

IEC GUIDE 104

Edition 5.0 2019-07

GUIDE



The preparation of safety publications and the use of basic safety publications and group safety publications

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ISBN 978-2-8322-7196-4

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD	3
INTRODUCTION	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 HORIZONTAL SAFETY FUNCTIONS and GROUP SAFETY FUNCTIONS	8
4.1 Assignment of HSF or GSF to a TC	
4.2 Preparation of BSP or GSP with the assigned HSF or GSF	
4.3 Monitoring of the assigned HSF or GSF	
5 Development of SAFETY publications	
5.1 General	11
5.1.1 Categories of BASIC SAFETY PUBLICATIONS and GROUP SAFETY PUBLICATIONS	11
5.1.2 References to other publications	12
5.1.3 SAFETY during the life of equipment	12
5.2 BASIC SAFETY PUBLICATION	12
5.2.1 Objective and object of a BASIC SAFETY PUBLICATION	12
5.2.2 Development of a BASIC SAFETY PUBLICATION	12
5.2.3 Scope of a BASIC SAFETY PUBLICATION	13
5.2.4 Revision of a BASIC SAFETY PUBLICATION	13
5.3 GROUP SAFETY PUBLICATIONS	
5.3.1 Objective and object of a GROUP SAFETY PUBLICATION	
5.3.2 Development of a GROUP SAFETY PUBLICATION	
5.3.3 Scope of a GROUP SAFETY PUBLICATION	
5.3.4 Revision of a GROUP SAFETY PUBLICATION	
5.4 PRODUCT SAFETY STANDARD	
5.4.1 SAFETY objectives and scope of a PRODUCT SAFETY STANDARD (PSS	,
5.4.2 Development of a PRODUCT SAFETY STANDARD	
6 Responsibilities of TCs with HORIZONTAL SAFETY FUNCTIONS or GROUP SAFETY FUNCTIONS.	
6.1 Co-operation and liaison with other TCs	15
6.2 Requests from PRODUCT TCs for new work	15
7 Responsibilities of PRODUCT TCs	16
7.1 General	16
7.2 Application of BASIC SAFETY PUBLICATIONS	16
7.3 Application of GROUP SAFETY PUBLICATIONS	16
7.4 New work requests to TCs with SAFETY functions	16
Annex A (informative) Structure of IEC SAFETY publications	18
Bibliography	19
Figure 1 – Assignment of an HSF or GSF to a TC	9
Figure 2 – Development of the first BASIC or GROUP SAFETY PUBLICATION	10
Figure 3 – Monitoring of HSF and GSF	11
Figure A.1 – Structure of IEC SAFETY publications	

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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.

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.

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