

---

---

**Safety of machinery — Hygiene  
requirements for the design of machinery**

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

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO 14159:2002](https://standards.iteh.ai/catalog/standards/sist/e4a38a0e-7202-47f6-ba9a-2815fc785b31/iso-14159-2002)

[https://standards.iteh.ai/catalog/standards/sist/e4a38a0e-7202-47f6-ba9a-  
2815fc785b31/iso-14159-2002](https://standards.iteh.ai/catalog/standards/sist/e4a38a0e-7202-47f6-ba9a-2815fc785b31/iso-14159-2002)



**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

ISO 14159:2002

<https://standards.iteh.ai/catalog/standards/sist/e4a38a0e-7202-47f6-ba9a-2815fe785b31/iso-14159-2002>

© ISO 2002

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.ch](mailto:copyright@iso.ch)  
Web [www.iso.ch](http://www.iso.ch)

Printed in Switzerland

## Contents

|   | Page |
|---|------|
| Foreword.....   | iv   |
| Introduction.....   | v    |
| 1 Scope .....   | 1    |
| 2 Normative references .....  | 1    |
| 3 Terms and definitions .....   | 1    |
| 4 Hazards .....   | 4    |
| 5 Hygiene requirements and/or measures .....  | 4    |
| 5.1 Strategy for selecting hygiene measures .....   | 4    |
| 5.2 Hygienic design .....   | 7    |
| 6 Verification of hygiene measures and test methods .....   | 11   |
| 7 Instruction handbook, maintenance and cleaning.....   | 11   |
| 7.1 Instruction handbook .....  | 11   |
| 7.2 Maintenance and cleaning .....  | 11   |
| 8 Additional information (limitations of use) .....   | 12   |
| Annex A (informative) Categorization of machinery and associated equipment for intended use.....                                    | 13   |
| Annex B (informative) Examples of good and bad hygienic design features.....  | 14   |
| Annex C (informative) Relationship between International Standards referenced in clause 2 and corresponding European Standards..... | 29   |
| Bibliography.....   | 30   |

## 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.

**ITEH STANDARD PREVIEW**  
**(standards.iteh.ai)**

ISO 14159:2002

<https://standards.iteh.ai/catalog/standards/sist/e4a38a0e-7202-47f6-ba9a-2815fe785b31/iso-14159-2002>

## 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.

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

ISO 14159:2002

<https://standards.iteh.ai/catalog/standards/sist/e4a38a0e-7202-47f6-ba9a-2815fc785b31/iso-14159-2002>

# 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 (GPS) — Surface texture: Profile method — Terms, definitions and surface texture parameters*

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

ISO 12100-2:—<sup>2</sup>, *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 affect 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-returned) 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

ITeH STANDARD PREVIEW  
(standards.iteh.ai)

<https://standards.iteh.ai/catalog/standards/sist/e4a38a0e-7202-47f6-ba9a-2815fc785b31/iso-14159-2002>

**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

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[ISO 14159:2002](https://standards.iteh.ai/catalog/standards/sist/e4a38a0e-7202-47f6-ba9a-2815fc785b31/iso-14159-2002)

<https://standards.iteh.ai/catalog/standards/sist/e4a38a0e-7202-47f6-ba9a-2815fc785b31/iso-14159-2002>

**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.

ITeH STANDARD PREVIEW

### 5.1.3 Elements of risk assessment (standards.iteh.ai)

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?

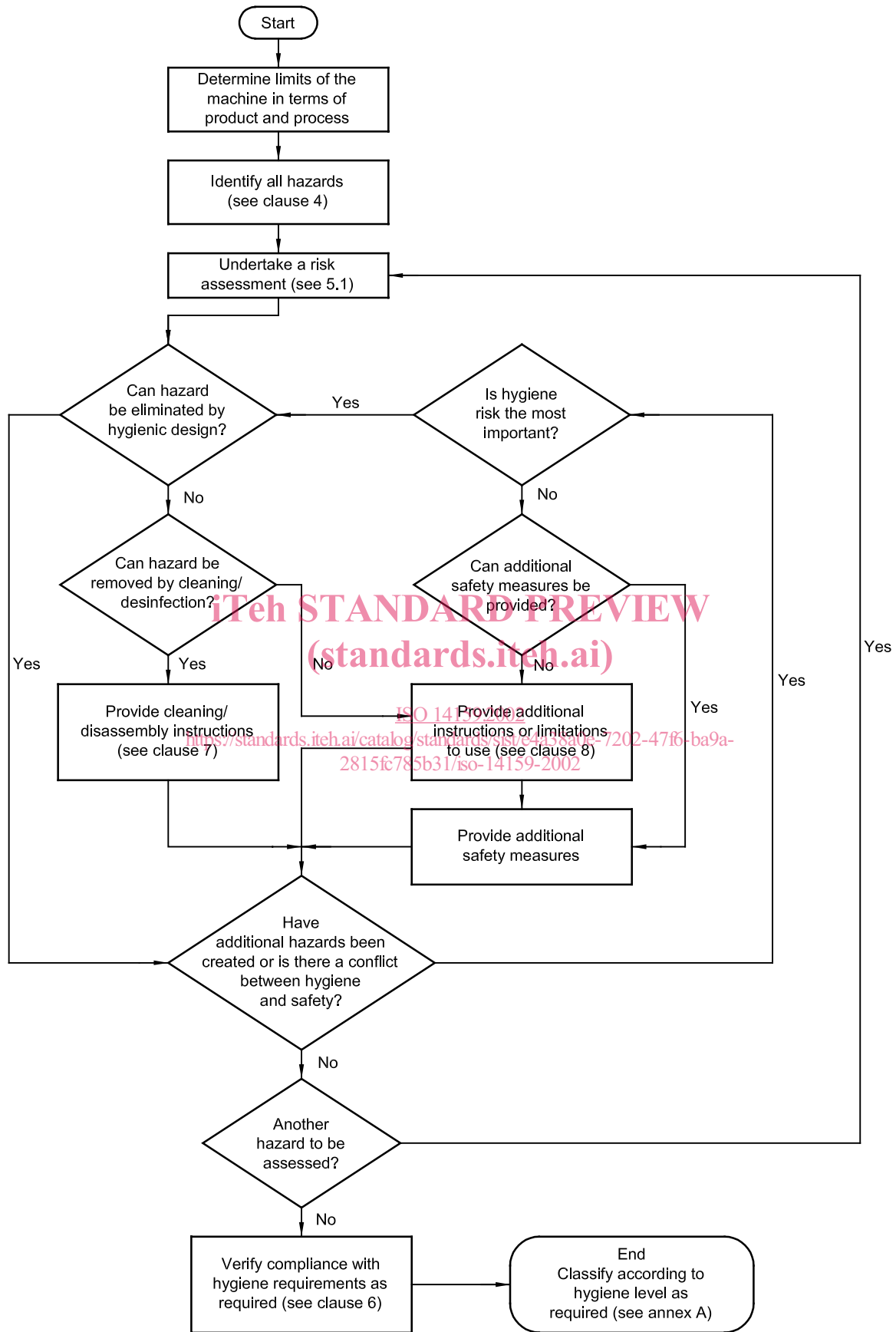


Figure 1 — Schematic risk assessment procedure