

Dairy Equipment Fabrication Short Comings and Challenges: An Auditors Perspective

Presented by
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and 3-A CCE
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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)

2019 Revision



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

2019 Revision

Reference to 3-A Sanitary Standards

- **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.

The PMO Grade A Inspection Program Covers Milk from the Cow to the Carton



The PMO has 18 “Sections”
and 20 “Appendices”.



No calf, no man and no machine can do a safe, complete and satisfactory job of milking cows without TUG & PULL.

That's one of the big reasons why—in 1950—more thousands of farmers than ever before* switched to Surge. Not just more farmers but more *thousands* of farmers.

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ALVIN SILVERSTEIN

PMO Section 7.

ITEM 9r. UTENSILS AND EQUIPMENT - CONSTRUCTION



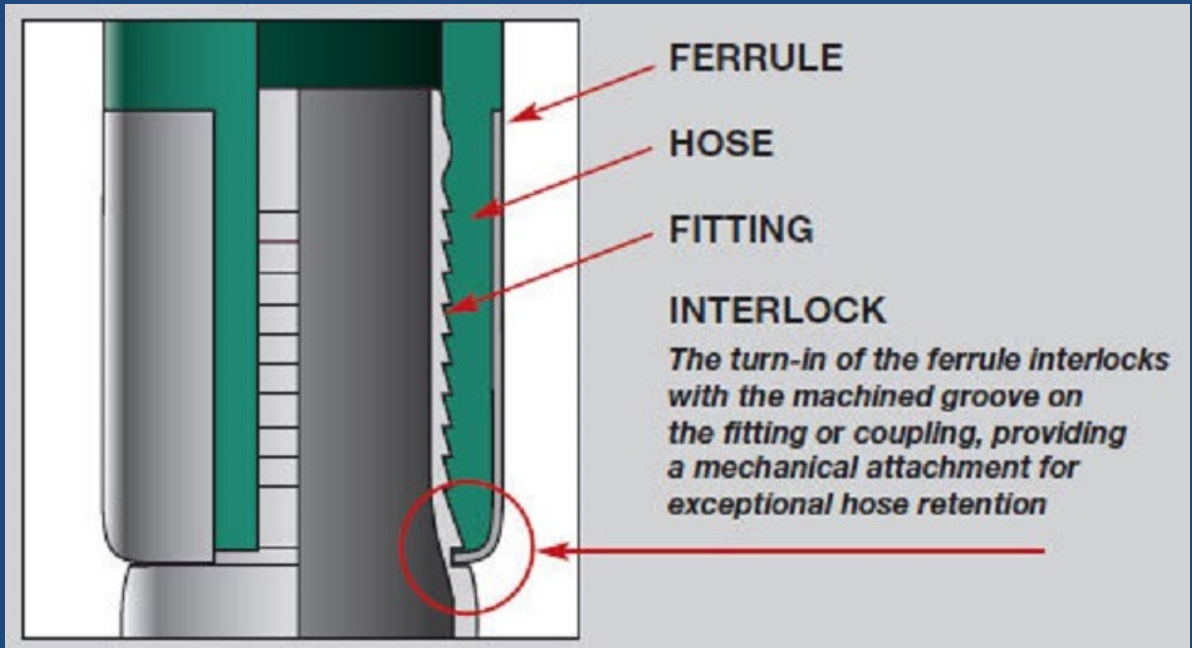


NOTE: 3-A Sanitary Standards and Accepted Practices for dairy equipment are developed by 3-A Sanitary Standards, Inc. (3-A SSI). 3-A SSI is comprised of

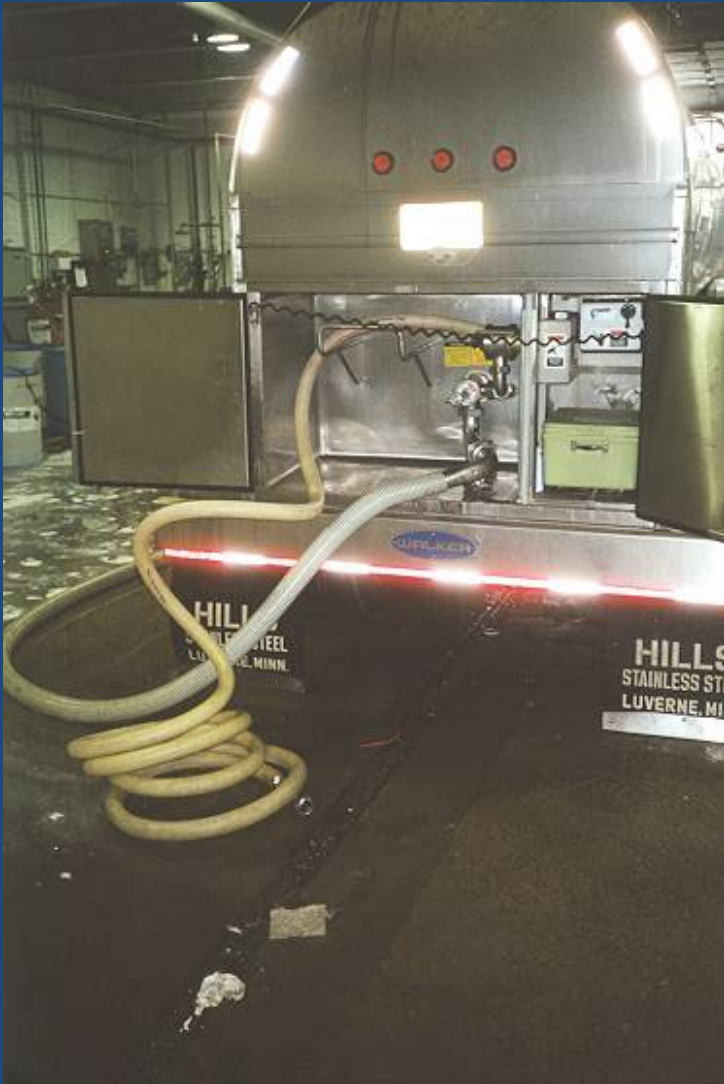
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Slip Joints



PMO Section 7 Item 14r. and Appendix B Part VIII Milk Tanker Permitting and Inspection









PMO Section 7. Item 15p.(A).3b. “Protection from Contamination”

- b. If the area is not completely enclosed or doors of the unloading area are open during unloading, a suitable filter is required for the manhole or air inlet vent and suitable protection shall be provided over the filter material either by design of the filter holding apparatus or a roof or ceiling over the area. When weather and environmental conditions permit, manhole openings and covers of milk tank trucks may be opened outdoors for the short period of time necessary for the collection of samples for animal drug residue screening.

HTST Pasteurization Systems



PMO Section 7. Item 16p.

**PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING,
RETORT PROCESSED AFTER PACKAGING, AND FERMENTED
HIGH-ACID, SHELF-STABLE PROCESSING AND
PACKAGING**



FSMA Implementation for Grade A Milk Processors began in September 2018

Appendix “T” placed in the 2017 Revision of PMO. The first dairy companies to be evaluated under this HACCP based inspection program by the US FDA were completed an Appendix “T” evaluation in 2018.

Under PMO Appendix “T” Equipment and Processes need to be evaluated to ensure that the systems are cleanable and properly cleaned and Sanitized after each day used.

The 3-A Sanitary Standards are a building block for verifying this requirement.

3-A Sanitary Standards and Practices



3-A Sanitary Standards

Physical/ Chemical Properties

- Nontoxic/Non-contaminating
- Inert/Impervious
- Corrosion Resistant
- Non-reactive
- Non-absorbent

Mechanical Properties

- Durable
- Smooth
- Free of Cracks & Crevices

Operational Properties

- Cleanable/Inspectable
- Reduced Maintenance

**Slide Barrowed from another presentation posted on the 3-A Website.

EDTCF

- Engineering, Design and Technical Construction File
- An EDTCF, Table of Contents is to be on hand for the audit visit.

Quality Management Program

- 3-A CCE's are required to evaluate a 3-A Symbol Use Authorization Applicant's QM, QA or QC Program. While an ISO 9001-2015 certificate is not required under the 3-A TPV program, having a certified program is considered a plus and is recorded by the CCE's in the Third Party Verification (TPV) report.
- On-site Audit Visits are required.

Material Selection

- Rubber and Rubberlike Materials
- Plastic Materials
 - 3-A Sanitary Standards for Rubber and Rubberlike Materials #18-03
 - 3-A Sanitary Standards for Plastics #20-27

These standards contain test criteria for a material's compatibility with product and the ability to withstand the environment of intended use!

3-A Sanitary Standard for General Requirements

ANSI/3-A 00-01-2018

D1.2 Nonmetals

D1.2.1 Plastic, rubber and rubber-like materials may be used for gaskets or seals. When permitted by specific equipment 3-A Sanitary Standards or 3-A Accepted Practices, plastic, rubber and rubber-like materials may be used for other components.

D1.2.1.1 Plastic, rubber and rubber-like materials, when used as product contact surfaces, shall be inert and non-toxic, nonabsorbent, fat-resistant, relatively resistant to scratching, scoring, decomposition, crazing, and chipping under normal use and when exposed to the conditions encountered in the environment of their intended use, including cleaning, sanitizing treatment, and/or sterilization.

D1.2.1.2 Plastics, rubber and rubber-like materials, when used as product contact surfaces, shall not impart flavor or odor to the products under repeated use conditions.

Note: D1.2.1.2 does not apply to the 3-A SSI Symbol Authorization program.

Standard Compliance Declaration Statement for Plastics

- **US FDA Food Contact Status**
- When used unmodified and processed in accordance with Good Manufacturing Practices (GMP) for food contact applications, this product will comply with the U.S. Food and Drug Administration's food additive regulation Title 21 CFR 177.1520(c) 3.2c. This product may be used to produce articles or components of articles used in contact with food for all food types described in Table 1 and Conditions of Use C-H described in Table 2 of U.S. FDA's regulation 21 CFR §176.170(c). The preceding statement refers to regulatory requirements only, not to the product's physical utility. It is the responsibility of the article producer or food packager to determine that the article is suitable for its intended use.

Other Considerations

- **Heavy Metals of High Concern (Cadmium, Lead, Mercury and Chromium 6) per EU 94/62/EC and Conference of Northeastern Governors Recommendations (CONEG)**
- **Conflict Minerals (Dodd-Frank Wall Street Reform and Consumer Protection Act)**
- **Allergens (Food)**

To the best of our knowledge, there are no raw materials, including additives, that have their origin in peanuts, soybeans, milk, eggs, fish, shellfish (mollusks), crustaceans, tree nuts, mustard, celery, sesame, sunflowers, lupine, animal or vegetable proteins, caffeine, monosodium glutamate (MSG), colorants (including carmine and cochineal), corn, wheat, barley, rye, triticale, gluten, mushrooms, yams, and/or phenylalanine and its derivatives. No sulfates, sulfites, or sulfur dioxide are used in the synthesis of this material. This evaluation is based on information provided by our raw material and additive suppliers for the presence of the allergen-stimulating substances shown above. Therefore, although we believe this product to be free of the specified known allergy stimulating food substances, we cannot guarantee this.

CIP & COP





Threads in a product contact area?

Valves for product sampling.



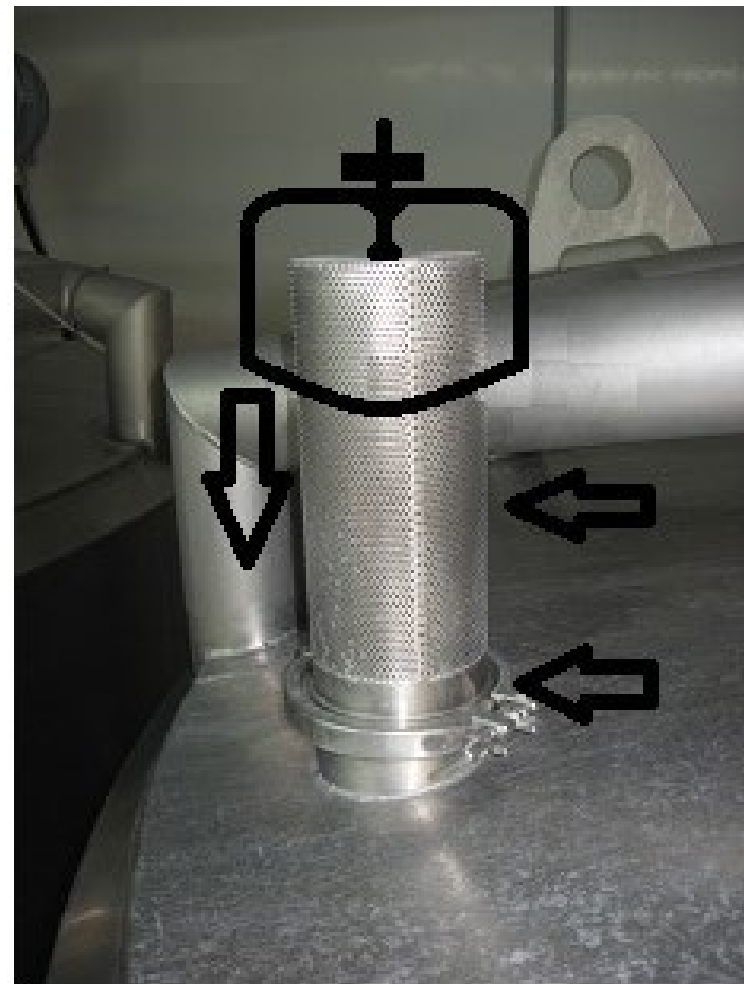
Sensors & Sensor Fittings.



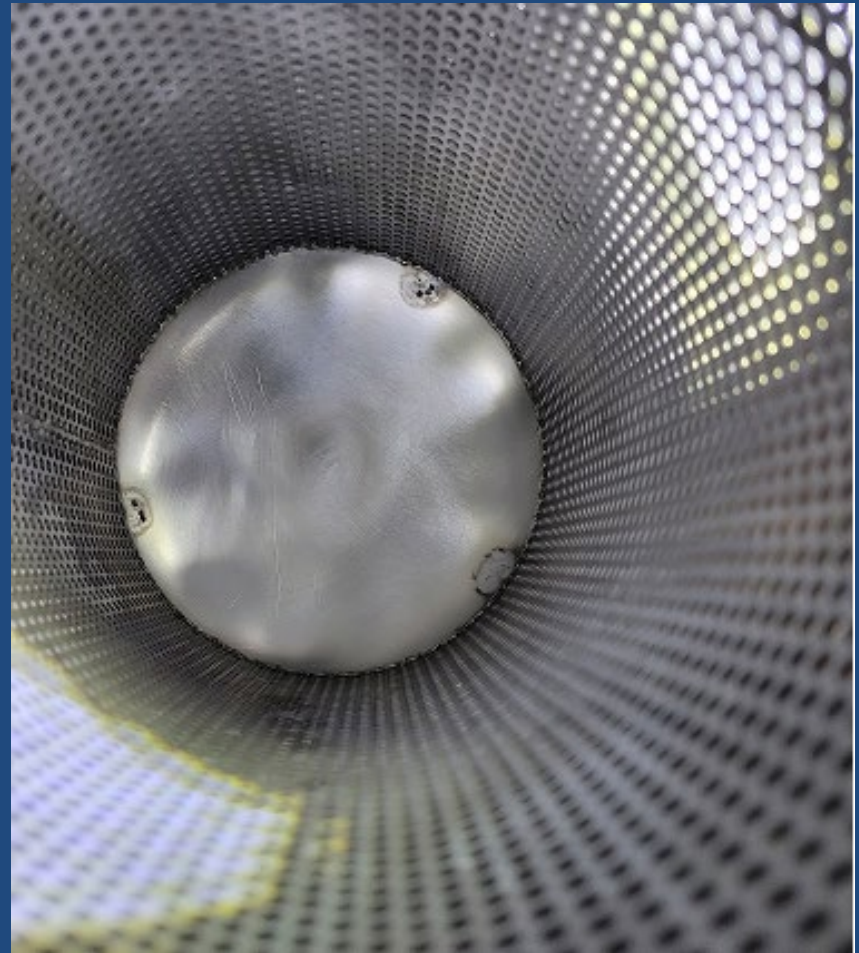
Constructed to withstand the environment of intended use?



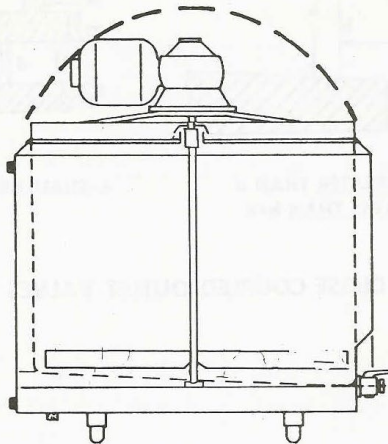
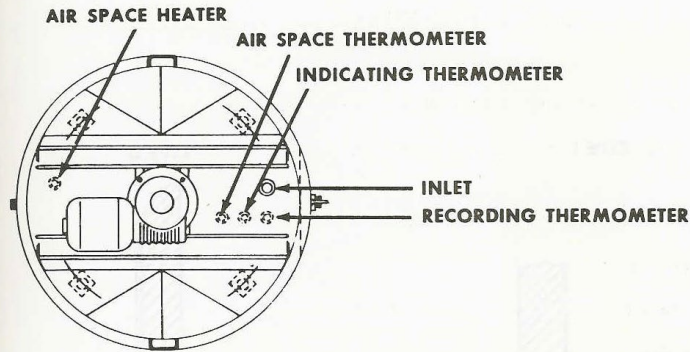
Batch Processor Vat Vents



Batch Processor Vat Vents

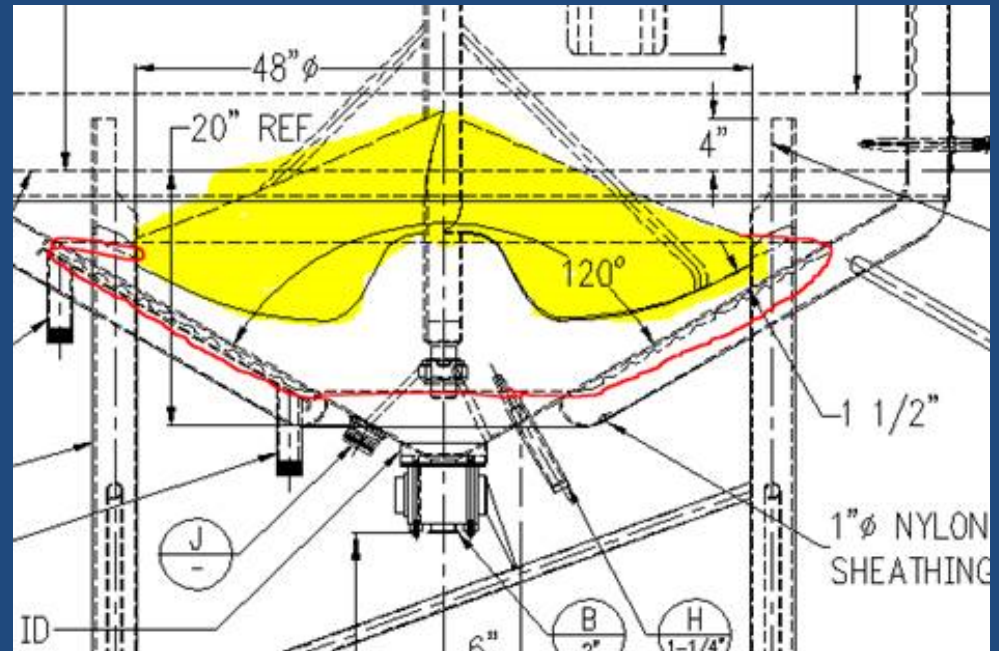


Batch Pasteurization



SCHEMATIC OF VAT

Figure 4



Non-Product Contact Surfaces. Coatings shall adhere.



Non-Product Contact Surfaces. Coatings shall adhere.

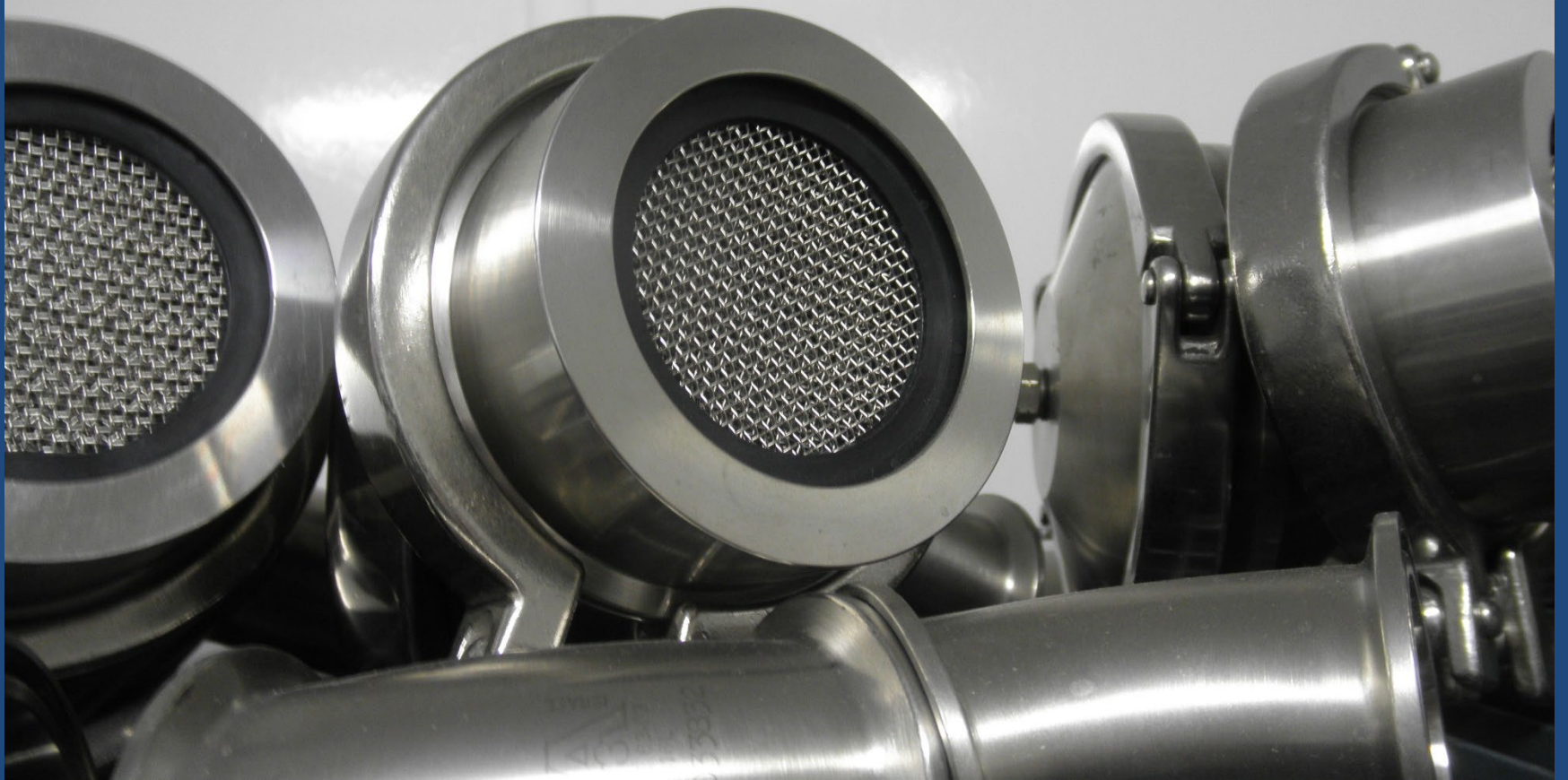


Filling and Packaging Equipment





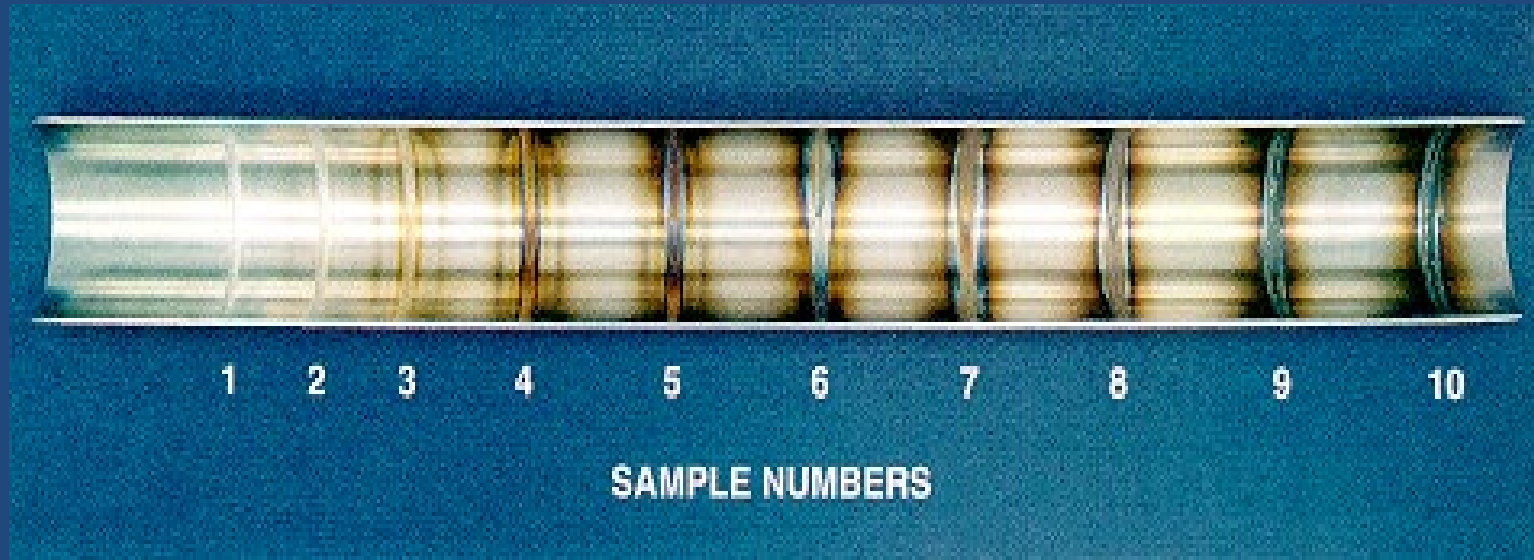
Woven Wire Screens in Filler Nozzles





Sanitary Welding

Heat Tint Levels on the Inside of Welded 316L Stainless Steel Tube



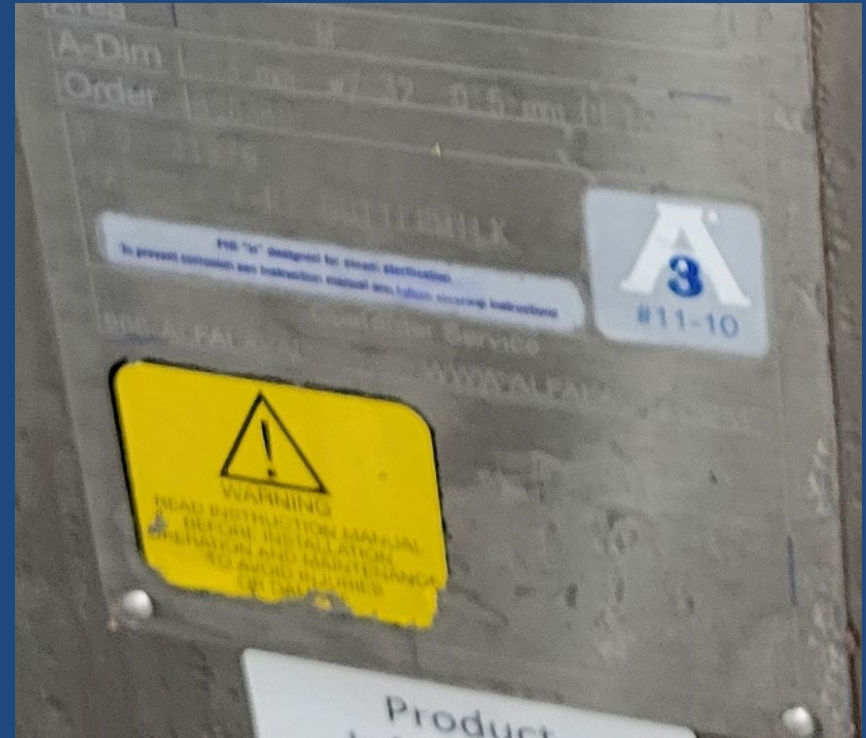
The Sample Numbers refer to the amount of oxygen in the purging gas:

**No.1- 10ppm No.2 - 25ppm No.3 - 50ppm
No.4 - 100ppm No.5 - 200ppm No.6 - 500ppm No. 7 - 1000ppm
No.8 - 5000ppm
No.9 -12500ppm No.10 -. 25000ppm**

Display of the 3-A Symbol



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Display of the 3-A Symbol



Questions???



Thank you for your attention.

