Hygienic design of food processing equipment and hygienic practices during maintenance operations

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42.1 Introduction
There is a global trend in the food industry towards minimal food processing and preservation. Consumer demand for ‘fresh-like’ additive-free foods, that maintain their nutritional and sensorial properties during preparation, conservation, packaging, storage and finally consumption, is on the rise. But the general tendency to apply mild processing and conservation techniques to achieve that purpose, often shortens the shelf-life of food, may put foods at risk and may compromise consumer health. Therefore, more than ever, good hygienic engineering and design practice is one of the tools to reduce or exclude microbial (e.g. pathogens), chemical (e.g. lubricating fluids, cleaning chemicals) or physical (e.g. glass, wood) contamination of food. Proper hygienic design also may eliminate product ‘held-up’ within the process equipment where it could deteriorate and affect product quality on rejoining the main product flow. As such, good hygienic design may prevent that one batch cross-contaminates a subsequent batch. Good hygienic design also reduces the downtime required for an item of process equipment to be cleaned, while at the same time allowing to increase the time to produce. Therefore, although initially more expensive than similarly performing poorly designed equipment, hygienically designed equipment will be more cost effective in the long term.

To reduce and eliminate product recalls, lost production, and site closure, due to contamination arising from poorly designed equipment, this chapter intends to inform food safety professionals and inspectors/auditors about the risks associated with poor hygienic design. With typical examples of poor hygienic design, the necessary technical and practical guidance will be given to identify and control
equipment related food safety hazards. As such, this chapter may help the food manufacturer to select
the most suitable food processing equipment, to construct an installation that meets all current and future
hygienic requirements, and to set up an appropriate food safety management plan (e.g., HACCP) to
eliminate or control all food safety hazards along the food chain.

In a first section, an overview is given of the current legislation and standards dealing with
the hygienic design of food processing equipment. Section two lists the basic hygienic requirements
that food processing equipment must meet to produce safe food products. The third section describes
the hygienic and food grade materials that can be used in the construction of food processing
equipment; followed by a section that outlines the requirements to the surface finish. In section five
and six, we will make recommendations with respect to the hygienic design of respectively open and
closed equipment for processing of food. In section seven, consideration will be given to the hygienic
installation of food processing equipment in the food factory. The last sections deals with hygienic
practices during process equipment maintenance operations in the food industry.

42.2 Legislation

European Machinery Legislation and sanitary standards
Food equipment intended to be sold in European countries and designing operations in food factories
must comply with (Moerman, 2011):

Á European Machinery Legislation, consisting of the Machine Directives 2006/42/EC & 98/37/EC
department of the European Commission
Á Materials and Articles intended to come into contact with Food Directive 89/109/EEC
Á Materials and Articles intended to come into contact with Food Regulation EC N° 1935/2004
Á Council of Europe Guideline on Metals and Alloys used as Food Contact Materials
Á Plastics and Materials in Contact with Food Regulations Directives 2002/16/EC & 2002/72/EC
Á prEN 1672-1 standard
Á EN 1672-2 standard
Á EU commission - Scientific Committee on Veterinary Measures relating to Public Health: Cleaning
and Disinfection of Knives in the Meat and Poultry Industry
Á Several EN Food Machinery-specific Standards, applicable to specific food production equipment
(e.g. mixers, cutters, cooking equipment, etc.), developed by CEN/TC153
Á 41 EHEDG guidelines

ments 91/368/EEC & 93/44/EEC) requires that all equipment used to handle food should be
hygienically designed: (a) be so constructed, be of such materials and be kept in such good order,
repair and condition as to minimize any risk of contamination of the food; (b) with the exception of non-
returnable containers and packaging, be so constructed, be of such materials and be kept in such
good order, repair and condition as to enable them to be kept thoroughly cleaned and, where
necessary, disinfected, sufficient for the purposes intended; (c) be installed in such a manner as to
allow adequate cleaning of the surrounding area.

prEN1672-1 and EN1672-2 are Harmonized European standards specifying machinery, safety, and
hygienic requirements for various food industries, drawn up by the Technical Committee CEN/TC 153
of the Comité Européen de Normalisation (CEN). prEN 1672-1 deals especially with how to arrange
interlocking of guards to allow safe cleaning according to the hygiene requirements (coded magnetic
switches), how to apply electrical safeguards in wet environments and during hose-down operations,
how to contain product to avoid slip risks, and how to proceed with safe hopper feeding and product
loading. prEN 1672-1 also provides the user instructions for safe and effective clearing blockage,
cleaning, setting up and maintenance. EN 1672-2 sets design principles and requires the choice of a
design which meets both safety and hygiene objectives. These two standards are supported by
around forty EN food machinery-specific Standards.

EHEDG guidelines are developed by members of European research institutes and universities,
food companies and food equipment manufacturers. EHEDG was founded in 1989 to provide
European food equipment manufacturers and Food manufacturers guidance in the implementation of
the hygienic requirements defined in the Machine Directives 2006/42/EC & 98/37/EC, and the EN
standard 1672-2. Several members of EHEDG participate in CEN/TC 153 to develop EN standards
with respect to the construction of safe and hygienic food equipment.
Regulation (EC) No 852/2004 on the hygiene of foodstuffs that replaces Directive 93/43/EEC, sets out the framework for standards of food hygiene and food control. Both directives describe general requirements for food premises, specific requirements for rooms where food is prepared, particular requirements for transport, equipment, food waste, water supply, personal hygiene, storage/handling and training. To fulfil all these requirements, Directive 93/43/EEC and Regulation (EC) No 852/2004 have adopted the principles of HACCP as tool to identify and control food safety hazards (EC, 1993 & 2004). Therefore, the EC has published a Guidance document to facilitate the implementation of the HACCP principles in food and food related businesses (EC, 2005).

British sanitary standards
In Great Britain, the following hygienic standards are developed:

- Campden Food & Chorleywood Research Association Guidelines;
- Chilled Food Association - Hygienic Design Guidelines 2002
- Institute of Food Science & Technology Food and Drink™ Good Manufacturing Practice: A guide to its Responsible Management, 5th edition, 2007

US sanitary standards
In the US, the following Government Agencies and Private Organizations have published sanitary standards for food processing equipment (Moerman, 2011):

- US Dept. of Agriculture (USDA): Food Safety and Inspection Service (FSIS) 11.000 series: Facilities, Equipment & Sanitation;
- USDA Guidelines for the Sanitary Design and Fabrication of Dairy Processing Equipment;
- International Association of Milk, Food, and Environmental Sanitarians, Inc. (IAMFES): committee on Sanitary Procedures ®A Sanitary Standards®
- American Society of Mechanical Engineers (ASME): ANSI-ASME F2-1: rFood, Drug and Beverage Equipment®& ASME Bioprocess Equipment International Standard (ASME BPE-2009);
- Baking Industry Sanitation Standards Committee: ANSI-BISSC Sanitation Standards;
- AFDOUS (Association of Food and Drug Officials of the United States): AFDOUS Frozen Food Code®
- NSF international: a) Food Service Equipment Standards; b) Food preparation and Service Equipment;
- American Meat Institute (AMI) checklists, to allow processors to conduct a sanitary design audit of the equipment based on assigned points

To develop US sanitary standards, both NSF and 3-A cooperate with EHEDG.

International standards:
Several international operating organisations have developed hygienic standards on their own (Moerman, 2011):

- ISO 14159:2002 Safety of Machinery - Hygienic Requirements for the Design of Machinery;
- ISPE Baseline® Guides, ISPE Guides, ISPE Good Practice Guides;
- Codex Alimentarius (developed by Food and Agricultural Organization (FAO) of the United Nations and the World Health Organization);
- Codex HACCP Code;
- GMP ™ WHO standards;

42.3 Basic hygienic requirements
Processing equipment intended to produce safe food should at least meet the following basic hygienic requirements (Holah, 2000; Lelieveld, 2003):

- Construction materials used for equipment must be completely compatible with the product, environment, cleaning chemicals and disinfectants, and the methods of cleaning and disinfection.
• Product contact surfaces (including the welds in the product contact area) should have a smooth finish enough to enable them to be easily cleaned.
• Food equipment should be designed as to prevent bacterial ingress, survival, growth and reproduction on both product and non-product contact surfaces of the equipment. The food processing equipment must be constructed to ensure effective and efficient cleaning over the life of the equipment.
• Welding or continuous bonding are preferred over fastenings. Exposed screw threads, nuts, bolts, screws and rivets must be avoided whenever possible in product contact areas. Alternative methods of fastening can be used where the washer used has a rubber compressible insert to form a bacteria-tight seal.
• To make permanent pipe joints, welding is the preferred method of joining. These welds must be continuous and smooth. Screwed pipe couplings must be crevice-free and provide a smooth continuous surface on the product side. Flanged joints must be sealed with a gasket to avoid ingress of microorganisms.
• In design, construction, installation and maintenance, hollow areas of equipment such as frames and rollers must be eliminated or they shall be hermetically sealed. As such, bolts, studs, mounting plates, brackets, junction boxes, nameplates, end caps, sleeves and other such items must be continuously welded to the surface, and shall not be attached via drilled and tapped holes.
• Niches such as pits, cracks, crevices, open seams, gaps, lap seams, inside threads that accumulate dirt and hamper the cleanliness of the process equipment are not allowed (Fig. 42.1).
• Dead spaces, dead ends, pockets or other conditions which may trap food, harbour contamination, prevent effective cleaning and disinfection, and allow cross-contamination, shall be avoided.
• All inaccessible horizontal flat areas, ledges, projections, protrusions, recesses, edges, etc. where product scrap can accumulate, should be eliminated.
• The exterior of non-product contact surfaces should be so arranged that harbouring of contamination in and on the equipment itself, as well as in its contact with other equipment, floors, walls or hanging supports, is prevented.
• All pipelines and equipment surfaces in the product zone must be so arranged that they are self-draining (Fig. 42.2) to minimize contamination and corrosion risks when liquid food, cleaning and disinfection solutions, and rinsing water are retained during idle periods. Microbes can flourish in stagnant pools of water, when supported by nutrients which are trapped in the internal pockets. Moreover accumulated and pooling cleaning solutions may contaminate food products.
• Certain equipment surfaces operate at or below the natural dew point of water vapour. Equipment design, therefore, should not permit the formation of condensate that may enter the food zone and contaminate product, or product-contact surfaces.
• All parts of the equipment shall be readily accessible for inspection. Because potential contaminants on representative surfaces throughout the product contact zone must be readily detectable, all surfaces in the product zone must be immediately visible for inspection, or the design of the equipment shall allow readily dismantling without the use of tools for such inspection. Equipment surfaces must be readily accessible for manual cleaning and disinfection (Fig. 42.3), unless it can be demonstrated that the result of in-place cleaning and disinfection procedures without dismantling is equivalent to the result of dismantled and manual cleaning procedures. All potential obstructions to cleaning, disinfection and maintenance should be avoided or minimized.
• Instruments not only must be hygienically designed, but also hygienically installed.
• Equipment design also must ensure hygienic compatibility with other equipment and systems, such as electrical, hydraulics, steam, air and water.
• Maintenance equipment enclosures and human machine interfaces such as push buttons, valve handles, switches and touchscreens, must be designed, to ensure food product, water or product liquid does not penetrate or accumulate in and on the enclosure or interface. Also, physical design of the enclosures should be sloped or pitched to an outside edge to avoid use as storage area. Doors, covers and panels should be designed so that they prevent entry and/or accumulation of soil. To facilitate cleaning, they should be easily to remove.
• Bearings should be mounted outside the product area to avoid contamination of food products by lubricants and to exclude the ingress of bacteria. When the bearing is within the product area, its design should allow the passage of cleaning fluid.
• Food grade oil should be used, and leaking of oil onto food product has to be excluded. A drip pan which protects the product zone should be used, or motors driving equipment components such as agitators, belt drives, etc. should be placed outside the product area. If they are within the splash area, they should be protected by a removable cover.
Fig. 42.1 The pits, cracks, crevices, recesses, open seams, gaps, lap seams, bolts and threads will accumulate dirt and will make this equipment uncleanable (courtesy of John Butts, Land O’Frost).

Fig. 42.2 All surfaces in the product zone are designed to be self-draining for liquid food, cleaning and disinfection solutions, and rinsing water (courtesy of Krones).

Fig. 42.3 Product contact surfaces of this equipment are not readily accessible for manual cleaning and disinfection. Moreover, the dome screw with drive slot and washer create gaps and crevices where debris collects (courtesy of Joe Stout, American Meat Institute).
**42.4 Materials of construction**

*General recommendations*

Construction materials for food processing equipment, process piping and utilities should be homogeneous, hygienic (smooth, non-porous, non-absorbent, non-toxic, easy cleanable, impervious and non-mould supporting), inert (non-reactive to oil, fat, salt, etc.; may not adulterate the food by imparting deleterious substances to it, nor affect its organoleptic characteristics), chemical resistant (corrosion proof; non-degrading and maintaining its original surface finish after sustained contact with product, process chemicals, cleaning agents and disinfectants), physically durable and mechanical stable (resistant to steam, moisture, cold, heat, the actions of cleaning and sanitizing agents; resistant to impact, stress and fatigue; resistant to wear, abrasion, erosion and chipping; not prone to cracks, crevices, scratches and pits, unbreakable) and easily to maintain, in agreement with the guidance described in EHEDG guidelines N° 8 and N° 32. Additional requirements could be availability, welding ability, machinability and capability of being shaped. Notice that materials which are worked (for instance: bent, cut, sheared, extruded or drawn) during manufacture may require additional treatment (such as passivation) following fabrication in order to render them corrosion-resistant. Hence, materials should be selected that are suitable for surface treatment (Hauser et al., 2004a).

Product contact surfaces - all the surfaces exposed to direct contact with the product as well as indirectly impacted surfaces from which splashed product, condensate, liquid or solid particles may run off, drop off, or may fall into the product - should be constructed of materials that meet the highest hygienic requirements, while materials used in the construction of components located in the non-food contact area may be of a lower grade.

*Use of metals and alloys*

Carbon steel cannot be used in the food contact area due to its corrosion sensitivity, especially by salt and chlorine containing bleach. To retard its corrosion, it is often galvanized (zinc plated) but, with time, galvanized steel becomes damaged when the zinc coating peels off. The only permitted applications of galvanized steel is in contact with dry and non-acidic foodstuffs. Painted steel never shall be used in the neighbourhood of food because paints often contain zinc, lead, cadmium and phenolics. Moreover, paint can crack or flake, and some cleaning agents rupture the physical integrity of paints. Paint that peels off can fall onto the product, creating a health risk. Paint surfaces used in non-product contact areas may crack or flake and should be repainted immediately.

Especially the austenitic chrome-nickel or chrome-nickel-molybdenum steels are used for the construction of equipment and machining in the food industry. Stainless steel AISI SS 304(L) can be used for the construction of food processing equipment and food processing support systems in applications with low chloride levels (up to 50 mg/l [ppm]), near neutral pH (between 6,5 and 8) and at low temperatures (up to 25°C). However, stainless steel AISI SS 304 is sensitive to sodium hypochlorite and to salt that is usually present in food in high contents. In these less appropriate circumstances, it can still be used for exterior equipment surfaces, motor and electrical cabinets, etc. Because cheaper grade AISI SS 304/304(L) will suffer some corrosion over a long time period, the small additional cost of using AISI SS 316/316L rather than AISI SS 304/304L almost certainly will be worthwhile in terms of trouble-free operation. Stainless steel AISI SS 316(L) is commonly used as construction material for food processing equipment. However, as temperatures approach 150°C, even AISI SS 316 stainless steels may suffer from stress-corrosion cracking in regions of high stress and exposed to high levels of chloride. Therefore, other stainless steel types were developed to overcome that problem (e.g., duplex steel and nickel alloys) (Hauser et al., 2004a).

The best known application of copper are vessels, traditionally used in many breweries and distilleries. Copper does not really constitute a food safety problem but it is recommended to avoid direct food contact with copper utensils, as it can cause unacceptable organoleptic effects. Moreover, copper can be quickly and severely affected by strong alkaline detergents, sodium hypochlorite, acidic and salty food, making it not really suitable in the food contact zone. The copper alloys brass (60-70% copper, 30-40% zinc) and bronze (80-95% copper, 5-20% tin) are more prone to corrosion by alkaline and acidic detergents, salty and acidic food than the ferrous steels. They become quickly porous, especially brass that undergoes de-zincification by acid and steam.

Because aluminium is attacked by alkaline detergents, sodium hypochlorite and acidic food, the use of uncoated aluminium utensils should be limited. Anodised aluminium is acceptable in the food contact area. Exposure to aluminium is usually not harmful, but its intake should be limited.

Lead, cadmium and mercury in food contact materials absolutely should be avoided. Notice, however, that these components are largely present in electrical and electronic components. In 2003, the EU adopted the Directive on the restriction of the use of certain hazardous substances in electrical
and electronic equipment (RoHS) Directive (2002/95/EC). Alloys for food contact may only contain aluminium, chromium, copper, gold, iron, magnesium, manganese, molybdenum, nickel, platinum, silicon, silver, tin, titanium, zinc, cobalt, vanadium and carbon.

Use of plastics
Plastic materials may be used to preclude metal-to-metal contact (e.g., for bearing surfaces), as guides and covers, or for hoses because of their plasticity and corrosion resistance. These plastics should be odourless, non-porous, smooth and free from cracks, crevices, scratches and pits which can harbour and retain soil and/or micro-organisms after cleaning. They may not absorb product constituents and micro-organisms, must have high mechanical strength (resistant to ageing, creep, brittleness, fatigue, etc.) and good wear/abrasion resistance, shall be resistant to heat, cold flow, hydrolysis, electrostatic charging, etc. Further, no migration of plasticizers, monomers or additives into the food product shall occur.

When using a plastic material (belt, gaskets, electric cables, etc.), it is of utmost importance to secure that the material is able to withstand all temperatures from -50°C to temperatures as high 121°C (steam sterilization) without cracking or breaking. Moreover, the plastic material must be chemical resistant to solvents, acid, alkaline, reducing and oxidising agents, cleaning and disinfection agents and corrosive food gases at these temperatures. The equipment manufacture should test the chemical and temperature resistance of the plastic material (Partington et al., 2005; Moerman, 2011).

Use of rubbers
Elastomers must be chemically resistant to fat, cleaning agents and disinfectants; they may not show expansion and shrinking under the influence of temperature changes or chemical fluids; they must be abrasion resistant (e.g., rotary shaft seals, or seals in static applications that are subjected to abrasion from dry material product); and they must retain their surface and conformational characteristics (no loss of elasticity, no embrittlement, no rubbed-off parts, no crevices, etc.). However, elastomers can be degraded by product, by cleaning agents, by disinfectants and by thermal and mechanical stress much earlier than metal components, with as results: leakage of lubricants, loss of bacteria tightness, increased adherence and retention of dirt and bacteria in crevices leading to permanent product and process contamination, insufficient cleaning and problematic disinfection. Partly destroyed sealings allow ingress of liquids containing chlorides under gaskets and seals, so that a high chloride concentration may subsist between damaged sealings and adjacent metal, which favors crevice corrosion even in stainless steel. Therefore, gaskets and seals preferably should be of a removable type. Appropriate rubber materials are fluor elastomers, natural, silicone, neoprene, EPDM, nitrile and nitrile/butyl rubber. Their resistant characteristics can be found in table 42.1 (Partington et al., 2005).

<table>
<thead>
<tr>
<th>Contact Medium</th>
<th>Natural rubber</th>
<th>Acrylonitrile butadiene rubber</th>
<th>Silicone rubber</th>
<th>Ethylene propylene rubber</th>
<th>Chloroprene</th>
<th>Fluor elastomer</th>
</tr>
</thead>
<tbody>
<tr>
<td>temperature range</td>
<td>-60 to 80°C</td>
<td>-35 to 120°C</td>
<td>-70 to 200°C</td>
<td>-60 to 135°C</td>
<td>-40 to 230°C</td>
<td>-30 to 180°C</td>
</tr>
<tr>
<td>Hot water (120°C)</td>
<td>-</td>
<td>++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Hot water (145°C)</td>
<td>-</td>
<td>-</td>
<td>+++</td>
<td>+++</td>
<td>-</td>
<td>+++</td>
</tr>
<tr>
<td>NaOH (5%; 90°C)</td>
<td>++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>NaOH (5%; 140°C)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>++</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>H₃PO₄ (2%; 90°C)</td>
<td>-</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>H₂PO₄ (2%; 140°C)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>++</td>
<td>-</td>
<td>+++</td>
</tr>
<tr>
<td>HNO₃ (1%; 70°C)</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>++</td>
<td>+</td>
<td>+++</td>
</tr>
</tbody>
</table>

+++ = unlimited resistance; ++ = limited resistance; + = only short contact; - = non-resistant; - - = absolutely non-resistant

Other materials
Other materials such as insulation, wood, etc. are not allowed within the product contact area (exceptions are butcher blocs; wooden barrels, etc.). To avoid their exposure to the outside, they must be permanently and tightly sealed off from the product zone.

Glass may be used as a food contact surface, but its application is not recommended due to the potential for breakage. Specially formulated glass materials such as Pyrex have proven successful. When glass is used, it must be durable, and break and heat resistant. Some applications where glass is used are light and sight openings into vessels, and in very limited extent glass piping. Replacement by transparent alternatives like Perspex or polycarbonate is recommended (Hauser, 2004b).
Ceramics are very resistant to acids and sufficiently resistant against lye. They are very hard and can withstand pressures of 100-400 MPa. They are used in the coating of other stable materials, in the production of ceramic membranes, and in the construction of pipes or processing equipment for very sensitive products. The main drawbacks of ceramics are their brittleness and porosity. To be food safe, all ceramic surfaces into direct contact with food must have smooth, unbroken and lead-free glassy surfaces, entirely free of crazing (small hairline cracks) and blemishes. Although low doses of bacteria might hide in a crack, in contact with food that small colony can become a large culture.

The use of nanomaterials in the food industry may present potential risks, requiring the need for risk assessments to identify and quantify these risks. Some nanoparticles have been found to exhibit negative effects on tissues such as inflammation, oxidative stress and signs of early tumour formation (Stone et al., 2009; FAO/WHO 2010; Becker et al., 2011). Because nanoparticles may become wasted in surface waters along with cleaning solutions, experimental evidence is needed to demonstrate that these nanoparticles can be removed from this surface water if it is used as a source of drink water.

The European Hygienic Engineering & Design Group clearly states that materials which have been modified with antimicrobial chemicals may not be considered as a substitute for hygienic design. Micro-organisms may build up resistance against such chemicals over a period of time, and antimicrobial chemicals are only effective if the microorganisms are in intimate contact with them.

42.5 Surface finish
Product contact surfaces must be finished to a degree of surface roughness that is smooth enough to enable them to be easily cleaned and disinfected. The surface finish must be such that there are no cracks, pits or cavities were water or soil might remain. In the pharmaceutical industry, a surface finish of roughness $Ra \leq 0.4 \mu m$ is often used, while a surface finish of roughness $Ra \leq 0.8 \mu m$ is considered as acceptable for the food industry. Surface roughness, $R_a$, of enclosures in hygienic production areas should not exceed 2.5 $\mu m$. Surfaces will deteriorate making cleaning more difficult (Hauser, 2004a).

42.6 Hygienic design of open equipment for processing of food

42.6.1 permanent and dismountable joints

Permanent joints
It is better to use permanent rather than dismountable joints, because the latter type of joints may give rise to projections, protrusions, edges, recesses, metal-to-metal contact, etc. In that way, welded joints are preferred over mechanical fixings, such as bolted or screwed joints.

Permanent joints of equipment should preferably be welded, but notice that several types of common defects may arise in welded joints (e.g. misalignment, cracking, porosity, inclusions) which can act as a source of microbiological problems. All welds in the product contact area are recommended to be continuously welded and with sufficient weld seam protection (inert shield-gas protection at both sides) in agreement with EHEDG guideline N° 9 and N° 35. Higher alloyed filler metal in comparison to the welded material may reduce the risk for corrosion. Welds must be polished to have the same surface finish ($R_a \leq 0.8 \mu m$), appearance, etc. as the surrounding materials. They should be inspected for any discolouration and defects (Hauser et al., 1993; Kopitzke et al., 2006).

Fig. 42.4 (a) In the product contact area (1), product debris may become trapped at the step (2) and in the crevices and metal-to-metal contact areas between the seams (3), if overlapped sheets of metal are intermittently welded (4) instead of continuously welded. (b) Overlapped sheets of metal must have continuous welds (5) and sloped edges (6) for easy cleaning. (c) However, it is still better to avoid overlapping sheets of metal, and to give preference to smooth continuously welded sheets (Lelieveld et al., 2003; Hauser et al., 2004b).
To avoid crevices at metal-to-metal interfaces where product debris may become trapped, intermittent or spot welds are not acceptable (all welds should be continuous or filled) and overlapping must not be used (Fig. 42.4a). If overlapping is unavoidable due to the need for added strength at the weld location, reliable draining and cleaning conditions of shadow areas must also be taken into consideration. In the case of thick sheets, the edge of the upper plate must be sloped to avoid areas at the overlap edge which can retain soil and be difficult to clean (Fig. 42.4b). However, it is still better to avoid overlapping sheets of metal, and to give preference to smooth continuously welded sheets (Fig. 42.4c) (Hauser et al., 2004b).

Sharp corners (≤ 90°) and welding in sharp corners of equipment (Fig. 42.5a & b) must be avoided. Radiused corners (sloped sides) and welding seams away from corners and preferably made at the non-product contact side are recommended (Fig. 42.5c). Weld fillets in the food area should have a minimum radius of 6 mm. If the material is less than 4 mm thick, the minimum radius should be 3 mm. Where a corner cannot have a radius of greater than 3 mm, its cleanability should be demonstrated by testing.

Fig. 42.5 (a) Welded seams in ≤ 90° corners of receptacles containing food product (1) will create uncleanable areas where residual soil (2) will accumulate. (b) Well-rounded corners (radius R ≥ 3 mm) and correctly welded seams in the plain area avoid any hygiene risk (Lelieveld et al., 2003; Hauser et al., 2004b).

Use of adhesives on metal-to-metal joints should be avoided. If adhesives are used for permanent joints they must be compatible with materials, products and cleaning/disinfecting agents with which they are in contact. All bonds should be continuous and mechanically sound so that the adhesives do not separate from the base materials to which they are bonded.

**Dismountable joints**

Dismountable joints (e.g. of plates or appendages) fixed by fasteners (e.g. screws or bolts) must only be used if dismantling is unavoidable. Joining components with hexagon nut-and-bolt pairs which protrude in the product zone or with screws exposed to product is not allowed. Besides crevices, screws, bolts and nuts also give rise to metal-to-metal contact corrosion, and create gaps, dead areas and/or exposed threads (Fig. 42.6 and Fig. 42.7).

Fig. 42.6 Screws may not be exposed to food product (1) because debris collects in the screw drive, because they give rise to metal-to-metal contact corrosion (2), and because they create gaps, dead areas (3) and crevices (4). Countersunk screws with slots or other drive configurations are not recommended for the reasons mentioned, and incorrect machining of the countersunk hole may cause the screw to either (a) form a pocket in which debris collects or (b) to protrude into the product flow giving rise to circumferential crevices where debris may become trapped. (c) Pan, dome, round and truss screws are not suitable because they protrude in the product flow. (d) Socket head cap screw are not allowed in the food area because debris accumulates in the recess or socket to fit an Allen wrench for turning. In addition, the use of counterbores is not recommended for all reasons mentioned earlier (CFPRA, 1983; Lelieveld et al., 2003; Hauser et al., 2004b).
Exposed bolt ends and nuts in the product zone (1) are not allowed because they give rise to metal-to-metal contact corrosion (2), exposed threads (3), and crevices (4). Debris also tends to adhere to and around fixings and provides nutrients for microbial slime growth. Exposed threads should be cut to the correct length or preferably domed nuts should be used (Lelieveld et al., 2003; Hauser et al., 2004b).

Wing nuts and pop rivets are also not allowed on the product side. It is recommended to have a plain or domed bolt head sited on the product side, to cover exposed threads with domed nuts, and to use solid rivets instead of pop rivets. (Fig. 42.8). But overall, the use of welded butt-joints that are ground and polished instead of fastenings is more preferred (CFPRA, 1983).

Correct design of bolt-heads and their effective sealing with metal-backed elastomers gaskets (Fig. 42.9) can render them hygienic. The head of the hexagon headed bolts will be plain or domed. Domed nuts can be used to cover exposed threads. Sealing the crevice between the bolt-head and the food-contact surface will protect the annular clearance between the shank of the bolt and the hole through which it passes.

(a) Wing nuts are often used where adjustment is required but debris collects around and in the exposed portion of the slot behind the nut. (b) It is recommended to cover exposed threads with domed nuts. (c) Pop rivets (1) are not recommended where construction necessitates this type of fabrication. Solid rivets (2) should be used (CFPRA, 1983).

(a) To prevent crevices at the product side (1), screws, pins or a stud welded on the non-product side (2) should be used. (b) A bold head (3) that is hexagonal (4), domed (5) and provided with a sloped circular collar (6, 7) is easily cleanable, and the metal backed (8) elastomer gasket (9) is used to seal the thread (Lelieveld et al., 2003; Hauser et al., 2004b).
Dismountable joints must be crevice-free and provide a smooth continuous surface on the product side. Further, metal-to-metal contact should be avoided. Therefore, where components butt against one another in the product area, the crevice between them should also be sealed by means of an elastomer. Compression of the seal can be controlled by means of screws and interference-fit location pins on the reverse side to the product (Fig. 42.10a). A flange like connection can control compression (Figure 42.10b). The design of the groove for the seal must allow space for expansion in order to avoid extension of seal material into the product area during heating.

**Fig. 42.10** Where components butt against one another in the product area (1), the crevice between them should also be sealed by means of an elastomer (2). (a) Compression of the seal can be controlled by means of interference-fit location pins (3) and screws (4) on the reverse side to the product. (b) A flange like connection can control compression (Lelieveld et al., 2003; Hauser et al., 2004b).

Split pins, self-tapping screws, staples, spring tension pins, bushing, etc. which may loose and cause damage to other equipment and physical danger to the consumer are unsuitable fastenings. Tape, rubber bands and wire should not be used to permanently modify equipment. A designer also must avoid very small fastenings, and fixings in plastics which can't be identified by metal detectors. Stainless steel or dull-nickel plated fixings should be used as specified in the fixings and fastenings handbook. Finally, one must take care for sufficient space around fixings for cleaning (min. 25 mm).

42.6.2 **Hygienic design of process vessels, containers, bins, etc.**

*Interior and exterior design of process vessels, containers, bins, etc.*  
Appropriately designed and installed process vessels shall meet the following recommendations:

*For good drainability and cleanability, food-containing equipment (tanks, vessels, troughs, reservoirs, bins, etc.) shall have their discharge outlet at the lowest level; their bottom shall be sloped (more than 3° towards the outlet), and their corners shall be well-rounded. These corners should preferably have a radius equal to or larger than 3 mm. Sharp corners (≤90°) must be avoided (Fig. 42.11).*

**Fig. 42.11** For good drainability and cleanability, equipment (tanks, vessels, troughs, reservoirs, bins, etc.) used in the processing of food (1) shall have their discharge outlet at the lowest level; their bottom shall be sloped (more than 3° towards the outlet), and their corners shall be well-rounded. Where food product and cleaning solutions are not allowed to drain, residual soil (2) will be left (Lelieveld et al., 2003; Hauser et al., 2004b).
Equipment without bottom outlets must be pivoted (Fig. 42.12) for fully discharging of product and cleaning solution. Materials or contaminants from the exterior of the vessel may not gain access to the food product being discharged. Besides fully drainability, the vessel tipped for discharge also should be designed for improved cleanability (e.g., vessel corners should be well rounded; hinges must allow for maximum cleanability).

Fig. 42.12 To fully empty containers without bottom outlet, they must tip over an angle of at least 93°. The interior and exterior of the container must be designed to exclude any contamination of the food product when it is drained. Vessel should have well rounded bottom corners, with hinges designed for maximum cleanability (Lelieveld et al., 2003; Hauser et al., 2004b).

The design of the top rims of product containing equipment (e.g. open tanks, chutes, boxes) must avoid ledges where product can lodge and which are difficult to clean (Fig. 42.13a). Open top rim designs must be rounded and sloped for drainage (Fig. 42.13b). If the top rim is welded to the wall, the weld must be flush and polished to provide a smooth surface and the rim must be totally closed. Any holes, therefore, must be sealed by welding or by fitting sealed caps (Fig. 42.13b).

Fig. 42.13 Top rims may impart rigidity to the construction. (a) However, a rim with an upper horizontal part provides a surface where debris may collect. When the rolled-over part of the rim is badly designed, it may provide a ledge where product debris can lodge. This soil can indirectly affect the product. (b) Open top rims must be rounded in a way that at one side the product drains back in the bulk of the product, while the more exterior part of the rim must allow drainage to the outside. Where preference is given to closed top rims, the top rim should be welded correctly to the wall over its full length. The weld must be flush and polished to provide a smooth surface and the rim must be totally closed. Any holes, therefore, must be sealed by welding or by fitting sealed caps (CFPPRA, 1983).
Lids are used (e.g., for process vessels, tanks, bins,) to avoid contamination of product from the environment during processing or storage. They can be completely detachable for cleaning, but if they are non-removable they must be sloped for drainage. If hinged covers are used the hinge must be designed in such a way that it can be cleaned easily and that accumulation of product, dust and foreign bodies (including insects etc.) is avoided. When the vessel is covered, no sharp corner at the top should be created when the lid is placed on the vessel. Flat lids provide a horizontal surface where dirt may accumulate. Moreover a sharp corner is created at the top near the seal. Preference should be given to domed lids with a sloped top that collects less dirt and allow for proper drainage of liquids. (Fig. 42.14).

Fig. 42.14 (a) Covers are used (e.g., for process vessels, tanks, bins, etc.) to avoid contamination of food product (1) from the environment during processing or storage. When the vessel (2) is covered with a flat lid (3), a horizontal surface is provided where dirt may accumulate. Moreover a sharp corner (4) is created at the top near the seal. This seal (5) is not very appropriate because over-compression may lead to protrusion of the seal in the product area, thereby impeding cleaning; while under-compression may lead to both indentations and crevices and failure to provide a reliable seal. Even when it is not visibly leaking, the seal may permit the ingress of microorganisms. (b) Preference should be given to domed lids (3') with a sloped top that collect less dirt and allow for proper drainage of liquids. The present gasket groove allows for controlled compression of the gasket (5') at the product side (Lelieveld et al., 2003; Hauser et al., 2007).

Elastomers can be deformed, but the volume cannot be reduced! This means that when a flat gasket is compressed so that the thickness is reduced by say 20 per cent, the width of the gasket is increased by 25 per cent, assuming that the length can be kept constant. As a consequence, a considerable amount of movement takes place at the edges of the gasket. In view of the inconsistency of the friction between stainless steel and elastomers it is most uncertain how the deformation of the gasket will take place. Over-compression of the flat gasket (Fig. 42.15a) may affect the hygienic characteristics of equipment in two ways. Firstly, over-compression may lead to destruction of the gasket, particularly if it is heated (such as during hot cleaning and/or sterilisation).

Fig. 42.15 (a) Over-compression of the gasket (2) may lead to protrusion of the gasket (3) into the product area (1), thereby impeding cleaning and draining. Moreover, because the gasket may exceed the maximum allowable limit of compression during thermal expansion, it may become brittle and fail. (b) Insufficient compression of the gasket (4) may give rise to a crevice (5) between the two flanges and possibility of leakage. (c) It is good practice to slope (6) the groove that receives the gasket in a way that space for expansion (7) is provided at the non-product side while controlled compression of the gasket is possible at the product side (8). A further possibility to reduce the effects of friction is to avoid even compression of the gasket by using gaskets with a profiled section which "involute" along the sealing faces rather than sliding under compression (Lelieveld et al., 2003; Hauser et al., 2007).
The gasket may exceed the maximum of compression caused by thermal expansion and become brittle and fail to perform, while particles of it may break off and contaminate the product. Secondly, over-compression may lead to protrusion of the gasket into the product flow, thereby impeding cleaning and draining. Under-compression (Fig. 42.15b) is also highly undesirable as it may lead to both indentations and crevices and failure to provide a reliable seal. Even when it is not visibly leaking, the seal may permit the ingress of micro-organisms. It is good practice to slope the groove that receives the gasket (Fig. 42.15c), in a way that space for expansion is provided at the non-product side while controlled compression of the gasket is possible at the product side. Such design also allows to reduce the area of the gasket in direct contact with the food product. A further possibility to reduce the effects of friction is to avoid even compression of the gasket by using gaskets with a profiled section which “involute” along the sealing faces rather than sliding under compression.

As with metals, not all polymeric materials and elastomers exhibit the same coefficients of thermal expansion (Fig. 42.16). Therefore, not only the dimensions of the metal components but also those of the seal must be correct, ensuring adequate compression at the product side, under all conditions of intended use. Attention must be given to thermal expansion at high temperatures (e.g. during hot cleaning and sterilisation) and to loss of resilience at low temperatures (e.g. during the manufacture of ice cream). To ensure a smooth durable surface with sufficient temperature and corrosion resistance, equipment manufacturers tend to use polytetrafluoroethylene (PTFE) as gasket material in food processing equipment. However, PTFE has insufficient resilience and expands significantly more than stainless steel (expansion coefficient for PTFE is approx. 100×10⁻⁶/°C, compared to approx. 16×10⁻⁶/°C for stainless steel). Due to this large difference in thermal expansion coefficient, a heat treatment changes the shape of the PTFE gasket (gasket protrusion occurs) and after cooling down a crevice occurs. For a gasket of 5 mm thickness and a temperature change from 20°C to 120°C and back, the crevice may be 36 µm wide if there is no resilience at all (in practice the gap will be slightly smaller). Therefore, seals made from non-resilient materials should not be used.

Conventionally designed right-angled grooves containing O-rings invariably create gaps and crevices that are impossible to clean in-place and/or to sterilise in-line (Fig. 42.17). One cause is that the elastomer material of the O-ring has a significantly higher thermal expansion coefficient than steel. During heating the seal will expand to cover an increasingly larger surface of steel, protecting micro-organisms trapped between the O-ring and the steel surface against contact with hot water, chemical solution or steam. Although the seal contact surface will usually reach the correct temperature during treatment with hot water or steam, the water activity in the grooves will be too low for the destruction of most microorganisms at the temperature and time applied. After cooling down and shrinkage of the seal, the surviving micro-organisms may be released and will multiply and contaminate the product. Additionally, repeated thermal expansion of the seal into the product flow may result in it suffering damage which will not only contaminate the product but may also progressively reduce its ability to seal again upon re-cooling.
Fig. 42.17 (a) A conventionally designed right-angled groove (2) contains an O-ring (3) that is compressed between the sealing faces of two stainless steel surfaces (4) to separate the product area (1) from the outside. Such a rectangular groove-O-ring design invariably create gaps and crevices (5) that are impossible to clean in-place and/or to sterilise in-line. The groove provides sufficient space for micro-organisms (6) to enter via the crevice. (c) During heating, due to the difference in thermal expansion between metals and elastomers, the O-ring will expand (7) to cover an increasingly larger surface of steel, protecting micro-organisms (8) trapped between the O-ring and the steel surface against contact with hot water, chemical solution or steam. (d) After cooling down and shrinkage of the seal, the surviving micro-organisms may be released (9) and will multiply and contaminate the product (Lelieveld et al., 2003; Hauser et al., 2007).

Installation of agitators in open vessels (e.g., kettles)

Equipment like stirrers, homogenisers or mixers should preferably be arranged in such a way that the need to seal shafts into the product is avoided. Where mounting of the equipment outside the product zone is possible, the mixer used to mix open product should be fixed beside the equipment, not only to prevent the contamination of the product with dripping oil, but also to avoid the introduction of soil, and concomitantly spoiling microorganisms and pathogens into the product along with overhanging electrical cabling (Fig. 42.18).

Fig. 42.18 (a) A motor and cabling mounted over any exposed product (1) can contaminate it by soil, condensate or lubricants (2). (b) The motor drive (3) and power line should be placed beside the equipment. A self-draining protection sheet with upstand (4) in combination with a cowl (5) on the shaft must exclude any food safety risk. The bottom side of the thrower ring (cowl) should be made inspectable (Lelieveld et al., 2003; Hauser et al., 2004b).

Permanently mounted agitators in closed vessels

Top entering agitators with shaft seals are typically mounted to a vessel using a flanged or hygienic clamp connection, with hygienic O-rings or gaskets to seal between the mating surfaces. The selected mounting arrangement must support the agitator mounting design loads while achieving an appropriate seal. The upstand for the top mounting of the agitator should have limited length L because of the difficulty of cleaning of the annular space in-place. The annular space between the agitator shaft and agitator nozzle shall, for cleaning purposes, have the target maximum L/A ratio of 2:1. At least a 25 mm gap is required to facilitate CIP spray coverage (Fig. 42.19) (CFCRA, 1997; ASME, 2009).
Fig. 42.19 The top entering agitator with motor (1) is mounted to a vessel using a flanged or hygienic clamp connection (2), with hygienic O-rings or gaskets (3) to seal between the mating surfaces. A retained gasket having limited compression is more hygienic than an O-ring in the face for sealing the joint. The agitator shaft (4) passes through the mounting flange via a seal (5). The upstand (6) for the top mounting of the agitator should have limited length L because of the difficulty of cleaning of the annular space (7) in-place. The annular space between the agitator shaft (4) and agitator nozzle (6) shall, for cleaning purposes, have the target maximum L/A ratio of 2:1. Agitator motors (1) should be equipped with permanently lubricated bearings. Where lubrication is required, the design and construction shall be such that lubrication cannot leak, drip, or be forced into the product zone. Self-lubricating agitator shaft (packing) seals (8) shall be provided with convenient means for adjustment to prevent leakage and to allow for complete drainage to the exterior. In that way, accumulations of foreign material in the event that leakage does occur can be avoided. Further, a drip protection plate (9) can be provided to prevent lubricant from entering the product zone (CFCRA, 1997; ASME, 2009).

Agitator motors should be equipped with permanently lubricated bearings. Where lubrication is required, the design and construction shall be such that lubrication cannot leak, drip, or be forced into the product zone. Self-lubricating agitator shaft (packing) seals shall be provided with convenient means for adjustment to prevent leakage and to allow for complete drainage to the exterior (Fig. 42.19). In that way, accumulations of foreign material in the event that leakage does occur can be avoided. Further, drip protection is commonly provided to prevent lubrication from entering the product zone. All surfaces of shaft seal ring assemblies passing through a bowl or cover shall be accessible, removable or retractable to permit cleaning of all product zone surfaces.

Fig. 42.20 Rotary shafts running at a high number of revolutions are held in place in an adaptor sleeve with a radial roller bearing (1). (a) Single dynamic seals (2) are lubricated by a lubricant (top mounted agitator) or the product (bottom mounted agitator) which may be transported past the seal and back again, contaminating further the product. They may be easy to clean if properly designed but they will not prevent the passage of microorganisms, and hence they are not suitable in aseptic process equipment. There is also a narrow annular space (3) at the product side in the proximity of the seal, which makes cleaning very difficult. (b) A double seal arrangement (4) allows the use of a barrier medium (5), such as steam, hot water, condensate or a disinfectant solution which makes it well-suited from a microbiological standpoint. The volume of the annular gap around the shaft is reduced (6), improving the cleanability of the seal and its proximity (Holah, 2000).
Rotary shafts running at a high number of revolutions are held in place in an adaptor sleeve with a radial roller bearing. Single dynamic seals (Fig. 42.20a) will not prevent the passage of microorganisms. If properly designed, they may be easy to clean but not bacteria tight because rotating shafts may exhibit some axial mobility. This makes single dynamic seals unsuitable for aseptic equipment. A narrow annular space at the product side in the proximity of the seal such as shown in Fig. 42.20a must be avoided because it is difficult to clean. The space around the seal should be as wide as possible. Rotary shafts with double seal arrangement allow the use of a barrier medium, and have been shown to be well-suited from a microbiological standpoint. In Fig. 42.20b, one seal is seated rigidly in the housing (longitudinal shading), while the other moves with the shaft. The sealing surface between the two seals must be lubricated. If the shaft opening has product flowing through it, which could be the case with agitators having a shaft entry from the bottom of vessels, the product itself can be directly used as lubricant. The product flowing through can be carried away by the barrier medium, which could be steam, hot water, condensate or a disinfectant solution (e.g., alcohol). The sterile fluid may scavenge the microorganisms that enter the space between the seals, maintaining absolutely sterile conditions. Which flushing fluid should be used will depend on the product and the process but both the barrier medium and lubricant chosen must be product-compatible. To avoid transfer of microorganisms from the outside of the equipment to the inside, without a adequately long exposure to antimicrobial fluid the distance between the two seals must always be sufficiently large (Lelieveld, 2003; Hauser, 2007).

Bearings in the product area should be avoided but an application may mandate the use of foot bearings. In example given, if the shaft of a top entry agitator is very long, a foot bearing may be required at the bottom of the vessel to steady it. It shall be of a packless bearing type. The foot bearing must be mounted well clear of the base so as not to impede free draining of product and also so as to allow easy cleaning of their supports. Design features and/or procedures required to ensure cleanability are: drain holes, spray ball and/or wand additions, increased CIP flow, operating the steady bearing immersed in CIP fluid. The arrangement of wear surfaces (bushing, shaft, or shaft sleeve) shall facilitate drainage. A longitudinal or helical groove may be cut in either the bush or the shaft. It should be deep enough to allow access into the bearing of either the product as a lubricant or the detergent for cleaning (Fig. 42.21). Sealed bearings should not be used in the product area because they can cause hygiene risks at their seals. If, however, their use is unavoidable, their lubricants should be specified as being allowed with the food contact.

![Fig. 42.21](image)

(a) Cleaning may be impeded due to too tight clearance (1) in the foot bearing itself (2), and due to too little clearance between it and the base (3). Horizontal ledges (4) where product may accumulate or where liquids are not allowed to drain must be avoided. (b) The foot bearing is now mounted clear of the bottom of the vessel (5), allowing free flow of product and cleaning solution around it. Preferably bearing pedestal support members (6) should be made of solid construction. Hollow constructions are not recommended, but if used, they shall be of sealed (welded) construction, inspected for integrity. Round legs are preferred over flat members, even if the latter are radiused. The legs should be flush welded in-place to the tank bottom (7). All welds must be ground and polished to blend smoothly with the adjacent surfaces. The agitator shaft is provided with grooves (8) in the bearing area to facilitate both lubrication by fluid products and cleaning. Sloped and radiused surfaces (9) reduce the probability of debris getting lodged on the top of the foot bearing and allow for proper drainage of liquids (e.g., cleaning solution) (CFCRA, 1997; Lelieveld et al., 2003; Hauser et al., 2004b; ASME, 2009).
Hygienic design of agitators

Agitators and agitator shaft assemblies passing through the seals shall be designed and constructed to be smooth, with all surfaces meeting all the hygienic design criteria applicable to a product contact area. Agitator shaft assemblies shall be readily accessible to allow all surfaces to be effectively cleaned via spray, directed flow, immersion or cleaning-in-place. Agitator ends shall have surfaces of minimum area immediately adjacent to the recipient ends and no longer than necessary to ensure proper incorporation of ingredients into a mix.

The design of agitator product contact parts should minimize the occurrence of crevices, void spaces and dead spaces in grooves. All voids should be closed by either fabrication (welding) or approved sealing techniques (O-rings, seals, etc.) to give surfaces ground flush and free of crevices at points of metal-to-metal contact. Metal-to-metal joints (e.g., keyways, hub-to-shaft joint, hub-to-end cap joint, etc.) may allow ingress and accumulation of product and/or microorganisms. (Fig. 42.22a & b; Fig. 42.23)

Food quality gaskets under controlled compression may seal the propeller hub to the shaft and to the impeller nut (end cap) that secures the end of the agitator shaft (Fig. 42.22c). Alternatively, the hub should be welded to the shaft and the end cap (Fig. 42.22d). Because debris may collect on exposed screw threads, the hub shall not be fastened to the shaft by means of a screw. To avoid any screwed joints (even bolts with dome head nuts and washers of suitable food grade material), the blade appendages (stirrers, homogenisers, mixers, etc.) should be welded to the hub. As an alternative to hub-to-shaft and subsequently impeller blade-to-hub attachment, blades immediately can be attached to shafts by welding. All welds used in the assembly of agitator parts should be grounded and polished.

Permanently joined metal surfaces with a total included internal angle less than 135° on agitators (e.g., at hubs and nuts) shall have a radius of not less than 3 mm tangential to both adjacent surfaces. Corners (e.g., at hubs, nuts, spanner flats, etc.) must be radiused to facilitate cleaning, and horizontal areas must be sloped to prevent debris from becoming lodged on the surfaces and to allow for maximum drainability. Machined transitions such as shaft steps, coupling surfaces, spanner flats, etc. should have 15° to 45° sloped surfaces. Impellers with flat, horizontal surfaces (e.g., flat-blade disc turbines, concave-blade disc turbines) may require additional design and/or cleaning practice to ensure drainage and cleanability, e.g., drain holes, spray ball and/or wands additions, increased CIP flow, adjusted spray coverage, and faster impeller rotation.

Agitators permanently mounted are not required to be removable if they are readily accessible and do not interfere with drainage from the tank. Where permanently installed agitators are equipped with an outer frame to which rubber, plastic or other similar scraping edges are attached, these scrapers shall be readily removable from the agitator. In kettles, however, it is recommended that the entire unit shall be constructed so that it can be tilted or lifted out of the kettle.

![Fig. 42.22](image-url) (a) The hub (2) is secured to the shaft (1) by means of a screw (3), which is exposed to product that may collect in and around the screw head. The hub-to-shaft connection gives rise to a metal-to-metal joint (6) that may permit the ingress of product and bacteria. Agitator blades (4) should be welded to the hub, although screw connections are sometimes observed. These exposed screw heads (even bolts with dome head nuts and washers of suitable food grade material) again will create a food safety hazard, and the blade-to-hub connection gives rise to a new metal-to-metal joint (6). To avoid the latter problem, the joint between the blade and the lug on the hub can be sealed by a thin gasket. Keyways (5) exposed to product are not recommended, because product and micro-organisms may be retained in the keyway. Keyways may require additional design and/or cleaning practice to ensure drainage and cleanability, e.g. spray ball and wand additions, increased CIP flow and adjusted spray coverage. (b) Once the hub (2) is secured to the shaft (1), an end cap (impeller nut, 7) is screwed on the interior male thread end of the shaft. The non-welded impeller hub-to-shaft and hub-to-end cap connections give
rise to crevices and metal-to-metal joints (respectively 6° and 6°) that may allow the ingress of product and bacteria. In that way, the keyway also may retain product and micro-organisms. The sharp corners of the spanner flats (9) on the end cap may be difficult to clean. (c) Food quality gaskets under controlled compression respectively may seal the propeller hub to the shaft (8) and to the end cap (8°). Keyway (5), where employed due to mechanical design considerations, shall have edge radii not less than 3 mm. The corners of the spanner flats on the end cap have been radiused (9°.

(d) An all-welded impeller assembly (e.g., hubs, blades, end cap) is still more preferred. Impeller hubs welded to the shaft are preferred over removable hubs. Although the designer may omit the hub, and immediately can attach the blades to the shaft (4). Finally, also the end cap can be welded to the shaft (7° (CFCRA, 1997; Lelieveld et al., 2003; Hauser et al., 2004b; ASME, 2009).

Fig. 42.23 The hub is secured to the shaft by means of bolts with dome head nuts, which are exposed to product that may collect in and around the screw head. This non-welded hub-to-shaft joint also lacks a food grade gasket that could seal the dead spaces in the groove and avoid crevices at points of metal-to-metal contact. Ingress and accumulation of product and/or microorganisms at the inside is observed. Welds also have a high degree of roughness (courtesy of Burggraaf & Partners).

Welded in-tank shaft connections are preferred, although in-tank threaded shaft connections (Fig. 42.24f) and in-tank shaft couplings (Fig. 42.24a-e) are allowed if they are of acceptable hygienic design. Threaded shaft connections are preferred over in-tank shaft couplings, although shaft rotation of the first is limited to a single direction to avoid that the shaft sections separate. The designer must ensure that the use of a threaded shaft connection is appropriate for the selected shaft diameter and design loads. To avoided exposure of the threads to the product, O-rings or flat gaskets (preference for the first mentioned) should be used to seal mating surfaces (Fig. 42.24f). Hygienic bolted coupling construction may be used where appropriate for the particular application. The preferred location for fastening hardware is on the underside of couplings, and the fasteners typically used should be hex-head cap screws, acorn-head cap screws and threaded studs with acorn nuts (Fig. 42.24d). These fastener heads shall be free of raised or engraved markings that might inhibit cleanability. Again O-rings or flat gaskets (preference for the first mentioned) should be used to seal coupling mating surfaces. Elastomer seal washers (Fig. 42.24b-d) must avoid metal-to-metal contact.

Fig. 42.24 (a) Bolted agitator couplings with flat hexagon head screws without elastomer gasket under the bolt head and the nut give rise to metal-to-metal crevices (1) that may allow the ingress of food product and bacteria. Moreover, debris may lodge in and around the bolt thread (2). The absence of a circumferential O-ring or flat gasket gives rise to another metal-to-metal crevice, and product and microorganisms may be retained in the cavity (3). (b, c) Agitator couplings made by means of domed hexagon bolt heads and nuts (4) provided with an elastomer gasket (5) under the bolt head and the nut allow for a crevice free joint without metal-to-metal contact. Due to the presence of a circumferential O-ring (6) or flat gasket (7), no product and microorganisms can enter.
inside the agitator coupling. Corners are radiused (8). However, there is still a horizontal flat surface at the upper side of the agitator coupling where debris may lodge. (d, e) Aseptic applications require for fastening hardware at the bottom side of the agitator coupling, and the upper parts of the coupling should be sloped to minimum 15-45° (9) to prevent debris from collecting at these places and to allow for maximum drainability. (f) The most optimal agitator coupling in an aseptic environment is a threaded shaft connection with a O-rings or flat gasket (preference for the first mentioned) to seal the mating surfaces to avoid exposure of the interior thread. The corners of the spanner flats on the end cap have been radiused (10) (CFCRA, 1997; Hauser et al., 2004b; ASME, 2009).

**Good insulation practices**
Non-chloride-releasing insulation material should be used. For thermal insulation of vessels, appropriate qualities of rock wool are acceptable. However, for piping, styrofoam, foam glass or another rigid foam are better choices over fibrous materials. The problem with fiberglass batting is, that this material has already proven to be an excellent harbourage of dust, insects and rodents, and a clean-up and maintenance nightmare if not properly installed and maintained. Therefore, it is highly recommended to install fully welded, vapour tight, aluminium or stainless steel cladding of appropriate thickness, that resists tear and abrasion. The exterior of the insulation protection should be smooth, properly sealed to avoid ingress of dust, liquor, air and moisture, and should be installed in a correct way with joints facing downwards. Such ingress could promote corrosion between the walls, assisted by possible microbial growth. Damaged or wet insulation should be repaired or immediately replaced (Fig. 42.25). Insulated lines should be kept high overhead where there is less chance for food products to contact the insulation. Pipes that are frequently soiled by food products or require periodic disassembly may be left un-insulated. Insulation is also often omitted around steam pipes inside cleanrooms, to preserve a clean exterior surface.

### 42.6.3 Equipment framework
The number of support legs and cross bracings should be reduced but shall be of sufficient number and strength and so spaced that the process equipment will be adequately supported. Cross bracers should be fitted in a diamond configuration to. Solid cross members as structural members are preferred over hollow section members. Although for use in the horizontal plane and to minimize horizontal ledges and crevices, completely sealed hollow section members are still more preferable over open profile angle or channel sections (Fig. 42.25a). Round section members or square section members turned through 45° that provide sloping surfaces are recommended (Fig. 42.25b).

For the design of framework that will be exposed to continuous vibrations (e.g.; drying towers, etc.) the use of open profile construction should be considered. Small fatigue cracks can arise from vibration, allowing penetration of moisture, soil and micro-organisms in closed profiles. For vertical parts of frames all the cross sections shown in Figure 42.25 can be used when legs and supports are designed with open profiles, the folding should be turned outward for easy cleaning, or alternatively as completely closed pipes.

![Fig. 42.25](image_url)

*(a) Prevent unnecessary flat open and closed horizontal support members on which debris can lodge. (b) Round section, square section members turned through 45° and open profile members provide sloping surfaces (Lelieveld et al., 2003; Hauser et al., 2004b).*
Rolled hollow sections must be sealed by welding, should be filled or made drainable, away from the product zone. Plastic plugs are less recommended. Tubular sections shall not be penetrated e.g. with fasteners, and hence drilled and tapped holes are not allowed. Preference should be given to welded plugs when fastening to hollow sections. Welded studs and tapping plates are not recommended.

42.6.4 Feet

Feet begin at the point where they attach to the leg or the body of the equipment and end at the support point on the floor. These feet are non-product contact surfaces but have a hygienic significance because they may become a harbourage of soil and create a source of secondary contamination to the products (e.g., during pressure cleaning, dirt present on the feet may splash on the food contact surfaces).

Use a minimum number of support legs/floor mountings, because they are important obstacles for cleaning and service personnel. However, feet must be sufficient in number and strength and so spaced that the equipment will be adequately supported. The general rule is to minimize the floor contact area, but the contact face of the foot must be sufficient to absorb the pressure. If the equipment is heavy and requires leg pads to distribute the load, such pads or bases shall be fastened to the floor. The manner in which feet are fastened to the floor depends on the type of floor, and the presence of equipment (e.g. machinery producing heat, etc.) or services (e.g. electricity, etc.) immediately below the surface. Fastening to the floor may occur by bolting, but chemical anchors without bolting (fixing to floors by means of a polymer seal) are more recommended. If the equipment must be bolted to the floor, pads or bases shall be sealed or grouted to the floor (Fig. 42.26). Care must be taken during installation to assure that the foot pad does not span over cracks, grout lines, or other floor imperfections. Whenever anchor bolts have been drilled into the floor, the holes must be sealed with epoxy or similar materials, dependent on the floor, so that water and dirt are not allowed to leak into the hole. Floor fixings should be of stainless steel, and have dome nuts fitted.

Fig. 42.26 If the equipment is heavy, the contact face of the foot (2) with the floor (1) must be sufficient to absorb the pressure. To distribute the load, feet should be provided with leg pads or bases (4) welded to the foot leg (3). The foot may be fastened to the floor by means of (a) stainless steel anchor bolts (5) which must have (a) seal washer(s) (6) and (a) dome nut(s) (7) fitted. When the equipment must be bolted to the floor, pads or bases shall be sealed (figure left, 8) or grouted (figure right, 8) to the floor.

Fig. 42.27 Feet ends may be round (ball feet), may have a foot base with flat (not recommended) or sloped surfaces (recommended), or may consist of a pivot-socket arrangement where pivot-end of the spindle may freely swivel in the socket or internal cavity of a separate load-bearing foot base. Feet ends with horizontal flat surfaces are not recommend. For maximum drainability, all surfaces of the feet not in contact with the floor should be sloped, with rounded corners and smooth welds (APV Baker, 2001).
Fixed feet should be radiused, free of sharp corners and crevices at the fixing point. Feet ends may be round (ball feet), may have a foot base with flat (not recommended) or sloped surfaces (recommended), or may consist of a pivot-socket arrangement where pivot-end of the spindle may freely swivel in the socket or internal cavity of a separate load-bearing foot base (Fig. 42.27). This type of connection allows relative inclination of the foot stem and foot base like in an articulate bone joint, and is optimal to allow equipment to be repositioned or moved to uneven surfaces without loss of stability. Due to the non-rigid nature of the foot leg-foot base transition and because the load of the supported equipment is more evenly distributed about the surface of the socket, articulated support feet can better cope with the vibratory or oscillatory movements of the process equipment.

![Fig. 42.28](image)

(a) Foot spindle (1) is inserted into a bush (3) which is welded to a foot base (2). The foot spindle is rigidly fastened to the foot base by means of a screw (4). This foot is not hygienically designed because the upper part of the foot base forms a non-drainable flat surface (5). Debris and water may collect into the crevice formed between the inner surface of the bush and the inserted part of the spindle, and around the fastening (4). (b) The foot spindle (1) is all-around flush welded (3) to the foot base (2) from which the upper surface parts (4) are now sloped to make them drainable (Hauser, 2008).

All exposed surfaces shall have a smooth finish such that soil may be cleaned from the surface using manual cleaning techniques, and be free of pits, folds, cracks, crevices, and other imperfections in the final fabricated form, when installed on the machinery and within the specified load conditions. Hence, feet may not create dirt traps, and further they must be self-draining which means that they shall not have pockets which retain liquids (Fig. 42.28b). Provide feet with fixing holes only if bolting to the floor is necessary, but avoid the use of extra brackets. Fig. 42.29 shows some examples of hygienically designed feet.

![Fig. 42.29](image)

(a) Adjustable ball feet, (b) stair riser legs, totally sealed, with sloped top and set off the riser, (c) pivotal machine levelling mount from which the threaded spindle is completely concealed in a closed pipe that is in-welded in a sheet metal leg (courtesy of Koss Industrial, Inc.; courtesy of Kevin Farnum)

Equipment should be adequately located in position, with all its feet having a contact face that is even so as to ensure complete contact with or to allow fixation to the floor. For proper installation on uneven or inclined floors, it is not allowed to level food processing equipment with improvised shimming. Equipment feet adjustable by min. +/- 75 mm should be used. When adjustable feet with threads are used for that purpose, the threaded spindle for levelling should be completely concealed in closed profiles/pipes or enclosed so as not to cause accumulation of dirt and contaminants in the thread.
The load-bearing foot may also include a rubber layer underneath or rubber can be embedded in the load-bearing foot. The elastomeric material may damp the vibrations of the operating equipment and may prevent slipping of the foot on the support surface. The rubber used shall be of sufficient low Durometer to provide a tight continuous seal with the flooring material.

42.6.5 Castors
Castors are applicable in those places where equipment has to be made mobile in order to facilitate inspection and cleaning of equipment and process rooms. Transportable equipment (e.g., conveyors) also allow to change the lay-out of process lines in function of the demand for food products that have to be produced (e.g. frozen vegetable industry). However, a castor assembly shall not be used in the product zone. In example given, containers designed for elevated dumping shall not be equipped with attached castors if, when raised, the castors are over the product zone.

Castors should be made of a material that suits the floor quality, the expected loading and the frequency of movement. If underspecified castors are used, the body of their wheels can break up due to being overloaded. In general, the heavier the load, the larger the wheel required for the castor. Large wheels roll more easily, are generally more manoeuvrable and ride better over obstructions and floor cracks, tracks, ruts than smaller wheels. Large wheels also provide sufficient clearance between the lowest part of the equipment and the floor for easy cleaning and inspection.

Although cast iron wheels are virtually indestructible and are able to withstand the highest loads, their use in the food industry is not recommended (not acceptable), because they are prone to general corrosion and because of the damage which they cause to floor surfaces. Castors manufactured from zinc plated mild steel should be avoided, because that coating on the wheel may wear away, resulting in corrosion and increased friction between the wheels and the castor forks (horns). Paint shall not be used as coating. Castors manufactured from zinc plated mild steel require the swivel bearing and wheel axle to remain lubricated to prevent them from corroding. Hence, lubrication of the swivel bearings and wheel/axle surfaces should be regularly and properly done, especially because lubricant can be washed away by regular cleaning. Castors (body, mounting plate, etc.) manufactured from stainless steel with stainless steel swivel bearings need no lubrication to prevent corrosion. Stainless steel axles in combination with an outer PTFE bushing provide self-lubrication of the wheel/axle surfaces. However, worn wheels and PTFE bushing still will need periodical replacement.

![Fig. 42.30](image)

Thermosetting plastics, particularly phenolics, are widely used in the food industry because they withstand high temperatures and can carry high loads. However, they can become damaged by poor quality flooring and by defects in floors, such as concrete joints and ridges. Phenolic wheeled castor types are often worn to a flatter profile or their tread is spalling. Thermoplastic wheels have better impact resistance than phenolic wheeled castors, but they have poor resistance to higher temperatures. However, these wheels don’t need bearings. Where possible, the wheel should have a
colour (e.g. blue). High temperature rubber wheeled castors have a high temperature thermoplastic centre with a bonded high temperature rubber tyre. They will wear and may be damaged by poor or abrasive surfaces, and acids, oils, chemicals and other substances may be harmful to rubber. These soft tread wheels, however, may ride more easily over bumps, level changes, joints, drainage gullies, etc., and are less destructive to tiled, linoleum, etc. floors.

Swivel castors (Fig. 42.30) only function well when they are securely mounted to a rigid frame so the swivel bearing kingpin axis remains vertical at all times. Rigid castors must be mounted (welded, sealed, or readily removable) in a way that their axis and wheels are in alignment. All structural members (mounting plate and horn) shall have a minimum of horizontal flat surfaces. The plate mounting shall be constructed to have a flat top surface. The angle between the top surface and the edge of the plate shall be 90° or less. Mounting holes and other devices provided for installation shall be so designed as to prevent the formation of pockets or areas difficult to clean. The horn assembly or fork shall be constructed so that the surface facing the wheel shall have no concave surface except that part joining the horn plate. Included angles between all surfaces should have a minimum radius of 6 mm. Kingpin assemblies, which have the nuts or rivets at the bottom, shall have suitable caps covering the ends. The minimum clearance between horn assembly and wheel for wheels having a diameter Ø 10 cm in diameter should be 6 mm all round, while that minimum clearance should be 10-12 mm all round for wheels with diameter > 10 cm. Brakes and locking devices should comply with the hygienic requirements mentioned above.

Preference should be given to single-wheeled castors because dual-wheeled castors are more sensitive to contamination, and are more difficult to inspect and to clean. Castor wheels should be constructed so as to have no concave surfaces facing the horn assembly except that part which joins the hub. The included angles between all vertical and horizontal surfaces shall have a radius of not less than 6mm. Wheels should have solid webs, smooth-sided, without ridges or crevices, and their tread-face should be smooth and flat. Rubber wheeled castors should have a tyre, from which tread and shoulder are free of grooves, lugs, voids, sipes, dimples, indentations, carves, etc. wherein foreign matter can penetrate the tyre. If bolted, axle bolt ends should be flush and should not extend more than two-and-a-half exposed threads beyond the retaining nut. Excess threads should be cut off and covered with a "dome" type nut. The use on the axle of cotter pins or castellated nuts to keep the wheel attached to the horn assembly, is not acceptable. Two PTFE washers (combination seals) can be fitted, one either side of the wheel, to prevent direct contact (e.g. metal-to-metal contact) between the wheel and the castor body. Although it is expected that the life of these washers should almost be as long as that of the wheel, these washers can become worn, and then must be replaced immediately. In general, washers (retaining washer under a nut) should not be used between the horn of the castor and the axle retaining nut, because there they are more exposed to impact from the outside.

Roller or ball bearings should be used. Roller can carry heavier loads, while ball bearings wheels roll more easily but carry lighter loads. All bearing arrangements must ensure that no crevices or dead areas are present which could adversely affect cleanability and/or functional life. If no self-lubricating bearings (stainless steel with PTFE bushing) are used, they should be lubricated every six months. In corrosive environments, lubrication of bearings should occur once a month. In the food industry where the lubricant is washed away by daily cleaning, lubrication is sometimes required after each washing. Bearings in castors (wheels and swivel horns) should preferably be of the sealed type. These seals used to contain the lubricant oil or the grease in the bearings will wear, ultimately allowing leakage. Their integrity must be regularly checked and they should be replaced at defined maintenance intervals. If plain ball-race bearings are used, they must be cleanable and, when required, capable of being disinfected and re-packed with food grade grease as necessary.

42.6.6 Belt conveyor

Conveyor frame should have an open structure (Fig. 42.31) with a minimum of hidden areas/surfaces. But guards are required in places where a drive station, a pulley, rollers or the conveyor belt may cause injury. The guards, however, should be easily to dismount to allow for complete cleaning. Solid cross members as structural members are preferred over hollow section members, although completely sealed hollow section members are still more preferable over open profile angle or channel sections, to minimize horizontal ledges and crevices. Hollow sections should be sealed by welding.

Conveying surfaces shall be supported by a minimum amount of carrying surface or bed as required (Fig. 42.32b). The use of solid plate that expands the whole top surface of the conveyor table to provide support to a belt is likely to increase contamination problems, and cause excessive wear of the belt (Fig. 42.32a). Non-removable bearing surfaces for belts cannot be cleaned easily. Rollers shall be used where practical, or line supports that are easily removable for cleaning. The conveyor
belt should have minimal debris retention, and running under turned over section of side cladding (overhanging belt edges) is not allowed because the whole surface of the belt cannot be cleaned, and the belt cannot be lifted up to allow cleaning and inspection of internal surfaces and support members. But also pivoted covers cannot be cleaned easily. The use of fixed hinges is not recommended because of the great difficulty of removing debris and microbial slime from between the hinge segments (Fig. 42.32a). Side guides used to contain product should be capable of being removed. But removable guides also may cause problems because of the possibility of the fastening system working loose. The conveyor frame must be designed so that the sides of the belt are turned up to form an integral guide to the belt. Besides this guide cladding can be made removable allowing for effective cleaning (Fig. 42.32b).

Fig. 42.31 Conveyor frames should have an open structure without horizontal surfaces and with a minimum of hidden areas/surfaces. At the outside, the framework consists of vertical plate members positioned longitudinally, which also serve as a lateral belt guide. The conveyor-frame is an all welded construction with solid round cross-members, welded at the outside frame work. The use of bolts and nuts for fastenings is reduced to a minimum. The cross-members not only act as structural frame members, but also as belt supports. The weld-on flat cross-members are provided with gaps to accommodate the freely located plastic wear strips that help to support the conveyor belt. No bolt holes or nuts were used for fastening ultra-high-molecular-weight (UHMW) polyethylene wear strips. To minimize cleaning time, these belt supports are easily lifted out of the frame by means of a quick tension-release arrangement and without manual tools. The cut-outs in the frame allow spraying and cleaning of the inside of the conveyor without lifting the belt. Although the conveyor shown is provided with a swivel-mounted roller that permits to release tension, providing improved access to the space between belt and bearing table for cleaning and disinfection. The frame member closest to the point where the belt runs onto the drive roller sprocket also serves as a guard. Stand-off legs keep fasteners out of the food zone (courtesy of Dorner conveyors).

Fig. 42.32 (a) The use of solid plate (2) expanded over the whole top area of the conveyor table to provide support to a belt (1) is likely to increase contamination problems, and cause excessive wear of the belt. Non-removable bearing surfaces (2) for belts cannot be cleaned easily. The conveyor belt should have minimal debris retention, and running under turned over section of side cladding (overhanging belt edges) is not permitted as the whole surface of the belt cannot be cleaned (4), and the belt cannot be lifted up to allow cleaning and inspection of internal surface and support members. But also pivoted covers (3) cannot be cleaned easily. The use of fixed hinges is not recommended because of the great difficulty of removing debris and microbial slime from between
the hinge segments (5). Side guides used to contain product should be capable of being removed. But removable guides also may cause problems because of the possibility of the fastening system working loose. (b) The conveyor frame (6) must be designed so that the sides of the belt are turned up to form an integral guide to the belt (7). Besides this guide cladding can be made removable allowing for effective cleaning (detachable cover). The conveyor belt shall be supported by a minimum amount of carrying surface or bed (8) as required. Rods, slats, rollers or like supports shall be used where practical (CFPRA, 1983; Hauser et al., 2004b).

The drive motor of the belt conveyor should not be positioned over the product flow, as this may result in contamination of the product by lubricants discharged from the drive system. Otherwise, an adequately sized drip tray should be fitted. However, motors should be rather located below the line of the product flow because the exposed motor may have a fan that will blow dust and dust-borne microbes around the place. The motor, gears and the chain must be covered to avoid any contamination of food product (e.g., enclosure in a hygienically designed and hermetically sealed housing). However, a chain guard (essential from an occupational safety point of view), when open, may provide a place where product may accumulate, allowing microbes to multiply to large numbers and so posing a contamination risk for the food product on the belt (Fig. 42.33).

Fig. 42.33 Motors should be rather located below the line of the product flow. Both gears, chains and motors of belt drives must be covered to avoid any contamination of product. However, a chain guard (essential from an occupational safety point of view), when open, may provide a place where product may accumulate, allowing microbes to multiply to large numbers and so posing a contamination risk for the food product on the belt (courtesy of Dorner conveyors).

Fig. 42.34 (a) Where possible, the motor, gears and the chain should be enclosed in a hygienically designed enclosure or hermetically sealed housing. (b) An even better solution is applying a direct driven (drum motor) instead of a chain driven system (courtesy of Den Rustfri Stålindustris Kompetencecenter & Interroll).

Also notice that drive motors installed below food products are quickly splashed and difficult to keep clean. The motor is also often of a type that cannot be washed with a high pressure hose using water and cleaning agents. In that case, installed below the line of the product flow, the gears and
motors of belt drives must be covered. Alternatively, cleanable and sealed motors (wash down or easy clean motors) which do not require ventilation or housings, can be used. Where needed, the motor, gears and the chain should be enclosed in a hygienically designed enclosure or hermetically sealed housing (Fig. 42.34a). IP55/54/67 motors can be easily cleaned and drained of water around the motor, if they are provided with enough air space for cleaning and disinfection, maintenance and repair. Where possible, use drum motors (motorized pulleys) (Fig. 42.34b) that are fully closed, non-ventilated, conveyor belt drives where motor and gearwheels are at the inside, submerged in a bath of food grade lubricant, providing at the same time lubrication and cooling. Drum motors make gears and chains redundant.

The design of rollers, pulleys and sprockets shall be free of end recesses and shall be closed if hollow. A welded construction should be preferred to a sealed design (Fig. 42.35).

![Fig. 42.35](a) Pressed-in roller ends (1) create dead areas and crevices, where residues of product and soil may accumulate. (b) Flush roller ends (5) which are properly welded (6) to the roller and to the shaft (2) avoid any hazard and can be cleaned easily (CFPRA, 1983; Hauser et al., 2004b).

Embedded reinforcements, as well as fabric backing materials in conveyor belts, must be covered to avoid contact with the product. Cut edges of belts which incorporate reinforcing materials must be sealed to prevent penetration by wicking (capillary action) of liquids into the interior (Fig. 42.36).

![Fig. 42.36](a) Cut edges of belts (1) which incorporate reinforcing materials (2) are prone to penetration of liquids into the interior by wicking (capillary action). (b) Therefore, embedded reinforcements, as well as fabric backing materials (2) in conveyor belts, must be covered to avoid contact with the product. The edge should be suitably sealed and covered in a way that the covered edge (4) is shaped with as a round rim (Lelieveld et al., 2003; Hauser et al., 2004b).

### 42.6.7 Covers and guards

It is difficult to obtain motors, gearboxes, etc. that meet the recommendation of EN 1672-2. Protecting any of these items by means of covers or guards is recommended. These guards must also protect the food product from contact with drive parts such as lubricated chains, sprocket wheels, etc. The requirement of guarding machinery to ensure safety in operation may easily conflict with hygiene
requirements unless considerable care is taken in its design, construction, installation and maintenance. However, these housings or guards should be removable to provide access for cleaning. From a hygienic and safety point of view, totally removable covers, guards or cladding rather should be avoided. They may not be put back, creating a hazard for the operators in the environment of the process equipment and exposing the food product at risk. Covers and guards also may become damaged during removal. Bars, perforated/punched sheet and weld mesh (Fig. 42.37) stainless steel guards with an open area of 40-50% give good protection from moving equipment parts, and permit access for cleaning and disinfection by spray nozzles or hosing down procedures. For good drainability, covers should always have an angle and should be free of panel joints.

![Fig. 42.37 Example of a hygienically designed guard (courtesy of P.T. Group)](image)

Where possible, hinged covers and guards that pivot outboard should be used. But use as few hinges as possible, and use hinges with the least number of parts. In view of cleaning and disinfection, continuous and piano hinges are not allowed. Block or pin hinges are a possible option, but should have removable hinge pins or be lift-off. Finally, the exterior of enclosures is more easily to clean if internal hinges are used.

![Fig. 42.38 Electrical enclosures can also be sealed to a wall (with food standard silicon seal), or shall be spaced away at least 30 mm or at a distance equal to 1/5 of the shortest dimension of the electrical enclosure parallel to that wall, to prevent a soil trap being created at the rear of the enclosure and to allow for adequate access for cleaning. Suspending members should be constructed of a solid steel round tubing to prevent the formation of a flat horizontal surface whereupon dirt may collect (courtesy of Rittal).](image)

**42.6.8 Maintenance enclosures**

Maintenance enclosures (e.g. electric control panels, junction boxes, pneumatic/hydraulic enclosures) must be designed, constructed, and maintainable to ensure that the product, water, or product liquid does not penetrate into, or accumulate in or on the enclosure. The cabinet and operator panel are mounted where they will be least exposed to splashes. Electrical control cabinets mounted on the exterior of the equipment shall be watertight and sealed to the supporting member with food standard silicon seal, or spaced sufficiently away from the member to permit cleaning of all surfaces. A minimum of 20 mm between the control and supporting member shall be provided. Electrical enclosures can also be sealed to a wall (with food standard silicone seal), or shall be spaced away at least 30 mm or at a distance equal to 1/5 of the shortest dimension of the electrical enclosure parallel to that wall. The distance between the cabinet base and the floor should be no less than 0.3 m.
Horizontal surfaces should be minimised or avoided, by installing a top roof with a minimum 30° inclination towards the front to allow water to run off and prevent that tools are placed on the top. The front edge of the inclining cabinet top should reach beyond the front door and the seal (Fig. 42.38). To prevent condensate dripping from the field box into the product, field boxes should not be placed in or above the contact area. Furthermore, field boxes should be located such that easy access for maintenance and cleaning is practicable. All connections (e.g. cable ladders or wire trays, trunking, conduit, cable, etc.) to cabinets or field boxes should be made via the bottom side of the cabinet. Connections of cables and wires to housings must be sealed (Moerman, 2011).

The control and indicator devices must be constructed of durable and mechanical stable (unbreakable, resistant to steam, moisture and the actions of cleaning and sanitizing agents, abrasion and corrosion resistant) material. Commonly used food grade plastics for the construction of control devices and indicator lights are Polyamide (PA), Polycarbonate (PC), Polyoxymethylene (POM), Silicone and Acrylonitrile butadiene Styrene (ABS). Control devices and indicator lights in contact with food should be shaped such as to avoid the accumulation of dirt and bacteria, and to facilitate cleaning (Fig. 42.39). The device heads must have smooth and crevice free surfaces that are easy to clean. Device head to front panel transitions must be smooth, without corners and edges. Push buttons, when touched, should not penetrate deeply in the front panel far beyond an (protruding) frame edge surrounding the button. Connections must be conceived in such a way, that protruding parts, strips and concealed corners are restricted to a minimum. The connections of inside surfaces must be made with curves of sufficient diameter. Seals should fill the gaps between the fixed and moving device parts, to avoid the ingress of product residues, lubricants and organic materials. A perfect, hermetic seal is also required to prevent the ingress of moisture, dust and dirt within the control panel. An IP67 or IP67K ingress protection rating for control panel enclosures is highly recommended. The preferred installation positions for control and indicator devices are declining and vertical surfaces, such that fluids (splashed food and cleaning solutions) are able to flow from the control panel, at least in cleaning position. Adequate space should be provided between control and indicator devices for easy cleaning. More hygienic alternatives to control panels with push buttons and selection switches are membrane panels with a ≥ 2% inclination or touch screen displays.

![Control panel with hygienic control and indicator devices](image)

**Fig. 42.39** Control panel with hygienic control and indicator devices. Seals should fill the gaps between the fixed and moving device parts, to avoid the ingress of product residues, lubricants and organic materials. A perfect, hermetic seal is also required to prevent the ingress of moisture, dust and dirt within the control panel. Adequate space should be provided between control and indicator devices for easy cleaning (courtesy of Elan-Schmersal).

### 42.7 Hygienic design closed equipment for processing of liquid food

#### 42.7.1 Process and utility lines

*Hygienic design of process and utility lines*

To avoid the formation of standing 'pools' of liquid that can support the growth of microorganisms, process and utility piping runs should be sloped to at least 3% in the direction of flow and should be properly supported to prevent sagging (Fig. 42.40 and Fig. 42.41).
Fig. 42.40 (a) Sagging of piping must be avoided because standing pools of liquid can support the growth of microorganisms. Changes in the level of horizontal runs of pipelines should be avoided otherwise there will be an undrainable section. Horizontal runs of pipe which are routed vertically up and then down to avoid beams, doorways or other obstructions will allow air to collect in the raised section. (b) Process and utility piping runs should be sloped to at least 3% in the direction of flow. Piping must be installed in a way that air doesn’t collect in the raised section. Whilst automatic air release valves can be installed to remove trapped air, the resulting dead leg may cause contamination and/or cleaning problems. Where liquid collects in a lower horizontal pipe section, fitting a valve in a shortened tee allows that liquid to be drained (CFCRA, 1997).

Fig. 42.41 Non-drainable pipe (courtesy of Knuth Lorenzen, personal communication)

Blanked-off tees should be avoided where possible as they constitute a potential hazard. A dead space, being an area outside the product flow, where liquid or gas can become stagnant and where water is not exchanged during flushing, is formed. An air pocket may be present if the branch of a blanked-off tee is pointing vertically upwards (Fig. 42.42a). Hence it will prevent liquids (cleaning solutions, disinfectant solutions or hot water) from reaching all surfaces to be treated, with as result that cleaning-in-place and decontamination processes will be unsatisfactory. Drain points pointing downwards act as a dead leg (Fig. 42.42b) are not acceptable because they provide an area of entrapment which may not be reached by cleaning or sterilizing procedures, and hence they lead to
contamination of the product. During a hot water treatment, the hot water also will stagnate in the downwards pointing pocket, so that the temperature of the surfaces in the dead area may be lower than required as the consequence of heat loss. A downwards pointing dead area also will collect condensate during steam sterilisation (Fig. 42.42c), with as result that again the temperature of the surfaces in the dead area may be lower than required.

![Diagram](image)

Fig. 42.42 (a) When cleaning and disinfection solutions (1) flow through the piping, an air pocket (2) will be formed if the branch of a blanked-off tee is pointing vertically upwards. This will prevent the solutions from reaching the surface in the dead leg. (b) Drain points pointing downwards (3) again act as a dead leg, providing an area of entrapment which may not be reached by cleaning or sterilizing procedures, and hence they lead to contamination of the product. Moreover, during a hot water treatment, the hot water also will stagnate in the downwards pointing pocket, so that the temperature of the surfaces in the dead area may be lower than required as the consequence of heat loss (4). (c) A downwards pointing dead area also will collect condensate (6) due to heat loss (4) during steam sterilisation (5), with as result that again the temperature of the surfaces in the dead area may be lower than required (Lelieveld et al., 2003; Hauser et al., 2007).

The direction of the flow of food product has a significant influence on the residence time in the dead leg. When the food product flows in the direction as indicated in Fig. 42.43a, b & c, part of the product will stand still in the dead leg, especially if the length or depth of the T-section is too long. If the length of the T-section is equivalent to the diameter of the main pipe, a flow velocity of 2 m/s in the main pipe already results in a reduced velocity of 0.3 m/s in the T-section. This decrease in flow velocity provides a relatively stable pocket or dead leg in which product residues can accumulate and microorganisms begin to multiply. Long T-sections outside of the main flow of cleaning solutions are also very difficult to clean. During cleaning there is much less transfer of thermal (heat), chemical (detergent and disinfectant chemicals) and mechanical energy (action of turbulent flow) to the food residues in the zones and T-sections which are outside the main flow of cleaning liquids than to the soil in the main flow. Notice that flow away from the deadleg (Fig. 42.43a & c) gives rise to more contamination problems and worse cleaning, as velocities in these dead legs are even much lower.

A properly designed food processing line should not have unnecessary dead legs, and where they cannot be excluded, they should be in the correct position for the selected cleaning and decontamination process and should be as short as possible. For pipe diameters of 25 mm or larger, T-sections should have a depth/length of preferably under 28 mm, while for smaller pipe diameters this length should be smaller than the diameter. Blanked-off tees should be positioned such that they are a few degrees above the horizontal. The dead-leg will then be drainage but not necessarily cleanable even if made as short as possible. If a sensor must be installed in a process line, it should be installed in a bend on a shortened tee in a position that the flow of cleaning fluid should be directed into the tee (Fig. 42.43e and f). Where an angle valve is installed in the process piping circuit, this valve also must be mounted in a shortened tee so that no or a minimum of annular space above the side branch is formed. Again the flow of cleaning solution must be directed into the tee.

For most liquids, the dead leg should be positioned as shown in Fig. 42.43e, d, f. Especially the configuration in Fig. 42.43f is quite acceptable, because the flow directed into the short dead leg provides sufficiently high velocities for proper cleaning. If the dead leg is very short, configuration Fig. 42.43d is acceptable, although flow across a dead leg results in much lower velocities within it and thus only provides moderate cleaning. Configuration Fig. 42.43e may not be suitable, if products contain any particulate matter, which may accumulate in the dead leg. In all cases, the cleaning procedure must take the presence of the dead leg into account.
Fig. 42.43 When the food product flows in the direction as indicated in (a), (b) and (c), part of the product will stand still in the dead leg, especially if the length or depth of the T-section is too long. Long T-sections outside of the main flow of cleaning solutions are also very difficult to clean. For most liquids, the dead leg should be positioned as shown in (d), (e), and (f). Especially the configuration in (f) is quite acceptable if \( l \leq d \), because the flow directed into the short "dead leg" provides sufficiently high velocities for proper cleaning. If the dead leg is very short \( (l \leq d) \), configuration (d) is acceptable, although flow across a "dead leg" results in much lower velocities within it and thus only provides moderate cleaning. Configuration (e) may not be suitable, if products contain any particulate matter, that may accumulate in the dead leg (CFCRA, 1997; Lelieveld et al., 2003; Hauser et al., 2007).

Flow diversion should not be done in a way that would cause part of the product to stand still in a dead leg. The two-valve system for flow diversion (Fig. 42.44a) creates a dead leg towards the closed valve. The correct type of valve is shown in Fig. 42.44b.

Fig. 42.44 (a) Flow diversion should not cause part of the product (1) to stagnate in a dead area (2). The system of two butterfly valves (3) for flow diversion creates a dead area (2) towards the closed valve. (b) The correct type of valve is shown on the right (Lelieveld et al., 2003; Hauser et al., 2007).

For horizontal piping, eccentric reducers should be used instead of concentric reducers, because the latter provides a dead spot where condensate and dirt may collect (Fig. 42.45).
Changes in pipe diameter should be made by the use of reducers to ensure a smooth transition of the product flow. In vertical piping, a concentric reducer is fully acceptable for food product (1) to flow. However, this is not the case for horizontal piping, where the concentric reducer (2) prevents full drainage if product flows is in the wrong direction. A dead spot is created where condensate and dirt (3) may collect. For horizontal piping, eccentric reducers (4) are preferred. The reducers should be long enough (4) to avoid shadow zones. If a short eccentric reducer (5) is applied, a potential shadow zone (6) will be created (Lelieveld et al., 2003; Hauser et al., 2007).

**Hygienic integration of process and utility piping in food factories**

Welding of attachments on food processing support piping is not recommended. They can cause stress on the pipe and the part of the supporting anchoring structure. All hangers and supports have to be designed in such a way that they either move together with the pipe (roll or slide) or that they can swing without exposing any stress either on the pipe or on the part of the supporting anchoring structure.

All process and utility piping should be grouped together in pipe trains whenever possible. All these process and utility piping should preferably be positioned in a way that all exterior surfaces are readily accessible, to allow cleaning from all sides. The points of use should also be grouped, in an attempt to minimize individual ceiling drops. Vertical entrance of piping into the equipment is more hygienic than horizontal piping runs. Running of process and utility piping over open equipment in food preparation areas cannot be accepted, and nesting of ductwork should be avoided.

**42.7.2 Hoses**

The use of hoses is less recommended, because failure of hoses can occur due to overstretching, kinking, rough handling, mechanical impact, ageing, fatigue, abrasion, corrosive atmospheres, etc., and because the chance that leakage of liquid occurs is much higher than when fixed piping is used. Therefore, hoses need regularly inspection for damage, deterioration and cleanliness. They should be cleaned and maintained in good mechanical condition. Braided (woven wire or fabric) covers on hoses should not be used.
Hoses out of service shall be pendant without touching the floor, and may never hang over open process equipment. Notice that hoses attached to stainless steel pipes should be clamped at the very end of the pipe to minimize the amount of dead space between the clamped portion and the end of the pipe (Fig. 42.46). Hoses should not exceed 3 meters in length. When not in use, the ends of the hoses should be covered or capped to maintain proper hygienic conditions.

42.7.3. Pipe joints

Welded pipe joints
It is strongly recommended that the number of joints, whether welded or detachable, is minimised. Cold bending of pipes is highly preferable to the use of prefabricated bends which have to be installed using joints. Although more hygienic, this is still true for welded joints (Fig. 42.47) as they also remain the weaker places in a process system.

Fig. 42.47 Stainless steel sanitary tubing joints should be made by automatically orbital welding where possible (Kopitzke et al., 2006).

Welding is the preferred method of joining, provided that it is done correctly. Stainless steel sanitary tubing joints should be made by automatically orbital welding (Fig. 42.47) where possible and hand welding in those places that are difficult to access. However, those welds that are difficult to access should wherever possible, be completed in the workshop prior to installation on the plant. The applied materials should be easily weldable, and higher alloyed filler metal in comparison to the welded material should be used to improve the corrosion resistance. Piping with the correct interior diameters should be applied because any mismatch in diameters or thickness may result in misalignment introducing a step in the wall or bore. If the diameters of the pipes to be joined are not the same, then the smaller pipe should be expanded to match the larger. Misalignment also can be due to incorrect fitting up (missed coincidence between the axes of the two coupled components) prior to welding. Alignment and clamping tools are available to ensure accurate alignment. Misalignment tolerance must be limited to less than 20% of the wall thickness.

For proper welding, the parts to be welded should be adequately prepared. Cutting should be done with a mechanical mill or saw to ensure that the cut face is exactly at right angles to the longitudinal axis of the pipe. Any burrs must be removed with either a file or emery paper. Care must be taken not to remove the corner edges of the pipe, as this can give rise to problems with fusion of the root of the weld. The pipe surface 25 mm either side of the weld should be roughened up with a stainless steel wire brush, or emery paper. Then both pipe ends and roughened surface area should be degreased with a solvent and cleaned from contaminants. Any organic substances remaining on the metal surface are vaporised during the welding process and form bubbles (porosity) in the weld metal, that may trap product.
After two deburred pipe ends are aligned and butted together to a gap of less than 0.25 mm between both pipe faces, a butt weld joint is made by fusing together the two stainless steel edges with the aid of filler material. If the gap during the joint preparation is too wide, a crack running along the weld metal itself may be the result (centre line cracking). Full penetration welds, should be used whenever possible to avoid pockets where volumes of gas or contaminants can be trapped. Single pass welds should be utilized instead of multi-pass welds to avoid trapped volumes. The weld metal should exactly fill the joint and remain flush with the surface. Under-penetration leaves a crevice at the joint, while excessive over-penetration can give rise to hold up of product in pipework once taken into service. The weld metal in the joint must be fully fused to the parent, otherwise a crevice will form at the interface between weld and plate. Weld zones should be continuous, smooth, and flush with the parent metal. Welding always should occur with sufficient weld seam protection, because insufficient inert gas shielding or no internal purge will result in roughened welds of lower corrosion resistance, that are prone to increased adhesion of soiling and that are difficult to clean. Typically, where inert gas shielding was inadequate, significant discolouration or carbonisation in the heat affected zone is observed.

Weld slag and debris generated within the pipe must be removed from the inside and outside of the weld by proper maintenance and cleaning practice with an alkaline detergent solution prior to the start of the production process. This is followed by rinsing with water of good microbiological quality, usually chlorinated water to 2 ppm available chlorine maximum. After draining the access points should be covered and sealed. In some circumstances there is an additional requirement to passivate the weld area or product contact side. The welds may be mechanically polished (outside) or electro-polished (inside & outside), but air leakage should be monitored after the polishing procedure.

Weld seams finally should be visually inspected on any discolouration and surface breaking defects, usually by endoscopy and aided by dye penetrant tests that highlight these defects. Inspection personnel should be trained and act with caution to avoid internal surface damages while handling endoscopic tools (Hauser et., 1993; Kopitzke et al., 2006).

**Detachable pipe joints**

Pipe work may be designed for rapid regular dismantling to permit cleaning, or the plant may be designed for cleaning-in-place (CIP) or sterilizing-in-place (SIP) without dismantling the plant. In such equipment it is important to avoid crevices and gaps where product residues can accumulate and potentially begin to decompose. Therefore, from a hygienic point of view, the use of threaded piping is not recommended, because they provide crevices and areas where bacteria can adhere and proliferate. To make detachable joints, also the use of conventional O-ring grooves is not recommended, because these groove designs leave a considerable free space in the groove. Other hygienic requirements for detachable joints include coaxial alignment of the two mating bores, axial stop for controlled compression of the seal, room for thermal expansion of the seal, and avoidance of sharp edges such that seals are not damaged. Where there are depressions and steps of more than 0.2 mm in the pipe work, the bow of cleaning fluid may not thoroughly wash the surface and proper drainability of the piping will be hampered. Hence, when making bolted flange fittings, a lot of care should be taken to avoid offsets, gaps, penetrations, and voids. A further aspect to be considered is that the seal material must be compatible with both the system product and also the cleaning fluids which may be at a much higher temperature.

A number of specific pipe couplings and also seal arrangements have been developed for hygienic applications. Some types are covered by national, international or internal company standards, but many of these have been in use for some considerable time and are not considered to be compatible with current requirements in some areas of the food and drink industry (Table 42.2).

### 42.7.4 Hygienic design of pumps

*Hygienic Design of Centrifugal pumps*

Whilst it is often convenient for the arrangement of pipework to orientate the casing of a centrifugal pump so that the outlet port is pointing vertically up, this will result in the pump casing retaining liquid up to the level of the inlet port. The pump casing is drainable through the outlet port if the pump's outlet is arranged to point horizontally at the bottom, or the pump casing can be made drainable through its suction port if installed in vertical execution (Fig. 42.48).
Hygienic design of rotary lobe pumps

Rotary lobe pumps having unhygienic design features can only be cleaned effectively after dismantling. To avoid any introduction of contaminants into food product and to allow for CIP without dismantling, rotary lobe pumps should be hygienically designed. Metal-to-metal joints should be eliminated by hygienic application of O-rings; O-ring groove design should be improved and O-rings should be positioned more appropriately, or alternatively gaskets having controlled compression should be used; sharp corners must be rounded to a minimum radius of 3 mm; the length of the annular space within the mechanical seals should be reduced by changing the design of these mechanical seals (e.g., the elements of the mechanical seal should be reversed and the radial distance increased); any exposed threads (e.g., threads of the rotor shafts, Fig. 42.49a) should be covered by crevice-free domed retainer nuts; or even better, the rotors and shafts should be designed as an integral construction so that rotor retaining nuts and associated metal-to-metal joints can be eliminated, and so that the inside of the front cover can be made completely flat and free of space holes for rotor retainers.

Some types of rotary lobe pumps are traditionally positioned in such a way that draining is impossible without dismantling but the same type of pumps can also be designed for installation in a drainable position. In example given, the inlet and outlet ports of rotary lobe pumps have been arranged traditionally in the horizontal position as this has again been convenient for connecting the pipework. This results in the retention of liquid in the casing up to the level of the inlet and outlet ports. Now, lobe pumps are available with the ports arranged in the vertical plane (Fig. 42.49b) so that it is possible to drain the casing.
42.7.5 Sensors and Instrumentation
Incorrect mounting of sensors in process lines will result in large dead areas which are unacceptable (Fig. 42.50). Instrument branches, that could become a dead leg when not properly installed, should be installed vertically upwards to keep condensates, debris, suspended solid particles, flakes, etc. from collecting in the sensor or from falling into the sensor and the measurement system. However, the length of the dead area must be as short as possible and its cleanability must be demonstrated. For all pipe diameters the length of the up-stand should be smaller than its diameter (l ≤ d).

**Fig. 42.50** Pressure gauge mounted on a too long tee branch such that unacceptably large dead area is created (courtesy of Huub Lelieveld, personal communication).

It is possible to avoid such dead areas by mounting e.g. the pressure transmitter on a swept tee (Fig. 42.51). However, swept tees must be used with caution, as a swept tee in a horizontal pipeline could hamper draining. Swept tees should be mounted in a vertical pipeline. Dimension l must be as short as possible relative to dimension 'd', maximum l = d. Alternatively, pressure transmitters with tubular membranes, with the same inner diameter as the adjacent pipelines can be installed in standard spherical valve bodies welded into the piping by means of clamp fittings. The stainless steel diaphragms are sealed by O-rings fitted into grooves such that there is no metal-to-metal joint on the product side (Fig. 42.52). This way of mounting of pressure transmitters provides a dead-space free, flush transition from the process line to the pressure transmitters.

**Fig. 42.51** Incorrect mounting of sensors (2) in process lines (1) may give rise to tees with closed ends (3) that if too long will result in large dead areas. (a) But a swept tee if mounted in a horizontal pipeline may impede drainage (4). Swept tees should be mounted in a vertical pipeline. Dimension l must be as short as possible relative to dimension 'd', maximum l = d (Lelieveld et al., 2003; Hauser et al., 2007).
Pressure transmitter with tubular membranes, having the same inner diameter as the adjacent pipeline, can be integrated into the process, installed by means of a clamp fitting in a standard spherical valve body welded into the piping. The stainless steel diaphragm is sealed by O-rings fitted into grooves such that there is no metal-to-metal joint on the product side. This way of mounting of a pressure transmitter provides a dead-space free, flush transition from the process line to the pressure transmitter (courtesy of WIKA).

Temperature measurement is usually based on electronic detection of a change in resistance. The actual temperature sensor elements used integrate either Platinum thin film resistors (Pt100 etc.), or employ other sensing elements with a varying electrical resistance against temperature (NTC or PTC resistors). Also semiconductor devices are common. The temperature sensor element itself is covered by a protective sleeve, a highly-polished, closed tube typically made of stainless steel. Only one surface of the thermowell has fluid contact, the sensor being installed inside. For these temperature sensors, a close thermal and mechanical contact to the liquid to be measured is needed. Therefore, often a paste with high thermal conductivity is used inside thermowells.

Temperature sensors may not be mounted on a too long tee branch because an unacceptable large dead area is then created. Thermowells with flanged process connection (Fig. 42.53) can be integrated into the process, installed by means of clamp fittings in standard spherical valve bodies welded into the piping. The sheath of the probe is welded into one of two blanks which are sealed to the spherical valve body by O-rings fitted into grooves such that there is no metal-to-metal joint on the product side. This way of mounting of a temperature sensor provides a dead-space free, flush transition from the process line to the blank containing the thermowell (courtesy of WIKA).
A surface probe with the inner diameter of its pipe the same as that of the adjacent piping is, from a hygienic point of view, an excellent choice. However, the thermowell can also be directly fitted via an orbital welded pocket (Fig. 42.54). Attention should be given to the quality of the weld, which must be smooth and continuous. Furthermore, to avoid shadow areas, the direction of the flow must be as indicated.

Fig. 42.54 To avoid dead areas, the pocket for the temperature probe (2) may be welded in the product flow (1) through the pipeline. Attention should be given to the quality of the weld (3), which must be smooth and continuous. Welding of the temperature probe into the bend may be done off-line, after which the bend can be built permanently (by welding) or with dismountable joints into the piping system. In the latter case, the bend section is detachable (4) (Lelieveld et al., 2003; Hauser et al., 2007).

For temperature measurement in tanks and larger vessels, the thermowells can be continuously welded to the tanks with welding balls or welding collars, after which the inner welding seam is polished and passivated after welding. Sensors also can be installed via a hygienic process connection sandwiched (detachable seal joints such as O-rings) into the pipeline (Fig. 42.55). The dimensions of the O-ring and the design of the groove to be used for mounting sensors are critical to achieving controlled compression of the seal. The O-ring needs periodic maintenance with an inspection of the O-ring upon dismantling. Used O-rings should not be re-installed.

Fig. 42.55 In the product area (1), a sensor (2) can be installed via a weld-in adapter (3) and a hygienic process connection sandwiched (detachable seal joints such as O-rings, 4) (Lelieveld et al., 2003; Hauser et al., 2007).

42.7.6 Hygienic design of valves
Valves are used to change the direction of the flow of product or cleaning solutions (selection of the product routing), to regulate the flow and pressure, to protect a process system against overpressure. The cleanliness of a valve is largely determined by its internal geometry, the way in which the inlet and outlet connections are made, and the seal between the fluid and the external environment. The seals may be under a static load or dynamic with linear or rotary motion. Valves must meet the following hygienic requirements:

- fully drainable, without the need to dismantle;
- resistant to wear and easy to maintain;
- minimum number of seals, positively retained and flush with adjacent surfaces;
- dynamic seals on valve shafts in contact with product must provide an absolute barrier between the product and the environment to prevent microbial recontamination;
- where unavoidable, springs in contact with product should have minimum surface contact area;
- allow rapid visual detection of internal leakage.
Hygienic requirements for different types of valves (CFCRA, 1997; Schonrock, 2005):

Diaphragm valves used as back pressure valve need visual detection of leakage (usually there are leakage holes in the valve bonnet), because damage to the diaphragm can result in product leaking through into the non-product side. Such an event may give rise to contamination, and cleaning and disinfection will become nearly impossible. To avoid premature rupture, it should be replaced at regular intervals depending upon the operating conditions. Diaphragm valves must be installed for full drainability.

Butterfly valves comprise a disc, and further a rubber seal clamped between the halves of the body providing both a seat for the disc to close on and a seal for the disc spindles. If properly designed, they are hygienic low-cost valves, with as main properties: low resistance to flow, and their appropriateness to be automated and cleaned in-place. Butterfly valves with a stream-lined disk free of external ribs are hygienic. However, product containing fibrous material may build up on the leading edge of the disc, and butterfly valves are suitable as long as the seals are not worn. Seals can wear and break down after a period of time due to the frequent opening and closing of the butterfly valve. Product can also migrate along the shafts due to product pressures in the system. Therefore, butterfly valves should preferably disassembled for manual cleaning. If butterfly valves are in use, appropriate cleaning and maintenance schedules must be implemented.

Traditional ball valves are considered as unsuitable for process installations that are cleaned in-place. Due to the presence of crevices in their internal construction, the area between ball, housing and seal face is uncleanable. Food product is transferred in the annular dead space when the valve is operated from its open to its closed position. When the ball valve is then rotated back from its closed to its open position to allow CIP, the food product trapped in the annular space between the sphere and the housing will not be removed by cleaning-in-place. Moreover, ball valves may retain condensate in their internal cavities. Often the design incorporates cavity fillers or encapsulating seals to prevent product flow around the exterior of the ball but product still may find its way under the seat surface and become an area for bacterial growth. Ball valves in existing installations must be disassembled completely for manual cleaning. However, the design and construction of a ball valve are such that it is not easily dismantled for cleaning. Certain ball valves with improved design allow for cleaning-in-place, especially in a half open position. For some applications, connections have been made to the housing so that the annular space may be continuously purged with steam throughout production.

Plug valves are unsuitable for CIP, because product is carried around the clearance between the plug and the body during the rotation of the plug. Three-way plug cock valves allow 90° changes in flow direction of both food product and cleaning solutions. They have the disadvantage that they neither can be automated or cleaned in-place. However, plug valves can be easily manually cleaned after dismantling, which - due to their simple design - can be done very easily.

Pressure relief valves are valves where the valve head is lifted off its seat when the product pressure exceeds that at which the valve has been set. Product then may be discharged to drain through the discharge port. To flush the inside of the valve body and the discharge port during cleaning-in-place, the valve must be opened by moving the lever through 90°. The valve body must be in a position so that it is fully drainable to the outlet side, and should be mounted on a short tee to avoid a large dead-leg on which product will be retained throughout the production.

Check valves with springs, hinges and flappers should be avoided as they quickly become contaminated and could give rise to cleaning problems. When spring loaded check valve are used, the coil springs having product contact surfaces shall have at least 2 mm openings between coils, including the ends when the spring is in a free position. Spring-loaded check valves must be fully disassembled for manual cleaning. The use of ball-type check valves is the preferred practice. Springless floating ball check valves have a streamlined internal design which may reduce the potential for material to clog or hang up. Check-valves must be installed in a position that allows full drainage of the check valve.

Tank outlet valves should be installed as close as possible to the product vessel to reduce the dead-leg formed by the stub pipe that connects the bottom valve with the vessel. They may be manually or mechanically operated and cleaned depending upon their design features.

Mixproof valves are an essential part of automated processing, not only separating two different products but also preventing product contamination from cleaning fluids during mechanical cleaning. The valve uses double seats that can be operated independently, separated by a self-draining opening to the atmosphere between the valve seats. The vent space must also be cleanable and avoid a pressure build-up in case of a leak from a seal. The outlet from the vent line must be visible so leakage can be easily detected. A steam or sterile barrier may also be applied in the atmospheric opening (vent) to prevent ingress of microorganisms.
Linear plug and stem valves may incorporate a lip seal to limit microbial contamination via the reciprocating shaft. This seal is easily cleanable but will not prevent the ingress of microorganisms. A hole is required to detect product leakage when the lip seal wear becomes excessive. Arrangements incorporating an O ring seal are less hygienic because product can enter the clearance around the stem and become trapped in the O-ring groove from which it cannot be removed by in-place cleaning. For aseptic processing applications where ingress of microorganisms must be prevented, the shaft may be sealed by means of a diaphragm and bellows. In case of the diaphragm type, the diaphragm must be replaced at regular intervals and a leakage hole must be provided that indicates failure of the diaphragm. With respect to the bellows sealed linear plug and stem valve, the bellows will rupture after a period of service and need to be replaced at regular intervals. Moreover, if the product contains particulates, there may be a cleaning problem because particulate material may become trapped in the convolutions of the bellows. A steam barrier between the atmospheric and product sides of the valve stem is another method of preventing ingress of microorganisms.

42.8 Installation of the food processing equipment in the food factory

42.8.1 Clearance with respect to the floor, walls and adjacent equipment
There should be enough clearance under the machine to allow for adequate cleaning and inspection to be carried out effectively. With that purpose, the process equipment should be installed as high off the ground as possible. The minimum height should be a function of the depth of the bottom surface above the floor (indicative: 150-300 mm). For large sized equipment, greater distances apply (at least 0.5 m from walls), as it is necessary to be able to walk around such equipment and at least with enough room to facilitate cleaning. If the equipment is sealed against the mounting surface, care must be taken to avoid gaps, cracks or crevices where insects or microorganisms can remain/survive after cleaning.

Installation of large equipment (e.g., freezing equipment, meat curing chambers, etc.) on feet is technically not always possible. An alternative is sealing the equipment onto the factory floor. Proper sealing the perimeter between the equipment and the subfloor must prevent water from accidentally getting into this space. But sealing, especially with silicone, has not always proven to be successful in excluding wet and unhygienic conditions.

Equipment must not be mounted beneath tanks or vessels so that maintenance and cleaning are impeded but must be easily accessible. Increased elevation of tanks and vessels facilitates cleaning and maintenance operations beneath them but water and condensation running down their sides may allow microbial growth and certainly must not fall onto exposed product.

Fig. 42.56 (a) If not appropriately designed, walkways and stairs over open product (1) may contaminate it. Open-mesh steps (2) that are not enclosed by vertical risers (3), the absence of a cover over the product area (4) and the handrail and its mountings hanging (5) over product area put the open food product at risk. (b) Now, the steps are enclosed (6), the handrail is mounted inside the walkway (7), solid anti-slip steps and floor-plates are used (8), and fully-welded, continuous kick plates are in place to prevent the open product from getting contaminated (Hauser, 2004b).
42.8.2 Raised walkways and stairs
Raised walkways or stairs (Fig. 42.56) over exposed product should be avoided because dirt may be transferred from clothing or footwear onto product lines beneath. The use of covers and hygienically designed walkways should be both considered. The decking of platforms and steps (cross-overs on conveyor-systems) should be constructed from solid plates containing a raised anti-slip material as deck. The steps can be given a small inclination for improved drainability. Mesh must be avoided to prevent soil from being transferred into the product. Further fully-welded continuous kick plates should be in place, designed as a one-piece construction. Platforms and stairs should have generous radii in the corners of kick plates, etc., to allow cleaning and disinfection. Handrails should not overhang the walkway and must be attached to the inside of the walkway. Risers of staircases must be enclosed and the steps should be constructed of the same anti-slip material as the deck.

42.9 Hygiene practices during maintenance operations in the food industry

42.9.1 Maintenance and repair, a necessary evil
Physical equipment of any field or of any plant and industry are susceptible to failure through breakdown, deterioration in performance owing to wear and tear with time and to obsolescence due to improvement in technologies. Therefore, machinery should be regularly checked with respect to its performance. Equipment maintenance checks should include an assessment of the equipment's overall condition and integrity (e.g., is it working properly), the sources of physical contaminants (e.g., damaged, lost or worn parts, rust, loose/flaking paint, broken parts such as needles and blades, loose parts on equipment prone to vibration, polymeric deposits, friction, fatigue, chemical reaction, etc.), the microorganism harbourage sites (e.g., worn or frayed hoses, gaskets or belts, porous welds, product contact surfaces). Increase in noise, lubricant consumption, temperature rise or increased leakage is usually the consequence of failure of equipment and its components. Worn parts should be replaced as soon as practical, not only to ensure that production is maintained but also to prevent that debris from worn or broken parts enters the product or contaminates the production line.

The operator also must ensure equipment used for critical measurements is calibrated, and uniquely identifiable. It must be used within its design and capacity (e.g., accuracy, calibration range, conditions of use). Items requiring calibration could include thermometers, temperature recorders, scales, test weights, metal detectors, gas analyzers, pressure or heat sensors, chemical assessment equipment, flow meters, etc.

42.9.2 Scheduled preventive maintenance
Scheduled preventive maintenance should be preferred over inefficient breakdown maintenance and repetitive repair. No longer does the maintenance department have the luxury of extended periods of available equipment downtown in order to carry out maintenance. Instead the maintenance function is moving toward a more predictive approach. If the failure characteristics of the equipment are known, predictive maintenance can detect the failure well in advance and appropriate actions can be taken in a planned and organized manner. Predictive maintenance makes use of a group of emerging scientific technologies that can be employed to detect potential failures: vibration analysis, thermal imaging, ultrasonic measurement and oil analysis. The maintenance technicians should be skilled to use these diagnostic tools, and they must have detailed knowledge of the operating characteristics of the equipment to make the correct failure diagnosis. By means of a risk analysis, the manufacturer may define which parts of the system are critical, allowing to define the necessary treatment (to which interval, to which time point, and with which measures). That maintenance schedule should be frequently reviewed during the initial operating period of an installation to establish the optimum maintenance frequency (Jha, 2006).

42.9.3 Proper a priori design, installation and working practices that may reduce the occurrence of unhygienic conditions during maintenance and repairs
Proper design and installation of the processing equipment and utility services, and common-sense measures create the appropriate conditions to keep up a sanitary process environment during maintenance and repairs (Moerman, 2011):

- Equipment should be of such a design that the need for physical entry into the system is minimized. Enough space and clearance should be provided so that all equipment parts and components are readily and easily accessible for inspection, maintenance and troubleshooting.
- Mechanical, electrical, pneumatic, hydraulic and electronic components, together with distribution conduits, valves, pumps, pressure reducers, gas cylinders, vacuum sources, compressors, etc. should be relocated to a technical room or technical corridor adjacent to the production room, so that
maintenance personnel can access the technical area without special gowing or disruption of the cleanliness of the high hygiene space below.

- Use lamps with high light output so that the factory staff can perform inspections of the food processing equipment and the process environment more easily and profoundly, enhancing the detection of grease, leaking oil, failures, maintenance residues, etc. Torches to light dark places with process equipment should be resistant against breakage.
- Maintenance managers and supervisors should implement Maintenance Best Practice eliminating the sources of breakdown and contamination that cause downtime, quality holds and lost profits.
- Correct maintenance attitudes must help to ensure that the production area and products are kept free from contamination by undesirable microorganisms, filth, debris, or machine parts. Regularly audits should be done to verify if the maintenance staff or contractors have adopted the correct hygienic practices during maintenance operations.

42.9.4 Maintenance and repair operations according to the principles of hygienic design

Maintenance and repairs should occur according to the principles of proper hygienic design to ensure that safe food is produced once production is resumed. The following recommendations should be followed (Moerman & Degraer, 2003; Moerman, 2011):

- The construction materials used during maintenance and repair must be compatible with the food product or process aid they contain, and may not introduce contaminants that would present a risk to food safety. Piping and components should be constructed out of the same materials to prevent contact corrosion between dissimilar metals.
- Work in black steel and stainless steel must always be kept separated. Spare parts should be pre-packed in plastic, stored segregated from other non-stainless steel products.
- The inlet and outlet connections of the product should be fitted with protective caps before being sealed with shrink wrap in order to prevent the ingress of impurities, insects and small animals in pipes and fittings.
- Prior to use, process equipment and components should be examined for debris, oil, or grease; and if necessary should be cleaned.
- The body and internal parts must be handled carefully to ensure that the machined surfaces are not damaged.
- Use as much as possible piping with the same internal and external diameter over the whole factory, in particular to avoid misalignment (missed coincidence between the axes of two coupled pipe components) prior to welding.
- Re-assemble piping and equipment components using a new seal, and check for leaks and retighten as necessary.
- All fastening devices should be secured firmly.
- If old insulation containing asbestos has to be removed, all precautions should be taken to avoid the spreading of asbestos fibers in the food processing environment.
- For insulation work, preference should be given to rigid foam rather than fibrous materials that have already proven to be an excellent harbourage of dust, insects and rodents. Afterwards, the insulation should be covered with properly sealed cladding of appropriate thickness, that resists tear and abrasion.
- When a new cable has to be installed, it should not be supported from a previously installed cable because a hygienically unacceptable entangled cable bundle may be formed. The cables should be fastened individually in a distance no less than 25 mm from each other to allow for proper cleaning.
- The use of temporary devices, such as tape, wire, string, etc. should be avoided. If strips are the only option, they should preferably be of a stainless steel type that can be detected by means of a metal detector. Alternatively, a plastic strip of a colour that is not omnipresent in the food product and food factory could be used. Temporary fixes should be replaced in a timely manner by permanent repairs.
- Always determine the correct installation situation and direction of fluid flow. Install for maximum cleanability and drainability.
- Calibrated equipment that is non-conforming (i.e. broken, expired calibration period) must be identified as non-conforming, and further recalibrated, repaired or replaced.

42.9.5 Personal hygiene practices during maintenance operations in the food industry

Before the onset of maintenance and repair operations, all maintenance workers shall comply with the requirements for personal hygiene appropriate to the area where maintenance and repairs will be executed (Holah & Taylor, 2003; Smith & Keeler, 2007; NZFSA, 2009):

- Both the food manufacturer’s own maintenance staff and contractors should follow the food manufacturer’s guidance with respect to personal safety and hygiene.
It is recommended to force the maintenance staff or contractors to fill out a health questionnaire before allowing that maintenance staff or contractor to enter the food production area. The food manufacturer must restrict access of any person with obvious health problems such as the flu, colds, skin lesions, uncovered sores or wounds, etc. All personnel is in fact responsible for reporting any such condition to their supervisor before beginning or continuing work.

The use of cosmetics, medical substances (ointments, plaster or band-aid for wound healing, safety pins) or other chemicals (suntan products, etc.) on the skin are not allowed.

Eating, drinking, chewing (gum, toothpicks, straws, etc.) and smoking, are not allowed during maintenance operations.

Maintenance staff or contractors are not allowed to enter the food production area with their casual clothes. They should be stored away from the production area. Protective clothing shall be worn, not only to safeguard the person’s casual clothes during the work but also to protect the food product. In order to avoid contamination of work surfaces, maintenance personnel should wear clean coveralls.

Maintenance workers that worked in a less clean area that has high microbiological activities (raw materials) must change their garments prior to entering a high clean area where sensitive food products (e.g., finished products) are produced. Hair nets, headbands, caps, bump hat, hard hats, beard nets or other devices must be worn to control hair lost into the food, on food surfaces and into packaging.

All hands piercings, jewelry, watches should be removed.

Hands should be washed thoroughly, including in between fingers, before entering a food processing area and after eating, drinking, smoking or using the restroom. The use of gloves may be advisable. Gloves are to be maintained in a clean, sanitary and intact condition. Gloves used in less hygienic (raw material) side of the plant must not be used in high hygienic risk areas.

Foot wear should be clean. If it is necessary to stand on or over machinery, the process equipment shall be covered to prevent foot wear dirt and debris from contaminating the surface. It is also recommended to cover footwear with overshoes just prior to walking on the process equipment.

Maintenance staff or contractors must remove all unsecured objects which could fall into the product, such as pens, pocket notebooks, small screw drivers, pencils behind the ear, non-attached ear plugs, nuts and bolts in shirt pocket, etc. They must be stored in the tool box or the carrier used to bring parts to the work site.

**42.9.6 Hygiene practices during maintenance operations in the food industry**

**Recommended hygiene practices to be taken before the onset of maintenance and repair operations**

The following measures and actions will create the appropriate hygienic conditions to execute maintenance and repair without compromising the safety of the food produced with that equipment when production resumes (Jha, 2006; Smith & Keeler, 2007; NZFSA, 2009):

- Some work such as drilling or welding will inevitably produce debris and dust. Where possible, production operators should remove food processing equipment from the processing room before repairs are made. Coverings such as tarp or plastic sheeting (polyethylene or equivalent film) can be draped over equipment to reduce contamination.
- Maintenance could be done in a separate room outside the food processing area.
- If entry in process equipment is required, a plastic cover film must be laid down on the bottom of the process equipment.
- Where practical, maintenance tools should be dedicated for use in specific areas of their operation to avoid cross contamination.
- Tools used for repairs and maintenance must not come in contact with, or compromise the hygienic status of any product or packaging material. The maintenance tools must be free of rust, peeling paint, niches and threads; and without wooden handles or knurling soft rubber grips. They should be non-corrosive, easy to clean and inspect, with smooth finish and hard plastic grips, and with fitted heads for equipment longevity. They must be designed in a way that they cannot damage the process equipment.
- The maintenance tools must be clean and used with care so that they cannot be left in the production equipment.
- Maintenance equipment and tools may not transfer microorganisms in a hygienic room from its prior use in a less hygienic area.
- Ordinary steel wool or steel brushes should never be used on stainless steel surfaces as particles of steel may get embedded in stainless steel surfaces and rust.
- Debris from engineering workshops (such as swarf and other unwanted materials) must be prevented from entering processing or support areas. This is especially important where engineering
workshops have access ways (e.g. doorways) that lead into processing or support areas. This may be achieved by keeping doors closed, the use of swarf mats, boot washes, etc.

**Recommended hygiene practices during maintenance and repair**

The following hygiene practices should be followed during maintenance and repair (Smith & Keeler, 2007; NZFSA, 2009):

- During maintenance operations, light sources used to provide the necessary light for proper maintenance and repair should not be placed above open process equipment, or the lamp should be housed in a shatter-resistant fixture to avoid that shattering of glass may lead to broken fragments falling into that open processing equipment during its maintenance. By using a protective PTFE coating, one may also maintain the integrity of the lamp in the event of breakage. Light sources used during maintenance operations should not contain mercury.
- Opening the distribution system will expose the system to particles from the outside environment. The contamination risk can be minimized by using strict specifications on how to conduct activities, such as cutting pipe work, and handling pipes and components before the actual installation. Precautions should be taken to prevent the distribution of any contamination residues or mechanical damage residues in the surroundings. Vacuum cleaners should be applied to extract maintenance debris at the place where the maintenance takes place, drip pans should be used to collect oil, etc. Equipment openings must be protected to maintain the interior of the process equipment and components free from any external contamination.
- Equipment components subjected to maintenance, spare parts and tools should not be placed on the ground or walking surface (e.g., deck), but on a plastic pallet, in a receptacle, a box, a carrier or a trolley provided with a plastic cover. In the food processing area, no wooden pallets should be used to store new or replaced equipment components.
- Whenever parts and tools are stored in the production area, they should preferably be kept in rooms or lockers reserved for that use.
- Equipment components in service should be clearly indicated, and/or placed in quarantine.
- Take care not to lose nuts, bolts, etc. when removing them from machinery. Because small parts easily can be misplaced, loose bolts, nuts, screws, rivets, washers, etc. should be stored in maintenance receptacles.
- Bolts, nuts, screws, etc. of a lower alloy composition may not be left behind on stainless steel, because they may induce corrosion.
- Maintenance personnel should not walk on the cladding of insulated piping to prevent that it becomes damaged.
- Food grade maintenance chemicals (lubricants, heat transfer liquids, etc.) that do not provoke corrosion should be used.
- Personnel must be trained and suitably skilled in the correct access, handling and use of approved maintenance compounds, or have access to documented directions.
- Maintenance products (oils, greases, lubricants, ammonia, glues, chemical products, etc.) should not be left in the food processing environment when maintenance operations are ceased (e.g., during the night, during weekends, during collective holidays, etc.). They shall be stored separately from food products in clearly labeled (identifying the maintenance compound) and closed containers (e.g., bulk supply) in dedicated secure storage facilities.
- Maintenance compounds that are řn-useô or for řmediate-useô may be stored in processing and support areas, but only in quantities necessary for immediate use. When transferred from their original container (e.g., bulk supply) to a new container (e.g., řn-useô or for řmediate-useô, the latter must be labeled with the name of the maintenance compound.
- Empty maintenance compound containers must not be re-used in a way that food product could get contaminated. All containers/implements should be labeled for chemical use onlyô
- Excessive lubricant and grease should be removed to prevent them from coming into contact with the product or food contact areas.
- Avoid placing dirty, greasy, oily hands on any surface with which the product comes into contact.

**Recommended hygiene practices after maintenance and repair**

After maintenance and repair operations, the following practices should be followed (Smith & Keeler, 2007; NZFSA, 2009):

- Maintenance tools or machinery must be removed or returned to storage without delay once maintenance or repair work is completed. Therefore, maintenance technicians must verify if all maintenance tools and components are removed after maintenance and repair to ensure nothing is
left where it may enter the product or damage equipment. An inventory can be made of all tools prior to maintenance.

Any maintenance waste and other refuse (e.g., packaging materials, broken components, failed parts, dirt, dust, spilled oil) must be regularly removed to a suitable storage area and without delay.

Equipment that could be a source of contamination must be physically isolated from processing lines and product, or removed from processing areas. Damaged or decommissioned equipment that remains in processing areas must be clearly identified as such, to ensure that it is not used. Decommissioned equipment may be stored outdoors, but should be placed on a hard standing (e.g. concrete, sealed or paved area) and covered.

If emergency repairs were required during production, any product that may have been left sitting for long periods of time or become contaminated during repairs should be disposed of.

The operator must have a procedure to ensure that equipment returned to use (e.g., after repairs and maintenance, re-commissioning or having previously been idle) is not a source of contamination to product, because of bad maintenance or repair, because repair is not conform the rules of appropriate hygienic design, or because maintenance dirt is left.

Maintenance debris (e.g., abraded particles, swarf) must be flushed from the system after maintenance and repairs.

When it was necessary to break into the system for maintenance or inspection, equipment should be thoroughly cleaned any time maintenance or repairs of any type are performed in a food processing facility. The equipment and area should be cleaned with solutions of detergents and disinfectants in the right concentration, then rinsed, and finally dried prior to resuming production.

**42.9.7 Evaluation of the quality of maintenance work done and record keeping**

Before production resumes, the food manufacturer must evaluate if finished maintenance operations and repairs meet the expectations with respect to the quality of the maintenance and repairs. In this perspective, the following practices should be followed:

- Equipment must be subjected to a pre-operational check before processing re-commences. Are all technical problems solved? Are maintenance and repairs done in a way that the process equipment allows to produce safe food products once production resumes?
- Equipment operating under validated conditions must be revalidated if the repairs and maintenance activity may affect its validated status (e.g. replacing temperature probes/sensors in ovens/freezers).
- Maintenance records or job sheets (including when and how the defect/breakdown was repaired, who conducted the work, who has signed-off that it was completed and that appropriate equipment return to use procedures followed). Comprehensive maintenance records will assist the operator to verify that the repairs and maintenance program is working correctly.

**42.10 Acknowledgment**

We would like to thank our colleagues of the European Hygienic Engineering & Design Group for their permission to use their knowledge and photographic material generated in several EHEDG guidelines, in particular EHEDG documents N° 8, 10, 13, 14, 16, 20, 23, 25, 32, 35. I would like to recommend the reader of this chapter to consult these documents in which the content of this chapter is approached in a more detailed way.

**References**

- Den Rustfri Stålindustriis Kompetencecenter (2006a), Conveyors, with a focus on hygieø Guideline N° 5, version 1.0, Danish Technological Institute, Kolding, Denmark, 60 p.


