



Agricultural Marketing Service  
U.S. DEPARTMENT OF AGRICULTURE

**USDA GUIDELINES  
FOR THE SANITARY  
DESIGN AND FABRICATION OF  
DAIRY PROCESSING EQUIPMENT  
02/2022**

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**1. Purpose**

The following criteria, guidelines and principles set forth the sanitary design and fabrication features required by United States Department of Agriculture (USDA), Dairy Grading Branch (DGB) for the acceptance of equipment intended for use in dairy plants surveyed and approved for USDA grading service. The DGB is a user fee supported service. Therefore, charges will be made for the review of drawings or equipment and for related travel and other expenses.

USDA/AMS/Dairy Programs  
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 Naperville, IL 60563  
 Phone: 630-810-9999

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 Dairy Grading and Standardization  
 Division  
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**2. Scope**

The DGB utilizes established 3-A SSI Sanitary Standards and Accepted Practices for equipment that fall under the scope of a particular standard or practice. In the event that a piece of equipment reviewed does not fully comply with the applicable 3-A SSI Sanitary Standards or Accepted Practice, however, the equipment does meet the minimum requirements of the USDA Dairy Equipment Guidelines, the DGB will evaluate the discrepancy. If it can be determined that the equipment in question will not contribute to unsanitary conditions and/or public health issues, DGB will still issue a letter of acceptance and certificate.

***3-A SSI Sanitary Standards and 3-A SSI Accepted Practices Websites***

[www.3-a.org](http://www.3-a.org)

[www.techstreet.com/3Agate.html](http://www.techstreet.com/3Agate.html)

The 3-A Sanitary Standards provide criteria for materials and fabrication for specific types of dairy equipment. Examples of equipment covered by 3-A Sanitary Standards are centrifugal and positive displacement rotary pumps, compression valves, non-coil batch processors, and bag collectors for dry milk products. The 3-A SSI Accepted Practices establish criteria for the materials, fabrication, and installation of processing systems which employ component pieces of equipment, many of which are covered by 3-A Sanitary Standards. Examples of 3-A Accepted Practices are Spray Drying Systems, HTST Pasteurizer Systems, and Culinary Steam Producing Systems.

If the applicant would like to receive a USDA DGB Certificate of Acceptance, the USDA DGB will still require an inspection of the equipment even if the equipment bears the 3-A symbol. Equipment bearing a 3-A symbol will be subjected to routine plant survey evaluation for sanitation under the [USDA Dairy Plant Survey Program](#). If the routine inspection reveals deficiencies with materials, design, fabrication, or workmanship, which appear to violate the USDA Dairy Equipment Guidelines and/or applicable 3-A Sanitary Standards, DGB will request the fabricator to make appropriate modifications. In the case of noncompliance with the 3-A SSI Sanitary Standard or Accepted Practice, a Report of Alleged Non-Compliance (RAN) may be filed with 3-A SSI.

Equipment buyers are encouraged to request USDA-DGB acceptance for equipment as a provision of their purchase contract. The requirement should be clearly written so as not to confuse USDA-DGB acceptance with compliance with other requirements, such as 3-A SSI Sanitary Standards or requirements of other Federal or State Agencies. Equipment accepted under the USDA Dairy Livestock and Poultry Equipment Review program, or approved by the USDA, Food Safety and Inspection Service (FSIS), or State inspection agencies does not infer acceptance by the USDA DGB. When a USDA-DGB review is requested of equipment for which there are no 3-A Sanitary Standards or Accepted Practices, USDA will use the following general criteria, guidelines, and principles of this document. Sections 4-10 shall apply unless modified by “Section 12-18 Special Considerations”.

### 3. References

- “3-A Sanitary Standard for General Requirements ANSI/3-A 00-01 2018” is referenced throughout the document including images.
- 3-A Sanitary Standard for Sifters for Dry Products Number 26-06
- 3-A<sup>®</sup> Sanitary Standards for Hose Assemblies, Number 62-02
- 3-A<sup>®</sup> Sanitary Standard for Sight and/or Light Windows and Sight Indicators in Contact with Product Number 65-01
- 3-A<sup>®</sup> Sanitary Standards for Shear Mixers, Mixers, and Agitators, Number 73-01
- 3-A Sanitary Standard for Spray Cleaning Devices Intended to Remain in Place, Number 78-03
- 3-A<sup>®</sup> Sanitary Standards for Personnel Access Ports for Wet Applications, Number 84-02
- 3-A Sanitary Standard for Equipment Feet and Supports, Number 88-01
- 3-A<sup>®</sup> Accepted Practices for the Sanitary Construction, Installation, Testing and Operation of High-Temperature Short-Time and Higher-Heat Shorter-Time Pasteurizer Systems, Number 603-07
- 3-A<sup>®</sup> Accepted Practices for Permanently Installed Product and Solution Pipelines and Cleaning Systems Used in Milk and Milk Product Processing Plants, Number 605-04
- 3-A<sup>®</sup> Accepted Practices for A Method of-Producing Culinary Steam, Number 609-03
- “[Machinery's Handbook](#)” published by Industrial Press, Inc., 200 Madison Ave., New York, NY 10157.
- ASTM G31 *Laboratory Immersion Corrosion Testing of Metals*
- Title 21 Code of Federal Regulations, Parts 170-199

- ASTM G31 *Laboratory Immersion Corrosion Testing of Metals*
- American Welding Society (AWS)/ American National Standards Institute (ANSI)-D18.1

#### 4. Definitions

1. **Bond:** Adhesive materials or possibly cohesive forces holding components together. This definition does not include press and shrink fits.
2. **Brazing:** A bonding process between materials by heating them to the brazing temperature with a filler metal having a melting point above 840°F (450°C) and below the melting point of the base metal. The filler metal flows between the closely fitted surfaces of the joint by capillary action.
3. **Brazing Filler Metal:** The metal or alloy used as a filler metal in the brazing process that has melting point above 840°F (450°C) and below the melting point of the base metal.
4. **Burr:** A thin ridge or sharp edge remaining after cutting, drilling, grinding, polishing, shearing or punching a material.
5. **CIP-able:** The design and fabrication of equipment which allows the equipment surfaces to be cleaned by CIP methods for a prescribed time and at a prescribed concentration, flow rate, pressure, and temperature demonstrated to be effective. <sup>1</sup>
6. **Cleaned-in-Place (CIP):** The process of removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned.
7. **Clean-Out-of-Place: (COP):** Removal of product residues and soil from equipment when it is removed from its installed position. The equipment or assembly may be partially or totally disassembled. Cleaning is accomplished by circulating chemical solutions and water rinses in a wash tank. The wash tank may be fitted with circulating pump(s).
8. **Cleanable or Cleanability:** When Materials of construction, design and fabrication will ensure that surfaces will allow the removal of product residues and soil.
9. **Close Coupled:** Mounting or connecting of components so that the intervening product contact area separating the components is as short as possible. <sup>1</sup>
10. **Corrosion Resistant:** A surface or material which has the property to retain its original surface characteristics through its predicted service period when exposed to the conditions encountered in the environment of intended use. This includes contact with product, cleaning and sanitizing chemicals, steam, or sterilization compounds or solutions. <sup>1</sup>
11. **Coatings, Overlays and Encapsulations:** A process where a different material is deposited to create a new product contact surface. There is a buildup of new

material. The coating, overlay, or encapsulation material does not alter the physical properties of the substrate. 1

12. **Dead End or Space:** An area in which product, ingredients, cleaning solution, or sanitizing solution, or other matter, may become trapped, retained, or not completely removed during production or ensuing cleaning procedures.
13. **Dry Cleaning:** Cleaning without the aid of liquid using a vacuum cleaner and/or dry brushes and other tools manipulated by hand.
14. **Dry Dairy Product:** Dry Milk, dry milk product or other dairy product that is free of visible moisture or added moisture, free flowing, granular, crumbled, diced, shredded, or cubed.
15. **Essential Functional Reason:** A condition or feature of the design or fabrication of a piece of equipment that cannot be modified and is required for the proper operation of the equipment. 1
16. **Fillers:**
  - a. **Horizontal Fillers-** Fill the container as it moves in a horizontal plane. This would include fillers with turntables or forming/filling wheels.
  - b. **Vertical Fillers-** Fill the container as it moves in the vertical plane.
17. **Fittings, Clean in Place (CIP):** Fittings designed to be cleaned while fully assembled. If the fitting has a removable joint, the joint shall be self-centering, gasketed, and the gasketed joint forms a substantially flush interior surface.
18. **Fittings Manually Cleaned:** Removable joint fittings that are not capable of CIP and require disassembly for manual cleaning. (*i.e. Bevel Seat Fittings*)
19. **Inlet:** An opening that allows product, solutions, ingredients, steam, or air to enter the equipment.
20. **Inspectable:** Item or area that can be made available or exposed for close visual observation.
21. **Manual Cleaning:** Cleaning method to remove all soil from product contact surfaces while completely or partially disassembled. Soil removal is promoted with cleaning solutions and water rinses with the assistance of one or a combination of brushes, nonmetallic scouring pads, scrapers, and/or high- or low-pressure hoses, with cleaning aids manipulated by hand. When this method of cleaning is required, the equipment design shall be easily disassembled. The disassembly may be done with or without simple hand tools.
22. **Non-product Contact Surface:** All exposed surfaces from which splashed product, liquids, or other soil cannot drain, drop, diffuse or be drawn into or onto the product, product contact surfaces, open packages, or the product contact surfaces of package components. 1



23. **Non-Toxic Materials:** Substances, which under the conditions of their use, comply with applicable requirements of the applicable FDA Regulation.
24. **Outlet/Product Outlet:** An opening that allows product or solutions to exit the equipment or vessel.
25. **Perforated Screens:** Metal sheets, which have punched, cut, drilled or formed openings or holes.
26. **Permanent Joint:** A joint between two components which is unable to be disassembled. 1
27. **Processing Area:** A room or area suitable for the manufacturing and packaging of dairy products.
28. **Product:** Milk, milk products, including all related dairy products, or fraction thereof which is to be produced, processed or packaged by the equipment.
29. **Product Contact Surface:** All surfaces which are exposed to the product and from which splashed product, liquids, material or soil may drain, drop, diffuse or be drawn into the product, interiors of product containers, onto the product contact side of packaging materials or onto surfaces that come into contact with product contact surfaces of packaging materials.

**Note:**

*The product contact surfaces of exposed product conveyors and packaging equipment may be isolated by sanitary shielding or other acceptable means of clear demarcation. (See Section 13 & 14)*

30. **Readily Accessible:** A location that can be safely reached by personnel from the floor, other permanent work area or stable platform (permanent or moveable.) 1
31. **Regulatory Agency:** The state or local agency having regulatory jurisdiction, or the validation for compliance (testing, timing and sealing) with legal pasteurization criteria as set forth in the PMO.
32. **Readily Removable:** A design, fabrication, including installation that will allow the equipment or appurtenance(s) of the equipment to be quickly separated with or without the use of simple hand tools.
33. **Roughness Average ( $R_a$ ):** The arithmetical mean of the absolute values of the surface profile departure within a sampling length. (ANSI)/American Society of Mechanical Engineers (ASME) B46.1 *Surface Texture Waviness and Lay*. Available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017-2392, Phone: (212) 705-7722.
34. **Safe Water:** Water from a supply properly located, protected, and operated, and shall be of a safe, sanitary quality. The water shall meet the standards as described in the National Primary Drinking Water Regulation of the

Environmental Protection Agency (EPA) (Refer to B4, Reference No. 4) or Category I Reclaimed Process Water as described in Appendix D of the PMO.

35. **Sanitizing or Sanitization:** A process applied to a clean surface which is capable of reducing the numbers of the most resistant human pathogens by at least 5 log<sub>10</sub> reductions (99.999%) to 7 log<sub>10</sub> reductions (99.99999%) by applying hot water, hot air, or steam, or by applying an EPA-registered sanitizer according to label directions. Sanitizing may be affected by mechanical or manual methods. <sup>1</sup>
36. **Sealed:** Closed to the penetration of fluids by the application of one or more continuous welds, soldering, brazing, coatings, overlays, encapsulations, adhesives, rubber, rubber-like or plastic gasket under compression, mechanical force seals or press-fits or shrink-fits.
37. **Shadow Areas:** Obstructed areas on product contact surfaces where cleaning solutions will not flow or impinge directly across and onto the surfaces to be cleaned.
38. **Simple Hand Tools:** Shall mean implements or utensils normally used by operating and cleaning personnel. (*i.e. screwdriver, wrench, or mallet.*)
39. **Splash Contact Surface:** Non-product contact surfaces that during normal operation or use are subject to accumulations of soil and which require routine cleaning.
40. **Soil:** Unwanted organic residue or inorganic matter. <sup>1</sup>
41. **Solder:** The metal or alloy used as a filler metal in soldering, which has a melting point not exceeding 840°F (450°C) and below the melting point of the base metal.
42. **Soldering:** A joining process that produces coalescence of materials by heating them to the soldering temperature and using a filler metal having a melting point not exceeding 840°F (450°C) and below the melting point of the base metals. The filler metal is distributed between closely fitted surfaces of the joint by capillary action by wetting of the surfaces by using soldering flux.
43. **Solution:** Water or any mixture of water and cleaning agents, or sanitizers used for flushing, cleaning, rinsing, or sanitizing.
44. **Solution Contact Surfaces:** All interior surfaces of the equipment or system, including associated piping, and tanks that are used for supplying and recirculation cleaning and/or sanitizing solutions. This does not include equipment or pipelines used to supply concentrated cleaning and sanitizing chemicals from bulk storage to the point of chemical addition.
45. **Sterilization:** A process affected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria and inactivates relevant bacterial spores of public health concern. <sup>1</sup>

46. **Substantially Flush:** Mating surfaces or other associated surfaces, such as gaskets, butt welds, and fitting alignment, that are not more than (+/-) 1/32 in. (.031 in) off-set. <sup>1</sup>
47. **Surface Coating:** Shall mean the results of a process whereby a different material is deposited upon a surface to create a new surface with altered functional characteristics and there is an appreciable build-up (greater than 1 micrometer) of new material. Surface coating may include;
- Chemical (conversion coatings except anodizing).
  - Engineering Plating. (e.g., electro-deposition, gold)
  - Thermal Spraying (e.g., flame, plasma, arc spraying)
  - Physical Vapor Deposition.
  - Chemical Vapor Deposition.
  - Overlays and Encapsulation.
48. **Surface Treatment:** Process whereby chemical compositions or mechanical properties of the existing surface are altered and there is no appreciable build-up (less than 1 micrometer) of new material. Surface treatments may include;
- Mechanical (grinding, shot peening, glass beading, polishing)
  - Thermal (surface hardening laser, electron beam)
  - Diffusion (carbonizing, nitriding)
  - Chemical (etching, oxidation, passivation)
49. **Viscous Product:** Shall mean semi-fluid product which is pumpable or flowable at packaging condition. <sup>1</sup>

## 5. Engineering Drawings

- A. Engineering drawings of the entire piece of equipment are generally required for evaluation of details for USDA acceptance. Engineering drawings must be of sufficient detail to clearly show:
- The dimensions of each part;
  - The minimum radii dimensions of internal angles of less than 135 degrees;
  - The product contact surface finish specifications;
  - The specifications for welds and other permanent joints;
  - The design details for flanges, or gasketed joints which are to include enlarged drawing(s) (at least 2X) of the details of O-ring retaining grooves as appropriate;
  - The dimensions of O-rings, gaskets, and any other type of seals; and
  - Explanations about company welding symbols and metal finishes.
- B. Dimensions may be shown in either English or metric measurement terms. The required materials listings and terminology on the drawings should be in English or include translations into English. Concept or assembly drawings should also be provided as they are useful in showing the general configuration of the equipment and the relationship of component parts to each other. If the applicant needs to have the equipment reviewed in a shorter time an on-sight visit can be conducted or by

drawings sent for review. A request can be made for a meeting to review drawings and/or parts for a quicker turnaround time as well. Alternatively, the review can be performed on a finished piece of equipment on-site, either at the equipment manufacturer or at a processing plant. The requirements for this type of review are:

- Safe access must be provided.
- All product contact surfaces must be clean and available for inspection.
- Food and Drug Administration/Code of Federal Register (CFR) and 3-A Sanitary Standards certifications for all rubber and plastic materials should be available.

## 6. Application of Service

- A. To initiate a sanitary design review, the perspective applicant may contact the DGB by telephone, fax, e-mail, or mail. A request for inspection is to be accompanied by an Equipment Review Request form (see below). Applicants are advised that a minimum of 40 working days advance notice is required for any foreign travel and a minimum of 14 working days advance notice is required for domestic travel. Design evaluations and travel to inspection sites is based on a first-come-first-served basis and inspector availability. Applicants are encouraged to contact the DGB, National Field Office, Lisle, Illinois to verify inspector availability and schedules prior to submitting a request for service. If the date(s) requested is not a suitable date the DGB will contact the requestor to arrange an agreeable date for all parties.

<b>U. S. Department of Agriculture Agricultural Marketing Service Dairy Programs Equipment Review Request</b>										
Applicant (Name and Address)	Party Responsible for Payment if other than Applicant (Name and Address) Confirmation Required (Letter or Fax) Received	Equipment Located at (Name and Address)								
Website										
Tax Identification No. (TIN)	Tax Identification No. (TIN)	Inspection Date(s) Requested:								
Contact	Contact	Contact								
Telephone	Telephone	Telephone								
Fax	Fax	Fax								
Type of Equipment: Dairy <input type="checkbox"/> Livestock and Poultry <input type="checkbox"/> 3-A Third Party Verification <input type="checkbox"/>										
Signature of Applicant	Date	Email								
<input type="checkbox"/> <b>Domestic Inspection:</b> A minimum of fourteen (14) working days notification is required to insure specialists have ample time to make arrangements for the trip. If specialists are unavailable, the next available date acceptable to all parties will be assigned.										
<input type="checkbox"/> <b>Foreign Inspection:</b> A minimum of forty (40) working days advance notice is required for any foreign travel. The forty-nine days will start from the date this request form is received by the Dairy Grading Branch. If specialists are unavailable, the next available date acceptable to all parties will be assigned. Hotel accommodations (USDA Dairy must pay): Best mode of transportation from airport (train, taxi, company pickup...): Does the Hotel accept Visa credit cards: <input type="checkbox"/> Yes <input type="checkbox"/> No										
If submitting electronically, please sign and mail or fax a copy of this form to the address below: <b>Dairy Equipment Review , and Livestock and Poultry Equipment Review Address: USDA/AMS/DAIRY PROGRAMS, Dairy Grading Branch Design Review Section Room 2746 – South Building, 1400 Independence Ave. SW STOP 0230, Washington, DC 20250-0230; Tel: 202 720-3171 Fax: 202 720-2643</b>										
According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0126. The time required to complete this collection of information is estimated to average 3 minutes per person including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA’s TARGET Center at 202-720-2600 (voice and TDD). To file a complaint of discrimination, write USDA, Director, Office of Civil Rights, Room 326-W, Whitten Building, 1400 Independence Avenue, SW, Washington, DC 20250-9410 or call 202-720-5964 (voice and TDD). USDA is an equal opportunity provider and employer.										
<b>FOR OFFICIAL USE ONLY</b>										
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## 7. Equipment Review Introduction

- A. The equipment review will encompass three aspects; design, construction materials and fabrication as they relate to the equipment's cleanability.

### 7.1. Design

- A. Design review will include both product contact and nonproduct contact surfaces in accordance with the criteria outlined in the Foreword section of this publication.

### 7.2. Construction Materials and Fabrication

- A. Fabrication will be evaluated by the physical inspection of completed units, usually at the fabricator's facilities or at the dairy plant. The equipment will be checked for workmanship, metal finish, and adherence to the accepted drawings.

### 7.3. Cleanability

- A. Cleanability will be evaluated on a completed unit after a period of actual use. The cleanability inspection may require extensive disassembly of component parts to fully evaluate design characteristics as they relate to cleanability. Equipment cleanability is directly related to the basic design. In general, equipment for manual cleaning must be designed so that access to product contact surfaces can be easily achieved with the use of simple tools generally available to a dairy plant production employee. Equipment intended for CIP (clean-in-place) cleaning must be designed so that all product contact surfaces will be subjected to sufficient cleaning solution to completely remove all product residue during the cleaning cycle. While bacterial swab tests of cleaned surfaces and bacterial tests of finished products are important indicators of cleanliness, they will not constitute the sole criteria of design suitability. Physical inspection of surfaces will be the primary method for the evaluation of cleanability.

## 8. Equipment Review Procedure

- A. Equipment offered for review should be designated by a specific model number or descriptive name for clear identification. Equipment which may be manufactured in both sanitary and non-sanitary configurations may bear the same basic model number provided that a prefix or suffix is added to clearly differentiate the styles.
- B. Equipment submitted for design review during the blueprint stage will be granted a preliminary acceptance pending satisfactory demonstration of fabrication workmanship and cleanability. Full, unrestricted acceptance will be granted upon successful completion of all three aspects of the review process.
- C. Acceptance will be further identified according to the mode of cleaning for which the unit is designed. The acceptance will be designated as follows:
  - a. **Manual Cleaning-** Acceptance when cleaning is accomplished by complete disassembly and manual cleaning.

- b. **Partial CIP**- Acceptance with CIP cleaning of major portions of the unit and with the disassembly and manual cleaning of some component parts.
- c. **Full CIP**- Acceptance with complete CIP cleaning of entire unit.

D. Upon acceptance of a particular unit, the manufacturer accepts the responsibility of informing the USDA, DGB, about subsequent design changes and to submit such design modifications or improvements for review and acceptance.

## 8.1. Certificate of Acceptance

A. Upon acceptance of a piece of equipment, the applicant has the option of requesting a Certificate of Acceptance (see below). The certificate may be used in sales brochures, displays, etc., to show that the piece of equipment has been reviewed and accepted by the USDA- DGB. The certificate expires 5 years from the date of issue. If during the 5-year period, any changes are made to the design, materials of construction, or fabrication of the equipment, all changes shall be submitted to the USDA-DGB for review and comment. If the design changes do not affect the status of the accepted equipment, the acceptance will continue without interruption. It is the applicant's responsibility to notify the USDA-DGB if they wish to renew their certificates after the 5-year period has expired.

**UNITED STATES DEPARTMENT OF AGRICULTURE  
MARKETING AND REGULATORY PROGRAMS  
AGRICULTURAL MARKETING SERVICE**

**EQUIPMENT ACCEPTANCE CERTIFICATE**

Firm:

Model Designation:

\_\_\_\_\_  
Date of Issuance

\_\_\_\_\_  
U.S. Department of Agriculture  
Marketing and Regulatory Programs  
Agricultural Marketing Services  
Dairy Grading Branch  
1400 Independence Ave., SW  
Washington, DC 20250-0230

\_\_\_\_\_  
Date of Expiration

The issuance of this form is based on U.S. Department of Agriculture, Dairy Grading Branch, Equipment Design Review Section, evaluation of the equipment listed above for compliance with:

This form does not limit USDA's responsibility to take appropriate action in cases in which evidence of non-compliance, improper maintenance, or non-sanitary conditions have been observed.



United States Department of Agriculture



DA-161 (09-04) Destroy previous editions.



## 9. Materials

### 9.1. Product Contact Surfaces

- A. All materials having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use including cleaning and sanitization treatment or sterilization. <sup>1</sup>
- B. **Stainless Steel:** Shall be of the Association for Iron and Steel Technology (AIST) 300 series or corresponding Alloy Cast Institute (ACI) types or stainless steel that is non-toxic and non-absorbent and which under conditions of intended use is equal in corrosion resistance to stainless steel of the AIST 300 series (excluding types 301 and 302) or corresponding ACI types, except that:
- a. AIST 302, 303 and 400 series may be used for springs, cutting blades, and when heat treating is required. These grades of stainless steel shall have adequate corrosion resistant properties for the conditions of use.
  - b. *The data for AIST 300 series are contained in the AISI Steel Products Manual, Stainless & Heat Resisting Steels, Table 2-1. American Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086, Phone: (412) 776-1535.*
  - c. *The data for ACI types are contained in the Steel Casting Handbook, Supplement 2, Steel Founders Society of America, 780 Mc Ardle Dr., Unit G, Crystal Lake, IL 60014, Phone: (815) 455-8240, Fax: (815) 455-8241, Internet: [www.sfsa.org](http://www.sfsa.org)*
- C. **Solder:** Shall be gold, nickel/chrome or silver-containing metals (sometimes referred to as silver solder); shall be corrosion-resistant, free of cadmium, lead and antimony, and shall not impart any toxic substance to the product under normal use and when exposed to the conditions encountered in the environment of its intended use. This includes cleaning, sanitizing treatment, and/or sterilization.
- D. **Metal Alloys:** Are metals other than noted in “Stainless Steel” (*see above*) shall be as corrosion resistant as 300 Series Stainless Steel. This may be shown when metal alloys or metals are tested in accordance with ASTM G31 *Laboratory Immersion Corrosion Testing of Metals* and have a corrosion rate of less than 10.0 mil per year. The test parameters, including the type of chemical(s), their concentration(s), and temperature(s), should be representative of cleaning and sanitizing conditions used in the equipment. Alloys containing lead, leachable copper or other toxic metals are not to be used. (*See Appendix*)
- E. **Plastic Materials:** Shall comply with one of the following: <sup>1</sup>
- a. A regulation listed in Title 21 Code of Federal Regulations, Parts 170-199.
  - b. A prior sanction letter, unless previously rescinded.
  - c. Meets the criteria for Generally Recognized As Safe (GRAS) status (including but not limited to a GRAS regulation or GRAS notice).

- d. A valid Threshold of Regulation (TOR) exemption request.
- e. Is the subject of an effective Food Contact Surface (FCS) [Food Contact Notification \(FCN\)](#)? Section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) states that an FCN is effective for the manufacturer, the Food Contact Substance (FCS), and the conditions of use identified in the notification only.
- f. Determination that migration has not been made and is supported by a current Letter of No Objection (or Opinion Letter), issued by the United States Food and Drug Administration (USFDA).

**F. Rubber and Rubber Like Materials (Flexible, soft-type):** Shall comply with one of the following: <sup>1</sup>

- a. A regulation listed in Title 21 Code of Federal Regulations, Parts 170-199.
- b. A prior sanction letter, unless previously rescinded.
- c. Meets the criteria for Generally Recognized as Safe (GRAS) status (including but not limited to a GRAS regulation or GRAS notice).
- d. A valid Threshold of Regulation (TOR) exemption request.
- e. Is the subject of an effective Food Contact Surface (FCS) Food Contact Notification (FCN)? Section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) states that an FCN is effective for the manufacturer, the Food Contact Substance (FCS), and the conditions of use identified in the notification only.
- f. Determination that migration has not been made and is supported by a current Letter of No Objection (or Opinion Letter), issued by the USFDA.
- g. except that:
- h. RTV (*Room Temperature Vulcanization*) silicone material shall not be used in lieu of a gasket in a product contact area

**Note:**

*When plastic, rubber or rubber like materials are used as product contact surfaces, certification that the materials comply with the requirements of materials items 9.1.E and 9.1.F shall be provided to USDA. All certifications shall include the following information:*

- *Documentation shall be on company letterhead.*
- *Material trade name or type shall be noted.*
- *Declaration of compliance with the appropriate Food and Drug Administration The corresponding CFR shall be cited: (i.e. 21 CFR 177.2600 or 21 CFR 177.1580)*
- *Signature of a responsible certifying official.*

**G. Adhesives:** Shall be non-toxic and comply with the applicable Food and Drug Administration regulations (21 CFR Part 175).

**H. Carbon, Ceramics, Silicon Carbide, or Tungsten Carbide:** Shall be inert, non-porous, non-toxic, non-absorbent, insoluble, and resistant to scratching, scoring, and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment.

- I. **Silver Bearing Solder or Brazing Material:** Shall be corrosion-resistant; free of cadmium, lead and antimony; non-absorbent; and shall not impart any toxic substance to the product when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment or sterilization.
- J. **Materials Used for Surface Treatments and Coatings:** All materials and components used for surface treatments and coatings and residues remaining on product contact surfaces shall be documented to show they comply with the appropriate provisions of the following:
- a. FDA regulations 21 CFR 175, Subpart C - Substances for Use as Components of Coatings, or
  - b. FDA regulations 21 CFR 177, Subpart B - Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces, or
  - c. FDA regulations 21 CFR 177, Subpart C - Substances for Use Only as Components of Articles Intended for Repeated Use, or
  - d. Nickel:
    - 1. QQ-N-290a- Federal Specification for Nickel Plating Electrodeposited) November 12, 1971. Both documents available from the General Services Administration, 18th & F Sts., NW, WFCIA, Washington, DC 20405 (202-472-2205), or
    - 2. MIL-C-26074E Military Specification: Coatings, Electroless Nickel Requirements For. Standardization, Document Automation & Production Service (Department of Navy), 700 Robbins Avenue, Building 4, Section D, Philadelphia, PA 19111-5094, Phone: (215) 697-2179, Fax: (215) 697-1462.
    - 3. (See Appendix 2.)
  - e. Rubber and Rubber-Like materials:
    - 1. Shall comply with the provisions of Section 9.1.E of these guidelines.
  - f. Plastic materials:
    - 1. Shall comply with the provisions of Section 9.1.F of these guidelines.
- K. **Glass:** Shall be restricted to specific uses and shall be of a clear, heat resistant, shatter-resistant type.
- L. **Woven Cotton, Linen, Silk, or Man-made Fibers:** Shall be used only for dry products flexible connectors and for certain sifting, filtering and screening applications.
- M. **Caulking Materials, including silicone, silastic, or stainless-steel epoxy types:** May be used to seal pockets or crevices on exterior, non-product contact surfaces.
- a. *These materials are not acceptable for use on product contact surfaces, except as permitted by the 3-A 26- Sanitary Standard for Sifters for Dry Milk and Dry Milk Products and as an adhesive for bonded gaskets.*

- N. **Paint:** Shall be limited to the coating of non-product contact surfaces. Parts removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted.
- O. **Lubricants:** As provided by FDA regulations, lubricants which have incidental food contact shall be limited to those specified in 21 CFR Part 178.3570. The amount used shall be the minimum required for the desired technical effect on the equipment and shall not exceed any prescribed limitations. *Example: Light coating of mineral oil on chill rolls to prevent sticking of process cheese.*
- P. **Other Materials:** Other materials having certain inherent functional properties which are required for specific applications shall be submitted for review and evaluation for each application.

## 9.2. Non-Product Contact Surfaces

- A. All nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If the surfaces are coated, including painted surfaces, the coating shall adhere. All nonproduct contact surfaces shall be relatively nonabsorbent, durable, and cleanable. Parts that are removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted. <sup>1</sup>

## 10. Fabrication

### 10.1. Product Contact Surfaces

- A. Surfaces, including fabricated, welded, soldered and brazed joints, shall be at least as smooth as a 32  $\mu\text{in.}$  (0.8  $\mu\text{m}$ )  $R_a$  finish and shall be free of pits, folds, crevices, and cracks in the final fabricated form, except that;
- a. The 2B mill finish on stainless steel sheets is also considered as smooth as or smoother than a polished number 4 finish. No further finishing is required if the 2B finish is free of defects, such as pits, scratches, chips, or flakes, in the final fabricated form. *(Use of adhesive protective paper is recommended during equipment fabrication to prevent or minimize damage to stainless steel finishes.)*

<b>Note:</b>
The 2B finish on stainless steel plate ( $>3\text{mm}$ ) and bars are usually not as smooth as the 32 $\mu\text{in.}$ (0.8 $\mu\text{m}$ ) $R_a$ finish on sheets due to less cold rolling and therefore unacceptable for product contact surfaces without additional surface preparation.

- B. Electropolishing is an acceptable surface treatment provided the surface has been properly prepared to a surface finish that is at least a 32  $\mu\text{in.}$  (0.8  $\mu\text{m}$ )  $R_a$  before the process is applied. Electropolishing will not remove surface irregularities such as pits, folds, or crevices.

- C. The minimum thickness of electrodeposited coatings on product contact surfaces shall be not less than 0.0002 inches (0.005mm).
- D. Ceramic materials used as coatings for product contact surfaces shall be at least 0.003 inch (0.08mm) thick and shall not crack, craze, chip, or spall.
- E. Mechanical surface treatment by shot peening or glass beading of product contact surfaces is acceptable provided the treatment serves a specific functional purpose, i.e., in order to provide product release on butter and cheese equipment to a maximum 125  $\mu\text{in Ra}$  (3.18  $\mu\text{m}$ ) The use of this surface treatment will be evaluated on a case by case basis. The surfaces shall be prepared to a surface finish that is at least a 32  $\mu\text{in Ra}$  (0.8  $\mu\text{m}$ ) before the process is applied.
- F. Cast metal coatings used as product contact surfaces shall be at least 0.040 inch (1.0mm) thick.
- G. Carbon, ceramic, and plastic materials shall be as at least as smooth as a 63  $\mu\text{in Ra}$  (1.6  $\mu\text{m Ra}$ ) finish and shall be free of chips, pits, cracks, feathering, gouges and tooling marks in the final fabricated form. Except that:
  - a. Machined plastic materials may have a surface finish that is at least as smooth as a 125  $\mu\text{in Ra}$ . (3.18  $\mu\text{m Ra}$ )
- H. Surfaces in contact with gaskets, seals, or O-rings in product contact shall be at least as smooth as a 32  $\mu\text{in Ra}$  (0.8  $\mu\text{m Ra}$ ) finish.

## 10.2. Permanent Joints

- A. Permanent joints shall be continuously welded, ground, and polished to a 32  $\mu\text{in}$ . (0.8  $\mu\text{m}$ )  $R_a$  finish which is free of pits, folds, crevices or projections except that:
  - a. Welds in aluminum product contact surfaces shall be free of pits, folds and crevices using the Gas Metal-Arc Welding process with backing bar, and the combination of Gas Metal Arc Welding (GMAW) and Gas Tungsten Arc Welding (GTAW), or equivalent.
  - b. The surfaces shall be slightly finished with a stainless-steel wire brush, resulting in maximum weld surface irregularity of twelve thousandth of an inch (0.03mm) differential within 1/8 in. (3mm) increments. The maximum weld height shall be 1/8 in. (3mm).
- B. Properly constructed gasketed junctures. Flanged junctures shall be mated accurately and be constructed so the internal sealing edges of the flanges form a sharp 270-degree angle to create a tight pinch seal with the gasket. Interior surfaces shall be substantially flush, with no recessed or protruding unsupported gasket material.

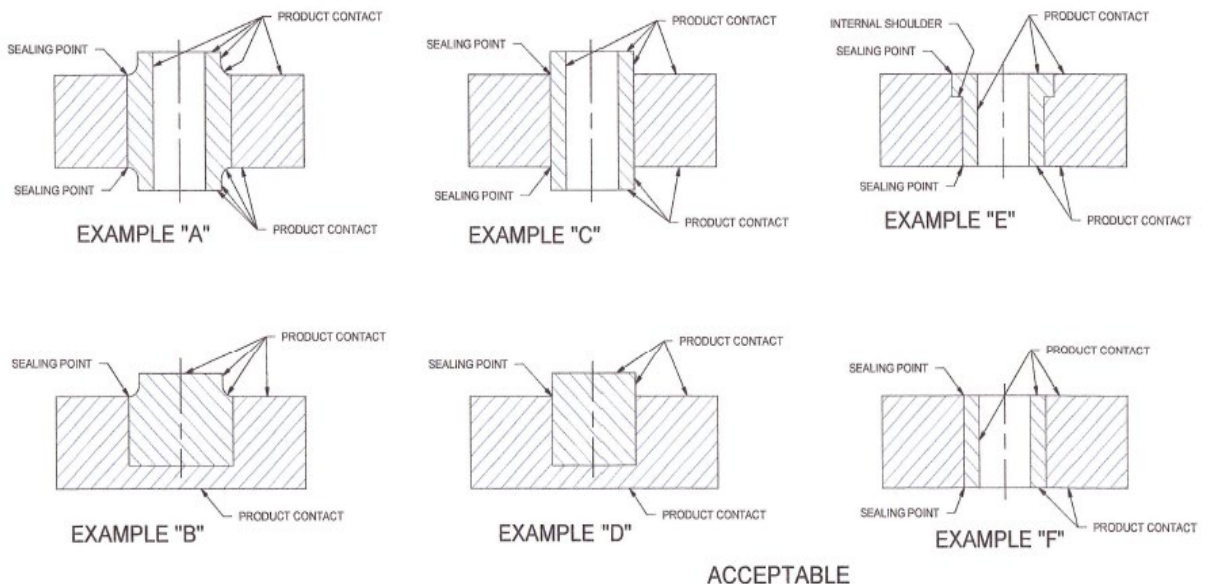
## 10.3. Soldering and Brazing

- A. Solder and Brazing with accepted materials may be used provide crevice free joints.

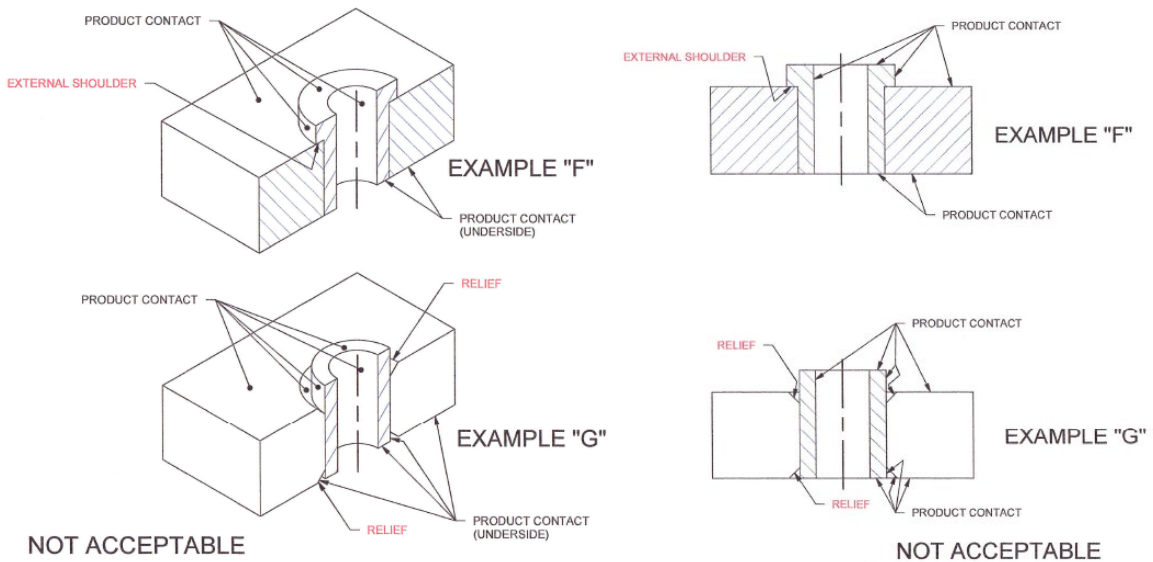
## 10.4. Fittings

- A. CIP Fittings are designed to be cleaned while fully assembled. If the fitting has a removable joint, the joint shall be self-centering, employ a gasket, and the resulting gasketed joint forms a substantially flush interior surface. Manually Cleaned Fittings are removable joints at are designed to be disassembled for manual cleaning. Manually cleaned fittings may or may not have a gasket.
- B. Interference Fits or Expansion Fits:
- Interference fits or expansion fits may be used to produce crevice free permanent joints in metallic product contact surfaces when neither welding nor soldering is practical. Joints of these types may only be used to assemble parts having circular cross sections free of shoulders or relieved areas. For example: They may be used to assemble round pins or round bushings into round holes. In both types of fit, the outside diameter of the part being inserted is greater than the inside diameter of the hole.
  - In the case of the interference fit, the parts are forced together by applying pressure. The pressure required is dependent upon the diameter of the parts, the amount of interference and the distance the inner part is forced into the outer part.
  - In the case of an expansion fit, the diameter of the inner part is reduced by chilling to a low temperature. Dry ice is commonly used to shrink the inner part. Alternatively, shrink fits are made by heating the outer part. Less assembly force is required for this type of fit. (See the following illustrations of acceptable force fits and expansion fits.)

### Examples: 1





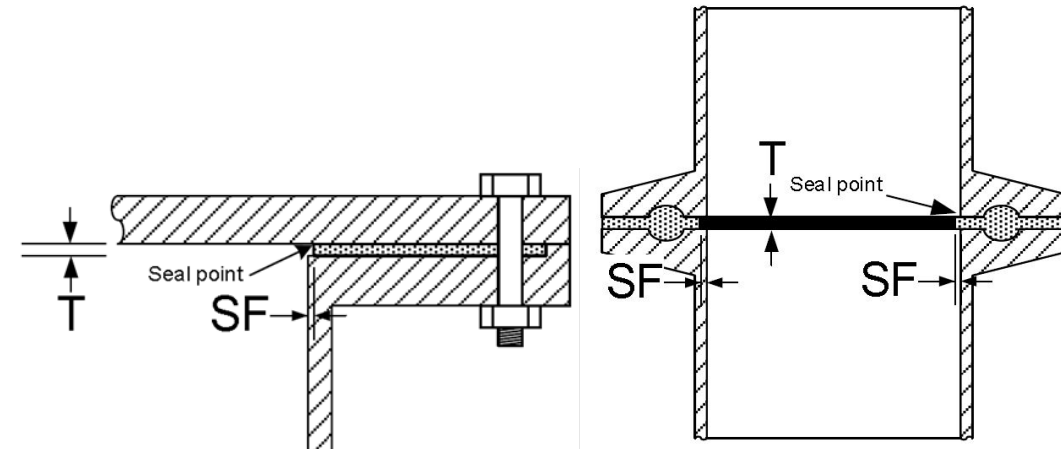


- d. The design of interference or expansion fit depends on a variety of factors. The designer should follow recommended practices to assure that a crevice free joint is produced. A recognized authoritative reference is "Machinery's Handbook" published by Industrial Press, Inc., 200 Madison Ave., New York, NY 10157.
- e. If interference fit or expansion fit procedures are to be used for metal to plastic or plastic to plastic joints, supporting documentation shall be available to demonstrate the joints suitability. The tightness of the interference fit or shrink-fit seal shall be validated to demonstrate that there is no migration past the seal under the intended conditions of use.
- f. Rubber and rubber-like materials, plastic materials, and carbon or ceramic seal may be bonded. The bond shall be continuous and mechanically sound. The materials shall not separate from the base materials to which it is bonded when exposed to the conditions encountered in the environment of their intended used, including cleaning and sanitizing treatment, and/or sterilization. 1

## 10.5. Non-Permanent Joints

- A. Nonpermanent junctures which are intended for disassembly and manual cleaning shall be appropriately gasketed, when necessary. Non-gasketed junctures are acceptable in certain applications which will be evaluated on a case by case basis. The junctures shall be constructed so they are easily removable with or without the use of simple hand tools. Wing, "T", or palm nut style fasteners are preferred over hex or dome nuts for non-product fastening applications in order to facilitate dismantling for cleaning or inspection.
  - a. Exceptions may be made, on a case by case basis, for instances when conventional bolting may be required for safety, pressure or vacuum conditions
- B. Gasketed joints may be used for sanitary fittings and equipment components. The interior of the gasket groove shall be designed so the groove is inspectable and cleanable when the gasket is removed. 1

- C. Flat gasketed joints that are intended for CIP shall form a substantially flush interior surface. Gasketed joints shall be no deeper than their thickness with "T" no less than 1/32 in. (0.794 mm). 1



*Substantially Flush (SF) = 1/32" (0.794 mm) maximum. 1*

## 10.6. Sanitary Tubing

- A. Sanitary tubing used to convey product shall be made of stainless steel and where welded, may have an “as-welded” interior surface finish that shall be free of pits, folds, crevices, cracks, and misalignments as per AWS/ANSI D18.1. (Refer to B1, Reference 5.) The weld discoloration in the as-welded condition shall be either weld 1, 2, or 3. Product piping and other tubular components shall be installed with good workmanship and supported in such a manner that will prevent sagging. Product piping shall be installed with sufficient slope for drainage.

## 10.7. Flexible Tubing

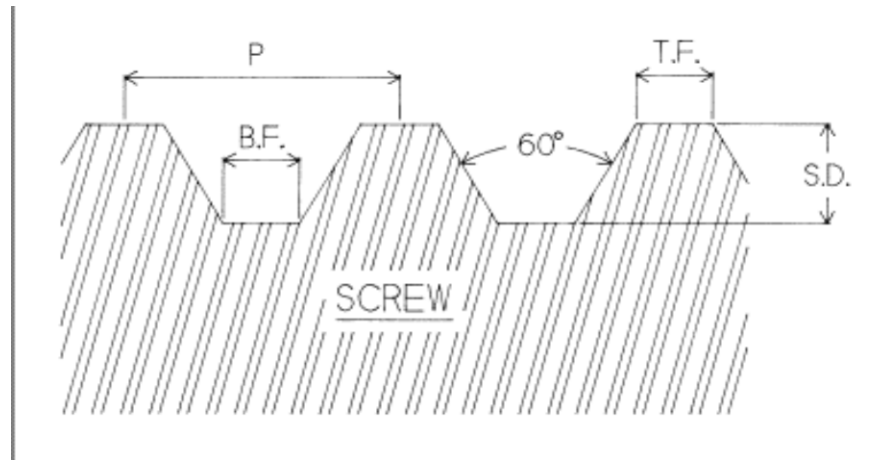
- A. Sanitary tubing made of flexible rubber or plastic may be used for the following applications:
- a. Loading or unloading of movable tanks, vessels, or trucks.
  - b. Temporary hookups while equipment or permanent piping is being installed.
  - c. The prevention of vibration transmission.
  - d. Applications where it is important to see the product flow.
  - e. Short jumpers for connecting equipment to CIP circuits.
  - f. Permeate handling on some membrane systems.
  - g. Short jumpers required in conveying product for mechanically moving parts.
- B. When flexible tubing is slipped over a pipe stub and fastened with a clamp, the clamp shall be easily removable, and the hoses stubs shall be removed for daily manual cleaning. Screwdriver applied worm screw type clamps (radiator hose clamps) are unacceptable. An alternative is to have a flexible hose assembly that complies with the applicable 3-A Sanitary Standard 62-, 3-A<sup>®</sup> Sanitary Standards for Hose Assemblies.



## 10.8. Exposed Threads

- A. Use of threads is not recommended. Threads should not be used when other means of attachment is available. When no acceptable alternative is available, and/or threads are required for essential functional reasons, the following criteria shall apply:
- a. The threads shall conform to the dimensions of the coarse "Acme" thread, the "Brass Valve Stem Thread", or other similar coarse thread design accepted by the DGB.
  - b. Where exposed threads are necessary for attaching components, the threads shall be of sanitary design conforming to one of the following illustrations:

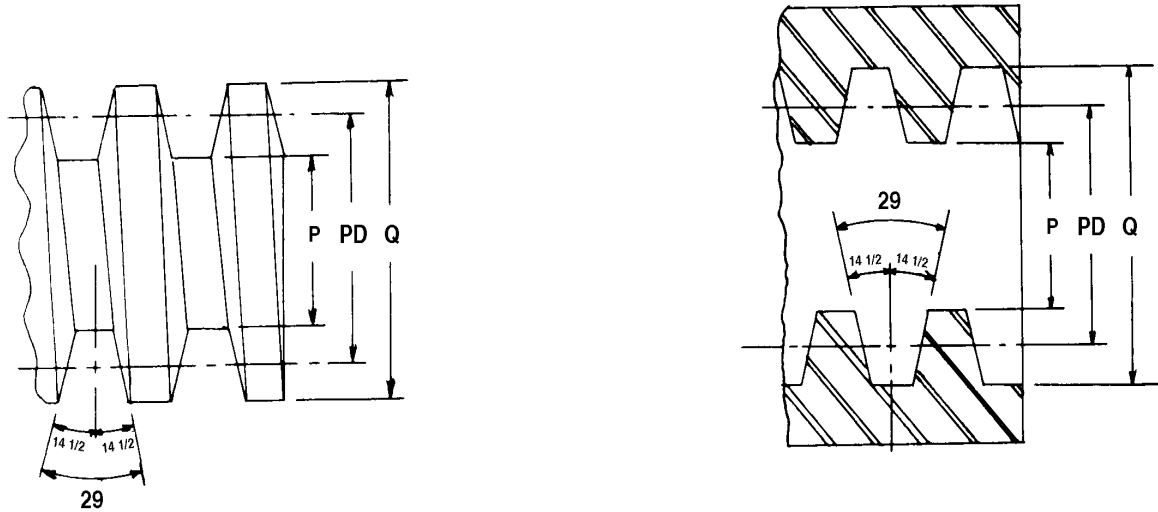
***The American Standard Stub Acme Conforming to the Drawing:***



P = PITCH	P = 1/T.P.I.
S.D. = SINGLE DEPTH	S.D = 0.433 x P
T.F. = TOP FLAT	T.F. = 0.250 x P
B.F. = BOTTOM FLAT	B.F. = 0.227 x P
T.P.I. = THREADS PER INCH	

*(The thread angles shall be not less than 60 degrees and with not more than 8 threads to the inch (25.4mm), and not less than 5/8 in. (15.9 mm) major basic diameter.)*

**ACME Thread conforming to the following drawing:**



**Trapezoid Thread**

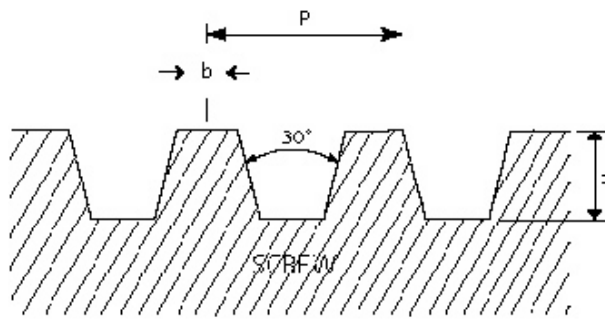
**EXTERNAL THREAD DIMENSIONS**

Size	Acme Threads per in.	P	Q	Pitch Dia.	Tolerance P,Q & P.D.
1	8	1.317	1.462	1.3995	+0.000 / -0.018
1 1/2	8	1.849	1.994	1.9315	+0.000 / -0.019
2	8	2.381	2.526	2.4635	+0.000 / -0.020
2 1/2	8	2.913	3.058	2.9955	+0.000 / -0.021
3	8	3.445	3.590	3.5275	+0.000 / -0.022
4	6	4.509	4.695	4.6120	+0.000 / -0.025

**INTERNAL THREAD DIMENSIONS**

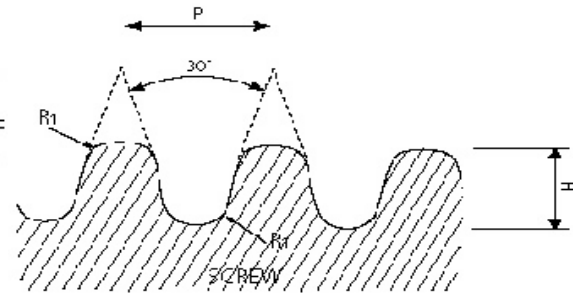
Size	Acme Threads per in.	P	Q	Pitch Dia.	Tolerance P,Q & P.D.
1	8	1.352	1.497	1.4145	+0.018 / -0.000
1 1/2	8	1.884	2.029	1.9465	+0.019 / -0.000
2	8	2.416	2.561	2.4785	+0.020 / -0.000
2 1/2	8	2.948	3.093	3.0105	+0.021 / -0.000
3	8	3.480	3.625	3.5425	+0.022 / -0.000
4	6	4.544	4.730	4.6270	+0.025 / -0.000

### Trapezoid Thread DIN103



$P = P_{tch}$	
$H = \text{Depth of thread}$	$H = 0.5 \times P$
$b = \text{Top / Bottom flat}$	$b = 0.37 \times P$

### Knuckle Thread DIN405



$P = \text{Pitch}$	
$H = \text{Depth of thread}$	$H = 0.5 \times P$
$R_1 = \text{Radius}$	$R_1 = 0.24 \times P$

#### 10.9. Knuckle Thread

- A. The length of a nut, if used on any of threads described in the examples 1, 2, 3, and 4, shall not exceed 3/4 of the basic thread diameter. The nut shall be of the open type. Equipment components with exposed threads as described previously shall be designed for disassembly and manual or COP cleaning.

#### 10.10. Enclosed Threads

- A. Where enclosed threads are necessary, the enclosed threads shall conform to all of the following:
- a) *The enclosed threads shall be sealed from the product contact surfaces by means of an O-ring, gasket or similar type seal.*
  - b) *The assembly using enclosed threads shall be designed for CIP cleaning.*
  - c) *The seal shall have a controlled compression by means of a positive stop to prevent overtightening and/or extrusion of the seal.*
  - d) *The tightness of the seal shall be validated to demonstrate that there is no migration past the seal under the intended conditions of use.*
  - e) *Enclosed threads shall be cleanable and drainable.*
- B. Allen-head and slot-head style bolts or screws are not acceptable on product contact surfaces. If a bolted construction is necessary in a product contact area, the bolt shall be of hex-head design and properly sealed as noted in 10.10.A. *Use of bolted construction should be avoided if possible.*
- C. Welded or sealed threaded studs are preferred fabrication over threaded blind holes.

## 10.11. Coil Springs

- A. Coil springs having product contact surfaces shall have openings between the coils of at least 3/32 inch (2mm) including the ends, when the spring is in a relaxed condition.
- B. Coil springs shall not have the end coils ground flat if they are to clean by CIP. Coil springs with the end coils ground flat shall be disassembled for manual cleaning.
- C. Coil springs shall be made of round cross-section stock.
- D. When used, modified coil ends terminating with ears or tabs, shall not be modified to produce square or rectangular shaped ears or tabs.
- E. Coil springs under compression conditions of intended use shall not eliminate all spacing between the coils. There shall be a minimum of 1/32 in (0.794 mm). Space between each coil when under compression or the spring shall be designed for COP or manual cleaning.
- F. A spring may have point contact at the end coils and at intermediate coils with retainer rings, and axial contact with rotating shafts, as required for torque transmission and maintaining spring alignment. <sup>1</sup>
- G. All applications and assemblies using coil springs shall be designed, fabricated, and installed to make product contact surfaces available for close visual observation when either in an installed position or when removed.
- H. Springs less than 1 in. (25.4 mm) outside diameter may have spacing between coils of less than 3/32 in. (2.38 mm) When the spring is in the relaxed condition and, when under compression, some spacing shall remain between the coils. Such springs shall be intended for COP or manual cleaning. <sup>1</sup>

## 10.12. Radii

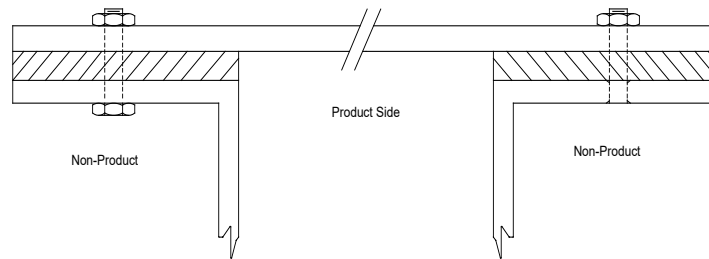
- A. The radii where the head(s) and the side wall(s) of a tank or vessel join shall be a minimum of 3/4 in. (19.0 mm).
- B. All internal angles of less than 135 degrees on product contact surfaces shall have at least a 1/4-inch (6.35 mm) radius. Except that:
  - a. Fillets of welds where one or both of the pieces being joined are 3/16 of an inch (5mm) thick or less, or in the case of round bar stock, the diameter of one or both parts joined is 3/8 in. (9.52 mm) or less, the minimum radii of the welds shall be at least 1/8 in. (3.18 mm).
  - b. Smaller radii may be used for functional reasons. In this case, the radius shall not be less than 1/32 inch (0.794 mm). When radii less than 1/32 inch (0.794 mm) are needed, they shall be approved on a case-by-case basis provided the product contact surfaces are readily accessible and inspectable.

- c. Smaller radii may be used when larger radii will have an adverse effect on the dairy product. For example, curd cutting knives or cheese hoops. When radii less than 1/32 inch (0.794 mm) are needed, they shall be approved on a case-by-case basis and the product contact surfaces shall be readily accessible and inspectable.
- d. Internal angles of grooves in gaskets, gasket grooves, or gasket retaining grooves shall be not less than 1/32 inch (0.794 mm) except for standard 1/4 inch (6.35 mm) cross section and smaller O-ring grooves. See item e below.
- e. The internal angles of retaining grooves for standard O-rings shall have minimum radii per the following table:

O-Ring Cross Section, Nominal	O-Ring Cross Section, Actual (AS 568)	O-Ring Cross Section, Actual (ISO 3601-1)	Minimum Groove Radius
1/16 in.	0.070 in.	1.80 mm	0.016 in. (0.406.35)
3/32 in.	0.103 in.	2.65 mm	0.031 in. (0.787 mm)
1/8 in.	0.139 in.	5.55 mm	0.031 in. (0.787 mm)
3/16 in.	0.210 in.	5.30 mm	0.062 in. (1.575 mm)
1/4 in.	0.275 in.	7.00 mm	0.094 in. (2.39 mm)

- C. Radii in gasket retaining grooves and seats for seals with a nonstandard circular, square, rectangular, or other shaped cross section O-ring with the shorter dimension 1/4 in. (6.35 mm) and smaller shall be those radii closest to the standard circular cross section O-ring as specified in the table above. To determine minimum radius in the retaining groove for a nonstandard O-ring, compare its cross-section dimension with those shown in column 2 of the Table above, determine which is closest, and use the applicable minimum groove radius. For a square O-ring, use the flat-to-flat side dimension for comparison. For a rectangular or other shaped O-ring, use the dimension that will fit into the retaining groove.
- D. There are no minimum radii requirements for:
  - a. Soldered and brazed joints or for the product contact junctures of press or shrink fits.
  - b. The product contact junctures of flat sealing surfaces. (See illustration)

## Flat Sealing Surfaces 1



- c. Exposed sanitary threads except for the knuckle thread, DIN 405, provided for by Section 10.9.A.
  - d. Gasket retaining grooves for bonded gaskets. Width, depth, and radii are at the discretion of the fabricator.
  - e. For retaining grooves for mechanical force seals or for the juncture between product contact surfaces and the exposed part of an O-ring.
- E. In the case of a machined component when a radius in a 90° corner is replaced with a pair of 135° angles, the distance between the corners (the hypotenuse of the resulting isosceles right triangle) shall be no less than 1/32 in. (0.794 mm) inch for the dimension “H” in the illustration E43.

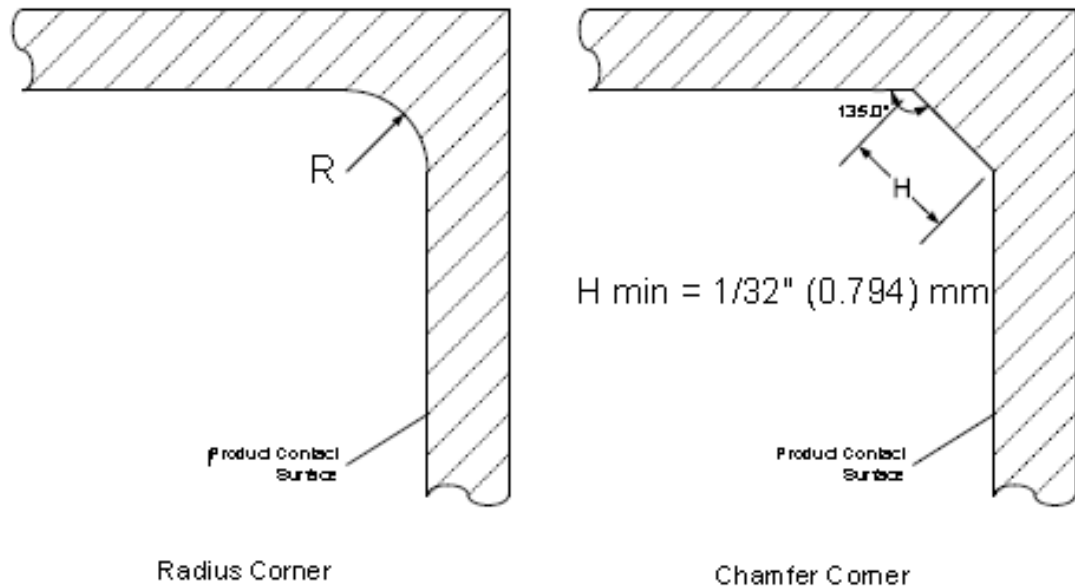


Illustration E43 1

- F. Internal angles less than 135 degrees created by machining or forming of the material shall have at least a 1/4-inch (6.35 mm) radius unless required for essential functional reasons. In no case shall such radius be less than 1/32 inch (0.794 mm).

- G. There is no sanitary reason for a minimum radius on external angles which are in product contact. Nevertheless, it is customary to relieve sharp edges slightly for safety reasons. Care must be taken so that any such relieved edges do not create cracks or crevices upon assembly of component parts such as flanged joints.

### 10.13. Draining

- A. All product contact surfaces shall be self-draining except for normal adherence. When for essential functional or safety reasons self-draining is not possible, the equipment shall be drainable.
- B. Equipment bottoms shall be constructed so they will not sag, buckle, or prevent complete drainage. The bottom slope of equipment which is 6 feet (1829mm) in diameter or lineal distance from a drainage outlet or less shall be at least 1/4 inch (6.35 mm) per foot (305mm). The bottom slope of equipment which is greater than 6 feet (1829mm) in diameter or lineal distance from a drainage outlet shall be at least 1/2 inch (13mm) per foot (305mm).

### 10.14. Cleaning

- A. When mechanical cleaning is intended as the only means for cleaning, the equipment design shall assure that all product contact surfaces will be free of cracks, crevices and dead-end areas that would impede cleaning. Also, the prescribed mechanical cleaning procedure shall be proven to effectively clean the equipment.
- B. If mechanical cleaning is intended to clean only portions of the equipment, the operator's manual shall clearly identify those components which require disassembly and manual cleaning.
- C. All product and cleaning solution pipelines, sanitary pipe fittings, valves, instrument fittings, appurtenances, and components which are part of the equipment shall comply with applicable 3-A Sanitary Standards or 3-A Accepted Practices as appropriate.
- D. Equipment intended for COP or manual cleaning shall be designed and fabricated so all product contact surfaces are readily accessible and inspectable either when in an installed position or when removed. Junctures between components may or may not be gasketed or sealed. All demountable appurtenances shall be readily removable. 1
- E. Equipment intended for CIP cleaning shall be designed and fabricated so all product contact surfaces including all non-removed appurtenances can be CIP cleaned. Junctures between components shall be sealed or designed to be readily removable for manual or COP cleaning. 1

### 10.15. Inspectability

- A. When parts having product contact surfaces are too large or heavy for manual handling, appropriate mechanical means for handling shall be provided by the fabricator or user. 1

- B. All surfaces to be CIP cleaned including all non-removed appurtenances, shall be readily accessible and inspectable. All demountable components shall be readily removable. 1
- C. When cleanability by CIP has been documented and accepted, the design shall provide representative surfaces that are readily accessible, and inspectable. 1

#### 10.16. Mixers and Agitators

- A. Refer to the 3-A Sanitary Standard 73- (3-A<sup>®</sup> Sanitary Standards for Shear Mixers, Mixers, and Agitators) Except that:
  - a) When the agitator shaft has an internal bearing cavity, the diameter of the cavity (Dimension A) shall be greater than its depth (Dimension B) See the cross-section illustration E59

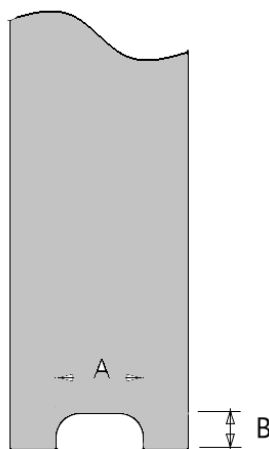


Illustration E59

#### 10.17. Seals and Sealing Materials

- A. Rotating shafts shall not have lubricated bearings, including factory sealed bearings, in the product contact areas. Such lubricated bearings shall be mounted to provide a minimum of 1 inch (25mm) exterior open space on the shaft between the mechanical seal for the bearing and the nearest part of the sanitary seal or the opening to the product contact area. The 1 inch (25mm) minimum space shall be open to the atmosphere and be easily accessible for inspection and cleaning.
- B. Where for specialized functional or safety reasons, bearing assemblies must be positioned within or in close proximity to the product contact areas, the bearings shall be the permanent factory sealed, non-greaseable type. Alternative designs will be considered. The alternative design shall provide for;
  - a. Means to completely isolate the bearing assemblies and provide for the collection of all lubricants in the event of a catastrophic bearing or seal failure, or



- b. Lubricant impregnated (*plastic bushing*) bearing materials which have been reviewed and accepted by the DGB.
- C. Alternative designs shall be considered on a case-by-case basis. The use of food grade lubricant is not considered as an alternative to the above criteria for lubricated bearings.
- D. Seal assemblies for rotary shafts for liquid applications shall be of the packless type, of sanitary design, durable for the application, and readily demountable. Stacked or nested "V" ring seals are **NOT** considered as packing.
- E. Seal assemblies for rotary shafts for dry products applications shall be of sanitary design, durable for the application, and readily demountable. Shaft seal designs using adjustable followers are acceptable if provisions are made for easy dismantling. Air purge type seal designs may also be acceptable.
- F. Woven or braided packing material may be used only for dry product applications. This type of packing material shall be discarded when the unit is disassembled for wet cleaning. Reuse of woven or braided packing material is prohibited.

#### **10.18. Air Under Pressure**

- A. Air under pressure to be introduced directly into product, onto a product contact surface or into a product contact surface of a container shall be produced in accordance with the "3-A Accepted Practice 604-. *"Supplying Air Under Pressure in Contact with Milk, Milk Products and Product Contact Surfaces"*.

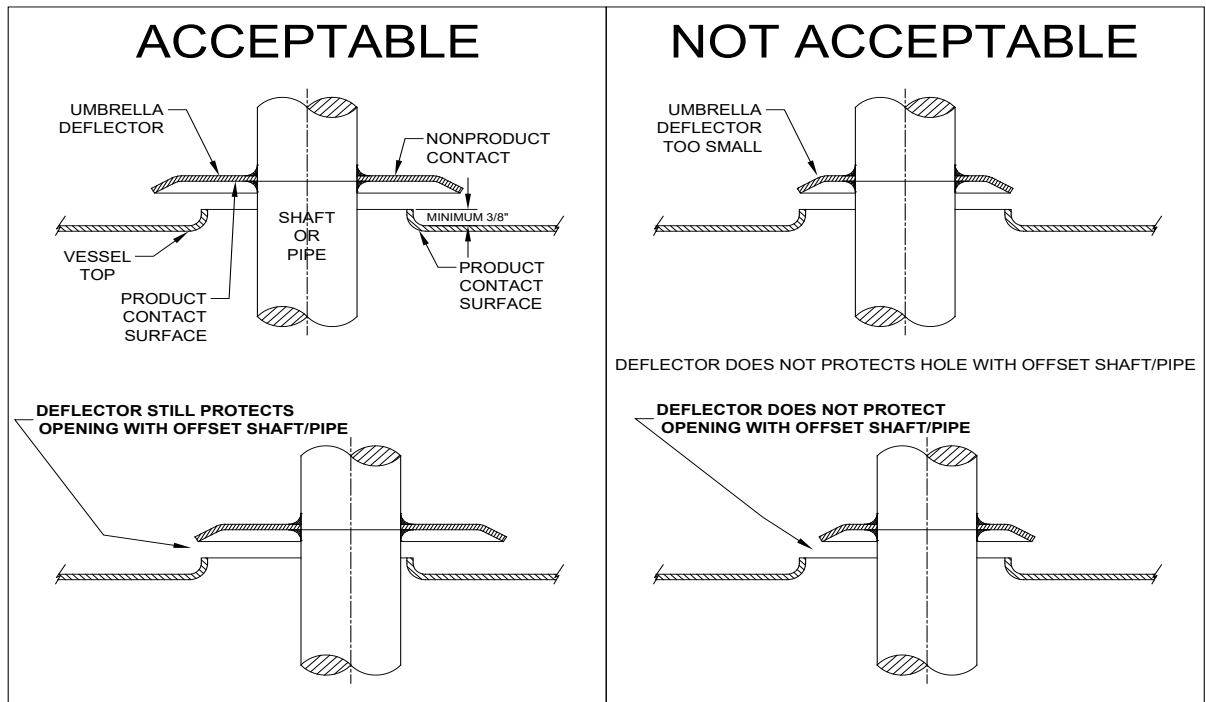
#### **10.19. Covers, Panels, Doors or Access Ports**

- A. Covers, panels, doors, or access ports shall be provided to allow access to the interior of the equipment.
- B. Covers, panels, doors, or access ports shall provide protection against the entrance of contaminants.
- C. Sight or light openings shall comply with the 3-A Sanitary Standard 65-. *"Sight and/or Light Windows and Sight Indicators in Contact with Milk and Milk Products"*.
- D. Personnel entry openings for dry applications shall be not less than 15 inches (381mm) by 20 inches (508mm) for oval openings or 18 inches (457mm) in diameter for round openings.
- E. Personnel entry openings for wet applications shall comply with the applicable 3-A Sanitary Standard 84-. (*Personnel Access Ports for Wet Applications.*)
- F. Covers, panels, doors, or access ports into equipment are not limited to round or oval shapes. Regardless of shape, the opening cover must protect the product, be easily cleanable and meet the criteria of section 10.19.

- G. Covers, panels, doors, or access ports into vessels shall meet these requirements:
- a. Sufficiently rigid to prevent buckling.
  - b. Self-draining including "U" channel bracing or frames.
  - c. Adequate, conveniently located, and with welded, formed or crevice free handles.
  - d. May or may not be gasketed. If the cover, door or panel is not gasketed, a downward flange of at least 3/8 (9.5mm) inch along all edges is required.
  - e. Gasket material shall be solid. Open cell foam, smooth surfaced closed cell foam or hollow interior materials are not acceptable.
  - f. Close fitting.
  - g. The use of hinges, wing nuts, latches, and similar easy-opening fastening devices are recommended to allow easy access without special tools.
  - h. Any hinges, wing nuts, latches, and similar easy opening fastening devices used shall be attached so as to minimize the use of fasteners and the creation of cracks and crevices.
  - i. Hinges shall be of a sanitary design that can be readily disassembled. Continuous or piano-type hinges shall not be used on the equipment or its control cabinets.
  - j. This does not preclude use of piano type hinges on electrical boxes used on dairy processing equipment when they are located well outside of the product zone and not subject to product residues or repeated washing.
  - k. Openings through a product contact surface shall have permanently attached sanitary connections or shall be flanged outward at least 3/8 in. (9.52 mm).
  - l. The personnel entry opening cover shall be of the inside or outside swing type. If the cover swings inside it shall also swing outside away from the opening for disassembly and cleaning. No threaded or ball joints shall be employed within the product zone to attach the cover and its appendages. The cover and its appendages shall be removable without tools. The cover for a top-entering opening shall be of the outside swing type only.
  - m. Other openings shall have removable covers, which shall be pitched to the outside, and be downwardly flanged as noted in 10.19.G.d to make close contact with the edges of the outwardly flanged openings in the product contact surface.
  - n. If braces or frames are made of hollow components, the integrity of the component shall not be compromised by drilling into the hollow interior. If bolting is required, studs welded to the exterior is the preferred method.

Alternatively, fully welded sleeves through the hollow frames or a fully welded blind tapped plug shall be employed to isolate the hollow interiors.

- o. Covers shall be designed so when in the open position, liquid from the exterior surfaces will not drain into the vessel. Also, when fully opened, drops of condensate on the underside will not drain into the vessel.
- p. Bridges and fixed covers shall slope to the outside edges of the tank for complete drainage and shall have a raised flange not less than 3/8 inch (9.5mm) in height where the edges meet the main covers. Bridges and fixed covers shall be integral or welded to the lining and shall be installed so the underside is accessible for cleaning and inspection without completely entering the vessel. Bridges shall not exceed 24 inches (610mm) in width.
- q. All non-permanently attached sanitary pipelines, agitators, and other appurtenances entering vertically through a product contact surface shall be fitted with a sanitary umbrella (downward curved) deflector that overlaps the edges of the outward flanged opening to prevent the entrance of contaminants (*See Example r*). <sup>1</sup>



(Example r) <sup>1</sup>

- r. Equipment that requires adjustment during operation shall be designed so adjustment can be made without the operator having to reach within the product zone through any entrance.
- s. Sample cocks, vacuum release valves or air release valves shall be of sanitary design and have a relatively flush interior sealing surface. They shall be easily dismantled for cleaning. Non-sanitary threaded fittings and valves are not acceptable.

- t. Dry products equipment shall be equipped with dust-tight covers or means for dust removal and control.

#### **10.20. Guards and Other Safety Devices**

- A. Guards required by personnel safety standards shall be removable for cleaning and inspection of the equipment. Guards shall be designed to minimize the accumulation of debris and liquids

#### **10.21. Spray Devices**

- A. Spray devices that are left in place during production shall comply with the applicable 3-A Sanitary Standard 78-.
- B. Mechanical cleaning spray devices installed within a product contact area during processing operations shall be designed and installed to allow for easy removal for inspection and cleaning of spray holes or slits.
- C. Other devices, not of sanitary design, shall be removed after cleaning is completed and shall be designed and located to allow easy installation and removal.
- D. Holes in product contact surfaces for retaining pins shall be at least 5/32-inch (4mm) diameter.

#### **10.22. Service Piping and Lines**

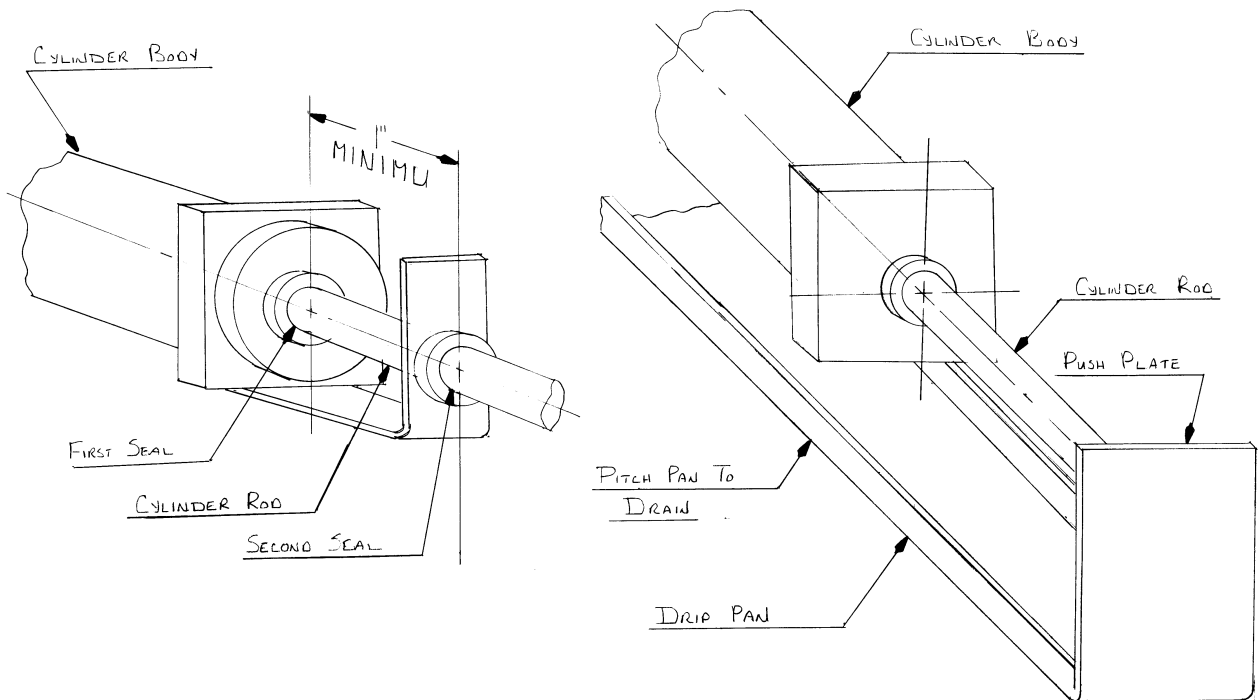
- A. Exposed braided coverings of cables or hoses shall not be used.
- B. Electrical and utility connections shall be as remote as practical from the product contact areas of the equipment.
- C. Exhaust air from pneumatic equipment shall be piped away from product and product contact surfaces.
- D. Components using machinery fluids (e.g. lubricating and hydraulic fluids, and signal transfer fluids) shall be installed to prevent fluid ingress into the product or onto product contact surfaces.
- E. Hose clamps of the enclosed worm gear type shall not be used.

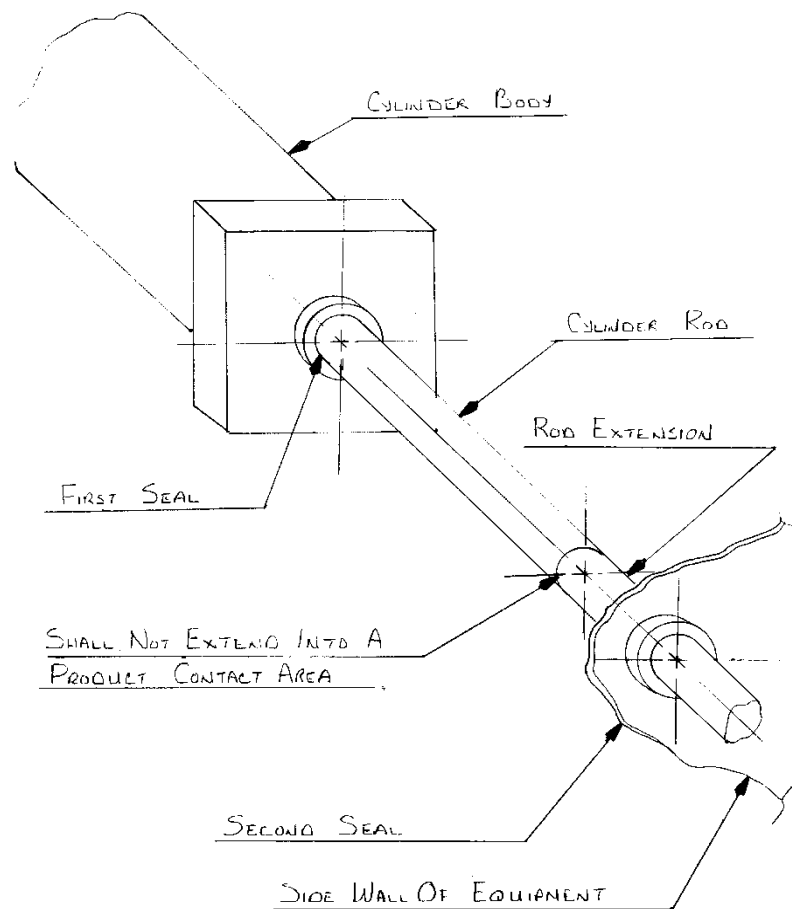
#### **10.23. Culinary Steam and Piping**

- A. If the equipment provides for direct injection of steam into the product, the steam shall be produced in accordance with the 3-A Accepted Practice 609- *“Method of Producing Steam of Culinary Quality”*.
- B. The steam piping connection(s) to the product contact surfaces shall be made in such a way that product cannot enter the steam lines. All components downstream from the sanitary check valve shall be of sanitary design and be easily removable for cleaning and inspection.

## 10.24. Cylinders

- A. Any part of the shaft of a pneumatic or hydraulic cylinder that enters the cylinder and extends over exposed product, or a product contact surface shall be provided with a sanitary shield or be of a sanitary design. Sanitary shielding can be accomplished with a long drip plate (so that all exposed product and product contact surfaces are shielded when the shaft is fully extended), or any other shield arrangement that protects the surfaces and product. A sanitary design may include; double seals (with 1-inch of clear space between them, provided the space between the seals is not in the product zone), doubling the length of the shaft so the part that enters the cylinder never extends over the product zone, or other sanitary design features.





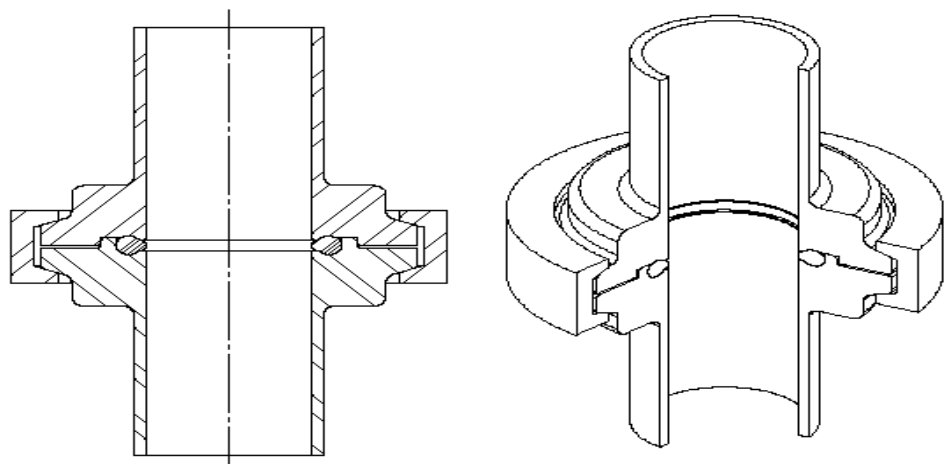
## 10.25. Hoses and Connectors

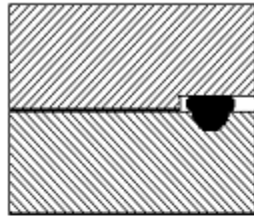
- A. When a high-pressure hydraulic hose is located on a machine so that hose rupture could allow product contamination, that portion of the hose shall be enclosed in a larger secondary protective hose or tube, or other means to protect the product from contamination.
- B. Flexible connectors for dry products having product contact surfaces shall have straight sides without corrugations and shall be readily cleanable.

## 10.26. Gaskets, O-rings and Seals

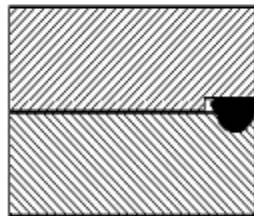
- A. Gaskets shall be removable or bonded.
- B. Bonded rubber, rubber-like materials and bonded plastic materials having product contact surfaces shall be bonded in a manner that the bond is continuous and mechanically sound. When exposed to the conditions encountered in the environment of intended use, cleaning and bactericidal treatment or sterilization, the rubber and rubber-like material or plastic material does not separate from the base material to which it is bonded.
- C. Grooves in gaskets shall be no deeper than their width, except as appropriate for gasket sealing applications on large equipment. If the groove in the gasket is deeper than its width, the gasket shall be removable and reversible for cleaning.

- D. Dimensions and profiles of gasket grooves or gasket retaining grooves for bonded gaskets are at the discretion of the fabricator.
- E. Gasket retaining grooves 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 O-rings with cross-section dimensions 1/4 in. (6.35 mm) or smaller. Except that:
  - a. For functional reasons, the depth of gasket retaining grooves of removable gaskets shall be no deeper than the width.
- F. Gaskets between flat sealing surfaces shall create a substantially flush surface with the interior product contact areas. The juncture shall create a crevice free joint, without unsupported gasket material. (*Refer to Section 10.5.C.*)
- G. Equipment designs with two or more O-rings or seals in a row between product contact and non-product contact surfaces shall have a leak-detection port between them that is open to the atmosphere and visible to the operator. The leak-detection port shall be a minimum of 1/8 in. (3.18 mm) in diameter. However, if this area is designed for disassembly and manual or COP cleaning, the leak detect port is not required.
- H. Gasketed joints employing recessed O-rings or seals which are intended for CIP shall be substantially flush so that a portion of the O-ring or seal surface will be partially exposed to cleaning solutions (See following illustrations of examples). 1





**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 )**

## 10.27. Perforated Surfaces <sup>1</sup>

- A. Perforations located in a product contact area may be round, square, rectangular, or crescent-shaped.
- B. If round, the holes shall be at least 1/32 in. (0.794 mm) in diameter.
- C. If square or rectangular, the least dimension shall be at least 0.02 in. (0.51 mm) with corner radii of no less than 0.005 in. (0.127 mm).
- D. If crescent-shaped, the opening shall be at least 0.004 in. (0.102 mm) wide at the widest part and the perforations shall be at least 0.02 in. (0.508 mm) long. Internal angles of the perforations shall be well defined and free of crevices. One side of the perforated component may have machine mark indentations around the perforations. The other side may have projections around the perforations, together with shallow open grooves between the rows of perforations.
- E. All perforations shall be free of burrs.
- F. Surfaces with perforations smaller than 1/32 in. (0.794 mm) shall be readily accessible and be designed for CIP cleaning.

## 10.28. Shafts <sup>1</sup>

- A. Shafts that pass through a product contact surface above the product level shall be designed to provide means to prevent the entrance of contaminants through the portion of the opening surrounding the shaft.



- B. Shafts that pass through a product contact surface below the product level or designed to be located outside a processing area shall have a packless-type seal of sanitary design that is readily accessible and inspectable.

## 10.29. Bearings

- A. Bearings having a product contact surface shall be of non-mechanical, non-lubricated or product-lubricated type. (e.g. bushing, etc.)
- B. Lubricated bearings, including permanently sealed types, when used, shall be located outside the product contact surface with at least 1 in. (25.4 mm) clearance between the bearing and the nearest product contact surface or sanitary seal and such clearance shall be open for inspection (*Refer to Section 10.17*).

## 11. Non-product Contact Surfaces

- A. Non-product contact surfaces including frame assemblies, drive assemblies, mechanical actuators, support members, etc., shall be designed and fabricated so as not to contribute to unsanitary conditions. These areas are to be such that they do not detract from a clean environment for food processing. Primary concern shall be focused on those non-product contact surfaces which are in close proximity to product contact surfaces and may be subjected to product residues and splashing. Non-product contact surfaces which are located well outside of the product zone and not subjected to product residues and splashing **do not** have sanitary significance and **should not** be criticized for construction characteristics. In general, the further away from the product zone the less the non-product contact surfaces are to be criticized.
- B. The following criteria shall apply **only** to those non-product contact surfaces which are subject to product residues and splashing:
  - a. Non-product contact surfaces including frame assemblies shall be free of pockets and crevices and be readily cleanable. This can be attained by continuous welding, however, skip or strip welding may be employed provided that intervening crevices are suitably sealed or caulked. Although epoxy metal or silastic type caulking materials may be used for such sealing, it should be realized that this is usually only a temporary measure and that periodic maintenance will be required. Epoxy metal or silastic type caulking materials are significantly more durable when the materials can be applied to mating components prior to assembly.
  - b. Where applicable, motor housings and hydraulic cylinders shall be isolated from product contact areas by sanitary shields or guards. (**Note for Inspectors:** when properly shielded or located where they are not subject to product residues and splashing, construction details of these components should not be criticized) *See Section 11.A.*

- c. Surfaces to be coated shall be effectively prepared for coating. This preparation may include, but is not limited to, grinding of welds, polishing of cast surfaces, cleaning of surfaces so the covering adheres properly, etc.
  - d. Stainless steel equipment frames and exterior non-product surfaces may be glass beaded if desired. If not made of corrosion-resistant metal, they shall be painted or coated.
- C. All non-product contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If the surfaces are coated, including painted surfaces, the coating shall adhere. All non-product contact surfaces shall be relatively nonabsorbent, durable, and cleanable. Parts removable for cleaning having both product contact and non-product contact surfaces shall not be painted.
- D. Non product contact surfaces shall have relatively smooth finishes and be relatively free of pockets and crevices.
- E. Permanent joints subject to product residue shall be continuously welded. Welded junctures do not require grinding or polishing. The following are acceptable methods of fabrication:
- a. Exposed threads shall be minimized. The exposed threads shall not exceed one half the nominal diameter of the thread, except that:
    - 1. Exposed threads that are subject to routine product splash during processing and cleaning shall be covered by an enclosed (*Cap or Dome*) nut.
- F. If the framework and exterior panels of the equipment are not made of corrosion resistant metal, they shall be painted or coated. When coatings are used, they shall be free from delamination, pitting, flaking, galling, blistering, or distortion when exposed to the conditions encountered in the environment of intended use. This includes cleaning and sanitizing.
- G. Where welding is not possible for functional or safety reasons, bolted joints may be used. When braces or frames are hollow, the integrity of the braces or frames shall not be compromised by drilling into the hollow interiors. Fully welded plugs into the hollow frame for blind holes or fully welded sleeves through the hollow frames shall be employed to isolate the hollow interiors. Studs welded to the exterior is preferred rather than bolting to or through the hollow frames.
- H. Knurled surfaces shall not be used in areas subjected to product residues and splash.
- I. Recessed socket head bolts shall not be used, except that:
- Recessed socket head bolts may be used provided they are away from any product (or splash) contact surfaces or
  - may be shielded from any product residues or
  - mounted so that the socket heads drain.
  - Recessed socket head bolts may be used on rotating horizontal shafts.

- J. Blind Rivets (*Pop Rivets*) shall not be used. However, they are allowed on the nameplates of purchased parts. For example: Gear reducers, pneumatic cylinders, hydraulic cylinders, motors, electrical enclosures, instrument transmitter housings, cast components, etc.
- K. When external lap joints for sheathing over insulated areas are used, they shall be overlapped downward, and overlapped joints shall be effectively sealed between the mating surfaces with suitable sealants.
- L. Control panels and electrical boxes shall be continuously welded to the surface to which they are mounted or, properly sealed with caulking material or mounted with approximate 1-inch (25mm) stand-offs.
- M. Hinges on control panels or electrical boxes shall not be the continuous or piano-type hinges. Except that:
  - a. Piano type or continuous hinges on control panels or electrical boxes may be used when they are located remotely or well outside of the product zone and not subject to product residues or repeated washing

### 11.1. Supports

- A. Legs or casters shall provide a clearance between the lowest fixed point on the equipment and the floor of at least 4 inches (102mm) when the equipment base outlines an area in which no point is more than 12 ½ inches (318mm) from the nearest edge of the base, or a clearance of at least 6 inches (152mm) when any point is more than 12 ½ inches (318mm) from the nearest edge.
- B. Casters, if provided, shall be easily cleanable, durable, and of a size that will permit easy movement of the equipment. If bolted, excess threads should be cut off or covered with a "dome" type nut.
- C. Adjustable legs shall comply with the 3-A Sanitary Standard 88- (Machine Leveling Feet).
- D. Equipment with a closed base to be mounted on the floor shall have the base sealed in a bed of mastic or grouting.
- E. If mounted on a slab or island, the base shall be designed for sealing to the slab or island surface. The slab or island shall be of sufficient height so that the bottoms of all product connections are at least 4 in. (102 mm) above the floor. The mounting surface of the slab or island shall be coated with a suitable layer of waterproof mastic material, which will harden without cracking. The junction of the equipment base and the slab or island shall be sealed.
- F. If mounted directly on a wall or column, the area of attachment of the equipment to its mounting surface shall be designed for sealing to the wall or column. If the design of the equipment is to be mounted offset from a wall or column it shall

provide at least a 4 in. (102 mm) clearance between the outside of the equipment and the wall or column.

- G. Supporting structures, braces, catwalks, stairs, and handrails are not considered as non-product contact surfaces of the equipment but are considered as part of the building structure.

## 11.2. Name and Information Plates

- A. Company name or information plates shall be fully bonded to the unit. Welding of metal plates or adhesive mylar stickers are preferred. However, plates may be bonded with a suitable adhesive or the crevice conditions may be sealed with caulking. The use of pop rivets is not acceptable. (**Note for Inspectors:** name plates on motors, gear drives, bearing bosses, actuating cylinders, etc., which are located outside of the area where they are not subject to product residues and splashing should not be criticized) *Refer to Section 11.J.*
- B. Non-metallic, adhesive-backed name and information plates are also acceptable.
- C. When an additional information plate is necessary to convey special information, it shall be attached in close proximity to the nameplate. Alternatively, this information may appear on the nameplate.

**THE FOLLOWING SPECIAL  
CONSIDERATION SECTIONS  
PROVIDE CRITERIA AND GUIDANCE  
IN ADDITION TO THOSE PROVIDED IN  
THE PREVIOUS SECTIONS. UNLESS  
SPECIFICALLY MODIFIED BY THESE  
SPECIAL CONSIDERATION SECTIONS,  
ALL MATERIALS AND FABRICATION  
CRITERIA IN SECTIONS 9 AND 10  
APPLY.**

## 12. Special Considerations for Pasteurization Equipment

- A. When the equipment or installation of a processing system includes a High Temperature Short-Time (HTST) or Higher Heat Shorter-Time (HHST) pasteurizer, USDA recommends that details of the proposed pasteurizer system be additionally presented for review and acceptance by the state regulatory agency responsible for inspecting, timing, and sealing the system upon installation. The state regulatory agency personnel receive training and guidance from the U.S. Public Health Service (USPHS), a federal agency of the Food and Drug Administration of the Department of Health and Human Services. DGB of USDA defers to USPHS for engineering expertise and leadership in the public health aspects of pasteurizer design and operation.
- B. The "3-A Accepted Practice for the Sanitary Construction, Installation, Testing and Operation of High Temperature Short-Time and Higher Heat Shorter-Time (HHST) Pasteurizers, Revised," should be used as guidance for design and installation of HTST systems. Any new or unusual aspects of such systems should be presented for review to the state inspection agency or to the Milk Safety Branch, (HFF-346), FDA, Department of Health and Human Services, 330 C Street, S.W., Washington, DC 20204. Telephone 202-205-8178, FAX 202-205-5560.

## 13. Special Considerations for Exposed Product Conveyors

**Note:**

*Exposed product conveyors will be evaluated using the criteria of the 3-A Sanitary Standards for Mechanical Conveyors for Dry Milk and Dry Milk products; or the Sanitary Standards for Belt-Type Feeders as appropriate.*

*However, exposed product conveyors which do not meet the scope criteria of the above referenced standards shall meet the following criteria.*

- A. Non-sanitary construction for drive mechanism components such as riveted roller type chains, cleated belts, round resilient belts, and friction drives may be considered as non-product contact surfaces provided one of the following methods of isolation is provided.
  - a. Clearly identifiable boundary demarcations. A clearly identified demarcation may include equipment intended to locate product in a set position on the conveyor belt. These may include but not limited to a funnel or hopper, robotic arm, slicer, feed conveyor or other fitment that will locate all product in a set position.
  - b. A minimum of 1 inch (25mm) open clearance between the product contact area and the drive components shall be required when the product contact area boundaries are designated by closed construction such as close-fitting shields enclosing the entire drive component section.
- B. Drive components and lubricated bearings with a minimum open clearance of 1 inch (25.4 mm) that are located in a position where product cannot touch these components and remain on the conveyor (e.g. bearings or drive components located

well below or outside of the product contact surfaces of the conveyor belt so the product cannot remain on the belting and touch these surfaces).

- C. Solid conveyor belts having direct product contact shall be endless. Metal stitching, clips or lacing are not acceptable methods of joining belt ends.
- D. Mechanical bearings that are capable of greasing shall be located at least 1 inch (25.4 mm) from the sides of the conveyor. This area shall be open for inspection and cleaning.
- E. Mechanical bearings of the permanent factory sealed type that are unable to be greased, may be located at least ½ inch (13 mm) from sides of the conveyor. Due to the limited amount of grease in the sealed bearing, migration from a failed bearing should be minimal. This area shall be open for inspection and cleaning.
- F. Belts which have absorbent core or backing material, that is woven and allows liquid wicking into the belt edges and backing material shall have these areas sealed with:
  - a. the same material as used for the product contact surface; or
  - b. a sealant which complies with the applicable Food and Drug Administration regulations for repeated food contact for the product which is being conveyed; or
  - c. sealants applied that are equally as durable as the belting material and applied in sufficient thickness so that it shall remain intact without peeling, blistering, delaminating, flaking, etc., during the expected life of the belt.

**Note:**

*If it can be proven that liquids will not wick along the core or backing material fibers sealing the edges of the belt is not required. (Refer to item 13.Q)*

- G. When continuous, solid belting material is used for direct product contact, the area between the top and bottom runs of the belt and at the side frame areas may have non-sanitary construction. Provided that liquids, debris, or product residues are prevented from migrating onto or into product and/or product contact surfaces.
- H. The area between the belts may have exposed bolt heads (if needed for engineering reasons) and the welds need only to be continuous, pit and snag free, with no minimum radii or polishing requirements. Bolted junctures shall be gasketed so there are no crevices. This includes the bolt heads and cap nuts if used.
- I. When modular type or open belting material is used for direct product contact, the area between the top and bottom runs of the belting material are considered to be product contact and meet all product contact criteria. Except that:
  - a. The areas between the top and bottom runs of the belt, and the side frame areas may have non-sanitary construction provided liquids, debris, or product residues are prevented from migrating onto the product contact surfaces by the use of sanitary constructed shields and guides.

- J. Open belting and approved plastic link belting that weigh 50 pounds or less may be removed and placed in a COP tank for cleaning. If the belting weighs more than 50 pounds or cannot be easily removed, shall be provided with an integral mechanical cleaning device(s) that are located so all exposed surfaces of the belting and sprockets are automatically cleaned. Cleaning solution catch pans or trays if used, shall be designed to be drainable and accessible for cleaning and inspection.
- K. Substitution of the integral mechanical cleaning device with manual cleaning techniques using hand-held high-pressure spray systems is unsatisfactory
- L. Conveyor rollers for either direct product contact or for the support of belting material shall comply with the following criteria:
  - a. They shall be of sanitary design and constructed from acceptable materials.
  - b. Half knurled or slight roughened surfaces are acceptable.
  - c. Hollow rollers shall be completely sealed to prevent liquids from gaining access to interior voids.
  - d. End cap junctures shall comply with the permanent joint criteria of Section 10.2.
  - e. Rollers shall not contain integral lubricated, including sealed ball or roller style bearings. However, internally driven rollers may contain internal lubricated bearings. The internal drive rollers shall be of a sanitary design. Section 13.M.
  - f. Recessed bushing or bearing surfaces shall be of sanitary design appropriate for mechanical cleaning or be readily removed for daily manual cleaning.
  - g. The diameter of a recessed bearing cavity shall be greater than its depth.
- M. Internally driven rollers shall be of sanitary design. The design shall assure that the internal lubricants cannot leak and contaminate product and the product contact side seals are of sanitary design. Each design proposal shall be evaluated on a case by case basis.
- N. Conveyors which run partially submerged in chilled brine systems are not required to meet the sanitary construction requirements. Bent wire conveyors and specified plastic link conveyors which are not acceptable for other exposed product conveyors may be acceptable for brine system discharge conveyors. Conveyors incorporating these designs will be evaluated on a case-by-case basis. The conveyors shall be designed so that lubricated bearings including the factory sealed type are not immersed in the brine and they can be removed from the brine for cleaning as needed. Such conveyors shall not be cleaned while immersed in the brine tank or flume unless the tank or flume has been drained.
- O. Flat top solid belting and modular link style belting for direct product contact shall be evaluated for acceptance on a case-by-case basis.



- P. When conveyors discharge into product hoppers or vessels, all bearings, drives and other non-sanitary areas located above shall be shielded to prevent contamination of the product in the hopper or vessel below.
- Q. Belting which includes fiber core or backing material shall be subject to a wicking test. Commercially available, water-based food coloring shall be the test solution. Undiluted food coloring shall be applied directly to the backing material and/or the cut edge of the belting for imbedded fibers. Any coloring penetration or migration along the fibers greater than 1 mm shall be considered evidence of unacceptable wicking properties of the materials.

#### 14. Special Considerations for Packaging Machines

**Note:**

*The DGB utilizes the established 3-A SSI Sanitary Standards and Accepted Practices for equipment that fall under the scope of a particular standard or practice. In the event that the equipment reviewed, does not fully comply with the applicable 3-A SSI Sanitary Standards or Accepted Practice, the USDA Guidelines may be applied. If it can be determined that the equipment in question does not fully comply with the 3-A SSI Sanitary Standard or Accepted Practice but complies with the minimum requirements of the USDA Guidelines, USDA can still issue a letter of acceptance and certificate.*

- A. Exposed product, product contact surfaces, or product contact surfaces of packaging materials shall have a sanitary design and protected from contamination from mechanical and non-product contact areas of the equipment. This may be accomplished by the proper design and use of catch pans or sanitary shields.

##### 14.1. Viscous and Dry Product Vertical and Horizontal Packaging Machines

- A. Film unwind assemblies, exposed threads, conventional air or vacuum fittings, folding assemblies or forming apparatus for packaging materials, suction cups to move packaging materials, cutting or slitting assemblies, arms or similar parts which extend over the product contact surface of the packaging material are not required to meet product contact criteria if they are kept dry during production and cleaning of the packaging. These parts do not have direct product contact, and there is little likelihood of contaminants or liquids draining from these surfaces onto product contact surfaces or dropping materials onto or into exposed product are not required to meet product contact criteria.
- a. Covers, shields or equally effective method may be used to ensure these areas remain dry during production and cleaning. (*Appendix 8*)
  - b. The materials of construction meet product contact requirements. For example; 300 series stainless steel (except 301 and 302), or other acceptable metals or coatings, plastic or rubber materials complying with FDA Regulation 21 CFR part 170 through 199.

- c. All welds shall be continuous, free of pits and snags. Polishing of welds is not required.
  - d. There are no radii requirement for internal angles less than 135 degrees.
- B. If the components noted in Section 14.1.A will be subject to wet washing, or liquid may drip onto product contact surfaces, onto the product contact surfaces of the packaging materials or into exposed product shall be considered as product contact and meet all product contact criteria. Alternatively, product contact surfaces, product contact surfaces of the packaging materials or exposed product may be isolated from the unsanitary surfaces above by sanitary designed shields, guards or catch pans.
- C. Conventional electrical wiring and connections for heat sealing clamps, bars, wheels, etc. shall be acceptable when their method of use, location, or sanitary shielding do not create unsanitary conditions contributing to the contamination of the product or product contact surfaces.
- D. When a greased or sealed bearing is used in the end(s) of packaging material feed rollers, the bearings shall be a minimum open space of 1 in. from the edges of the packaging material or there shall be some other means of demarcation. This may incorporate the use of O-rings, drip edges, or grooves to isolate the surfaces of the rollers that contact the packaging material.
- E. When engineering and fabrication exceptions are granted for intricate assemblies, they shall be designed to be readily removable for cleaning and inspection.
- F. Subassemblies designed to be removed and cleaned as a unit in a COP tank shall be designed so that all areas effectively clean. The subassemblies shall meet the following criteria:
- a) The sub-assemblies shall be free of all crevices.
  - b) All bolted junctures that are not disassembled shall be gasketed to isolate the threads and to prevent ingress of liquid and debris.
  - c) Sub-assemblies may be loosened or partially disassembled to allow complete cleaning of the unit.
  - d) Sub-assemblies that have product contact and painted non product contact surfaces shall not be cleaned in a COP tank.
  - e) Assemblies with greased or factory sealed bearings shall not be submerged and cleaned in a COP tank.

#### 14.1.1. Vertical Fillers

- A. Areas after the film has been formed around the filling tube and the film is overlapped and ready for heat sealing, will be evaluated for Good Manufacturing Practices (GMP). However, will not be required to be crevice free provided that the surrounding areas are kept free from product and/or residue.
- B. When liquid filling nozzles are a used, drip pans, shields or deflectors may be used to demarcate non-product contact areas from product contact areas below. GMP's

will be required in these non-product contact areas located above the filling nozzle(s). However, the requirement to be free of crevices will not be required provided the surrounding areas are kept free from product and or residues.

- C. Product contact surface areas on the film feed (i.e. areas that touch the product side of the film or located above) will not be required to be crevice free as long as the areas are kept dry. This will require a special effort on the part of the equipment manufacturer and equipment users to ensure these areas stay dry during product runs and cleaning. Special guards, sheets, or covers, may be required. There shall be instructions in the owner's manual on proper operation and cleaning of these areas. *(Refer to the requirements noted in 14.1.A and 14.1.B)*
- D. Compressed air may be used to clean these areas. Compressed air shall comply with the 3-A Accepted Practice 604-.

#### 14.1.2. Horizontal Fillers

- A. The areas after the container(s) have been formed and the film opening pulled tight closing the container; will not be required to be crevice free as long as the surrounding areas are kept free from product and/or residue.
- B. Areas located above the film path after the folding plow where the film is pulled tight, are not considered to be product contact even though they are located above the folded film.
- C. All appurtenances that enter the folded film or formed container prior to filling (air nozzles, gas nozzles, etc.) shall be considered to be product contact and meet all product contact criteria.
- D. All areas located above the formed container while held in the opened position from which materials may drop, drain or be drawn into the container shall be considered to be product contact and meet all product contact criteria or be shielded by a sanitary shield.
- E. Product contact surface areas on the film feed (i.e. areas that touch the product side of the film or located above) will not be required to be crevice free as long as the areas are kept dry. This will require a special effort on the part of the equipment manufacturer and equipment users to ensure these areas stay dry during product runs and cleaning. Special guards, sheets, or covers, may be required. There shall be instructions in the owner's manual on proper operation and cleaning of these areas. *(Refer to the requirements noted in 14.1.A and 14.1.B)*

#### 15. Special Considerations for Cheese Brine Systems and Related Equipment

- A. Stainless steel tanks should be made from 316 series stainless steel. A 2B mill finish is satisfactory. All welds shall be continuous, snag and pit free. Polishing of the welds is not required. There are no minimum radii requirements for internal angles less than 135 degrees.

- B. Concrete, concrete coated, or ceramic tile covered tanks shall have a smooth, cleanable interior surface. Exposed aggregate, pockets, bubbles, form impressions, missing grouting, flaking or galling of the surface is unacceptable. If a coating or sealer is used, it shall comply with the applicable FDA regulation 21 CFR Part 170 through 199.
- C. Pit tanks shall have perimeter walls which extend at least 1 foot (305mm) above the floor level of the room.
- D. The design and construction of the wooden frames or other components for fiberglass tanks shall be substantial enough to bear the weight loading when the tank or flume system is filled with brine without stressing or breaking the fiberglass coating.
- E. The fiber glassed components shall be constructed with a final, resin rich coating that results in a smooth cleanable surface free of pits, checks, cracks, ripples or waves on both interior and exterior surfaces.
- F. All openings, bored holes for pipe or conduit passage, cut-outs, or attachments to the fiber glassed surfaces of the tank shall be fully sealed or fiberglass covered to prevent the entrance of moisture into the wooden frame.
- G. When fiberglass tanks are stacked or "piggy-backed" the exterior of all but the lowest tank shall meet the same fabrication criteria as the interior surfaces of the tank which contact the brine and product.
- H. Stacked or "piggy-backed" tanks or flumes shall provide the following clearances:

Between bottom of tank and floor. (Also applies to single level tanks or flumes)	
Tank Width (in feet)	Minimum Clearance (in inches)
Up to 3 (0.9m)	12 (305mm)
3 to 6 (0.9 - 1.8m)	20 (508mm)
6 to 8 (1.8 - 2.4m)	22 (559mm)
8 to 10 (2.4 - 3.0m)	24 (610mm)
10 to 12 (3.0 - 3.7m)	26 (660mm)
12 to 14 (3.7 - 4.3m)	28 (711mm)
14 to 16 (4.3 - 4.9m)	30 (762mm)
Over 16 (4.9m)	36 (914mm)

**Note:**  
All tank measurements are exclusive of projecting ribs, cross beams, or top lips.

- I. Between each tank and any tank above it shall be at least 18 inches (457mm), as measured between any projections or cross beams of the upper tank and the top lip of the lower tank except that, if the upper tank has ribs or cross beams which project downward 12 or more inches (305mm), the clearance shall be 24 inches (610mm). If the bottom tank is divided into narrow flumes (less than 20 inches (508mm) wide)

which interfere with movement in the bottom tank for manual cleaning, the clearance shall be 24 inches (610mm).

- J. Between the uppermost tank top lip and the ceiling of the room shall be at least 18 inches (457mm). If there are ceiling joists or beams projecting downward there shall be compensating clearance to facilitate manual cleaning.

**Note:**

Lesser clearances may be considered if the brine tank or flume system is provided with a mechanical spray cleaning system.

- K. Perimeter clearance between a tank or flume system and the walls of the room shall be at least 24 inches (610mm).
- L. The aisle spacing between adjacent tanks shall be at least 24 inches (610mm), except that two long rectangular shaped tanks may be butted against each other on the long side in accordance with the following criteria:
- a. There is at least 24-inch (610mm) aisle clearance on the remaining four sides.
  - b. The upper crevice between the two tanks is appropriately sealed.
  - c. The underside contact points are properly sealed and form a flush surface with the bottom of the tanks. Deep recesses created by tank lips are unacceptable.
- M. When fiberglass tanks or flumes are mounted directly on the floor, the following criteria apply:
- a. The tank to floor juncture shall have a curved cove molding with at least a 1-inch (25.4 mm) radius to facilitate cleaning of the juncture.
  - b. There shall be no mounting brackets for pipelines, electrical connections, etc., which breach the fiberglass integrity and would permit entrance of liquid into any interior void areas under the tank or flume.
  - c. The tank or flume system is mounted to permit access around the exterior for cleaning and inspection.
- N. When tanks or flumes are stacked or "piggy-backed", sanitary means shall be provided for personnel access to the upper tanks to prevent contaminants from entering the lower tanks.
- O. Provision shall be made so the brine can be pumped out of the system so the tanks or flumes can be cleaned. Separate brine storage tanks or product storage tanks may be used.
- P. Plastic or rigid PVC piping suitable for potable water systems may be used for the transport of brine. Brine piping shall be rigidly supported and self-draining.
- Q. Butterfly type valves are acceptable for use on brine distribution piping.

- R. Threaded fittings may be used for brine spray nozzles.
- S. Pumps complying with the criteria within the 3-A Accepted Practices for Permanently Installed Sanitary Product-Pipelines and Cleaning Systems, Used in Milk and Milk Products Processing Plants for circulating cleaning solutions are satisfactory. However, food grade pumps may be used on purified brine which does not contain dairy solids or particulate.
- T. Specially constructed Archimedes screw or jet type pumps may also be used provided that the construction materials are corrosion resistant and there are no lubricated bearings above or under the brine surface. All motors, drive assemblies, lubricated bearings, etc., shall be appropriately isolated or shielded to prevent contamination of the brine.
- U. Baffles, gates, baskets, frames, racks, and other appurtenances shall be mechanically sound, sufficiently strong for the intended use, and corrosion resistant. Parts shall not be painted. Threaded and bolted construction, woven plastic or stainless-steel screen material, and braided stainless steel cables are satisfactory. There are no minimum radii requirements.
- V. Baskets, frames, or racks which are removed from the brine for cleaning and storage or staging for loading shall not be stored on the floor. Sanitary storage racks or platforms shall be provided.
- W. Systems shall have facilities, suitable to their size, for skimming, filtering, cooling, and adjustment of brine strength. Pasteurization or ultraviolet (UV) treatment of the brine is encouraged.
- X. A hoist(s), if used, shall have all non-sanitary surfaces such as the drive, hoist chain, cables, pulleys, rollers, etc., provided with a sanitary shield(s) to protect any exposed product, product contact surfaces, or brine below the hoist.

## 16. Special Considerations for Cheese Molds

- A. All mold surfaces are to be considered product contact surfaces as most users routinely save cheese whey solids and butterfat for human consumption.
- B. The radius requirements of Fabrication Items 10.12 A-G shall apply except when required for:
  - a. Bending of thin, smooth or perforated metal sheets of 16-gauge thickness or thinner. In such instances, internal radii shall be not less than 1/32 inch (0.8 mm) and the short side of a 180-degree bend shall not exceed 3/8 inches (9.5mm) in length. See Figure J.1 for an example of an acceptable formed stiffening rim on the top of a metal cheese mold.

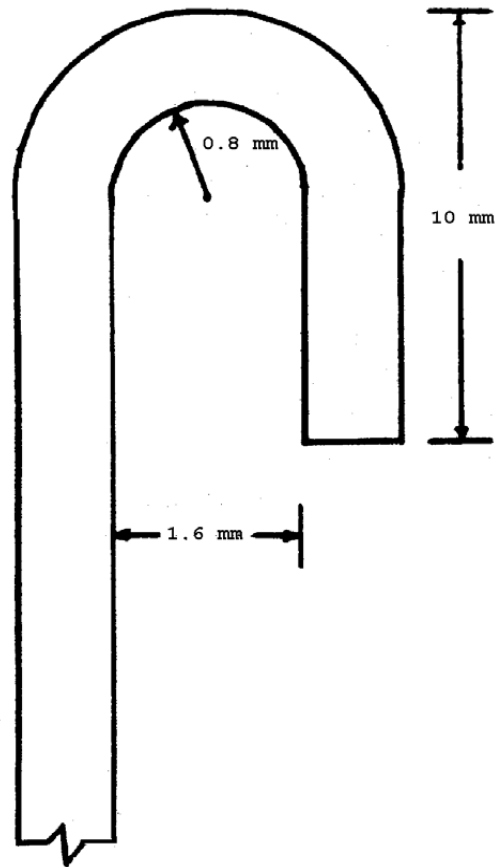


Figure J.1

- b. Maintaining the desired shape of the cheese.
  - c. Functional requirements during the molding, cooling, mirror welding or friction welding of plastic components.
- C. When close tolerance areas are required for functional reasons, perforations shall be located to facilitate cleaning. See Figures J.2 and J.3 for examples of alternate placement of required perforations.

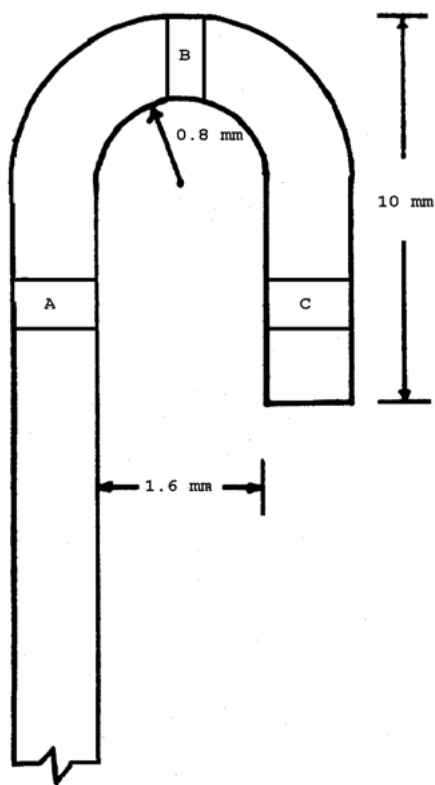


Figure J.2

Figure J.2 Perforations in a formed stiffening rim on the top of a metal cheese mold is required at one or more of locations A, B, or C to facilitate cleaning.

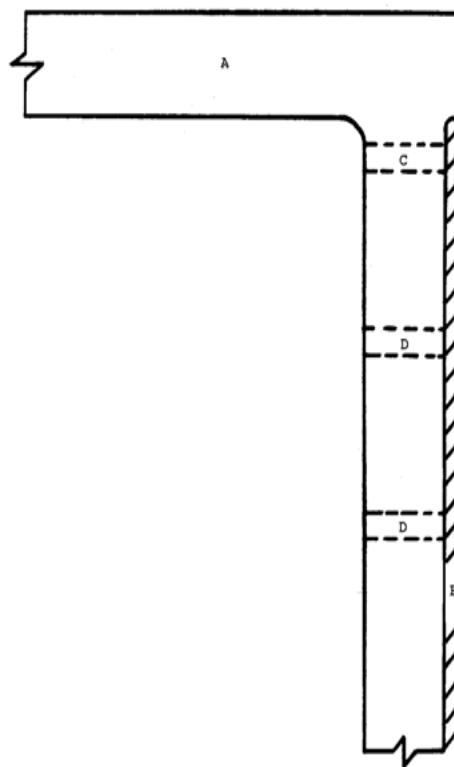


Figure J.3

A. Cheese mold body  
 B. Perforated drain screen on inside  
 C. Required perforation for cleaning  
 D. Perforations for whey drainage

- D. Mechanical cleaning is required when component perforations are 1/32 inch (0.8 mm) or less in diameter, or when component parts such as a bonded plastic cheese cloth are cleaned as assembled units.
- E. All component parts are to be fully accessible for inspection or cleaning. Demountable parts are to be readily demountable. There shall be no non-inspectable surfaces.
- F. When air pressure is used for release of the cheese from the mold, the air supply shall comply with the 3-A<sup>®</sup> Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product Contact Surfaces, Number 604-.

### 16.1. Stainless Steel Molds

- A. Non-perforated metal components shall be continuously welded, ground and polished as required by Sections 10.1.A. and 10.1.B. and 10.2.A.



B. Spot welding of perforated screen material may be utilized in accordance with the following criteria (See Figure J.4):

- a. The weld shall be at the apex of a preformed dimple in the screen.
- b. The entire apex surface of the dimple shall be welded.
- c. Spot welded perforated screens shall be separated by at least 1/16 inch (1.5mm).
- d. The preformed dimple in the screen shall be no deeper than its width.

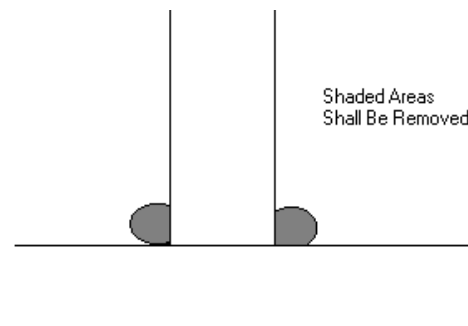


Figure J.4

- C. Glass beading of molds is acceptable under the guidance of Section 10.1.E.
- D. Component parts may be held together (spring tension, positioning pins, "R" clips, etc.) during routine use and cleaning procedures. See Sections 16.C, 16.D, and 16.E.

## 16.2. Plastic Molds

- A. All plastic molds shall require mechanical cleaning.
- B. Mold strengthening ribs, especially those located on mold lids, shall not create non-drainable pockets or other obstructions to free draining.
- C. Fabrication materials shall comply with Section 9.1.E and 9.1.F.
- D. When heat, ultrasonic or chemical welding is used to attach plastic components, all deformed material shall be removed to eliminate any cracks, crevices, pits or folds. No radius is required at these junctures.



- E. All injection sites, perforations, machined surfaces, etc. shall be free of ripples, distortion, flashing, loose strings or shavings of plastic.
- F. Plastic colors shall comply with the applicable FDA regulations.

- G. When plastic components are used in conjunction with stainless steel components, all assemblies shall comply with 16.2.C, 16.2.D and 16.2.E. Components shall fit loose enough to allow movement that will permit cleaning solution to flow between the stainless and plastic components so there are no non inspectable areas.
- H. Mold parts shall not be fastened together with non-sanitary threaded fasteners. If sanitary threaded fasteners are used, complete disassembly for manual cleaning will be required.
- I. Textured surfaces of the mould interiors necessary for the proper draining and texture of the cheese block exterior will be evaluated on a case-by-case basis.

### 16.3. **Mold Washing Devices: (Non-Recirculating Type)**

- A. All washing devices shall be equipped with automatic temperature controls.
- B. Automatic solution concentration and addition controls are encouraged.
- C. Mold washing devices shall be constructed of stainless steel.
- D. Mold washing devices are exempt from the requirements of fabrication Sections 10.1.A, 10.12.A-G, and 10.26.E.
- E. All interior surfaces including bolted construction shall be free of all cracks and crevices. All bolted construction should be avoided. However, if for functional reasons bolted construction is required, all bolted junctures shall have no exposed threads, crevices and shall be gasketed including the bolt heads and dome nuts.
- F. The exposed threads in the interior of the washing unit shall be avoided. Except that:
  - a. Threaded fittings may be used for spray nozzles and 3-A Sanitary fittings.
- G. All internal welds of the mold washing device shall be smooth, pit, and snag free. Grinding and polishing of welds is not required.

*\* Non-Recirculating Type means a self-contained unit that is not connected to a central CIP system. The cleaning solution is dumped daily and not saved for day to day usage.*

## 17. Special Considerations for Mechanical Cleaning Systems for Large Equipment or Vessels

**Note:**

*These guidelines are not intended for the construction of small parts washers, COP tanks or cheese mold washers*

- A. All appropriate sections of these guidelines apply to large vessels or equipment designed and fabricated for mechanical cleaning. Special attention shall be placed on:
- a. Interior product contact surfaces shall be self-draining except for normal adherence. When for essential functional or safety reasons self-draining is not possible, the equipment shall be drainable.
  - b. Equipment bottoms shall be constructed so they will not sag, buckle, or prevent complete drainage. The bottom slope of equipment which is 6 feet (1829mm) in diameter or lineal distance from a drainage outlet or less shall be at least 1/4 inch (6.35 mm) per foot (305mm). The bottom slope of equipment which is greater than 6 feet (1829mm) in diameter or lineal distance from a drainage outlet shall be at least 1/2 inch (13mm) per foot (305mm).
  - c. The equipment design shall assure that all product contact surfaces will be free of cracks, crevices and dead-end areas that would impede cleaning. Also, the prescribed mechanical cleaning procedure shall be proven to effectively clean the equipment.
  - d. If mechanical cleaning is intended to clean only portions of the equipment, the operator's manual shall clearly identify those components which require disassembly, removal, and manual cleaning.
  - e. All equipment utilizing mechanical cleaning shall be designed so it can be easily opened periodically to inspect that all product contact surfaces are being adequately cleaned. Also, to provide easy access to all internal gasketed surfaces to allow gasket replacement and proper gasket maintenance.
  - f. All product contact surfaces shall be easily accessible for inspection and cleaning, either when in an assembled position or when removed. Removable parts shall be readily demountable.
  - g. All product and cleaning solution pipelines, sanitary pipe fittings, valves, instrument fittings, appurtenances, and components which are part of the equipment shall comply with applicable 3-A Sanitary Standards or 3-A Accepted Practices as appropriate.
  - h. Hinges for access ports and covers of equipment shall be demountable and readily cleanable. Continuous or piano type hinges are unsatisfactory.

- i. Mechanical cleaning spray devices installed within a product contact area to be left in place during production shall comply with the applicable 3-A Sanitary Standard 78-.
  - j. Spray devices not of sanitary design, shall be removed after cleaning is completed and shall be designed and located to allow easy installation and removal.
- B. Equipment and appurtenances included in a mechanical cleaning system for large vessels or equipment for which there are applicable 3-A Sanitary Standards shall comply with all criteria within those standards except as specifically exempted by this section.
- C. The mechanical cleaning system shall include a mechanical cleaning unit dedicated to and used exclusively for the supply and recirculation of cleaning or sanitizing solutions. The mechanical cleaning unit may be provided as an appurtenance to the equipment or may be an existing unit provided by the processing facility. The mechanical cleaning unit may include but is not limited to the following:
- a. Cleaning and sanitizing solution pump(s);
  - b. Cleaning and sanitizing solution tank(s);
  - c. Cleaning and sanitizing solution supply and return valve(s) and valve manifold(s);
  - d. Fittings;
  - e. Cleaning and sanitizing solution heat exchanger(s) or steam injector(s);
  - f. Instrument fitting(s) and;
  - g. Strainers.
- D. All cleaning and sanitizing solution contact surfaces included in recirculation cleaning circuits shall comply with the materials, design and finish requirements of product contact surfaces, except for those of castings for cleaning and sanitizing solution heat exchanger(s)/steam injector(s).
- E. A No. 2B finish shall be considered as acceptable for all cleaning and sanitizing solution contact surfaces.
- F. Castings for cleaning and sanitizing solution contact surfaces shall be at least as smooth as an Alloy Cast Institute (ACI) Surface Indicator Scale SIS-1.

*Copies of the SPECIFICATIONS FOR VISUAL INSPECTION OF CAST SURFACE FINISH as well as the SURFACE INDICATOR SCALE can be obtained from the Alloy Casting Institute Division, Steel Founders' Society of America, Cast metal Federation Building., 455 State Street, Des Plaines, IL 60016, 70829-99160.*

- G. Appurtenances, such as plug valves, instrument fittings, sample cocks, pumps, or other specified components not designed to be mechanically cleaned shall be readily demountable and easily disassembled for manual cleaning and sanitizing. Operator instruction manuals provided with the equipment shall identify all such

appurtenances or parts requiring supplemental manual cleaning and provide instructions for their disassembly.

- H. There shall be no exposed threads on cleaning and sanitizing solution contact surfaces.
- I. Cleaning and sanitizing solution pumps designated solely for mechanical cleaning recirculation shall be provided with an information plate permanently affixed to the pump, next to the name plate stating: *"This pump shall be used solely for pumping cleaning and/or sanitizing solutions"*.
- J. All valves to be included in the mechanical cleaning system shall be provided with automatic actuators which shall be programmed to pulse during the cleaning cycle so that all product contact surfaces of the sealing face and the gaskets are adequately cleaned.
- K. All manually operated valves shall be disassembled and manually cleaned during each cleaning cycle.
- L. Each separate cleaning circuit, including product and cleaning and sanitizing solution lines, shall be provided with sufficient access points, such as valves, fittings, or removable sections to make possible adequate inspection and examination of representative interior surfaces.
- M. The mechanical cleaning unit shall be designed so the suction intake of the primary circulating pump shall be flooded at all times during the cleaning cycle.
- N. Cleaning solution temperature shall be automatically controlled using a temperature control system with a response range of +/- 5 degrees F (+/- 3 degrees C). The temperature control sensor shall be located in the cleaning solution return line.
- O. There shall be no cross-connections between any cleaning / sanitizing solution circuit and any product circuit. Provisions shall be made to effectively separate and positively prevent the commingling of product and cleaning and sanitizing solutions during processing. This may be accomplished by the use of a properly designed Block, Bleed, Block valving assembly, a 3-A compliant mix-proof valve(s) or a physical disconnect.
- P. Connection of the mechanical cleaning unit and the safe water supply shall meet all installation codes of the appropriate regulatory agency.
- Q. Reverse osmosis permeate or cow water (condensed vapors removed from liquid dairy products by vacuum evaporation) produced in compliance with USDA criteria may be used as a pre-rinse directed to drain or to make up cleaning solutions. However, this water cannot be used as a final rinse or to make up sanitizing solutions unless specifically approved by the appropriate State water control regulatory authority and USDA. Approvals of this nature shall be handled on a case by case basis.

## 18. Special Considerations for Lactose Equipment

- A. Product contact surfaces upstream from the point where the dairy fats and solids are removed from the mother liquor shall meet the requirements for sanitary design, materials and fabrication of dairy processing equipment as outlined in sections 9 and 10. For example, the point of dairy fat and solids separation in a lactose centrifuge occurs as the mother liquor passes through the basket screen.
- B. Product contact surfaces from which liquids may drip, drain or be drawn into contact with the separated dairy fat and solids shall also meet the requirements for sanitary design and construction of dairy processing equipment as stated in item A above. This may include some surfaces downstream from the point where the dairy fats and solids are removed from the mother liquor.
- C. Surfaces in contact with lactose crystals **and** from which liquids will not drip, drain or be drawn into the dairy by-products may be constructed using the following criteria:
  - a. Equipment shall be constructed of non-toxic material meeting applicable Food and Drug Administration regulations. The materials shall be resistant to corrosion, pitting and flaking. The use of stainless steel is recommended but optional.
  - b. A 2B mill surface finish is accepted on lactose contact surfaces made of stainless steel. Surface finishes equivalent to a number 4 finish are not required.
  - c. Welds should be continuous, relatively smooth and free of pits, folds and snags. Where necessary for functional reasons, skip welds may be used. Grinding and polishing of welds is not required.
  - d. Minimum radii of internal angles of less than 135 degrees are not required. However, it is recommended that sharp corners be avoided.
  - e. Bolted construction and exposed threads are acceptable on dry lactose applications

## 19. Validation of Prior Acceptance

- A. An Applicant who has any model of equipment or component which has successfully completed the review and evaluation process and is published in the Accepted Equipment Listing is required to re-validate its acceptance every five years.
- B. If the applicant wishes to renew their Certificate of Acceptance, prior to the expiration of the current Certificate of Acceptance, the Applicant shall provide a letter or e-mail requesting to renew their certificate.

The letter or e-mail should contain the following:

1. Name and address of the company requesting the renewal.
2. USDA project number.
3. All model(s) and/or model number(s) listed on the current certificate.
4. Changes to the design or materials of construction.
  - a. *If there have been no changes, the letter shall reflect that no changes have been made to the design or materials of construction since the previous Certificate of Acceptance was issued.*
5. Name of person requesting the renewal for the applicant

## 20. Resolution of Reports of Noncompliance

- A. When a question arises as to whether a piece of USDA Accepted equipment complies, a user, fabricator, or other interested party may submit a letter of complaint to the Chief of the DGB via mail, facsimile, or e-mail at:

USDA, AMS, Dairy Programs Dairy Grading Branch  
 Design Review Section Room 2746 - South Building  
 1400 Independence Avenue, SW STOP 0230  
 Washington, DC 20250-0230  
 Phone: (202) 720-3171  
 Fax: (202) 720-2643  
 Email: [Dairyinfo@usda.gov](mailto:Dairyinfo@usda.gov) (Atten: Branch Chief)

- B. The letter or e-mail should contain the following:

1. The party making the complaint
2. The address and phone number of the complainant
3. The name or type of equipment or utensil in question
4. Where the equipment or utensil is located

5. The equipment or utensil manufacturer
6. The model number and serial number (if known)
7. The specific reason(s) for suspecting noncompliance (reference the standard if known)

<b><i>Examples:</i></b>
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<i>Improper finish on product contact surfaces, piano-style hinge on cover, tack welds on exterior surfaces, or unacceptable materials used for construction. (Noncompliance is not limited to the examples.)</i>
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- C. The DGB, Equipment Review Staff will act in an expeditious manner to determine the validity of the complaint, and if it is determined to be valid, who is the responsible party.

## 21. Equipment Manufacturer Responsibilities

- A. If the equipment manufacturer is determined to be the responsible party and they agree to correct the noncompliance issue, they are to submit an Equipment Review Request (See Exhibit 1) to initiate a USDA review of the corrective actions. The DGB will then determine with the manufacturer a mutually agreeable time in which to correct the noncompliance of the identified piece of equipment and, if necessary, of all like items in the marketplace with the same deficiency. While the corrections are being made, the USDA Acceptance will continue uninterrupted. Additionally, the manufacturers will provide documentation on their quality control procedures to assure that the noncompliance will not recur.
- B. If the equipment manufacturer is determined to be the responsible party and they decide not to correct the noncompliance, they will be notified that the USDA Acceptance for the equipment is withdrawn. Notification of the withdrawal of USDA Acceptance will be provided to the Food Safety and Inspection Service (FSIS), State regulatory officials, and appropriate Trade Associations.
  - C. The manufacturer is responsible for all costs associated with evaluation of the resolution of the noncompliance.

## 22. Equipment User Responsibilities

- A. If the equipment user is determined to be the responsible party and they agree to correct the noncompliance, they are to submit an Equipment Review Request (See Exhibit 1) to initiate a USDA review of the corrective actions. The DGB will determine with the user a mutually agreeable time in which to correct the noncompliance. While the corrections are being made, the USDA Acceptance will continue uninterrupted.



- B. If the equipment user is determined to be the responsible party and they decide not to correct the nonconformance, they will be notified that the USDA Acceptance for their specific piece of equipment (*Serial Number*) is withdrawn. Notification of the withdrawal of USDA Acceptance will be provided to the FSIS, State regulatory officials, appropriate Trade Associations, and the equipment manufacturer.
- C. The user is responsible for all costs associated with evaluation of the resolution of the noncompliance.

**23. Appendix**

**23.1. Stainless Steel and Equivalent Materials**

- A. Stainless steel conforming to the applicable composition ranges established by AISI A959 or *AIST Stainless Steels: A Steel Products Manual* for wrought products or by ACI for cast products, for wrought products, or by ACI for cast products, should be considered in conformance to the requirements of Section D2 herein. Cast grades of stainless-steel corresponding to types 302, 304, and 316 are designated CF-16F, CF-8, and CF-8M, respectively. The chemical compositions of these cast grades are covered by ASTM specifications A351/A351M, A743/A743M and A744/A744M

**TABLE 1**

<b>WROUGHT PRODUCTS TYPICALLY USED</b>				
<b>UNS # Grade Designation</b>	<b>ASTM Material Standard Pub. No.</b>	<b>AISI/SAE Grade Designation</b>	<b>Properties</b>	<b>ASTM Grade Designation</b>
S30300	A582	303	Free-Machining S.S.; Austenitic	303
S30400	A276 A666	304	Austenitic S.S.	304
S30403	A276 A666	304L	Low Carbon Austenitic S.S.	304L
S31600	A276 A666	316	Austenitic S.S. plus Mo*	316
S31603	A276 A666	316L	Low Carbon Austenitic S.S. plus Mo*	316L

\*Molybdenum

**TABLE 2**

CAST PRODUCTS			
UNS # Grade Designation	ASTM Material Standard Pub. No.	ACI Grade Designation	Common Names
J92500	A351 A743 A744	CF-3	Cast 304L
J92800	A351 A743 A744	CF-3M	Cast 316L
J92600	A351 A743 A744	CF-8	Cast 304
J92900	A351 A743 A744	CF-8M	Cast 316
J92180	A747	Nb7 Cu – 1	Cast 17-4 PH
J92110	A747	Nb7 Cu –2	Cast 15-5 PH
N26055	A494	CY5Sn BiM	Alloy 88
J92701	A743	CF-16F	Free Machining Austenitic S.S.

**TABLE 3 - OPTIONAL METAL ALLOYS**

Optional metal alloys having the following compositions are examples considered in compliance with Section 9 herein. (Percentages are maximums unless range is given.)

	<b>UNS N0836 7</b>	<b>UNS S2180 0</b>	<b>UNS S2016 1</b>	<b>UNS N2605 5</b>	<b>UNS N2645 5</b>	<b>UNS S1740 0</b>	<b>UNS S1550 0</b>	<b>UNS S3290 0</b>	<b>UNS R2050 0</b>	<b>UNS R5040 0</b>
	ASTM A743	ASTM A743		ASTM A494	ASTM A494	ASTM A747	ASTM A747		ASTM A560	ASTM B67
	Mat=1 Std	Mat=1 Std		Mat=1 Std	Mat=1 Std	Mat=1 Std	Mat=1 Std		Mat=1 Std	Mat=1 Std
	CN- 3MN	CF-10 SMnN		CY5Sn BiM	CW- 2M	Nb7Cu -1	Nb7Cu -2		50Cr- 50Ni	C-2
Com. Name	<b>AL- 6XN7</b>	<b>Nitroni c-60</b>	<b>Gall- Tough</b>	<b>Alloy 88</b>	<b>Hastell y-C7</b>	<b>17-4 PH</b>	<b>15-5 PH</b>	<b>329 Duplex</b>	<b>50/50</b>	<b>Titani m</b>
<b>C</b>	0.03	0.10	0.15	0.05	0.02	0.07	0.07	0.08	0.10	0.10
<b>Mn</b>	2.00	7.00-9.00	4.00-6.00	1.50	1.00	0.70	0.70	1.00	0.30	
<b>Si</b>	1.00	3.50-4.50	3.00-4.00	0.50	0.80	1.00	1.00	0.75	1.00	
<b>P</b>	0.04	0.04	0.04	0.03	0.03	0.035	0.035	0.04	0.02	
<b>S</b>	0.01	0.03	0.04	0.03	0.03	0.03	0.03	0.03	0.02	
<b>Cr</b>	20.0-22.0	16.0-18.0	15.0-18.0	11.0-14.0	15.0-17.5	15.5-17.5	14.0-15.50	23.0-28.0	48.0-52.0	
<b>Ni</b>	23.5-25.5	8.00-9.00	4.00-6.00	Balance	Balance	3.60-4.60	3.50-5.50	2.50-5.00	Balance	
<b>Mo</b>	6.0-7.0			2.0-3.5	15.0-17.5			1.00-2.00		
<b>Nb</b>						0.15-0.35	0.15-0.35			
<b>Cu</b>	0.75					2.50-3.20	2.50-3.20			
<b>N</b>	0.18-0.26	0.08-0.18	0.08-0.20			0.05	0.05		0.30	0.03
<b>Fe</b>	Balance	Balance	Balance	2.00	2.00	Balance	Balance	Balance	1.00	0.30
<b>Sn</b>				3.0-5.0						
<b>Bi</b>				3.0-5.0						
<b>W</b>					1.0					
<b>Ti</b>									0.50	Balance
<b>Al</b>									0.25	
<b>Other</b>										H = 0.015 O = 0.25

*Metal alloys or metals other than the those noted in the previous table may be as corrosion resistant as 300 Series Stainless Steel. This may be shown when metal alloys or metals are tested in accordance with ASTM G31 Laboratory Immersion Corrosion Testing of Metals and have a corrosion rate of less than 10.0 mil per year. The test parameters, including the type of chemical(s), their concentration(s), and temperature(s), should be representative of cleaning and sanitizing conditions used in equipment. Alloys containing lead, leachable copper, or other toxic metals are not to be used.*

### 23.2. Electroless Nickel Alloy

A. An electroless nickel alloy coating having the following composition is deemed to be in compliance with section 8.2.10 herein:

1. Nickel - 90% minimum,
2. Phosphorous - 6% minimum and 10% maximum as a supersaturated solution of nickel phosphide in nickel,
3. Trace amounts of carbon, oxygen, hydrogen, and nitrogen,
4. No other elements allowed.

**TABLE 4 - Linear Conversion (in. to mm)**

IP (in.) fraction	IP (in.) decimal	SI (mm)	IP (in.) fraction	IP (in.) decimal	SI (mm)	IP (in.) fraction	IP (in.) decimal	SI (mm)
1/32	0.03125	0.794	33/64	0.515625	13.10	1	1	25.40
3/64	0.046875	1.19	17/32	0.53125	13.49	1-1/4	1.25	31.75
1/16	0.0625	1.59	35/64	0.546875	13.89	1-1/2	1.50	38.10
5/64	0.078125	1.98	9/16	0.5625	14.29	1-3/4	1.75	44.45
3/32	0.09375	2.38	37/64	0.578125	14.68	2	2	50.80
7/64	0.109375	2.78	19/32	0.59375	15.08	2-1/4	2.25	57.15
1/8	0.125	3.18	39/64	0.609375	15.48	2-1/2	2.50	63.50
9/64	0.140625	3.57	5/8	0.625	15.88	2-3/4	2.75	69.85
5/32	0.15625	3.99	41/64	0.640625	16.27	3	3	76.20
11/64	0.171875	4.37	21/32	0.65625	16.67	3-1/4	3.25	82.55
3/16	0.1875	4.76	43/64	0.671875	17.07	3-1/2	3.50	88.90
13/64	0.203125	5.16	11/16	0.6875	17.46	3-3/4	3.75	95.25
7/32	0.21875	5.56	45/64	0.703125	17.86	4	4	101.6
15/64	0.234375	5.95	23/32	0.71875	18.26	4-1/2	4.50	114.3
1/4	0.25	6.35	47/64	0.734375	18.65	5	5	127.0
17/64	0.265625	6.75	3/4	0.75	19.05	5-1/2	5.50	139.7
9/32	0.28125	7.14	49/64	0.765625	19.45	6	6	152.4
19/64	0.296875	7.54	25/32	0.78125	19.84	7	7	177.8
5/16	0.3125	7.94	51/64	0.796875	20.24	8	8	203.2
21/64	0.328125	8.33	13/16	0.8125	20.64	9	9	228.6
11/32	0.34375	8.73	53/64	0.828125	21.03	10	10	254.0
23/64	0.359375	9.13	27/32	0.84375	21.43	12	12	304.8
3/8	0.375	9.52	55/64	0.859375	21.83	15	15	381.0
25/64	0.390625	9.92	7/8	0.875	22.22	18	18	457.2
13/32	0.40625	10.32	57/64	0.890625	22.62	20	20	508.0

27/64	0.421875	10.72	29/32	0.90625	23.02	24	24	609.6
7/16	0.4375	11.11	59/64	0.921875	23.42	25	25	635.0
29/64	0.453125	11.51	15/16	0.9375	23.81	30	30	762.0
15/32	0.46875	11.91	61/64	0.953125	24.21	35	35	889.0
31/64	0.484375	12.30	31/32	0.96875	24.61	36	36	914.4
½	0.500	12.70	63/64	0.984375	25.00	40	40	1016.0

**TABLE 5 - Linear Conversion (in. to cm; ft to m)**

IP (in.)	SI (cm)	IP (in.)	SI (cm)	IP (ft)	SI (m)	IP (ft)	SI (m)
45	114	75	190	10	3.05	35	10.7
48	122	80	203	12	3.66	36	11.0
50	127	84	213	15	4.57	40	12.2
55	140	85	216	18	5.49	50	15.2
60	152	90	229	20	6.10	60	18.3
65	165	95	241	24	7.32	70	21.3
70	178	96	244	25	7.62	80	24.4
72	183	100	254	30	9.14	90	27.4

**TABLE 6 - Volumetric Capacity Conversion (gal to L)**

IP (gal)	SI (L)	IP (gal)	SI (L)	IP (gal)	SI (L)	IP (gal)	SI (L)
1	3.78	200	757.0	1,000	3,785	7,500	28,388
5	18.93	300	1,136	1,500	5,678	10,000	37,850
10	37.80	400	1,514	2,000	7,570	20,000	75,700
15	56.80	500	1,892	2,500	9,462	30,000	113,550
20	75.70	600	2,271	3,000	11,355	40,000	151,400
25	94.60	700	2,650	3,500	13,248	50,000	189,250
100	378.50	800	3,028	4,000	15,140	75,000	283,875
150	567.80	900	3,406	5,000	18,925	100,000	378,500
175	662.40						

**TABLE 7 - Flow Rate Conversion (gpm to Lpm)**

<b>IP (gpm)</b>	9.4	24.0	43.0	69.0	102.0	182.0	5 ft/s
<b>SI (Lpm)</b>	35.6	90.8	163.0	261.0	386.0	689.0	1.5 m/s

## 24. **Instruction Handbook, Maintenance, and Cleaning**

A. The instruction handbook includes the following items:

### 24.1. **Installation of the Equipment and Associated Equipment**

A. Information is provided so that, after the equipment is installed, it maintains its hygienic integrity (e.g., drainability and Inspectability).

### 24.2. **Instructions for Use**

A. Measures are described on the use of the equipment so that when used correctly the product is not exposed to factors that can lead to contamination.

### 24.3. **Maintenance**

A. A system of measures is recommended to ensure that the hygienic integrity of the equipment is maintained during the intended lifetime. This information should include specific gasket, seal or O-ring materials where they are used because of product characteristics (e.g. high fat or high acid) or operational characteristics (e.g. vacuum or steam applications or when used to create a bacterial tight seal between product contact surfaces and non-sanitary threads).

### 24.4. **Cleaning**

A. The instructions specify typical routine procedures for cleaning, sanitizing, rinsing, and inspection for cleanliness and, where appropriate, sterilization. Recommended cleaning and sanitizing procedures, materials, implements, and agents should be specified. Recommended cleaning and sanitizing procedures, materials, implements, and agents shall be compatible with the materials of construction. Where dismantling is required, specific instructions shall be provided.

## 24.5. Special Cleaning Instruction

- A. Cleaning of areas of the equipment that are not to be subjected to normal washdown or wet cleaning. (*e.g. film unwind areas and container forming assemblies*).
- B. Type of cleaning chemicals and cleaning regimen that is to be used on the materials of construction for the piece of equipment.
- C. Areas of the equipment or assemblies that require disassembly and manual cleaning.
- D. Special tools that are to be used for cleaning of the equipment. (*e.g. no metal scrapers, etc*)

25. **History**

Version	Description/[Reason]
Current Document: CPPS-00.00.00.00-POP-CF-M-v20201110	
<b>DATE</b>	20201110
Previous Document(s)	
USDA Guidelines for The Sanitary Design and Fabrication of Dairy Processing Equipment (2001)	