



# GUIDE

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**Guidelines for safety-related risk assessment and risk reduction for collaborative safety system**

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**Guidelines for safety-related risk assessment  
and risk reduction for collaborative safety system**

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IEC Guide 127 has been prepared, in accordance with ISO/IEC Directives, Part 1, Annex A, by the IEC Advisory Committee on Safety (ACOS).

The text of this Guide is based on the following documents:

Draft	Report on voting
SMBNC/81/DV	SMBNC/87/RV

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Guide is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at [www.iec.ch/members\\_experts/refdocs](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/publications](http://www.iec.ch/publications).

## INTRODUCTION

Standardization deals with safety aspects in many different forms across a wide range of technologies and for many products, processes, services and systems (referred to as "products and systems" in this document). Products and systems are becoming more complex and must be safeguarded accordingly. Furthermore, machine learning, autonomy and other technologies that enable real-time human-machine collaboration and coexistence between humans and autonomous machines should be considered as well.

This document provides practical guidance on drafting standards so as to include collaborative safety aspects. The underlying principles of this document can also be used wherever collaborative safety is considered, and as a useful reference for other stakeholders such as designers, service providers, policy makers and regulators.

The approach described in this document is intended to establish risk assessment criteria for the use of products and systems, including use by vulnerable people, when risks arising individually from machine, human, and the environment change dynamically and independently of each other, and thus to reduce risks as needed.

This document 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 a workplace, in a household environment, or for recreational activities. The goal is to achieve tolerable risk for people, property and the environment.

Additional topics and considerations are under study for the next revision of IEC Guide 127 such as different types of users (e.g. professional, unskilled, maintenance, and supervisor) and categorization of risks.

## 1 Scope

This document provides recommendations on drafting standards so as to include safety aspects where humans, machines, and the operational context mutually associate to mitigate risk by providing protective measures in standards.

This document supplements ISO/IEC Guide 51 and IEC Guide 116 by specifying additional recommendations relevant to collaborative safety-related aspects in standards.

This document supplements, in particular, the safeguarding and complementary protective measures (Step 2) and can include protective measures taken by the user (e.g. provision and use of additional safeguards), both illustrated in IEC Guide 116:2018, Figure 5.

This document is not applicable for the development of publications related to medical devices, which is covered by ISO/IEC Guide 63 [1].

NOTE 1 The safety implications of a cybersecurity attack that has potential to cause harm to humans are included in IEC Guide 116.

NOTE 2 The IEC Standardization Management Board (SMB) has decided that Guides such as this one can have mandatory requirements which shall be followed by all IEC committees developing technical work that falls within the scope of the Guide, as well as guidance which may or may not be followed. The mandatory requirements in this Guide are identified by the use of "shall". Statements that are only for guidance are identified by using the verb "should". (See ISO/IEC Directives, IEC Supplement:2021, A.1.1.)

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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/IEC Guide 51:2014, *Safety aspects - Guidelines for their inclusion in standards*

IEC Guide 116:2018, *Guidelines for safety related risk assessment and risk reduction for low voltage equipment*

## Bibliography

- [1] ISO/IEC Guide 63, *Guide to the development and inclusion of aspects of safety in International Standards for medical devices*
  - [2] IEC 62061:2021, *Safety of machinery - Functional safety of safety-related control systems*
  - [3] ISO 13849-1:2023, *Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design*
  - [4] IEC White Paper "Safety in the Future", 2020
  - [5] ISO/IEC TR 5469:2024, *Artificial intelligence - Functional safety and AI systems*
  - [6] IEC TS 62998-3:2023, *Safety of machinery - Safety-related sensors used for the protection of persons - Part 3: Sensor technologies and algorithms*
  - [7] IEC TS 62998-1:2019, *Safety of machinery - Safety-related sensors used for the protection of persons*
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