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GUIDE

Guidelines for safety related risk assessment and risk reduction for low voltage equipment

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

GUIDELINES FOR SAFETY RELATED RISK ASSESSMENT AND RISK REDUCTION FOR LOW VOLTAGE EQUIPMENT

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 first edition of IEC Guide 116 has been prepared, in accordance with ISO/IEC Directives, Part 1, Annex A, by the IEC Advisory Committee on Safety (ACOS). This is a non-mandatory guide in accordance with SMB Decision 136/8.

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

Four months' vote	Report on voting
C/1614/DV	C/1634/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.

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

This non-mandatory IEC Guide is intended to be applied to risk assessment and risk reduction for safety of low voltage equipment.

This IEC Guide reflects ISO/IEC Guide 51 and gives additional guidance to ISO/IEC Guides 50, 51, and 71 on more detailed practical information for carrying out risk assessment and on basics to implement risk reduction, in order to assess risks commonly considered during all relevant phases of the life of low voltage equipment.

This IEC Guide is intended to be applicable for TCs and SCs when they elaborate their own safety standards for the related products, if they have decided to carry out a structured risk assessment. This Guide can also be used when new features of a product are not covered by existing standards.

The use of this Guide implies that safety-related standards are also taken into account when available (see also Annex B) and using them automatically reflects the state of the art as defined in ISO/IEC Guide 2.

GUIDELINES FOR SAFETY RELATED RISK ASSESSMENT AND RISK REDUCTION FOR LOW VOLTAGE EQUIPMENT

1 Scope

This non-mandatory IEC Guide complements ISO/IEC Guide 51 and establishes guidelines useful for achieving safety in low voltage (LV) equipment. These guidelines include risk assessment, in which the knowledge and experience of the design, use, incidents, accidents and harm related to low voltage equipment are brought together in order to assess the risks during the relevant phases of the life of the equipment, as specified in Clause 6, and to implement the basics for risk reduction measures. This IEC guide should be used by technical committees as far as appropriate and to the extent they decide to apply it.

This IEC Guide gives additional guidance to ISO/IEC Guide 50, 51 and 71 on the information required to allow risk assessment to be performed. Procedures are described for identifying hazards, estimating and evaluating risk (including comparison of risks) and risk reduction where necessary. Risks considered in this document include possible damages to persons, property, and livestock. It is not intended that the structure of this guide be adopted by technical committees.

The purpose of this IEC Guide is to provide guidance for technical committees for decisions to be made on the safety of low voltage equipment and the type of documentation required to verify the risk assessment carried out. Components intended not to be used alone can only be assessed insofar as the manufacturer can predict the reasonably foreseeable use.

The voltage range considered in this IEC Guide is up to 1000 V a.c. (1 500 V d.c.). Low voltage equipment generating internal voltages higher than 1 000 V a.c. (1 500 V d.c.) are covered, provided these voltages are not touchable (example: TV set with internal HV cascade).

Product standards shall require that the equipment documentation include adequate information for the safe use of equipment.

This guide does not cover components used within the electrical distribution system or within an electrical system or machines whose risk assessment depends to a very large extent on how they are used and incorporated in an electrical system or installation.

NOTE Protective measures to be taken by the user of a product are subject to legal requirements in many countries, especially in the occupational health and safety framework.

This IEC Guide itself is not intended to be used for the purpose of certification. Product committees are encouraged to include a clause in product safety standards pertaining to risk assessment, to be used when the requirements of the standard do not fully encompass all possible hazards with equipment within the standard's scope. This clause should incorporate the principles of this Guide.

2 Normative references

The following referenced documents are indispensable for the application 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.

IEC Guide 104:2010, *The preparation of safety publications and the use of basic safety publications and group safety publications*

ISO/IEC Guide 50:2002, *Safety aspects – Guidelines for child safety*

NOTE Guide 50 applies in conjunction with ISO/IEC Guide 51:1999.

ISO/IEC Guide 51:1999, *Safety aspects – Guidelines for their inclusion in standards*

ISO/IEC Guide 71, *Guidelines for standards developers to address the needs of older persons and persons with disabilities*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
low voltage equipment
set of electrical devices or electrical apparatuses necessary to perform a specific task such as generation, transmission, distribution, utilisation of electric energy and with a supply or output voltage not exceeding 1 000 V for alternating current and 1 500 V for direct current

NOTE Examples of equipment are electric power generator, electrical switchgear and controlgear assemblies, electrical wiring systems, air conditioning units.

3.2
harm
physical injury or damage to persons, property, and livestock

[ISO/IEC Guide 51, definition 3.3, modified]

3.3
hazard
potential source of harm

NOTE The term hazard can be qualified in order to define its origin (e.g. electrical hazard, mechanical hazard) or the nature of the potential harm (e.g. electric shock hazard, cutting hazard, toxic hazard, fire hazard).

[ISO/IEC Guide 51, definition 3.5]

3.4
hazard zone
any space within and/or around a LV equipment in which persons, or livestock can be exposed to a hazard

3.5
hazardous event
event that can cause harm

NOTE A hazardous event can occur over a short period of time or over an extended period of time.

3.6
hazardous situation
circumstance in which persons, property and livestock or the environment are exposed to at least one hazard. The exposure can immediately or over a period of time result in harm

[ISO/IEC Guide 51, definition 3.6, modified]

3.7
incident
past hazardous event

NOTE An incident that has occurred and resulted in harm can be referred to as an accident. Whereas an incident that has occurred and that did not result in harm can be referred to as a near miss occurrence.

3.8
intended use
use of LV equipment in accordance with the information for use provided by the supplier

[ISO/IEC Guide 51, definition 3.13, modified]

3.9
malfunction
situation for which the electrical equipment does not perform the intended function due to a variety of reasons, including:

– variation of a property or of a dimension of the processed material or of the work piece;
– failure of one (or more) of its component parts or services;
– external disturbances (e.g. shocks, vibration, electromagnetic interference);
– design error or deficiency (e.g. software errors);
– disturbance of its power supply;
– surrounding conditions (e.g. condensation due to temperature change).

3.10
protective measure
measure intended to achieve adequate risk reduction, implemented:

– by the designer (inherent design, safeguarding and complementary protective measures, information for use) and
– by the user (organisation: safe working procedures, supervision, training; permit-to-work systems; provision and use of additional safeguards; use of personal protective equipment)

3.11
reasonably foreseeable misuse
use of LV equipment in a way not intended by the designer, but which may result from readily predictable human behaviour

[ISO/IEC Guide 51, definition 3.14, modified]

3.12
residual risk
risk remaining after protective measures have been taken (see also Figure 1)

NOTE This IEC Guide distinguishes:

– the residual risk after protective measures have been taken by the designer;

– the residual risk remaining after all protective measures have been implemented by the user.

[ISO/IEC Guide 51, definition 3.9, modified]

3.13
risk
combination of the probability of occurrence of harm and the severity of that harm

[ISO/IEC Guide 51, definition 3.2]

3.14
tolerable risk
risk which is accepted in a given context based on the current values of society

[ISO/IEC Guide 51, definition 3.7]

3.15
risk assessment
overall process comprising a risk analysis and a risk evaluation

[ISO/IEC Guide 51, definition 3.12]

3.16
safety
freedom from unacceptable risk

[ISO/IEC Guide 51, definition 3.1]

3.17
safety integration
application of the "3-step-methodology" (see Figure1) to reduce the residual risk of a LV equipment below the level of tolerable risk

NOTE See A.2 for further information.

3.18
adequate protection
protection which permits to achieve the risk reduction to a tolerable level

3.19
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 If a single fault condition results in one or more other fault conditions, all are considered as one single fault condition.

[IEC Guide 104:2010, definition 3.8]

4 Basic principles

4.1 Principle of safety integration

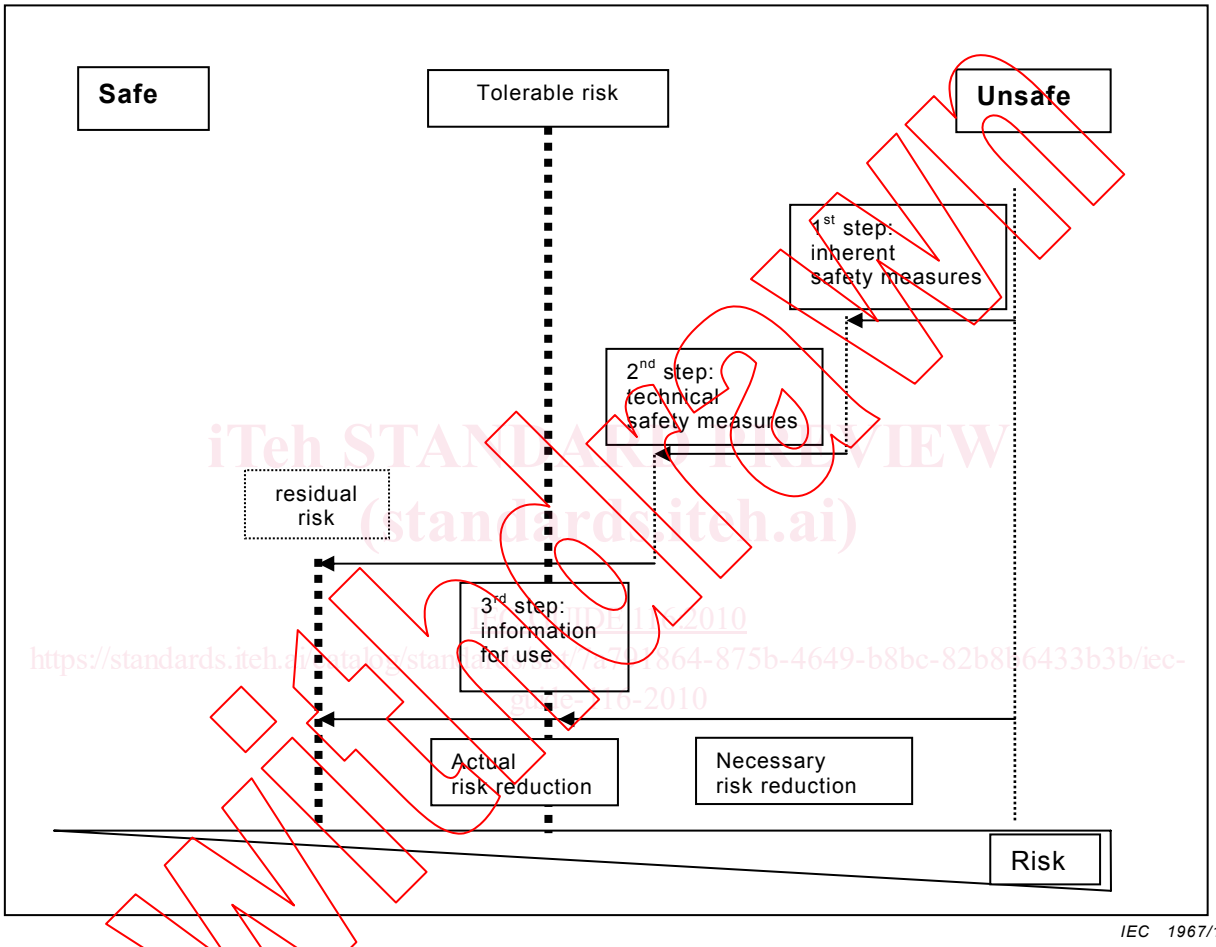
Figure 1 shows the principle of safety integration. The minimum necessary risk reduction is the reduction in risk that has to be achieved to meet the tolerable risk for a specific situation. The concept of necessary risk reduction is of fundamental importance in the development of the safety requirements for electrical equipment. The purpose of determining the tolerable risk for a specific hazardous event is to state what is deemed reasonable with respect to both components of risk (see 7.2 and Figure 2).

The tolerable risk will depend on many factors (for example, severity of injury, the damage to property, the number of people exposed to danger, the frequency at which a person or people are exposed to danger and the duration of the exposure).

In case of choices between options for different safety measures in product standards, these standards should clearly show the principles how the manufacturers have to implement risk assessment including safety integrations by their own thorough investigations about their equipment. In such cases manufacturers have increased responsibility for the safety of their products. Especially when products get more and more complex, manufacturers themselves have the best knowledge of the specific characteristics and related contents of their own equipment. Further the following inputs may also be considered:

– requirements from various origins, both general and those directly relevant to the specific application;
– guidelines from various origins;

– discussions and agreements with the different parties involved in the application;
– international discussions and agreements; the role of national and international standards are becoming increasingly important in arriving at tolerable risk criteria for applications;
– industry standards and guidelines;
– independent industrial, expert and scientific advice from advisory bodies;
– current values defined by all involved stakeholders.



NOTE Sometimes it is possible that tolerable risk is already achieved by applying step 1 or steps 1 and 2.

Figure 1 – Principle of safety integration

4.2 Basic concepts

Safety-related risk assessment is a series of logical steps which starts with the determination of the limits of the LV equipment (see Clause 5) The next step entails, in a systematic way, the examination of the hazards associated with LV equipment (see Clause 6). After a subsequent risk estimation (see Clause 7) and risk evaluation and/or risk comparison (see Clause 8), risk assessment is followed, whenever necessary, by risk reduction (see Clause 9). When this process is repeated, it gives the iterative process for eliminating hazards as far as practicable and for implementing protective measures.

Risk assessment includes (see Figure 2):

a) risk analysis,
   1) determination of the limits of the LV equipment (see Clause 5);
   2) hazard identification (see Clause 6);