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## Safety aspects — Guidelines for their inclusion in standards

*Aspects liés à la sécurité — Principes directeurs pour les inclure dans les normes*

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## Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) are worldwide federations of national standards bodies (ISO member bodies and IEC national committees). The work of preparing International Standards is normally carried out through ISO and IEC 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 or IEC, also take part in the work. ISO collaborates closely with IEC on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft Guides adopted by the responsible Committee or Group are circulated to the member bodies for voting. Publication as a Guide 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 document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

ISO/IEC Guide 51 was prepared by a Joint Working Group of the ISO Committee on Consumer Policy (COPOLCO) and the IEC Advisory Committee on Safety (ACOS). This third edition cancels and replaces the second edition (ISO/IEC Guide 51:1999) which has been technically revised.

The main changes compared with the second edition are as follows:

- strengthened focus on risk reduction in the overall risk assessment process, including revised [Figure 2](#);
- replacement of the term “harmful event” with the term “hazardous event”;
- updating of terms used in the context of consumer safety;
- revision of [Figure 3](#) to specify the risk reduction steps in greater detail;
- addition of a new Introduction providing more background information;
- addition of specific provisions and references relative to vulnerable consumers;
- revision of [Clause 2](#) (Normative references) and the Bibliography;
- reorganization and consolidation of the content in [Clauses 6](#) and [7](#).

## Introduction

Work on standards deals with safety aspects in many different forms across a wide range of technologies and for most products, processes, services and systems (referred to as “products and systems” in this Guide). The increasing complexity of products and systems entering the market makes it necessary to place a high priority on consideration of safety aspects.

This Guide provides practical guidance to drafters of standards to assist them in including safety aspects in standards. The underlying principles of this Guide can also be used wherever safety aspects require consideration, and as a useful reference for other stakeholders such as designers, manufacturers, service providers, policy makers and regulators.

The approach described in this Guide aims at reducing risk that can arise in the use of products or systems, including use by vulnerable consumers. This Guide aims to reduce the risk arising from the design, production, distribution, use (including maintenance) and destruction or disposal of products or systems. The complete life cycle of a product or system (including both the intended use and the reasonably foreseeable misuse) is considered, whether the product or system is intended to be used in the workplace, in the household environment, or for recreational activities. The goal is to achieve tolerable risk for people, property and the environment, and to minimize adverse effects on the environment.

Hazards can pose different safety problems and can vary significantly depending on the end user of a product or system, including the integrity of control mechanisms, and the environment in which a product or system is used. Whereas it is possible to control risks to a greater extent in the workplace, this might not be the situation in the home environment or when vulnerable consumers use the product or system. Consequently, this Guide might need to be supplemented by other publications for particular fields of interest or users. An indicative list of such publications appears in the Bibliography.

This Guide is intended to be applicable to the drafting of all new standards and to existing standards at their next revision.

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It is important to distinguish the respective roles of quality and of safety. However, it might be necessary to consider quality requirements in standards to ensure that the safety requirements are consistently met.

NOTE 1 The term “standard” used throughout this Guide includes international standards, technical specifications, publicly available specifications, technical reports and guides.

NOTE 2 Standards can deal exclusively with safety aspects or can include clauses specific to safety.

NOTE 3 Unless otherwise stated, when the term “committee” is used in this Guide, it refers to technical committees, subcommittees or working groups of both ISO and IEC.

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# Safety aspects — Guidelines for their inclusion in standards

## 1 Scope

This Guide provides requirements and recommendations for the drafters of standards for the inclusion of safety aspects in standards. It is applicable to any safety aspect related to people, property or the environment, or to a combination of these.

NOTE 1 For example, it can be applicable to people only, or to people and property, or to people, property and the environment.

NOTE 2 The term “products and systems” used throughout this Guide includes products, processes, services and systems.

NOTE 3 Safety aspects can also be applicable to long-term health consequences.

## 2 Normative references

There are no normative references.

## 3 Terms and definitions (standards.iteh.ai)

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

### 3.1

#### **harm**

injury or damage to the health of people, or damage to property or the environment

### 3.2

#### **hazard**

potential source of *harm* (3.1)

### 3.3

#### **hazardous event**

event that can cause *harm* (3.1)

### 3.4

#### **hazardous situation**

circumstance in which people, property or the environment is/are exposed to one or more *hazards* (3.2)

### 3.5

#### **inherently safe design**

measures taken to eliminate *hazards* (3.2) and/or to reduce *risks* (3.9) by changing the design or operating characteristics of the product or system

### 3.6

#### **intended use**

use in accordance with information provided with a product or system, or, in the absence of such information, by generally understood patterns of usage

3.7

**reasonably foreseeable misuse**

use of a product or system in a way not intended by the supplier, but which can result from readily predictable human behaviour

Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of users, e.g. the elderly, children and persons with disabilities. For more information, see ISO 10377.

Note 2 to entry: In the context of consumer safety, the term “reasonably foreseeable use” is increasingly used as a synonym for both “intended use (3.6)” and “reasonably foreseeable misuse.”

3.8

**residual risk**

risk (3.9) remaining after risk reduction measures (3.13) have been implemented

3.9

**risk**

combination of the probability of occurrence of harm (3.1) and the severity of that harm

Note 1 to entry: The probability of occurrence includes the exposure to a hazardous situation (3.4), the occurrence of a hazardous event (3.3) and the possibility to avoid or limit the harm.

3.10

**risk analysis**

systematic use of available information to identify hazards (3.2) and to estimate the risk (3.9)

3.11

**risk assessment**

overall process comprising a risk analysis (3.10) and a risk evaluation (3.11)

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3.12

**risk evaluation**

procedure based on the risk analysis (3.10) to determine whether tolerable risk (3.15) has been exceeded

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3.13

**risk reduction measure**

**protective measure**

action or means to eliminate hazards (3.2) or reduce risks (3.9)

EXAMPLE *Inherently safe design* (3.5); protective devices; personal protective equipment; information for use and installation; organization of work; training; application of equipment; supervision.

3.14

**safety**

freedom from risk (3.9) which is not tolerable

3.15

**tolerable risk**

level of risk (3.9) that is accepted in a given context based on the current values of society

Note 1 to entry: For the purposes of this Guide, the terms “acceptable risk” and “tolerable risk” are considered to be synonymous.

3.16

**vulnerable consumer**

consumer at greater risk (3.9) of harm (3.1) from products or systems, due to age, level of literacy, physical or mental condition or limitations, or inability to access product safety (3.14) information



## 4 Use of the terms “safety” and “safe”

**4.1** The term “safe” is often understood by the general public as the state of being protected from all hazards. However, this is a misunderstanding: “safe” is rather the state of being protected from recognized hazards that are likely to cause harm. Some level of risk is inherent in products or systems (see 3.14).

**4.2** The use of the terms “safety” and “safe” as descriptive adjectives should be avoided when they convey no useful extra information. In addition, they are likely to be misinterpreted as an assurance of freedom from risk.

The recommended approach is to replace, wherever possible, the terms “safety” and “safe” with an indication of the objective.

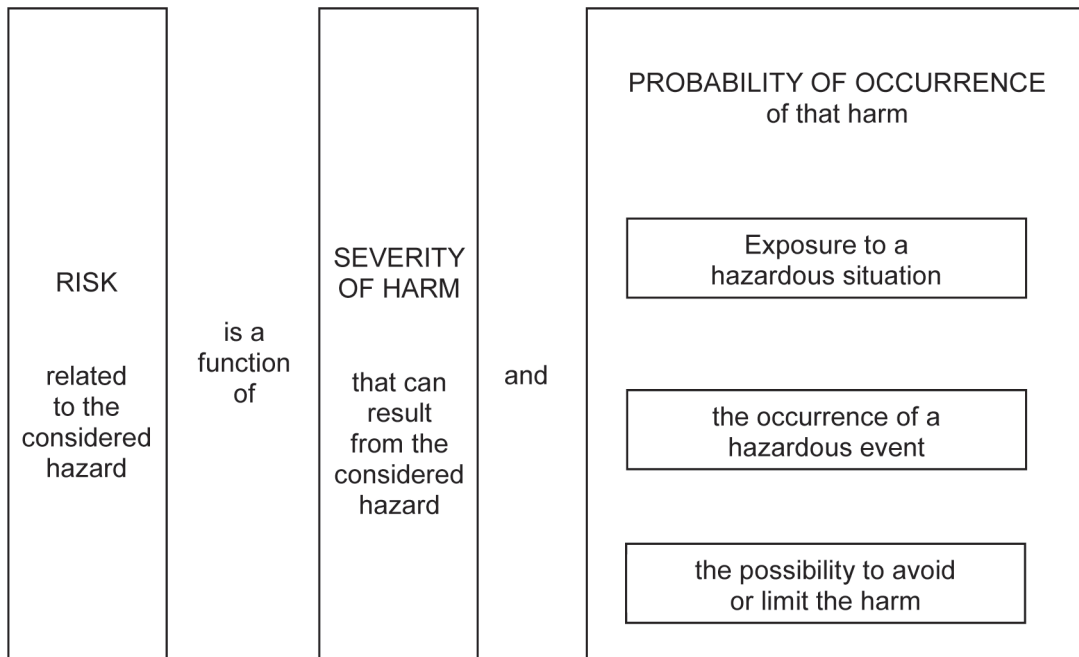
**EXAMPLES** “Protective helmet” instead of “safety helmet”; “protective impedance device” instead of “safety impedance”; “slip resistant floor-covering” instead of “safe floor-covering”.

## 5 Elements of risk

The risk associated with a particular hazardous situation depends on the following elements:

- a) the severity of harm that can result from the considered hazard;
- b) the probability of occurrence of that harm, which is a function of:
  - the exposure to the hazard;
  - the occurrence of a hazardous event;
  - the possibilities of avoiding or limiting the harm.

The elements of risk are shown in Figure 1.



**Figure 1 — Elements of risk**

## 6 Achieving tolerable risk

### 6.1 Iterative process of risk assessment and risk reduction

The iterative process of risk assessment and risk reduction for each hazard is essential in achieving tolerable risk. The critical issue for drafters of standards to address, as a product or system goes through the supply chain from development to disposal, is to determine whether the iterative process of risk assessment is assumed by:

- the standards drafting committee, to perform the risk assessment for specific and known hazards (e.g. a product-specific standard that is used to demonstrate regulatory compliance); or
- the standard readers/users, to perform the risk assessment (e.g. manufacturer/supplier of the product or system) for hazards that they identify (e.g. based on ISO 12100 or ISO 14971).

The following procedure should be used to reduce risks to a tolerable level (see [Figure 2](#)):

- a) identify the likely users for the product or system, including vulnerable consumers and others affected by the product;
- b) identify the intended use, and assess the reasonably foreseeable misuse, of the product or system;
- c) identify each hazard (including reasonably foreseeable hazardous situations and events) arising in the stages and conditions for the use of the product or system, including installation, operation, maintenance, repair and destruction/disposal;
- d) estimate and evaluate the risk to the affected user group arising from the hazard(s) identified: consideration should be given to products or systems used by different user groups; evaluation can also be made by comparison with similar products or systems;
- e) if the risk is not tolerable, reduce the risk until it becomes tolerable.

[Figure 2](#) shows the iterative process of risk assessment and risk reduction.

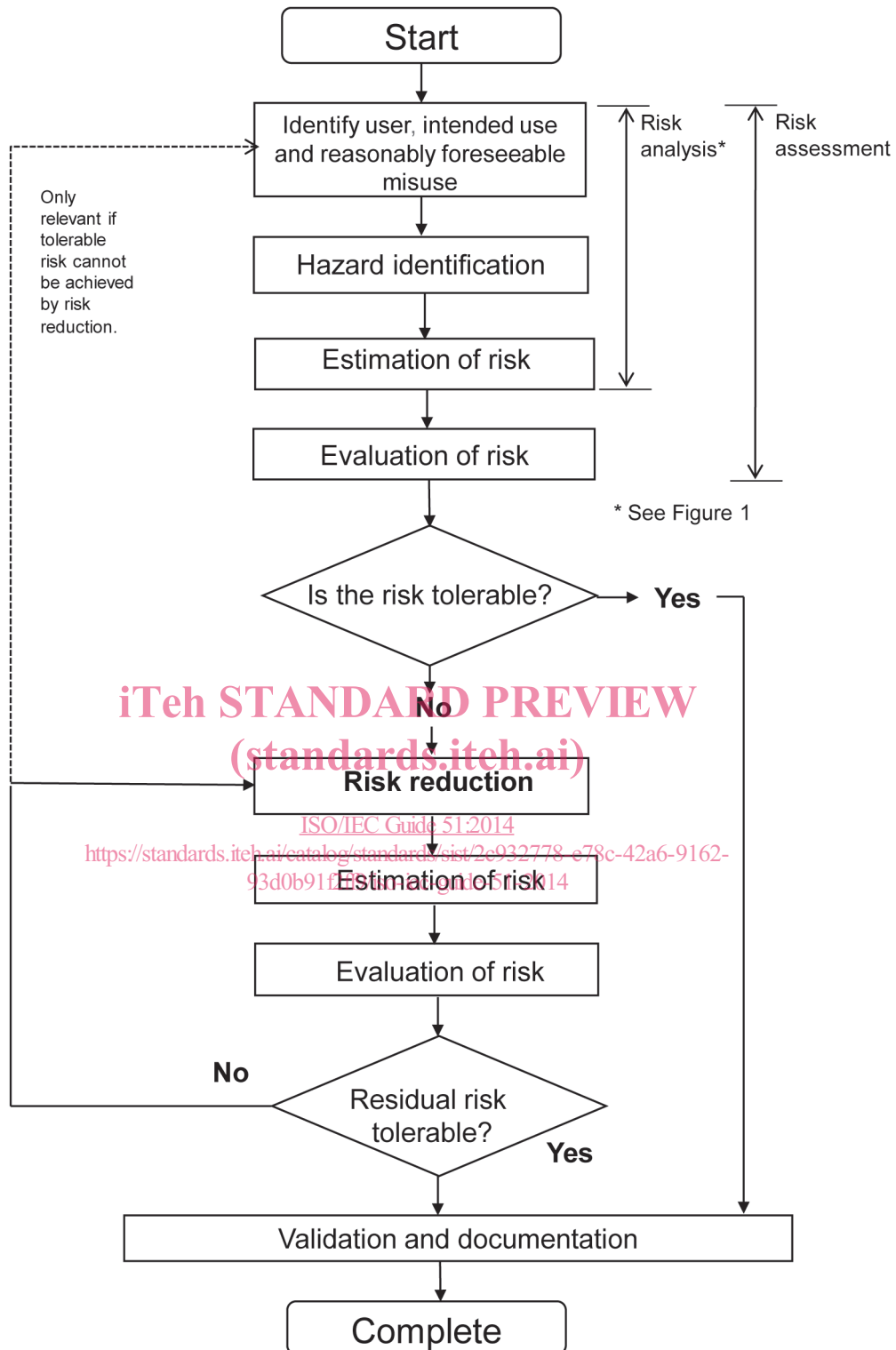


Figure 2 — Iterative process of risk assessment and risk reduction

## 6.2 Tolerable risk

**6.2.1** All products and systems include hazards and, therefore, some level of residual risk. However, the risk associated with those hazards should be reduced to a tolerable level. Safety (as defined in 3.14) is achieved by reducing risk to a tolerable level, which is defined in this Guide as tolerable risk. The purpose