GUIDE 51

Safety aspects — Guidelines for their inclusion in standards

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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

Draft Guides adopted by the responsible Committee or Group are circulated to national bodies for voting. Publication as a Guide requires approval by at least 75 % of the national bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this Guide 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 the Joint ISO/IEC Technical Advisory Group, *Safety*.

This second edition cancels and replaces the first edition (ISO/IEC Guide 51:1990), which has been technically revised.

This Guide may be revised in due course on the basis of practical experience. Committees writing standards are invited to inform the ISO Central Secretariat or the IEC Central Office of any difficulties encountered with the implementation of its provisions.

As safety will pose different problems it is impossible to provide a set of precise provisions that will apply in every case. Consequently, this Guide may need to be supplemented by other publications for particular fields of interest.

Safety aspects — Guidelines for their inclusion in standards

1 Scope

This Guide provides standards writers with guidelines for the inclusion of safety aspects in standards. It is applicable to any safety aspect related to people, property or the environment, or a combination of one or more of these (e.g. people only; people and property; people, property and the environment).

This Guide adopts an approach aimed at reducing the **risk** arising from the use of products, processes or services. The complete life cycle of a product, process or service, including both the **intended use** and the **reasonably foreseeable misuse**, is considered.

NOTE 1 Quality is not a synonym for **safety** and consequently the respective roles of quality and of **safety** should not be confused. However it may be necessary to consider quality requirements in standards to ensure that the safety requirements are consistently met.

NOTE 2 The term “standard” used throughout this Guide includes International Standards, Technical Specifications, Publicly Available Specifications and Guides.

NOTE 3 Although this Guide is intended primarily for use by standards writers, its underlying principles may be used wherever safety aspects are being considered.

NOTE 4 Standards may deal exclusively with safety aspects or may include clauses specific to **safety**.

NOTE 5 Unless otherwise stated, the term “committee(s)”, when used in this Guide, is meant to cover both ISO and IEC technical committees, subcommittees or working groups.

NOTE 6 Terms defined in clause 3 are printed in bold type throughout this Guide.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Guide. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Guide 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 3864:1984, *Safety colours and safety signs.*

ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis.*

ISO 7001:1990, *Public information symbols.*

IEC 60417:1998 (all parts), *Graphical symbols for use on equipment.*

ISO/IEC Guide 14:1977, *Product information for consumers.*

ISO/IEC Guide 37:1995, *Instructions for use of products of consumer interest.*

ISO Guide 41:1984, *Standards for packaging — Consumer requirements.*

ISO/IEC Guide 50:1987, *Child safety and standards — General guidelines.*

IEC Guide 104:1997, *The preparation of safety publications and the use of basic safety publications and group safety publications.*

3 Terms and definitions

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

NOTE In other publications slightly different definitions may apply for the same terms, but the concepts are broadly the same.

3.1
safety
freedom from unacceptable **risk**

NOTE Adapted from ISO/IEC Guide 2:1996, definition 2.5.

3.2
risk
combination of the probability of occurrence of **harm** and the severity of that **harm**

3.3
harm
physical injury or damage to the health of people, or damage to property or the environment

3.4
harmful event
occurrence in which a **hazardous situation** results in **harm**

3.5
hazard
potential source of **harm**

NOTE The term **hazard** can be qualified in order to define its origin or the nature of the expected **harm** (e.g. electric shock hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).

3.6
hazardous situation
circumstance in which people, property or the environment are exposed to one or more **hazards**

3.7
tolerable risk
risk which is accepted in a given context based on the current values of society

NOTE See 5.3.

3.8
protective measure
means used to reduce **risk**

NOTE Protective measures include risk reduction by inherently safe design, protective devices, personal protective equipment, information for use and installation, and training.

3.9
residual risk
risk remaining after **protective measures** have been taken

3.10
risk analysis
systematic use of available information to identify **hazards** and to estimate the **risk**

3.11
risk evaluation
procedure based on the **risk analysis** to determine whether the **tolerable risk** has been achieved

3.12
risk assessment
overall process comprising a **risk analysis** and a **risk evaluation**

3.13
intended use
use of a product, process or service in accordance with information provided by the supplier

3.14
reasonably foreseeable misuse
use of a product, process or service in a way not intended by the supplier, but which may result from readily predictable human behaviour

4 Use of the words "safety" and "safe"

The use of the words **safety** and safe as descriptive adjectives should be avoided because they convey no useful extra information. In addition, they are likely to be interpreted as an assurance of guaranteed freedom from **risk**.

The recommended approach is to replace, wherever possible, the words **safety** and safe by an indication of the objective.

Examples are:

— "protective helmet" instead of "safety helmet";

— "protective impedance device" instead of "safety impedance";

— "non-slip floor-covering" instead of "safety material".

5 The concept of safety

5.1 **Safety** is dealt with in standards work in many different forms across a wide range of technologies and for most products, processes and services. The increasing complexity of products, processes and services entering the market requires that the consideration of **safety** aspects be given a high priority.

There can be no absolute safety: some **risk** will remain, defined in this Guide as **residual risk**. Therefore a product, process or service can only be relatively safe.

5.2 **Safety** is achieved by reducing **risk** to a tolerable level — defined in this Guide as **tolerable risk**. **Tolerable risk** is determined by the search for an optimal balance between the ideal of absolute safety and the demands to be met by a product, process or service, and factors such as benefit to the user, suitability for purpose, cost effectiveness, and conventions of the society concerned. It follows that there is a need to review continually the tolerable level, in particular when developments, both in technology and in knowledge, can lead to economically feasible improvements to attain the minimum risk compatible with the use of a product, process or service.

5.3 **Tolerable risk** is achieved by the iterative process of **risk assessment** (**risk analysis** and **risk evaluation**) and risk reduction (see Figure 1).

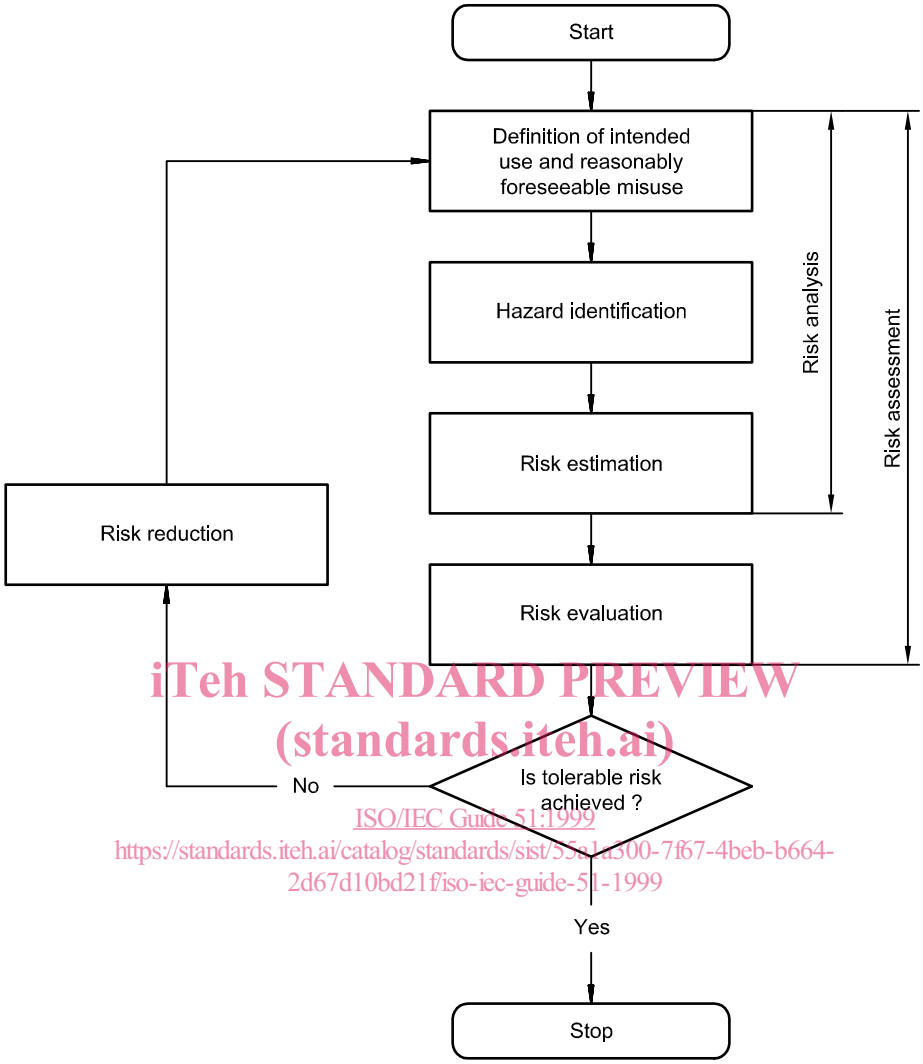

Figure 1 — Iterative process of risk assessment and risk reduction

6 Achieving tolerable risk

The following procedure (see Figure 1) should be used to reduce **risks** to a tolerable level:

a) identify the likely user group(s) for the product, process or service (including those with special needs and the elderly), and any known contact group (e.g. use/contact by young children);

b) identify the **intended use** and assess the **reasonably foreseeable misuse** of the product, process or service;

c) identify each **hazard** (including any **hazardous situation** and **harmful event**) arising in all stages and conditions for the use of the product, process or service, including installation, maintenance, repair and destruction/disposal;

d) estimate and evaluate the **risk** (see Figure 1) to each identified user/contact group arising from the **hazard(s)** identified;

e) judge if the **risk** is tolerable (e.g. by comparison with similar products, processes or services);

f) if the **risk** is not tolerable, reduce the **risk** until it becomes tolerable.

When reducing **risks** the order of priority should be as follows:

1) inherently safe design;

2) protective devices;

3) information for users.

This procedure is based on the assumption that the user has a role to play in the risk reduction procedure by complying with the information provided by the designer/supplier (see Figure 2).

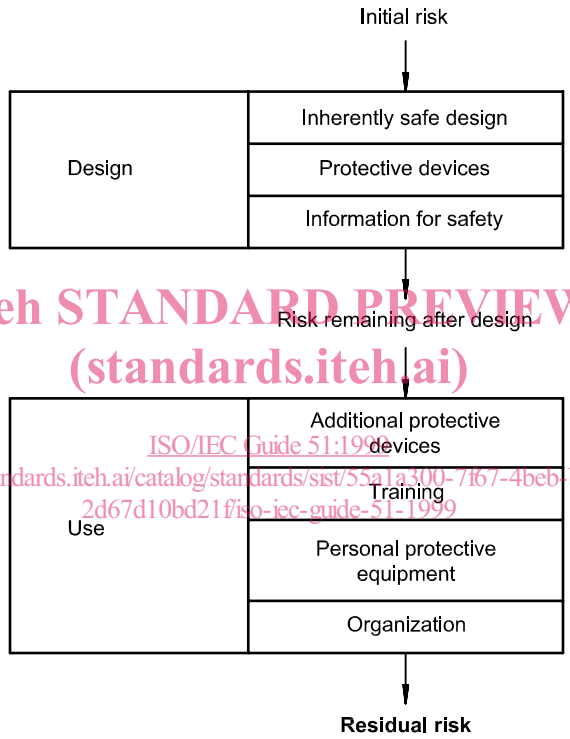

Figure 2 — Risk reduction

The steps taken in the design procedure are shown in order of priority. The steps to be taken by the user are not in order of priority because this would depend on the application. It is emphasized that the additional protective devices, personal protective equipment and provision of information to users should not be used as substitutes for design improvements.

7 Safety aspects in standards

7.1 Types of safety standard

Close coordination within and among committees (see clause 1, note 5) responsible for preparing standards on different products, processes or services is necessary in order to achieve a coherent approach to the treatment of **safety**. The use of a structured approach is recommended to ensure that each specialized standard is restricted to