



3-A Sanitary Standards, Inc.
Third Party Verification Program



Dairy Practices Council
Kansas City, MO.
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Third Party Verification (TPV) Inspection Program

- 3-A SSI History/ Mission
- 3-A SSI Standards/ Accepted Practices
- 3-A Symbol
- TPV Program / TPV Manual
- CCEs Certification and Continuing Education
- Highlights and Overview of a TPV Inspection

What is 3-A SSI?

3-A Sanitary Standards, Inc. (3-A SSI) is a not-for-profit 501(c)(3) Accredited Standards Developing (ASD) organization dedicated to protecting public health.

3-A SSI executes its mission by: (a) developing 3-A Sanitary Standards and 3-A Accepted Practices for sanitary equipment design, fabrication and materials of construction; and (b) by providing a TPV program to monitor equipment conformance to individual 3-A Sanitary Standards.

History of 3-A SSI

1920
First Standard

1944 USPH
Participation

1956
First Symbol

2002
3A-SSI

2003
TPV

Today

3-A SSI Structure

The interest groups included the Food Processing Suppliers Association (FPSA), the International Association for Food Protection (IAFP), the International Dairy Foods Association (IDFA), the American Dairy Products Institute (ADPI), and the 3-A Symbol Administrative Council. Representatives of the U.S. Department of Agriculture and the U.S. Food and Drug Administration also participated in the discussions of a new organizational structure between 1999 and 2002.

- **Regulatory Sanitarians**
- **Food and Beverage Processors**
- **Equipment Fabricators**

History of 3-A SSI

Since the introduction of the 3-A Symbol in 1956, the use of the 3-A Symbol was based on a system of self-certification by the applicant. The 3-A Symbol Administrative Council, Inc. was responsible for the general administration of the 3-A Symbol licensing program. The development and maintenance of all '3-A' consensus documents was accomplished through an informal collaboration of organizations representing the three primary interest groups – dairy equipment manufacturers, dairy equipment users and state and federal regulatory sanitarians.

History of 3-A SSI

During the late 1990s, the key stakeholders evaluated the need for a new structure to support the entire range of these activities.

Representatives of the U.S. Department of Agriculture and the U.S. Food and Drug Administration also participated in the discussions of a new organizational structure between 1999 and 2002.

History of 3-A SSI

3-A Sanitary Standards, Inc. (3-A SSI) officially began operations in January 2003. Representatives of the three interest groups became vested in the leadership of a new, independent nonprofit organization with a full time professional staff. 3-A SSI is responsible for administration of the 3-A Symbol program, coordination of all consensus documents, education on sanitary design, and other activities.

History of 3-A SSI

With the creation of 3-A SSI, a new Third Party Verification (TPV) inspection requirement was implemented as a condition for holding authorization to use the 3-A Symbol. The TPV requirement applies to all equipment built to 3-A Sanitary Standards that is licensed to display the 3-A Symbol. A licensee must engage an inspection/verification professional accredited by 3-A SSI, a Certified Conformance Evaluator (CCE), to conduct an on-site evaluation of finished equipment and other product attributes to affirm the equipment conforms to the provisions of the applicable 3-A Sanitary Standard.

History of 3-A SSI

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3-A SSI Mission

Mission Statement

It is the mission of 3-A Sanitary Standards, Inc. to enhance product safety for consumers of food, beverages, and pharmaceutical products through the development and use of 3-A Sanitary Standards and 3-A Accepted Practices.



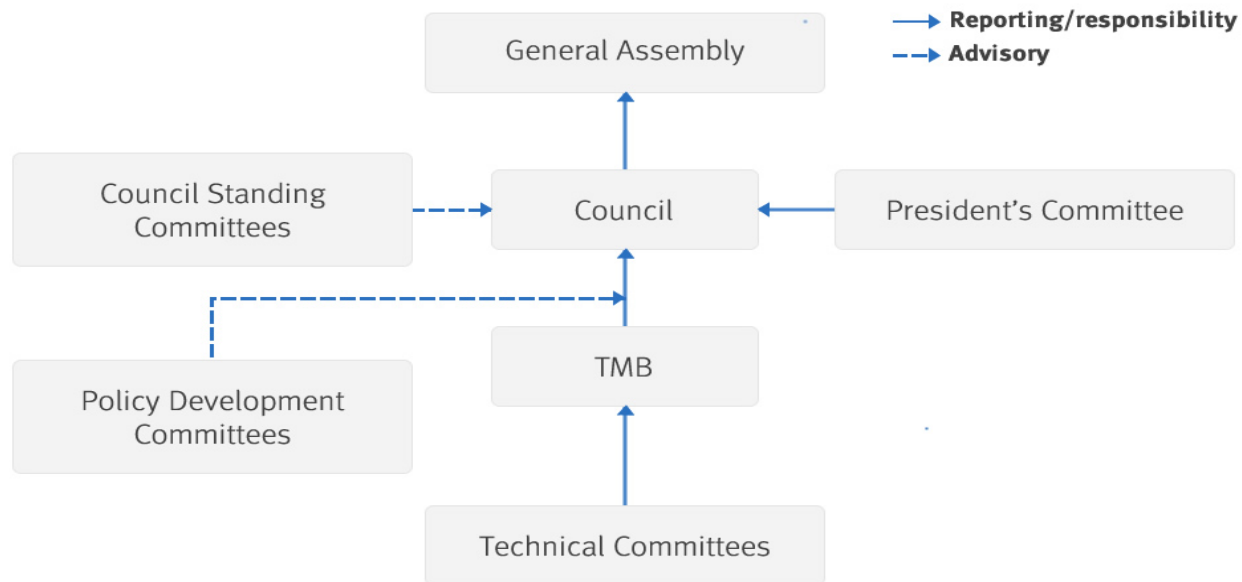
3-A SSI Mission

- Promoting Food Safety Through Hygienic Design Values
- Maintain and advance a credible Third Party Verification Program
- Promote worldwide recognition and adoption of 3-A Sanitary Standards and 3-A Accepted Practices.
- Administer an efficient consensus process for standards development.
- Serve as an authoritative resource on sanitary equipment design, addressing the education and training needs of all stakeholders.



Hierarchy of Standards Developing Organizations

ISO governance structure



The Secretary General is a member of the President's Committee, reports to the President and to Council and receives advice from the policy and advisory groups (who also advise Council). The Central Secretariat is responsible for supporting the governance and policy and advisory structure and the operations of ISO.

Hierarchy of Standards Developing Organizations

ISO is an independent, non-governmental organization made up of members from the national standards bodies of 165 countries. Our members play a vital role in how we operate, meeting once a year for a General Assembly that decides our strategic objectives.

We have a Central Secretariat in Geneva, Switzerland, that coordinates the system. Operations at the Central Secretariat are directed by the Secretary General.

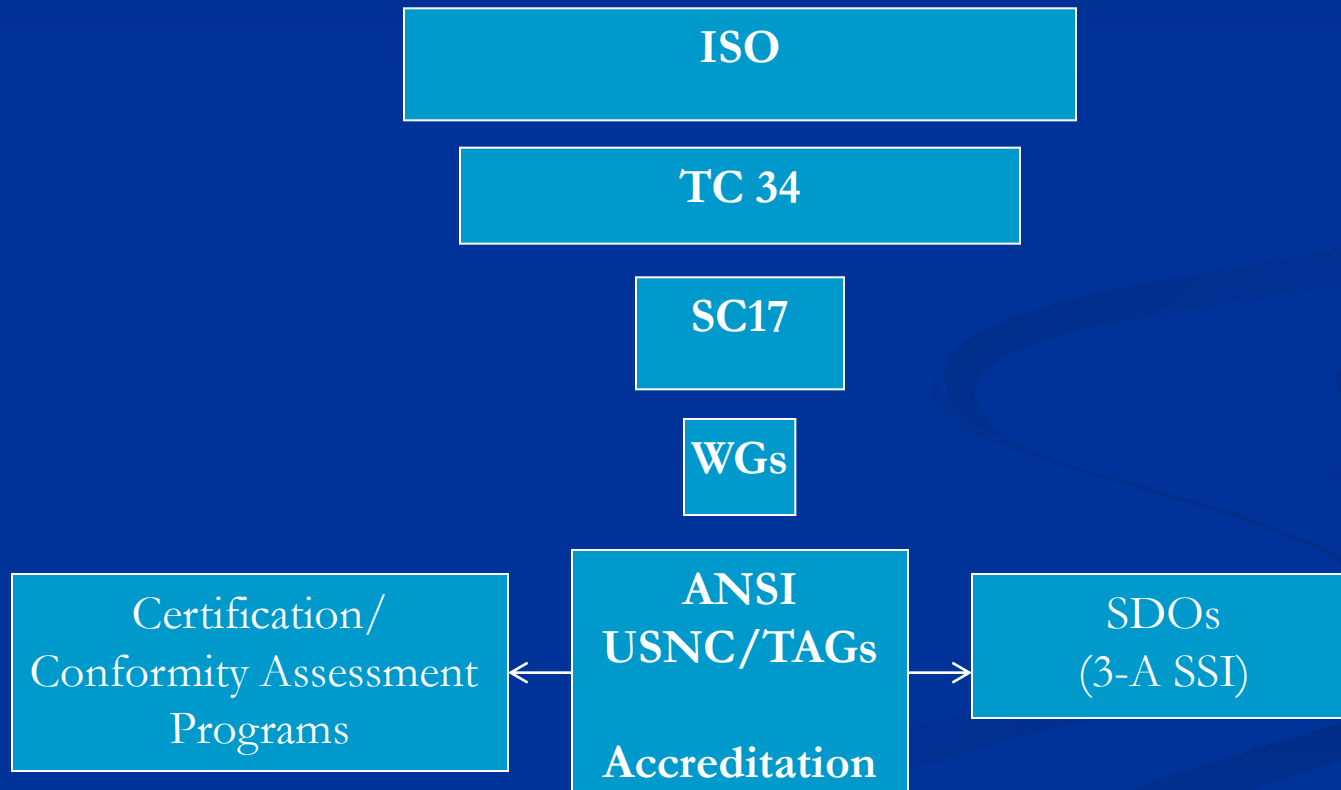
ISO 22000:2005

Food safety management systems -- Requirements for any organization in the food chain

Hierarchy of Standards Developing Organizations

ISO 22000:2005

Food safety management systems -- Requirements for any organization in the food chain



ANSI represents the US on 611 TCs

3-A SSI Standards & Practices

- **Written hygienic design criteria for equipment designed and manufactured for use in milk and food products.**
- **Designed for cleanability and inspectability**

3-A Sanitary Standards

- 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.

3-A Sanitary Standards

- 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.

Standards & Accepted Practices

■ Standard

- (71) 3-A Standards
- Equipment Design
- Meets intent of (PMO)
- Third Party Verification
- Symbol for Conformance

■ Accepted Practice

- (10) 3-A Accepted Practices
- Process/Systems
- Installation criteria
- Regulatory requirement
- Advisory Guideline
- Process Certification available

3-A Sanitary Standards WGs

- **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**
- **General Requirements**

3-A Heat Exchanger Standards

■ Heat Exchangers

- Plate (11-)
- Tubular (12-)
- Scraped Surface (31-)
- Heat Exchangers; Freezers for Frozen Food (19-)
- Steam Injection Heaters (61-)

3-A Symbol

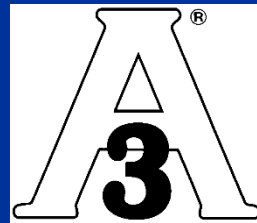
How can you tell whether the food processing equipment you use or specify meets criteria for sanitary design? You can rely on 3-A SSI design criteria and the extra assurance of sanitary design integrity that comes from the voluntary Third Party Verification (TPV) inspection programs of 3-A SSI.

3-A Sanitary Standards and 3-A Accepted Practices serve a critical role in the public health and safety of the food processing system.

3-A does not approve, accept or endorse any equipment or products. 3-A only grants authorizations to display the 3-A Symbol

3-A Symbol

Mark of conformity for equipment designed and manufactured to a 3-A Sanitary Standard



11-09

3-A[®] Sanitary Standard for Plate Type Heat Exchangers, Number 11-09

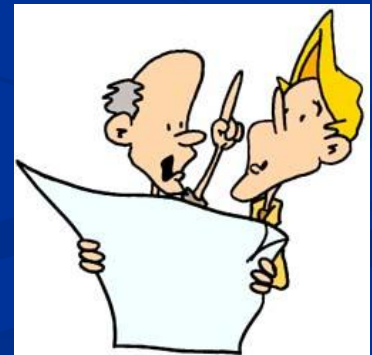
TPV Program

The TPV Program provides added assurance that equipment or systems showing the 3-A Symbol fully complies with the specific 3-A Sanitary Standards named.



TPV Program

- 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 Candidate/ Holder
- Scope of TPV program and CCE credentialing set by 3-A SSI



TPV Program

The TPV inspection program is designed to enhance the integrity of the 3-A SSI programs by affirming that equipment fabricated in accordance to 3-A Sanitary Standards or processing systems are manufactured and installed in accordance to 3-A Accepted Practices.

The independent TPV inspection programs of 3-A SSI provide assurance of hygienic equipment design and thereby benefits regulatory sanitarians, equipment fabricators, processors, and consumers.

TPV Program

Manual for Third Party Verification for 3-A Symbol Authorization and 3-A Process Certification (http://www.3-a.org/TPV/pdf/TPV_Manual.pdf) includes complete details on the TPV requirements for the 3-A Symbol Authorization and the 3-A Process Certification programs. The manual shows the policies and procedures for:

- Equipment suppliers to verify conformance to 3-A Sanitary Standards and to obtain and maintain authorization to use the 3-A Symbol, and
- Processors to verify conformance to 3-A Accepted Practices and to obtain and maintain 3-A Process Certification.
- The manual also contains procedures for submitting nonconformance reports, how they are resolved, and de-listing procedures for proven nonconformance.

TPV Program

- The TPV inspection is performed under an agreement between the CCE and the applicant. All fees and expenses for the inspection are to be established between these two parties.
- The TPV inspection for use of the P3-A Symbol must be conducted by a CCE who has obtained the necessary P3-A qualification.

Criteria for Certified Conformance Evaluators:

Requirements for obtaining and maintaining the CCE credential

TPV Program

The Certified Conformance Evaluator (CCE) program is an accreditation program administered by 3-A SSI. The CCE credential is a primary requirement for the performance of the TPV inspection of the hygienic design of equipment. The TPV inspection is required for any of the following:

- **3-A Symbol Authorization**
- **3-A Process Certification**
- **3-A Replacement Part Qualification Certificate**
- **P3-A Symbol Authorization**

TPV Program

The CCE program is designed to enhance the integrity of the 3-A SSI programs by providing the industry with a register of professionals who have the appropriate qualifications, work experience and the demonstrated knowledge for evaluating and verifying equipment fabricated in accordance to ***P3-A Standards***, 3-A Sanitary Standards, or processing systems manufactured and installed in accordance to 3-A Accepted Practices. The independent inspection programs of 3-A SSI provide assurance of hygienic equipment design and thereby benefits regulatory sanitarians, equipment fabricators, processors, and consumers.

THIRD PARTY VERIFICATION REPORT FOR 3-A SYMBOL AUTHORIZATION

Applicant:

TPV Report Completion Date:

CCE:

Equipment Type:

Verification Location:

3-A Sanitary Standard:

3-A Authorization Number:

Applicant/Verification Contact (name and phone no.):

Type of Verification: ☐ New Authorization ☐ Report of Alleged Nonconformance (RAN) ☐ Renewal Authorization ☐ Appeal ☐ Amendment
☐ Follow-up ☐ Administrative Amendment ☐ Conditional ☐ Final

☐ Clean-in-Place Model Number(s) (use serial # if no model #) (use separate page, if needed):

☐ Clean-Out-of-Place/Manual Cleaning Model Number(s) (use serial # if no model #) (use separate page, if needed):

☐ Both CIP and COP. List Model Number(s) (use serial # if no model #) (use separate page, if needed):

Observations and Findings:

Declaration of Findings:

- ☐ Nonconformance (*Note: If any "No" items are checked, the "Nonconformance" box shall be marked.*) When the "Nonconformance" box is marked, additional statements specifically describing which criteria from the base 3-A Sanitary Standards were not in conformance must be included in the "Observations and Findings" column or on an attached page.)
- ☐ Conformance I, the undersigned CCE, do hereby certify that the equipment covered by this report has been thoroughly evaluated and complies with all the appropriate criteria of the covering 3-A Sanitary Standards.

CCE Signature:

To be completed by 3-A SSI Staff:

Received By:

Date Received

SUPPLEMENTAL INFORMATION SHEET FOR SYMBOL AUTHORIZATION

		Yes	No	NA	Observations and Findings
1	3-A Standard No. displayed within Symbol: (XX-XX)				
2	Manual(s)				
	Engineering Design and Technical Construction File (EDTCF)				
3	Copy of current 3-A Sanitary Standard(s) kept on file				
4	Quality control program verified				
5	Rubber certificates reviewed for all rubber parts				
6	Plastic certificates reviewed for all plastic parts				
7					
8					
9					
10					

Engineering Design & Technical Construction File

- The Engineering Design and Technical Construction File may further optionally contain the following:
- A list of the essential requirements of the standards or practices;
- Other technical specifications which were used when the equipment was designed;
- A copy of the instructions for the product (instruction manuals/instruction books);
- A description of methods adopted;
- Any technical report giving the results of tests carried out internally by Engineering or others;
- Documentation and test reports on any research or tests on components, assemblies and/or the complete product to determine and demonstrate that by its design and construction the product is capable of being installed, put into service, and operated in a sanitary manner (optional);
- A determination of the foreseeable lifetime of the product (optional);
- Engineering reports, Laboratory reports, Bills of material, Wiring diagrams, if applicable; Purchase order engineering files; Hazard evaluation committee reports, if executed; Customer specifications; and any notified body technical reports and certification tests.

Engineering Design & Technical Construction File

- Table of Contents (listing all documents within the EDTCF or the locations where the items may be found);
- A copy of the 3-A Sanitary Standard to be applied to the subject equipment;
- An overall drawing or general arrangement drawing of the subject equipment;
- Full detailed drawings, accompanied by any calculations, notes, test results, etc. required to check the conformity of the equipment to the 3-A Sanitary Standard or 3-A Accepted Practice;
- If essential, any technical report or certificate obtained from a competent testing body or laboratory;
- Instructions for cleaning of the subject equipment or item referenced by the standard (including a listing, as may be applicable, for all manually cleaned components or appurtenances and the procedures for cleaning of these items. (Example: silo tank door gasket);
- Material certifications for all materials of construction included in the equipment;
- For serial manufacturing, the internal measures that will be implemented to insure that the equipment will continue to be manufactured in conformity to the provisions of the 3-A Sanitary Standards or 3-A Accepted Practices;
- Change records; and copy of the 3-A Symbol authorization, if applicable.

Certified Conformance Evaluators



List of current CCEs: http://3-a.org/TPV/pdf/CCE_List.pdf

List of current CCEs Qualified to Conduct P3-A Inspections:
http://3-a.org/Pharmaceutical/pdf/P3A_CCE_List.pdf

TPV Program Inspection Sites

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

3-A SSI Annual Meeting

- May 11 – 15, 2014
- Milwaukee
- Education Program
- CCE Training
- Standards Development Working Groups

3-A SSI Information & Resources

- Quick Guides:

<http://www.3-a.org/>

- Third Party Verification:

<http://www.3-a.org/Resource/instructional/Third-Party-Verification-An-Overview/story.html>

This interactive module gives a general overview of the Third Party Verification inspection required for applying for 3-A Symbol authorization. It includes a basic outline of the requirements for a TPV inspection, a description of what an inspection entails, and some general information on the independent inspection professionals, Certified Conformance Evaluators.

CLEAN ...

What Does It Mean to You?

NOT DIRTY – Free from dirt or impurities

UNADULTERATED – Containing no foreign matter

WASHED – Freshly laundered or washed after use

EMPTY – Containing nothing at all

BLANK – Without anything on it, especially anything written

FREE OF PROBLEMS – Without problems or difficulties

SMOOTH-EDGED – Without rough or jagged edges

STREAMLINED – Simple and flowing in design

COMPLETE – Complete and unqualified

WITH NO FLAWS – Describes a gemstone without flaws

PERFORMED PRECISELY – Performed with best technique

INNOCENT – Not guilty of a specific crime

DESIGN CHOICES MAKE THE DIFFERENCE !

- Cleanability must be designed into equipment and systems. This feature cannot be added later.
- In order to CLEAN process equipment, the equipment must first be Cleanable

FEATURES AFFECTING CLEANABILITY INCLUDE:

MATERIALS & SURFACE FINISHES

RADII on wetted surfaces

DRAINABILITY – Free draining or drainable

CLEANING METHODS & CHEMISTRY plus

the ability to expose surfaces to cleaning solutions

MATERIALS of Construction

- **METALS** - STAINLESS & SPECIAL ALLOYS
- **NON-METALS** – ELASTOMERS, PLASTICS, CERAMICS
- **ADHESIVES** - BONDING AND ATTACHING
- **LUBRICANTS** – RESISTANT TO BREAKDOWN

ALL MUST BE SUITABLE FOR THE
ENVIRONMENT OF THEIR INTENDED USE
AND CONFORM TO CFR CRITERIA

SURFACE FINISHES

BASELINE CRITERIA = 32 microinch Ra = 0.8 micron Ra

1 Microinch (μin) = 0.000001 Inches

1 Micron (μm) = 0.000001 Meters

1 Meter = 1000000 microns = 39.3700787402 Inches.

**Metals: Mechanically Polished or Machined Smooth
Possibly Followed by Electropolish**

**Nonmetals: Smooth As Molded Surfaces
Same Finish Requirements as Metals**

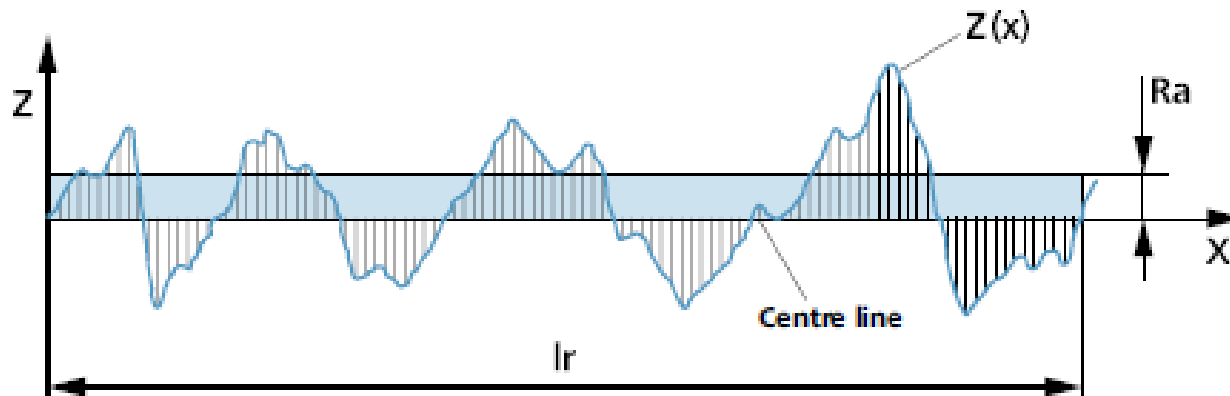
SURFACE FINISH EVALUATION

Portable Surface Roughness Gage (Profilometer)



Ra = Mean Roughness Value

Ra – parameter according to ISO 4287



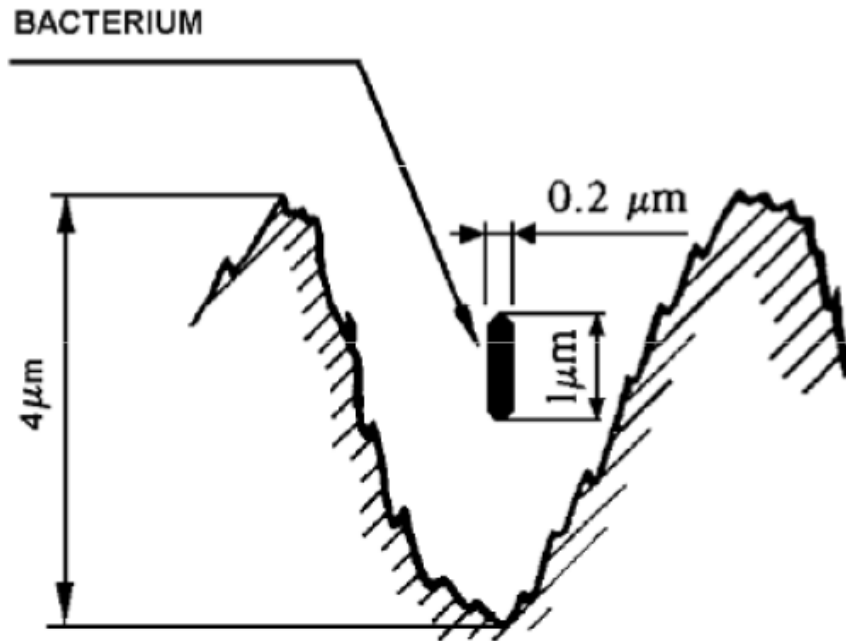
Ra – arithmetical mean deviation of the assessed profile

Ra is the arithmetic mean roughness value from the amounts of all profile values.

Ra does not differentiate between peaks and valleys and has therefore a relatively weak information character.

SURFACES Present Excellent Hiding Places!

32 Microinch Ra (0.8 Micron Ra) Finishes are Still Potential Bacteria Harbors!



- Typical representation of a surface profile of $R_a = 0,8\mu\text{m}$ roughness achieved by 180-240 grit mechanical polish.

RADII

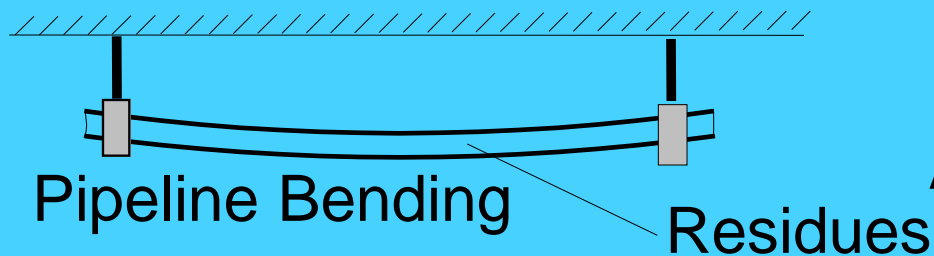
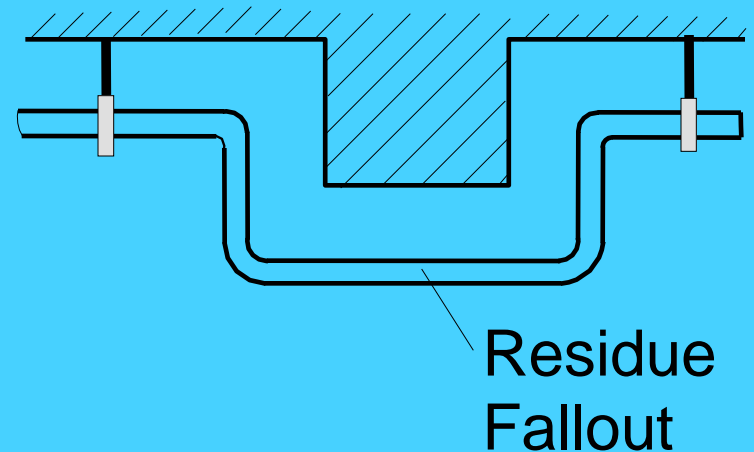
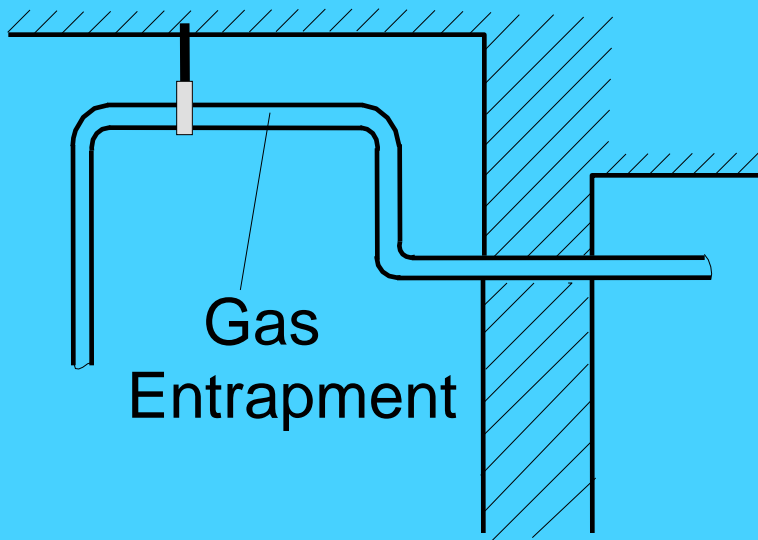
- 3-A APPLIES 0.25 inch AS A BASE LINE MINIMUM RADIUS IN PRODUCT CONTACT AREAS (Vessels are usually 0.5" minimum)
- SMALLER RADII ARE ALLOWED IN SPECIFIC APPLICATIONS ALTHOUGH THE TYPICAL MINIMUM RADIUS IS 0.0625" (1/16")
- THIS ASSURES ABILITY TO APPLY MANUAL CLEANING AS BRUSH BRISTLES ARE ROUND SHAPES THAT ARE SMALLER THAN THE MINIMUM ALLOWANCE.

DRAINABILITY

- EQUIPMENT MUST FREE DRAIN WHEN DISASSEMBLED TO ASSURE INSPECTABILITY OF PRODUCT CONTACT SURFACES
- PIPING SYSTEMS MUST FREE DRAIN TO ASSURE ALL CLEANING SOLUTIONS CAN BE REMOVED PRIOR TO PROCESSING
- FREE DRAINING ALSO ALLOWS STEAM STERILIZATION OF SURFACES BY ASSURING CONDENSATE REMOVAL

DRAINABILITY

Example: PROCESS PIPELINES



**Drainability Impacts
By Routing Pipelines
Around Building Features**

CLEANING REPEATABLY

- DEFINE THE DUTY or SOIL TYPE
- DEFINE THE CHEMISTRY
SOLVENT OR AQUEOUS BASED
- MANUAL or AUTOMATED SOLUTION APPLICATION
- And Perhaps Most Important....

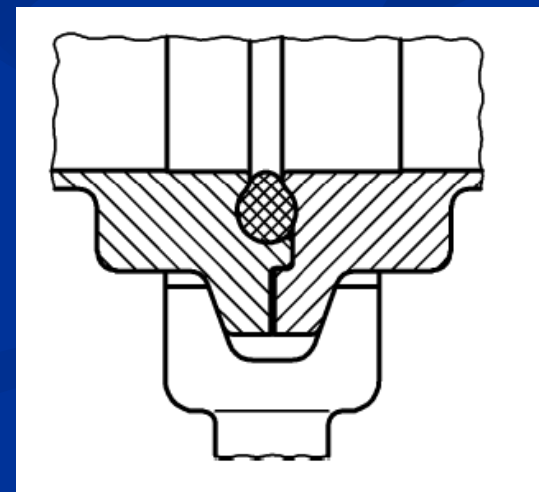
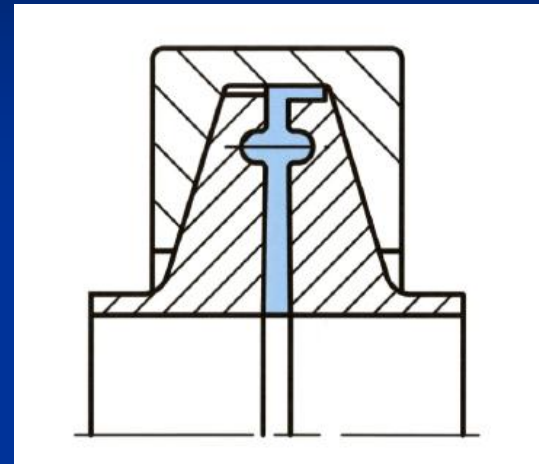
HOW DO YOU DETERMINE WHAT IS CLEAN ?

Welds, Connections, and Dead End Avoidance

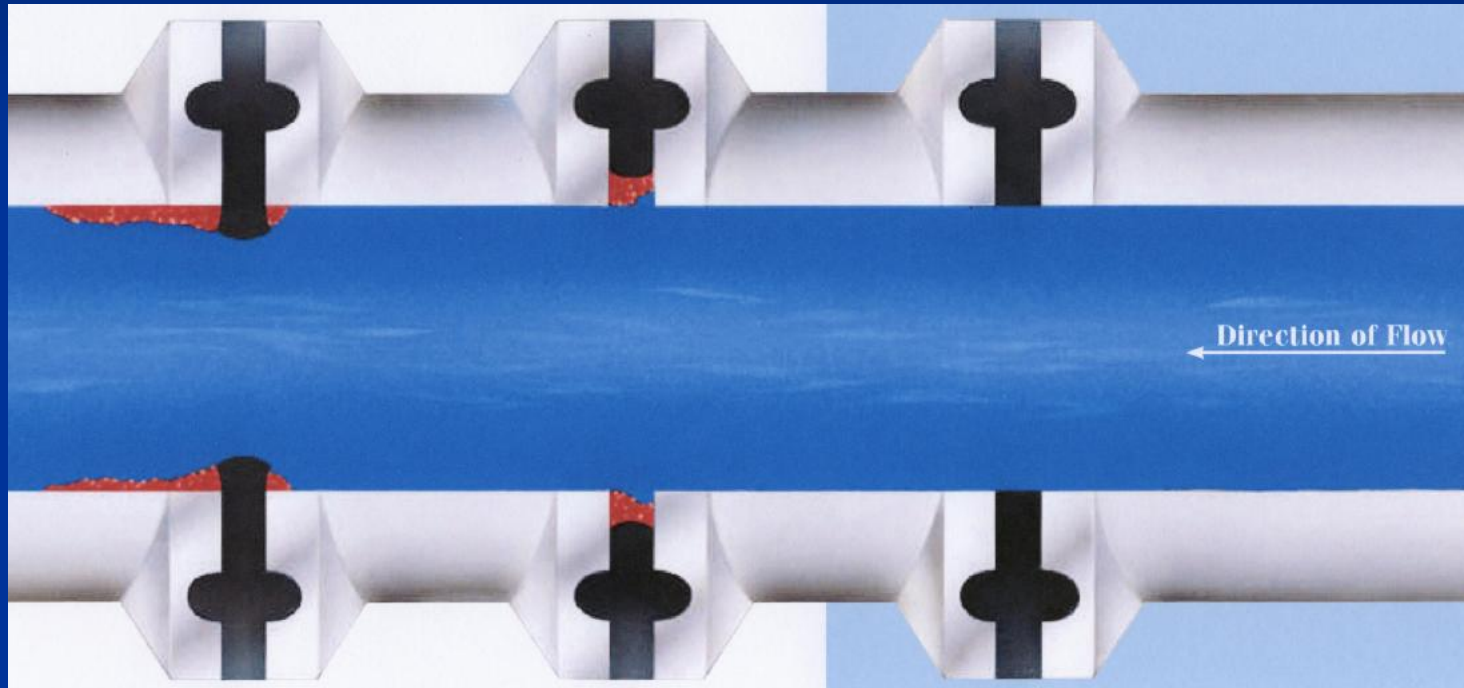
- Welding of Metals to Form Permanent Joints
- Manual or Automatic Orbital Welding
- AWS D18.1 and D18.2 Used as a Guide for Hygienic Welding Procedures
- Pipe or Tube Connection Fittings are used for Non-permanent Joints

Hygienic Clamp Connections

- Sanitary or Hygienic Clamp Connection Types – examples are ISO 2852 (Tri-Clamp) & DIN 11864-1 Form A
- Best if a Method is Applied to Control Compression of Elastomeric Seals



AREAS of Concern



**Variable Gasket Gaps are Possible
without Controlled Compression**

More Details on 3-A SSI

- More info available at 3-A SSI: www.3-a.org

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