CENELEC GUIDE 32

Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment

Edition 1, 2014-07

CENELEC decided to adopt this new CENELEC Guide 32 through CLC Decision D147/C137.

European Committee for Electrotechnical Standardization

Avenue Marnix, 17

B – 1000 Brussels

Tel: +32 2 519 68 71

Fax: +32 2 519 69 19

www.cenelec.eu

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Foreword

This Guide was prepared by CENELEC BTTF 143-1 “Alignment of the Low Voltage Directive under the New Legislative Framework”.

The text of the draft was approved by the CENELEC Technical Board as CENELEC Guide 32 on 2014-04-29.

This guidance document is a tool for Technical Committees and has been developed in response to EC Standardisation Mandate M/511. The content of this Guide reflects the requirements in the Low Voltage Directive 2014/35/EU.

This Guide has been prepared for the use of CENELEC Technical Bodies in charge of preparing standards, notably to help in preparing the relevant Annex ZZ. It is not intended to be imposed by regulatory authorities as a reference to demonstrate that a standard complies with the principal elements of the safety objectives for electrical equipment designed for use within certain voltage limits (Annex I of the LVD). However, regulatory authorities can take this Guide into account when evaluating standards in the context of Annex I of the LVD.

This Guide provides guidance to those developing and revising standards, specifications and similar publications. However, it contains important information that can be useful as background information for, amongst others, designers, architects, manufacturers, service providers, educators, communicators and policy makers.

While auditors and safety inspectors should always use a specific standard when it exists, this Guide provides useful information in the absence of a specific standard.

Introduction

This CENELEC Guide reflects ISO/IEC Guide 51, gives additional guidance to ISO/IEC Guide 71 and CEN/CENELEC Guide 14, in more detail with practical information for carrying out risk assessment and on basics to implement risk reduction. This is to help assess risks commonly considered during all relevant lifecycle phases of low voltage equipment.

This CENELEC Guide is intended to be applicable for TCs and SCs when they elaborate their own safety standards for the related products. 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 EN 45020, Definition 1.4.

1 Scope

This CENELEC Guide complements ISO/IEC Guide 51 and establishes useful guidelines 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 CENELEC guide should be used by Technical Committees as far as appropriate and to the extent they decide to apply it.

This CENELEC Guide gives additional guidance to ISO/IEC Guide 51 and 71 and CEN/CENELEC Guide 14 on performing a risk assessment in more detail with practical information. 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 damage to persons, property and domestic animals. It is not intended that the structure of this guide be adopted by Technical Committees.

The purpose of this CENELEC 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.

This CENELEC Guide applies to all electrical equipment designed for use with a voltage rating of between 50 V and 1 000 V for alternating current and between 75 V and 1 500 V for direct current. Voltage ratings refer to the voltage of the electrical input or output, not to voltages that may appear inside the equipment (see EU Guidance document “Guidelines on the application of Directive 2006/95/EC”).

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

2 General

This Guide includes both electrical equipment intended for incorporation into other equipment and equipment intended to be used directly without being incorporated.

This Guide does not cover basic components whose risk assessment depends to a very large extent on how they are used and incorporated into a machine, electrical system or installation.

NOTE 1 Moreover, the scope of the exclusion of basic components should not be misunderstood and extended to items like lamps, starters, fuses, switches for household use, elements of electrical installations, etc., which, even if they are often used in conjunction with other electrical equipment and have to be properly installed in order to deliver their useful function, are themselves to be considered electrical equipment in the sense of this Guide.

NOTE 2 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 CENELEC 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, especially for emerging technologies, where new hazards may arise.

An informative annex shall be added as an integral part of each standard that provides presumption of conformity to essential requirements of New Legislative Framework Directives.

This annex shall show how the requirements of the standard cover the essential requirements of the directive.

Annex A of this Guide identifies basic health and safety requirements, typically for Low-Voltage Equipment.

Annex D can be used as a tool for documenting a self-assessment by a Technical Committee.

If the risk assessment identifies aspects not directly related to health and safety, such as environment protection, energy consumption, climate change, etc., the risk reduction for health and safety related risks, in particular with respect to persons, overrules the priority of those other aspects. However, regulations related to such aspects shall be taken into account.

3 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 61508 series, *Functional safety of electrical/electronic/programmable electronic safety – related systems*CEN-CENELEC Guide 14, *Child Safety – Guidance for its Inclusion in Standards* [1)]

CENELEC Guide 29, *Temperatures of hot surfaces likely to be touched*

ISO/IEC Guide 51, *Safety aspects – Guidelines for their inclusion in standards (currently under revision)*

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

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

IEC 62443 series, *Industrial communication networks – Network and system security*

4 Terms and definitions

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

4.1
low voltage equipment
set of electrical devices or electrical apparatus necessary to perform a specific task such as generation, transmission, distribution, utilization of electrical energy and with a supply or output voltage not exceeding 1 000 V for alternating current and 1 500 V for direct current

Note 1 to entry: Examples of equipment are electric power generator, electrical switchgear and controlgear assemblies, electrical wiring systems, air conditioning units.

4.2
harm
physical injury or damage to persons, property, and domestic animals

Note 1 to entry: Physical injury or damage to persons also includes health aspects.

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

4.3
hazard
potential source of harm

Note 1 to entry: 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).

[SOURCE: ISO/IEC Guide 51, definition 3.5]

———————

1) Guide 14 applies in conjunction with ISO/IEC Guide 51.

4.4
hazard zone
any space within and/or around LV equipment in which persons, or domestic animals can be exposed to a hazard

4.5
hazardous event
event that can cause harm

Note 1 to entry: A hazardous event can occur over a short period of time or over an extended period of time.

4.6
hazardous situation
circumstances in which persons, property and domestic animals or the environment are exposed to at least one hazard

Note 1 to entry: The exposure can immediately or over a period of time result in harm.

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

4.7
incident
past hazardous event

Note 1 to entry: 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.

4.8
intended use
use of LV equipment in accordance with the information for use provided by the supplier

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

4.9
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)

4.10
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 (organization: safe working procedures, supervision, training; permit-to-work systems; provision and use of additional safeguards; use of personal protective equipment)

4.11
reasonably foreseeable misuse
use of LV equipment in a way not intended by the designer, but which may result from readily predictable human behaviour

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

4.12
residual risk
risk remaining after protective measures have been taken (see also Figure 1)

Note 1 to entry: This CENELEC 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.

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

4.13
risk
combination of the probability of occurrence of harm and the severity of that harm

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

4.14
tolerable risk
risk which is accepted in a given context based on the current values of society

[SOURCE: ISO/IEC Guide 51, definition 3.7]

4.15
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: ISO/IEC Guide 51, definition 3.12]

4.16
safety
freedom from unacceptable risk

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

4.17
safety integration
application of the “3-step-methodology” (see Figure 1) to reduce the residual risk of LV equipment below the level of tolerable risk

Note 1 to entry: See A.2 for further information.

4.18
adequate protection
protection which reduces risk to a tolerable level

4.19
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 1 to entry: If a single fault condition results in one or more other fault conditions, all are considered as one single fault condition.

[SOURCE: IEC Guide 104, definition 3.8]

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

4.20
safety-related security
system condition in which system resources are protected against safety hazards arising from unauthorized or accidental access through communication channels

Note 1 to entry: In some appliances the mains plug may be used as a communication channel (e.g. power-line communication).

4.21
threat
potential for violation of security, which exists when there is circumstance, capability, action, or event that could breach security and cause harm

[SOURCE: Derived from IEC/TS 62443-1-1:2009, definition 3.2.125]

5 Basic principles

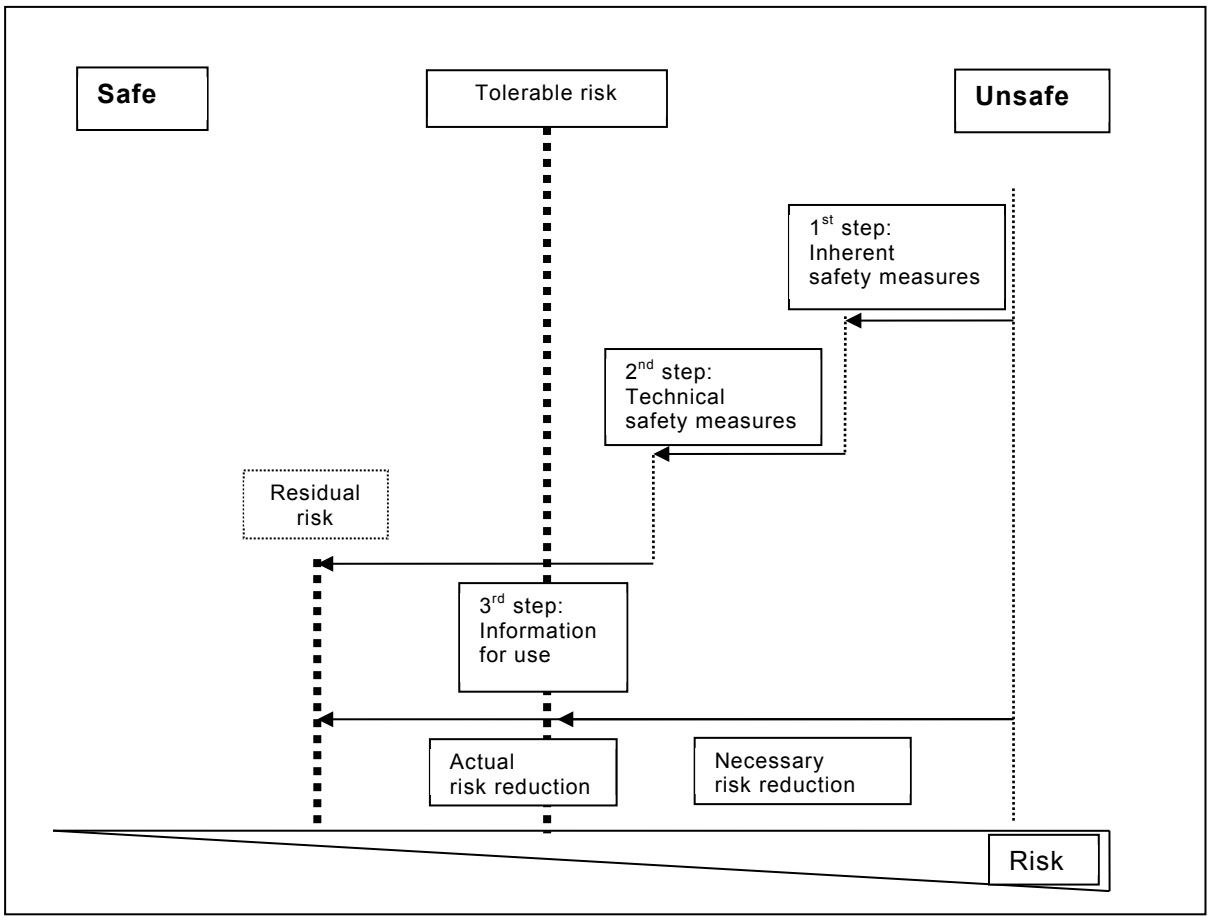
5.1 Principle of safety integration

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 8.2 and Figure 3).

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).

If there are choices between different safety measures in product standards, these standards should clearly show the principles governing how the manufacturers have to implement a risk assessment, including safety integrations by their own thorough investigations of their equipment. In such cases, manufacturers have increased responsibility for the safety of their products. This is particularly important with more complex products when the manufacturers themselves have the best knowledge of the specific characteristics and related contents of their own equipment. In addition, the following sources of information 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;
– user specifications.



IEC 1967/10

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

5.2 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 6). The next step entails a systematic examination of the hazards associated with LV equipment (see Clause 7). After a subsequent risk estimation (see Clause 8) and risk evaluation and/or risk comparison (see Clause 9), risk assessment is followed, whenever necessary, by risk reduction (see Clause 10). 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 6);
   2) hazard identification (see Clause 7);
   3) risk estimation (see Clause 8);
b) risk evaluation / risk comparison (see Clause 9).

Risk analysis provides the information required for the risk evaluation which in turn allows judgments to be made on the safety of the LV equipment.

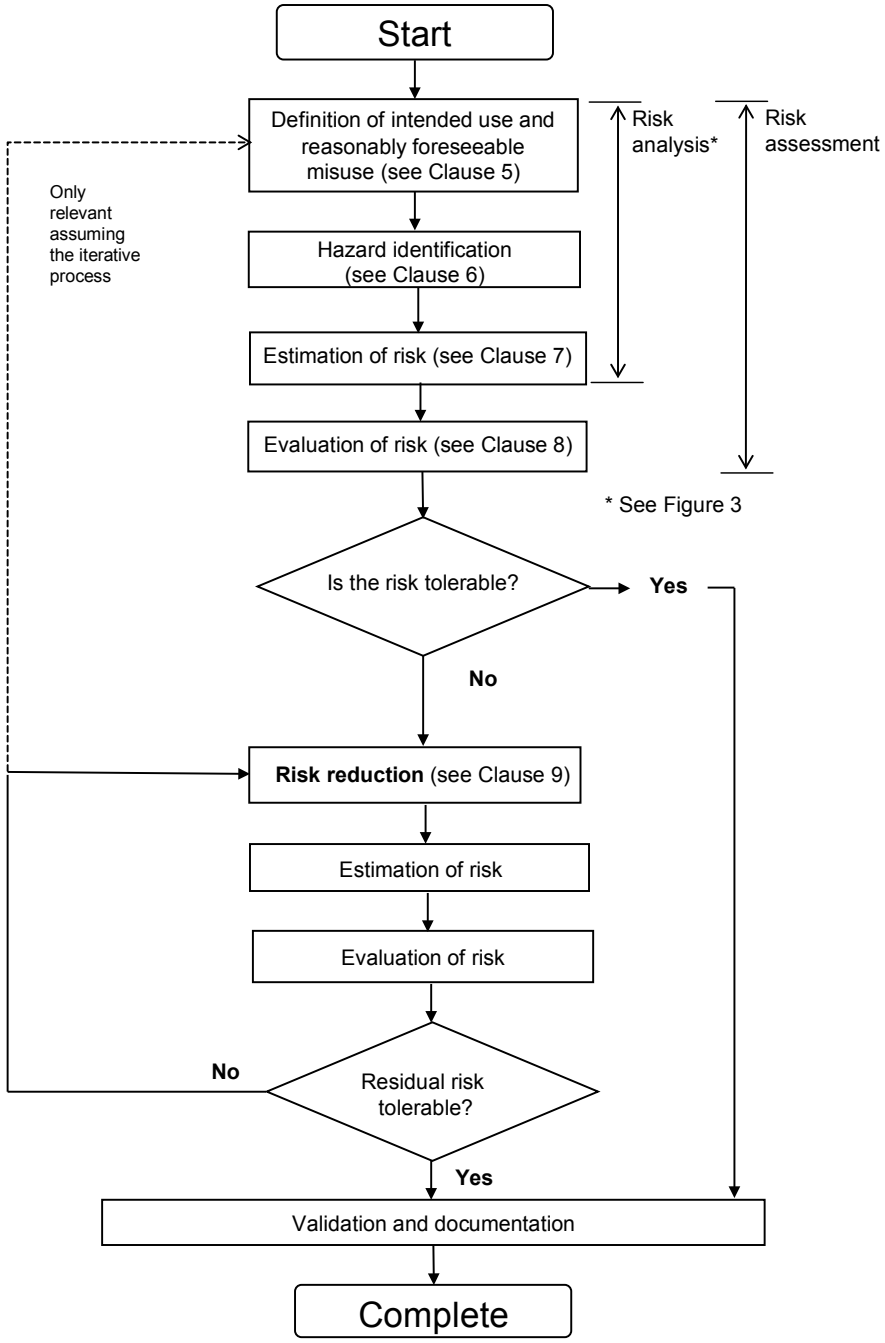
Risk assessment relies on judgmental decisions. These decisions shall be supported by qualitative methods complemented, as far as possible, by quantitative methods. Quantitative methods can be appropriate when the potential severity and extent of harm are high and

resources or data permit. Quantitative methods are useful for assessing alternative protective measures and determining what gives better protection.

NOTE The application of quantitative methods is restricted by the amount of useful data which is available and in many applications only qualitative risk assessment is possible.

The risk assessment shall be conducted in such a way that it is possible to document the procedure that has been followed and the results that have been achieved (see Clause 9).

Risk assessment determines whether risk reduction is required. Guidance on how to do risk reduction is given in Clause 10.



NOTE The process of risk assessment on LV equipment is to be implemented as follows:

– identify the appropriate scope and target users of the LV equipment (see Clause 6);
– identify the intended use and reasonably foreseeable misuse of the LV equipment (see Clause 6);
– identify the hazards during each life cycle stage of the LV equipment, such as design, manufacture, installation, maintenance, repair and disposal (see Clause 7);
– estimate the risks caused by each identified hazard (see Clause 8);
– evaluate the risks caused by identified hazards (see Clause 9);
– if the results of the risk assessment on the LV equipment show that the residual risk is at a tolerable level, no further action is needed (see Clause 9);
– if the residual risk is not tolerable, risk reduction has to be implemented (see Clause 10);
– the loop is repeated until the residual risk is reduced to a tolerable level.

Figure 2 – Iterative process of risk assessment and risk reduction

5.2.1 *Information for risk assessment*General

The information needed for risk assessment and any qualitative and quantitative analysis should include the following:

a) limits of the LV equipment (see Clause 6);
b) description of the various phases of the whole life cycle of the LV equipment (e.g. transport, assembly and installation, commissioning and use);
c) design drawings or other means of establishing the nature of the LV equipment;
d) any accident, incident or malfunction history of the actual or similar LV equipment (when available);
e) information regarding possible risks resulting, e.g. from emissions (noise, vibration, dust, fumes, etc.), chemicals used or materials processed by the LV equipment;
f) information for use supplied with the LV equipment, as available.

The information shall be updated as the design develops or when modifications are required.

Comparisons between similar hazardous situations associated with different types of equipment are often possible, provided that sufficient information about hazards and accident circumstances in those situations is available.

The absence of an accident history, a small number of accidents or low severity of accidents shall not be taken as an automatic presumption of a low risk.

For quantitative analysis, data from databases, handbooks, laboratories and manufacturers' specifications may be used provided that there is confidence in the suitability of the data. Uncertainty associated with this data shall be indicated in the documentation (see Clause 11).

5.2.2 Information related to LV equipment description

Information related to the LV equipment description should include:

a) anticipated LV equipment specification, including:
   – description of the various phases of the life cycle of the equipment (e.g. transport, assembly and installation, commissioning, maintenance and use);
   – design drawings or other means of establishing the nature of the equipment;
   – required energy sources and how they are supplied;
b) information for use of the equipment, as available.

5.2.3 Related standards and other applicable documents

Related documents include:

a) relevant publications such as International Standards;
b) safety data sheet and other relevant technical specifications.

5.2.4 Information related to application experience

Information related to application experience of the equipment should include:

a) any historical record of the actual or similar equipment (remains the manufacturer’s property), if it refers to data collected by the manufacturer;
b) damage to health history or accident records.

5.2.5 Relevant ergonomic principles

Information shall be included as far as health aspects are related:

a) as the design develops, or

b) when modifications are required.

6 Determination of the limits of the LV equipment

Risk assessment begins with the specification of the limits of the LV equipment.

a) Use limits, including the intended use and the reasonably foreseeable misuse. Aspects to be taken into account are, for example:

   1) the different operating modes of the LV equipment and the different intervention procedures for the users (including interventions required by malfunctions of the use of the LV equipment);

   2) the anticipated level of training, experience or ability of the users such as:

      i) operators;

      ii) maintenance personnel or technicians;

      iii) trainees and apprentices;

      iv) general public.

NOTE The use of the LV equipment (e.g. industrial, non-industrial and domestic) by persons identified by sex, age, dominant hand usage, or limiting physical abilities (e.g. visual or hearing impairment, size, strength) is to be taken into consideration when known.

b) Space limits. Aspects to be taken into account are, for example:

   1) range of movement;

   2) space requirements for installation and maintenance of the LV equipment;

   3) human interaction, e.g. "man-machine" interface;

   4) "machine-power supply" interface.

c) Time limits, i.e.:

   1) the “useful lifetime” of the LV equipment and/ or of some of its components (e.g. tools, wear parts), taking into account its intended use and reasonably foreseeable misuse;

   2) recommended service intervals.

d) Other limits, e.g.:

   1) environmental - recommended minimum and maximum temperatures, whether can be operated indoors or outdoors, in dry or wet weather, in direct sunlight, tolerance to dust and wet, etc.;

   2) housekeeping, level of cleanliness required.

When determining the limits of the LV equipment, the relevant phases of life of the LV equipment shall be taken into account.

7 Hazard identification

The essential step in any risk assessment is the systematic identification of possible hazards, hazardous situations and hazardous events during all phases of the LV equipment life cycle. A distinction has to be made whether the considered hazard, hazardous situation or hazardous event affects damage to persons and/or domestic animals and/or property. All phases of the life of the electrical equipment have to be taken into account, i.e.:

a) transport;

b) assembly and installation;

c) commissioning;

d) use;

e) de-commissioning, dismantling and disposal as far as safety is concerned.

NOTE In many countries there are national or regional legal requirements in respect to the use and handling of hazardous substances and to the recycling of electrical and electronic equipment.

The absence of an accident history, a small number of accidents or low severity of accidents shall not be taken as an automatic presumption of a low risk. Only when identified, can steps be taken to eliminate hazards or reduce risk associated with them.

To accomplish this it is necessary to identify the operations to be performed by the LV equipment and the tasks to be performed by persons who interact with it.

Task identification should consider all those tasks associated with all the phases of the life cycle of the LV equipment listed above. Task identification should also take into account, but not be limited to, the following task categories:

– setting;
– testing;
– programming;
– start-up;
– all modes of operation;
– removal of product from LV equipment;
– normal stop;
– emergency stop;
– unexpected start-up;
– faultfinding / trouble-shooting (operator intervention);
– cleaning and housekeeping;
– planned maintenance and repair;
– unplanned maintenance and repair;
– reasonably foreseeable misuse;
– security threats (communication, access channel).

All hazards, hazardous situations or hazardous events associated with the various tasks shall then be identified.

In addition, reasonably foreseeable additional hazards, hazardous situations or hazardous events not directly related to tasks shall be identified (e.g. seismic, lightning, excessive snow loads, noise, collapse or break-up of LV equipment).

Annex C gives examples of hazards, hazardous situations and hazardous events to assist in this process. Several methods are available for the systematic identification of hazards.

Annex D is a tool to identify and document the hazards which are relevant for the LV equipment which is assessed. On the basis of the safety principles and basic safety requirements described in Annex A, those hazards are identified and documented in the column “relevant YES / NO” in Annex D.

8 Risk estimation

8.1 General

After hazard identification (see Clause 7), risk estimation shall be carried out for each hazardous situation by determining the elements of risk given in 8.2. When determining these elements it is necessary to take into account the aspects given in 8.3. This completes the risk analysis.

8.2 Elements of risk

8.2.1 Combination of elements of risk

The risk associated with a particular situation or technical process is derived from a combination of the following elements:

a) the severity of harm;

b) the probability of occurrence of that harm, which is a function of:

   1) exposure to a hazardous situation;

   2) the occurrence of a hazardous event;

   3) the technical and human ability to avoid or limit the harm.

The elements are shown in Figure 3. Additional details are given in 8.2.2, 8.2.3 and 8.3.

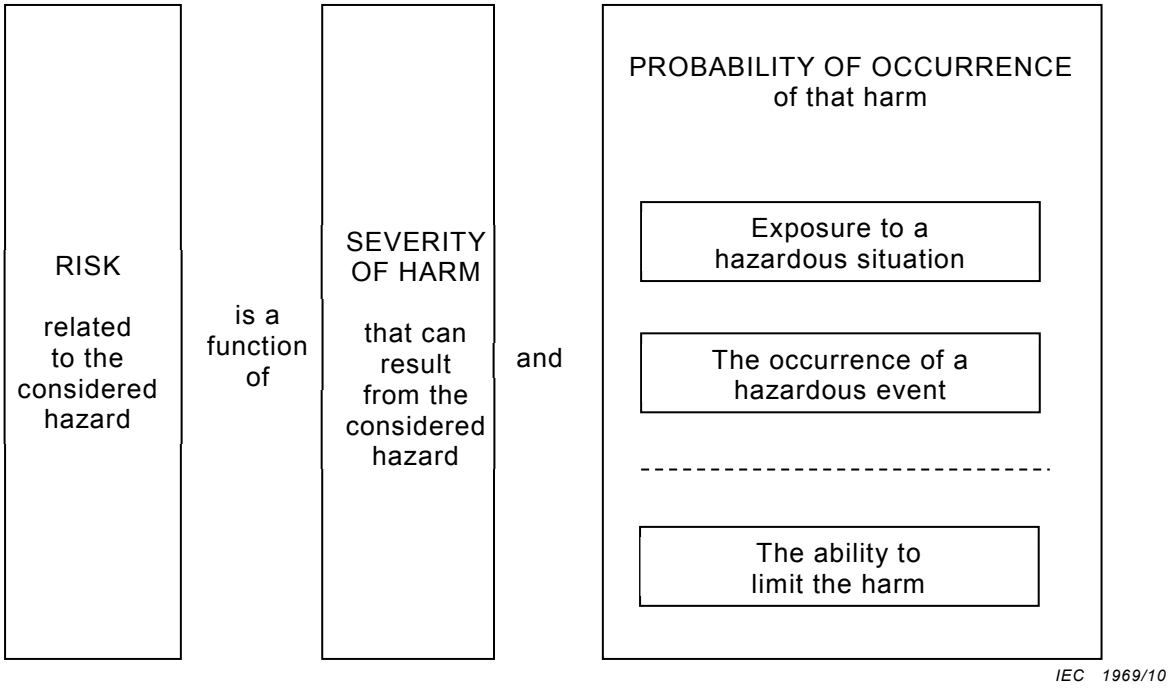


Figure 3 – Elements of risk for risk estimation

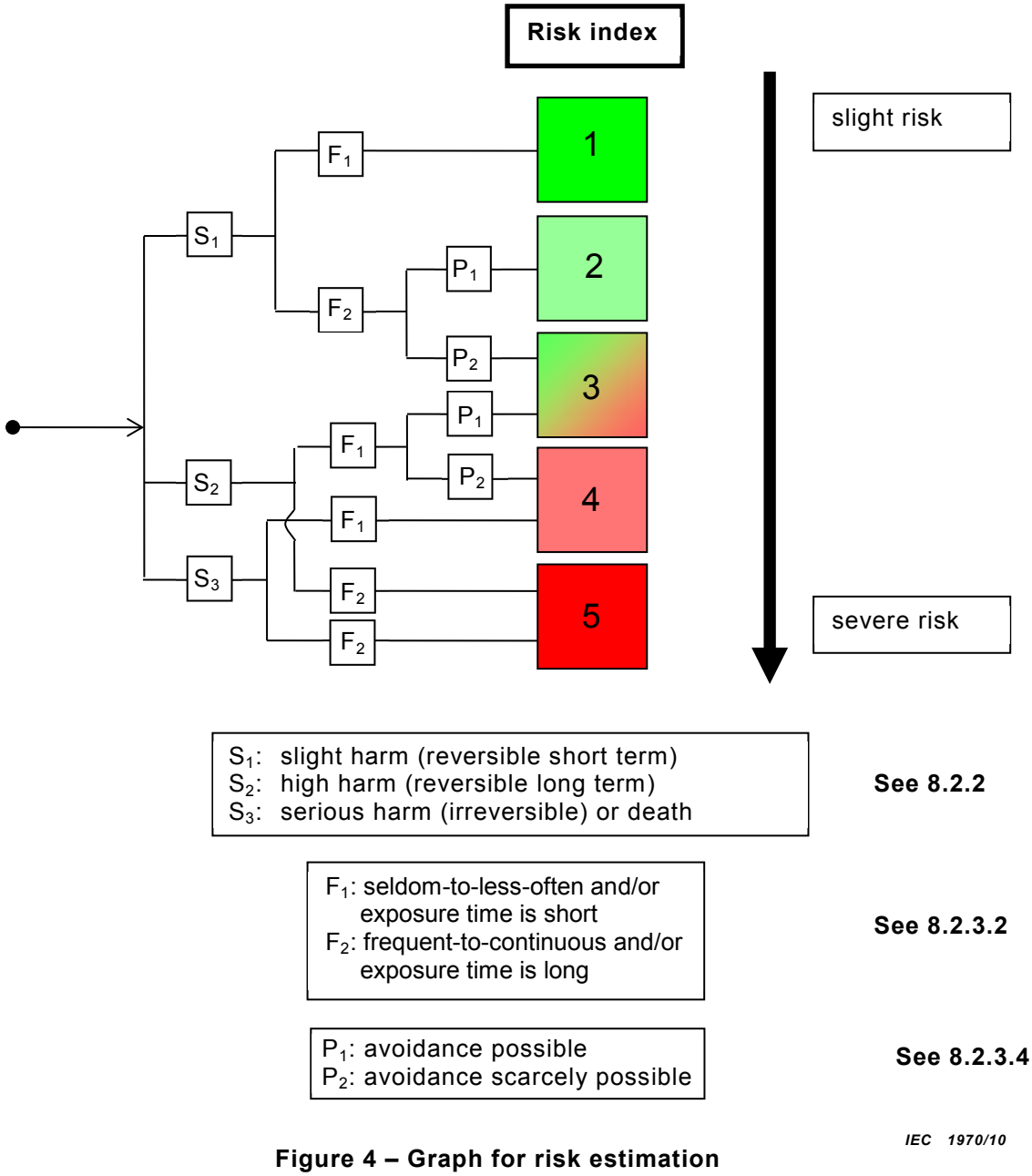


Figure 4 – Graph for risk estimation

8.2.2 Severity of harm

The severity can be estimated by taking into account:

a) the severity of harm:
   1) slight (normally reversible or repairable in short term), see S_1 in Figure 4;
   2) high (normally reversible or repairable in longer term), see S_2 in Figure 4;
   3) serious (normally irreversible or irreparable) or death, see S_3 in Figure 4;

b) the extent of harm:
   1) one person or the equipment itself or property in the next environment;
   2) several persons or damage in wider environment (e.g. affects a whole building or more).

If more than one person can be expected to be injured or killed, the probability of occurrence is F_2.

8.2.3 Probability of occurrence of harm

8.2.3.1 General

In estimating the risk, both normal conditions as well as single fault conditions shall be taken into account. The simultaneous occurrence of two independent and unrelated faults need not normally be taken into account, because the likelihood of such an event is so low that the risk is generally at a tolerable level. However, a second fault which is a consequence of the first fault is to be regarded as a single fault. A double fault situation with two independent and unrelated faults has to be considered when the first fault situation is not automatically detected. But considering this principle, TCs or SCs are also able to select the way by providing specifications, inspection or test requirements on insulation, isolation, components or protective devices, etc. for themselves.

Accident data can be available to indicate the probability and severity of injury associated with the use of a particular type of LV equipment and/or with a particular type of protective measure.

The probability of occurrence of harm can be estimated by taking into account 8.2.3.2 to 8.2.3.4.

8.2.3.2 Exposure to a hazardous situation

The parameters F_1 and F_2 in Figure 4 deal with the exposure of persons, domestic animals or property to the hazard and with the occurrence of a hazardous event.

Criteria for the exposure of persons, or domestic animals to a hazard are, e.g. the following:

a) need for access to the hazard zone (e.g. for normal operation (F_2), correction of malfunction (usually F_1), maintenance or repair (usually F_1));
b) nature of access (e.g. manual operation of the equipment (F_2) or automatic operation (usually F_1));
c) time spent in the hazard zone;
d) number of persons requiring access;
e) frequency of access;
f) protection already in place.

8.2.3.3 Occurrence of a hazardous event

Criteria for the occurrence of a hazardous event are, e.g. the following:

a) reliability and other statistical data;
b) accident history;
c) history of damage to health;
d) risk comparison (see 9.4).

NOTE The occurrence of a hazardous event can be of a technical or human origin.

8.2.3.4 Ability to limit harm

The parameters P_1 and P_2 in Figure 4 deal with the possibility of avoiding or limiting harm.

Criteria avoiding or limiting harm are, e.g., the following:

a) by whom the LV equipment is operated:
   – by skilled persons;
   – by unskilled persons;

  - unmanned;

b) the human ability to avoid or limit harm (e.g. reflex, agility, possible escape):
  - possible;
  - possible under certain conditions;
  - impossible;

c) any awareness of risk:
  - by general information;
  - by direct observation;
  - through warning signs and indicating devices;

d) by practical experience and knowledge:
  - of the LV equipment;
  - of similar LV equipment;
  - no experience;

e) how quickly the hazardous situation leads to harm:
  - suddenly;
  - fast;
  - slow;

f) the range of susceptibility to harm of the different exposed persons and the extent to which the harm can be reduced.

8.2.4 *Risk index*

The risk index can be regarded as a first step of risk evaluation and may express the terms from “slight risk” to “severe risk”. It may also be helpful to classify electrical, electronic and programmable control systems. The result of risk estimation cannot be the only basis for a final decision if further risk reduction is required (see also Clause 10).

The risk index describes a level of risk which is influenced by the severity of an injury expected from a hazard, and by:

– the probability of occurrence of an injury, and

– the possibility of avoiding an injury.

NOTE It is possible that different combinations of the elements of risk and the possibility of avoidance lead to the same risk index, e.g. $S_1/F_2/P_2$ and $S_2/F_1/P_1$.

8.3 Aspects to be considered during risk estimation

8.3.1 Exposure of persons and domestic animals

Risk estimation shall take into account all persons or domestic animals exposed to the hazards.

8.3.2 Type, frequency and duration of exposure

The estimation of the exposure to the hazard under consideration (including long-term damage to health) requires analysis of – and shall account for all modes of – operation of the LV equipment and methods of working. In particular, this affects the need for access during setting, teaching, process changeover or correction, cleaning, fault finding and maintenance.

The risk estimation shall account for situations when it is necessary to suspend safety functions (e.g. during maintenance).

8.3.3 Accumulation and synergy of effects

The effects of accumulated exposure and synergistic effects shall also be considered. Risk estimation when considering these effects shall, as far as practicable, be based on appropriate recognized data.

9 Risk evaluation

9.1 General

After risk estimation, risk evaluation shall be carried out to determine if risk reduction is required or whether tolerable risk has been achieved. A first information about the size of a risk gives the risk index in Figure 4. Depending on the kind of product, the aspects stated in 9.2 and the current values of society in 9.2.6, a decision has to be taken on whether risk reduction is required according to the principles of Clause 10. If so, appropriate protective measures shall be selected and applied and the procedure shall be repeated (see Figure 2) until tolerable risk has been achieved with respect to each hazard. During this iterative process, it is important for the technical committee to check whether additional hazards are created when new protective measures are applied. If additional hazards do occur, they shall be added to the list of identified hazards.

Basic safety and group safety standards as listed in Annex B can be used as recognized references when evaluating the risks dealt with in these standards.

The achievement of adequate risk reduction (see Clause 10) and a favourable outcome of risk comparison (see 9.4), applied when practicable, gives confidence that risk has been adequately reduced.

General principles for risk assessment are

a) identify slight risks and serious risks through risk evaluation based on the aspects defined in 7.3;

b) adopt the 3-step method to determine the level of risk reduction;

c) apply risk reduction as defined in Clause 10 for serious risks.

9.2 Aspects to be considered during risk evaluation

9.2.1 Human factors

Human factors can affect risk and shall be taken into account in the risk evaluation. This includes, for example:

a) interaction of person(s) with the LV equipment including correction of malfunctions;

b) interaction between persons;

c) stress-related aspects;

d) ergonomic effects;

e) competence of persons to be aware of risks in a given situation depending on their training, experience and ability.

The evaluation of the ability of exposed persons shall take into account the following aspects:

– application of ergonomic principles in the design of the LV equipment;

– natural or developed ability to execute the required tasks;

– awareness of risks;

– level of confidence in carrying out the required tasks without intentional or unintentional deviation;

– temptation to deviate from prescribed and necessary safe working practices.

Training, experience and ability can affect the risk but none of these factors shall be used as a substitute for hazard elimination, risk reduction by design or safeguarding where these protective measures can be implemented.

9.2.2 Reliability of protective measures

Risk evaluation shall take account of the reliability of components and systems. It shall:

a) identify the circumstances which can result in harm (e.g. component failure, power failure, environmental parameters, EM phenomena, electrical disturbances, vibrations);

b) when appropriate, use quantitative methods and proven in use processes to compare alternative protective measures;

c) provide information to allow the selection of appropriate safety functions, components and devices.

Those components and systems identified as contributing to the performance of safety functions need special attention, e.g. reliability, testing, resistance to environmental conditions.

When more than one safety-related device contributes towards a safety function, the selection of these devices shall be consistent when considering their reliability and their performance, e.g. a sensor, PLC and actuator have to be chosen correctly in order to fulfil the specific safety function.

Safety measures implemented during the design phase and technical safety measures are much more effective than protective measures in regard to skill or training, work organization, correct behaviour, attention, application of personal protective equipment. The relatively low reliability of such measures as compared to proven technical protective measures shall be taken into account in the risk evaluation. Therefore, the 3 steps shown in Figure 1 and Figure 5 have to be applied in order of priority.

9.2.3 Ability to defeat or circumvent protective measures

Risk evaluation shall take account of the ability to defeat or circumvent protective measures. The evaluation shall also take account of the incentive to defeat or circumvent protective measures, for example:

a) the protective measure slows down production, or interferes with any other activities or preferences of the user;

b) the protective measure is difficult to use;

c) persons other than the operator are involved;

d) the protective measure is not recognized by the user or is not accepted as suitable for its function.

The ability to defeat a protective measure depends on both the type of protective measure (e.g. adjustable guard) and its design details.

The use of programmable electronic systems introduces an additional possibility to defeat or circumvent if access to safety-related software is not properly designed, controlled and monitored. Risk evaluation shall identify where safety-related functions are not separated from other functions of the LV equipment and shall determine the extent to which access is possible. This is particularly important when remote access for diagnostic or process correction purposes is required.

9.2.4 Ability to maintain protective measures

Risk evaluation shall consider whether the protective measures can be maintained in the condition necessary to provide the required level of protection.

NOTE If the protective measure cannot easily be maintained in correct working order, this can encourage the defeat or circumvention of the protective measure to allow continued use of the LV equipment.

9.2.5 Information for use

Risk evaluation shall take into account the information for use.

NOTE See also ISO/IEC 82079-1 for structuring and presentation of information for use.

Information shall be provided to the user about the intended use of the product, taking into account all of its operating modes.

It shall contain all directions required to ensure safe and correct use of the LV equipment. With this in view, it shall inform and warn the user about residual risk.

Information for use shall not exclude uses of the LV equipment that can reasonably be expected from its design and description and shall also warn about the risk which would result from using the LV equipment in other ways than the ones described in the information, especially considering its reasonably foreseeable misuse and safety-related security threats.

Information for use shall cover, separately or in combination, transport, assembly and installation, commissioning, use (setting, teaching / programming or process changeover, operation, cleaning, fault finding and maintenance) and, if necessary, de-commissioning, dismantling and disposal.

9.2.6 Current values of society

Society tolerates the non-voluntary effect of a risk at a far lower degree than the voluntary effect of the same risk. Society grants special protection to some sections of the population, e.g. children and disabled persons. The strictness of the related laws and degrees also indicates the values of society. The contents of scientifically proven discussions and conventions should also be taken into account. Privately or unofficially discussed opinions should be of lower importance.

9.3 Elimination of hazards or reduction of risk by protective measures

All protective measures intended to reach this objective shall be applied according to the following sequence, referred to as the "3-step method" (see also Figures 1, 2 and 3):

– inherently safe design measures;

  NOTE 1 This stage is the only one at which hazards can be eliminated, thus avoiding the need for additional protective measures such as safeguarding or complementary protective measures.

– safeguarding;

– information for use about the residual risk (see 9.2.5).

Information for use shall not be a substitute for the correct application of inherently safe design measures or safeguarding.

NOTE 2 The inherently safe design measures are more effective than technical measures provided by the manufacturer of the LV equipment. These measures have preference over the measures provided by the user following the information for use.

Information for use about the residual risk may include:

a) correct operation of the equipment;

b) the recommended operation and related training requirements have been adopted;

c) users have been informed about the residual risks during the life cycle of the equipment;

d) the need for personal protective devices and related training requirements.

e) provision for safety-related security protection.

9.4 Comparison of risks

As part of the process of risk evaluation, the risks associated with the LV equipment can be compared with those of similar LV equipment or comparable products provided the following criteria apply:

– the similar LV equipment is safe in accordance with recognized International Standards;
– the intended use and the way both products are designed and constructed are comparable;
– the hazards and the elements of risk are comparable;
– the technical specifications are comparable;
– the conditions for use are comparable.

The use of this comparison method does not eliminate the need to follow the risk assessment process as described in this CENELEC Guide for the specific conditions of use (e.g. when a dishwasher for household application is compared with a washing equipment for cleaning printed circuits, the risks associated with the different materials shall be assessed).

10 Risk reduction

This objective may be met by removing the hazards or by reducing, separately or simultaneously, each of the two elements which determine the risk:

a) severity of harm from the hazard under consideration;
b) probability of occurrence of that harm.

Applying the following "3-step-method" in priority order (see Figure 5) will indicate that the residual risk has been adequately reduced in order to answer the question if the LV equipment is safe:

(1) the hazard has been eliminated or the risk reduced, for instance, by design or by the substitution for less hazardous materials and substances or by application of ergonomic principles;
(2) the risk has been reduced by the application of technical protective measures (devices) which adequately reduce risk for the intended use and are appropriate for the application;
(3) when the application of safeguarding or other protective measures is not practicable, information for use which shall not be regarded as a substitute for the correct application of a) and b), including notice of any residual risk which may exist including but not limited to:
    i) the operating procedures for the use of the LV equipment are consistent with the ability of personnel who use this equipment or other persons who can be exposed to the hazards associated with the LV equipment;
    ii) the recommended safe working practice requirements for the use of the LV equipment requirements have been adequately described;
    iii) the user is sufficiently informed about the residual risks in the different phases of the LV equipment life.

The following criteria can be regarded as helpful to decide if the residual risk associated with a specific hazard identified in Annex D is tolerable:

- Have all possibilities of implementation of inherent safety measure (see Figure 1) been taken into account?

- If technical safety measures (see Figure 2) have to be implemented, are there horizontal safety standards or group safety standards (see IEC Guide 104) or other standards from CENELEC/IEC or other organizations (SDO) developing International or European Standards, e.g. CEN/ISO, available which contain relevant requirements? If no, suitable

normative requirements from other SDOs are available, other safety publications can be useful.

- If there are no suitable requirements in standards described above, specific requirements have to be drafted applying the principles described in Clauses 7, 8, 9 and 10. The application of the iterative process described in Figure 2 and the determination of a risk index (see Figure 4) shall be executed until the necessary risk reduction for the LV equipment under consideration is reached.

At the end of the risk reduction procedure, it shall be checked that:

– all operating conditions and all intervention procedures have been taken into account;

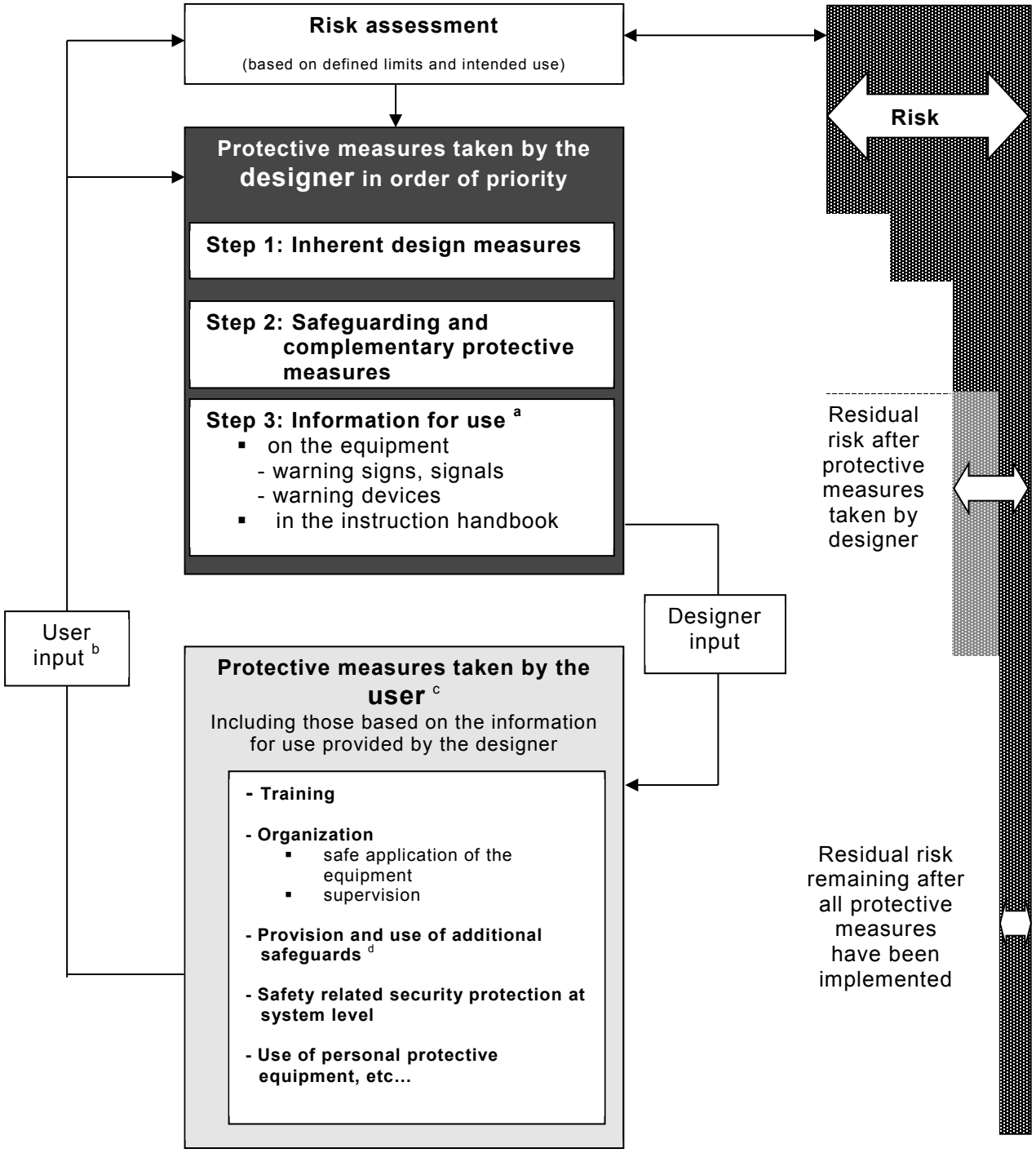
– the measures taken do not generate new hazards;

– the users are sufficiently informed and warned about the residual risks;

– the user's working conditions and the usability of the LV equipment are not jeopardized by the protective measures taken;

– the protective measures taken are compatible with each other;

– sufficient consideration has been given to the consequences that can arise from the use of equipment designed for professional / industrial use when it is used in a non-professional / non-industrial context.



[a] Providing proper information for use is part of the designer's contribution to risk reduction, but the protective measures concerned are only effective when implemented by the user.

[b] User input is that information received from either the user community regarding the intended use of the LV equipment in general or that which is received from a specific user.

[c] There is no hierarchy between the various protective measures taken by the user.

[d] Those protective measures required due to specific process(es) not envisioned in the intended use of the LV equipment or to specific conditions for installation that cannot be controlled by the designer.

Figure 5 – Risk reduction process

11 Documentation

For the purpose of this CENELEC Guide, documentation on risk assessment shall demonstrate the procedure that has been followed and the results that have been achieved. This documentation includes when relevant:

a) the LV equipment for which the assessment has been made (e.g. specifications, limits, intended use):
   – any relevant assumptions that have been made (e.g. loads, strengths, safety factors);
b) the hazards identified:
   1) the hazardous situations identified;
   2) the hazardous events considered in the assessment;
c) the information on which risk assessment was based (see 5.3 4):
   1) the data used and the sources (e.g. accident histories, experiences gained from risk reduction applied to similar LV equipment);
   2) the uncertainty associated with the data used and its impact on the risk assessment;
d) the objectives to be achieved by protective measures;
e) the protective measures implemented to eliminate identified hazards or to reduce risk (e.g. from standards or other specifications);
f) residual risks associated with the LV equipment;
g) the result of the final risk evaluation (see Figure 2) including security aspects.

Annex A
(normative)

Safety aspects
relating to low voltage equipment

A.1 General

The following list of safety aspects can be regarded as basic requirements when preparing safety publications. Which of these requirements are relevant for a specific product can be decided on the basis of the risk assessment procedure described in the present CENELEC Guide. There may be cases where hazards additional to those described in this annex are identified. In this case adequate risk reduction measures shall also be taken on the basis of the risk assessment procedure described in the present Guide.

NOTE This annex is based on Annex A of IEC Guide 104.

A.2 Preliminary observations

A TC is under an obligation to identify and assess potential hazards in order to address all those which apply to the equipment within its scope. It shall then prepare the publication, taking into account:

– the principles of safety integration,

– the assessment of the hazards set out in A.4 to A.7, and

– the requirements for information set out in A.8.

A.3 Safety integration

Electrical equipment shall be designed and manufactured so that it provides adequate protection for persons and, where appropriate, property.

This protection shall be provided against all hazards arising from the use of the equipment, listed in this annex, taking into account its functionality including the particularities of the equipment, or such hazards caused by external influences on the equipment itself.

The assessment of the hazards in this annex shall take into account situations of normal use and situations of reasonably foreseeable misuse.

The solutions adopted by the technical committee shall conform to safety principles, taking into account the generally acknowledged state of the art.

In selecting the most appropriate solution, the technical committee shall apply as far as reasonably possible the following principles in the order given:

– eliminate hazards or reduce risks by inherent design measures;

– take the necessary protective measures in relation to risks that cannot be reduced by inherent design measures;

– inform intended users and where appropriate other persons of the residual risks, indicate whether any particular training is required and specify any need to use personal protective equipment.

Equipment shall be designed and manufactured so that adequate protection is afforded in normal condition and in single fault condition.

Protection under a single fault condition can be achieved by the use of at least two means of protection (for instance: double insulation) or by the use of adequate safety margins (for instance: reinforced insulation).

A.4 Protection against electrical hazards

Except where specifically permitted for functional reasons, accessible conductive parts of equipment shall not be hazardous live.

The protective measures shall take into account electrical, mechanical, chemical and physical stresses to which the insulation is likely to be subjected during the normal use of the equipment.

In particular, the equipment shall provide adequate protection against electrical hazards, arising from:

a) leakage current;

b) energy supply;

c) stored charges;

d) arcs;

e) electric shock;

f) burns.

A.5 Protection against mechanical hazards

Where applicable, publications shall include adequate requirements against mechanical hazards caused by the equipment or by the effect of expected external forces acting on the equipment or by hazards in particular arising from:

a) instability;

b) break-down during operation;

c) falling or ejected objects;

d) inadequate surfaces, edges or corners;

e) moving parts, especially where there may be variations in the rotational speed of parts;

f) vibration;

g) improper fitting of parts.

A.6 Protection against other hazards

A.6.1 General

Where applicable, publications shall include requirements relating to the hazards addressed in A.6.2 to A.6.9.

A.6.2 Explosion

Explosion hazards can be caused by the equipment itself or by gases, liquids, dusts, vapours, or other substances which may be produced or used by the equipment or which may exist in the location where the equipment is to be used.

NOTE In the area of explosive atmospheres, attention is drawn to the specific risk assessment, zone area classification and equipment protection level.

A.6.3 Hazards arising from electric, magnetic, and electromagnetic fields, other ionizing and non-ionizing radiation

Equipment shall be designed and manufactured in such a way that electric, magnetic, and electromagnetic fields and other non-ionizing radiations generated by the equipment are limited to the extent necessary for its operation, and operate at a safe level.

Equipment shall be designed and manufactured in such a way that any emission of ionizing radiation is limited to the extent necessary for its operation and that the effects on exposed persons are non-existent or reduced to non-dangerous levels.

A.6.4 Electric, magnetic or electromagnetic disturbances

Equipment shall be designed and constructed so that it has sufficient immunity against electric, magnetic and electromagnetic disturbances to prevent any hazard arising. It shall also be designed to limit the emission of magnetic and electromagnetic disturbance so as not to interfere with other equipment, which can cause a hazard.

A.6.5 Optical radiation

Equipment shall be designed and constructed so that exposure to hazardous optical radiation (including LEDs, lasers, infrared and ultraviolet radiation, etc.) is avoided.

A.6.6 Fire

Appropriate tests to ensure that the risks of ignition from within the equipment and the spread of fire are limited shall be specified.

Provisions can include temperature-limiting devices, current-limiting devices, leakage current detection devices, methods of reducing fire spread and selection of appropriate materials.

NOTE The possible environmental damage caused by the use of flame retardants should be balanced against the benefits obtained though the reduction of the risk from fire.

A.6.7 Temperature

The two main aspects which need to be taken into account are:

– temperature of touchable surfaces, see CENELEC Guide 29;

– effects of temperature on materials and components.

A.6.8 Acoustic noise

Equipment shall be designed and constructed so that noise is limited as far as possible to acceptable levels. Where the resulting level is not acceptable, the manufacturer's instructions shall specify the use of external noise reduction measures (e.g. baffles or hoods) or the use of personal protective equipment).

A.6.9 Biological and chemical effects

Hazards can arise from and measures shall be specified to avoid hazards from:

a) microbiological causes such as pathogens, spoilage, micro-organisms or toxins; for example, ingress or retention of bacteria, spores, viruses, yeasts, and moulds;

b) chemical causes including those from cleaning and disinfecting substances; for example, lubricating oils and cleaning fluids;

c) foreign materials arising from raw materials, equipment or other causes; for example, allergens, pests, metals, and materials used in the construction of the equipment.

A.6.10 Emissions, production and/or use of hazardous substances (e.g. gases, liquids, dusts, mists, vapour)

Equipment shall be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided. Where the risk cannot be avoided, suitable warnings shall be provided to the user.

A.6.11 Unattended operation

Where equipment is foreseen for unattended operations under different conditions of use, it shall be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.

A.6.12 Connection to and interruption from power supply

The interruption and/or the re-establishment after an interruption of the power supply to the equipment shall not lead to dangerous situations. In particular the equipment shall not start unexpectedly and no moving part of the equipment shall fall in a dangerous way or be ejected.

A.6.13 Combination of equipment

If equipment is intended for use in combination with other equipment, each component shall be designed and instructions provided so that it is possible to assemble the equipment without creating hazards.

A.6.14 Implosion

Equipment shall be resistant against sources of implosion caused by negative pressure and shall not eject gases or other substances in a hazardous way.

A.6.15 Hygiene conditions

Equipment shall be able to be cleaned in such a way that it does not cause risks of infection.

A.6.16 Ergonomics

Equipment shall be designed and manufactured in accordance with ergonomic principles including the ability to be moved and handled safely.

A.7 Functional safety and reliability

A.7.1 General

For those applications within the scope of IEC 61508, the requirements in 5.2.5 of IEC Guide 104:2010 shall be followed.

A.7.2 Equipment design

Equipment shall be designed and constructed to be safe and reliable so as to prevent hazards arising, in particular so that:

a) it can withstand normal use in foreseeable environmental conditions, including electric, magnetic and electromagnetic disturbances considered as relevant in the product EMC standard or generic EMC standard;

b) it can withstand reasonably foreseeable misuse;

c) errors in logic (but occurring only one at a time) will not cause hazards;

d) interruptions or normal fluctuations in the power supply will not cause hazards.

A.7.3 Type related hazards

Potential hazards which may have to be taken into account in relation to some types of equipment include:

a) starting or stopping unexpectedly;

b) hazards resulting from failure to stop.

A.7.4 System faults

Where applicable, safety publications shall include requirements specifying that equipment shall be designed and constructed so as to prevent hazards, even after a system fault, or during and after interruptions or fluctuations in the power supply.

NOTE Further introductory information on functional safety is contained on the IEC website in the Functional Safety Zone (http://www.iec.ch/zone/fsafety).

In particular, the document "Functional safety and IEC 61508" provides a basic introduction to functional safety (http://www.iec.ch/about/brochures/pdf/technology/functional_safety.pdf).

A.8 Safety-related security

The following requirements related to security are derived from IEC 62443.

When a TC/SC identifies safety-related security risks in interfaces of electrical devices, e.g. USB, LAN, WLAN or remote control operation devices and subsequent communication layers (e.g. TCP ports) a qualitative approach to addressing security shall be determined and classified in one of the following categories taking into account the risk indexes as specified in Clause 7 and Figure 4:

a) Protection against casual or coincidental violation;

b) Protection against intentional violation using simple means with low resources, generic skills and low motivation;

c) Protection against intentional violation using sophisticated means with moderate resources, specific skills related to the considered equipment and moderate motivation;

d) Protection against intentional violation using sophisticated means with extended resources, specific skills related to the considered equipment and high motivation.

To reach a protection within a) to d) the TC/SC has to specify the means how to reach the following security levels:

1) The TC/SC shall provide measures for protection against a given type of threat by configuration during the design and installation phase.

2) The TC/SC shall determine through a risk assessment the need to protect the particular zone against the relevant level of threat (categories a) to d)).

3) The TC/SC shall specify on how the asset owner, system integrator, product supplier and/or any combination of these shall configure the zone, system or component to meet the particular security requirements described in a) to d).

Many protective measures on the safety-related security risks can only be managed at system level rather than at product level.

The TC/SC should consider the following foundational requirements for security when specifying the above mentioned means 1) to 3):

I. Identification and authentication control

II. Use control

III. System integrity

IV. Timely response to events

V. Resource availability

NOTE Examples of possible measures are:

— authentication and access control to protect systems and data against unauthorized access (may comprise technical and organizational means);

— integrity protection of data transmitted or stored device local to detect unauthorized manipulation.

A.9 Information requirements

a) The name of the manufacturer or supplier, or the brand name or trade mark, shall be clearly printed on the electrical equipment or, where that is not practicable, on its packaging. If appropriate, there shall also be marking to identify the date and place of manufacture.

b) Information provided with the equipment shall also include instructions for safe installation (assembly), maintenance, cleaning, operation and storage.

c) Where risks remain despite all the measures adopted, or in the case of potential risks which are not evident, appropriate warnings shall be provided.

d) The essential characteristics, the recognition and observance of which will ensure that equipment will be used safely and in applications for which it was intended and for which it can reasonably be foreseen, shall be marked legibly and indelibly on the equipment or, if this is not possible, in the accompanying instructions for use.

e) Information provided either by marking or in the instructions for use which is essential for the safe use of the equipment shall be easily understandable by the intended user.

Annex B
(informative)

Supporting standards

B.1 Basic safety standards

TCs and SCs elaborating basic safety standards can be found under the following address:

http://www.iec.ch/acos - click “Safety Functions” click “Horizontal Safety Functions”.

B.2 Group safety standards

TCs and SCs elaborating group safety standards can be found under the following address:

http://www.iec.ch/acos – click “Safety Functions” click “Group Safety Functions”.

Annex C
(informative)

Examples of hazards, hazardous situations and hazardous events

Hazard categories	Hazards	Examples	Hazardous situations	Hazardous events	Possible harm or damages
Electric shock and other electrical hazards	Leakage current	Connection of electrical wires	Current leakage at the ageing part of the wire	Touching with the ageing part of the wire	Current through human body
	Stored charges	Operation of electrical motors	Electrostatic discharge spark	Spark splashing on the combustible substances	Burn of motor/human
Fire hazards	External ignition source NOTE Guidance on how to deal with this issue is presently being elaborated.	Spread of fire to an equipment	Ignition of an equipment connected to other equipment	Spread of fire to other equipment	Burn of other equipment/human
	Internal ignition source	Spread of fire within an equipment	Component within the equipment heats up	Component starts burning	Burn of other equipment/human
Mechanical hazards	Instability	Erection of a distribution cabinet	Instable erection of the distribution cabinet	Fall of the distribution cabinet	Injury of human/property
	Sharp edges	Cleaning of equipment	Existence of sharp edge on the equipment	Touching with the sharp edge while cleaning the equipment	Cut of hand
	Vibration	Use of a drilling machine	Strong vibration of the drilling machine held by person	Fall of the drilling machine due to strong vibration	Injury of human
Other hazards	Acoustic noise	Use of a vacuum cleaner	Acoustic noise caused by the vacuum cleaner	Child being in the noise environment in long term	Ear drumming/deafness of child
	Use of hazardous substances	Operation of gas insulated switchgear	Use of sulphur hexafluoride (SF6) as insulating medium for gas insulated switchgear	Leakage of SF6	Poison of human
	Connection to power supply	Use of socket-outlet	Inserting plug into socket outlet with wrong behaviour	Touching the metal contact of the plug	Current through human body
Hazards arising from incorrect functioning	Logic errors in software	Operation of a control equipment	Logic error in software of the control equipment	Accessing the function module with logic error	Malfunction in control of the equipment
Hazards arising from electric, magnetic, and electromagnetic fields, other ionizing and non-ionizing radiation	Lightning	Operation of equipment	Lightning electromagnetic impulse around the equipment	Causing surge voltage in the equipment	Failure of the equipment
Ergonomics	Man-machine interface	Reading of data	Ambiguous character showing on the interface	Misreading of data	Wrong data acquired

Annex D
(informative)

Tool for the application of this CENELEC Guide

After having identified the hazards associated with the LV equipment and after having estimated and evaluated the associated risks, the result of the risk assessment can be documented in the following table. The left column lists the hazards described in Annex A. The 2nd column is the result of the hazard identification carried out by Technical Committees and the 3rd column documents the solution for reducing the risk associated with the relevant hazard. A simple verification by Technical Committees in the 3rd column is, e.g. the reference to a horizontal safety standard or group safety standard or a suitable standard from another SDO, e.g. CEN/ISO. Also, a technical solution which is not subject to a standard may be described.

Table D.1 – Risk assessment documentation

Requirement	Relevant yes / no?	Fulfilled by
A.2 Preliminary observations	Yes	Application of Annex A of this Guide
A.3 Safety integration	Yes	Application of this Guide, in particular application of the “3-step-method” – Inherent design measures – Protective measures – User information
A.4 Protection against electrical hazards		
a) leakage current		
b) energy supply		
c) stored charges		
d) arcs		
e) electric shock		
f) burns		
A.5 Protection against mechanical hazards		
a) instability		
b) break-down during operation		
c) falling or ejected objects		
d) inadequate surfaces, edges or corners		
e) moving parts, especially where there may be variations in the rotational speed of parts		

Requirement	Relevant yes / no?	Fulfilled by
f) vibration		
g) improper fitting of parts		
A.6 Protection against other hazards		
A.6.2 Explosion		
A.6.3 Hazards arising from electric, magnetic, and electromagnetic fields, other ionizing and non-ionizing radiation		
A.6.4 Electric, magnetic, and electromagnetic disturbances		
A.6.5 Optical radiation		
A.6.6 Fire		
A.6.7 Temperature		
A.6.8 Acoustic Noise		
A.6.9 Biological and chemical effects		
A.6.10 Emissions, production and/or use of hazardous substances (e.g. gases, liquids, dusts, mists, vapour)		
A.6.11 Unattended operation		
A.6.12 Connection to and interruption from power supply		
A.6.13 Combination of equipment		
A.6.14 Implosion		
A.6.15 Hygiene conditions		
A.6.16 Ergonomics		

Requirement	Relevant yes / no?	Fulfilled by
A.7 Functional safety and reliability		
A.7.2 Equipment design		
A.7.3 Type related hazards		
A.7.4 System faults		
A.8 Safety-related security Allocate the requirements 1) to 3) to the categories a) to d) taking into account the foundational requirements I. to V.		
a) Protection against casual or coincidental violation		
b) Protection against intentional violation using simple means with low resources, generic skills and low motivation		
c) Protection against intentional violation using sophisticated means with moderate resources, specific skills related to the considered equipment and moderate motivation		
d) Protection against intentional violation using sophisticated means with extended resources, specific skills related to the considered equipment and high motivation		
A.9 Information requirements		

Bibliography

ISO/IEC 82079-1, *Preparation of instructions for use – Structuring, content and presentation – Part 1: General principles and detailed requirements*

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

ISO 9241-210, *Ergonomics of human-system interaction – Part 210: Human-centred design for interactive systems*

EC Directive 2014/35/EU, *Electrical equipment designed for use within certain voltage limits*

Guidelines on the application of Directive 2006/95/EC
*(*http://www.iec.ch/about/brochures/pdf/technology/functional_safety.pdf)