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Varnost strojev - Splošne higienske zahteve za načrtovanje (ISO/DIS 14159:2026)

Safety of machinery - General requirements for hygienic design (ISO/DIS 14159:2026)

Sicherheit von Maschinen - Hygieneanforderungen an die Gestaltung von Maschinen
(ISO/DIS 14159:2026)

Sécurité des machines - Exigences générales relatives à l'hygiène lors de la conception
(ISO/DIS 14159:2026)

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ICS:

13.110

Varnost strojev

Safety of machinery

oSIST prEN ISO 14159:2026

en,fr,de

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DRAFT International Standard

ISO/DIS 14159

Safety of machinery — General requirements for hygienic design

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

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 199 *Safety of machinery*.

This second edition cancels and replaces the first edition ISO 14159:2002-04-01 Safety of machinery – Hygiene requirements for the design of machinery, which has been technically revised.

The main changes are as follows:

- References, terms and definitions were updated
- New [clause 5](#) “Hygiene requirements and hygiene measures”
- [Clause 6](#) “Hygiene Risk reduction” was structured in product-, splash- and non-product area
- Informative [Annexes A](#), C were deleted and replaced by
[Annex A](#) Examples of potential risks and possible solution
[Annex B](#) Examples of hygiene hazard

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

This International Standard is one of a series of standards relating to the safety of machinery (ISO 12100:2010). It is a Type B standard and as such very general.

This document does not deal with the hygiene-related risks to operators arising from the use of the machinery.

Hygiene risks are associated with the ability of a machine to prevent product contamination and to be freed from product debris and microorganisms that can compromise the health and safety of persons or domestic animals.

This standard considers machinery and their associated equipment and can be used to provide guidance to the manufacturers of machines, associated equipment and other equipment where hygiene risks to the consumer of the products can occur. Type C standard applicable to specific machines types can implement or modify the requirement of this standard. Furthermore, detailed B standards with requirements for specific sectors of machinery - depending on identified hazards - can be deduced on basis of this general Type B standard.

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, feed, beverages, pharmaceuticals, biotechnological products, cosmetics*). Other standards, for example machinery specific Type C standards, may be required to provide guidance for specific types of equipment and/or for specific industry sectors. Furthermore, detailed B standards with requirements for specific sectors of machinery - depending on identified hazards - can be deduced on basis of this general Type B standard.

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. This standard deals in particular with hygiene risks but also considers the possible conflict between safety and hygiene measures.

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.

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Safety of machinery — General requirements for hygienic design

1 Scope

This International Standard specifies general requirements for the hygienic design of machinery and associated equipment as well as instructions for use. 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 egress of microbiological agents from the machine.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

Reduction

ISO 21920:2022, *Geometrical product specifications (GPS) – Surface texture: Profile- Part 2: Terms, definitions and surface texture parameters*

ISO 20607:2019, *Safety of machinery — Instruction handbook — General drafting principles*

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

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

ISO/DIS 14159:2026(en)**3.3****cleaning in place**

cleaning (3.4) of a machine or an equipment of a machine without dismantling parts

Note 1 to entry: for example, providing circulation of flowing chemical solutions, cleaning liquid and water rinses onto and over surfaces.

3.4**cleaning**

removal of soil (see 3.33)

3.5**cleanable**

designed and constructed so that soil can be removed

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**

inactivation of pathogens and a wide range of other unwanted micro-organisms to an tolerable level

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, fitted with or intended to be fitted with a drive system consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application

Note 1 to entry: The term “machinery” also covers an assembly of machines which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole.

[SOURCE: ISO 12100:2010, 3.1]

3.14**manual cleaning**

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

ISO/DIS 14159:2026(en)**3.15****micro-organism (relevant)**

bacteria, fungi, yeasts, molds, 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-absorbent 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**

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 area**

machine and machine components surface which are exposed to the product or from which product or other materials can drain, drip, diffuse or be drawn into the product or product container

3.24**splash area**

area composed of surfaces on which part of the product can splash or flow along under intended conditions of use and does not return into the product

Note 1 to entry: Once product comes into contact with the splash area, it is no longer a product within the meaning of [3.22](#). It is then no longer used as a product and is therefore considered as soil.

3.25**non-product area**

any area other than product area or splash area

Note 1 to entry: Soil that comes into contact with the non-product area during the cleaning phase (rinsing) has no influence on the classification of this area

ISO/DIS 14159:2026(en)**3.26****easily cleanable**

designed and constructed to be cleanable by a simple cleaning method, where necessary after removing easily dismountable parts

Note 1 to entry: Simple cleaning methods could be, e.g. vacuum cleaning, cleaning in place (CIP) or cleaning after dismantling parts without the need of tools (e.g. spanner) for dismantling.

[SOURCE: EN 1672-2:2020, 3.6.2]

3.27**readily accessible**

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

3.28**readily removable**

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

Note 1 to entry: Simple hand tools are for example a screwdriver, wrench, mallet, or readily available dedicated tool(s) normally used by operating and cleaning personnel.

3.29**seal**

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

3.30**self-draining**

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

3.31**sensors**

devices or instrumentation attached to machinery for process monitoring/control

3.32**smooth**

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

3.33**soil**

any unwanted matter

3.34**sterilization**

a process aimed at removing or killing all forms of micro-organisms, including bacterial spores

3.35**sterilizability**

(equipment) designed to be capable of being sterilized

3.36**wet cleaning**

cleaning with the liquid solvent

3.37**dry cleaning**

solvent free cleaning

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3.38

verification

application of methods, procedures, test and other evaluations, in addition to monitoring to determine compliance

3.39

hygienic integrity

probability of a hygiene-related system satisfactorily performing the required hygiene functions under all the specified conditions within a specified period of time.

4 List of significant hazards

The significant hazards can arise from:

- a) microbiological causes, e.g.:
 - 1) pathogens (from e.g. opportunistic pathogens like salmonella, Enterobacter, coliform bacteria)
 - 2) microbiological toxins (from e.g. Bacillus cereus, Staphylococcus aureus) and biogenic amines of pathogens
 - 3) microorganism
 - 4) other biological causes, e.g.:
 - mono- and multicellular vermin (e.g. toxoplasma, tapeworm);
 - unconventional transmissible agents
- b) Chemical causes, e.g.:
 - cleaning and disinfection agents
 - lubricants
 - veterinary drugs
 - agricultural pesticides
 - contaminants, e.g. allergens, dioxins, polychlorinated biphenyl (PCB), mycotoxins, heavy metals
 - substances released by materials
- c) Physical causes, e.g.:
 - foreign bodies (e.g. bone fragments, metal parts and broken glass)
 - contaminants and radiation arising from raw material, machinery or other sources

Malfunction of machinery or malfunction of equipment e.g.:

- Interruption of the flow of modifying or protective gases
- Malfunction of filters
- Interruption of the flow of sterilized air
- Malfunction of pasteurizing or sterilizing system
- Malfunction of the cleaning system

can have an impact on hygiene causing hazardous situations.

Note 1 to entry further information of significant hazards is available in [Annex B](#)

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5 Hygiene requirements and hygiene measures

5.1 General

Either hygiene requirements or risk reduction measures or both shall be implemented

5.2 Risk assessment strategy

The risk assessment strategy for selecting hygiene measures is applicable to the product area, splash area and non-product areas.

NOTE For more information see EN 1672-2:2020 or ISO TR 14121-2:2013 / ANSI document ANSI B11.0 2023

5.2.1 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 12100:2010. This includes the following:

- identification of the process for which the machine is intended
- hazards associated with the product(s) produced (see [clause 4](#))
- hygiene risk assessment associated with each hazard identified (see [clause 5.2.3](#))
- hygiene risk reduction which can eliminate hazards or reduce risks associated with these hazards (see [clause 6](#))
- 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 7](#))
- description of residual risks and any additional precautions necessary in the information for use where applicable (see [clauses 7](#) and [8](#))

Applying measures to reduce hygiene risks, such as improving visibility, can sometimes raise safety risks.

The iterative hygiene risk reduction procedure is schematically represented in [Figure 1](#).

5.2.2 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.

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 various industrial sectors (e.g. a pump)?

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?

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?

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)?

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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)?

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.?

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?

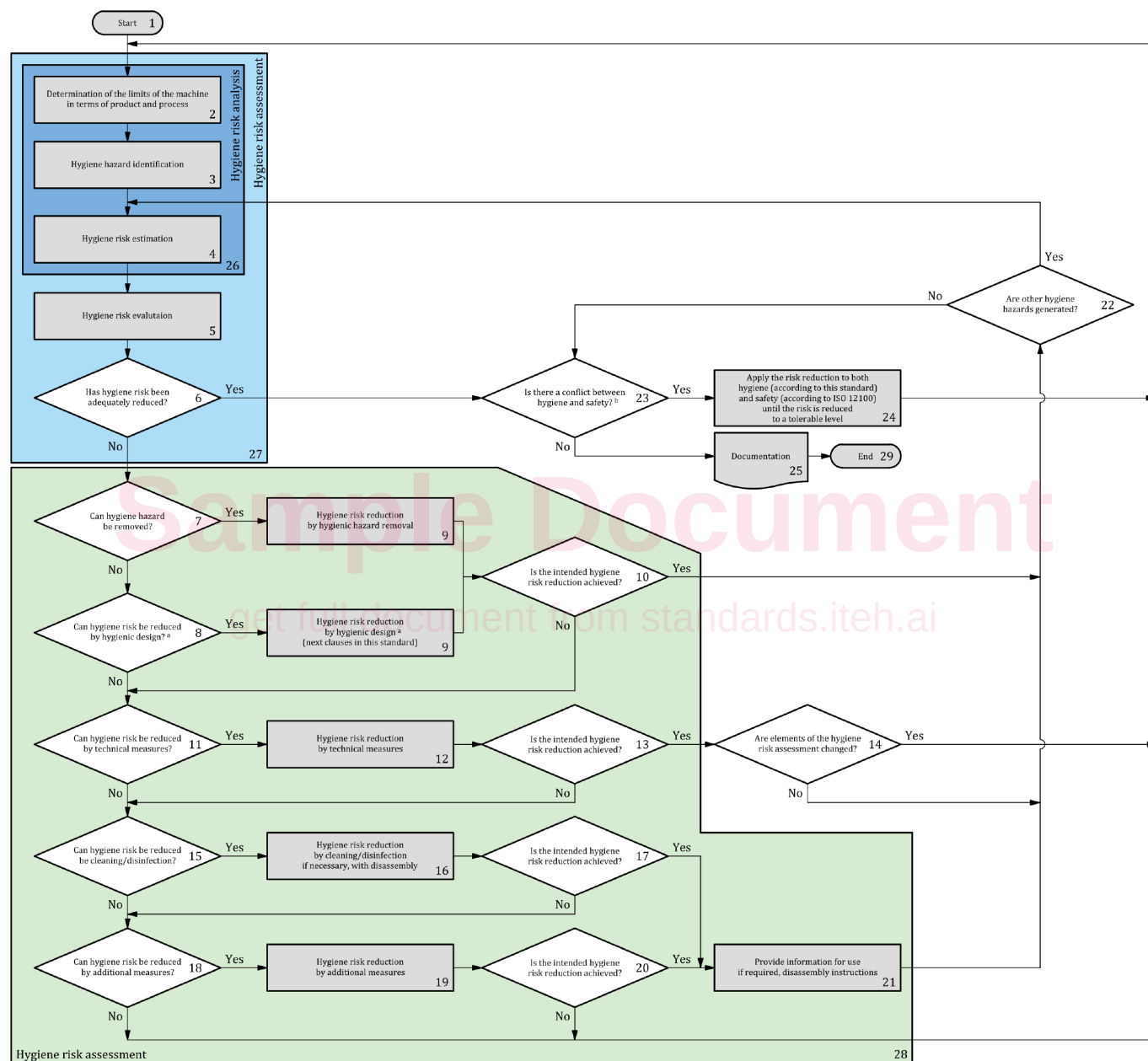


Figure 1 — Schematic iterative hygiene risk reduction procedure

5.2.3 Hygiene risk assessment (see [Figure 1](#), Item 27)

Hygiene risk assessment comprises