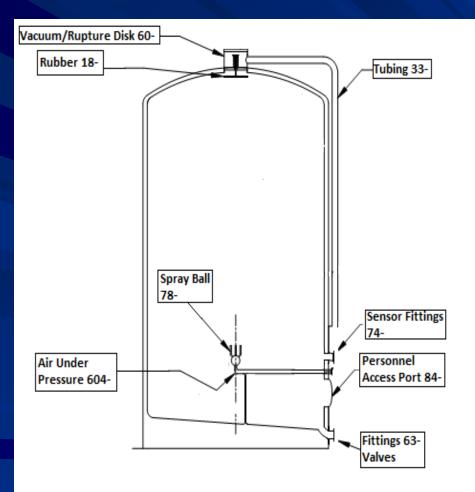
3-A Accepted Practices specify the criteria for the design, fabrication and installation of <u>systems</u> that come into contact with food.

## **3-A Accepted Practices**

Process and Cleaning Systems

- HTST and HHST Pasteurizer Systems (603-)
- Permanently Installed Product and Solution Pipelines and Cleaning Systems (605-)
- CIP for Equipment (613-)
- ESL/UP Practice (614-).
- Plant Support Systems
  - Air Under Pressure for Product Contact (604-)
  - Steam of Culinary Quality (609-)
  - Facilities Air Quality (612-)

# **How They Work Together**





## Seven Common Elements of 3-A Sanitary Standards and Accepted Practices

- 1) Scope of the Standard
- 2) Normative References
- 3) Definition of Terms Used
- 4) Description of Permitted Materials
- 5) Details of Fabrication
- 6) Appendix
- 7) Installation



Amplifies the Title to differentiate this document from all others.

Build a box around what the document covers.

Clearly identify the inlets and outlets

May state what the document doesn't cover

## **Normative References**

**B1** The following listed 3-A Sanitary **Standards, 3-A Accepted Practices and** other documents shall be considered as Normative References and the provisions of the referenced documents shall apply to this Standard {or Accepted Practice} without further reference in this document unless necessary to describe special considerations.

## Definitions

To define special or unusual terms used in the document.

Definitions not used in the document should not be included.

As appropriate, new definitions can be created.

Product Contact Surfaces: All surfaces which are exposed to the product and surfaces from which splashed product, liquids or material may drain, drop, diffuse **{Where Applicable}**, or be drawn into the product or onto product contact surfaces. **{Surfaces That Come Into Contact With Product Contact Surfaces Of Packaging Materials May Be Included In This Definition For Some Equipment.}** 

Nonproduct Contact Surfaces: All exposed surfaces from which splashed product, liquids, or other materials cannot drain, drop, diffuse **{Where Applicable}** or be drawn into or onto the product, product contact surfaces, open packages, or the product contact surfaces of package components.

# **Cleaning Definitions**

Clean-in-Place (CIP)

Clean-Out-of-Place (COP)

Manual Cleaning

Dry Cleaning

## **Materials**

To identify what materials can be used to fabricate the equipment.

Product Contact Surfaces
– Metals

- Nonmetals

Nonproduct Contact Surfaces

Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AIST) 300 Series, excluding 301, 302, and 303, (Refer to B4, Reference No. 5) or corresponding Alloy Cast Institute (ACI) types (Refer to B4, Reference No. 6) or metal which under conditions of intended use is at least as corrosion resistant as 304 stainless steel, and is nontoxic and nonabsorbent. (Refer to Appendix, Section H.) Where welding is involved, the carbon content of the stainless steel shall not exceed 0.08%.

Rubber and rubber-like materials may be used for **{All Required Application(s) Including Coatings}** and when used for the specified application(s), shall conform to the applicable provisions of 3-A Sanitary Standard, Number 18-.

Plastic materials may be used for **{All Required Application(s) Including Coatings}** and when used for the above-specified application(s), shall conform to the applicable provisions of 3-A Sanitary Standard, Number 20-.

# Fabrication

- Equipment is to be designed to be 100% cleanable.
- The design must preclude contamination of the product.
- Fabrication to 3-A criteria DOES NOT automatically imply compatibility with CIP cleaning methods.
- Illustrations are not to be interpreted as engineering drawings.

# Appendix

Generally considered as informational or advisory.

"Should" is the term used.

## **Appendix Sections**

Stainless Steels
Optional Metal Alloys
Product Contact Surface Finish
Air Venting
Engineering Design and Technical Construction File (EDTCF)

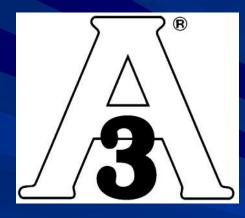
## Installation

This is an optional section.

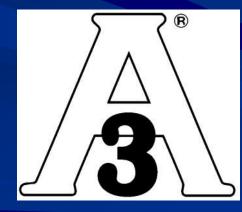
This may be in the body of the document or as part of the appendix.

Provides guidance for proper installation.

# Break



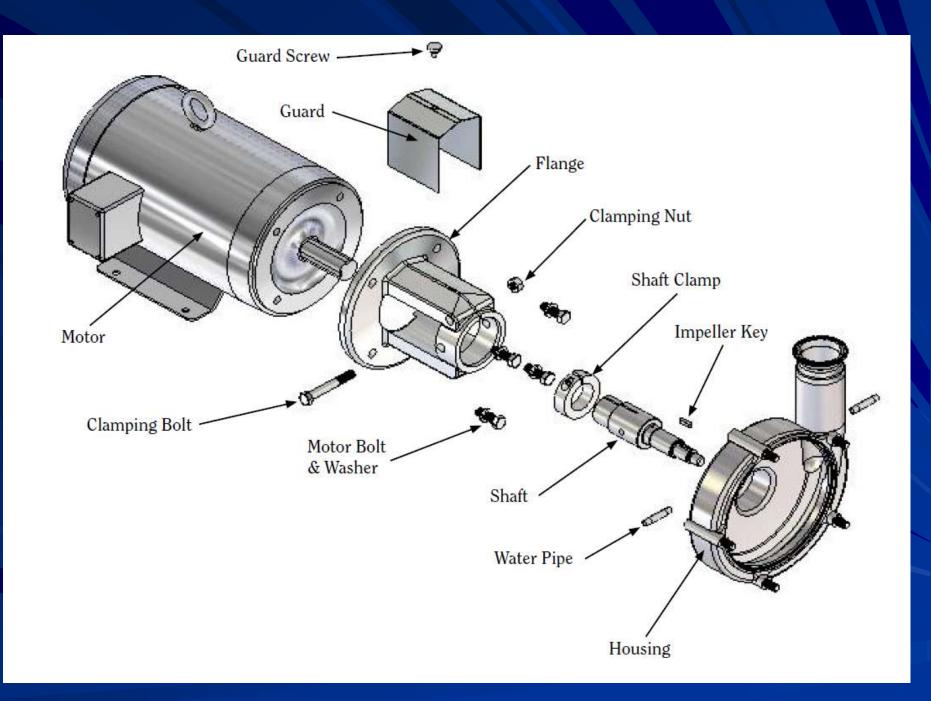
# Basics of Sanitary Design Part 2 Pump Evaluation, 02-10

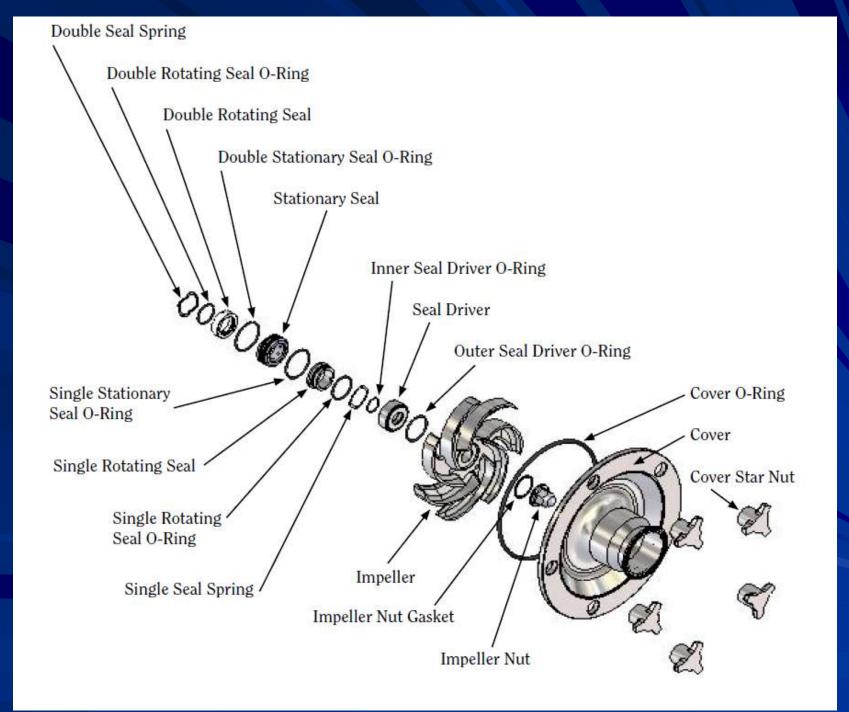


# Centrifugal Pump Evaluation









## While Disassembled –

All Radii Can Be Measured
 Agreement with Drawings Verified
 Exposure of Seals Verified
 Surface Finishes Verified
 General Suitability Confirmed
 Nonproduct Contact Matls Checked
 Agreement with Documentation

## While Disassembled –

CCE Checklist Completion
 Marking of Standard Performed
 Material Options Verified
 Understanding of QC Process
 Confirm Any Special User Guidance
 Reassembly Instructions Verified
 Facility Review and QC Verified

## D1 Surface Finish

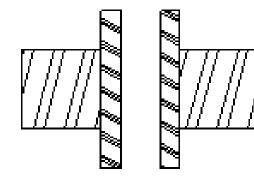
D1.1 All product contact surfaces shall have a finish at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form.

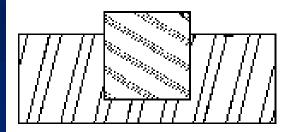
#### D2 Permanent Joints

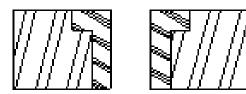
D2.1 All permanent joints in metallic product contact surfaces shall be continuously welded. Welded areas on product contact surfaces shall be at least as smooth as a No. 4 ground finish on stainless steel sheets, and be free of imperfections such as pits, folds, and crevices when in the final fabricated form except that:

D2.1.1 In such cases where welding is impractical, soldering, press-fitting or shrink-fitting may be employed where necessary for essential functional reasons such as bushings, internal bearings, pins and mechanical seal components. (See Appendix, Section E7.) D2.1.2 Silver bearing solder may be used around pins for sealing joints and producing fillets for minimum radii.

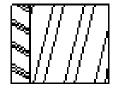
D2.1.3 Press-fitting, shrink-fitting or soldering shall produce product contact surfaces which are at least as smooth as a No. 4 ground finish on stainless steel sheets which are free of imperfections such as pits, folds and crevices. (See Appendix, Section E6.)











## D3 Coatings

D3.1 Coatings, if used, shall be free from surface delamination, pitting, flaking, spalling, blistering and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.

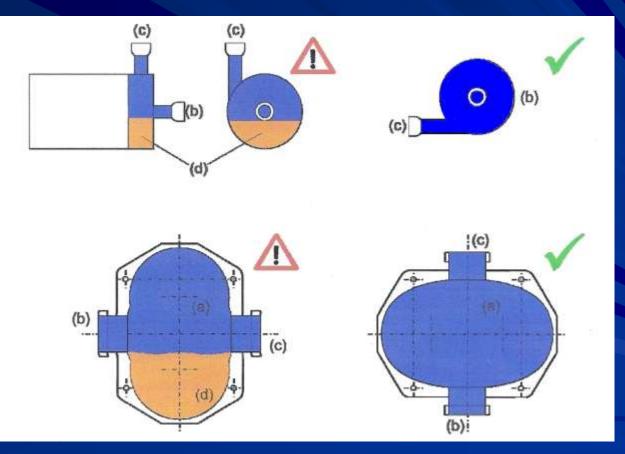
### D4 Cleaning

D4.1 Centrifugal and positive rotary pumps that are to be mechanically cleaned shall be designed so that the product contact surfaces of the pump and all nonremoved appurtenances thereto can be mechanically cleaned and are easily accessible and readily removable for inspection.

D4.2 Product contact surfaces not designed to be mechanically cleaned shall be easily accessible for cleaning and inspection when in an assembled position or when removed. Demountable parts shall be readily removable.

### D5 Draining

D5.1 All product contact surfaces shall be drainable when disassembled.



From EHEDG Doc. 10 (modified)

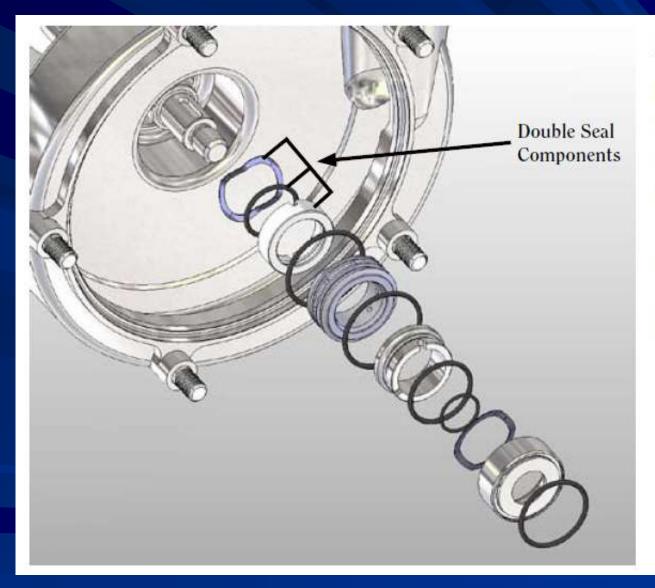
### D6 Fittings

D6.1 All sanitary fittings and connections shall conform to the 3-A Sanitary Standards for Sanitary Fittings for Milk and Milk Products, Number 63-.

D6.2 Rectangular flanges or round flange-type fittings may be used for specific applications such as connectors to hoppers or feeders.

## D7 Seals

D7.1 The shaft seal(s) shall be sanitary in design with all product contact parts demountable and accessible for inspection or cleaning, and shall not be of the packing type.



#### Figure 3

Remove seal driver/rotating seal assembly.

Discard rotating seal, o-rings and spring.

Remove stationary seal and discard.

Double Seal Only: Remove double rotating seal and double spring and discard.

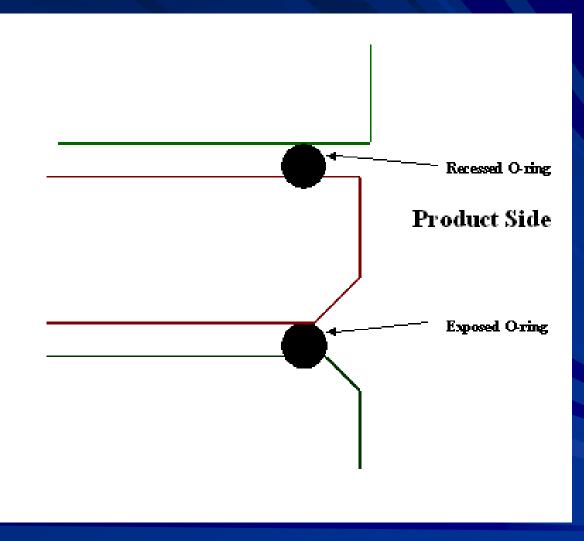
### D8 Gaskets

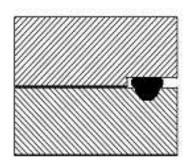
D8.1 Gaskets having a product contact surface shall be removable or bonded.

D8.2 Grooves in gaskets shall be no deeper than their width.

D8.3 Gasket retaining grooves in product contact surfaces for removable gaskets shall not exceed 1/4 in. (6.35 mm) in depth or be less than 1/4 in. (6.35 mm) wide except those for standard 0-rings smaller than 1/4 in. (6.35 mm), and those provided for in Section D6.1.

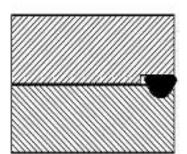
D8.4 Gaskets, when used, shall be self positioning and form a substantially flush interior joint.





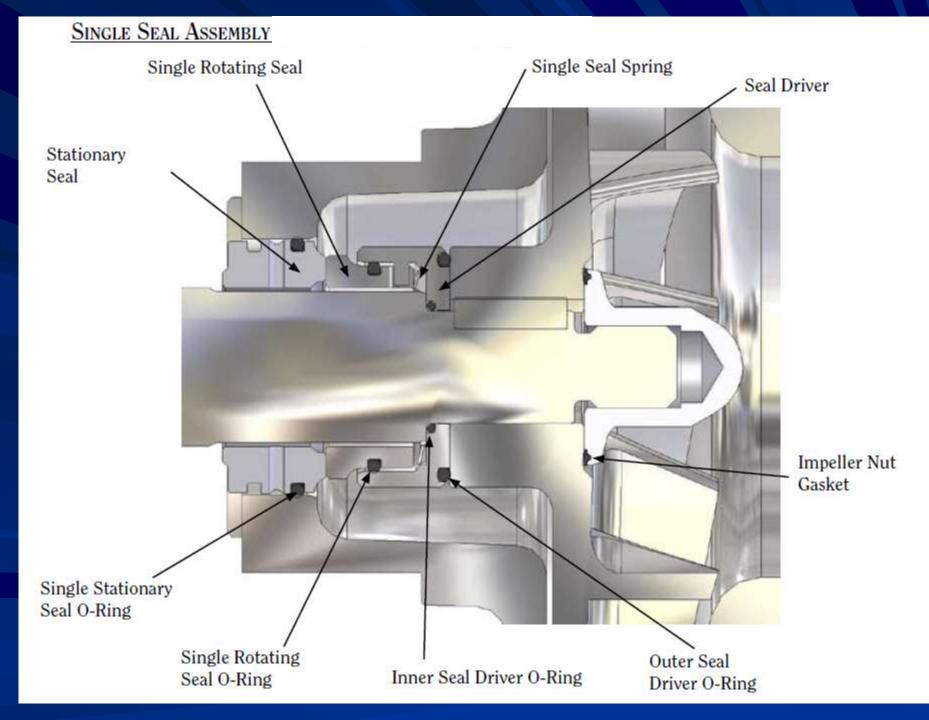
#### HARD TO CLEAN RECESSED SEAL LOCATION

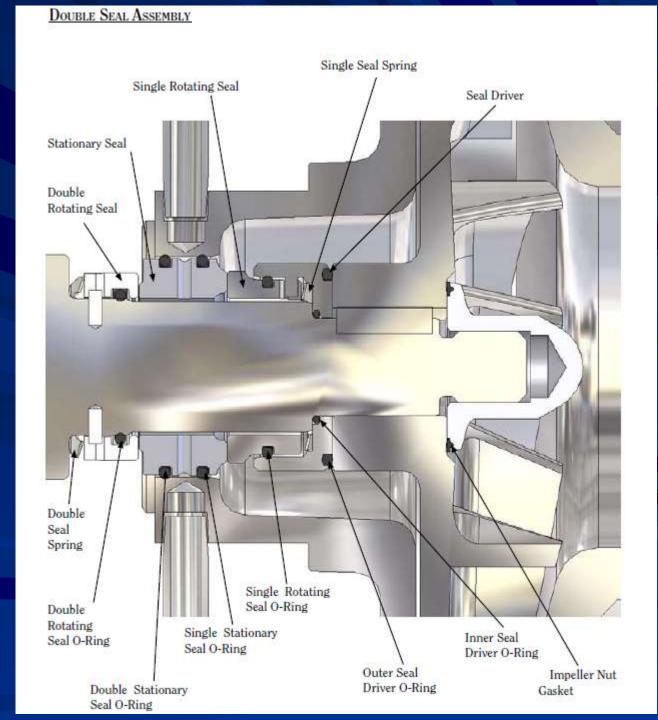
#### (NOT ACCEPTABLE FOR CIP CLEANING. MUST BE DISASSEMBLED FOR CLEANING)



EASY TO CLEAN BY C.I.P.

( SEAL LOCATED AND COMPRESSED TO FIT FLUSH OR WITH SLIGHT BULGE )





#### D9 Radii

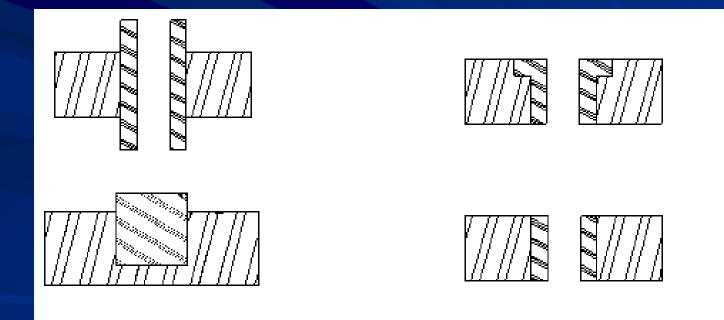
D9.1 All internal angles of less than 135° on product contact surfaces shall have radii of not less than 1/8 in. (3.18 mm) except that:

D9.1.1 Smaller radii may be used when they are required for essential functional reasons, such as those in seal components; slots in the heads of impeller or rotor retaining fasteners; and rotor-to-body clearance areas. In no case shall such radii be less than 1/32 in. (0.794 mm) except that:

D9.1.1.1 The radius at the intersection of press-fits, shrink-fits and flat sealing surfaces is zero by nature of the design and definition of this type of fabrication. D9.1.2 The radii in grooves in gaskets or gasket retaining grooves shall be not less than 1/16 in. (1.59 mm), except for those for standard 1/4 in. (6.35 mm) and smaller O-rings and those provided for in Section D6.1.

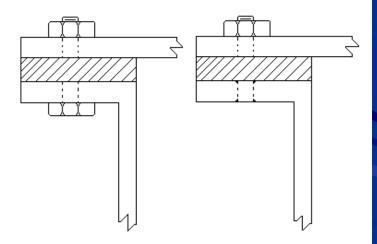
D9.1.3 Radii in standard O-ring grooves shall be as specified in Appendix E9.

D9.1.4 Radii in nonstandard O-ring grooves shall be those radii closest to a standard O-ring as specified in Appendix E9. There are no minimum radii requirements for soldered joints or for the product contact junctures of press or shrink fits.



There are no minimum radii requirements for the product contact junctures of flat sealing surfaces.

# Flat Sealing Surface



# D10 Springs

Coil springs having product contact surfaces shall have at least 3/32 in. (2 mm) openings between coils including the ends when it is in a free position.

### D11 Threads

D11.1 There shall be no threads on product contact surfaces except for holding the impeller or rotor to the shaft.D11.2 Shaft threads must conform to one of the following thread specifications:

### D11.2.1 Exposed Threads

1. Pumps with exposed shaft threads shall be designed for manual cleaning.

2. Threads shall conform to Appendix E8.1.

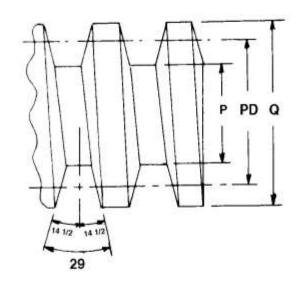
3. Threaded angles shall be not less than 60°.

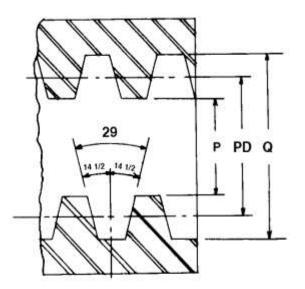
4. There shall not be more than 8 threads per in. (25. mm).

5. The nut shall be of the open type.

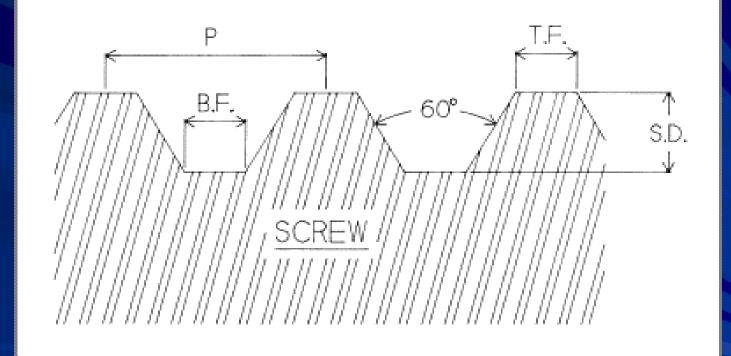
6 The length of the nut shall not exceed three-fourths of the thread's basic diameter.

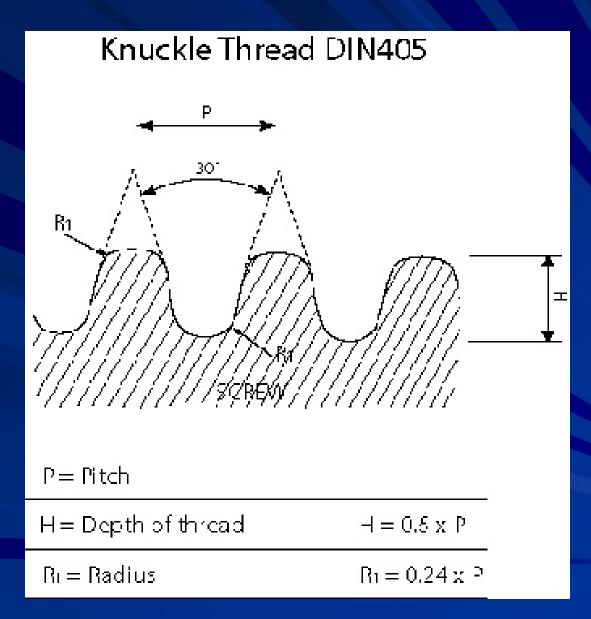
# **ACME Thread**





# **American Standard Stub Acme Thread**





#### D11.2.2 Enclosed Threads

D11.2.2.1 Pumps with enclosed shaft threads shall be designed for mechanical cleaning.

D11.2.2.2 These are threads that have been sealed from the product by means of an O-ring, gasket or similar type seal. The seal shall have controlled compression by means of a positive stop.

D11.2.2.2.1 This controlled compression shall provide a seal which has been validated to demonstrate that there is no migration past the seal under the intended conditions of use.

D11.2.2.2.1.1 The European Hygienic Engineering and Design Group (EHEDG) test for bacterial tightness is an acceptable method of determining migration past the seal. Other equally effective tests may be used as well. D11.2.2.2.1.2 The manufacturer will provide seal replacement procedures that will ensure bacterial tightness as specified in D11.2.2.2.1.1, above.

D11.2.2.3 Thread specifications are designated by the manufacturer.

D11.2.2.4 Bolts, screws or nuts may be used for rotor or impeller retention.

D11.2.2.4.1 If a nut is used, it shall be of the enclosed type.

D11.2.2.4.2 If slotted fasteners are used, the slot(s) shall meet the criteria of Section D9, Radii, and the slot(s) shall be not less than 1/8 in. wide and no deeper than  $2-\frac{1}{2}$  times their width and shall be inspectable.

D11.2.2.4.3 The seal shall be designed so it is capable of being maintained bacterially tight. The manufacturer will provide user guidance for inspection, maintenance, and replacement of the seal as justified by historical data or scientific evidence.

D11.2.2.5 Enclosed threads shall be cleanable and drainable. The manufacturer will also provide validated cleaning procedures, should the area behind the seal become soiled.

#### D12 Bonded Parts

D12.1 Pump impellers, rotors, stators or housings may be made of, covered with or bonded with rubber, rubber-like or plastic materials. D12.2 Housing liners shall be removable or bonded. D12.3 Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces shall be bonded in a manner that the bond is continuous and mechanically sound so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded. D12.4 Components within seal assemblies may be bonded with adhesives.

#### D13 Sterilization Systems

D13.1 Pumps designed to be used in a processing system to be sterilized by heat shall comply with the following:

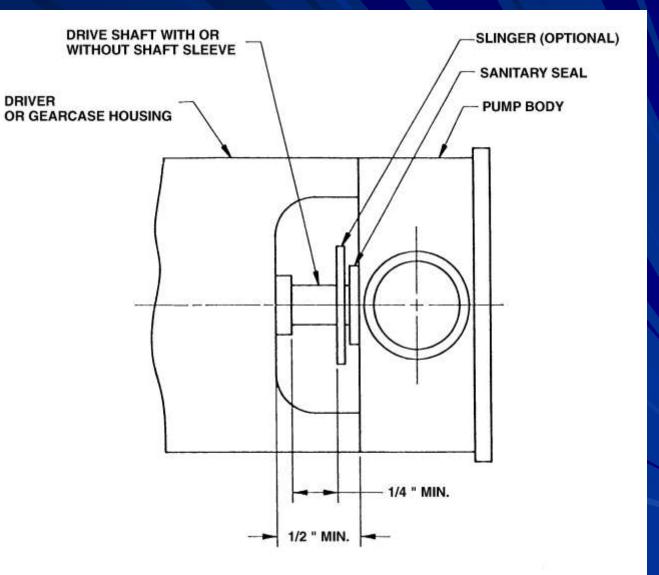
#### D14 Inspectibility

D14.1 A pump shall be designed that (See Appendix, Section E10):

D14.1.1 The open area between the exterior of the driver or gear case housing to the exterior of the product chamber shall be 1/2 in. (12 mm) minimum width and of sufficient area to allow unrestricted viewing of the pump shaft(s) or seal components at the potential leak site. This area shall be self-draining.

D14.1.2 At least 1/4 in. (6mm) of the shaft(s) exclusive of the seal components shall be visible.

D14.1.3 Guards required by a safety standard that will not permit accessibility for cleaning and inspection shall be designed so that they can be removed with the use of simple hand tools. 1. DRIVER OR GEARCASE HOUSING 2. DRIVE SHAFT 3. SLINGER (OPTIONAL) 4. SANITARY SEAL 5. PUMP BODY 6. ½" MINIMUM 7. ¼" MINIMUM



# **D15 Nonproduct Contact Surfaces**

D15.1 Nonproduct contact surfaces shall have a smooth finish, free of pockets and crevices, and be readily cleanable and those surfaces to be coated shall be effectively prepared for coating.

### D16 Supports

### D16.1 Baseplate Mounted

D16.1.1 A baseplate mounted unit consists of some or all of the following components:

- 1. Pump
- 2. Motor

3. Mechanical reduction unit such as a gearbox, gearhead drive, variable speed drive, chain and sprocket system or belt and pulley system.

- 4. Pedestal
- 5. Coupling
- 6. Guard
- 7. Baseplate
- 8. Legs

D16.1.2 The baseplate(s) shall be constructed of (a) solid metal plate(s) or (b) tubular metal that has all open ends sealed by welding.

D16.1.3 The metal shall be stainless steel or coated or painted mild steel.

#### D16.2 Legs

D16.2.1 Legs, when used, shall be adjustable or fixed with rounded ends or have flat load bearing feet suitable for mounting to the floor and have no exposed threads.

D16.2.2 Legs made of hollow stock shall be sealed.

D16.2.3 Legs shall be of sufficient length to provide a minimum clearance between the lowest part of the base, pump, motor or drive and floor no less than 4 in. (100 mm) on pumps with legs designed to be fixed to the floor or pumps having a horizontal base area of more than 1 ft2 (0.095 m2). D16.2.4 Legs shall be of sufficient length to provide a minimum clearance of 2 in. (50 mm) on pumps having a horizontal base area of 1 ft2 (0.095 m2) or less and not designed to be fixed to the floor. **Copyright© 3-A Sanitary Standards, Inc., McLean, VA 02-10 7** 

D16.2.5 If casters or wheels are used they shall be of sufficient size to provide a clearance between the lowest part of the base and the floor of not less than 4 in. (101.6 mm). Casters or wheels, if provided, shall be easily cleanable, durable, and of a size that will permit easy movement of the centrifugal or positive rotary pump.

# More Details on 3-A SSI

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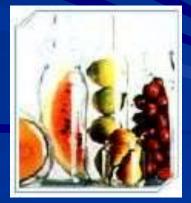
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# **Questions?**

