

JULY 2021
EDITION

Food Safety Equipment Design Principles

CHECKLIST & GLOSSARY



Meat
Foundation
Research. Education. Scholarship.

2021 Food Safety Equipment Design Task Force

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JBT Corporation
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Multivac, Inc.
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Cargill Meat Solutions
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Ed Miniat, Inc.
Hormel Foods Corporation
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Maple Leaf Foods, Inc.
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Revised: June 2021

Recommended Citation

2021 Food Safety Design Taskforce (ed.). 2021. Food safety equipment design principles: checklist & glossary. Meat Foundation, Arlington, VA.

Introduction

The original Sanitary Equipment Design Task Force was charged with developing equipment sanitary design principles that meet the expectations of the meat and poultry industries. The task force also developed a checklist tool that equipment manufacturers and processors can use to assess equipment. Since their inception, the Sanitary Equipment Design Principles have helped drive significant improvements in equipment design and sanitation practices. Leveraging the prominence of the Sanitary Equipment Design Principles, the 2021 Food Safety Equipment Design Task Force (FSEDTF) was charged with expanding on the existing principles and checklist to encompass all aspects of food safety, with a particular focus on foreign material.

The FSEDTF is comprised of representatives from equipment manufacturers, with insight from meat and poultry processing companies. The FSEDTF designed the principles and criteria in consultation with certifying organizations and government officials.

Equipment design is critical in reducing the risk of contamination of food products by pathogens and foreign material. Optimizing the design and performance criteria for equipment and related systems by establishing industry-wide specifications benefits the entire industry by promoting principles intended to reduce contamination and associated recalls. Although these principles were developed for equipment used in meat and poultry establishments, they may be applicable for other similar wet cleaning food operations.

Importance of Design Principles

- Provide an opportunity for equipment providers and equipment users to work together to identify issues of common concern;
- Provide a forum to enable the food safety design conversation to happen ahead of time rather than when equipment reaches the plant floor;
- Create a standardized food safety focus for equipment evaluation;
- Because they are Principles, not standards, they do not limit how the need is to be met;
- Food Safety Design Principles define our industry expectations;
- Encourage and allows for innovation and drives continuous improvement.

Checklist Scoring

- **S = Satisfactory -- Full Points:** Usable as is without changes or alternate procedures to meet the expectation.
- **M = Marginal -- Half Points:** Does not meet the expectation, but can be overcome through alternate procedures. May be an opportunity for improvement through redesign.
- **U = Unsatisfactory -- Zero Points:** Does not meet the expectation and cannot be overcome through alternate procedures. May require redesign.
- **NA = Not applicable -- Remove points from total**

10 Principles of Food Safety Design

All principles apply to all parts of the equipment, unless otherwise specified.

(*) Denotes further explanation provided in the glossary.

1. Made of Compatible Materials

Construction materials used for equipment must be robust and compatible with the product, environment, chemicals, and sanitation methods.

| Principle 1 - MADE OF COMPATIBLE MATERIALS | | | | | | |
|--|---|---|----------------|----------|--------|------------------|
| | Description | Reference | S, M, U, NA | Comments | Points | Points Available |
| 1.1 | Product contact surfaces must be made with materials which are degradation resistant, non-toxic, and non-absorbent in accordance with relevant standards and regulations. | NSF 4.1, 4.2, NSF/ANSI/3A 14159-1 | | | | 10 |
| 1.2 | Stainless steel is 304 or 316 grade, or equivalent, and appropriate for use.* | NSF 4.2.1, AMIF 2013 | | | | 10 |
| 1.3 | Plastics and composites remain intact without degradation or changes in shape, structure, or function through standard operating, sanitation, and storage protocols. | AMIF 2013, 21 CFR Parts 175, 176, and 177 | | | | 10 |
| 1.4 | Plated, painted, and coated surfaces are not used for food contact surfaces or for surfaces above the product zone. | AMI | | | | 10 |
| 1.5 | If 1.4 cannot be met, then coatings must remain intact and the equipment manual provide guidance on frequency of monitoring and recoating. | NSF 5.1.8 | | | | 10 |
| 1.6 | Cloth back belts are not used. | NSF 5.3.3 | | | | 10 |
| 1.7 | Materials not used include wood, enamelware, uncoated aluminum, uncoated anodized aluminum, etc. per NSF/ANSI/3A 14159-1. | NSF 4.1.1, 4.2.1.2, 4.3 | | | | 10 |
| 1.8 | Metals are compatible with one another.* | NSF 5.2.1 | | | | 10 |
| 1.9 | Materials are compatible with the product and the environmental conditions they will be exposed to, as well as, the cleaning methods and chemicals. | NSF 4.1, 4.2, AMI | | | | 10 |
| 1.10 | Materials do not leach, impart flavor, or otherwise alter the product. | NAMI 2021 | | | | 10 |
| | | | | SCORE | | 100 |

10 Principles of Food Safety Design

2. Accessible for Inspection, Maintenance, and Sanitation

Equipment and parts shall be readily accessible for inspection, maintenance, and sanitation; without the use of tools.

| Principle 2 - ACCESSIBLE FOR INSPECTION, MAINTENANCE, & SANITATION | | | | | | |
|--|---|----------------------|-------------|----------|--------|------------------|
| | Description | Reference | S, M, U, NA | Comments | Points | Points Available |
| 2.1 | Surfaces in the product zone readily accessible for sanitation and inspection. | NSF 5.1.2 | | | | 15 |
| 2.2 | Disassembly is as tool free and easy as possible for components with inaccessible surfaces (<i>i.e.</i> , do not allow penetration of detergent) that require routine sanitation. | NSF 5.1.2 | | | | 15 |
| 2.3 | Where access or disassembly is not possible during routine sanitation, equipment allows for alternate methods, such as CIP or COP, with the means to verify effectiveness. | NSF 5.1.2, AMIF 2013 | | | | 10 |
| 2.4 | Parts remain attached or hang on the equipment for easy cleaning and to prevent damage or loss. Separate parts baskets, carts, or racks are supplied as an alternative and designed in accordance with the principles. | AMI | | | | 5 |
| 2.5 | Safety features, such as guards, allow for effective sanitation and inspection. If removal is necessary for routine or periodic sanitation, work instructions are provided. | NSF 5.1.16, AMI | | | | 10 |
| 2.6 | Product catch pans or drip pans drain away from product zones and are accessible for sanitation and inspection. If removal is necessary for routine or periodic sanitation, pans can be easily removed and reassembled. | AMI | | | | 10 |
| 2.7 | Belting and rail system is accessible for sanitation and inspection. If needed, lifters are incorporated into or provided with the equipment. If used, belt supports, scrapers, or rub bars are accessible or easily removed without tools. | NAMI 2021 | | | | 10 |
| 2.8 | If used, tension is removed easily without tools to allow access to conveyor bed. If belting must be removed for periodic sanitation, designated storage protocol is provided. | AMI | | | | 10 |
| 2.9 | Surfaces in non-product zones are accessible for cleaning and inspection. | NSF 5.2.2 | | | | 10 |

10 Principles of Food Safety Design

| Principle 2 - ACCESSIBLE FOR INSPECTION, MAINTENANCE, & SANITATION | | | | | | |
|---|---|------------------|--|-------|--|-----|
| 2.10 | Installations allow for 12” of clearance to the floor for accessibility. Product contact surfaces allow for 18” of clearance to the floor, including return conveyor paths. | NSF B.13, AMI | | | | 10 |
| 2.11 | Equipment is located 30” from overhead structures and 36” from the nearest stationary object, including walls. | AMI | | | | 5 |
| 2.12 | Hoses (air, vacuum, product, pneumatics, etc.) and hose assemblies are easily removed for sanitation. | NSF 5.1.15 | | | | 10 |
| 2.13 | Air, vacuum and product hoses are transparent or semi-transparent and meet product contact surface guidelines. | AMI | | | | 10 |
| 2.14 | Pneumatic systems do not exhaust in or near product contact areas. Cylinders, supply lines, and return lines are sealed and do not allow ingress or egress. | AMIF 2013 | | | | 10 |
| 2.15 | Equipment designed to eliminate the need for walkovers. | NAMI 2021 | | | | 10 |
| | | | | SCORE | | 150 |

10 Principles of Food Safety Design

3. No Product, Liquid Collection, or Other Material Collection

Equipment should be self-draining to assure that product, liquid (which can harbor or promote the growth of bacteria), and other materials do not accumulate, pool, or condense on the equipment.

| Principle 3 - NO PRODUCT, LIQUID, OR OTHER MATERIAL COLLECTION | | | | | | |
|--|---|---------------------|----------------|----------|--------|------------------|
| | Description | Reference | S, M, U, NA | Comments | Points | Points Available |
| 3.1 | Exposed and enclosed surfaces are designed to eliminate pooling or collection and be self-draining. | NSF 5.1.5, B.1, B.2 | | | | 20 |
| 3.2 | Horizontal framework is rounded. If squared, framework must be angled to prevent pooling. | NSF B.12, AMIF 2013 | | | | 20 |
| 3.3 | Surfaces, such as large sheet metal, are sufficiently supported to prevent warping or denting and subsequent pooling. | AMIF 2013 | | | | 10 |
| 3.4 | Liquids and other materials do not drip, drain, or draw into product zones. | AMI | | | | 20 |
| 3.5 | Belts are adequately supported to prevent pooling or unwanted collection. | AMI | | | | 10 |
| 3.6 | Materials used shall be non-absorbent. | NSF 4.2, 4.3 | | | | 20 |
| | | | | SCORE | | 100 |

10 Principles of Food Safety Design

4. Hollow Areas are Hermetically Sealed

Hollow areas of equipment such as frames and rollers are eliminated wherever possible or permanently sealed. Bolts, studs, mounting plates, brackets, junction boxes, nameplates, end caps, sleeves, and other items must be continuously welded to the surfaces, not attached via drilled and taped holes.

| Principle 4- HOLLOW AREAS ARE HERMETICALLY SEALED | | | | | | |
|---|---|-------------------------|----------------|----------|--------|------------------|
| | Description | Reference | S, M, U, NA | Comments | Points | Points Available |
| 4.1 | Rotating components, such as drives, sprockets, support rollers, or belt pulleys, are solid or, if not able to be solid, fully sealed with continuous welds.* | AMI | | | | 25 |
| 4.2 | Hollow tube construction is avoided, unless required for structural purposes, and not acceptable at or above product zones. If used below product zones, it must be fully sealed with continuous welds. | NSF 5.2.1 | | | | 25 |
| 4.3 | There are no fastener penetrations into hollow tube construction. | AMI | | | | 25 |
| 4.4 | Leg adjustments should be external, or hermetically sealed if internal, and cleanable. | NSF 5.2.4, AMIF 2013 | | | | 15 |
| 4.5 | Name plates and tags are minimized. If necessary, should not be above or adjacent to contact surfaces. Rivets or other methods which create lap joint attachments are not used. | AMIF 2013 | | | | 20 |
| | | | | SCORE | | 110 |

10 Principles of Food Safety Design

5. No Niches

Equipment parts should be free of niches such as pits, cracks, corrosion, recesses, open seams, gaps, lap seams, protruding ledges, inside threads, bolt rivets, and dead ends.

| Principle 5 - NO NICHES | | | | | | |
|-------------------------|---|-----------------------|----------------|----------|--------|------------------|
| | Description | Reference | S, M, U, NA | Comments | Points | Points Available |
| 5.1 | Product contact surfaces are smooth and textures shall not exceed an Ra average of 32 μ -inch.* | NSF 5.1.1, AMIF 2013 | | | | 10 |
| 5.2 | Non-product contact surface textures shall not exceed an Ra average of 125 μ -inch.* | AMIF 2013 | | | | 10 |
| 5.3 | Internal corners with angles less than 135 degrees shall have a continuous radius, <i>i.e.</i> fillet, of at least 1/8 inch.* | NSF 5.1.9 | | | | 10 |
| 5.4 | There are no lap joints.* | NSF 7.1.7, B.4 | | | | 10 |
| 5.5 | Allow for space between two adjoining pieces to permit physical cleaning action (<i>e.g.</i> 0.5 inch), minimize lap joints with spacers.* | AMI 2013 | | | | 10 |
| 5.6 | Caulking is not used in or above the product zone. | AMI | | | | 10 |
| 5.7 | Welds are continuous, smooth, and polished, free of pits, cracks, and corrosion. | NSF 5.1.7, AMI | | | | 10 |
| 5.8 | Assemblies, such as bushings, sprockets, and bearings, are accessible or disassembled for sanitation.* | AMI | | | | 10 |
| 5.9 | Barbed hose fittings are not used. Vulcanized hose fittings are preferred. | AMI | | | | 10 |
| 5.10 | Press and shrink fits are not used.* | AMI | | | | 10 |
| 5.11 | Fasteners are not used in or above the product zone. | AMI | | | | 10 |
| 5.12 | If 5.11 cannot be met, fasteners either do not have exposed threads or have threads wide enough to facilitate cleaning and have a positive locking method to prevent falling or vibrating off, <i>e.g.</i> ACME 60°.* | NSF 5.1.11, AMIF 2013 | | | | 10 |
| 5.13 | Belt scrapers consist of one solid piece, positioned with the mount away from the product drop zone, and are removed without tools. | AMI | | | | 10 |
| 5.14 | Belt supports are constructed from single pieces of material. | AMI | | | | 10 |
| 5.15 | Rolled edges that create a hollow space are avoided.* | NAMI 2021 | | | | 10 |
| | | | | SCORE | | 150 |

10 Principles of Food Safety Design

6. Operational Performance

During normal operations, the equipment must perform so it does not contribute to unsanitary conditions; the harborage and growth of bacteria; or the creation of foreign material.

| Principle 6 - OPERATIONAL PERFORMANCE | | | | | | |
|---------------------------------------|---|---------------------------------|-------------|----------|--------|------------------|
| | Description | Reference | S, M, U, NA | Comments | Points | Points Available |
| 6.1 | Buttons on control panels are not mounted in or above product zones, easily cleaned, and resist damage. | AMIF 2013 | | | | 10 |
| 6.2 | Compressed air used on product or contact surfaces is filtered and dried to prevent moisture, based on product risk. Final filtration is located as close to the product contact zone as possible.* | AMI | | | | 15 |
| 6.3 | Motors, gearboxes, and bearings are not located in or above product contact zones. | NSF 5.1.13.3, 5.13.4, AMIF 2013 | | | | 20 |
| 6.4 | Non-product contact areas do not cross contaminate product or product contact zones.* | AMI | | | | 15 |
| 6.5 | Surfaces near the product contact zone areas are designed as if they were product contact zone areas. | AMI | | | | 10 |
| 6.6 | Product contact surfaces are made to prevent build-up of product residue during operations. | AMI | | | | 15 |
| 6.7 | Shafts that pass through a product zone shall have separation between the drive motor and the wall of the equipment.* | NSF 5.1.13, B.9 | | | | 15 |
| 6.8 | Identification placards are secure and are not damaged or removed through standard operating and sanitation procedures. Equipment manual provides guidance on frequency for replacement as needed. | NAMI 2021 | | | | 10 |
| 6.9 | Seals and O-rings are avoided when possible, when needed are designed to minimize product contact, entry into product zone upon failure, and detectable as provided at 8.7. | NSF 5.1.10 | | | | 10 |
| | | | | SCORE | | 120 |

10 Principles of Food Safety Design

7. Maintenance Enclosures

Maintenance enclosures and human machine interfaces such as push buttons, valve handles, switches and touchscreens, must be robust to ensure integrity and designed to prevent product residue or water penetration or accumulation. Also, enclosures should be sloped or pitched to avoid use as a storage area or residue accumulation point.

| Principle 7 - MAINTENANCE ENCLOSURES | | | | | | |
|--------------------------------------|--|---------------------|----------------|----------|--------|------------------|
| | Description | Reference | S, M, U, NA | Comments | Points | Points Available |
| 7.1 | Maintenance enclosures and human machine interfaces are not located over open product zones. | AMIF 2013 | | | | 10 |
| 7.2 | Maintenance enclosures and human machine interfaces are fastened to the frame in a manner consistent with the food safety design principles. | AMI | | | | 10 |
| 7.3 | Utility supply lines, pipes and wiring are controlled without bundling and allow clearance for sanitation. | AMIF 2013 | | | | 5 |
| 7.4 | Utility lines are 12" off of the floor and cleanable. | AMI | | | | 5 |
| 7.5 | Conduit and supply lines are not routed above product contact areas. | AMI | | | | 10 |
| 7.6 | Maintenance enclosures in direct wash down areas must be able to withstand cleaning and sanitation, including high pressure washing. Door design should prevent accumulation in or around the seal. Door gaskets should be non-porous and cleanable. | AMIF 2013, NEMA, IP | | | | 10 |
| | | | | SCORE | | 50 |

10 Principles of Food Safety Design

8. Compatibility With Other Plant Systems

Equipment that requires additional sub systems, such as exhaust, drainage, or automated cleaning systems, does not create food safety design risk because of the soil load, operational conditions, or standard sanitation operating procedures.

| Principle 8 - COMPATIBILITY WITH OTHER SYSTEMS | | | | | | |
|--|--|-----------|----------------|----------|--------|------------------|
| | Description | Reference | S, M, U, NA | Comments | Points | Points Available |
| 8.1 | Exhaust systems have welded seams or are otherwise permanently sealed, with no flange or threaded connections, with adequate access for sanitation and inspection. | AMI | | | | 10 |
| 8.2 | Ducts have a drain that directs drainage away from equipment and is properly fastened. | AMI | | | | 10 |
| 8.3 | Compressed air and pneumatic cylinder outlets do not exhaust onto, or in the direction of, product contact surfaces. | AMIF 2013 | | | | 5 |
| 8.4 | In sections of ductwork that are not easily cleaned through access opening, validated CIP systems are utilized. | AMIF 2013 | | | | 10 |
| 8.5 | Equipment drainage is properly fastened and capacity is sufficient for operation and sanitation, <i>i.e.</i> no overaccumulation while draining a CIP system. | AMIF2013 | | | | 10 |
| 8.6 | Fan cooled motors do not blow air onto, or in the direction of, product contact surfaces. | AMIF 2014 | | | | 5 |
| 8.7 | Breakable or removable parts are detectable, dependent on the capability of the system, <i>i.e.</i> made with detectable materials, control measures, failure alerts, etc. | NAMI 2021 | | | | 10 |
| | | | | SCORE | | 60 |

10 Principles of Food Safety Design

9. Cleanable to a Microbiological Level

Food equipment must be constructed to ensure effective and efficient cleaning over the life of the equipment with minimal degradation. The equipment should be designed to prevent bacterial ingress, survival, and growth, as well as preclude introduction or accumulation of allergens, chemicals, or foreign material, on both product and non-product contact surfaces.

| Principle 9 - CLEANABLE TO A MICROBIOLOGICAL LEVEL | | | | | | |
|--|---|--------------------|-------------|----------|--------|------------------|
| | Description | Reference | S, M, U, NA | Comments | Points | Points Available |
| 9.1 | Constructed and easily maintained in a cleanable condition to prevent the ingress, survival, and growth of microorganisms and allow for the removal of allergens. | NSF 5.1, AMIF 2013 | | | | 25 |
| 9.2 | Surfaces are organoleptically cleanable based on sight, touch, and smell. | AMI | | | | 25 |
| 9.3 | Surfaces and product zones are free from biological, chemical, and physical contamination, such as microbes, allergens, and foreign material, after routine sanitation and meet preoperational criteria, according to the product risk.* When requested, data are available to demonstrate criteria can be met. | AMI | | | | 25 |
| 9.4 | Surfaces are accessible for mechanical cleaning and sanitation treatment to prevent biofilms formation. | AMI | | | | 25 |
| | | | | SCORE | | 100 |

10 Principles of Food Safety Design

10. Validated Cleaning and Sanitizing Protocols

Procedures for sanitation must be clearly written, designed and proven effective and efficient. Chemicals and procedures recommended for cleaning and sanitation must be compatible with the equipment and the manufacturing environment to prevent damage.

| Principle 10 - VALIDATED CLEANING AND SANITIZING PROTOCOLS | | | | | | |
|--|--|-----------|----------------|----------|--------|------------------|
| | Description | Reference | S, M, U, NA | Comments | Points | Points Available |
| 10.1 | The sanitation process is a part of the equipment design. | AMI | | | | 15 |
| 10.2 | The need for periodic deep cleaning beyond routine sanitation is eliminated. | AMI | | | | 10 |
| 10.3 | Procedures for routine and periodic sanitation are provided, easy to understand, safe, practical, effective, and efficient. Procedures account for the use of tools and parts storage to prevent damage. | NSF 6.2.2 | | | | 10 |
| 10.4 | Components are capable of withstanding sanitation procedures through the respective lifetime of the equipment or each component. | AMI | | | | 15 |
| 10.5 | Components are able to withstand anticipated temperatures of operational, routine, and periodic sanitation procedures; with consideration for thermal shock.* | AMI | | | | 10 |
| | | | | SCORE | | 60 |

10 Principles of Food Safety Design Summary

| Principle | Score | Points Available | Percent (%) |
|---|-------|------------------|-------------|
| 1. Made of Compatible Materials | | 100 | % |
| 2. Accessible for Insepction, Maintenance, and Sanitation | | 150 | % |
| 3. No product, Liquid, or Other Material Collection | | 100 | % |
| 4. Hollow Areas are Hermetically Sealed | | 110 | % |
| 5. No Niches | | 150 | % |
| 6. Operational Performance | | 120 | % |
| 7. Maintenance Enclosures | | 50 | % |
| 8. Compatibility With Other Plant Systems | | 60 | % |
| 9. Cleanable to a Microbiological Level | | 100 | % |
| 10. Validated Sanitation Protocols | | 60 | % |
| Combined Score | | 1000 | % |

References

NSF – National Science Foundation

ANSI – American National Standards Institute

AMI – American Meat Institute (a predecessor organization of NAMI)

AMIF – American Meat Institute Foundation (a predecessor organization of FMPRE)

NAMI –North American Meat Institute

NEMA – National Electrical Manufacturers Association

IP – International Protection Code set by the International Electrotechnical Commission

21 CFR – Code of Federal Regulations Title 21 – Food and Drugs

Glossary

Principle 1.2

Stainless steel is 304 or 316 grade, or equivalent. The American Iron and Steel Institute (AISI) assigned the designation “type 300 stainless steel” to 18-8 stainless steel. The AISI 300 series stainless steels are all variations on the original 18-8 alloy (18% chromium, 8% nickel). The higher chromium content, along with the addition of nickel, imparts greater corrosion and oxidation resistance, and superior ductility in the annealed condition. Unlike basic carbon steel or 12% Cr stainless, this alloy is non-magnetic. Typically, 304, 316 or 316L stainless steel is used in food processing.

Principle 1.8

Metals are compatible with one another. Indicates that a metal in contact with other metals must be compatible and will not result in galvanic corrosion (where metals in contact with each other oxidize or corrode).

Principle 4.1

If utilizing hollow rotating components that are fully sealed with continuous welds, consider filling with dye. Filling a small percentage (15-25%) of the available space in a member with dye will allow for coverage of the interior and be evident externally in the event of a leak. The cavity does not need to be fully filled. The unit should be completely welded first, then stand the cylinder vertically and drill a small hole in one end. Insert the liquid and weld the small hole closed. Source: Joe Stout

Principle 5.1

Product contact surface textures shall not exceed an Ra average of 32 μ-inch. Surfaces shall be free of imperfections such as pits, folds, cracks, and crevices. Surface textures shall have a maximum Ra average of 32 μ in (0.81 μ m). Average roughness (Ra) is the most commonly specified parameter for surface finish measurements.

Ra is calculated by an algorithm based on the average length between peaks and valleys, while accounting for deviations from the mean line on the entire sample surface. Ra averages all peaks and valleys of the roughness profile, then neutralizes outliers so that extremes have no significant impact.

Roughness may be measured using contact or non-contact methods. Contact methods involve dragging a measurement stylus across the surface; these instruments include profilometers. Non-contact methods are also used. Source: Various

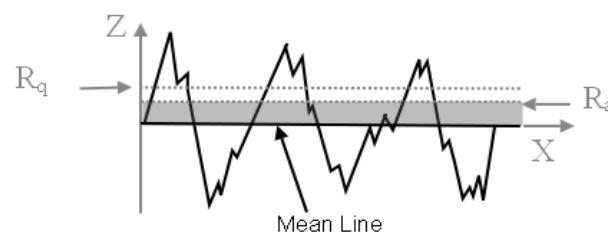


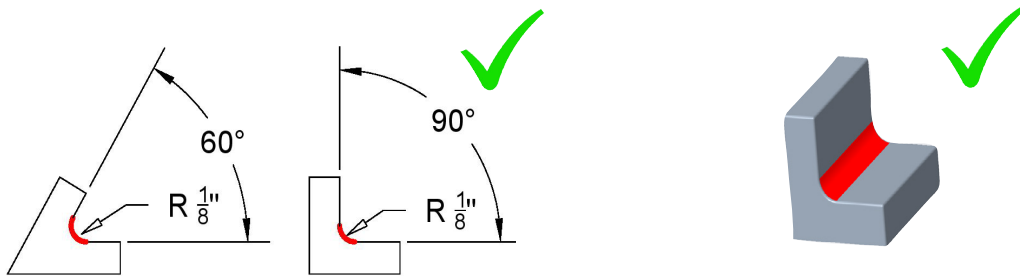
Image Source: Rubert & Co Ltd.

Principle 5.2

Non-product contact surface textures shall not exceed an Ra average of 125 µ-inch. See previous image.

Principle 5.3

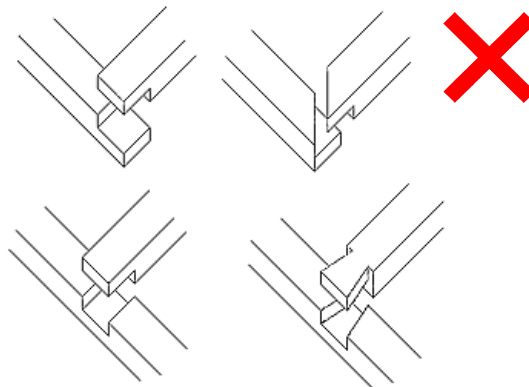
Internal corners with angles less than 135° shall have a continuous radius, *i.e.* fillet, of at least 1/8 inch. For effectiveness and efficiency of cleaning food processing equipment, all areas must be accessible and subject to the application of mechanical action, detergent and sanitizer penetration. Sharp internal angles are hard to access and penetrate with liquids, while gently curved corners allow access to remove soil and biofilms.



Principle 5.4

There are no lap joints. A “lap joint” describes joining two pieces of material by overlapping them without a hermetic seal. For example: two flat stainless steel plates stitch welded or bolted together, making the surface area between the two plates inaccessible for sanitation. The same example would be acceptable if the plates were continuously welded instead of stitch welded to create a hermetic seal and prevent bacterial harborage in between the two plates.

Examples of unacceptable lap joints (if not hermetically sealed) include:



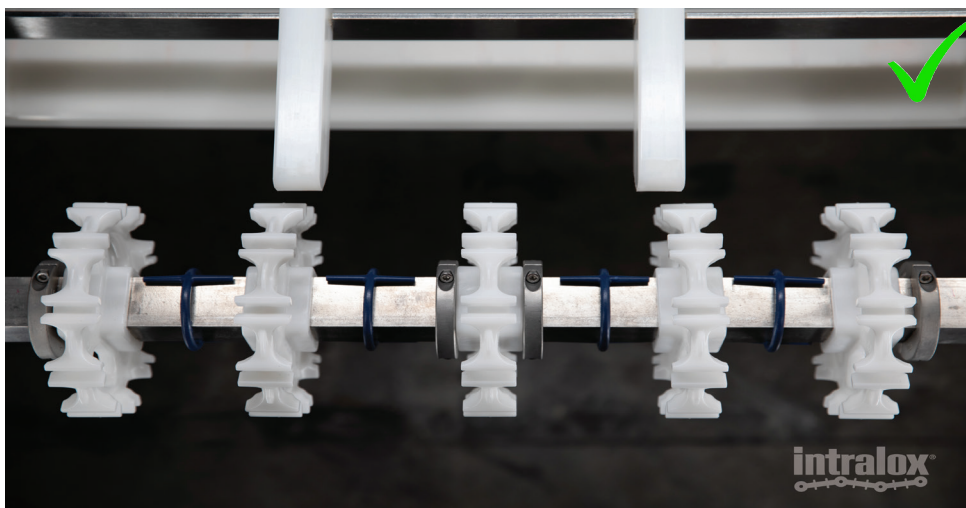
Principle 5.5

Allow for space between two adjoining pieces to permit physical cleaning action. For example, hermetically sealed spacers may be used.



Principle 5.8

Assemblies, such as bushings, sprockets, and bearings, are accessible or disassembled for sanitation. To allow for cleaning, including chemical penetration and mechanical action, assemblies should be movable on a fixed shaft to shift to gain access to clean the shaft or the assemblies should be removable to allow access.

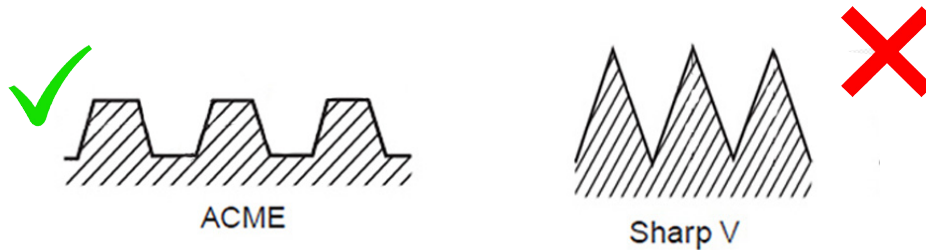


Principle 5.10

Press and shrink fits are not used. These are not permitted for use as they do not allow for movement and associated cleaning and penetration of detergents, mechanical action or sanitizers.

Principle 5.12

Fasteners in or above the product zone either do not have exposed threads or have threads wide enough to facilitate cleaning and have a positive locking method to prevent falling or vibrating off, e.g. ACME 60°. Fastener thread width and shape effects the ability to remove debris. Simply put, it is easier to clean a wider U-shaped thread (ACME) than a narrow V-shaped thread.



Principle 5.15

Rolled edges that create a hollow space are avoided. Rolled edges should not roll far enough to create a niche or hollow space that is inaccessible for cleaning.



Principle 6.2

Compressed air used on product or contact surfaces is filtered and dried to prevent moisture, based on product risk. Final filtration is located as close to the product contact zone as possible. Risk assessment is needed to determine the components needed to achieve the appropriate purity level. Multiple stages of aerosol or coalescing filters should be utilized. 0.3 micron final filtration is recommended as the minimum requirement, especially for non-product contact applications. For product applications, 0.01 micron final filtration is recommended at 99.9999% efficiency, depending on the associated product risk.

Principle 6.4

Non-product contact areas do not cross contaminate product or product contact zones. Non-contact surface areas are typically made to different standards (such as surface roughness) and may be exposed to a different level of risk.

Principle 6.7

Shafts that pass through a product zone shall have separation between the drive motor and the wall of the equipment. The separation or gap prevents debris from the drive motor from contacting product or product contact surfaces. This is most relevant for mixers or blenders when a shaft supporting paddles or blades passes through the product zone.



The drive motor is separated from the blender wall to prevent oil or grease from entering the blender.

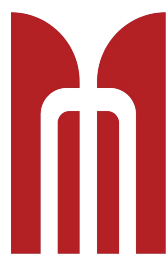
Principle 9.3

Surfaces and product zones are free from biological, chemical, and physical contamination, such as microbes, allergens, and foreign material, after routine sanitation and meet preoperational criteria, according to the product risk. Generally speaking, preoperational criteria are set by the customer through sanitation process validation, depending on product risk. Though potentially applicable in other environments, for equipment used in a post-lethality or otherwise ready-to-eat environment, the recommended measures of cleanable include:

- <1 CFU per 25 square centimeters or <1 CFU per 10 ml when the item is rinsed for APC.
- Acceptable Relative Light Unit (RLU) value for swabs to detect residual ATP. The acceptable RLU value must be determined for each operation based on the monitoring tool(s) in use.
- Negative result for swabs to detect residual protein or carbohydrate.

Principle 10.5

Components are able to withstand anticipated temperatures of operational, routine, and periodic sanitation procedures; with consideration for thermal shock. Equipment that may be subject to thermal shock, either through routine operations or on an as needed basis for sterilization following an event, all equipment components should be able to withstand heating to 160°F for up to 30 minutes. Procedures to protect sensitive components should be provided.



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