

GUIDE



**The preparation of safety publications and the use of basic safety publications
and group safety publications**
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IEC GUIDE 104:2019

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**THE PREPARATION OF SAFETY PUBLICATIONS AND
THE USE OF BASIC SAFETY PUBLICATIONS AND
GROUP SAFETY PUBLICATIONS**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This fifth edition of IEC Guide 104 has been prepared, in accordance with ISO/IEC Directives, Part 1, Annex A, by the IEC Advisory Committee on Safety (ACOS). This Guide is a mandatory Guide in accordance with SMB Decision 136/8.

This fifth edition cancels and replaces the fourth edition published in 2010.

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

- alignment with terms and definitions of ISO/IEC Guide 51:2014;
- reference to IEC Guide 108 in the introduction;
- creation of BASIC SAFETY PUBLICATION and GROUP SAFETY PUBLICATION subcategories to clarify the different types of document (requirements, guidance, mandatory test procedures and reference data);
- improved structure: new titles and subclauses;

- addition to the responsibilities of the technical committees (TCs) with HORIZONTAL SAFETY FUNCTION: development of their publications in collaboration with customer TCs and monitoring the use of their SAFETY publications;
- replacement of Annex A and the associated text by reference to IEC Guide 116;
- shortened status statement for publications with BASIC SAFETY PUBLICATION designation;
- addition of the scope items of a PRODUCT SAFETY STANDARD.

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

Four month's vote	Report on voting
C/2145/DV	C/2173/RV

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, terms in UPPERCASE are defined in Clause 3.

A bilingual version of this publication may be issued at a later date.

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INTRODUCTION

Technical committees dealing with subjects relating to SAFETY for the whole, or for a specific part, of their activities, are required by SMB Decision 136/8 to follow the provisions of this document, which is to be used in conjunction with the ISO/IEC Directives and with the Guides listed under Clause 2.

The objective of this document is to improve the consistency of the SAFETY requirements across IEC publications. For this purpose, mandatory procedures are defined in this document for limiting overlaps and contradictory SAFETY requirements. Consequently, this document can be considered as complementary to ISO/IEC Directives.

Depending on the situations, RISK reduction can be analysed and implemented by different approaches. Therefore, technical guidance about SAFETY aspects and RISK analysis is in principle optional and detailed in other non-mandatory Guides. However, ISO/IEC Guide 51 and IEC Guide 116 are referenced in this document for specific essential requirements for achieving SAFETY.

In this document, the term "technical committees", hereinafter referred to as TCs, also includes subcommittees. The term "publication" includes International Standard, Technical Report, Technical Specification, Publicly Available Specification and Guide. In addition, the term "product" includes individual product, process, service and combinations thereof, commonly known as "systems".

This document follows the principles of IEC Guide 108 with specific additions for SAFETY aspects.

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THE PREPARATION OF SAFETY PUBLICATIONS AND THE USE OF BASIC SAFETY PUBLICATIONS AND GROUP SAFETY PUBLICATIONS

1 Scope

This mandatory Guide defines procedures for the development of SAFETY publications, including the preparation and use of BASIC SAFETY PUBLICATIONS and GROUP SAFETY PUBLICATIONS. It also describes the procedures for the assignment of HORIZONTAL SAFETY FUNCTIONS or GROUP SAFETY FUNCTIONS to TCs, their relationship with PRODUCT TCs and their respective responsibilities.

In the context of this document, "SAFETY" relates to the SAFETY of persons, domestic animals, livestock and property.

This document does not cover:

- requirements and guidance for the inclusion of general SAFETY aspects in standards, which are covered by ISO/IEC Guide 51;
- guidance for SAFETY related RISK assessment and RISK reduction to be taken into account when developing SAFETY publications for low voltage equipment, which are covered by IEC Guide 116.

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2 Normative references

IEC GUIDE 104:2019

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 51 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

basic safety publication

BSP

publication on a specific SAFETY aspect, applicable to many electrotechnical products and of crucial importance to ensure the coherence amongst publications.

3.2 **group safety publication** **GSP**

publication covering all SAFETY aspects primarily for a specific group of products within the scope of two or more PRODUCT TCs

Note 1 to entry: GSPs are primarily intended to be stand-alone PRODUCT SAFETY STANDARDS, but may also be used by TCs as source material in the preparation of their publications, as detailed in 7.3.

3.3 **product safety standard** **PSS**

standard covering all SAFETY aspects of one or more products within the scope of a single PRODUCT TC

Note 1 to entry: Product includes equipment, software, installation and service.

3.4 **product TC**

technical committee with a scope which covers a specific family or group of products

3.5 **horizontal safety function** **HSF**

task assigned to a TC to prepare one or more BASIC SAFETY PUBLICATIONS within its scope

3.6 **group safety function** **GSF**

task assigned primarily to a PRODUCT TC to prepare one or more GROUP SAFETY PUBLICATIONS within its scope

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3.7 **normal condition**

condition in which all means of protection are intact

3.8 **single fault condition**

condition in which there is a fault of a single protection (but not a reinforced protection) or of a single component or a device

Note 1 to entry: If a SINGLE FAULT CONDITION results in one or more other fault conditions, all are considered as one SINGLE FAULT CONDITION.

Note 2 to entry: Reinforced protection is defined in IEC 60050-903:2013, 903-02-08.

3.9 **harm**

injury or damage to the health of people, or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1]

3.10 **hazard**

potential source of HARM

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.11

risk

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

Note 1 to entry: The probability of occurrence includes the exposure to a hazardous situation, the occurrence of a hazardous event and the possibility to avoid or limit the HARM.

[SOURCE: ISO/IEC Guide 51:2014, 3.9]

3.12

safety

freedom from RISK which is not tolerable

[SOURCE: ISO/IEC Guide 51:2014, 3.14]

4 HORIZONTAL SAFETY FUNCTIONS and GROUP SAFETY FUNCTIONS

4.1 Assignment of HSF or GSF to a TC

The assignment of HORIZONTAL SAFETY FUNCTIONS (HSFs) and of GROUP SAFETY FUNCTIONS (GSFs) is the responsibility of the Advisory Committee on Safety (ACOS), subject to confirmation by the SMB (Standardization Management Board).

Any TC may request an assignment of an HSF or a GSF to ACOS. The TC proposing an HSF or GSF shall provide to ACOS for review:

- the clear definition of the HSF with the safety aspects or the GSF with the group of products,
- a demonstration of the common benefits to several TCs, and
- a drafted scope of the first intended project of BSP or GSP according to 4.2.

The assignment of an HSF or a GSF to a TC is made with the purpose of:

- ensuring the consistency of IEC publications relating to safety aspects common to a number of TCs by avoiding duplication of work and contradictory requirements;
- reducing the size and cost of IEC publications by avoiding duplication of texts;
- improving mutual understanding among engineers of different technical disciplines.

The assignment gives mandate to the TC having:

- an HSF to develop associated BSPs;
- a GSF to develop associated GSPs.

For the structure of IEC SAFETY publications see Annex A.

The assignment process is shown in Figure 1.

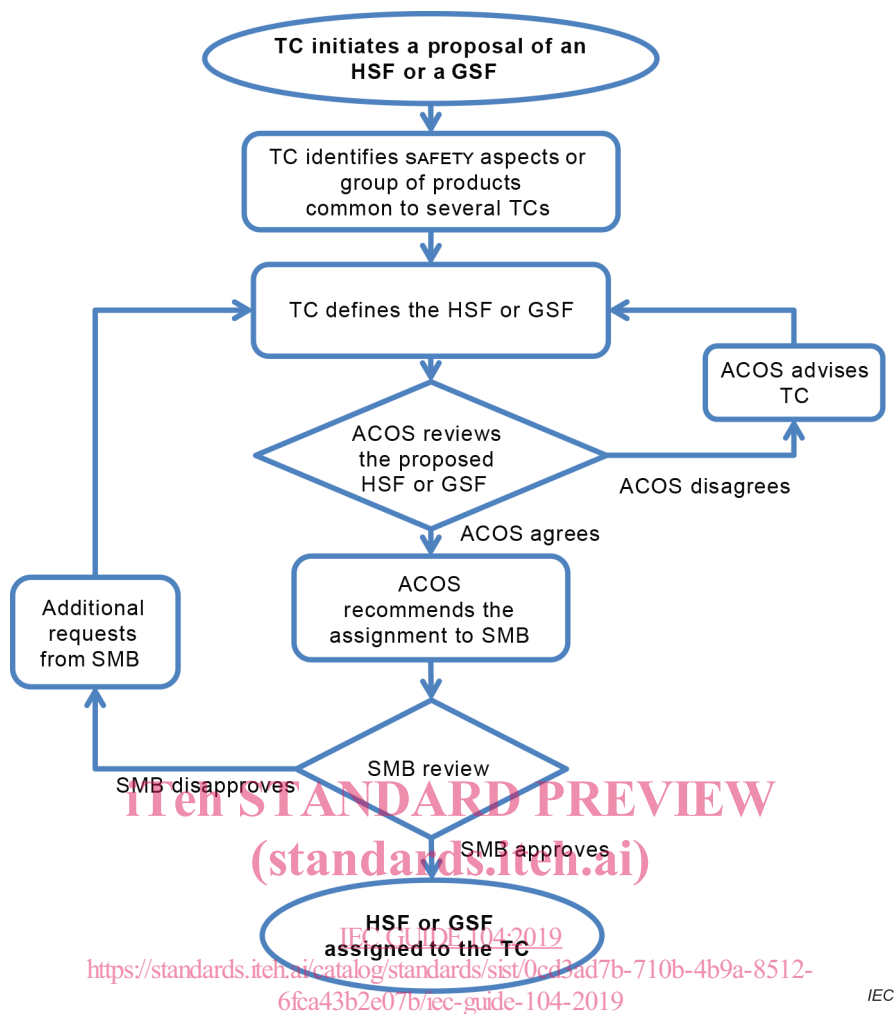


Figure 1 – Assignment of an HSF or GSF to a TC

4.2 Preparation of BSP or GSP with the assigned HSF or GSF

To ensure the consistency of the intended BSP or GSP with the HSF or GSF, its scope and the essential SAFETY requirements, guidance, mandatory tests or reference data of the first publication under a new assignment shall be submitted to ACOS for review before the new work item proposal process as shown in Figure 2.

The ACOS review consists in analysing

- the consistency of the BSP or GSP drafted scope including the exclusion(s) if any with the HSF or GSF,
- the RISK of overlap or contradictory requirements with other BSP and GSP,
- the potential customer TCs, and
- the formal support of customer TCs.