

MILK AND MILK PRODUCT EQUIPMENT

A GUIDELINE FOR EVALUATING CONSTRUCTION
(Revised August 2000)

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



FOREWORD

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

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

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BACKGROUND

Under the Grade A milk inspection program, approval of equipment is the responsibility of the state or local regulatory agency which issues the Grade A permit to the plant or farm in which the equipment is to be installed. In the case of a milk tank truck, or equipment to be installed on a milk tank truck, that approval authority rests with the agency which issues the license or permit or is otherwise responsible for regulating the sanitary construction aspects of the milk tank truck.

The United States Food and Drug Administration (FDA)/Public Health Service's (PHS) role in equipment evaluation is to provide technical assistance to state milk regulatory officials under the authority of various sections of the Public Health Service Act (including sections 301, 311, 314, and 361).

FDA also has a responsibility to provide general technical leadership to the States as specified in the "Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program for Certification of Interstate Milk Shippers..." and a 1977 Memorandum of Understanding (MOU) which obligates the FDA to abide by those Procedures.

To fulfill this responsibility in the area of equipment review, the FDA has responded to state requests for FDA technical opinions about whether specific equipment meets the intent of the Grade A Pasteurized Milk Ordinance. States have used these opinions to assist them in their decisions about whether to approve specific equipment for use under the Grade A milk safety program.

FDA's responses to these state requests have included written technical opinions and M-b coded memorandums. M-b coded memorandums are normally technical opinion letters regarding a specific piece of equipment intended for widespread use. FDA has also provided M-b memorandums for new equipment at the request of dairy equipment manufacturers and distributors.

II. EQUIPMENT REVIEW -- STRATEGY

1. The State

(a). It is intended that states will review:

- (1). equipment not described in this guideline as a direct FDA responsibility.**
- (2). compliance of equipment or systems which claim to meet a "3A" Standard or Practice (whether or not a "3A" symbol is involved).**

As in the past FDA will, upon request, assist states in conducting these equipment evaluations.

(b). A state making an equipment review:

- (1). may choose to collect the needed information and perform these reviews themselves,**
- or**
- (2). may require the manufacturer, distributor or other interested third party to prepare all, or any part(s) of, such a review, including gathering any needed supporting technical materials.**

In either case, conclusions regarding acceptability of the equipment should be made by the state.

A state equipment review should include a copy of the completed checklist, the state's conclusions and copies of the technical information which the state used to document items on the checklist and substantiate their conclusions.

States are encouraged to share their results with other states by providing copies (including the technical information they have gathered) to their FDA field milk specialist for review and through them to Milk Safety Branch for nationwide distribution.

(c). Reviews made by other states:

States are encouraged to accept the results of equipment reviews made by other states after FDA has verified them.

2. FDA

(a). FDA will continue to provide equipment evaluations at the request of states, or on its own initiative regarding those aspects of equipment that:

- (1). Are technically precedent setting;**
- (2). Are needed to resolve a difference of opinion or clarify a point of confusion;**
- (3). Involve engineering or computer skills not normally available in a state regulatory agency; and/or**
- (4). Involve types of instrumentation for critical public health controls of pasteurization or aseptic processing equipment for which FDA has not provided review criteria.**

(b). FDA milk specialists will assist states with the technical aspects of state equipment reviews as needed and will receive copies of the completed state reviews.

FDA milk specialists will, with input as appropriate from Milk Safety Team (MST) and Food Technology Branch, validate the state equipment review to confirm that the technical information provided adequately supports the state's conclusions. After this validation step has been completed, the FDA milk specialist will distribute copies of this information to state rating and regulatory officials in their region and to the MST.

FDA milk specialists will also distribute the results of equipment reviews made by FDA and by states in other regions (as provided to them by FDA Milk Safety Team) to the states within their region.

- (c). The MST will provide states, FDA milk specialists and other interested parties with training, training materials and guidance documents, as needed, to be able to perform, and/or review, evaluations of equipment using a nationally uniform technical standard.

MST will serve as the central collection point for completed state equipment reviews submitted by states through the FDA milk specialists. With the FDA milk specialists, MST will verify the conclusions of state equipment reviews and, upon concurrence, will distribute the conclusions and supporting technical materials to FDA milk specialists in all regions. MST will also publish the conclusions in the Interstate Milk Shippers List.

3. This Guideline

The detailed technical information in this guideline (appendices 1,2 and 4) and the check list provided (appendix 3) will aid state regulatory officials and other interested individuals in making nationally uniform evaluations of the materials, construction and fabrication of equipment used to collect, convey, store, transport, process and package Grade A dairy products.

This guideline will also provide manufacturers with knowledge of what documentation reviewers might expect them to provide in order to verify the acceptability of materials, construction and fabrication.

In addition, the "Specific Applications" section of this guideline will provide states and others with the direction they will need to obtain the specific information regarding the public health safeguards which are required in many types of systems and components of systems. This is the information which they will need to either make or review an evaluation of systems and components of systems and to determine whether such a review should be conducted by FDA.

NOTE: If a technical document (such as an ASTM standard, military specification or a Code of Federal Regulation citation) is referenced in this guideline, the most current revision or edition of that document should be used to make the review

4. Specific Applications

- (a).Types of equipment reviews

Dairy equipment can be reviewed as:

(1). A stand alone item, such as a valve;

or

(2). A component of a larger system, such as two valves used as the flow diversion device in a high temperature short time pasteurizer;

or

(3). A system, such as a pasteurizer, which has multiple component parts.

(b). Guidance for Specific Applications

In the case of systems and components of systems there are often additional public health requirements which must be satisfied in order for the equipment to be considered acceptable.

Verification that any such additional public health safe guards will be appropriately provided for is a vital part of the equipment review process for systems and components of systems.

Additional public health safeguards are specified for many applications such as pasteurization and aseptic processing equipment, aseptic and near aseptic packaging machines, milk condensing and drying systems, membrane processing systems such as ultra-filtration (UF) or reverse osmosis (RO) systems, various types of milking systems for harvesting milk from dairy animals, mechanical cleaning systems, and systems which produce culinary steam or air under pressure which is directed at a product contact surface.

General requirements for these and many other specific applications can be found in the current editions of the "Grade A Pasteurized Milk Ordinance..." (PMO) and the "Grade A Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade A Pasteurized Milk Ordinance..." (DMO).

Additional requirements for various applications can be found in various FDA coded memorandums and other technical correspondence. FDA Regional Milk Specialists and MSB can help direct state equipment reviewers and others to appropriate guidance documents.

III.
APPENDIX 1
--3A and 3A Symbols

- A. 3A Standards and Practices**
- B. The 3A Symbol and This Guide**

A. 3A Standards and Practices

While 3A Standards and Practices are not mandatory under the Grade A milk safety program, equipment which meets a current 3A Standard or Practice meets the requirements of the PMO.

If a 3A Standard or Practice provides a way to accomplish something not previously allowed under the Grade A milk safety program (such as the use, cleaning, and sterilization of multi-use woven wire screens in milk packaging machine filler valves), equipment constructed and operated in a manner which meets such a 3A exception is considered to be in compliance, unless or until FDA specifies otherwise.

B. The 3A Symbol and This Guide

Some dairy equipment is marked with a 3A symbol which indicates that the equipment manufacturer has certified that this piece of equipment meets a specific 3A Standard. (No symbols are issued for equipment which complies with a 3A Practice).

Three (3) concerns to equipment reviewers regarding equipment bearing the 3A symbol are:

- 1. Verification that equipment bearing a 3A symbol meets the standard under which the symbol was issued rests with milk sanitarians and others who deal with this equipment in the field.**

Equipment reviewers should evaluate the equipment against the specific standard, which it claims to meet, especially if it appears that the equipment does not meet the general requirements of the PMO.

If the reviewer finds that the equipment does not meet the standard under which the symbol was issued, a challenge should be filed with the 3A Symbol Council. The forms needed to file such a challenge are available from the 3A Symbol Council, from FDA Milk Specialists and from the Milk Safety Team in Washington D.C.

If the reviewer finds that equipment meets a current 3A Standard but violates the construction requirements of the PMO, the reviewer should immediately notify their FDA Regional Milk Specialist and through them, the Milk Safety Team.

- 2. Meeting a specific 3A Standard does not assure that the equipment meets the requirements for all possible uses.**

One example of this might be a valve which meets the compression valve standard (and is allowed to bear the 3A Symbol for that standard) but does not meet the specific requirements needed to be part of a block and bleed system used to separate milk products from cleaning solutions.

- 3. 3A Standards are rewritten as needed. Older equipment which met a previous 3A Standard and which bears a 3A Symbol, should be evaluated using the current PMO requirements, not the revised 3A Standard for that type of equipment.
Older equipment, which meets the PMO but no longer meets a current 3A Standard, is in compliance.**

Older equipment which is in violation of the PMO, is not in compliance regardless of the presence of a 3A Symbol, i.e., equipment with "white Dairy Metal" (containing 5% lead) in a product contact area.

III

APPENDIX 2— Materials, Fabrication, and Documentation

- A. Materials**
 - (1) Metals
 - (2) Non Metals
 - (3) Sterilization
 - (4) Non-product Contact Surfaces

- B. Fabrication**
 - (1) Surface Texture
 - (2) Permanent Joints
 - (3) Bonded Materials
 - (4) Coatings
 - (5) Cleaning and Inspectability
 - (6) Draining
 - (7) Fittings, Valves, Instruments and Similar Appurtenances
 - (8) Sanitary Tubing
 - (9) Gaskets
 - (10) Radii
 - (11) Threads
 - (12) Perforated Product Contact Surfaces
 - (13) Springs
 - (14) Multiple Use Woven Material
 - (15) Sterilization Systems
 - (16) Shafts and Bearings
 - (17) Openings and Covers
 - (18) Overhead Shielding
 - (19) Agitators
 - (20) Support or Mounting
 - (21) Slabs or Islands
 - (22) Air Venting
 - (23) Guards and Other Safety Devices
 - (24) Non-product Contact Surfaces

- C. Documentation**
 - (1) Engineering Design and Technical Construction File (EDTC)
 - (2) EDTC Content
 - (3) Confidentiality

- D. Glossary**

- E. Sources of Standards Referenced in Footnotes**

A. MATERIALS

(1). Metals

(a). Stainless Steel

Product contact surfaces should be of stainless steel of the American Iron and Steel Institute (AISI) 303, 304, 316 Series³ or corresponding Alloy Cast Institute (ACI) types.⁴ Cast grades of stainless steel corresponding to types 303, 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.⁵ Metal which under conditions of intended use is at least as corrosion resistant as stainless steel of the foregoing types, and is nontoxic and nonabsorbent, can also be used, except that:

Equipment may also be made of stainless steel of the AISI 400 Series that is made as corrosion resistant as AISI 300 Series by surface treatment or coating(s) or made of nontoxic, nonabsorbent metal that is as corrosion resistant, under the conditions of intended use, as stainless steel of the AISI 300 Series.

(b). Optional Metal Alloys

Metal alloy of the following types may be used but only in applications requiring disassembly and manual cleaning. (See table 1)

Equipment made of optional metal alloy may have product contact surfaces modified by surface treating or coating.

(c). Electroless Nickel Alloy Coating

An electroless nickel alloy coating having the following composition is acceptable:

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

Equipment to be manually or mechanically cleaned may be covered by an engineering coating of electroless nickel alloy conforming to the applicable provisions of military specification MIL-C-26074 E, as amended.⁶

Equipment may also be made of other nontoxic structurally suitable metal(s) that have their product contact surfaces modified by surface coating(s).

TABLE 1 -- OPTIONAL METAL ALLOYS

	UNS NO8367	UNS S21800	UNS S20161	UNS N26055	UNS N26455	UNS S17400	UNS S15500	UNS S32900	UNS R20500	UNS R50400
	ASTM A743 Grade CN-3MN	ASTM A743 Grade CF-10 Smnn		ASTM A494 Grade CY5SnBiM	ASTM A494 Grade CW-2M	ASTM A747 Grade CB7Cu-1	ASTM A747 Grade CB7Cu-2		ASTM A560 Grade 50Cr-50Ni	ASTM B67 Grade C-2
C	0.03	0.10	0.015	0.05	0.02	0.07	0.07	0.20	0.10	0.10
Mn	2.00	7.00-9.00	4.00-6.00	1.5	1.00	0.70	0.70	1.00	0.30	
Si	1.00	3.50-4.50	3.00-4.00	0.5	0.80	1.00	1.00	0.75	1.00	
P	0.040	0.040	0.040	0.03	0.03	0.035	0.035	0.040	0.02	
S	0.010	0.030	0.040	0.03	0.03	0.03	0.03	0.030	0.02	
Cr	20.0-22.0	16.00- 18.00	15.0-18.0	11.0-14.0	15.0-17.5	5.50-17.7	14.0-15.50	23.0-28.0	48.0-52.0	
Ni	23.5-25.5	8.00-9.00	4.00-6.00	Balance	Balance	3.60-4.60	4.50-5.50	2.50-5.00	Balance	
Mo	6.0-7.0			2.0-3.5	15.0-17.5			1.00-2.00		
Cb						0.15-0.35	0.15-0.35			
Cu	0.75					2.50-3.20	2.50-3.20			
N	0.18- 0.26	0.08-0.18	0.08-0.20			0.05	0.05		0.30	
Fe	Balance	Balance	Balance	2.00	2.00	Balance	Balance	Balance	1.00	0.30
Sn				3.0-5.0						
Bi				3.0-5.0						
W					1.0					
Ti									0.50	Balance
Al									0.25	
other										H=0.015 N=0.03

NOTE: Metal alloys or metals other than the above 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 20 mil per year. The test parameters such as the type of chemical(s), their concentration(s) and temperature(s) should be representative of cleaning and sanitizing conditions used in dairy equipment. Alloys containing lead, leachable copper or other toxic metals should not be used.

(d). Solder

Solder, when used, should be silver bearing solder and should be corrosion resistant, free of cadmium, lead and antimony, nonabsorbent, and should 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).

(e). Aluminum

Aluminum is satisfactory for certain dry products applications. Aluminum may be used for liquid or high moisture content product contact surfaces only when a specific functional requirement exists and the parts are not subjected to strong caustic cleaning solutions or to the corrosive action of dissimilar metals.

The aluminum type chosen for the application shall be demonstrated to be appropriate and acceptable for the intended use. (Provisions have been made in existing 3-A Standards for Aluminum Association designations 5052, 6061, 6063, A-360, A-380, A-319, A-315G, and C-413, Danish Standards DS#3002 and #4261, and ASTM standards B179, and S12c for certain specified uses.)

(2). Nonmetals

(a). Rubber and rubber-like materials may be used where functionally appropriate.

Rubber and rubber-like materials when used for the above specified application(s) should conform with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-Like Materials Used as Product Contact Surfaces in Dairy Equipment”, Number 18- (or equivalent).

(b). Plastic materials may be used where functionally appropriate.

Plastic materials when used for the above specified application(s) should conform with the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastic Materials Used as Product Contact Surfaces for Dairy Equipment,” number 20- (or equivalent).

When used in sight and/or light openings and as direct reading gauge tubes, plastic should be of a clear, heat resistance type.

(c). Durability of rubber and plastic

Rubber and rubber-like materials and plastic materials having product contact surfaces should be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization).

(d). Bonded Rubber

The final bond and residual adhesive, if used, on bonded rubber and rubber-like materials and bonded plastic materials should be nontoxic⁷.

(e). Carbon/Ceramic

Where materials having certain inherent functional purposes are required for specific, limited applications, carbon and/or ceramic materials may be used. Carbon and/or ceramic materials should be inert, nonporous, nontoxic, nonabsorbent, insoluble, resistant to scratching, scoring, and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization), except that ceramic material used for Ph probe sensors and ceramic filter modules for ultrafiltration (UF) or reverse osmosis (RO) processes may be permeable only to the extent necessary to accomplish their function.

(f). Glass

Glass may be used in sight and/or light openings, as direct reading gauge tubes and in dairy farm milking pipelines. When used, it should be of a clear, heat-resistant, non-toxic type.

(g). Paper

Single service sanitary type gaskets may be used on parts which must be disassembled for daily cleaning.

(3). Sterilization

In a processing system to be sterilized by heat and operated at a temperature of 250EF (121EC) or higher, all materials having a product contact surface(s) should be such that they can be: (1) sterilized by saturated steam or water under pressure (at least 15.3

psig or 106 kpg) at a temperature of at least 250E F (121EC) or higher; and (2) operated at the temperature required for processing.

(4). Materials for Non-product Contact Surfaces

Materials for non-product contact surfaces should be of corrosion-resistant material or material that is rendered corrosion resistant. If coated, the coating used should adhere. All non-product contact surfaces should be relatively nonabsorbent, durable, and cleanable. Parts removable for cleaning having both product contact and non-product contact surfaces should not be painted.

B. FABRICATION

(1). Surface Texture

All product contact surfaces should have a finish at least as smooth as No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form. Surface finish equivalent to 150 grit or better as obtained with silicon carbide, properly applied on stainless steel sheets, constitutes a No.4 ground finish. A maximum Ra of 32 micro-inch (0.80), when measured according to the recommendations in ANSI/ASME B46.1⁸ - Surface Texture, is considered to be equivalent to a No. 4 finish.

(2). Permanent Joints

(a). Welding

Where welding is involved, the carbon content of the stainless steel should not exceed 0.08%.

All permanent joints in metallic product contact surfaces should be continuously welded. Welded areas on product contact surfaces should be at least as smooth as No. 4 ground finish on stainless steel sheets, and be free of imperfections such as pits, folds, and crevices when in the final fabricated form except that:

(b). Soldering

In such cases where welding is impractical, soldering, may be employed where necessary for essential functional reasons.

Silver bearing solder may be used for producing fillets for minimum radii or other appropriate functional purposes.

(c). Press fits or shrink-fits

Press-fits or shrink-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 of these fits the outside diameter of the part being inserted is greater than the inside diameter of the hole.

In the case of the press-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 member is forced in.

In shrink-fits, the diameter of the inner member is reduced by chilling it to a low temperature. Dry ice is commonly used to shrink the inner member. Heat may also be applied to the outer member of the press-fit. Less assembly force is required for this type of fit.

The design of these fits depends on a variety of factors. The designer should follow recommended practices to assure that a ~~joint is produced~~ **joint is produced**. A recognized authoritative reference is Machinery's handbook published by Industrial Press Inc., 200 Madison Avenue, New York, NY 10157.

(d). Surface finish

Press-fitting, shrink-fitting or soldering should produce contact surfaces which are at least as smooth as No. 4 ground finish on stainless steel sheets and which are free of imperfections such as pits, folds and crevices.

(3). Bonded Materials

Bonded rubber and rubber-like materials and bonded plastic materials having product contact surfaces should be bonded in a manner that the bond is continuous and mechanically sound so that when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization if applicable) the rubber and rubber-like material or the plastic material does not separate from the base material to which it is bonded.

(4). Coatings

Coatings, if used, should be free from surface delamination, pitting, flaking, spalling (chipping), blistering and distortion when exposed to the conditions encountered in the environment of intended use and in cleaning and bactericidal treatment (or sterilization).

(5). Cleaning and Inspectability

Equipment that is to be mechanically cleaned should be designed so that the product contact surfaces and all nonremovable appurtenances thereto can be mechanically cleaned and are easily accessible and readily removable for inspection. Removable parts shall be readily demountable employing simple hand tools, which are available to operating or cleaning personnel; except that equipment that is to be CIP cleaned should have representative product contact surfaces easily accessible for inspection.

Product contact surfaces, not designed to be mechanically cleaned, should be accessible for cleaning and inspection when in an assembled position or when removed.

Appurtenances having product contact surfaces should be readily removable using simple hand tools or they should be cleanable when assembled or installed and should be easily accessible for inspection.

(6). Draining

All product contact surfaces, when properly installed, should be self-draining except for normal clingage. However, if the product contact surfaces are not self-draining, they should have sufficient pitch to suitable drain points so they can be drained.

(7). Fittings, Valves, Instruments and Similar Appurtenances

Sanitary fittings and connections which conform with the appropriate 3-A Sanitary Standards are acceptable. All other fittings must be reviewed using the criteria in this document.

The thermometer connections and/or openings, if provided or required, should be located so that the thermometer is not influenced by a heating or cooling jacket.

If the fittings for temperature sensing devices do not pierce the tank lining, either the temperature sensing element receptacles should be securely attached to the exterior of the lining or means to attach the temperature sensing element(s) securely to the exterior of the lining should be provided.

The bulb of the temperature sensing devices, in tanks and similar storage vessels, should be located to permit the registering of the temperature of the product when the tank contains no more than 20% of its capacity.

(8). Sanitary Tubing

All metal tubing should conform with the applicable provisions for welded sanitary product pipelines found in the 3-A Accepted Practices for Permanently Installed Product and Solution Pipelines and Cleaning Systems Used in Milk and Milk Product Processing Plants , Number 605- or equivalent and with the 3-A Sanitary Standards for Polished Metal Tubing for Dairy Products , Number 33- or equivalent.

Tubing used to convey product should be stainless steel tubing, except that flexible rubber or plastic tubing may be used for the following applications:

(a). Loading or unloading of tank trucks; or

(b). Short flexible jumpers when needed for a functional reason such as joining a pipeline to a weigh tank.

(9). Gaskets

Gaskets having a product contact surface should be removable or bonded.

Grooves in gaskets should be no deeper than their width unless the gasket is readily removable and reversible for cleaning, (i.e., storage tank door gaskets).

Gasket retaining grooves in product contact surfaces for removable gaskets should not exceed 1/4 in. (6.35 mm) in depth or be less than 1/4 in. (6.35 mm) wide except those for standard O-rings smaller than 1/4 in. (6.35 mm) and those allowed in the 3-A Standard for Sanitary Fittings , Number 63-.

(10) Radii

All internal angles 135° or less on product contact surfaces, should have a minimum radii of 1/4 in. (6.35 mm) except that:

(a). Minimum radii for fillets of welds where head(s) and the side wall(s) of tanks join should not be less than 3/4 in. (19.05 mm).

(b). Smaller radii may be used when they are required for essential functional reasons. In no case should such radii be less than 1/32 in. (0.794 mm).

(c). The radii in gasket retaining grooves or grooves in gaskets, should be not less than 1/16 in. (1.59 mm) except for those standard, 1/4 in. (6.35 mm) and smaller O-rings, and those provided for in the 3-A Standards for Sanitary Fittings , Number 63-.

(d). The radii in grooves for standard 1/4 in. (6.35 mm) and smaller O-rings should not be at least:

0.016 in. (0.406 mm) for 1/16 in. (1.80 mm) O-rings

0.031 in. (0.787 mm) for 3/32 in. (2.65 mm) O-rings

0.031 in. (0.787 mm) for 1/8 in. (3.55 mm) O-rings

0.062 in. (1.575 mm) for 3/16 in. (5.30 mm) O-rings

0.094 in. (2.388 mm) for 1/4 in. (7.00 mm) O-rings

(11). Threads

There should be no threads on product contact surfaces accept where necessary for non-permanent joints in piping and for making various attachments to equipment.

In such case(s) the threads should conform with the drawing, Fig. (1), Acceptable Sanitary Thread . The thread angle should be not less than 60° and with not more than eight threads to the inch (25.4 mm), nor less than 5/8 in. (15.88 mm) major basic diameter. The length of the nut should not exceed three-quarters of the basic thread diameter. The nut should be of the open type. Equipment with exposed threads as described above should be manually cleaned.

Equipment with enclosed threads, (such as acorn nuts used to attach impeller blades to pump shafts), should be designed for mechanical cleaning.

(12). Perforated Product Contact Surfaces

Perforations in product contact surfaces may be round, square, or rectangular. If round the holes should be a minimum of 1/32 in. (0.794 mm) in diameter. If square, or rectangular, the least dimension should be no less than 0.020 in. (0.51 mm) with corner radii of no less than 0.0050 in. (0.13 mm).

All perforations should be free of burrs.

(13). Springs

Any coil spring having product contact surfaces should have at least 3/32 in. (2.38 mm) openings between coils, including the ends when the spring is in the free position.

(14). Multiple Use Woven Material

Multiple use woven material may not be used unless provided for in a 3A Standard or Practice or in the Grade A Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade A Pasteurized Milk Ordinance... Examples of these exceptions include:

- woven cloth bag type filters in specific parts of dry milk or whey product handling systems; and
- autoclavable woven wire screens used in some packaging machine filler valves.

(15). Sterilization Systems

Equipment used in a processing system to be sterilized by heat and operated at a temperature of 250EF (121EC) or higher should comply with the following additional criteria:

- (a). The construction should be such that all product contact surfaces can be; (1) sterilized by saturated steam or water under pressure of at least 15.3 psig (106 kPa) at a temperature of at least 250EF (121EC); and (2) operated at the temperature required for processing.
- (b). Product contact surfaces to be used in such a processing system, which is designed so that the system is automatically shut down if the product pressure in the system becomes less than that

of the atmosphere and cannot be restarted until the system is re-sterilized, should have a steam or other sterilizing medium chamber surrounding the product contact surfaces.

(c). Where steam or other sterilizing medium is used, the steam lines or other sterilizing medium lines can be securely fastened to the equipment.

The equipment should be constructed so that the steam or other sterilizing medium chamber can be accessible for inspection.

(d). The seal(s) designed to be used in a processing system to be sterilized by heat and operated at a temperature of 250EF (121EC) or higher should be between the product contact surface and the steam or other sterilizing chamber.

(16). Shafts and Bearings

Shafts entering equipment outside of a milk room or processing area should have a seal of the packless type and sanitary design, and should be readily accessible for cleaning and inspection.

Where a shaft passes through a product contact surface, in a milk room or processing area, the portion of the opening surrounding the shaft should be protected to prevent the entrance of contaminants.

Bearings having a product contact surface should be of a nonlubricated type.

Lubricated bearings, including the permanent sealed type, should be located outside the product contact surface with at least 1 in. (25.4 mm) clearance open for inspection between the bearing and any product contact surface unless specifically provided for in a 3-A standards.

(17). Openings and Covers

A manhole(s) should be provided where necessary to allow larger equipment to be inspected. The inside dimensions of the manhole should not be less than 15in. by 20 in. (381.0 mm by 508.0mm) if oval, or 18 in. (457.2 mm) in diameter if round. The upper edge of a top-entering manhole opening should not be less than 3/8 in. (9.52 mm) higher than the surrounding area and if an exterior flange is incorporated in it, it should slope and drain away from the opening. The sleeve or collar of a manhole opening for an inside swing-type manhole cover should be pitched so that liquids cannot accumulate.

The manhole cover should be the inside or outside swing type. If the cover swings inside, it should also swing outside away from the opening for disassembly and cleaning. No threads or ball joints should be employed within the product zone to attach the manhole cover and its appendages. The manhole cover and its appendages should be removable with simple hand tools. The manhole cover for a top-entering manhole opening should be of the outside swing type. Removable covers for tanks and similar vessels should extend at least 3/8 in. (9.52 mm) downward over the edge of the vessel.

Sight and light openings, when provided, should be of such design and construction that the inner surfaces drain inwardly; and if designed for mechanical cleaning, the inner surface of the glass (or plastic) should be pitched so that liquids cannot accumulate. The glass (or plastic) should be readily removable. The inside diameter of the openings should be at least 3/4 in. (95.25 mm).

If provided, sight and light openings which conform with the applicable provisions of the 3-A Sanitary Standards for Sight and/or Light Windows and Sight Indicators in Contact with Milk and Milk Products , Number 65- are acceptable.

Openings through a fixed bridge; either hinged or removable covers, to which connections are not permanently attached, should be flanged upward at least 3/8 in. (9.52 mm).

All sanitary pipelines and other appurtenances entering through the cover should be fitted with a sanitary umbrella deflector that overlaps the edges of the opening.

Other openings, with the exception of agitator openings, should have a removable cover, which should be downwardly flanged to make close contact with the upper edges of the upwardly flanged opening in the cover surface. When the removable cover is located in the main cover, it should remain in position when the main cover is raised.

Covers and bridges should pitch to an outside edge (s).

(18). Overhead Shielding

Equipment should be provided with overhead shielding adequate to ensure that all product contact surfaces of the equipment and all product contact surfaces of dairy product packaging, which may travel through the equipment, are adequately protected from contamination.

(19). Agitators

Agitators which comply with 3-A Standard....., Number 74- are considered in compliance. All others should meet the following:

(a). Agitator shaft openings through the bridge or top enclosure should have a minimum diameter of 1 in. (25.4 mm) on equipment which requires removal of the agitator shaft for cleaning; or be of a diameter that will provide a 1 in. (25.4 mm) minimum annular cleaning space between the agitator shaft and the inside surface of the flanged opening on equipment which does not require removal for cleaning. Shielding should be provided which effectively protects against the entrance of dust, oil, insects, and other contaminants through the annular space around the agitator shaft. Any product contact or splash contact surfaces on the shielding should be readily accessible for inspection.

(b). The agitator driving mechanism, if provided, should be securely mounted in a position that will provide a minimum distance of 4 in. (101.6 mm), measured from the driving mechanism housing, excluding bearing bosses and mounting bosses, to the nearest surface of the equipment; and in such a manner that all surfaces of the equipment under or adjacent to the driving mechanism should be readily accessible for cleaning and inspection.

(c). The agitator should be of sufficient size and power to provide the needed result. The agitating device should be readily cleanable and should be one of the following types:

Top entering nonremovable type agitators should be readily accessible and cleanable. There should be at least a 1/2 in. (12.70 mm) space between the nonremovable agitator and the bottom of the lining, unless the agitator is mounted on a hinged-type cover.

The top-entering removable or demountable type agitator should be provided with an easily accessible, readily demountable coupling of either a sanitary type located within the lining or a coupling located outside the lining provided that it is above the shield provided to protect the annular space around the shaft. All product surfaces of the agitator should be visible, when the agitator is removed.

A bottom support or guide, if used, should be welded to the lining and should not interfere with drainage of the equipment. When the agitator shaft has a bearing cavity, the diameter of the cavity should be greater than the depth. The agitator should be easily demountable for cleaning of the bearing and any shaft cavity.

When a seal is provided for vertical agitators, the design should be such that (1) all product contact surfaces can be mechanically cleaned and (2) the seal assembly is easily accessible and readily demountable for inspection, or (3) be such that the seal may be readily disassembled for manual cleaning and inspection.

The side or bottom-entering type agitator and shaft, including the complete seal, should be readily demountable for cleaning. Non-removable parts having product surface should be designed so that the product contact surfaces are readily cleanable from the inside of the equipment. Seals for the agitator shaft should be of a packless type, sanitary in design, with all parts readily accessible for cleaning.

(20). Support or Mounting

The means of supporting the equipment:

If legs are used they should be smooth with rounded ends or with a flat, load bearing foot suitable for sealing to the floor, and have no exposed threads. Legs made of hollow stock should be sealed. Legs should provide a minimum clearance between the lowest part of the base and the floor of not less than 4 in. (101.6 mm).

If casters are used they should be of a sufficient size to provide a clearance between the lowest part of the base and the floor of not less than 4 in. (101.6 mm) to 6 in. (152.4 mm). Casters, if provided, should be easily cleanable, durable and of a size that will permit easy movement of the equipment.

If mounted on a slab or island the base should be designed for sealing to the slab or island surface.

When silos and other equipment are designed to be installed on a slab or an island, the dimensions of the slab or island should be such that the base of the equipment will extend beyond the slab or island at least 1 in. (25.4 mm) in all horizontal directions. The slab or island should be of sufficient height that the bottom of all product connections are not less than 4 in. (101.6 mm) above the floor. The surface of the slab or island should be coated with a thick layer of water proof mastic material, which will harden without cracking. The junction of the base and the slab or island should be sealed.

If mounted on a wall or column the point of attachment to its mounting should be designed for sealing. The mounting, if supplied by the manufacturer, should be designed for sealing to the wall or

column. The design of equipment to be mounted on a wall or column should be such that there will be at least a 4 in. (101.6 mm) clearance between the outside of the equipment and the wall or column.

If mounted on a pedestal, the base of the pedestal should be designed to provide adjustable legs and necessary clearance, normally 4 in. (101.6 mm) to 6 in. (152.4 mm) or be designed to be sealed to the pedestal.

(21). Slabs or Islands

When equipment is designed to be installed on a slab or an island, the slab or island should be of sufficient height that the bottom of all product connections are not less than 4 in. (101.6 mm) above the floor. The surface of the slab or island should be coated with a thick layer of water proof mastic material, which will harden without cracking. The junction of the equipment base and the slab or island should be sealed.

(22). Air Venting

Air venting of tanks and similar vessels must be adequate to protect the vessel from internal pressure or vacuum damage during normal operation and cleaning.

For example, when a 6,000 gallon tank (with 800 cu ft of 135°F hot air after cleaning) is suddenly flash cooled by 50°F water sprayed at 100 gpm the following takes place: Within one second, the 800 cu ft of hot air shrinks approximately 51 cu ft in volume. This is the equivalent in occupied space of approximately 382 gallons of product.

The shrinkage creates a vacuum sufficient to collapse the tank unless the vent, manhole, or other openings allow air to enter the tank at approximately the same rate as it shrinks. It is obvious, therefore, that a very large air vent such as the manhole opening is required to accommodate this air flow.

(23). Guards and Other Safety Devices

Guards required by a safety standard that will not permit accessibility for cleaning and inspection should be designed so that they can be removed with the use of simple hand tools.

(24). Non-product Contact Surfaces

Non-product contact surfaces should have a smooth finish, free of pockets and crevices, and be readily cleanable. Those surfaces to be coated should be effectively prepared for coating.

C. DOCUMENTATION

(1). Engineering Design and Technical Construction File (EDTCF)

The following is an example of an engineering design and technical construction file (EDTCF) which should be maintained by the fabricator as evidence that they meet these requirements.

(a). Purpose

To establish and document the material, fabrication and installation requirements for the engineering design and technical construction files for all products, assemblies and sub-assemblies supplied by the manufacturer thereof to be in compliance with the sanitary criteria.

It is recommended that appropriate portions of the engineering and construction file(s) be submitted with the applicable portions of the equipment review applications.

(b). Scope

Should specify the equipment (including specific model no., when appropriate) to which it applies.

(c). Responsibilities

Should specify who (name, title, address, phone #) in the company is responsible for maintaining, publishing and distributing this EDTCF, and providing information to individuals who have questions or need technical information regarding this equipment.

(2). EDTCF--Content

The EDTCF may consist of the following:

- (a). An overall drawing of the subject equipment;**
- (b). Full detailed drawings, accompanied by any calculations, notes, test results, etc., required to check the conformity of the equipment;**
- (c). A list of the essential requirements of the standards or practices and other technical specifications, which were used when the equipment was designed;**
- (d). Copy of 3A Symbol Authorization (if applicable);**
- (e). Verification of compliance to other applicable standards (such as 3A Practices or CFR requirements);**

- (f). A copy of the instructions for the product (Instruction Manuals/Instruction Books);
- (g). For serial manufacturing, the internal measures that will be implemented to insure that the equipment will continue to be manufactured in conformity (as needed);
- (h). Engineering reports (as needed);
- (i). Laboratory reports (as needed);
- (j). Bills of material (if needed);
- (k). Wiring diagrams (if applicable);
- (l). Other appropriate materials needed to verify compliance (as needed);
- (m). Documentation and test reports on any research or tests conducted on components, assemblies and/or the complete product to determine and demonstrate that by its design and construction the product is capable of being installed, put into service and operated in a sanitary manner (optional); and
- (n). A determination of the foreseeable lifetime of the product (optional).

If the equipment is a system or component of a system which is required to meet specific additional public health requirements, the file should also contain:

- (o). Verification of how all required safeguards are met; and
- (p). A proposal for an alternate PMO testing procedures (in PMO format), if applicable.

Engineering drawings of the entire piece of equipment are generally required for the evaluation of details. Engineering drawings should be of sufficient detail to clearly show:

- (a). The dimensions of each part;
- (b). The minimum radii dimensions of internal angles of less than 135 degrees;
- (c). The product contact surface finish specifications;
- (d). The specifications for welds and other permanent joints;
- (e). 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; and
- (f). The dimensions of O-rings, gaskets, and any other type of seals.

The required material 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.

The file would not normally include detailed plans or any other specific information in regards to sub-assemblies, tooling or fixtures used for the manufacture of the product, unless a knowledge of them is essential for the verification of conformity with the basic sanitary requirements.

The documentation referred to above need not permanently exist in a material manner in the EDTCF but it should be possible to assemble them and make them available within a period of time, commensurate with its importance. (One week is considered a reasonable time). At a minimum, each product EDTCF should physically contain an index.

The EDTCF may be in hard copy or software form.

(3). Confidentiality

The EDTCF is the property of the manufacturers and is shown at their discretion; except that those parts of their file which were submitted to a regulatory agency, as part of an equipment review, may be made available to milk safety regulators. This also means that portions of this material may become releasable under various state and federal freedom of information statutes.

D. GLOSSARY

- (1). Product:**
Should mean milk and milk products, including condensed and dry milk and whey products.
- (2). Solutions:**
Should mean water and/or those homogeneous mixtures of chemical solute(s) and solvents used for flushing, cleaning, rinsing and sanitizing.
- (3). Surfaces:**
 - (a). Product Contact Surfaces:**
Should mean all surfaces which are exposed to the product and surfaces from which liquids may drain, drop, diffuse or be drawn into the product.

Surfaces that contact the product contact surfaces of packaging materials may be included in this definition.
 - (b). Solution Contact Surfaces:**
Should mean the interior surfaces of the equipment or system which are used exclusively for the supply and recirculation of cleaning and/or sanitizing solutions, except those used to supply concentrated cleaning and/or sanitizing materials to the point of use.

With the exception of the drainage sections in this guide, product contact surface requirements should apply to solution contact surfaces.
 - (c). Nonproduct Contact Surfaces:**
Should mean all other exposed surfaces.
- (4). Cleaning**
 - (a). Mechanical Cleaning or Mechanically Cleaned:**
Should mean soil removal by impingement, circulation or flowing chemical detergent solutions and water rinses onto and over the surfaces to be cleaned by mechanical means in equipment or systems specifically designed for this purpose.
 - (b). Cleaned-In-Place (CIP):**

Should mean mechanical cleaning of equipment, of which the cleanability has been sufficiently established, such that all product or solution contact surfaces do not have to be readily accessible for inspection, i.e., silo-type tanks or welded pipelines.

(c). **Manual (COP) Cleaning:**

Should mean the removal of soil when the equipment is partially or totally disassembled. Soil removal is affected with chemical solutions and water rinses; with the assistance of one or a combination of brushes, nonmetallic scouring pads and scrapers, high or low pressure hoses and tank(s) which may be fitted with recirculating pump(s); and with all cleaning aids manipulated by hand.

(5). **Surface Modification:**

(a). **Acceptable coating processes include:**

- Chemical (conversion coatings) (anodizing)
- Electrodeposition² (chromium plating and nickel plating)
- Spraying (pneumatic, flame, plasma, arc spray)
- Physical Vapor Deposition
- Chemical Vapor Deposition
- Centrifugal Casting

(b). **Acceptable surface treatments include:**

- Mechanical (shot peening, glass beading, polishing)¹
- Thermal (surface hardening laser, electron beam)
- Diffusion (carburizing, nitriding)
- Chemical (etching, oxidation)
- Ion Implantation
- Electropolishing

(6). **Coatings:**

Should mean the results of a process where a different material is deposited to create a new surface. There is appreciable build-up of new material, typically more than 1 μ m.

(7). **Close Coupled:**

Should mean mating surfaces or other juxtaposed surfaces that are less than twice the nominal diameter or cross section of the mating surfaces or a maximum of 5 in. (127 mm) whichever is less.

(8). **Corrosion Resistant:**

Should mean the surface has the property to maintain its original surface characteristics for its predicted service period when

exposed to the conditions encountered in the environment of intended use including expected contact with product and cleaning, sanitizing or sterilization compounds or solutions.

- (9). **Dead End:**
Should mean an area or space wherein a product, ingredient, cleaning, or sanitizing agent, or other extraneous matter may be trapped, retained or not completely displaced during operational or cleaning procedures.
- (10). **Easily or Readily Accessible:**
Should mean a location which can be safely reached by an employee from the floor, platform or other permanent work area.
- (11). **Easily or Readily Removable:**
Should mean quickly separated from the equipment with the use of simple hand tools.
- (12). **Inspection:**
Should mean a close visual inspection of all product contact surfaces.
- (13). **Nontoxic Materials:**
Should mean those substances which under the conditions of their use are in compliance with applicable requirements of the Food, Drug and Cosmetic Act of 1938, as amended.
- (14). **Sanitizing or Sanitization:**
Should mean a process applied to a cleaned surface which is capable of reducing the numbers of the most resistant human pathogens by at least five log cycles (99.999%) to seven log cycles (99.99999%) by applying accumulated hot water or steam or by applying an EPA registered sanitizer according to label directions. Sanitizing may be affected by mechanical or manual methods.
- (15). **Simple Hand Tools:**
Should mean implements normally used by operating and cleaning personnel such as a screwdriver, wrench or hammer.
- (16). **Soil:**
Should mean the presence of unwanted organic residues or inorganic matter, with or without microorganisms, including food residue, in or on the equipment.
- (17). **Sterilization:**

Should mean a process affected by heat, chemicals, or other mechanical means that destroys all vegetative bacteria, and inactivates relevant bacterial spores.

(18). Substantially Flush:

Should mean mating surfaces or other juxtaposed surfaces should be within 1/32 in. (0.794 mm).

(19). Surface Treatments:

Should mean a process whereby chemical compositions or mechanical properties of the existing surface are altered. There is no appreciable build-up of new material or removal of existing material, typically less than 1 μ m.

E. SOURCES OF STANDARDS REFERENCED IN FOOTNOTES:

- (1). Smidt, F.A. Advance Materials and Processes. Surface modification. ASM International, Materials Park, OH 44073 (216-338-5151). Jan 1990:137(1):p61.**
- (2). QQ-C-320B-Federal Specification for Chromium Plating (Electrodeposited) June 17, 1974 with Amendment 4, April 10, 1987. QQ-N-290A-Federal Specification for Nickel Plating (Electrodeposited), November 12, 1971. Available from the General Services Administration, FSSB 420 East L'Enfant Plaza, S.W., Suite 8100, Washington, D.C. 20407 (202-755-0325).**
- (3). The data for this series are contained in the AISI Steel Products Manual, Stainless & Heat Resisting Steels, November 1990, Table 2-1, pp. 17-20. Available from the Iron and Steel Society, 410 Commonwealth Drive, Warrendale, PA 15086 (412-776-9460).**
- (4). Steel Founders Society of America, Cast Metal Federation Building, 455 State Street, Des Plaines, IL 0016 (708-299-9160).**
- (5). Model available from ASTM, 1916 Race Street, Philadelphia, PA 19103-1187 (215-299-5400).**
- (6). MIL-C-26074E - 30 October 1990 Military Specifications: Coatings, Electroless Nickel, Requirements For. Available from Standardization Document Order Desk (Dept. of Navy), 700 Robbins Avenue, Building 4, Section D, Philadelphia, PA 19111-5094 (215-697-4737 or 3321).**
- (7). Adhesives shall comply with 21 CFR Part 175 - Indirect food additives. Adhesives and components of coatings. Document for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (202-783-3238).**
- (8). Available from the American Society of Mechanical Engineers, 345 E. 47th Street, New York, NY 100167-2392 (212-705-7722).**

III
APPENDIX 3
Materials and Fabrication
Checklist

**MATERIALS
AND FABRICATION
CHECKLIST**

Date: _____
Reviewer: _____
State: _____
3rd Party Reviewer: _____
(If Applicable)

Please check (3) items that are ACCEPTABLE.
Mark items that are UNACCEPTABLE with a Cross (X).
(Only Complete Sections That Apply)

MATERIALS

1. METALS

_____ a. _____
(303, 304 or 316Cast (CF-16F, CF-8 or Cf-8M))

_____ b. **Alloys-accept**

_____ c. Coatings-acceptable type, electroless nickel

_____ d. Silver solder-acceptable, nontoxic

2. NONMETALS

_____ a. Rubber-acceptable type, appropriate class

_____ b. Plastic-acceptable type (I, II, III or IV)

_____ c. Durability

_____ d. Bonding materials meet 21 CFR 175

_____ e. Carbon and ceramic materials

_____ Limited use

_____ Inert, non-porous, nontoxic, nonabsorbent,
insoluble (except as provided in guidelines)

_____ Resistant to scratching, scoring &
distortion under

_____ f. Glass

_____ Limited to sight/light openings and direct
reading gauges

_____ Heat resistant, clear type

_____ g. Paper

_____ Sanitary single service gaskets limited to
use on parts disassembled daily

3. STERILITY (if applicable)

_____ Capable of being sterilized at 250° F.
(121 °C.) at PSIG (106Kpa)

**4. NONPRODUCT CONTACT
SURFACE**

_____ Corrosion resistant

_____ Relatively nonabsorbent

_____ Durable

_____ Cleanable

_____ If coated, coatings adhere

_____ No paint on removable parts with product
contact surfaces

FABRICATION

1. Surface Texture

_____ a. No. 4 ground finish (for a maximum Ra of
32 Micro Inch) on stainless steel (or
equipment)

_____ b. Free of pits, folds and crevices

2. Permanent Joints

_____ a. Welding-smooth as No. 4 ground finish &
free of pits, folds, and crevices

_____ b. Soldering-acceptable type/limited to
where welding is impractical

_____ c. Press-fits or shrink fits

_____ 1. Joint crevice free

_____ 2. Strictly limited to applications such
as installing small round pins or
bushings into small round holes

_____ d. Surface Finish

3. BONDED MATERIAL

_____ Meet guideline specifications

4. COATINGS (Metal, Ceramic, Plastic or Rubber)

_____ Free of surface delamination, pitting, flaking,
chipping, blistering or distortion under conditions
of use

5. CLEANING AND INSPECTABILITY

- a. Mechanically cleaned
 - 1. All product contact surfaces inspectable
 - 2. All non removable parts accessible
- b. CIP (limited to welded lines, silos and equipment for which mechanical cleaning effectiveness has been similarly established)
- c. Manually cleaned (not designed for mechanical cleaning)
 - 1. Easily accessible for cleaning and inspection

6. DRAINING

- Product contact surfaces are self draining or pitched to a drainable point

7. FITTINGS, VALVES, INSTRUMENTS, ETC.

- a. Acceptable type
- b. Acceptable installation

8. SANITARY TUBING

- 3A Standard, No. 33- (or equivalent)

9. GASKETS

- Meet guideline specifications

10. RADII

- Meet guideline specifications

11. THREADS

- None in product or solution contact surfaces except sanitary threads as allowed

12. PERFORATED SCREENS OR PLATES

- a. No woven wire
- b. Holes are adequate size
- c. Free of burrs, etc.

13. SPRINGS

- At least 3/32 in. (2.38mm) between coils including ends (in free position)

14. MULTIPLE USE WOVEN MATERIALS

- Limited to acceptable uses

15. STERILIZING SYSTEMS

- Meet guideline specifications

16. SHAFTS AND BEARINGS

- Meet guideline specifications

17. OPENINGS AND COVERS

- Meet guideline specifications

18. OVERHEAD SHIELDING

- Adequate/properly constructed

19. AGITATORS

- Meet guideline specifications

20. SUPPORT OR MOUNTING

- Meet guideline specifications

21. SLABS OR ISLANDS

- Meet guideline specifications

22. AIR VENTING

- Meet guideline specifications

23. GUARDS AND SAFETY DEVICES

- Removable as needed to allow cleaning and inspection

24. NONPRODUCT SURFACES

- Smooth/cleanable

DOCUMENTATION

1. DOCUMENTATION

- a. Included with application for review
- b. Contains information needed to complete the review

SUMMARY OF FINDINGS:

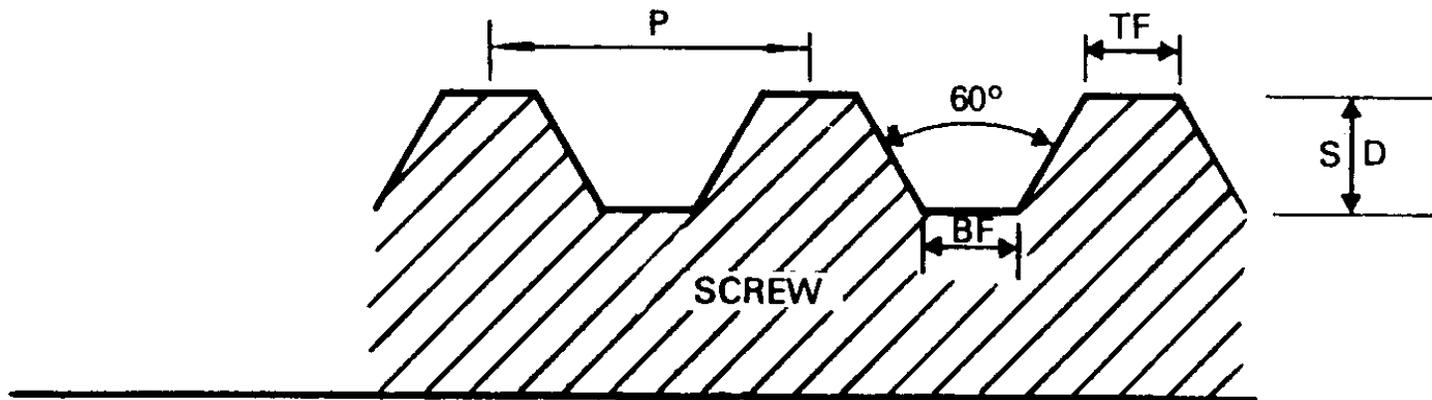
III

APPENDIX 4

Drawings

- Figure 1. Sanitary Thread**
- Figure 2. Acceptable Shields and Covers**
- Figure 3. Square Corner/Radius**
- Figure 4. Internal Angles and Corners**
- Figure 5. Dead Ends**
- Figure 6. Bolts in Product Areas**
- Figure 7. Equipment Supports and Mounting**
- Figure 8. Drainage of Pipes**
- Figure 9. Drainage of Vessels**
- Figure 10. Top Rim of Equipment**
- Figure 11. Permanent Joints - Welded**
- Figure 12. Connections**
- Figure 13. Unacceptable Weld (inadequate inert gas purge)**
- Figure 14. Unacceptable Weld (too much inert gas purge)**
- Figure 15. Unacceptable Weld (heat penetration too light)**
- Figure 16. Acceptable Weld**

Acceptable Sanitary Thread



P = PITCH

SD = SINGLE DEPTH

TF = TOP FLAT

BF = BOTTOM FLAT

TPL = TH'DS PER INCH

$$P = \frac{1}{TPL}$$

$$SD = 0.433 \times P$$

$$TF = 0.250 \times P$$

$$BF = 0.227 \times P$$

Figure 1

Square Corner/Radius

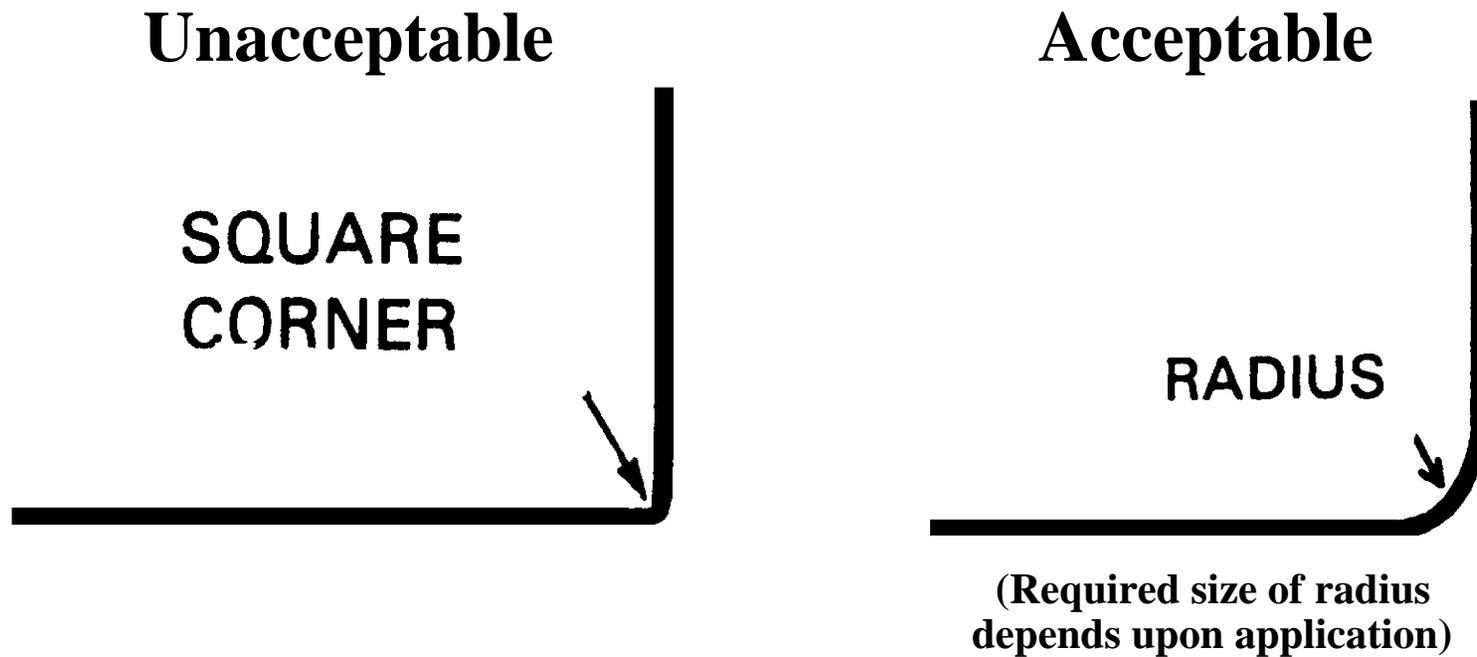
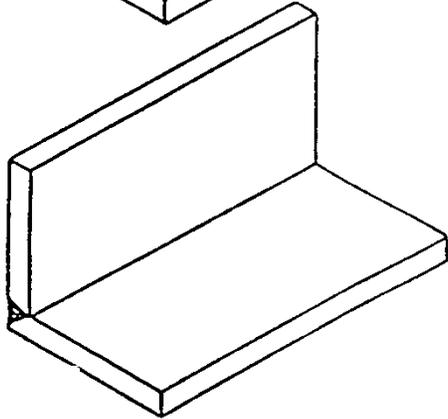
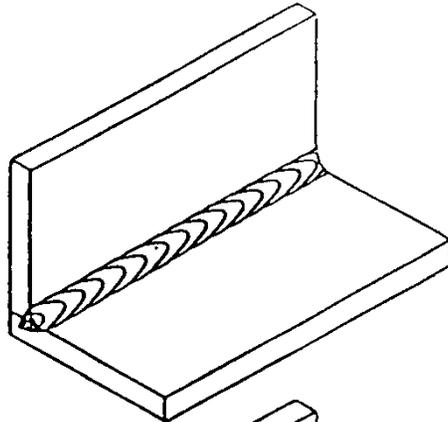


Figure 3

Internal Angles and Corners

Unacceptable



Acceptable

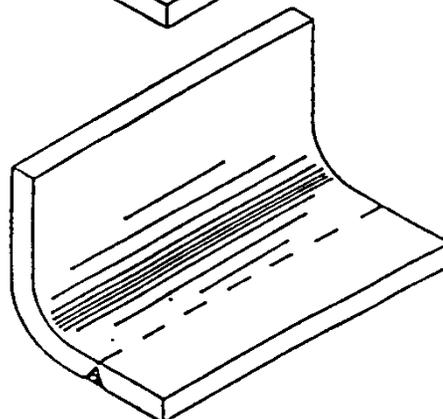
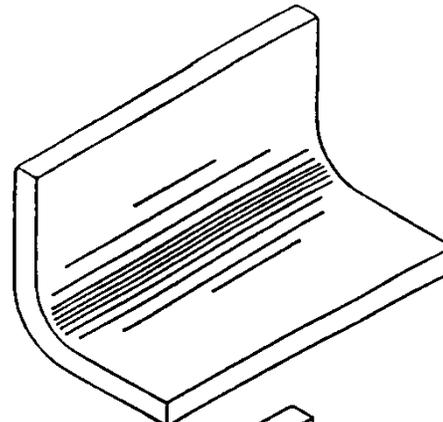
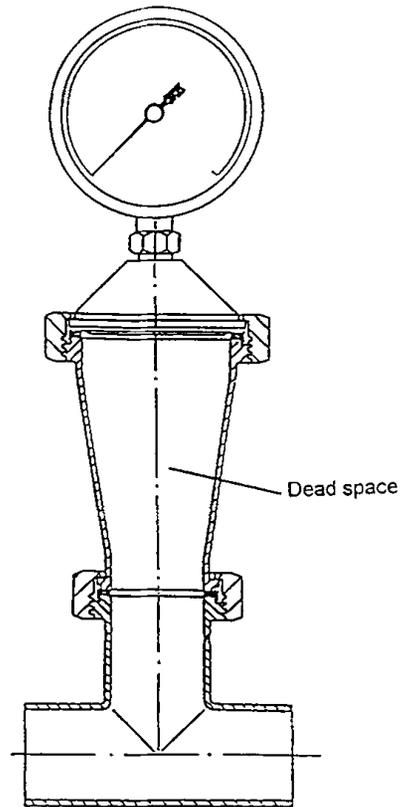


Figure 4

Dead Ends

Unacceptable



Acceptable

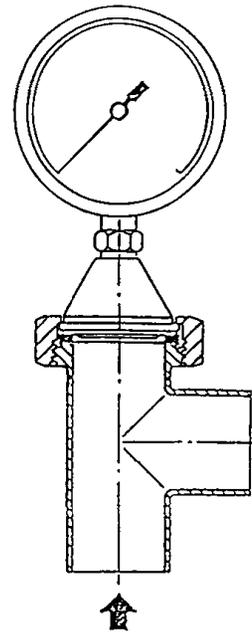
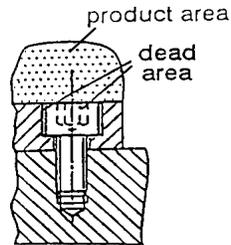


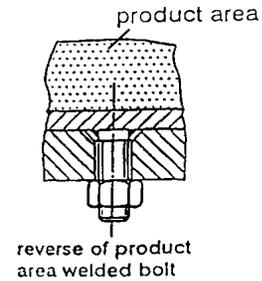
Figure 5

Bolts in Product Areas

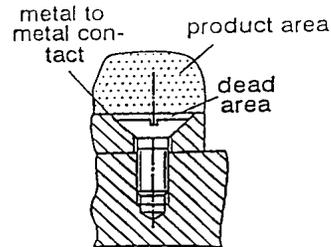
Unacceptable



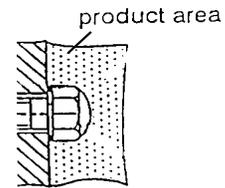
Acceptable



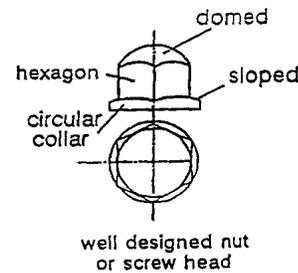
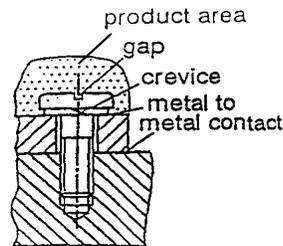
Unacceptable



Acceptable for limited application (such as attaching pump impeller to shafts)



Unacceptable

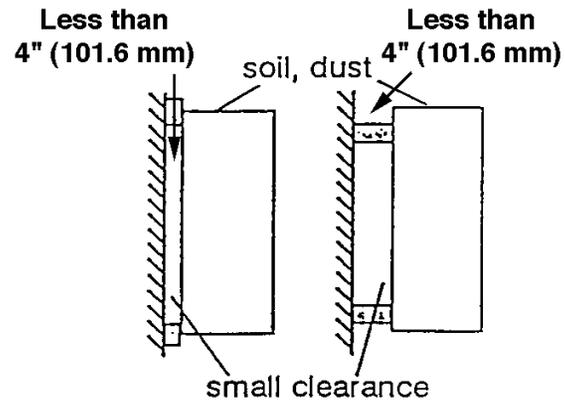
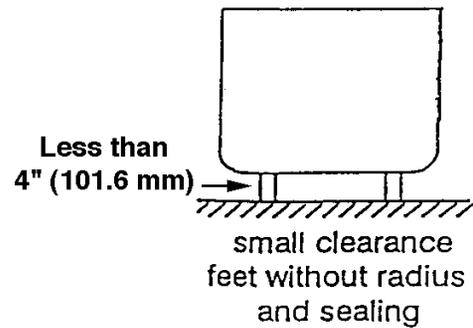


Source: EHEDG and Trends in Food Science and Technology (1995) Vol. 6(9) pp. 305-310 (modified)

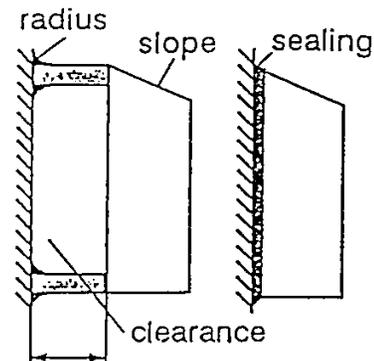
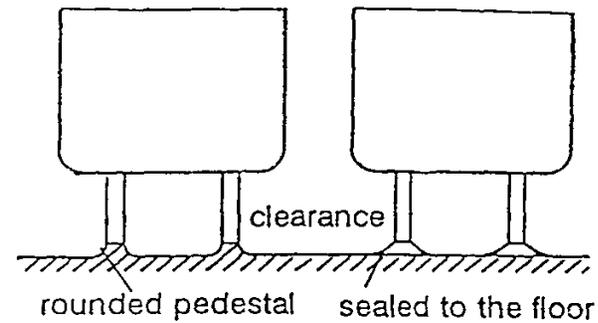
Figure 6

Equipment Supports and Mounting

Unacceptable



Acceptable

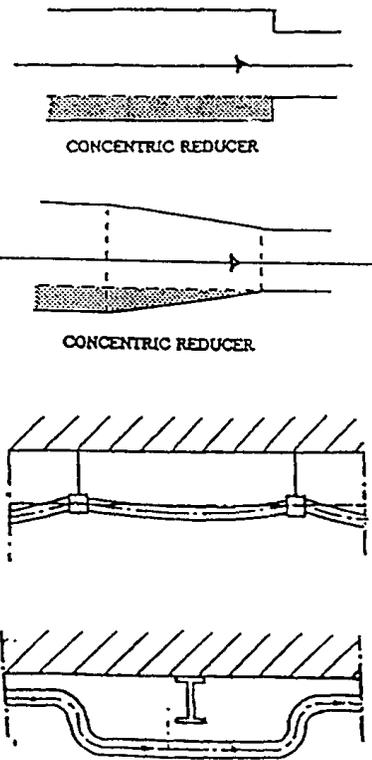


Source: EHEDG and Trends in Food Science and Technology (1995 Vol. 6(9) pp. 305-310) (modified)

Figure 7

Drainage of Pipes

Unacceptable



Acceptable

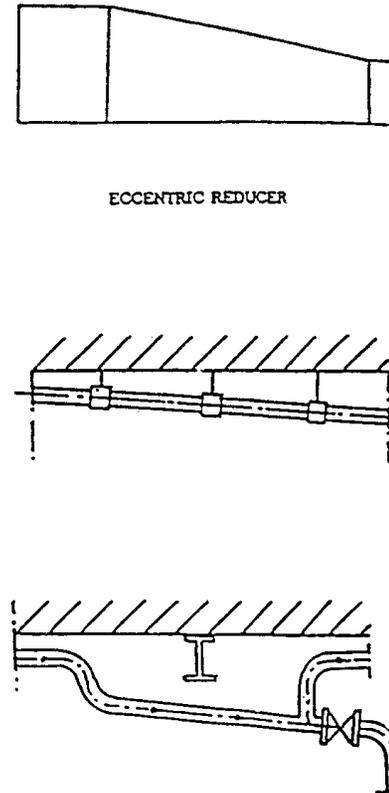
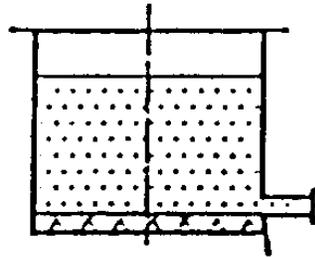


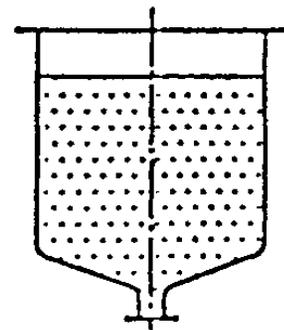
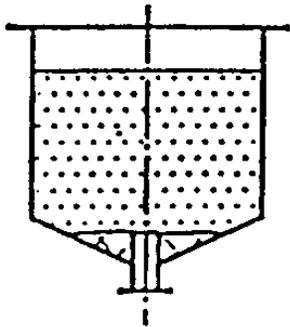
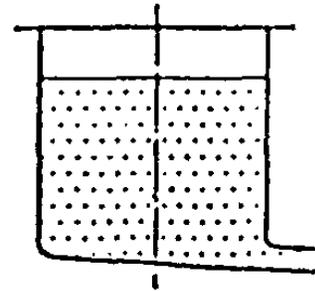
Figure 8

Drainage of Vessels

Unacceptable
not drainable design



Acceptable
drainable design

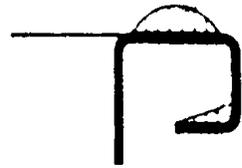


Source: EHEDG and Trends in Food Science and Technology (1995) Vol. 6(9) pp. 307) (modified)

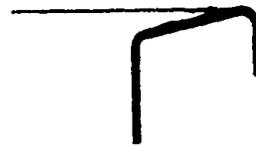
Figure 9

Top Rim of Equipment

Unacceptable



Acceptable

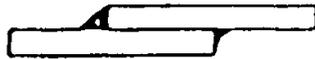


Source: EHEDG and Trends in Food Science and Technology (1995) Vol. 6(9) pp. 307) (modified)

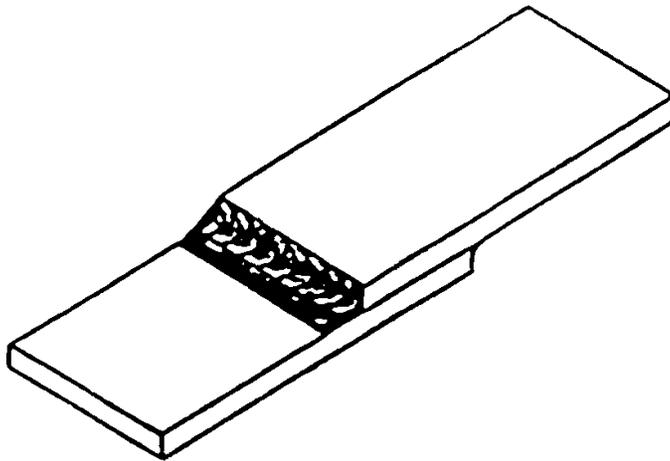
Figure 10

Permanent Joints – Welded

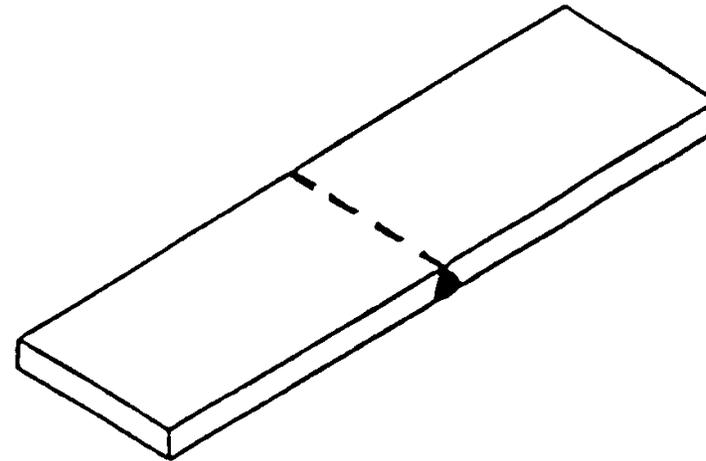
Unacceptable



Acceptable



Lap weld



Butt weld

Source: EHEDG and Trends in Food Science and Technology (1995) Vol. 6(9) pp. 306 (modified)

Figure 11

Connections

Unacceptable



gasket

DIN

**Pipe cross-section
(gasket shown)**

Acceptable



gasket fits here

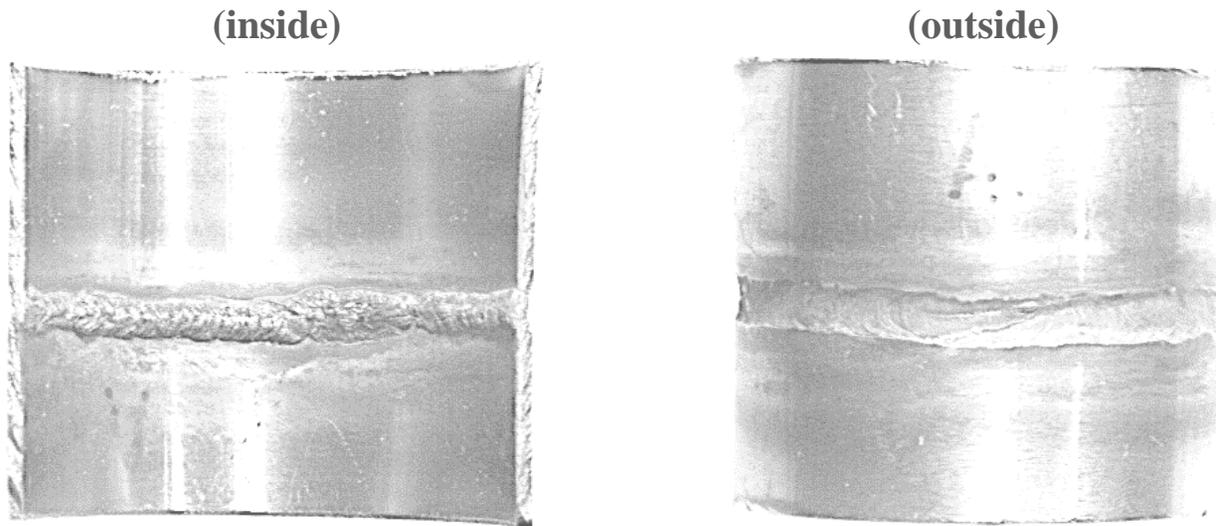
Tri-clamp

**Pipe cross-section
(gasket not shown)**

Figure 12

Judging Unpolished Welds

Unacceptable



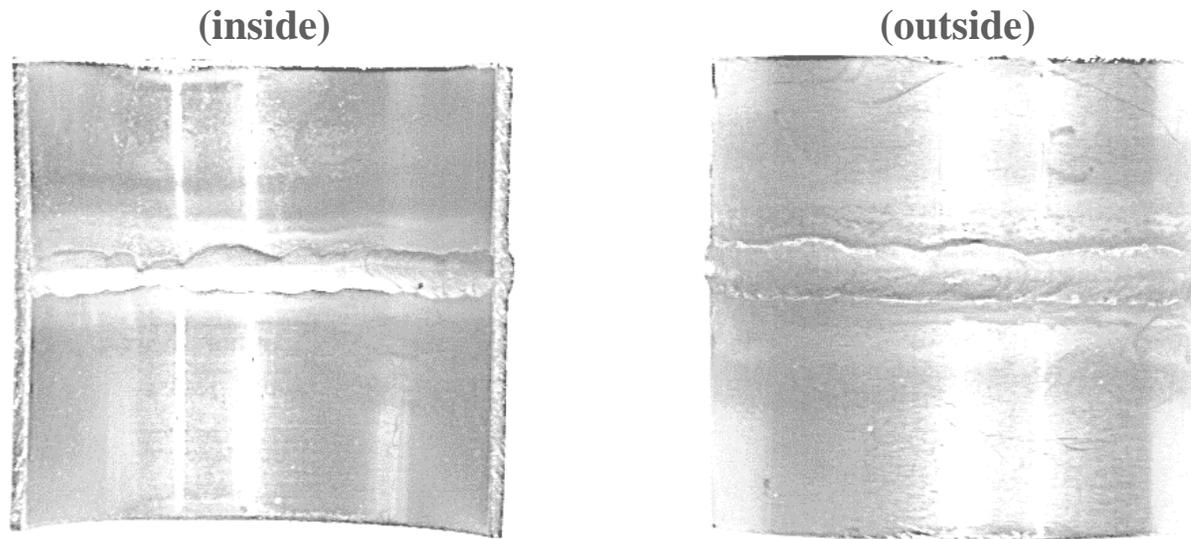
Weld badly sunken from the outside – heavy oxidation crusted in weld area.

Reason: Inadequate gas (inert gas) purge.

Figure 13

Judging Unpolished Welds

Unacceptable



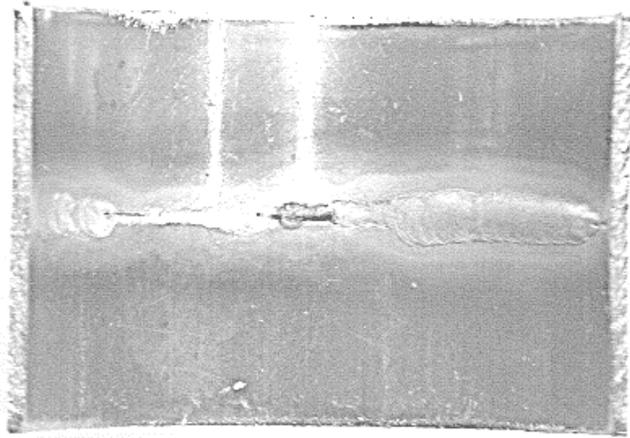
Weld pushed outward.

Reason: Too much purge (inert gas) pressure.

Figure 14

Judging Unpolished Welds

Unacceptable



(inside)

Heat penetration too light in some spots – causing misses or skips.

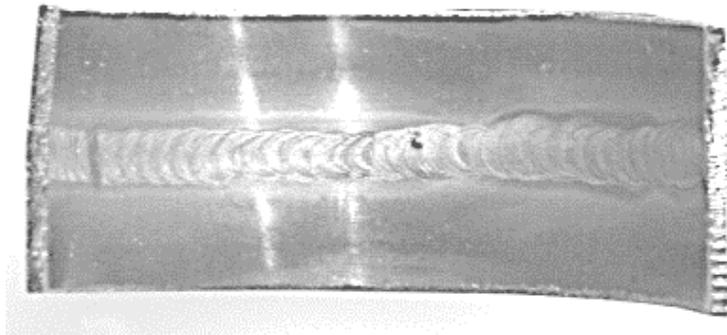
Reason: Weld speed too fast or low amps.

Figure 15

Judging Unpolished Welds

Acceptable

(inside)



(outside)

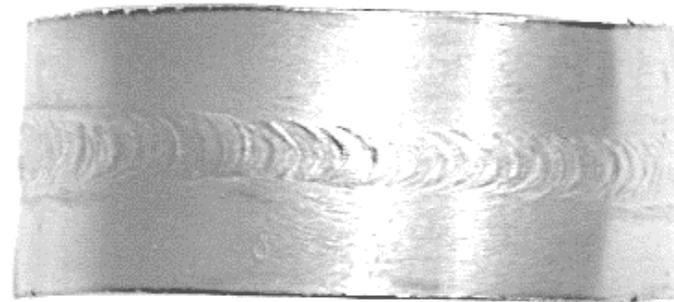


Figure 16