

Basics of Sanitary Design

Dan Erickson

Harold Wainess & Associates

**The Symbol
of Assurance**



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

3-A Sanitary Standards, Inc.
May 12, 2014



Welcome!

Lou Beaudette, 3-A SSI Chair



Program Chair Larry Hanson



Special Welcome!

Student Travel Award Recipients



Student Travel Award Recipients

- M. Alexandra Calle, Texas Tech University
- Brian Chau, University of California, Davis
- Byron Chaves, Texas Tech University
- Thomas Frederick, University of Tennessee
- Josh Ison, Texas Tech University
- Robson Machado, Penn State University

3-A SSI Executive Director

Tim Rugh





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 Structure**
- **Key Activities**



What is 3-A Sanitary Standards, Inc.?

- **Social 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

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.

The 3-A SSI Stakeholders

- Regulatory Sanitarians
- Processors (Users)
- Fabricators



3-A Sanitary Standards, Inc.

The 3-A SSI Structure

- As a social 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, Lou Beaudette, Admix, Inc.**
- **Vice Chair, Dan Meyer, ADPI**
- **Secretary, Ken Anderson, Harold Wainess Associates**
- **Treasurer, Carl Buell, Leprino Foods**
- **Larry Hanson, Johnsonville Sausage, LLC**
- **Robert F. Hennes, Chief, FDA/CFSAN-Milk Safety Branch**
- **Ronald Schmidt, University of Florida**
- **F. Tracy Schonrock, TPV Coordinating Committee**
- **David Seckman, FPSA**
- **Ken Vorgert, USDA/AMS, Dairy Grading Branch**

Directors

- **John T. Allan, IDFA**
- **Warren S. Clark, Jr., Consultant**
- **Lyle Clem, ESC, 3-A Steering Committee**
- **Ray Dyke, Agri-Mark, Inc.**

The 3-A SSI Staff

■ Primary organization activities:

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

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.



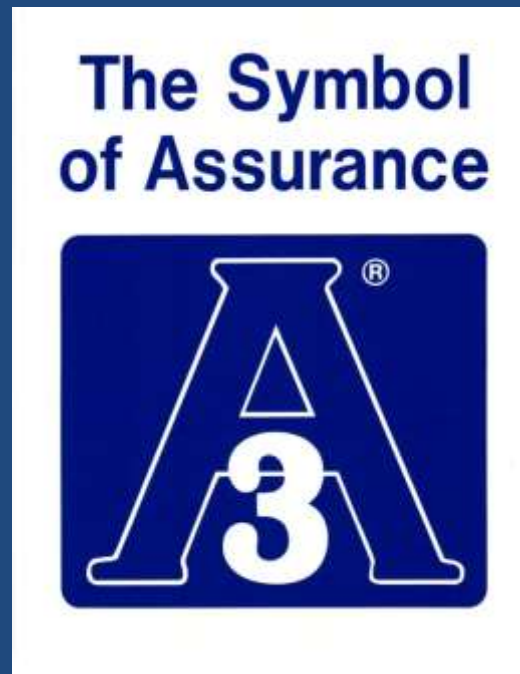
Use of the 3-A Symbol

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



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, material certificates, 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
- 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
 - 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?

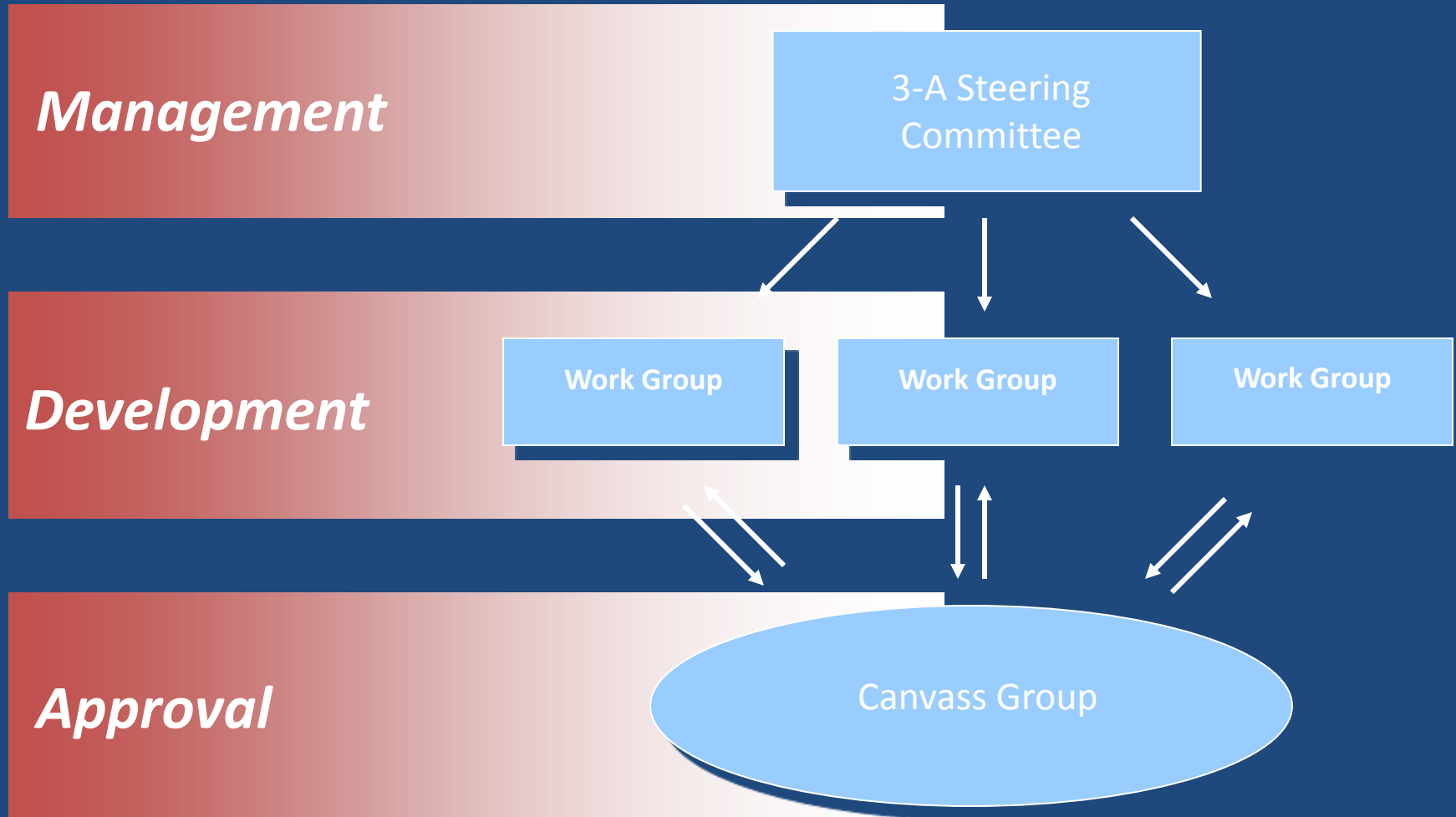


The Consensus Process

**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

Dan Erickson

**The Symbol
of Assurance**





Louis Pasteur

1822 - 1895

We tip our hat to
the Father of
modern
microbiology.

3-A Sanitary
Standards consider
and evaluate
processing
equipment on a
microbiological
level!

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

Dr. Pastuer's name
is synonymous with
processes that
render common
foods safe!

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.

MILK AND MILK PRODUCT EQUIPMENT

A GUIDELINE FOR EVALUATING CONSTRUCTION

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration



This document was used for many years by
regulators

FOREWORD

This Guide developed by the Milk Safety Team, Division of Cooperative Programs, U.S. Public Health Service/Food and Drug Administration is designed to assist milk regulatory officials in evaluating milk and milk product equipment for compliance with the Grade A Pasteurized Milk Ordinance.

The 3-A Standards Committees, the European Hygienic Design Group, USDA and others have provided valuable resource information in the development of this Guide.

We would like to offer our particular thanks to the National Conference on Interstate Milk Shipments Liaison Committee, Marlena Boardson (chair), Daniel J. Borer, Don Breiner, Rob Byrne, Warren S. Clark, Cary Frye, Ruth Fuqua, Lee Jensen, Charles Murphy, Gail Prince, Daniel F. Rackley; and the NCIMS Technical Committee, Karen J. Engebretson (chair), Kenneth Anderson, Robert Gotez, David Lattan, Jon Lauer, Terry Long, John T. O'Connor, Jeffery J. Ryan, Joseph E. Schlesser and Steven T. Sims; as well as the following FDA reviewers; Peter C. Baker, Thomas Bowman, Rodney D. Bridge, Robert N. Childers, Glen R Henderson, Robert F. Hennes, Lloyd A. Kinzel, Terry B. Musson, Raymond Niles, Charles D. Price, Joseph E. Schlesser Steven T. Sims, Joseph M. Smucker and Carla Williams for their work reviewing and improving this document.



3-A keeps the public safe

3-A Accepted Practices and the Grade A Pasteurized Milk Ordinance guide dairy processors in producing safe foods.

Editor's note: 3-A Today is a new column looking at issues in dairy processing, sanitation and regulation. 3-A SSI is an ANSI-accredited standards developer organization that serves manufacturers, users and regulators of dairy and food equipment. This article was written by Steven T. Sims and others.

In 1924, the U.S. Public Health Service published the Standard Milk Ordinance, based on the request for assistance from Alabama regarding a recommended Statewide Milk Sanitation Program. In 1926, the USPHS published more general guidance for state and local milk regulators to use as a model ordinance for adoption into their laws.

Since the early 1950s, this model ordinance and the milk safety program it supports has been jointly administered by the USPHS (in 1968 the program was transferred to the Food and Drug Administration) and the National Conference on Interstate Milk Shipments. The various revisions of this model ordinance have been known as the Grade A Pasteurized Milk Ordinance.

The 3-A organization has been promoting standards since the 1920s. In 1944, the Surgeon General of the United States agreed to participate with 3-A in the development of 3-A Sanitary Standards for the sanitary design and construction of dairy equipment. Since that time, equipment that is in conformance with a 3-A Sanitary Standard has been accepted as being in compliance with the equipment design and construction requirements of the PMO.

A new mission for a new century

3-A has evolved and changed over the years. In 2002, 3-A Sanitary Standards Inc. was incorporated as an independent, not-for-profit 501(c)(3) organization. 3-A SSI established a new mission and

comprehensive objectives and goals to enhance the positive role and visibility of the association.

The significant elements of the historic 3-A program were incorporated into the mission and goals of 3-A SSI as follows:

- Develop, maintain and publish uniform standards and accepted practices for the sanitary (hygienic) design, fabrication, installation and operation of equipment and machinery.
- Use state-of-the-art, science-based expertise for the development of sanitary standards and accepted practices.
- Harmonize with global standards and guidelines as appropriate.
- Promote the use of 3-A Sanitary Standards, 3-A Accepted Practices, and the 3-A Symbol.
- Authorize the use and maintain the integrity of the 3-A Symbol.
- Maintain a uniform system to regulate and enforce the proper use of the 3-A Symbol to best enhance consumer product safety.
- Provide education concerning sanitary design principles, application of 3-A Sanitary Standards, 3-A Accepted Practices, and use of the 3-A Symbol.

The role of the USPHS in 3-A has evolved as well. The milk safety program responsibilities assigned to the USPHS were transferred to FDA in 1968.

The FDA is the U.S. federal regulatory agency charged with the safety of dairy products on a national level. Normally, FDA fulfills this charge by direct inspection and regulatory action. In the case of the Grade A Milk Safety Program, FDA has chosen to fulfill this charge by providing technical assistance to state and local regulators.

Every two years, the NCIMS convenes to consider changes to the PMO and other NCIMS documents. Any changes

that are passed by majority of the state delegates then must be concurred with by FDA.

While the PMO has historically not specifically cited 3-A Accepted Practices, FDA has informally used these practices as guidance. It has not objected to systems that meet a current 3-A Accepted Practice. Some of the 10 3-A Accepted Practices include HITST and HHST Pasteurizer Systems, Milking & Milk Handling Equipment, Spray Drying and Instantizing.

Current status

Within the 2013 Revision of the PMO, the following text from Proposal 105 for both Grade A dairy farms and Grade A milk plants is included. The Note reads in part (bolding added for emphasis):

"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."

This new language formalizes PMO acceptance of the design and construction of a system that complies with one of the 10 current 3-A Accepted Practices and documents that state regulators and FDA may use these 3-A Accepted Practices as guidance when they evaluate such systems. ■

This article was written by Steven T. Sims and representatives of the FDA/CFSAN Milk Safety Team. Timothy R. Rugh is the executive director of 3-A Sanitary Standards Inc., www.3-a.org.



**Canadian Food
Inspection Agency**

**Agence canadienne
d'inspection des aliments**

**Dairy Establishment Inspection Manual
January 2010**



CFIA DEIM Chapter 13

- **CHAPTER 13 - THERMAL PROCESSING TASKS** Dairy Establishment Inspection Manual
- January 2010 13-18a
- **COIL VAT**
- When a coil vat is used for pasteurizing cream for butter-making, it must be pasteurized at the legal pasteurization
- temperature and time as specified by provincial regulations. Any coil vats used to pasteurize ice cream mix or
- other dairy products must be rated under the batch pasteurization tasks.
- **1.13.18.01 General Conditions**
- Coil vats shall be constructed of stainless steel and be in good mechanical and sanitary condition. Sanitary seal
- assemblies at the shaft ends should be of the removable type and cleaned daily. Old style equipment without
- sanitary seals will be accepted if the packing glands are maintained and operated without adverse effects. All new
- units must be provided with removable sanitary seals. Vat liner, coils, centreboard, covers, outlet valve, fittings
- and exterior surfaces must be clean and in good condition.

CFIA DEIM Chapter 13

- **CHAPTER 13 - THERMAL PROCESSING TASKS** Dairy Establishment Inspection Manual
- January 2010 13-18b
- ***COIL VAT***
- **Task Inspection Criteria**
- **1.13.18.01**
- **General Conditions**
- **(HS=2)**
- **(A) General Inspection Criteria for Dairy Plant Equipment**
- **(B) Specific Areas of Interest**
 - Clean and in good condition
 - - sanitary seals
 - - vat liner
 - - coils
 - - valves and fittings
 - - centreboard
 - - covers
 - • Bottom sloped to permit free drainage

CFIA DEIM Chapter 13

- **CHAPTER 13 - THERMAL PROCESSING TASKS** Dairy Establishment Inspection Manual
- January 2010 13-19a
- **1.13.18.02 Critical Controls**
- For control of pasteurization by coil vats, the vats shall be equipped with an indicating and a recording thermometer. Recording charts shall be marked to show all the required information to assess if proper pasteurization occurred for all applicable products.
- For those plants that do not have a recording thermometer, it is the responsibility of the plant personnel to prove that the product is properly pasteurized. One method would be to conduct a phosphatase test on the cream for each day's production (if more than one vat is produced a day, a composite test to include cream from each vat could be done).
- **ALL NEW UNITS MUST HAVE A RECORDING THERMOMETER.**
- No product shall be added to the vat after the beginning of the hold period and the product shall not be removed before the hold period is completed.
- The air space temperature above the product must be at least 3°C (5°F) higher than the minimum required temperature of pasteurization during the holding period. This could be accomplished by installing an air space heater or elevating the pasteurizing temperature.
- Each pasteurizing coil vat must be equipped with an air space indicating thermometer. **Coil vats that are not equipped with an air space indicating thermometer may be rated as satisfactory if a phosphatase test is done to verify the product has been properly pasteurized. All new units must be equipped with an air space indicating thermometer.**
- Vat covers may be open while cream is being heated. However, covers must be closed prior to the holding period to assure proper pasteurization of the air space during the holding time. Covers must be kept closed during the holding and cooling period.

Non-Coil Type Batch Pasteurizers

- **3-A[®] Sanitary Standards for Non-Coil Type Batch Pasteurizers for Milk and Milk Products, Number 24-02**
 - - *Formulated by*
 - *International Association of Food Industry Suppliers (IAFIS)*
 - *International Association for Food Protection (IAFP)*
 - *United States Public Health Service (USPHS)*
 - *The Dairy Industry Committee (DIC)*
- It is the purpose of the IAFIS, IAFP, USPHS, and DIC in connection with the development of the 3-A Sanitary Standards Program to allow and encourage full freedom for inventive genius or new developments. Batch pasteurizer specifications heretofore or hereafter developed which so differ in design, materials, and fabrication or otherwise as not to conform to the following standards but which, in the fabricator's opinion, are equivalent or better, may be submitted for the joint consideration of the IAFIS, IAFP, USPHS, and DIC at any time. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.
- - **A SCOPE**
 - - **A1** These standards cover sanitary aspects of non-coil type batch pasteurizers used to pasteurize milk, fluid milk products, or frozen dessert mixes, including those appurtenances necessary to meet pasteurization requirements. Batch pasteurizers may be either of the atmospheric or closed type. The latter may be operated at pressures from below to above that of the atmosphere.
 - - **A2** In order to conform with these 3-A Sanitary Standards, non-coil type batch pasteurizers shall comply with the following design, material, and fabrication criteria.
 - Use current revisions or editions of all referenced documents cited herein.



USDA GUIDELINES

FOR THE SANITARY

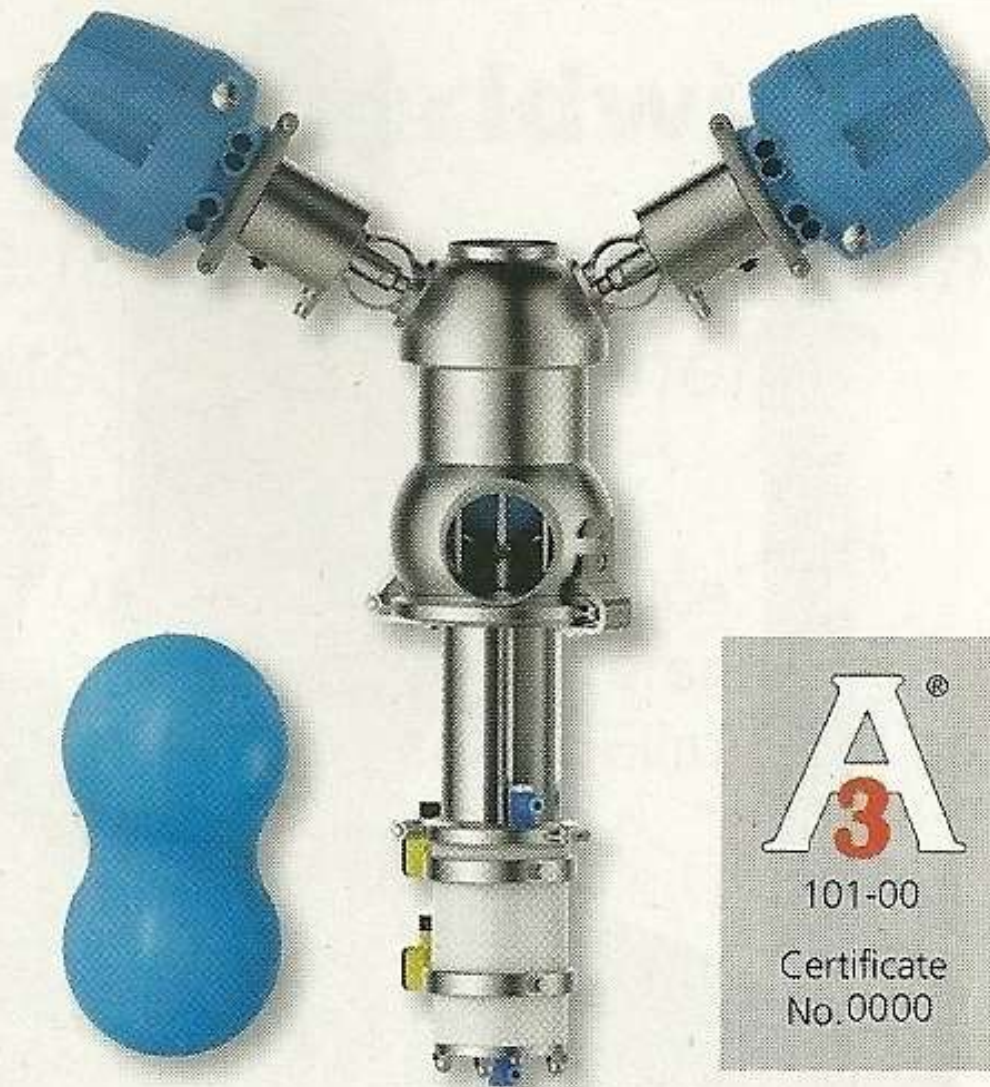
DESIGN AND FABRICATION OF

DAIRY PROCESSING EQUIPMENT

June 2001

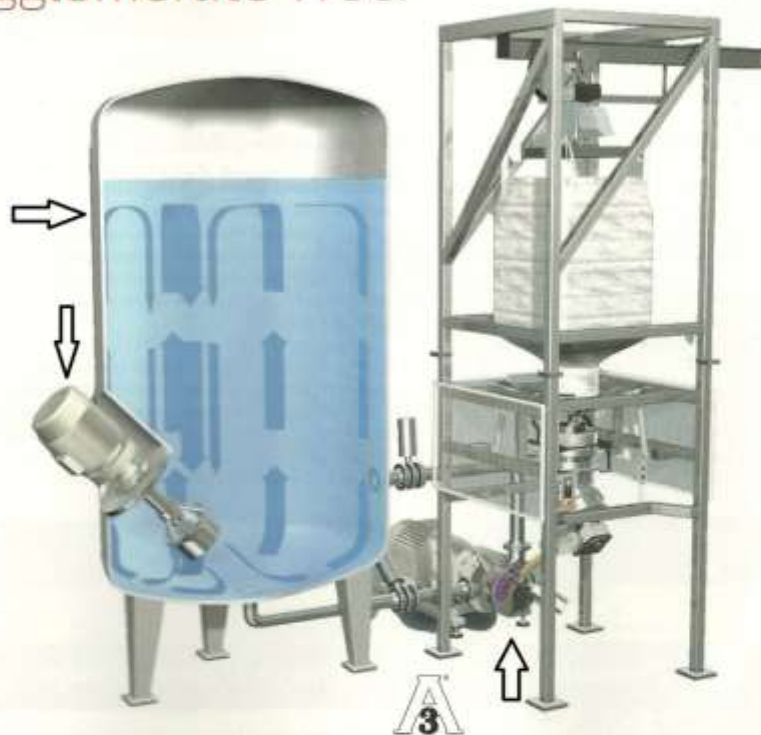
A3

S/N 04-03



**With apologies to the
manufacturer, this ad is
modified for illustration only.**

We Induct and Disperse.
Agglomerate-Free!

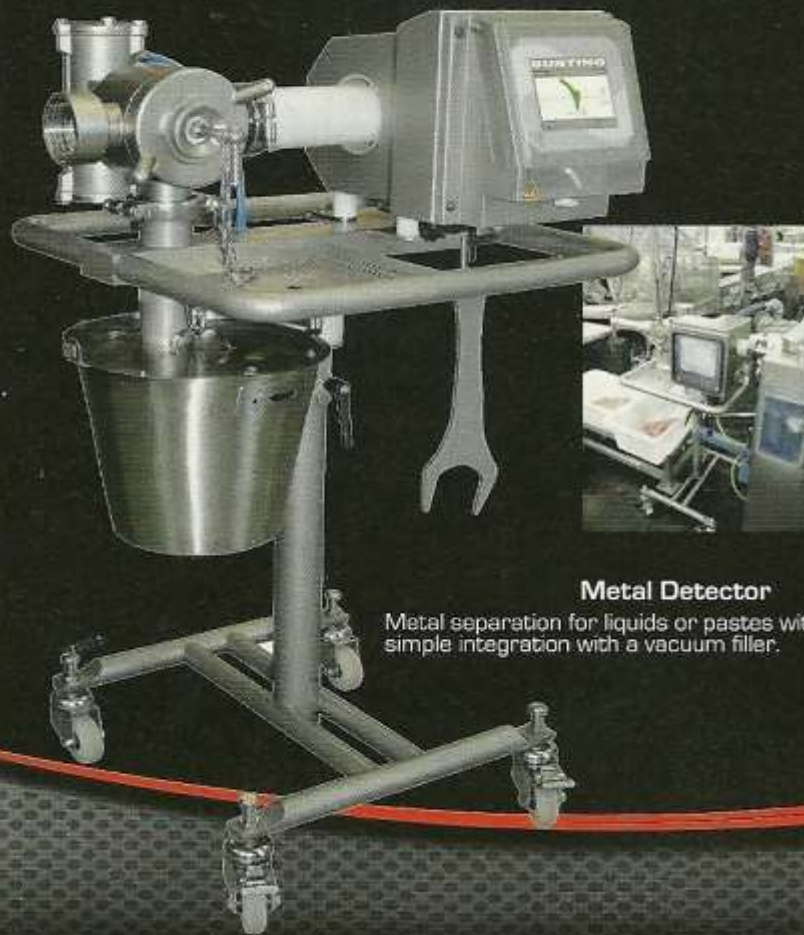


Dispersing dusty, sticky and thickening powders into liquid?
Call today to learn how **technology**
can save you time and money, offering dust-free induction,
wetting and agglomerate-free dispersing of Maltodextrine,
Pectin, Xanthan, Gum Arabica, and more.

With apologies to the equipment integrator, this ad is modified for illustration purposes only.

Rejection is Good

Protect your equipment and keep your product pure.



Metal Detector

Metal separation for liquids or pastes with simple integration with a vacuum filler.



Cartridge Style Magnetic Liquid Trap

Designed to provide continuous, dependable permanent magnetic protection in non-fibrous fluid environments.

With apologies to this manufacturer, this ad is modified for illustration purposes only.

Basics of Sanitary Design

Part 1

**The Symbol
of Assurance**



What is a 3-A Sanitary Standard?

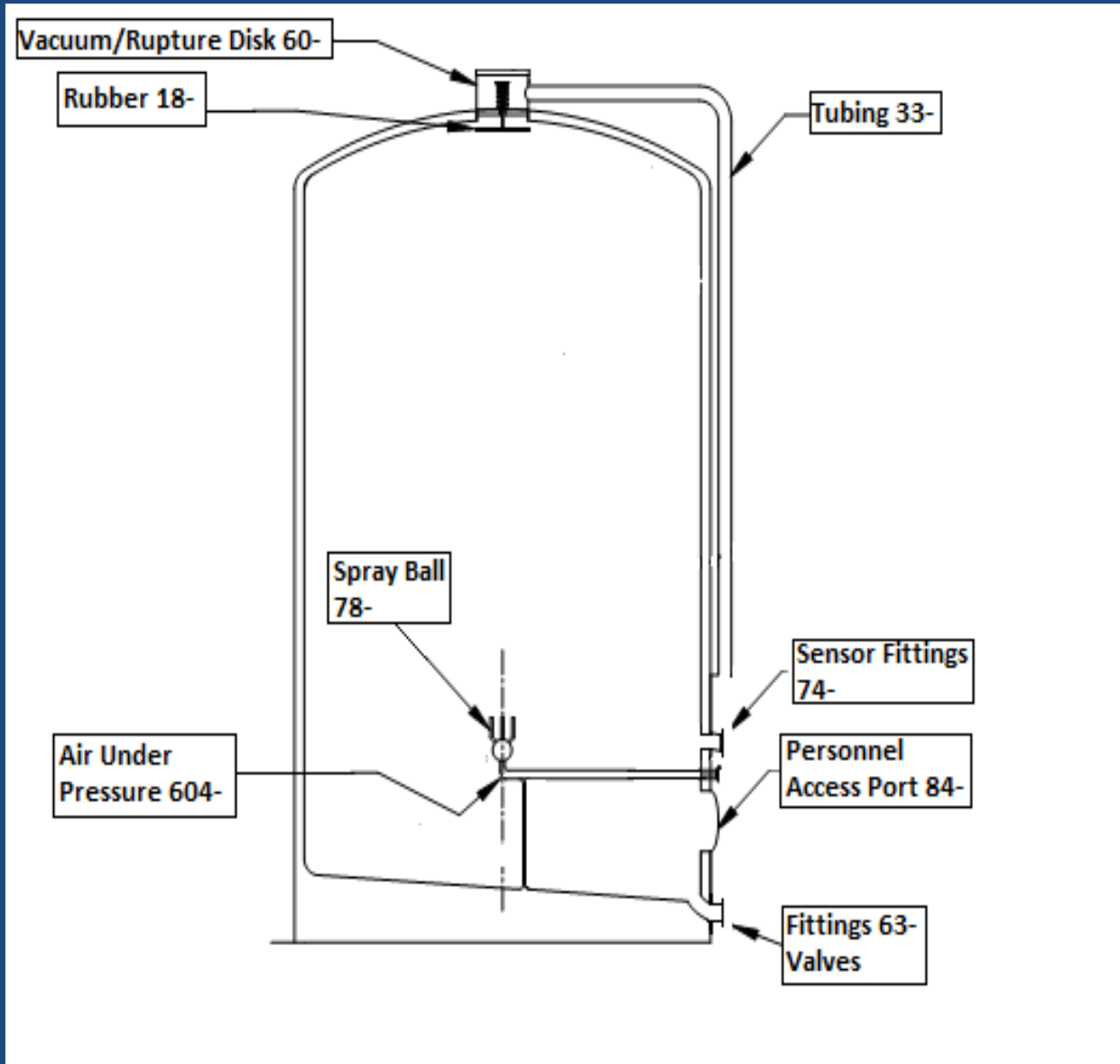
3-A Sanitary Standards specify the criteria for the design and fabrication of a specific type of equipment that comes into contact with food (Milk and Milk Products and Other Comestibles).



3-A Sanitary Standards

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

How They Work Together



Component parts that carry the 3-A Symbol
need no additional follow-up?



What is a 3-A Accepted Practice?

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

3-A Accepted Practices

- **Milking and Milk Handling Equipment (On Farm)**
606-05
- **Process and Cleaning Systems**
 - HTST and HHST Pasteurizer Systems 603-07
 - Permanently Installed Product and Solution Pipelines and Cleaning Systems 605-04
 - Crossflow Membrane Processing Systems 610-02
 - Spray Drying 607-05 and Instantizing 608-02
 - Farm Milk Cooling & Storage 611-00
- **Plant Support Systems**
 - Air Under Pressure for Product Contact 604-05
 - Steam of Culinary Quality 609-03
 - Plant Environmental Air Quality 612-00

E-3-A Sanitary Standards

**E-600 Egg Breaking and Separating.

**E-1500 Shell Egg Washer

**(Last Revision 01-1998)

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**

Scope

- Amplifies the Title to differentiate this document from all others.
- Build a box around what the document covers.
- Clearly identify the inlets and outlets (Beginning and ending points of defined equipment).
- May state what the document does not 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 (AISI) 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**
- **Suggested Cleaning and/or Validated Cleaning Procedures**
- **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

**The Symbol
of Assurance**



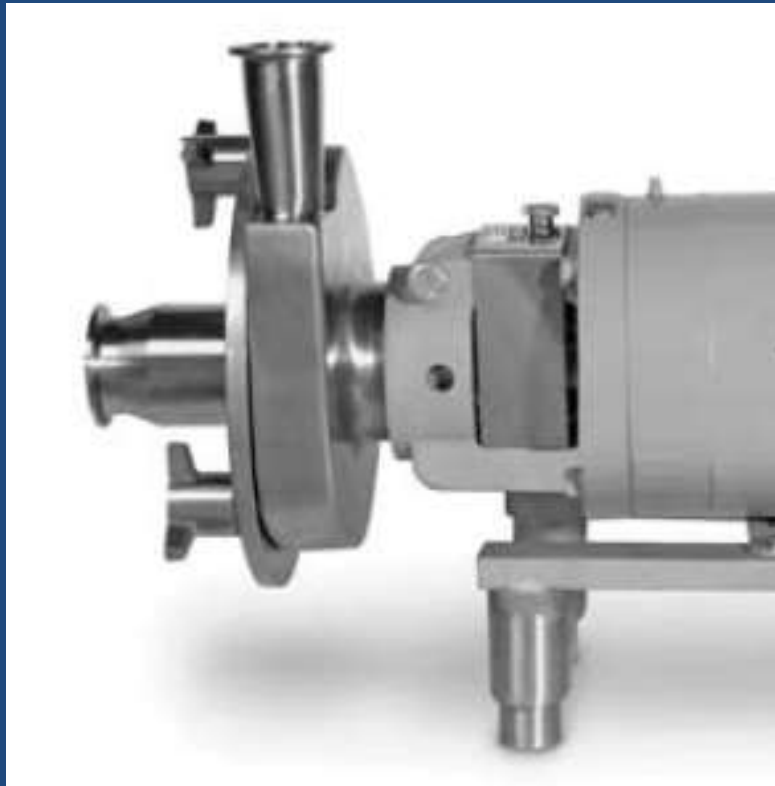
Basics of Sanitary Design

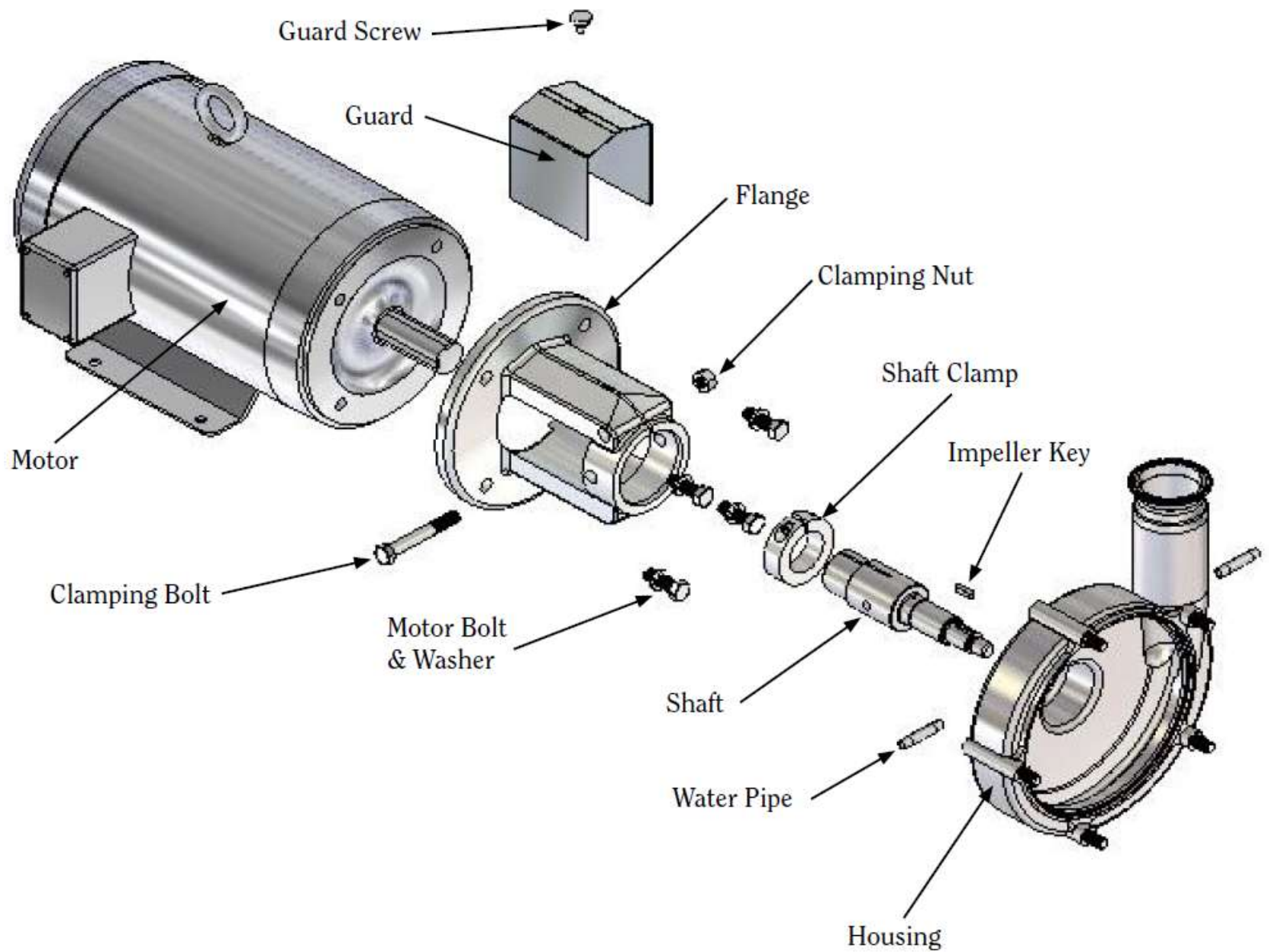
Part 2

CCE Evaluation



Centrifugal Pump





Double Seal Spring

Double Rotating Seal O-Ring

Double Rotating Seal

Double Stationary Seal O-Ring

Stationary Seal

Inner Seal Driver O-Ring

Seal Driver

Outer Seal Driver O-Ring

Single Stationary
Seal O-Ring

Single Rotating Seal

Single Rotating
Seal O-Ring

Single Seal Spring

Impeller

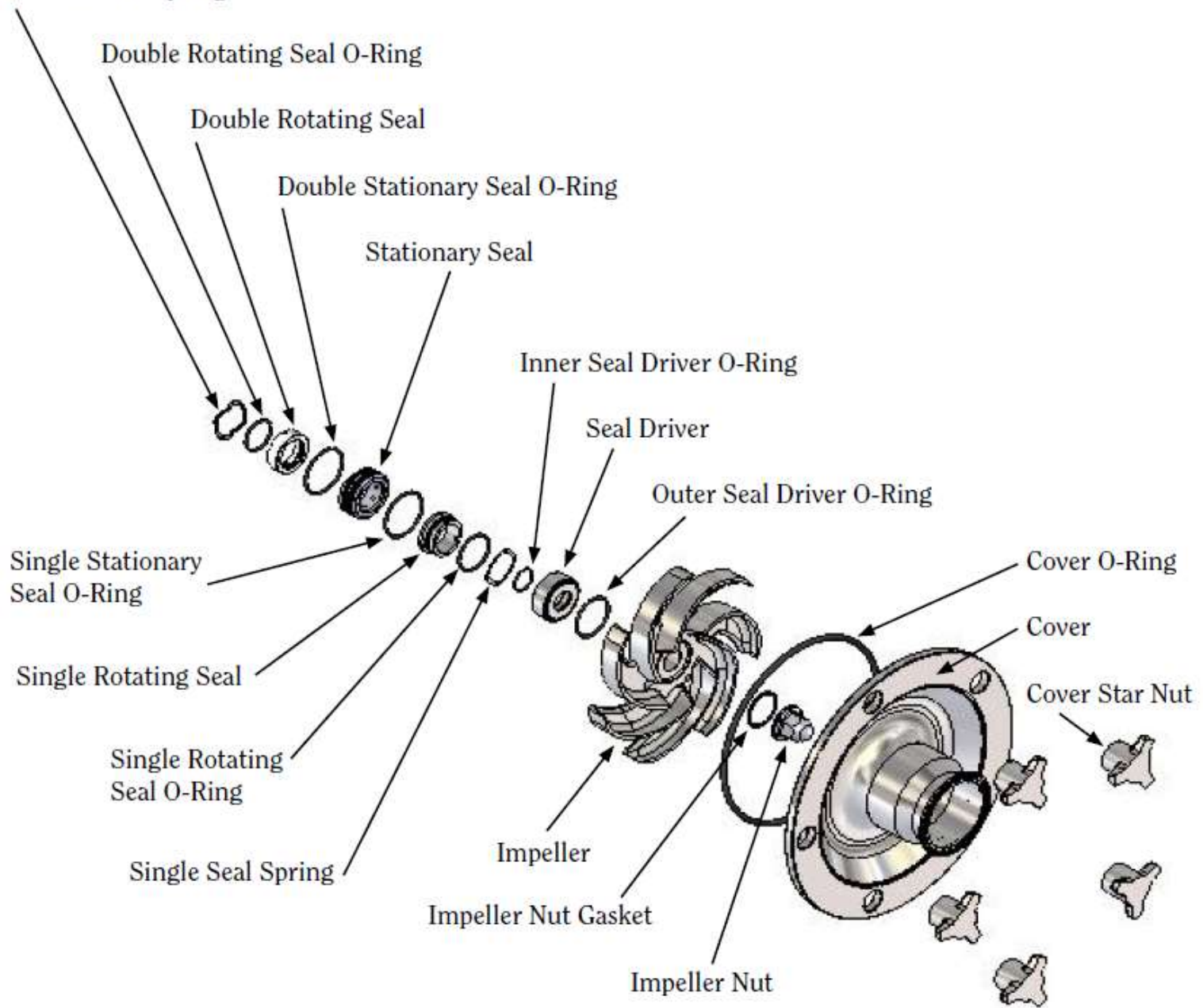
Impeller Nut Gasket

Impeller Nut

Cover O-Ring

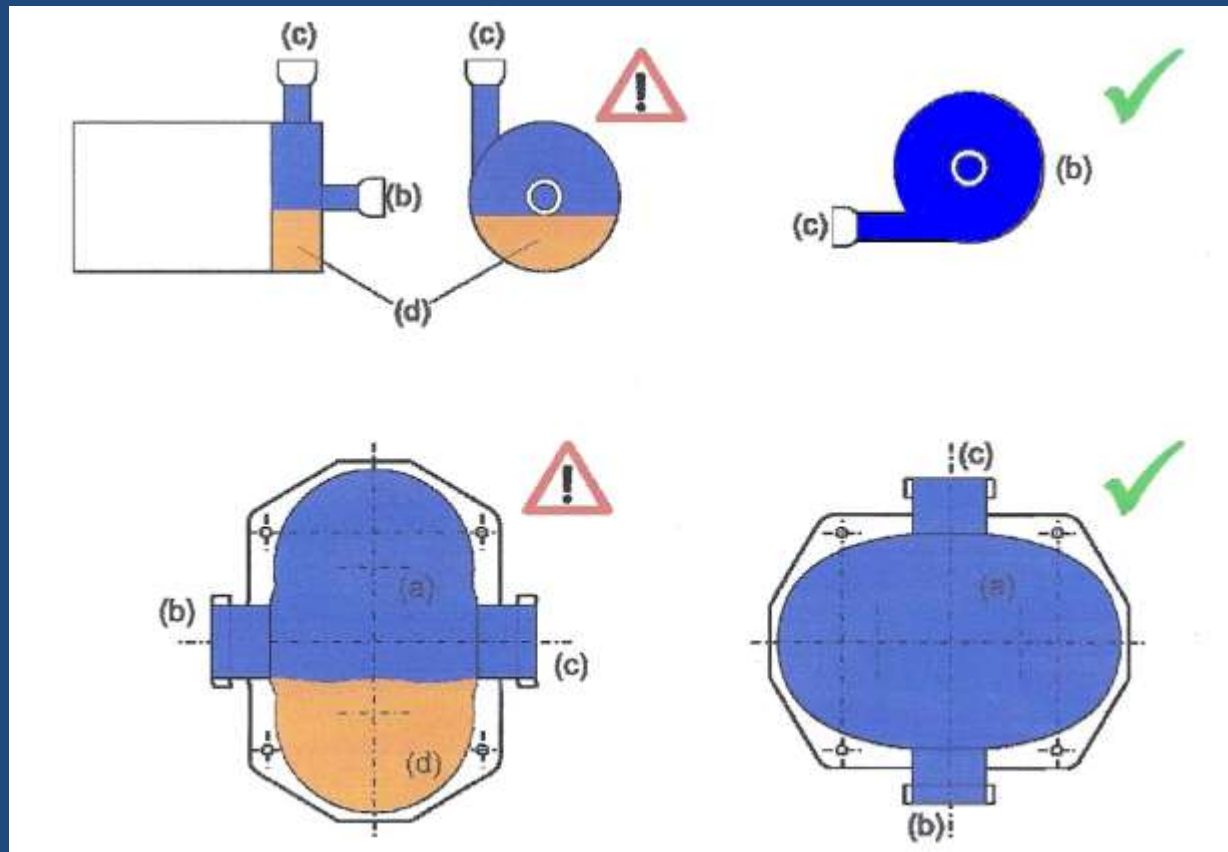
Cover

Cover Star Nut



D5 Draining

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



From EHEDG Doc. 10 (modified)

While Equipment is Disassembled –

- ✓ All Radii Can Be Measured
- ✓ Agreement of Equipment with Drawings (Verified)
- ✓ Exposure of Seals (Verified)
- ✓ Surface Finishes (Verified)
- ✓ General Suitability (Confirmed)
- ✓ Nonproduct Contact Materials (Checked)
- ✓ Documentation Reviewed and (Verified)

While Disassembled –

- ✓ CCE Checklist Completion**
- ✓ Marking of the Applicable Clauses of The Appropriate Standard**
- ✓ Material Options Verified**
- ✓ Understanding of QC Process**
- ✓ Confirm Any Special User Guidance**
- ✓ Assembly and Use Instructions Verified**
- ✓ Facility Review and QC Verified**

The On-Site Visit

Use of simple hand tools?



The On-Site Visit

- Grinding and Polishing.
- Completed in an area separate from areas where metals other than Stainless Steel are fabricated?
- Grinding and polishing tools used for finishing stainless steel not used on mild steel or other alloys.

The On-Site Visit

Angles and Radii.



The On-Site Visit



Tools of the trade.

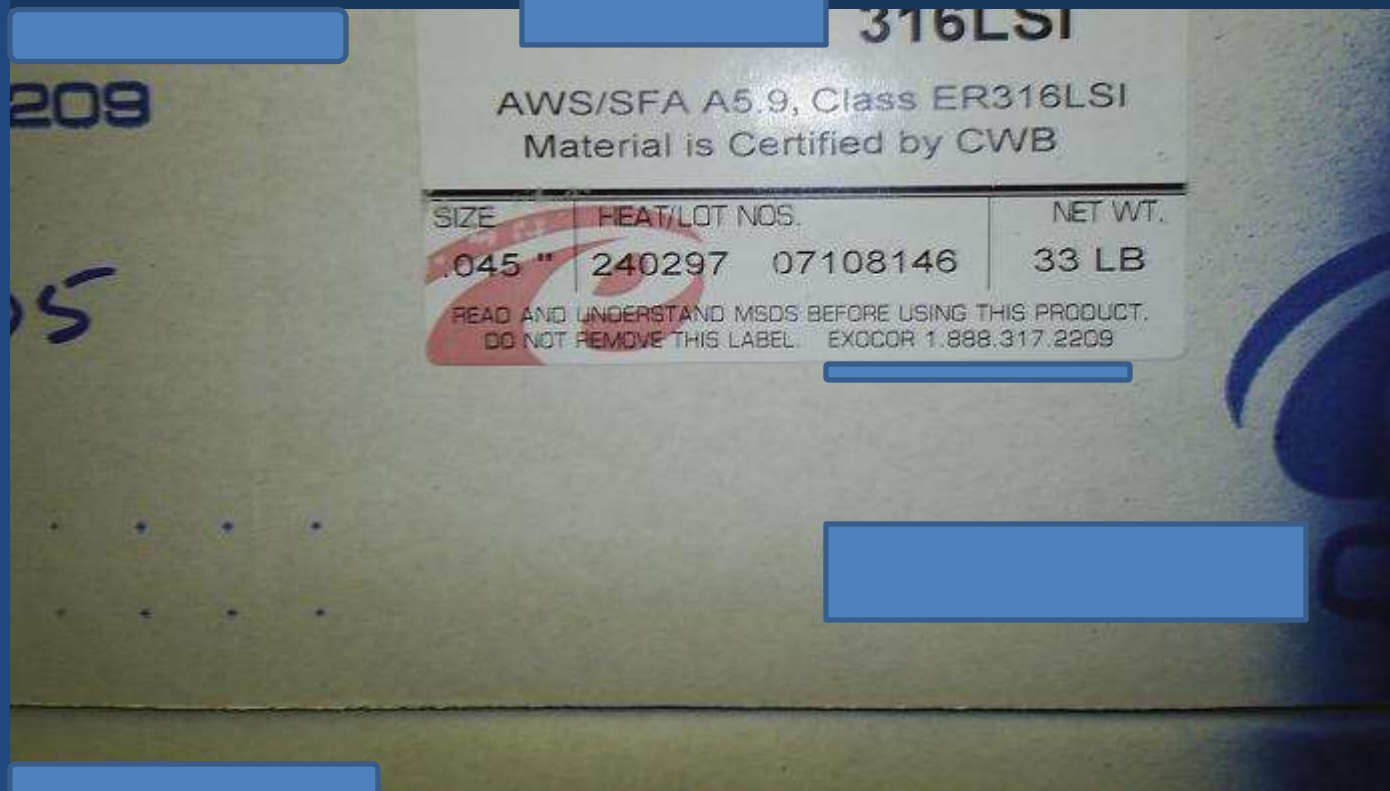
The On-Site Visit



Looks like square corners to us!

The On-Site Visit

Are welding materials such as filler rod compatible?



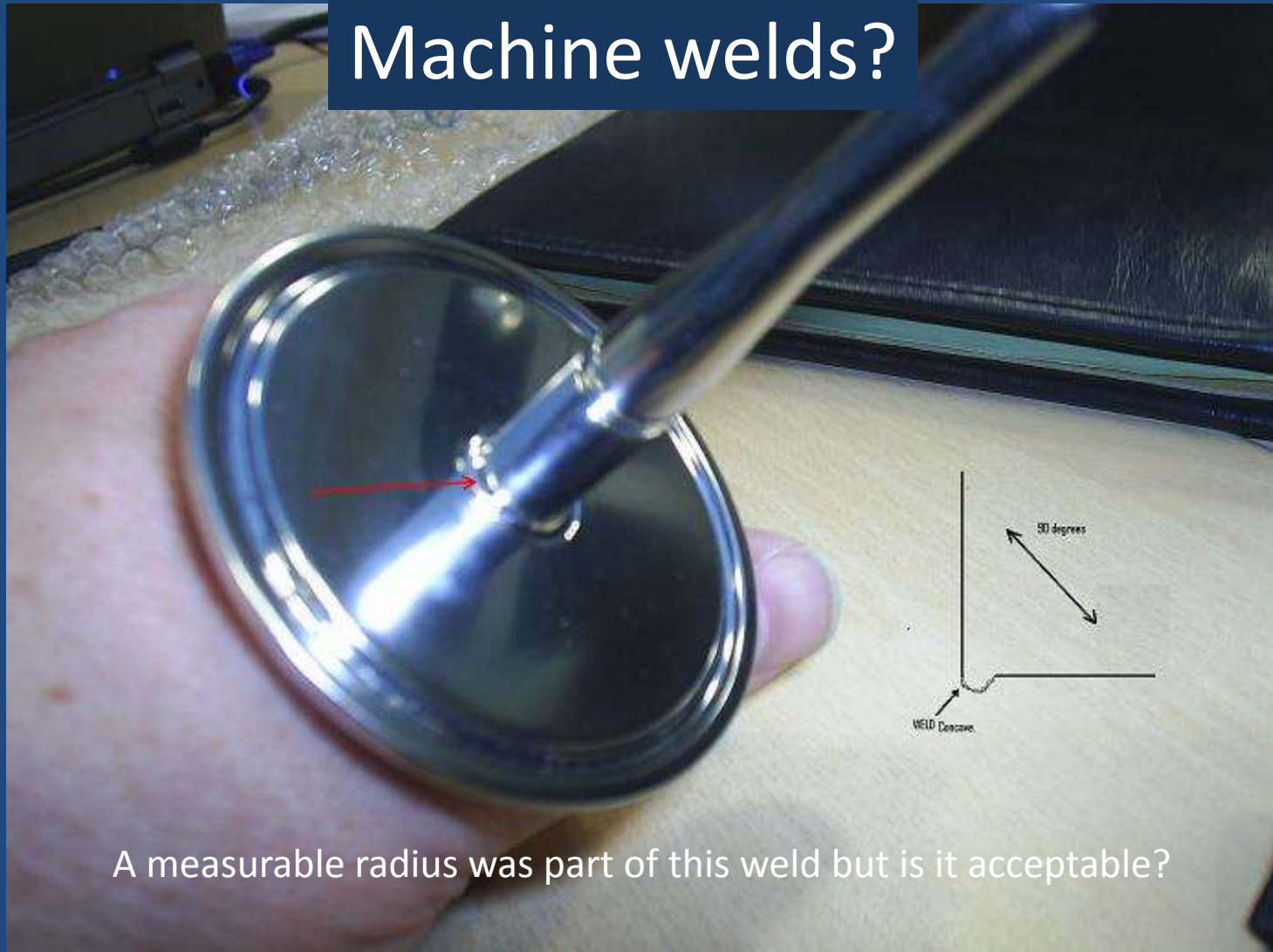
The On-Site Visit

Are welders properly trained and/or certified?



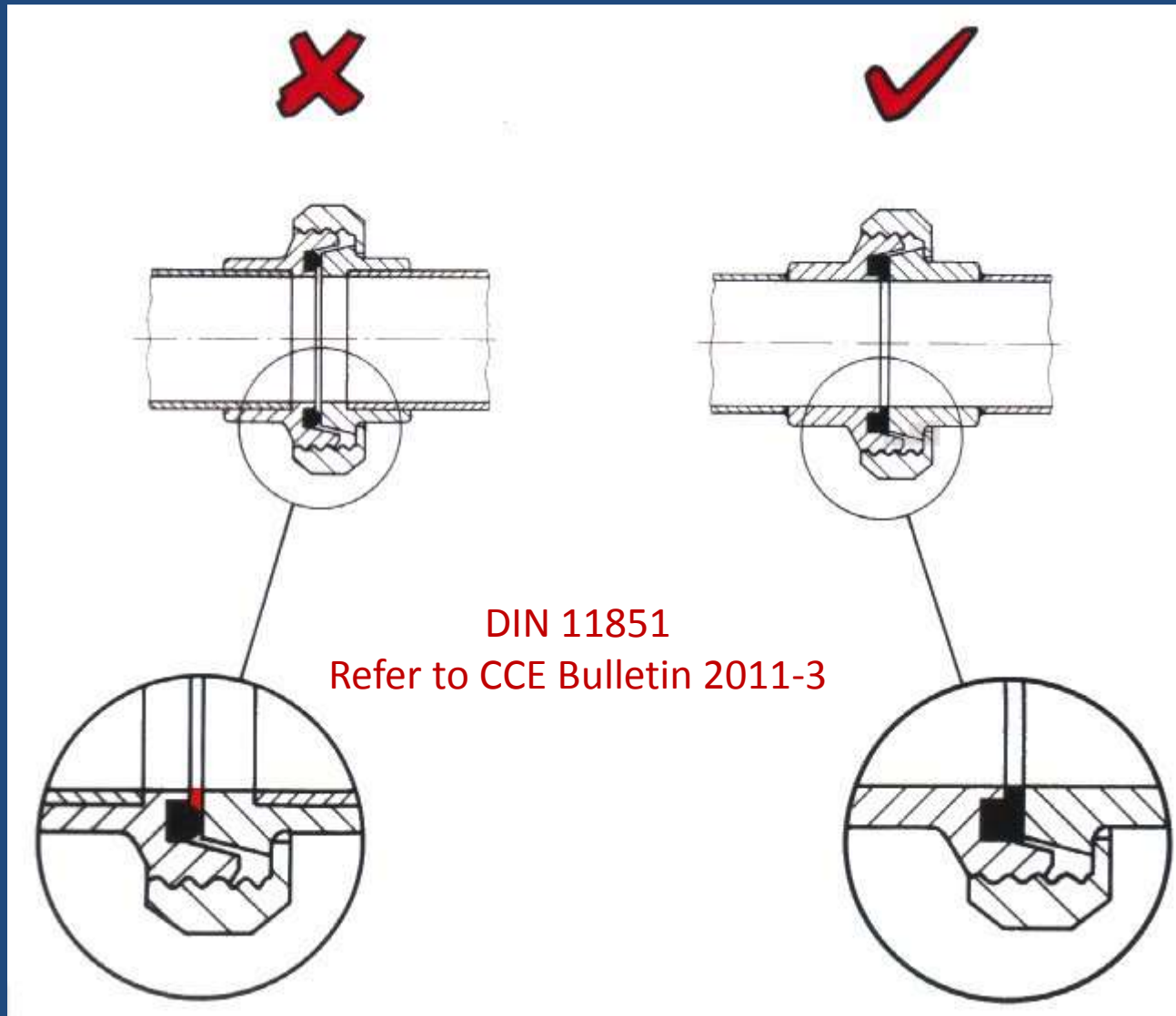
The On-Site Visit

Machine welds?

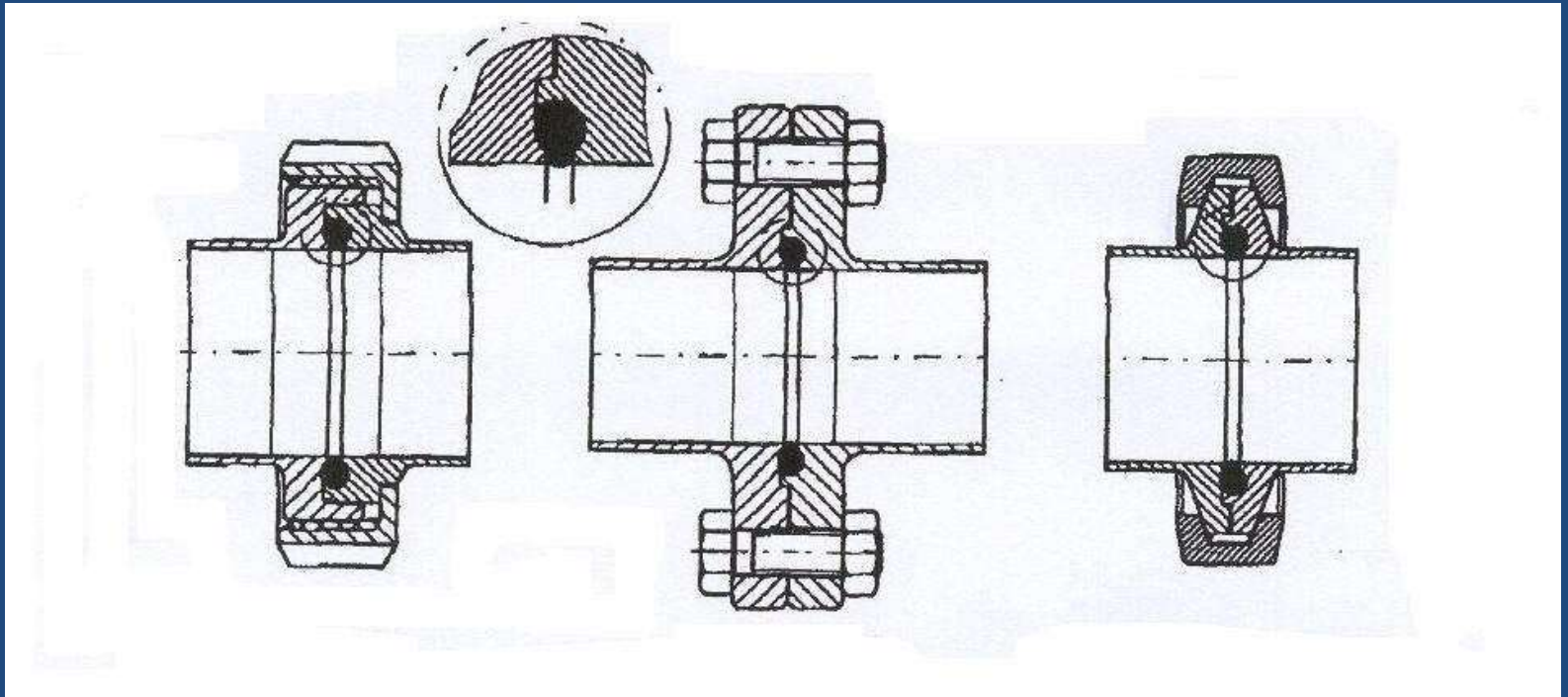


A measurable radius was part of this weld but is it acceptable?

JOINTS



DIN 11864

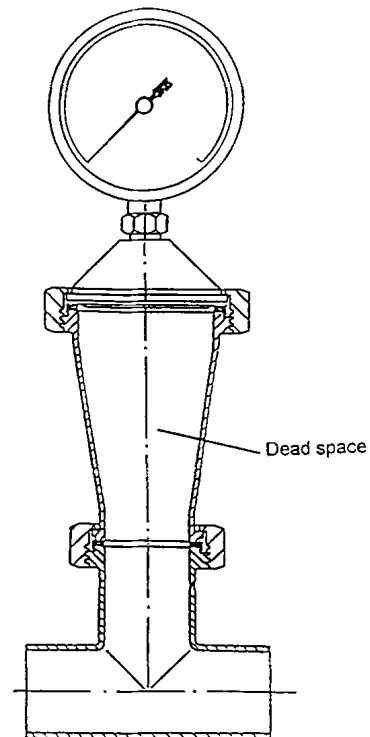


A 3-A Acceptable Type Fitting under Standard 63-

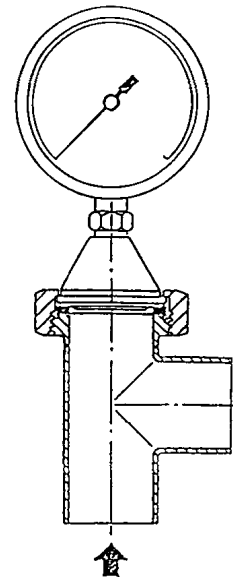
Sanitary Design

Dead Ends

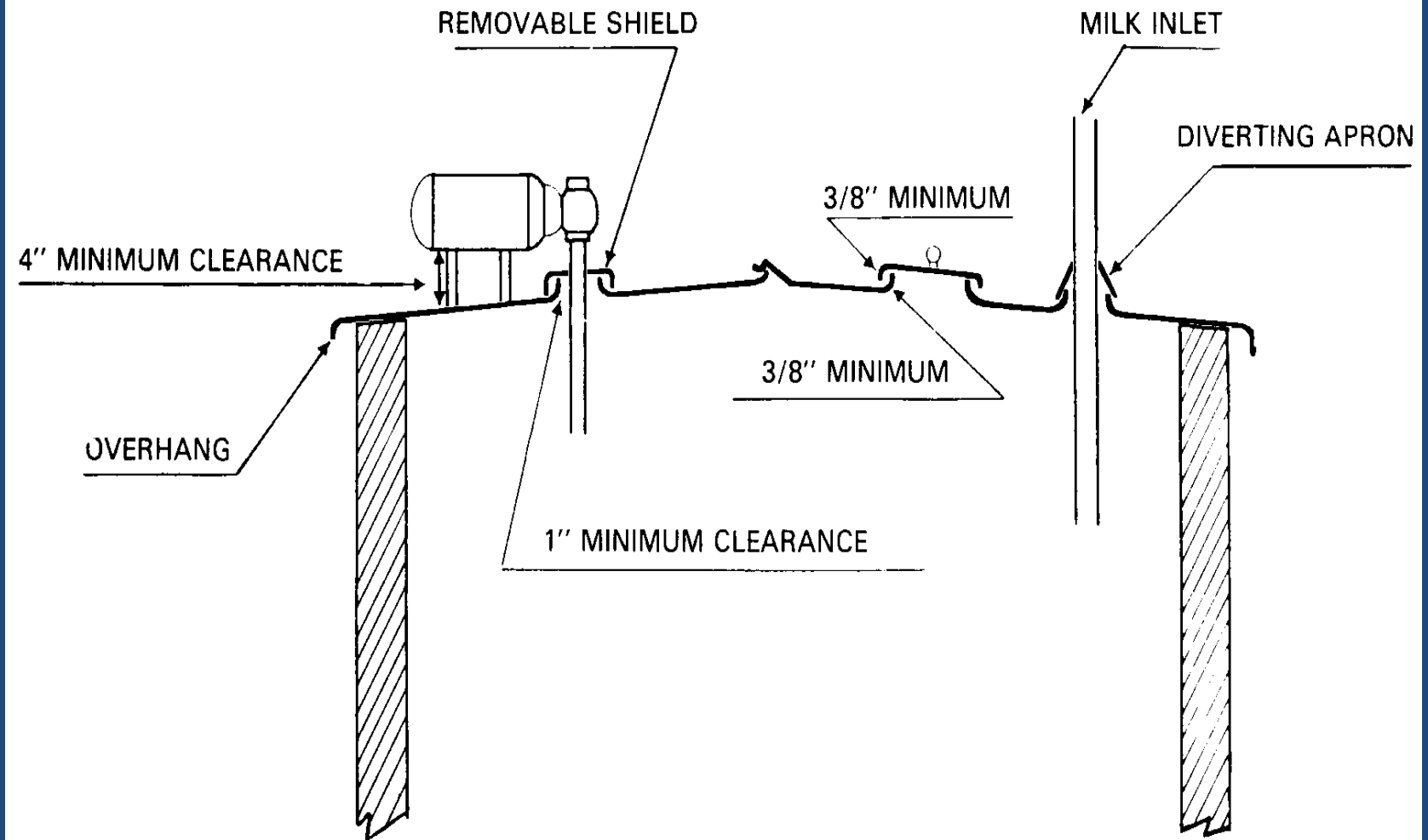
Unacceptable



Acceptable



Sanitary Design



Valves Close Coupled?





Vessels:
Insulated
Tanks
Uninsulated
Tanks.



Butterfly Valves:

Currently there is no 3-A Sanitary Standard that covers the butterfly type valve.

Butterfly Valve Disassembly



Easily Disassembled for cleaning and inspection?

Butterfly Valve Disassembly



Many regulatory agencies will allow their use if they are easily disassembled for cleaning and inspection after each day used.



Diaphragm Type Valves.

Leaks or damage to the diaphragm are easily detected by the equipment operator.



Clamp
stamped with
3-A Symbol?



Rising Stem
Compression
Valves.

Cleanable in a
CIP system?



Check Valves
and Vacuum
Breakers.



Product Holding Tubes?

Instructions for
installation in
3-A Accepted
Practices

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.

New terms: Ra of 32 μ inch (0.8 μ m) surface finish.



Some straight pipes are more difficult to clean than others.

“As cleanable as a straight piece of pipe”.

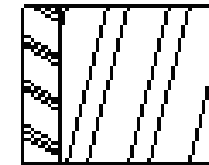
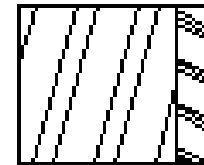
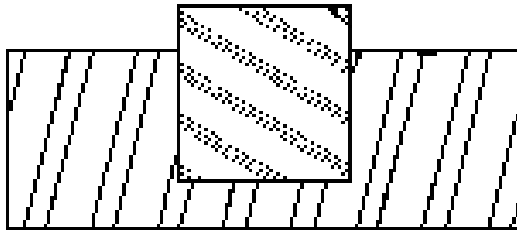
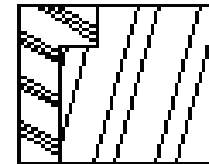
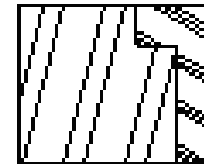
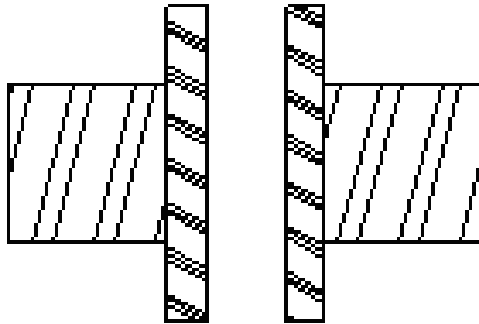
D2 Permanent Joints

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:

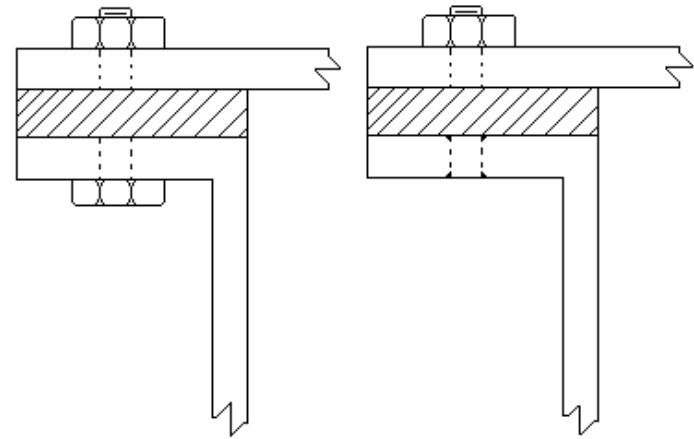
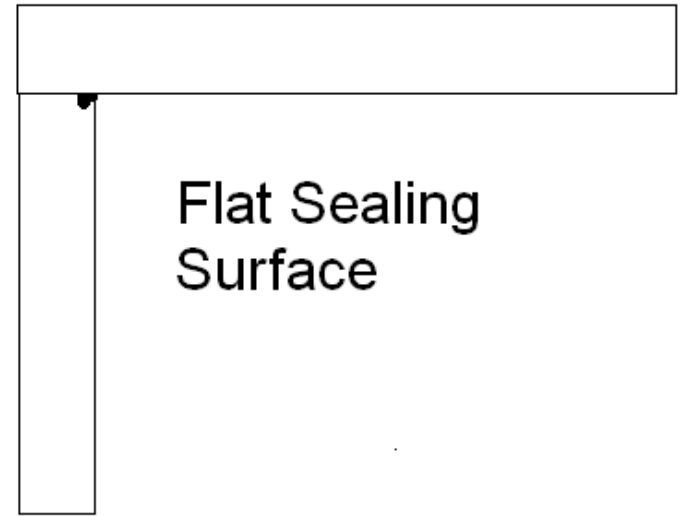
D2.1.1 In such cases where welding is impractical, soldering, press-fitting or shrink-fitting may be employed where necessary for essential functional reasons such as bushings, internal bearings, pins and mechanical seal components. (See Appendix, Section E7.)

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.)



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



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.

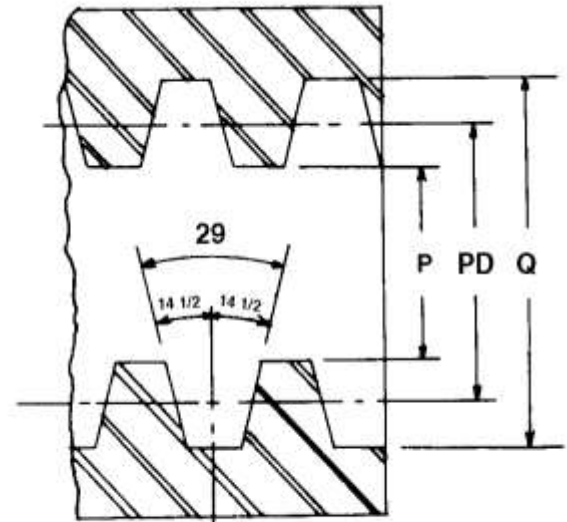
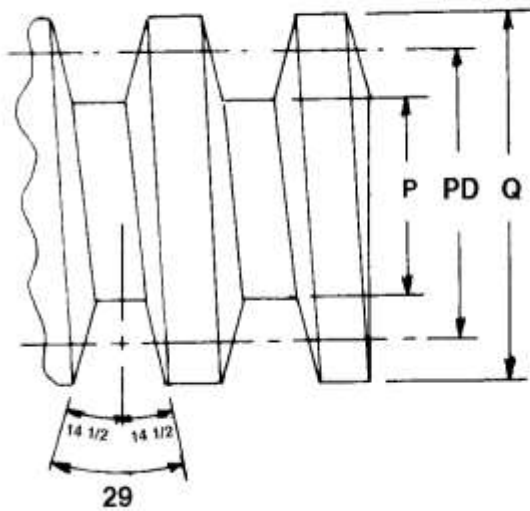
D11.2 Shaft threads must conform to one of the following thread specifications:

Exposed Threads vs. Enclosed Threads

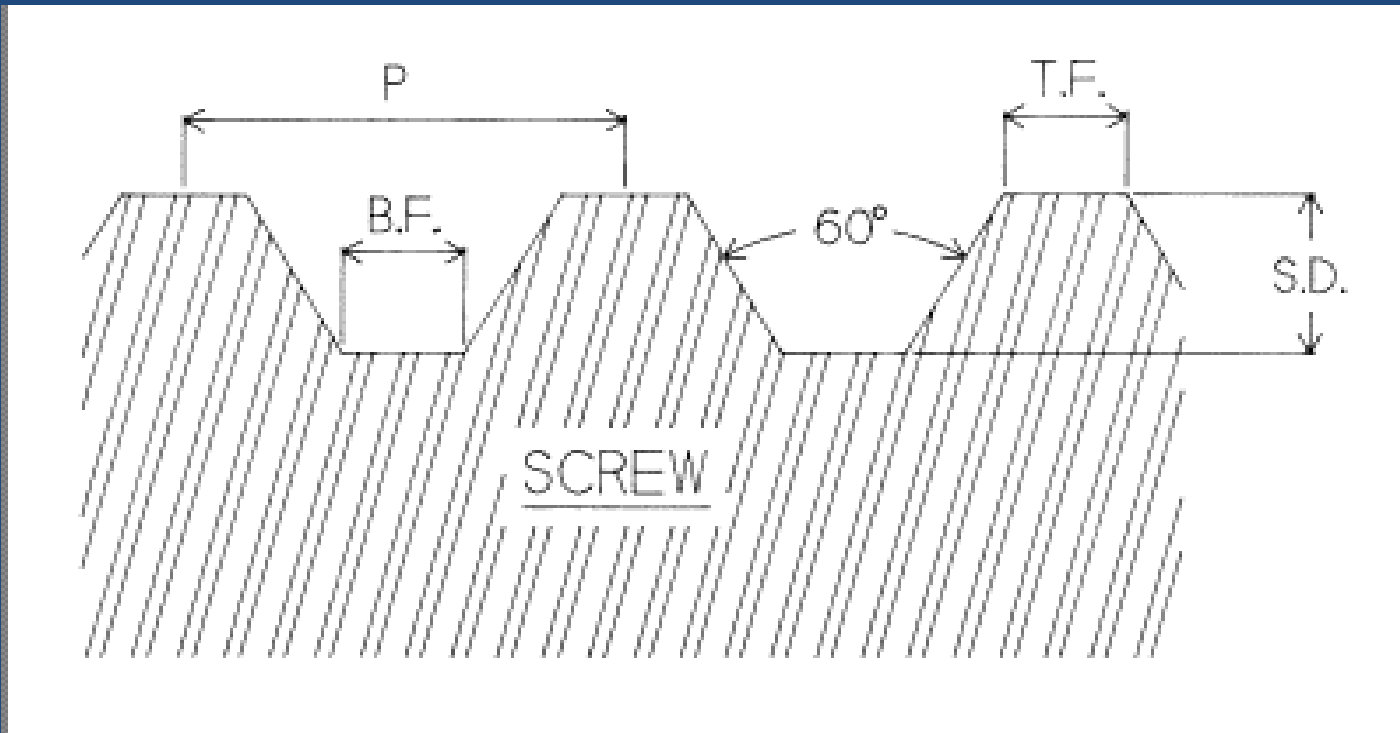
D11.2.1 Exposed Threads

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.

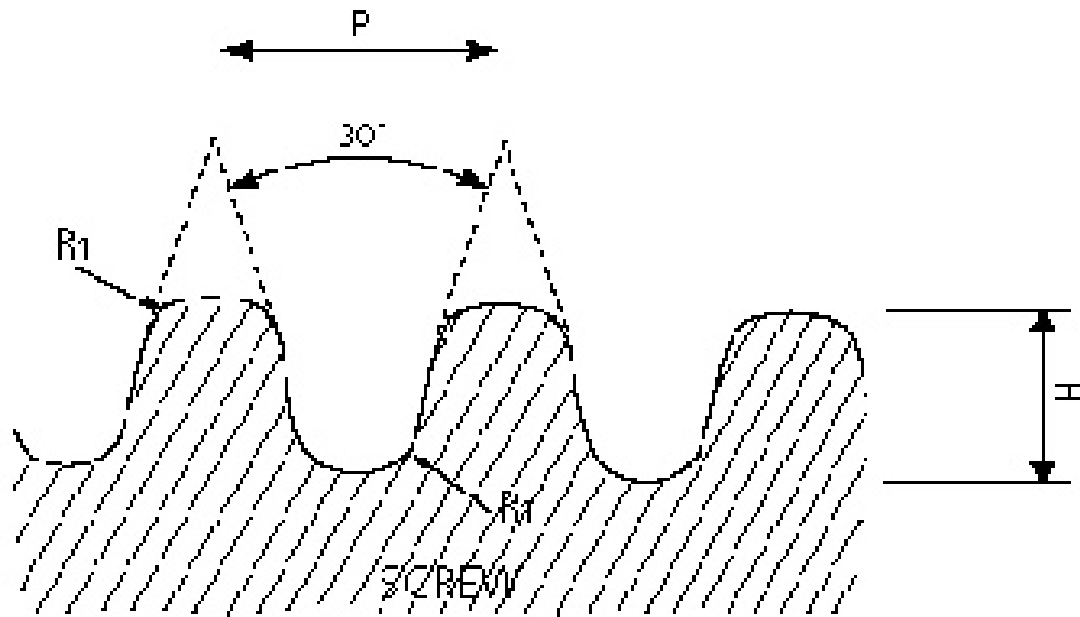
ACME Thread



American Standard Stub Acme Thread



Knuckle Thread DIN405



P = Pitch

H = Depth of thread

R_1 = Radius

$$H = 0.5 \times P$$

$$R_1 = 0.24 \times P$$

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 2-½ 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 Inspectability

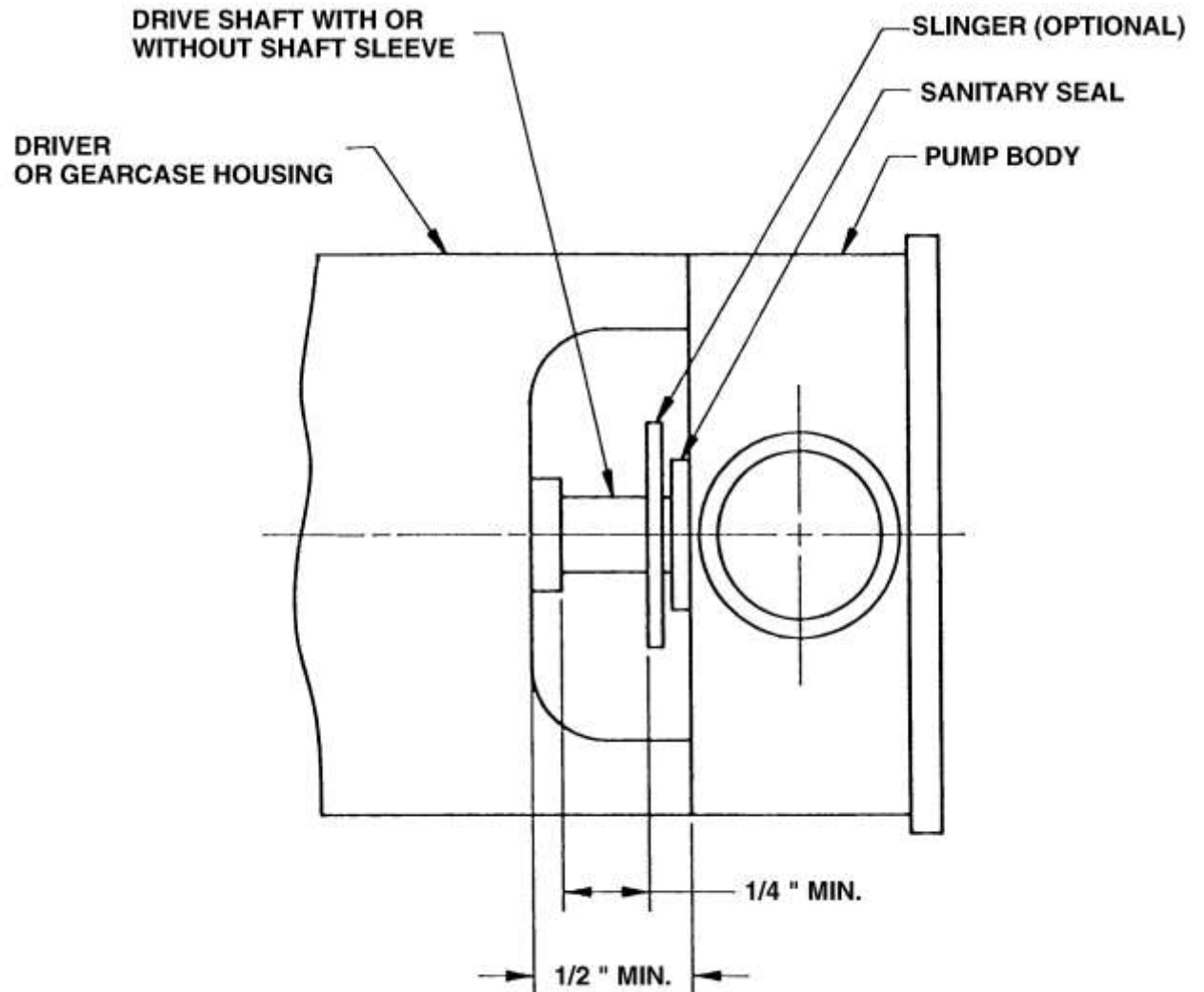
D14.1 A pump shall be designed that (See Appendix, Section E10):

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. $\frac{1}{2}$ " MINIMUM
7. $\frac{1}{4}$ " 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.

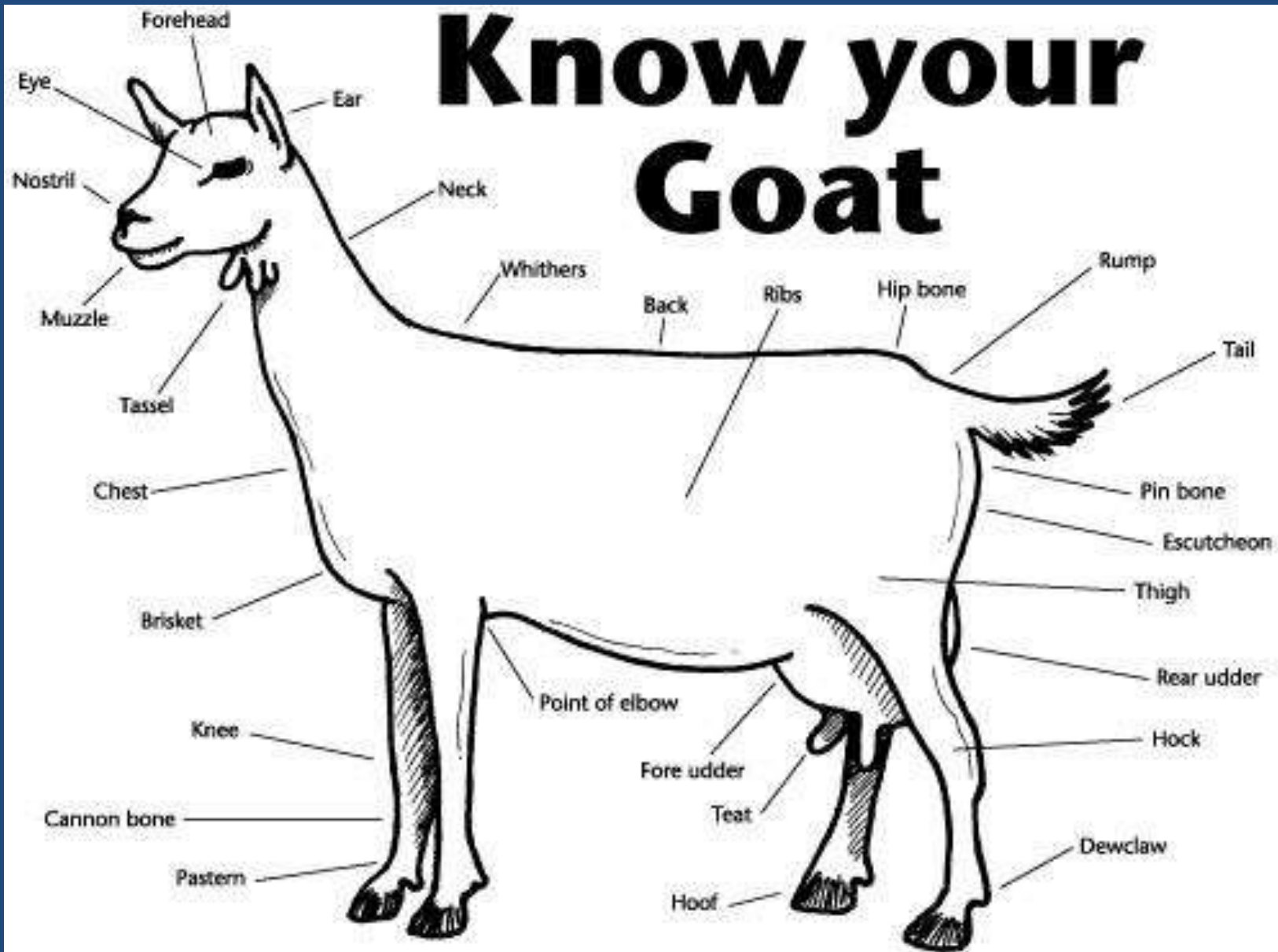
D16.2.3 Legs shall be of sufficient length to provide a minimum clearance between the lowest part of the base, pump, motor or drive and floor no less than 4 in. (100 mm) on pumps with legs designed to be fixed to the floor or pumps having a horizontal base area of more than 1 ft² (0.095 m²).

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.

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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.

Know your Goat



Strive to become as familiar with your processing equipment as possible!

More Details on 3-A SSI

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Visit us at: www.3-a.org

The screenshot shows the homepage of 3-A Sanitary Standards, Inc. The browser window has a single tab titled "3-A Sanitary Standards, Inc." and the address bar shows "www.3-a.org". The website header features the 3-A logo (a stylized 'A' with a '3' inside) and the company name "3-A Sanitary Standards, Inc." on the left. On the right, there are links for "ABOUT 3-A SSI" and "CONTACT", and a "FOLLOW US" section with icons for Facebook, LinkedIn, and YouTube. A dark teal navigation bar contains the following menu items: "3-A SYMBOL", "THIRD PARTY VERIFICATION", "NEWS & EVENTS", "STANDARDS & COMMITTEES", "KNOWLEDGE CENTER", and "PHARMACEUTICAL 3-A". The main content area is divided into three columns. The left column has a blue-tinted image of industrial equipment and a paragraph describing 3-A SSI as an independent, not-for-profit corporation dedicated to advancing hygienic equipment design for the food, beverage, and pharmaceutical industries. The middle column has a photo of a factory interior and another photo of a person working with yellow granules. The right column is titled "Sponsors" and lists sponsors under three levels: Platinum Level (Walker Engineered Products, G-M-I, Inc., Lee Industries - Fluid Technology, Rathgibson, SPX Flow Technology, Gamajet, part of the Alamo Group), Gold Level (Admix, Inc.), and Silver Level (Ghwa Industries Co., Ltd., VNE Corporation, International Association for Protection and Preservation of Food, United Industries, Inc., Kollmorgen, Exigo Manufacturing). Below the main content, there is a "Featured Video" section titled "More Than Just a Symbol" with a description and a link to "See other videos in our Video Resources". To the right of this is a video player showing a person in a lab coat working with equipment, with the title "More Than Just a Symbol" and a play button icon.

3-A Sanitary Standards, Inc.

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3-A SSI is an independent, not-for-profit corporation dedicated to advancing hygienic equipment design for the food, beverage, and pharmaceutical industries. We represent the interests of three stakeholder groups with a common commitment to promoting food safety and the public health — regulatory sanitarians, equipment fabricators and processors.

Online registration for the 2013 Annual Meeting is now closed. On-site registration begins May 20 at 2:00 pm.

Featured Video

More Than Just a Symbol

This is a great introduction to the 3-A Sanitary Standards organization and the 3-A Symbol licensing program.

See other videos in our Video Resources

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Expanded Knowledge Center

New Video Resources and supplemental print information available free:

- More Than Just a Symbol: The 3-A Story
- Essentials of Sanitary Design: The 3-A Format and Style Manual
- The Certified Conformance Evaluator and the TPV Inspection Overview
- Trust But Verify: The TPV Inspection for 3-A Symbol Authorization
- Maintaining 3-A Symbol Integrity: Reporting Alleged Non-conformance

3-A Sanitary Standards Are Becoming More Widely Known and Used in Many Markets



Questions?

**The Symbol
of Assurance**



