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ISO/TC COPOLCO / SC IEC/Advisory committee on safety

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Safety aspects - Guidelines for their inclusion in standards

Secretariat ISO/COPOLCO

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Introductory note

For comment and vote by members of COPOLCO and interested ISO Technical Committees, and by IEC National Committees
Safety aspects — Guidelines for their inclusion in standards

Aspects de 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) 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.

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 shall not be held responsible for identifying any or all such patent rights.


This third edition cancels and replaces the second edition (ISO/IEC Guide 51:1999) which has been technically revised.

The main changes with respect to the previous edition are as follows:

1) Strengthened focus on risk reduction in the overall risk assessment process (see improved figure 2),
2) The term “harmful event” has been replaced by “hazardous event”,
3) Updated use of terms in the context of consumer safety ,
4) The risk reduction steps in figure 3 are specified in more detail,
5) A new introduction giving additional background has been added,
6) Specific provisions and references to vulnerable persons have been added,
7) References have been re-allocated between the Normative References and the Bibliography,
8) Content in Clauses 6 and 7, “Achieving tolerable risk” and “Safety aspects in standards” has been reorganized and consolidated.
Introduction

Safety aspects are dealt with in standards work in many different forms across a wide range of technologies and for most products, processes, services and systems (hereafter referred to as "products and systems"). The increasing complexity of products and systems entering the market requires that the consideration of safety aspects be given a high priority.

This Guide provides practical guidance to standard writers to assist them in including safety aspects in standards. The underlying principles of this Guide may also be used wherever safety aspects require consideration. The Guide 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).

Hazards can pose different safety problems and can vary significantly depending on the user 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 may not be the situation in the home environment or when children or vulnerable consumers may use the product or system. Consequently, this Guide may 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 adopts an approach aimed at reducing risk, wherever the product is used, including use by vulnerable persons, which may arise during the use of products, or systems. This Guide aims to reduce the risk arising from the design, production, distribution, use, 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 is to be used in the workplace or in the household environment or for recreational activities. The goal is to achieve acceptable risk for people, property and the environment, with minimized adverse effects on the environment.

NOTE 1 Refer to ISO/IEC Guides 50 and 71 for specific examples for vulnerable persons.

Existing standards should implement changes reflecting this revised Guide accordingly at their next revision.

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

NOTE 4 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 5 The term "products and systems" used throughout this Guide includes products, processes, services and systems.

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 these (e.g. people only; people and property; people, property and the environment).

2 Normative references

The following referenced documents are indispensable for the application 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 3864 (all parts), Graphical symbols – Safety colours and safety signs

ISO 7000, Graphical symbols for use on equipment – Index and synopsis

ISO 7001, Graphical symbols – Public information symbols

IEC 60417 (all parts), Graphical symbols for use on equipment

3 Terms and definitions

For the purposes of this document, 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 For the purposes of this Guide, the terms "acceptable risk" and "tolerable risk" are considered to be synonymous.

3.2 risk

combination of the probability of occurrence of harm and the severity of that harm

NOTE The probability of occurrence includes the exposure to a hazardous situation, the occurrence of a hazardous event, and the possibility to limit the harm.

3.3 harm

injury or damage to the health of people, or damage to property or the environment
3.4 hazard
potential source of harm

3.5 hazardous event
event in which a situation may result in harm

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 For the purposes of this Guide, the terms "acceptable risk" and "tolerable risk" are considered to be synonymous.

3.8 risk reduction measure (protective measure)
any action or means to eliminate hazards or reduce risks

NOTE Examples include inherently safe design, risk reduction measures and information for use (see Figure 3).

3.9 residual risk
risk remaining after risk reduction measures (protective measures) have been taken

3.10 risk analysis
systemic 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 a 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 or system in accordance with information provided by the supplier

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

NOTE 1 Readily predictable human behaviour includes the behaviour of all types of human beings, e.g. the elderly, children and persons with disabilities. For more information, see ISO 10377, Guidance Standard -- Consumer product safety : A practical guide for suppliers.

NOTE 2 In the context of consumer safety a trend is emerging to use the term "reasonably foreseeable use" as a synonym for both "intended use" and "reasonably foreseeable misuse".
4 Use of the words "safety" and "safe"

4.1 "Safe" is the state of being protected from recognized hazards that are likely to cause harm. There is no such thing as being absolutely safe, that is, a complete absence of risk. In turn, there is no product or system without some risk.

4.2 The use of the words safety and safe as descriptive adjectives should be avoided when they convey no useful extra information. In addition, they are likely to be interpreted as an assurance of 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 Elements of risk

Inherently safe design measures are the first and most important step in the risk reduction process. This is because protective measures inherent to the characteristics of the product or system are likely to remain effective, whereas experience has shown that even well-designed safeguarding can fail or be violated and information for use may not be followed.

Safeguarding shall be used to protect whenever an inherently safe design measure does not reasonably make it possible either to remove hazards or to sufficiently reduce risks. Complementary protective measures involving additional equipment (for example, emergency stop equipment) may have to be implemented.

Due to the relatively low reliability of the effect of information for use, which may include organizational measures, correct behaviour, attention, application of personal protective equipment (PPE), skill or training, compared with proven technical protective measures, Information for use shall not be a substitute for the correct application of inherently safe design measures, safeguarding or complementary protective measures.

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

1) Severity of harm that can result from the considered hazard.

2) The probability of occurrence of that harm, which is a function of
   — the exposure to the hazard,
   — the occurrence of a hazardous event, and
   — the technical and human possibilities to avoid the harm.

The elements of risk are shown in Figure 1.
6 Achieving tolerable risk

6.1 Iterative process of risk assessment

The iterative process of risk assessment is essential to achieving tolerable risk. The writer of the standard may perform the risk assessment, e.g. a product-specific standard that is used to demonstrate regulatory compliance, or the user of a standard may perform the risk assessment (e.g. ISO 12100, ISO 14971).

The critical issue the standards writers shall address as a product or system goes through the supply chain from development to the user (consumer) is to determine whether the iterative process of risk assessment is assumed by:

— the standard writing committee for specific and known hazards,

— the standard reader/user for hazards to be identified by him/her.
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 some level of residual risk. However, the risk associated with those hazards should be reduced to a tolerable level. 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 or system, 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 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 or system.

NOTE The concept of reducing risk to a tolerable level varies significantly depending on whether the product or system is used in the workplace, in a public environment or by a consumer in the home. Whereas it is possible to control risks to a greater extent in the workplace through occupational training, protective procedures and equipment that workers are obligated to follow and use, this might not be taken into account in the home or public environment.

6.2.2 After the risk reduction measures have been implemented, their effectiveness should be validated to ensure they are effective. The outcome of a risk assessment should be documented. The document should demonstrate the procedure that has been followed, the hazards identified and the risk reduction measures employed to reduce risk to an acceptable level.

6.2.3 When considering safety aspects for products, processes and services, the foreseeable uses and potential misuses of the product shall be considered. Foreseeable use takes into consideration the developmental stage of the intended user since different age groups interact differently with products based on their behavioural, skill and physical capabilities. To many suppliers, this may appear that the user is not using the product for its intended purpose rather than normal expected behaviour that needs to be considered when designing a product.

All product suppliers shall consider safety aspects for the intended uses and the reasonably foreseeable misuses of the product, and to apply risk reduction measures to achieve a tolerable risk level. Product suppliers should also consider reasonably foreseeable uses of the product which although may not be intended uses are readily predictable based on the user population. In particular, when determining the risk posed by a consumer product, special consideration should be given for products that are intended for, or are used by, children and vulnerable consumers who are often unable to understand the risks involved. For example, a foreseeable use of a cell phone is that a small child will put the phone in its mouth.

Product suppliers shall provide risk reduction measures to achieve a tolerable risk level for their products.

6.3 Risk reduction

6.3.1 The minimum necessary risk reduction is the reduction in risk that has to be achieved to meet the tolerable risk (acceptable risk) for a specific situation. The concept of necessary risk reduction is of fundamental importance in the development of the safety requirements for products and systems. The purpose of determining the tolerable risk (acceptable risk) for a specific hazardous event is to state what is deemed reasonable with respect to both components of risk (see Figure 1).

NOTE ISO/IEC Guides 50 gives guidance on the needs of children and ISO/IEC Guide 71 covers the needs of vulnerable consumers such as children, the elderly, or persons with disabilities.

6.3.2 The tolerable risk (acceptable risk) will depend on many factors: for example, severity of injury, the damage to property or the environment, the frequency at which a person or people are exposed to danger and the duration of the exposure, and the practicability of the technical means to reduce the risk.

6.3.3 When several risks have to be dealt at the same time, caution shall be taken to avoid that the risk reduction measures chosen for one risk increases another risk.

6.3.4 If there is more than one option for risk reduction given in a safety standard, the standard should clearly show suppliers the principles of implementing a risk assessment so that they can conduct a thorough investigation to determine the most appropriate method of reducing risk to a tolerable level. In such cases suppliers have increased responsibility for the safety of their products and systems. It may also be appropriate
for the supplier to determine the most appropriate risk reduction measure if the equipment in question is particularly complex as they will have the best knowledge of its specific characteristics and components.

6.3.5 Furthermore, consideration can be given to the knowledge and information acquired during the preparatory work for standard development (see 7.3.2).

6.3.6 Figure 3 shows the principle of risk reduction by applying the “3-step method” at the design phase and additional measures at the use phase.

Figure 3 — Risk reduction: combination of efforts at design and use phase

1 An example is the risk remaining in a product or system when supplied to a customer or in a structural feature after installation.
6.4 Risk reduction procedure

6.4.1 The following procedure should be used to reduce risks to a tolerable level (also see Figure 2):

a) identify the likely user group(s) for the product or system (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 or system;

c) identify each hazard (including reasonably foreseeable situations and events) arising in the stages and conditions for the use of the product or system including installation, maintenance, repair and destruction/disposal;

NOTE Risk reduction measures (protective measures in order of priority) include risk reduction by inherently safe design, guards and protective devices, transport, storage, information for use and installation, training and personal protective equipment.

d) estimate and evaluate the risk to identified user/contact group arising from the hazard(s) identified. Consideration should be given to possible combinations of identified user/contact groups. Evaluation can also be made (e.g. by comparison with similar products or systems);

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

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

a) inherently safer design;

b) risk reduction measures;

c) information for users.

This order of priority should be applied because inherently safe design measures and built-in protective devices can usually be expected to eliminate the potential for user error or misuse. The greater the number of hazards left to be safeguarded by users (especially consumers) the more opportunities exist for human errors to be made. Information for use cannot therefore be expected to eliminate risks completely (although the potential for errors can be reduced by applying best practices of information communication).

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 and possibly by its feedback to the designer/supplier regarding improvements of safety aspects based on its experiences during use (see Figure 3).

7 Safety aspects in standards

7.1 Types of safety standard

Close coordination within and among committees responsible for preparing standards on different products, processes or services is necessary in order to achieve a coherent approach to the treatment of risk. The use of a structured approach is recommended to ensure that each specialized standard is restricted to specific aspects and makes reference to wider-ranging standards for all other relevant aspects. The structure is built on the following types of standard:

— basic safety standard, comprising fundamental concepts, principles and requirements with regard to general safety aspects applicable to a wide range of products and systems;
— group safety standard, comprising safety aspects applicable to several or a family of similar products or systems dealt with by more than one committee, making reference, as far as possible, to basic safety standards;

— product safety standard, comprising safety aspect(s) for a specific, or a family of, product(s) or systems within the scope of a single committee, making reference, as far as possible, to basic safety standards and group safety standards;

— safety standards containing safety aspects but which do not deal exclusively with safety aspects; these should make reference as far as possible to basic safety standards and group safety standards.

NOTE 1 See IEC Guide 104 for a structured approach in the fields of electrical and electronic engineering.

NOTE 2 See ISO Guide 78 for a structured approach in the field of machinery.


7.2 Analysis of proposed new standards

Every proposal for preparing or revising a standard on aspects of safety should identify what is to be included in the standard and for whom it is intended. This is usually achieved by answering the following questions:

a) To whom is the standard addressed?

— Who is going to use the standard and how?
— What do the users require from the standard?

NOTE The term “users” of the standard includes those implementing the requirements of the standard, those affected by it (such as consumers of a product or system) and those affected by a possible environmental impact.

b) What is the purpose of the standard?

Is it to become:

— a basic safety standard,
— a group safety standard,
— a product safety standard, or
— a safety standard containing safety aspects?

Consider its purpose, as follows.

— Which aspects relating to safety arise?
— Will the standard be used for testing?
— Will the standard serve as a basis for conformity assessment?

NOTE Details on use for conformity assessment are given in ISO/IEC 17007, Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment.
7.3 Preparatory work

7.3.1 Work on a standard starts with the identification of all the safety aspects to be covered. At this stage, it is essential to gather all relevant information (e.g. accident data, research reports). A detailed outline should then be prepared which will serve as a basis for the standard.

7.3.2 Before the work of drafting a standard begins, it is necessary to assemble within the committee expertise that reflects the knowledge required to develop the standard. Such knowledge includes, for example, the following:

- detailed working knowledge of the product or system;
- requirements and guidelines from various origins, both general and specific to the standard development;
- human behaviour studies and anthropometric data;
- injury/incident data or defect history of the product or system;
- feedback based on experience of end users of the product or system;
- knowledge of the available risk reduction measures (protective measures);
- knowledge of the implications of possible future developments of the product or system;
- industry standards and guidelines;
- best available independent industrial, expert and scientific advice from advisory bodies;
- current values shared by all involved stakeholders;
- legal frameworks.


NOTE 2 The absence of an incident history, a small number of accidents or low severity of injury should not be taken automatically as a presumption of a low risk.

7.3.3 Furthermore, the following inputs can also be considered:

- requirements from various origins, both general and those directly relevant to the specific application;
- guidelines from various origins;
- discussions and agreements with the different parties involved in the application;
- international discussions and agreements; the role of national and international standards are becoming increasingly important in arriving at tolerable risk criteria for applications;
- industry standards and guidelines;
- the best independent industrial, expert and scientific advice from advisory bodies;
- current values defined by all involved stakeholders;
- human behaviour studies and anthropometric data;
— end user feedback or observation of the product or system.

7.3.4 Once the content of the standard has been established, the following safety aspects should be considered (not all of these may be relevant to a given standard):

— intended use and reasonably foreseeable misuse;
— ability to perform under expected conditions of use;
— environmental compatibility (considering for example electromagnetic, mechanical and climatic phenomena;
— ergonomic factors;
— regulatory requirements;
— existing standards;
— availability and/or reliability of risk reduction measures;
— serviceability (including “service maintenance”, such as ease of access to serviceable items, method of refuelling/lubrication);
— durability and dependability of protective means;
— disposability (including any relevant instructions);
— special needs of users of the product or system (e.g. obvious vs. insidious);


— failure characteristics;
— markings and information;
— assembly instructions;
— safety instructions;
— labelling.


7.4 Drafting

7.4.1 General

The rules and recommendations given below apply to the drafting of documents intended to become safety standards and, whenever applicable, to the inclusion of safety aspects in other standards. They are more specific, being either additional or complementary, than those contained in the ISO/IEC Directives, Part 2.

The standard should contain those requirements important in eliminating hazards whenever possible, or otherwise in reducing risks. These requirements should be expressed in terms of risk reduction measures (protective measures) which shall be verifiable.
Special consideration should be given for products that are intended for or are used by children and vulnerable consumers who are often unable to understand the risks involved.

Requirements for risk reduction measures (protective measures) should:

— be laid down in precise and clearly understandable language, and
— be technically correct.

Standards should contain clear and complete statements specifying methods for verifying that the requirements have been met.

Requirements for performance-based risk reduction measures should include:

— a clear and comprehensive list of related risk(s), and
— specific indications of the protection to be assured.

NOTE It is advisable to express risk reduction requirements in terms of verifiable performance with regard to safety, using performance characteristics (parameters) together with their values (e.g. required stopping distance of x meters for a mobile machine with a traveling speed of 20 km/h as characteristic for the required performance of the braking system) rather than merely design descriptive characteristics.

The use of subjective terms or words should be minimized unless they are defined in the standard.

Writers of standards should be familiar with hazards and hazardous situations associated with the product or system which is the subject of the standard. The writers should consider including a list of the known hazards and/or hazardous situations common for the particular product or system (e.g. in the form of an Annex).

7.4.2 Information for use

7.4.2.1 Type of information

The standard should specify all information necessary for safe use to be provided to persons involved with the product or system (e.g. purchasers, installers, testing technicians, users, service personnel, suppliers).

In the case of products, the standard should clearly indicate:

— what information for safety is to be displayed on the product itself or on its packaging;
— what information for safety is it essential to be made clearly visible at the point of sale; or
— what information for safety is to be given in the instruction manual(s) for example, for installation, use, maintenance and disposal. This should include information on the necessity of training or personal protective equipment.

In addition, this information should describe appropriate working practices which, if followed by the persons involved, will significantly reduce the risks.

Where the safety of a product or system depends to a considerable degree upon appropriate working practices and these practices are not self-evident, a marking referring to the instruction manual(s) should be specified as a minimum.

In principle, superfluous or unnecessary information should be avoided as it tends to decrease the value of the information that is essential for safety aspects.
Markings and symbols (if suitable symbols exist) should be specified in accordance with International Standards (e.g. ISO 7000, IEC 60417, ISO 3864 series).

NOTE Principles for the preparation of instructions for use are given in ISO/IEC 82079-1.

7.4.2.2 Instructions

The standard should specify that instructions and information provided shall cover necessary conditions for operating the product or system.

In the case of products, the instructions shall cover the assembly, use, cleaning, maintenance, dismantling and destruction/disposal, as appropriate.

The content of an instruction should give product users the means to avoid a harm presented by a product hazard that has not been reduced or eliminated, enable users to make appropriate decisions concerning the use of the product, and directions to avoid the misuse of the product. Instructions may also give direction about remedial action if the product is misused such as ingesting bleach. Instructions and warnings with safety messages about product hazards should be written and presented separately to avoid confusing directions about product use.


7.4.2.3 Warning notices

The standard should specify that warning notices shall:

— be conspicuous, legible, durable and understandable,

— be worded in the official language(s) of the country(ies) where the product or system is intended to be used unless one of the languages associated with a particular technical field is more appropriate, and

— be concise and unambiguous.

Warning notices can include general or specific warning statements such as:

a) General warning statement:

— CAUTION - Some of the tests specified in this standard involve the use of processes which could lead to a hazardous situation.

b) Specific warning statement:

— DANGER - Attention is drawn to the hazard deriving from the use of the sodium salt of fluoroace

Safety signs shall comply with ISO 3864, ISO 7000, ISO 7001 and IEC 60417, and shall be comprehensible to users in all intended countries of use.

The content of a warning shall describe the product hazard, the harm presented by the hazard, and the consequences if the harm is not avoided. Effective warnings attract attention by using signal words (Danger, Warning or Caution), safety alert symbols, and a font in a type size and colour that is suitable to the product hazard. Where appropriate, warnings should be placed on the product in labels that are durable, in product manuals, in safety data sheets, and on organization websites.
7.4.3 Packaging

When relevant, standards shall specify requirements for the packaging of the product, to ensure appropriate handling of the packed product and the packaging itself, to maintain the integrity of the product and to eliminate or minimize hazards, such as injury, contamination or pollution. In this context, see ISO/IEC Guide 41.

7.4.4 Safety during testing

Standards specifying test methods may prescribe procedures and/or the use of substances or equipment which could create a risk, for example to the laboratory staff. Where relevant, the standard shall include warning statements, as follows:

- a general warning statement appearing at the beginning of the standard;
- specific warning statement(s), as appropriate, preceding the relevant text within the standard.

NOTE This is in accordance with the ISO/IEC Directives, Part 2, 6th edition, 2011, subclause 6.3.5.
Bibliography


[8] ISO 22727, Graphical symbols — Creation and design of public information symbols — Requirements

[9] IEC 62368-1, Safety of electronic equipment within the field of audio/video, information technology and communication technology (“risk-based standard”).


[18] ISO/IEC Guide 71, Guidelines for standards developers to address the needs of older persons and persons with disabilities


NOTE ISO/IEC Guides are available to all standard development committees at no cost from the National Standards Body.