Equipment Design Problems and Their Solution

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Product Zone Construction

- Surfaces smooth
- All surfaces accessible or removable
- Non-toxic
- Non-absorbent
- Corrosion-resistant
- Lead or lead solder not used
Product Zone Construction

- Radius
- Gaskets and Seals
- Hinges
- Welded Construction
- Conveyors
- Pumps
- Valves
- Tanks
- Dead ends
- Framework
Permanently joined surfaces with a total included internal angle less than 135° shall have a radius of not less than 6 mm (1/4 inch).

- **NOT ACCEPTABLE**
- **GOOD**

Radius
## O-ring groove radius

<table>
<thead>
<tr>
<th>O-ring Cross Section, Nominal (SAE AS 568)</th>
<th>O-ring Cross Section, Actual (SAE AS 568)</th>
<th>O-ring Cross Section, Actual (ISO 3601-1)</th>
<th>Minimum Groove Radius</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/16 in. (1.5 mm)</td>
<td>0.070 in.</td>
<td>1.78 mm</td>
<td>0.016 in. (0.41 mm)</td>
</tr>
<tr>
<td>3/32 in. (2.4 mm)</td>
<td>0.103 in.</td>
<td>2.62 mm</td>
<td>0.031 in. (0.79 mm)</td>
</tr>
<tr>
<td>1/8 in. (3.0 mm)</td>
<td>0.139 in.</td>
<td>3.53 mm</td>
<td>0.031 in. (0.79 mm)</td>
</tr>
<tr>
<td>3/16 in. (4.8 mm)</td>
<td>0.210 in.</td>
<td>5.33 mm</td>
<td>0.062 in. (1.58 mm)</td>
</tr>
<tr>
<td>1/4 in. (6.0 mm)</td>
<td>0.275 in.</td>
<td>6.99 mm</td>
<td>0.094 in. (2.39 mm)</td>
</tr>
</tbody>
</table>
Sanitary Fittings
3-A Sanitary Standard - 63-03
Gasket Connections

Gaskets shall be installed in a manner which results in a true fit to prevent protrusion in the product zone or creation of recesses or ledges between the joints.

![Diagram showing examples of gasket connections, labeled as "Not Acceptable" and "Good".](image)
Gasket Material

- Plastic and rubber
- Inert and non-toxic, nonabsorbent, fat-resistant
- Resistant to scratching, scoring, decomposition, crazing, and chipping under normal use.
  - Processing, cleaning, sanitizing treatment, and/or sterilization.

- So how do we do know this?
Gasket Material

- 3-A Sanitary Standard 18-03 - Multiple-Use Rubber and Rubber-like Material
- 3-A Sanitary Standard 20-27 - Multiple-Use Plastic Material
- Listed in Title 21 Code of Federal Regulations, Parts 170-199 for that use.
- Generally Recognized as Safe (GRAS) regulation or GRAS notice.
Hinges
Welds

- When improperly done
- Hard to clean
- Open surfaces conducive to biofilm formation
Conveyor systems

- Non-food grade construction
- What is the product?
- Does it make a difference?
- Ready-to-eat food
- Further Processed
Listeria in Carmel Apples

CDC, state health officials and FDA investigate an outbreak of Listeria monocytogenes infections.

Joint investigation indicated that commercially produced, prepackaged caramel apples were the likely source of this outbreak.
Product Conveyor Belt

Checked Material

Connection Not Cleanable
Product Conveyor
Sanitary side rails

Easily Removable
Stainless doesn’t always equal sanitary
Rusted Mild Steel Threaded Clamp

Brass Components
Acid Environment

Threaded Fittings
Sanitary Pump Design
3-A Sanitary Standard 02-11
Valves

- Design
- Intended use
- Ease of disassembly
Hmmm - Following CIP
Butterfly Valve
Disc Valve
3-A Sanitary Standard 57-02

Manual Clean

CIP Clean when pulsed
“White Dairy Metal”
Processing Tanks
3-A Sanitary Standard 01-09 or 32-03
Processing Tanks
3-A Sanitary Standard 01-09 or 32-03
Agitator shields
Dead End

- Normally not more than twice the distance of the pipe diameter not to exceed five inches
- Product, ingredients, and cleaning agents, or extraneous matter may be trapped, retained or not completely displaced in normal operation or cleaning procedures
Dead end cleaning video
Bolted Construction

Areas of Concern

- Lock nuts versus cap nuts
- Ease of disassembly
- Deeper Issues?
If you look deeper

- Perforations in hollow frame
What's the solution

Sleeve
Threaded Post
Pin and R-clip
Name Plates - no rivets or spot welds

OK, but it is on the outside

I’m not sure how!!!!
Changing focus on responsibility

- **Where Hygienic Design and Food Safety Law Collide**
  - 3-A SSI 2015 Annual Meeting and Education Program
    - Shawn K. Stevens, Food Industry Counsel, LLC
  - Proper equipment design is meant to preserve and protect the safety of food
  - Key component of Food Safety Modernization Act (FSMA)
  - How the new requirements impose new duties on processors
Changing focus on responsibility

- FDA FD 512 Course
  - Food Core III - Food Processing and Technology
  - West Lafayette, IN

- Onus is on the firm to “prove” that equipment is sanitary and cleanable following acceptable standard cleaning procedures.
Developing Collaborative Partnerships

Industry Role
- Research
- Understanding Sanitary Design
- Purchasing Specifications
- Internal Review Process

Regulatory Role
- Technical Resource
- Training Resource
- Interpret Rules
- Perform Reviews
ATCP 80.12  Equipment and utensils.

(1) Construction and maintenance.

(a) Equipment and utensils, including C-I-P systems, shall be of sanitary design and construction. Equipment and utensils, including C-I-P systems installed after the effective date of this chapter, shall comply with applicable "3-A Sanitary Standards" and "3-A Accepted Practices" listed in APPENDIX A to this chapter.

(b) Equipment and utensils shall be readily accessible for cleaning and inspection, and shall be designed and constructed so that they can be easily cleaned. Equipment and utensils shall be kept clean and in good repair.

No Requirement for formal review

History of providing this service

Other options

Hygienic Design Resources
Wisconsin Department of Agriculture, Trade and Consumer Protection Review Process

- Contact locally assigned Food and Dairy Specialist
  - Application process under development
- Evaluation of drawings and material specifications
  - May include on-site review
- Final Review
  - Issuance of review letter as appropriate
Hygienic Design Resources

- 3-A Sanitary Standards, Inc.
- USDA - Agriculture Marketing Services
- Atlantic-Midwest Dairy Equipment Review Committee (AMDERC)
3-A Review Process

- Third Party Verification Programs and Resources
  - Certified Conformance Evaluator (CCE)
  - Evaluate equipment for sanitary design and construction

- 3-A Symbol Holder List

http://www.3-a.org/Symbol/SymbolHolder_search.php
3-A® Sanitary Standards for General Requirements

- ANSI/3-A 00-00-2014

**SCOPE**

- A1 This 3-A Sanitary Standards define the general requirements for sanitary (hygienic) equipment intended for processing milk, milk products, foods, food ingredients, beverages, or other edible materials.

http://www.techstreet.com/3a/products/1883380
USDA - Agriculture Marketing Services Review Process

- Voluntary, user-fee supported equipment review and certification program
- AMS specialists equipment reviews for sanitary design and construction

http://www.ams.usda.gov/AMSv1.0/EquipmentReview
AMDERC Review Process

- **Committee Process**
  - Review of design drawings, material and construction information
  - May include field trials
  - Final Review
  - Issuance of FDA M-b as appropriate
  - Application Process for Review
What improvements would you recommend?

- Dead End
- Threaded Connections
- Bolted Fittings
- Annular Space Protection
- Condensation Removal
- Open entry points
What is your level of risk?
Thank you

Thank you for the opportunity to discuss “Equipment Design Problems and Their Solution”.

Questions?

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