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Safety of machinery — Hygiene requirements for the design of machinery

*Sécurité des machines — Prescriptions relatives à l'hygiène lors de la
conception des machines*

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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14159 was prepared by Technical Committee ISO/TC 199, *Safety of machinery*.

Annexes A to C are for information only.

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Introduction

This International Standard is one of a series of standards relating to the safety of machinery (ISO 12100 series). It differs from other safety standards, however, in that it is concerned with the associated hygiene risks of the machinery to the consumer of the product being processed, not to the operator of the machine.

Hygiene risks are very different from other safety risks. They are more associated with the ability of machines to be freed from product debris and micro-organisms, and thus preventing product contamination, rather than from the dangers of moving parts or electrical hazards to the operator. For this reason, and whilst this International Standard considers machines and their associated equipment, it can be used to provide guidance to the manufacturers of all equipment types where hygiene risks to the consumer of products to be processed by such equipment could occur.

This International Standard is a Type B standard (see ISO 12100) and as such is very general. It is applicable to all machines and associated equipment in applications where hygiene risks to the consumer of the product can occur (e.g., food, pharmaceuticals, biotechnology, cosmetics). Other standards, such as for example machinery specific Type C standards (see Bibliography), may be required to provide guidance for specific types of equipment and/or for specific industry sectors.

Historically, there have been cases where safety criteria have been addressed in machinery design without taking into account the implications linked to hygienic risks (and vice versa). In almost all cases, at least one of the different methods of design, safeguarding or residual safeguards can be chosen which will meet both safety and hygiene essential requirements and adequately control both risks. The option chosen shall satisfy both hygiene and safety risks, even if it may not be the most obvious option to have been adopted had the risk only been to safety or to hygiene.

When no design or safeguarding options are within the state of the art to adequately control both hygiene and safety risks, then one of the risks, or both, would have to be dealt with by residual safeguards, including instructions to the user. The assessment of the respective safety and hygiene risks shall indicate their relative significance, and the highest level of protection (i.e. safeguarding) shall be implemented to deal with the severest risk, and residual safeguards shall be used for the lesser risk.

The technical solutions given in this International Standard permit both objectives to be met for those significant and common risks identified as justifying common requirements specified in this International Standard.

Safety of machinery — Hygiene requirements for the design of machinery

1 Scope

This International Standard specifies hygiene requirements of machines and provides information for the intended use to be provided by the manufacturer. It applies to all types of machines and associated equipment used in applications where hygiene risks to the consumer of the product can occur.

This International Standard does not cover requirements relative to the uncontrolled egress of microbiological agents from the machine.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 4287:1997, *Geometrical Product Specifications (GP) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

ISO 12100-1:—¹⁾, *Safety of machinery — Basic concepts and general principles for design — Part 1: Basic terminology and methodology*

ISO 12100-2:—²⁾, *Safety of machinery — Basic concepts and general principles for design — Part 2: Technical principles*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1

associated equipment

all equipment associated with a machine, not defined as machinery (3.13), that is essential to the functioning of the machine for it to hygienically process a product (e.g. fittings, piping, tubing)

3.2

bond

joining of materials with an adhesive

1) To be published. (Revision of ISO/TR 12100-1:1992)

2) To be published. (Revision of ISO/TR 12100-2:1992)

3.3

cleaning in place

cleaning (3.4) of equipment by impingement or circulation of flowing chemical solutions, cleaning liquids and water rinses into, onto and over surfaces in equipment or systems without dismantling and designed for the purpose

3.4

cleaning

removal of soil (see 3.31)

3.5

cleanable

(equipment) designed to be freed from soil

3.6

consumer

end user of the product (including domestic animals)

3.7

corrosion resistant material

material having the property to maintain its original surface characteristics for its intended life time when exposed to the conditions encountered in the environment of intended use, including exposed contact with product, cleaning, disinfection, pasteurization or sterilization conditions

3.8

crevice

sharp, cleft-like, irregular opening of small depth which adversely affects cleanability

3.9

dead space

space wherein a product, cleaning or disinfecting agents, or soils can be trapped, retained, or not completely removed during the operation of cleaning

3.10

disinfection

process applied to a clean surface which is capable of reducing the numbers of vegetative micro-organisms, but not necessarily their spores, to a level considered safe for product production

3.11

hygiene

taking of all measures during product handling, preparation and processing to ensure its suitability for use by humans or domestic animals

3.12

joint

junction of two or more pieces of material

3.13

machinery

assembly of linked parts or components, at least one of which moves, with appropriate machine actuators, control and power circuits, joined together for a specific application, in particular for the processing, treatment, moving or packaging of a material

NOTE The term machinery also covers an assembly of machines.

[ISO 12100-1:—, 3.1]

3.14

manual cleaning

cleaning by manual means when the machinery is open, or partially or totally disassembled

3.15**micro-organism (relevant)**

bacteria, fungi, yeasts, moulds, spores and viruses that are able to contaminate, multiply or survive in the product and are able to be harmful or adversely affect product quality

3.16**non-toxic materials**

materials which, under the intended conditions of their use, will not cause the product to be harmful to humans or domestic animals

3.17**non-absorbant materials**

materials which, under the intended conditions of their use, do not retain substances with which they come into contact, so as to have no adverse effect on the hygiene of the product

3.18**pasteurization**

process that inactivates all relevant micro-organisms except some microbial spores

3.19**pasteurizable**

(equipment) designed to be capable of being pasteurized

3.20**pest**

mammals, birds, reptiles, vermin and insects which can adversely influence the product

3.21**practical test**

documented set of procedures and parameters used to determine an evaluation

3.22**product**

any substance intended to be applied or taken into humans or domestic animals (e.g. by ingestion, injection, topical application, insertion)

3.23**product contact surface**

machinery surfaces which are exposed to the product and from which the product or other materials can drain, drip, diffuse or be drawn into (self-retained) the product or product container

3.24**non-product contact surface**

all other exposed machinery surfaces including, where applicable, the splash area (3.32)

3.25**readily accessible**

location which can be reached by an employee from the floor, a platform or other permanent work area

3.26**readily removable**

designed to be separated from the machine with or without the use of simple hand tools

3.27**seal**

closure of an aperture so as to effectively prevent the entry or passage of unwanted matter

3.28

self-draining

combination of design, construction, installation and surface finish so as to prevent the retention of liquid except for normal surface wetting

3.29

sensors

devices or instrumentation attached to machinery for process monitoring/control

3.30

smooth

condition of a surface which satisfies hygienic requirements and is without surface defects (e.g. crevices) capable of retaining soil

3.31

soil

any unwanted matter

3.32

splash area

area composed of surfaces where product may come into contact and does not return to the product

3.33

sterilization

process that inactivates all micro-organisms and relevant microbial spores

3.34

sterilizability

(equipment) designed to be capable of being sterilized

4 Hazards

The hazards that can be associated with product handling, preparation and processing can arise from:

- biological causes such as pathogens, spoilage micro-organisms or toxins (e.g. ingress or retention of bacteria, spores, viruses, yeasts/moulds);
- chemical causes including those from cleaning and disinfection substances (e.g. lubricants, cleaning fluids, allergens);
- physical causes such as foreign materials arising from raw materials, equipment or other sources (e.g. allergens, pests, metals, materials used in the construction of the machine/equipment).

5 Hygiene requirements and/or measures

5.1 Strategy for selecting hygiene measures

5.1.1 General

The risk assessment strategy for selecting hygiene measures is applicable to both product and non-product contact areas.

5.1.2 Basic strategy for selecting hygiene measures

The basic strategy for selecting hygiene measures for the design of machinery and equipment shall be consistent with ISO 12100-1:—, clause 5. This includes the following:

- identification of the process for which the machine is intended;
- hazards associated with the product(s) produced (see clause 4);
- risk assessment associated with each hazard identified (see 5.1.3);
- design methods/measures which can eliminate hazards or reduce risks associated with these hazards (see 5.2);
- identification of any other hazards (either safety or hygienic) which can be introduced by methods used to reduce the risk associated with the hazard under analysis;
- means of verification of the effectiveness of the hazard elimination or the risk reduction method (see clause 6);
- description of residual risks and any additional precautions necessary in the information for use where applicable (see clauses 7 and 8).

This process is schematically represented in Figure 1. After this process has been undertaken for all hazards identified, it may be applicable to define the item of machinery according to one of the hygiene levels described in annex A in order to help clarify the intended use.

5.1.3 Elements of risk assessment

When undertaking the elements of the risk assessment, the following parameters are presented as guidance to the range and type of factors that shall be considered for the machine and its associated equipment.

- a) The intended use of the machine: Will the machine be used for one specific purpose only, for which the hazards are readily identifiable, or could the machine be used for a wide range of products in many industries (e.g. a pump)?
- b) The product type to be processed by the machine: Will the product be already contaminated (e.g. a raw material) or will it be “preserved” or aseptic?
- c) The degree of further processing: Will the product processed by the machinery subsequently undergo a further process which functions as a hazard elimination step (e.g. a heat treatment) or is the process for which the machine is intended the final process?
- d) Specific application of the product:
 - 1) Is the product to be used by the consumer immediately after processing or is there a product shelf-life in which the severity of the hazard could increase (e.g. relevant microbial growth)?
 - 2) Will the product be used by a specific consumer group to whom the hazard may present a more serious risk (e.g. a baby, elderly or infirm person)?
- e) The degree of cleaning, disinfection, pasteurization, sterilization and/or inspection: Is the machine to be cleaned, disinfected, pasteurized, sterilized and/or inspected after every use, routinely during the day, every day, or every week, etc.?
- f) The use of the machine: Is the machine likely to be well maintained or used infrequently, is it designed for high or continuous use or is misuse foreseeable?

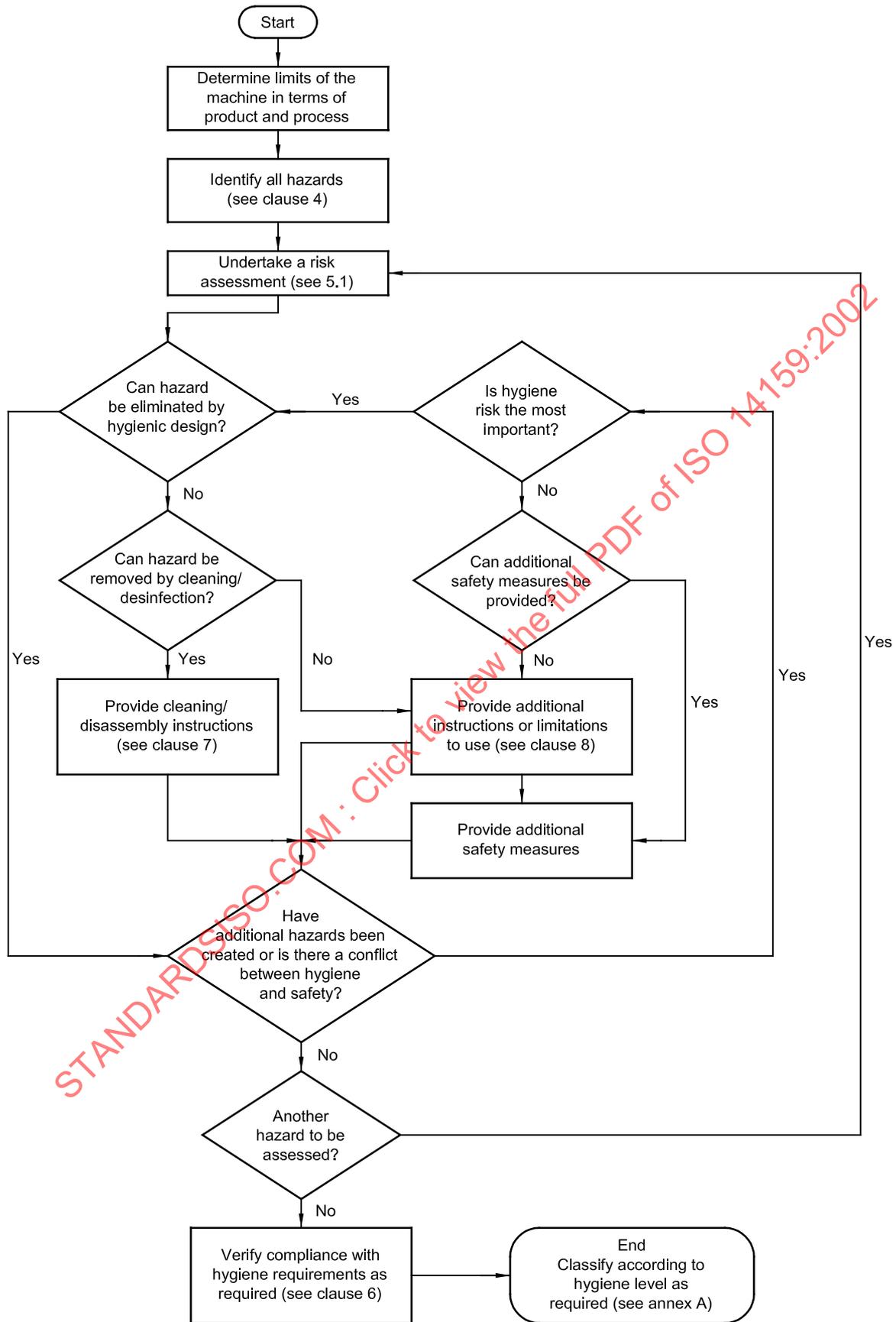


Figure 1 — Schematic risk assessment procedure

5.2 Hygienic design

5.2.1 Materials of construction

5.2.1.1 General

Materials shall be suitable for their intended use.

Surfaces of materials and coatings shall be durable, cleanable and, if necessary, capable of being disinfected, without breaks, resistant to cracking, chipping, flaking, erosion, corrosion and abrasion and prevent penetration of unwanted matter under intended use.

5.2.1.2 Product contact surfaces

In addition to the general requirements (see 5.2.1.1), materials used for product contact surfaces shall:

- be corrosion resistant to both product and cleaning/disinfection materials;
- be non-toxic;
- not contaminate or otherwise have any adverse effect on the product;
- be non-absorbent (except where technically or functionally unavoidable);
- be temperature resistant to processing and heat treatments where necessary (e.g. freezing, pasteurization, sterilization).

5.2.1.3 Metals

Product contact surfaces shall be:

- of stainless steel of a type appropriate for the application; or
- other metals (including solder) suitable for the conditions of intended use.

Product contact surfaces may be modified by surface treatment or coating(s).

5.2.1.4 Non-metals

Elastomers (e.g. rubber and rubber-like materials) and other polymers (e.g. plastic materials) may be used in product contact applications and shall conform with the appropriate requirements for the application.

Elastomers and other polymers having product contact surfaces shall be of such composition as to retain their surface and conformational characteristics when exposed to the conditions encountered in the environment of intended use and in cleaning, disinfection, pasteurization or sterilization.

Adhesives and the bonds created by their use shall be compatible with the surfaces, products and cleaning/disinfectant materials in which they are in contact. All bonds shall be continuous and mechanically sound so that the adhesives do not separate from the base materials to which they are bonded.

Where materials having certain inherent functional purposes are required for specific applications, product contact surfaces may be made of these materials (i.e. carbon, glass, ceramic materials).

Product contact surfaces may be modified by surface treatment or coating(s).

5.2.1.5 Non-product contact surfaces

In addition to the general requirements (see 5.2.1.1), materials used for non-product contact surfaces (including splash areas), under the conditions of intended use, shall:

- be of corrosion-resistant material or material that is treated (e.g. coating, painting) so as to be corrosion resistant to both product and cleaning/disinfection materials. When coated, the coating shall adhere;
- be non-absorbent (except where technically or functionally unavoidable);
- not contaminate or otherwise have any adverse effect on the product.

Parts removable for cleaning having both product contact and non-product contact surfaces shall be designed to ensure that hygiene risks are eliminated.

5.2.2 Design and fabrication of product contact surfaces

5.2.2.1 Surface texture

Surfaces shall be free of imperfections such as pits, folds, cracks and crevices. Technical requirements for surface finish according to ISO 4287, shall be given in the specific standards, if appropriate.

5.2.2.2 Cleaning and inspection

Surfaces shall be cleanable. For machinery intended to be disassembled, the design shall ensure that relevant areas are readily accessible for cleaning and inspection and the demountable parts shall be readily removable. Alternatively, machinery may be designed to be cleaned in place. Some machinery cleaned in place may need to be designed to allow ready access for inspection after cleaning.

5.2.2.3 Disinfection, pasteurization and sterilization

Machinery shall be designed such that surfaces can attain the required disinfection, pasteurization or sterilization conditions.

5.2.2.4 Microbial ingress

Where appropriate (e.g. aseptic process), machinery shall be designed to prevent micro-organisms migrating from the external environment onto product contact surfaces, either directly or via soils.

5.2.2.5 Draining

Surfaces of machinery intended to drain shall be self-draining or be drainable, except for normal wetting (see Figures B.1 and B.2).

5.2.2.6 Dead spaces

Dead spaces shall be avoided (see Figure B.3).

5.2.2.7 Joints

Permanent metal to metal joints shall be continuously welded. Permanent metal to non-metal or non-metal to non-metal joints shall be continuously welded or bonded. Jointed surfaces shall be flush (see Figure B.4).

Dismountable joints shall be flush and hygienically sealed at the product contact surface (see Figure B.5).

Only in cases where welding or bonding is impractical, soldering, press-fitting or shrink-fitting may be employed where necessary for essential technical reasons.

Silver-bearing solder may be used for flushing joints and producing fillets for minimum radii requirements.

Welding, press-fitting, shrink-fitting or soldering shall produce surfaces with a smooth finish free of imperfections such as pits, folds, inclusions, cracks and crevices.

5.2.2.8 Coatings

Where used, coatings shall be free from surface delamination, pitting, flaking, spalling, blistering and distortion.

5.2.2.9 Internal angles, corners and grooves

Internal angles and corners shall be designed using fillets and radii wherever practicable so that they are effectively cleanable (see Figure B.6).

Where used, grooves shall be wider than their depth.

5.2.2.10 Seals, gaskets, O-rings and joint-rings

Seals, gaskets, O-rings and joint-rings shall be designed to minimize product contact and be cleanable.

Thermal expansion and contraction shall be considered during design (see Figure B.7).

Where an elastomer is used as a seal between solid surfaces, the compression of the elastomer shall be considered during design (see Figure B.7).

5.2.2.11 Fasteners

Fasteners (e.g. screws, bolts, rivets) shall be avoided. Where technically unavoidable, fasteners shall be cleanable (see Figure B.8). There shall be no exposed screw threads or recesses.

Threads which may become product contact surfaces during dismantling operations should be designed to be cleanable.

5.2.2.12 Process flow disruption caused by intrusions

Intrusions (e.g. springs, openings, perforations) shall be avoided except where functionally necessary.

Where necessary, such process flow intrusions shall be cleanable in place or readily accessible for cleaning, disinfection and inspection.

5.2.2.13 Shafts and bearings

Where shaft seals are required, they shall be hygienic in design (i.e. packless) and shall be cleanable in place or readily accessible for cleaning, disinfection and inspection.

Where a shaft passes through a product contact surface, the portion of the opening surrounding the shaft shall be protected to prevent the entrance of contaminants (see Figure B.9)

Wherever possible, lubricated bearings, including the permanent sealed type, shall be located outside the product contact surface with adequate clearance open for inspection between the bearing and any product contact surface (see Figure B.9).

Bearings having a product contact surface shall be avoided. When technically necessary, these bearings shall be of a non-lubricated or product lubricated type (see Figure B.10) and cleanable. When a bottom support bearing is used, it shall not interfere with drainage of the equipment.

When provided, a shaft driving mechanism shall be securely mounted in a position that ensures a physical separation from product contact surfaces for cleaning and inspection.

5.2.2.14 Sensor and sensor connections

All sensors and sensor connections having product contact surfaces shall be installed to avoid crevices, dead spaces, and shall be drainable (see Figure B.3).

5.2.2.15 Other connections

All pipelines and other appendages entering the equipment shall be hygienically sealed and designed to prevent the ingress of soil.

5.2.2.16 Openings and covers

Panels, covers and doors shall be so designed that they avoid any adverse influence (e.g. entry and/or accumulation of soil) and shall be cleanable (see Figure B.11).

Where an opening is intended to provide human access, it shall meet the appropriate requirements for size and shape. If any exterior flange is incorporated in the opening, it shall slope and drain away from the opening.

Covers shall be sloped to an outside edge(s).

5.2.3 Design and fabrication of non-product contact surfaces

5.2.3.1 General

All machinery shall be designed and constructed in such a manner as to prevent the retention of moisture, ingress and harbourage of pests and soils, and to facilitate cleaning, inspection, servicing and maintenance. Where appropriate, equipment shall be designed such that non-product surfaces (including splash areas) can attain the required disinfection, pasteurization or sterilization conditions.

Permanent metal to metal joints shall be continuously welded wherever possible. Permanent metal to non-metal or non-metal to non-metal joints shall be continuously bonded.

Equipment to be mounted without supports shall be flush mounted and sealed (see Figure B.13).

5.2.3.2 Insulation

The insulation material shall be properly mounted and suitably sealed to prevent the ingress of contaminants (e.g. moisture or pests).

5.2.3.3 Supports

Supports shall be designed, fabricated and installed such that no water or soil can remain on the surface or within the supports. The possibility of adverse galvanic reactions between dissimilar materials shall be taken into consideration (see Figure B.12).

Sufficient clearance for cleaning and inspection shall be provided (see Figure B.13).

Where castors are used, they shall be of sufficient size to provide adequate clearance between the lowest part of the base and the floor for easy cleaning and inspection. Castors shall be easily cleanable, durable and of a size that permits easy movement of the equipment.

Where the machinery is to be floor- or wall-mounted, supports shall be designed for sealing to the mounting surface.

5.2.3.4 Product contact with machinery fluids

Machinery shall be designed, fabricated and installed to prevent the ingress of unwanted fluids (e.g. lubricating and hydraulic fluids, and signal transfer liquids) into the product. Where machinery failure can result in these fluids coming into contact with the product, these fluids shall be non-toxic and compatible with the product.

6 Verification of hygiene measures and test methods

Verification of compliance with hygiene requirements is undertaken using one or more of the following:

- examination of the functional specifications and drawings;
- examination of the fabricated machine; and/or
- undertaking of specific practical tests (if available).

The methods of verification of hygienic design depend on both the original risk analysis (see 5.1) and the specific purpose for which the machine was designed.

The majority of open product processing machinery is considered to be cleanable if its design complies with the requirements of clause 5 and of the specific standards. More complicated machinery may require assessment by means of a practical cleanability test.

The majority of closed product processing machinery is considered cleanable if the cleaning procedure can be verified by means of a practical test of the entire plant or its individual components. Some closed product processing machinery may be considered to be cleanable if its design complies with the requirements of clause 5.

Machines designed to be pasteurized, sterilized or for aseptic production, usually for closed product processing, shall require practical testing.

7 Instruction handbook, maintenance and cleaning

7.1 Instruction handbook

The instruction handbook shall include the following items:

a) Installation of the machinery and associated equipment

Information shall be provided so that, after the machinery is installed, it maintains its hygienic integrity (e.g. drainability) and there is adequate access for servicing and cleaning (see Figure B.14).

Measures shall be described on the use of the machinery so that, when installed correctly, the product is not exposed to factors that can lead to contamination.

b) Instruction for use

Measures shall be described on the use of the machinery so that, when used correctly, the product is not exposed to factors that can lead to contamination. Requirements for monitoring and control of critical hygiene parts shall be identified.

7.2 Maintenance and cleaning

7.2.1 Maintenance

A system of measures shall be recommended to ensure that the hygienic integrity of the machinery is maintained during its intended lifetime.

7.2.2 Cleaning

The instructions shall specify typical routine procedures for cleaning, disinfection, rinsing and inspection for cleanliness. Where appropriate, recommended cleaning materials (especially related to fabrication material chemical resistance) shall be specified. Where dismantling is required, specific instructions shall be provided.

8 Additional information (limitations of use)

In the event of the hygienic design (see 5.2) of the machinery being unable to control the risk associated with a specific hazard identified (see clause 4), or in the event of a product/operative safety compromise, additional information shall be required. Additional information could include, for example:

- further monitoring, cleaning and disassembly instructions;
- specific processing conditions (e.g. controlled temperature environment);
- limitations to the range of products that can be safely processed;
- the requirements for special machine guarding.

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Annex A (informative)

Categorization of machinery and associated equipment for intended use

Hygiene level	Description
1	Machinery which, following a hygiene risk assessment, needs only to partially conform with the requirements of this International Standard to meet the identified risk(s) and to produce a safe product.
2	Machinery which, following a hygiene risk assessment, conforms with the requirements of this International Standard, but requires planned disassembly for cleaning.
3	Machinery which, following a hygiene risk assessment, conforms fully with this International Standard and can be cleaned without disassembly.
4	Machinery which, following a hygiene risk assessment, conforms fully with this International Standard and has been designed for a specified heat, chemical or physical treatment to free the machinery from relevant micro-organisms.
5	Machinery which, following a hygiene risk assessment, conforms fully with this International Standard, will prevent microbial ingress and has been designed for a specified heat, chemical or physical treatment to free the equipment from relevant micro-organisms.

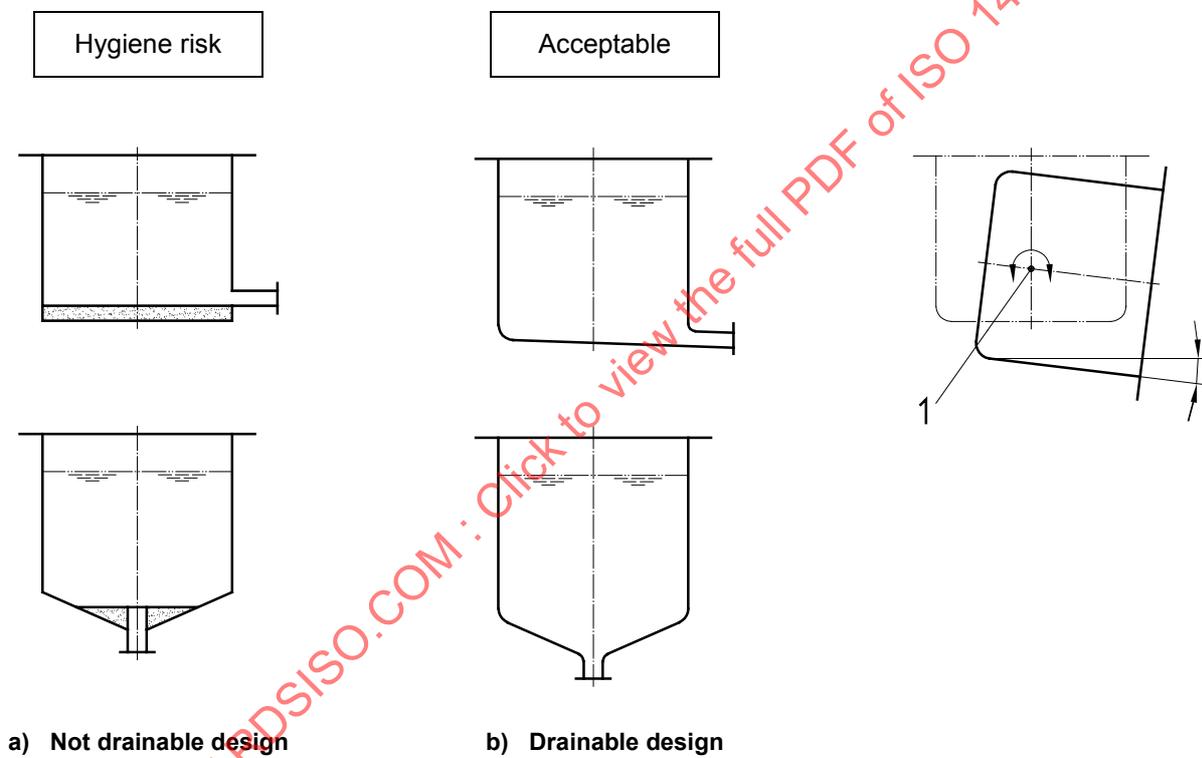
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Annex B (informative)

Examples of good and bad hygienic design features

Figures B.1 to B.14 show examples of a solution to an example of a particular problem with the objective of enhancing and illustrating the text of 5.2 and clause 7. In many cases, alternative solutions, which are equally as hygienic, could be found. Poor examples of hygienic design are illustrated on the left hand side of the page (hygiene risk) and good examples on the right hand side (acceptable).

NOTE Figures B.1 to B.14 have been derived from references [1] to [6] in the Bibliography.



Key
1 Hinge

Figure B.1 — Drainage of vessels

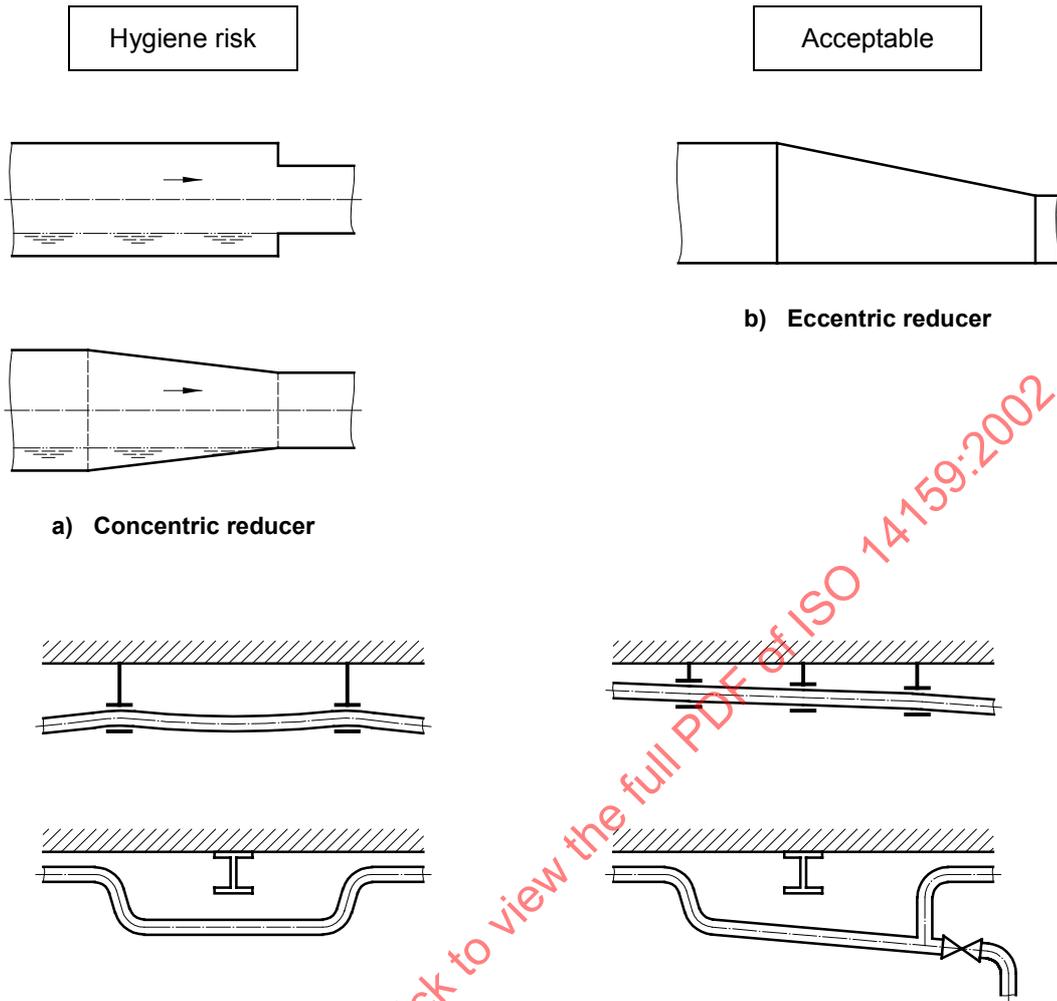
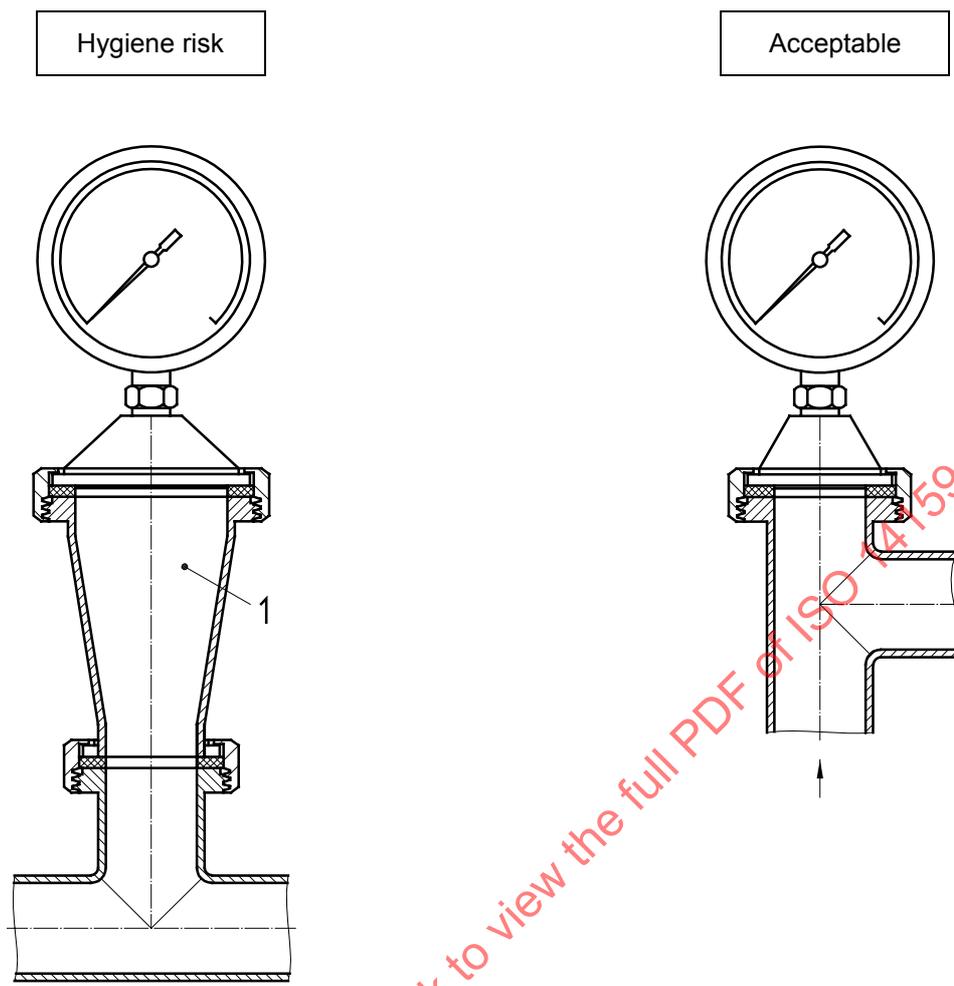
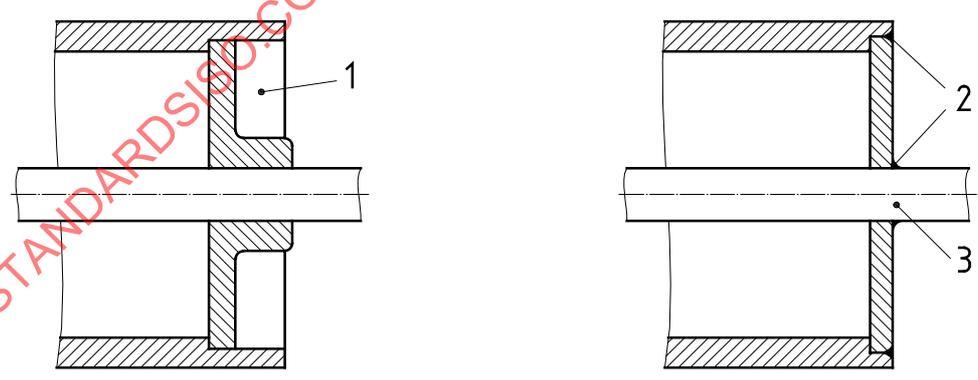


Figure B.2 — Drainage of pipelines

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a) Mounting of sensors

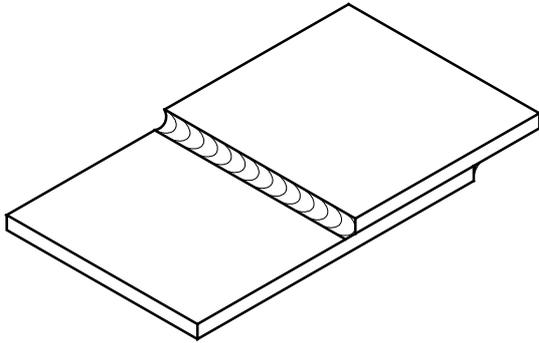


b) Conveyor roller construction

- Key**
- 1 Dead space
 - 2 Welds
 - 3 Shaft

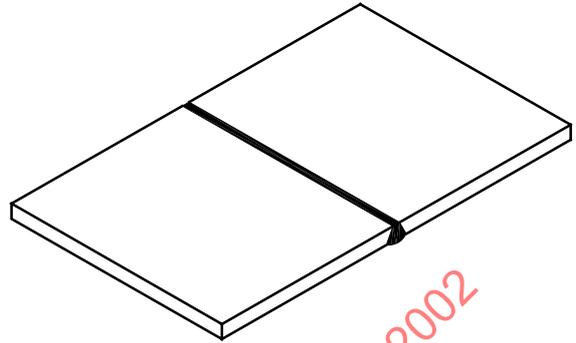
Figure B.3 — Dead space

Hygiene risk

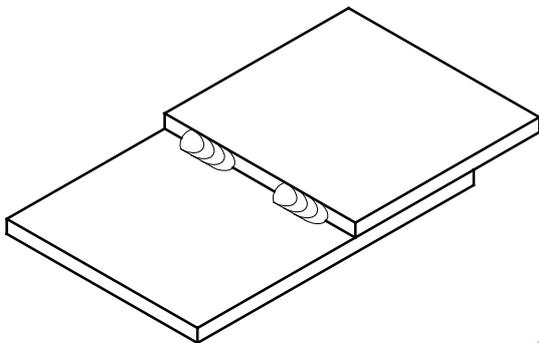


Continuously welded lap joint

Acceptable



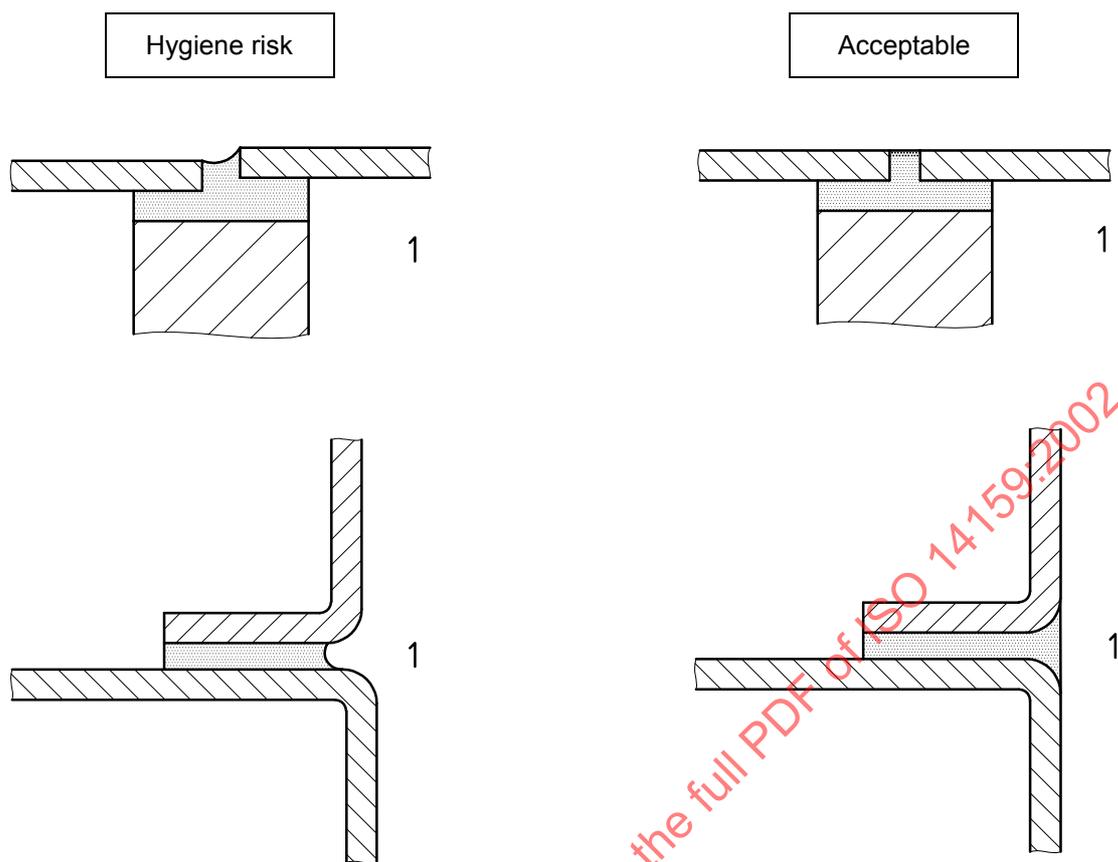
Continuously welded butt



Intermittently welded lap joint

a) Welded joints

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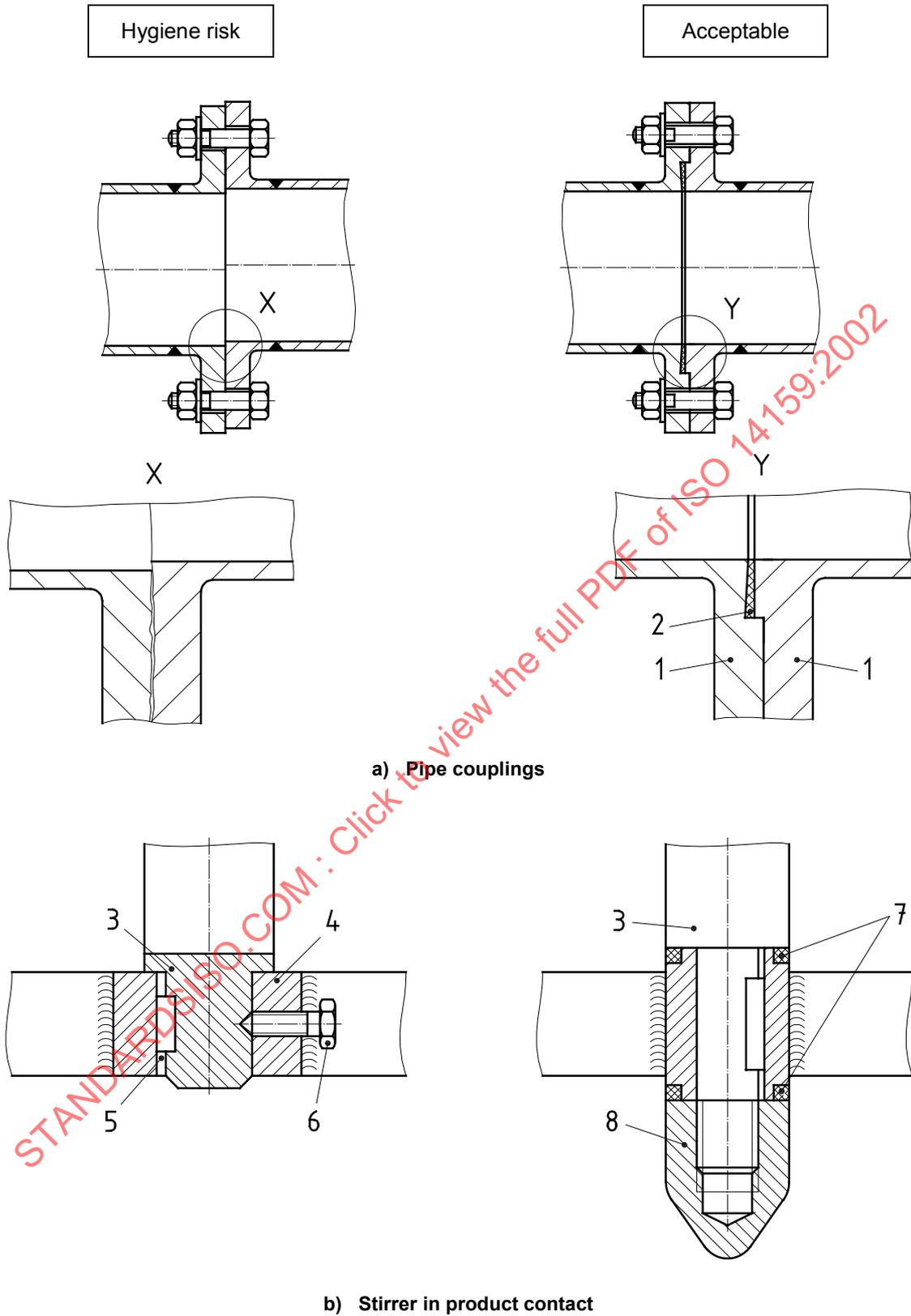


b) Bonded joints

Key

1 Product

Figure B.4 — Permanent joints



Key

- | | | | |
|---------------|------------------------|----------------------|----------------|
| 1 Metal | 3 Shaft | 5 Crevice | 7 Sealed joint |
| 2 Rubber seal | 4 Metal to metal joint | 6 Exposed screw head | 8 Sealed cap |

Figure B.5 — Dismountable joints

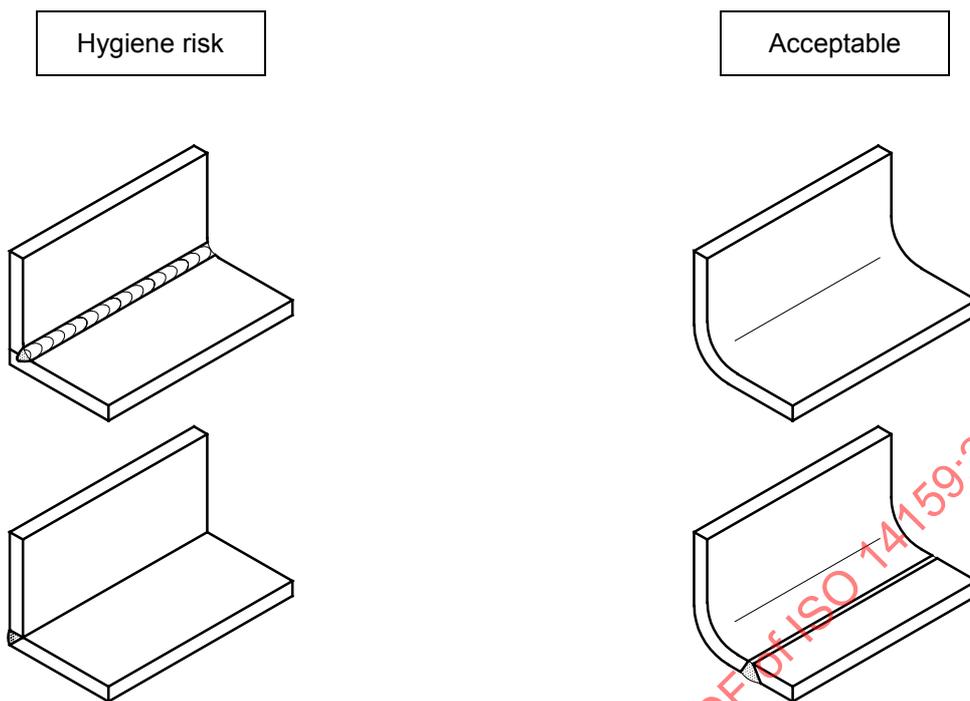
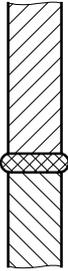


Figure B.6 — Internal angles and corners

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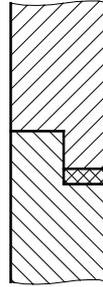
Hygiene risk

Acceptable

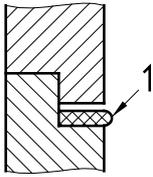


It is important to limit the compression to prevent damage to the elastomer structure, resulting in loss of contact pressure.

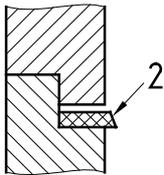
The same problem will occur when, due to ageing, resilience is lost.



When compressed by 15 %, 70° shore hardness rubber gaskets will provide a bacteria-tight seal



Non-resilient gasket materials "flow" under pressure. Temperature cycling will cause permanent leakage due to large differences between thermal expansion rates of metal and plastic (e.g. PTFE).



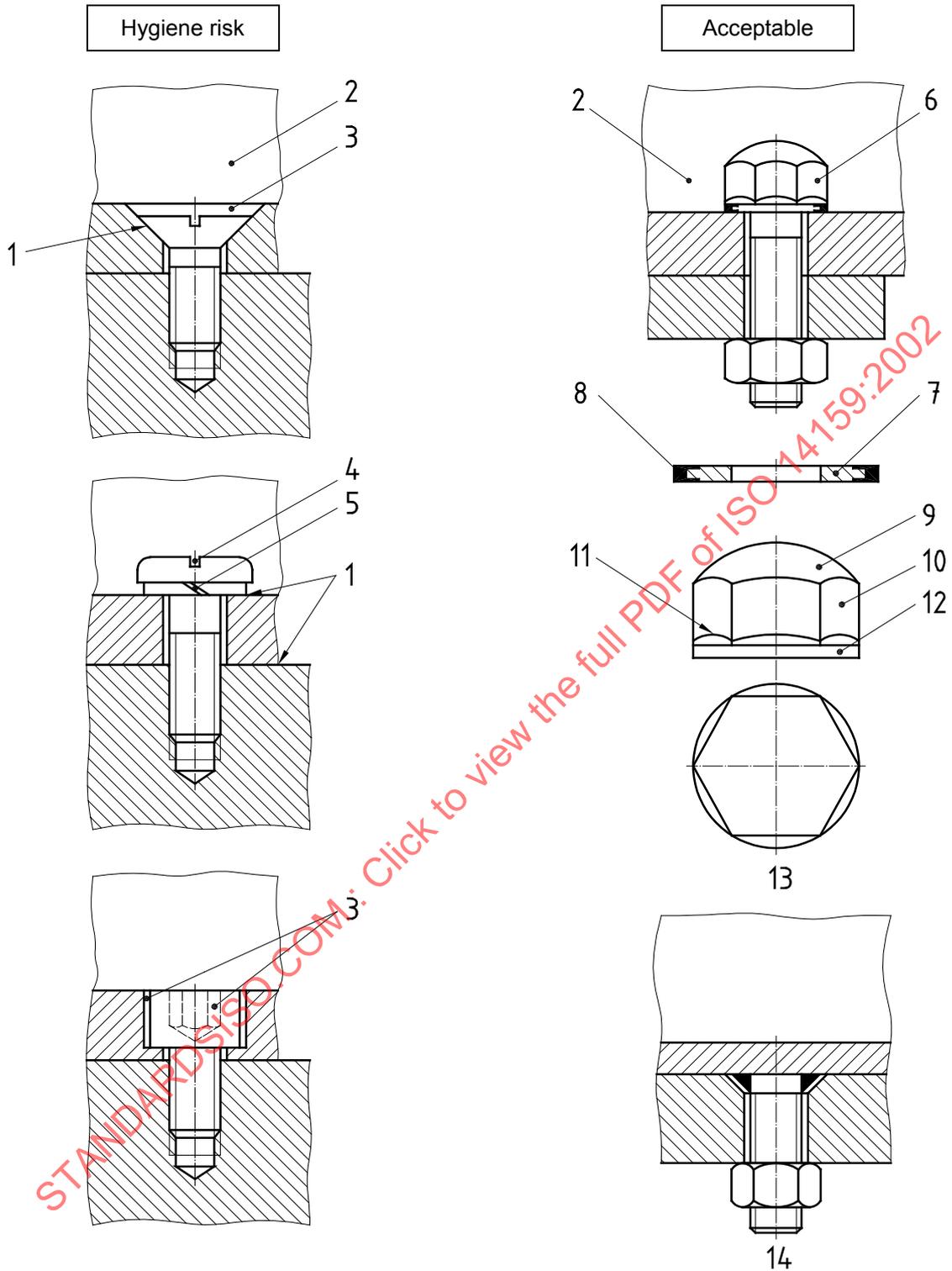
(Gap is not shown to scale.)

Key

- 1 High temperature
- 2 Low temperature

Figure B.7 — Controlled compression and thermal expansion of elastomers and polymers

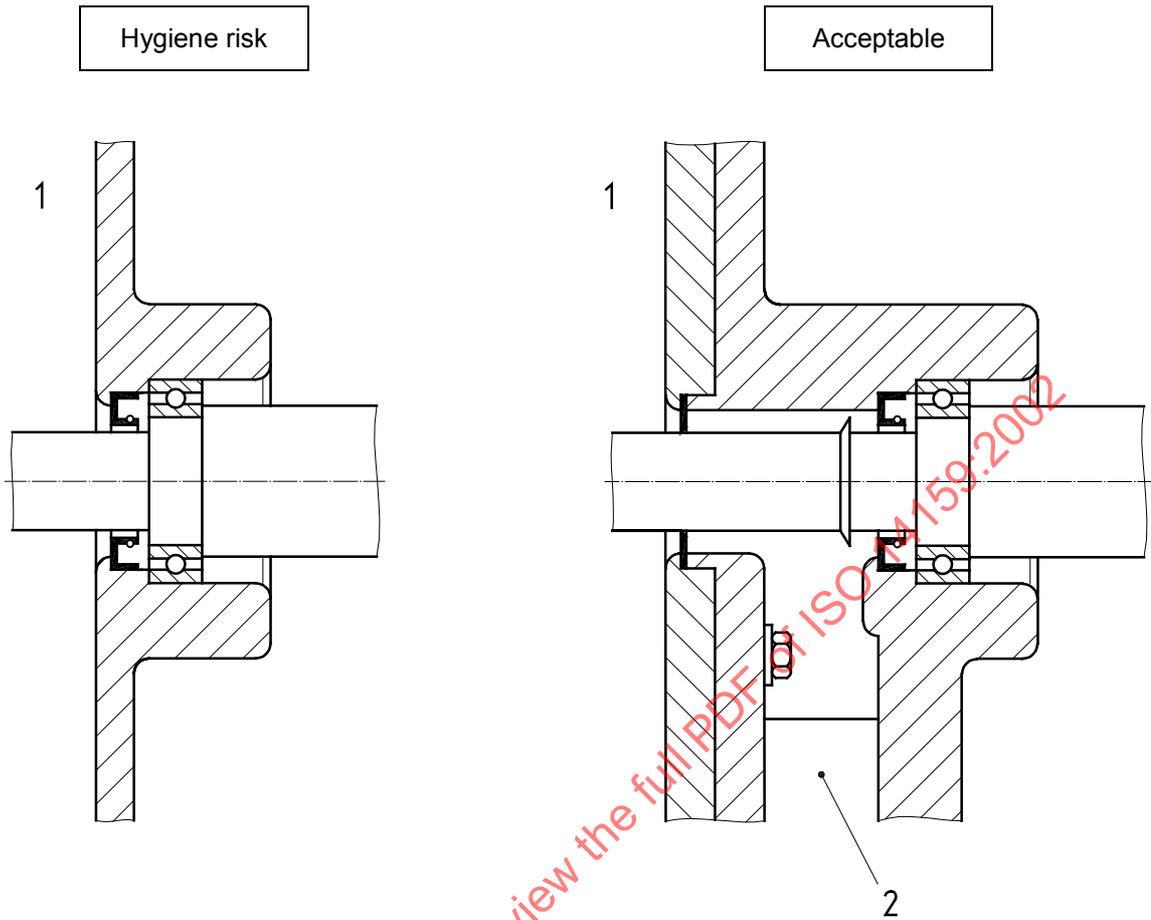
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Key

- | | |
|--------------------------|--|
| 1 Metal to metal contact | 8 Elastomer |
| 2 Product area | 9 Domed |
| 3 Dead area | 10 Hexagon |
| 4 Gap | 11 Sloped |
| 5 Crevice | 12 Circular collar |
| 6 Domed head | 13 Well designed nut or screw head |
| 7 Metal | 14 Reverse of product area welded stud |

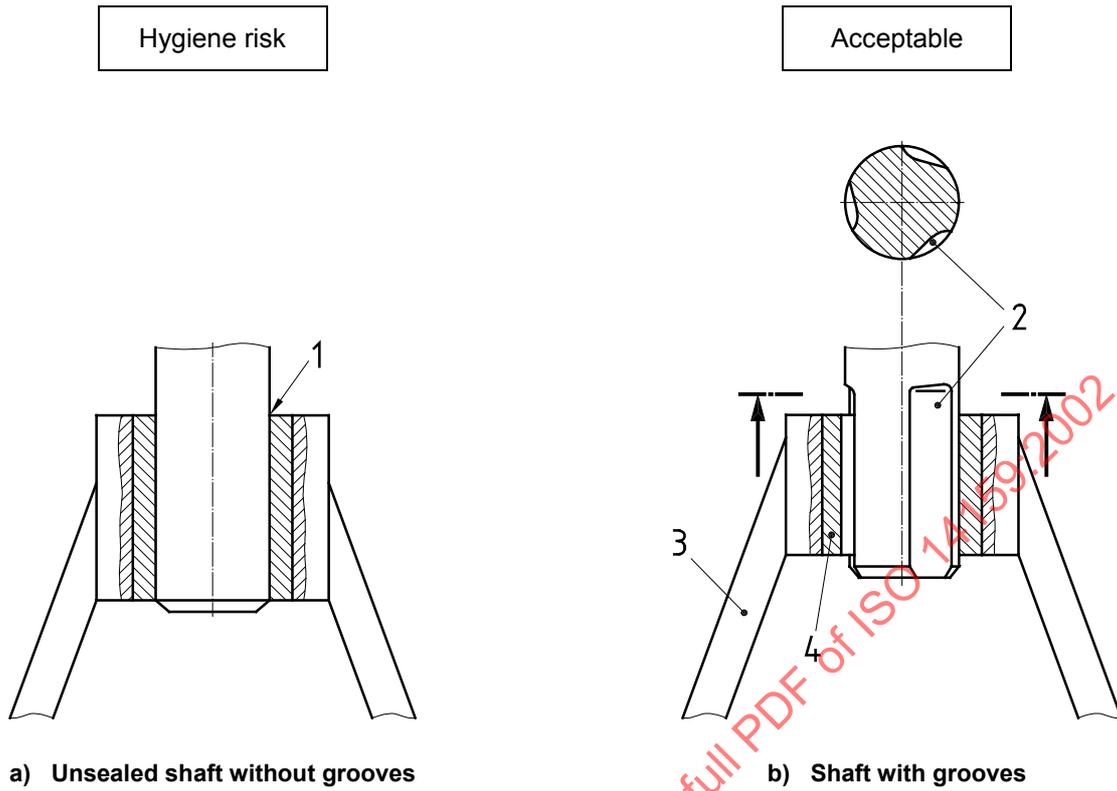
Figure B.8 — Design of fasteners



Key

- 1 Product side
- 2 Break to atmosphere

Figure B.9 — Shaft entry design



Key

- 1 Small clearance
- 2 Groove
- 3 Foot
- 4 Bearing

Figure B.10 — Product lubricated bearings