
Safety aspects — Guidelines for their inclusion in standards

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



COPYRIGHT PROTECTED DOCUMENT

© ISO/IEC 2014

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested 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.org
Web www.iso.org

Published in Switzerland

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Use of the terms “safety” and “safe”	3
5 Elements of risk	3
6 Achieving tolerable risk	4
6.1 Iterative process of risk assessment and risk reduction.....	4
6.2 Tolerable risk.....	5
6.3 Risk reduction.....	6
6.4 Validation.....	8
7 Safety aspects in standards	8
7.1 Types of safety standard.....	8
7.2 Analysis of proposed new standards.....	9
7.3 Preparatory work.....	9
7.4 Drafting.....	10
Bibliography	14

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.

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.

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.