GUIDE 51

Guidelines for the inclusion of safety aspects in standards

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) together form a system for worldwide standardization as a whole. 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.

This Guide was developed jointly by the Technical Advisory Group ISO/TAG 11, *Safety*, and the IEC Advisory Committee on Safety, IEC/ACOS. It is the first of a series intended to provide a harmonized approach to the concept of safety when preparing International Standards.

In view of the diversity of safety aspects in standardization, this Guide may need to be supplemented by sectoral guides, for example, as regards

- personal protection;
- fire prevention;
- health care and medicine;
- consumer products;
- packaging and transport of goods;
- machinery and equipment;
- chemicals;
- building and civil engineering;
- transport.

This Guide may be revised in due course on the basis of practical experience. Committees writing standards are invited to inform ISO/TAG 11, or IEC/ACOS respectively, of any difficulties encountered with the implementation of its provisions.

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Introduction

The concept of safety is closely related to safeguarding the integrity of people and property. With the increasing complexity of products, processes or services entering the market, it is obvious that safety has gained considerable importance in our contemporary world.

Safety is dealt with in standards work in many different forms, at different levels, in all areas of technology and for most products, processes or services.

Safety is a balance between freedom from risks of harm and other demands to be met by a product, process or service among which such items as utility, suitability for purpose, and the like are included.

There can be no absolute safety. Even at the highest level of safety, a product, process or service can only be relatively safe. The conventions of society, including levels of safety or degrees of risk, are subject to changes. In this respect, decision-making is based on two interrelated considerations: evaluating the risk and judging the safety.

Evaluating risk — assessing the probability of harm, the magnitude of the consequent injury by identifying the characteristics and the likely conditions of use relevant to safety and means of quantifying them — is an empirical scientific activity.

Judging safety — assessing the acceptability of risks — is an activity associated with such factors as the socio-economic and educational background of the society concerned, and whether design, or manufacturing processes, could play a role in increasing safety.

As safety will pose different problems it is impossible to provide a set of precise provisions and recommendations that will apply in every case. However, these guidelines, when followed on a judicious "use when applicable" basis, will help in developing reasonably consistent standards.

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Guidelines for the inclusion of safety aspects in standards

1 Scope

This Guide provides standards-writers with a concept of safety with the purpose of promoting safety through standards. It outlines procedures for identifying those characteristics of products that are relevant to safety and for making appropriate provisions for them.

The result may be a standard dealing exclusively with safety aspects or the inclusion of clauses specific to safety in a general standard.

NOTES

1 The term "standard" — used throughout this Guide — includes Technical Report and Guide.

2 Similarly, the term "product" — used throughout this Guide — includes "process", "service", and combinations thereof commonly known as "systems".

2 Normative references

ISO 3864 : 1984, *Safety colours and safety signs.*

IEC/ISO Directives, Part 2: *Methodology for the development of International Standards,* 1989.

IEC/ISO Directives, Part 3: *Drafting and presentation of International Standards*, 1989.

ISO/IEC Guide 2 : 1986, *General terms and their definitions concerning standardization and related activities.*

ISO/IEC Guide 7 : 1982, *Requirements for standards suitable for product certification.*

ISO/IEC Guide 37 : 1983, *Instructions for use of products of consumer interest.*

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

3 Definitions

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

3.1 safety: Freedom from unacceptable risk of harm. [ISO/IEC Guide 2:1986, definition 2.5.]

NOTES

1 In standardization, the safety of products is generally considered with a view to achieving the most favourable balance between a number of factors, including non-technical factors such as human behaviour, that will reduce risks to persons and property to an acceptable level (level of safety).

2 Sometimes, the word **safety** is also used instead of, or together with, a word describing the function — usually protection or warning/alarm. Although not incorrect, the word **safety** as a descriptive adjective need not be used in this case since it conveys no useful extra information but is likely to be interpreted as an assurance of guaranteed freedom from risks of harm. A recommended approach therefore is to replace, wherever possible, the word **safety** by an indication of the objective.

Examples are:

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

— "protective impedance device" (instead of "safety impedance").

3.2 risk: The probable rate of occurrence of a hazard causing harm and the degree of severity of the harm.

3.3 hazard: A potential source of harm.

3.4 harm: Physical injury and/or damage to health or property.

3.5 level of safety: A level of how far safety is to be pursued in a given context, assessed by reference to an acceptable risk, based on the current values of society.

3.6 safety standard: A document that deals exclusively with the safety aspects of a product, process or service.

NOTE — In some cases, standards covering more than safety aspects are also called "safety standards". Then, separate treatment of the safety aspects — as distinct from other aspects not related to safety — is essential.

3.7 intended use: The use of a product, process or service under conditions or for purposes in accordance with specifications and instructions provided by the supplier — including information for publicity purposes.

3.8 reasonably foreseeable misuse: The use of a product, process or service under conditions or for purposes not intended by the supplier, but which may happen, induced by the design of the product in combination with, or as a result of, common human behaviour.

4 Regulatory implications in relation to safety

Safety is of special concern to regulatory authorities. In many fields, regulations concerned with safety refer to standards, either making them mandatory or recognizing them as "approved" to provide means of compliance with statutory requirements: the "deemed to satisfy" approach.

Consequently, requirements dealing with safety aspects which could form part of governmental, or intergovernmental, regulations should receive priority when preparing standards.

5 General principles for developing standards

When preparing a standard, it is the task of a committee[1], bearing in mind both the intended use and reasonably foreseeable misuse of a product,

— to direct its attention to the aspects relevant to safety in identifying the hazards present, and

— to include requirements with a view to avoiding or reducing risks emanating from such hazards.

The following strategy should be used to prepare the standard:

a) identify the hazards arising from all stages and conditions for the use of the product, including installation, maintenance and eventual destruction/disposal;

b) evaluate the risks arising from the hazards identified;

c) judge the level of safety required;

d) eliminate hazards or minimize them by specifying design criteria ("built-in" safety).

Insofar as it is not reasonably practicable to eliminate or minimize hazards, it should be specified in the standard that appropriate protective means be recommended, or provided with the product in order to protect those at risk.

Insofar as these protective means are considered insufficient, or if their application would make the product unsuitable for use, it is necessary in the standard to specify the use of protective means independent of the product, such as protective means at the place where the product is used, or personal protective equipment for the user.

Where none of these measures can reasonably be specified — or else, in addition to them — suitable methods should be specified in the standard to warn those at risk

— of risks still remaining;

— of risks incurred when making protective means ineffective, or if protective equipment is not worn.

Independently of the character and extent of the measures specified, consideration should be given, as appropriate, to the inclusion in the standard of a statement on the need for training as regards safe use of the product.

It should be indicated in the standard which of the measures contained in the last three actions mentioned above should be detailed in the operating manual, and/or shown on the product.

6 Principles of preparing safety standards

6.1 Planning of work

Close coordination within and among committees responsible for different products is necessary in order to create a coherent approach to the treatment of safety in the preparation of standards. The use of a hierarchy of standards will ensure that each specialized standard is restricted to specific aspects and makes reference to standards of wider application for all other relevant aspects. Such hierarchy is built on

— **basic safety standard**, comprising basic concepts, principles and requirements with regard to general safety aspects, applicable to all kinds or a wide range of products, in the same, or similar, manner;

— **group safety standard**, comprising requirements with regard to safety aspects, applicable to several, or to a group of similar, products — in the same, or similar, manner — making reference, as far as possible, to relevant requirements (based on the appropriate level of safety), specified in "basic safety standards";

— **product safety standard**, comprising safety requirements for a specific product, or a group of products, which are necessary for, and applicable to, the specific product with a view to its intended use — making reference, as far as possible, to relevant requirements (based on the appropriate level of safety) specified in "basic safety standards" and "group safety standards".

6.2 Analysis

Every proposal for preparing or revising a safety standard — as for any standard — 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. What is the purpose of the standard?

Is it to become

— a basic safety standard?

1) 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.

— a group safety standard?

— a product safety standard?

Considering its purpose:

— Which aspects relating to safety arise?

— Will the standard be used for type testing?

— Will the standard serve as a basis for certification[1)]?

B. To whom is the standard addressed?

— Who is going to use it?

— Who will take whatever action(s) is required by it?

— What information (technical or other), and what emphasis need to be conveyed to enable readers to take the required action(s)?

C. How should the standard be written?

— What background or knowledge can one assume addressees of the standard to have?

— How can readers be expected to use it?

Work on a project starts with the identification of all the safety aspects to be covered. At this stage, it is essential to search for accident data and to study research reports. A detailed outline should then be prepared which will serve as a basis for the standard.

Safety standards are intended to avoid, to the extent possible, or to specify protection against, different kinds of hazards, among which are

— **mechanical hazards** (projections; sharp points or edges which may cause cuts/lacerations; excessive noise/vibration; impact; entrapment of limbs in moving and stationary equipment; stability factor; etc.);

— **electrical hazards** (electric arc which may cause eye damage or burns; electric shock or burns resulting from contact with parts normally at hazardous voltages; breakdown of insulation; leakage current; etc.);

— **thermal hazards** (high or low temperatures);

— **fire or explosion hazards** (hazards immediately linked with fire or explosion, or incurred as their secondary consequences, including damage to property);

— **chemical hazards** (inhalation, ingestion, or contact with harmful chemical agents);

— **biological hazards** (inhalation, ingestion, or contact with harmful biological agents);

— **radiation hazards** (radio-frequency, infra-red, ultra-violet, high-intensity visible light; coherent light; ionizing radiation; etc.).

Once the content of the future standard has been delineated, the following points may be used as help to indicate items which should be considered when dealing with aspects relating to safety.

a) Items pertaining to users' needs

1) ability to perform under expected conditions of use and environment (when relevant, ergonomic factors such as location of operating position, possible provision of seating, ease/method of operation of controls, access to controls, to be taken into account in this framework);

2) intended use and reasonably foreseeable misuse;

3) environmental compatibility;

4) regulatory requirements;

5) existing standards.

b) Items pertaining to product specifications and service requirements

1) reliability;

2) serviceability (including "service maintenance", such as ease of access to serviceable items, method of refuelling/ lubrication);

3) durability;

4) disposability (including any relevant instructions);

5) benign failure and fail-safe characteristics;

6) labelling, warnings, identification, traceability requirements, and instructions for commissioning, installation, use, maintenance and destruction/disposal, as appropriate.

6.3 Structure

A structure for safety standards for products is indicated in table 1.

6.4 Drafting

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

6.4.1 Title

While being as concise as possible, the title shall indicate without ambiguity whether the standard deals primarily with aspects of safety or contains merely some characteristics of products or aspects of practices that are relevant to safety. Generally, the complementary element of the title would serve this purpose.

1) Requirements for standards intended for product certification are given in ISO/IEC Guide 7.

Table 1 — Arrangement of elements

Type of element		Element	Subclause of this Guide
INFORMATIVE	Preliminary*)		
NORMATIVE	GENERAL	Title	6.4.1
		Scope	*)
		Normative references	*)
	TECHNICAL	Definitions	*)
		Symbols and abbreviations	*)
		Requirements for safety	6.4.2
		Sampling	*)
		Testing and compliance	6.4.3
		Information for safety	6.4.4
		Minimum marking	6.4.5
		Instructions for use, including installation and maintenance	6.4.6
		Packaging	6.4.7
		Normative annexes	*)
INFORMATIVE	Supplementary*)		

*) See IEC/ISO Directives, part 3.

If, for example, the standard covers exclusively safety aspects relating to the subject indicated in the main element of the title, then the complementary element shall be

"... — *Safety requirements*"

Where aspects relating to safety are one of several different aspects covered in the standard, then the word "safety" shall appear in the complementary element, so that it might end by

"... — ... *including safety*"

6.4.2 Requirements for safety

These clauses shall contain those qualitative and quantitative specifications important in reducing hazard. Wherever possible and appropriate, requirements specified should be expressed in terms of performance with regard to safety, rather than as descriptive characteristics. **Performance with regard to safety is described by several performance characteristics (parameters) together with their values (severity).**

Such characteristics may consist of requirements which relate

— the several performance characteristics and their values to **design**, and

— the several performance characteristics and their values to **testing**.

Whereas preference should be given to specifying requirements related to testing, design requirements are widely useful. The latter should be accompanied by the specification of corresponding test methods or, at least, of some other procedure for assessing compliance with the required performance characteristics and their values.

Requirements for safety shall be laid down:

a) in a precise and clearly understandable language;

b) so that they are technically correct and accurate;

c) so that it is possible to verify compliance with them.

NOTE — Subjective terms or words should **not** be used unless they are defined in the standard.

The intended use and reasonably foreseeable misuse of a product may require special attention being paid to the needs of the very young[1)], the elderly and the disabled.

6.4.3 Testing and compliance (verification)

Requirements for safety, tests or other methods for verifying compliance, and compliance criteria, are interrelated elements and shall always be considered together. Standards, therefore, shall contain clear and complete statements specifying methods for verification of proper design (e.g. type tests along with the number of test specimens), and, where appropriate, methods for verification of proper manufacture (e.g. routine tests) and their compliance criteria.

If the standard includes sampling inspection (e.g. sample tests), attention shall be paid to very carefully defining how samples are to be taken, the statistical method to be adopted (attributes, variables), and the sampling plans and procedures to be followed.

NOTE — See also the IEC/ISO Directives, Part 2, subclause 6.6.

1) See ISO/IEC Guide 50.

6.4.4 Information for safety

For cases where a hazard cannot be eliminated or minimized by "built-in" safety — including the replacement of hazardous substances by safer ones, or the use of appropriate guarding means — information for safety, in the standard, shall be required to be given to persons involved (for example, installers, operators, users, service personnel and other third parties).

Such information includes

— instructions/markings to specify the procedure or equipment to be used (prohibition or mandatory warning notices or safety signs);

— instructions/markings regarding certain risks pertaining to normal use or reasonably foreseeable misuse (warning notices or safety signs);

— instructions concerning the necessity of periodic maintenance or test.

In principle, superfluous or unnecessary instructions/markings shall be avoided as they tend to decrease the value of those instructions/markings that are essential.

NOTE — Markings and symbols should be specified in accordance with International Standards[1].

6.4.4.1 Warning notices

Warning notices shall

— be conspicuous, legible and durable;

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

— be concise and unambiguous;

— state the hazards involved and/or give ways in which risks may be reduced.

When instructing the person(s) concerned as to

— **what to avoid**: the recommended wording should include "no", "do not" or "prohibited";

— **what to do**: the recommended wording should include "shall be";

— **the nature of the hazard**: the recommended wording should include "caution", "warning", or "danger" as appropriate (see 6.4.8 for the meaning of these "signal words");

— **the nature of the safe conditions**: the recommended wording should include the noun appropriate to the safety device.

NOTE — The reason for recommending, but not requiring, specific wording is that in some cases the message may be conveyed in a substantially shorter form by avoiding these words. As an example, **stop** is shorter than **do not enter.** The shorter message is quicker to read and allows each letter to be larger for a given area of sign (thereby aiding legibility at a distance).

6.4.4.2 Safety signs

Safety signs shall comply with ISO 3864.

6.4.4.3 Special categories of users

The specification in the standard of information for safety may require special attention being paid to the needs of the very young[2], the elderly and the disabled.

6.4.5 Minimum marking

Every safety standard shall specify minimum marking, including at least

— **the name or trademark of the producer, supplier or importer;**

— **type designation;**

— **rating information for electrical products.**

In addition, it may be necessary to specify

— rating information for non-electrical products;

— conditions of use;

— reference(s) to relevant International Standard(s);

— year of manufacture, or of "ageing-out" (date of expiry);

— reference to instructions for installation, use and maintenance.

6.4.6 Instructions for use, including installation and maintenance

Instructions and information shall be required to cover safe conditions for setting the product into operation, its use, cleaning, maintenance, dismantling and destruction/disposal, as appropriate. In this context, the recommendations of ISO/IEC Guide 37 are relevant.

The standard shall clearly indicate what information, relevant to safety, is to be displayed on the packaging or on the product itself, or is to be given in the instruction manual(s) for installation, for use and for maintenance. In addition, this information shall be required to describe safe practices which, if followed by the persons concerned, will significantly reduce the risks.

1) See ISO 7000 and IEC 417.

2) See ISO/IEC Guide 50.