

### SLOVENSKI STANDARD SIST-TP CLC/TR 50713:2021

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# Razumno predvidljivi pogoji uporabe pri sklicevanju na oceno izpostavljenosti elektromagnetnim poljem (EMF)

Reasonably Foreseeable Use Conditions when referring to EMF Exposure Assessment

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#### SIST-TP CLC/TR 50713:2021

## TECHNICAL REPORT RAPPORT TECHNIQUE TECHNISCHER BERICHT

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**English Version** 

### Reasonably Foreseeable Use Conditions when referring to EMF Exposure Assessment

Conditions d'utilisation raisonnablement prévisibles dans le cadre de l'évaluation de l'exposition aux champs électromagnétiques Vernünftigerweise vorhersehbare Gebrauchsbedingungen, auf die bei EMF-Bewertungen Bezug genommen wird

This Technical Report was approved by CENELEC on 2021-07-13.

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European Committee for Electrotechnical Standardization Comité Européen de Normalisation Electrotechnique Europäisches Komitee für Elektrotechnische Normung

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### **European foreword**

This document (CLC/TR 50713:2021) has been prepared by CLC/TC 106X "Electromagnetic fields in the human environment".

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association.

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### Introduction

Directive 2014/53/EU (Radio Equipment Directive, RED) and Directive 2014/35/EU (Low Voltage Directive, LVD) require that equipment meets the electromagnetic fields (EMF) exposure requirements when used as intended as well as under reasonably foreseeable conditions. Consequently, all relevant product standards are to be revised to meet the new requirements introduced in these directives.

Both the above-mentioned directives introduce new wordings such as "conditions of use which can be reasonably foreseen" as well as "reasonably foreseeable conditions" which are considered synonymous phrases. These new wordings could be open to different interpretations. Therefore, there is a need for clarification of what "conditions of use which can be reasonably foreseen" and its synonyms "reasonably foreseeable conditions" as well as "reasonably foreseeable use" mean when dealing with the EMF compliance of different product categories and applications.

Reasonably foreseeable conditions not only take into account the user behaviour but also exposure conditions representative of all readily-predictable human and system behaviour including parameters such as the duration of exposure, time variability of transmitted power, simultaneously operated frequency bands, availability of manufacturer-approved accessories, and time averaging as defined in normative limits and exposure guidelines.

This document addresses only the EMF assessment perspective (both measurement and calculation).

This document refers to the wording of the underlying directives. The considerations are restricted to the EMF exposure assessment and not intended to be applied beyond EMF exposure assessment.

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#### 1 Scope

This document illustrates good practices and provides guidance with regard to the term "reasonably foreseeable use" as it relates to product compliance assessment standards concerning the exposure of humans to electric, magnetic and electromagnetic fields (EMF) as required in the Radio Equipment Directive (RED) and Low Voltage Directive (LVD). Other safety aspects and requirements from other directives are not covered by this document.

This document uses the term "reasonably foreseeable use", which in the context of this document is interchangeable with the terms "reasonably foreseeable conditions" and "conditions of use which can be reasonably foreseen". The document provides guidance that is not specific to individual equipment.

The document covers both occupational and general public use of equipment and also provides a rationale for the distinction between occupational use and use by the general public.

This document is limited to the standards in the scope of TC106X.

#### 2 Normative references

There are no normative references in this document.

#### 3 Terms and definitions

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

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

- ISO Online browsing platform: available at https://www.iso.org/obp
- (standards.iteh.ai)
- IEC Electropedia: available at http://www.electropedia.org/

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use of equipment in accordance with the information for use of user training provided by the manufacturer

Note1 to entry: According to the RED, intended use requires proper installation and maintenance of radio equipment and that radio equipment has to be used for its intended purpose.

Note 2 to entry: Some usage of a product, shown for advertising purpose only, might not be intended to be repeated by the user and is therefore not part of the intended use.

[SOURCE: CENELEC Guide 32:2016, definition 4.8, modified; IEV 903-01-13, modified]

#### 3.2

#### reasonably foreseeable use

intended use as well as use of equipment in conditions, which results from lawful and readily predictable human and system behaviour that can be anticipated by the manufacturer

Note 1 to entry: Use conditions explicitly excluded by the manufacturer in the information for use or user training, but nevertheless reasonably foreseeable under the assumption that the user has not read the information for use or has not followed training instructions, are deemed to represent reasonably foreseeable misuse and such conditions fall outside this definition.

Note 2 to entry: This document uses the term "reasonably foreseeable use". In this context, the terms "reasonably foreseeable conditions", "reasonably foreseeable use" and "conditions of use which can be reasonably foreseen" are interchangeable.

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#### 3.3

#### reasonably foreseeable misuse

any use conditions not included in "reasonably foreseeable use" or "unreasonable misuse", including use conditions which contradict the information for intended use or user training, even if considered reasonably predictable human behaviour

Note 1 to entry: Any potential misuse shall not be considered for the compliance assessment of equipment regarding human exposure to EMF.

[SOURCE: CENELEC Guide 32:2016, definition 4.11, modified; IEV 903-01-14, modified]

#### 3.4

#### unreasonable misuse

use conditions, which are based on not predictable or unlawful human behaviour

#### 3.5

#### general public

individuals of all ages and of differing health statuses, which may include particularly vulnerable groups or individuals, and who might have no knowledge of or control over their exposure to EMF

Note 1 to entry: In many cases, members of the general public are unaware of their exposure to EMF. These considerations underlie the adoption of more stringent exposure restrictions for the public than for workers while they are occupationally exposed.

Note 2 to entry: Consumers are considered to be members of general public.

Note 3 to entry: Conscious medical treatment to a maximum dosage is excluded.

#### 3.6

#### professional use

use conditions intended only for trained experts or instructed persons https://standards.iten.av/catalog/standards/sist/d55c3606-519a-4665-9c5c-

[SOURCE: IEV 851-11-12 modified]

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#### 3.7

#### worker

any person employed by an employer, including trainees and apprentices but excluding domestic servants

Note 1 to entry: The formal distinction between general public and worker is often given in national legislation.

[SOURCE: Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work]

#### 4 Distinction between general public and workers

Directive 89/391/EEC defines worker as any person employed by an employer, including trainees and apprentices but excluding domestic servants; an employer is any natural or legal person who has an employment relationship with the worker and has responsibility for the undertaking and/ or establishment.

Directive 89/391/ECC as well as Directive 2013/35/EU require information and training for workers who are likely to be exposed to risks from EMF at work.

Thus, the exposure guidelines distinguish whether the worker is aware of the EMF exposure or not and whether the person is professionally trained. What can be presumed as reasonably foreseeable use regarding a worker who is aware of the EMF exposure and professionally trained about the EMF exposure is different from what can be expected from an unaware and untrained worker. If workers are unaware of their exposure to EMF they are treated like members of the general public. The reference levels and basic restrictions for the exposure of the general public to electric, magnetic, and electromagnetic fields are stricter than for occupational exposure.

Equipment that is compliant with the requirements for general public is deemed to be usable for workers.

#### 5 Intended Use

This document considers mainly the placing on the market of equipment. The intended use implies proper installation and maintenance as well as using equipment for its intended purpose.

NOTE 1 The use of the equipment includes relevant accessories and components, as long as the mode of operation is approved by the manufacturer.

The manufacturer should provide sufficient documentation on the intended use of the equipment in a clear, understandable and intelligible language for general public and workers. Any labelling should be clear and understandable. Such user documentation may include a description of manufacturer-approved accessories and components, including software, which allow the equipment to operate as intended.

NOTE 2 The Blue Guide, in Chapter 3.1.4, provides more details on how the instructions and safety information is expected to be provided.

#### 6 Reasonably foreseeable use

#### 6.1 Fundamental elements of reasonably foreseeable use

Reasonably foreseeable use includes the reasonably foreseeable conditions under which a device is used.

The devices are required to meet applicable regulatory standards including EMF compliance. In the case of electromagnetic fields (EMF) exposure assessment, when the equipment operated by the user, three fundamental elements can easily be recognized:

- 1) The Device/Equipment, (standards.iteh.ai)
- 2) The User,
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- 3) The way the device is used, i.e. the way that user interacts with the device.

### 6.2 The device/equipment

#### 6.2.1 General

Regarding the device/equipment, sometimes called the device under test (DUT), two relevant parameters stand out;

- 1) The fixed elements (e.g. mechanical construction, software, etc.) of the device with its own possible environmental and safety considerations;
- 2) The variable elements that influence the actual EMF exposure of the user (eg., transmitted power, antenna tuning, etc.).

The actual device/equipment operation represents a key aspect of reasonably foreseeable use of the device. Therefore, both the actual operation of the device and the user behaviour should be taken into account when defining the "use".

#### 6.2.2 The user

The user's inherent characteristics or behaviours contribute to setting the reasonably foreseeable use conditions. These user-related parameters, such as physiology, anatomy and behaviours are considered in the product EMF compliance assessment, where very conservative test conditions are defined.

The user is not always the person who is exposed to EMF from the product. The user is responsible for reading the product manual and to ensure that the use conditions are followed as stated by the manufacturer in the information for use.

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#### 6.2.3 The device use

The use of the device/equipment is very closely related to defining the "reasonably foreseeable use-condition".

The following aspects should be taken into account when determining the "use-condition":

- Intended use defined by the manufacturer which usually represents the "normal" use;
- Other reasonably foreseeable use conditions explained in this document.

#### 6.3 Reasonably Foreseeable Use for the general public

Reasonably foreseeable use, including use conditions, considers use of an equipment that is

- properly installed and maintained;
- used for its intended purpose;
- based on actual system behaviour;
- used in a different way than the intended use stated by the manufacturer as long as this results from lawful and readily predictable human and system behaviour.

Specific usage cases and applicable assessments of individual equipment may be considered in the product standards.

A behaviour is lawful when it is in line with applicable legislation or does not deliberately or negligently create non-compliance. There could be a number of unlawful behaviours which are not related to EMF; these behaviours should not be considered. (standards.iteh.ai)

A behaviour is readily predictable when the behaviour is reasonable and normal but not reckless.

The realm of reasonably foreseeable uses comprises usages and exposure conditions that are realistically possible when using the equipment for its intended purpose. The consideration of reasonably foreseeable conditions should take into account the following:

- the technical and functional characteristics of the equipment,
- the realistic exposure conditions as well as
  - the duration of exposure,
  - time and spatial averaging as defined in normative limits,
  - actual equipment power level behaviour,
  - lawful and readily predicable human behaviour,
  - installation and operation parameters such as
    - time variability of transmitted power,
    - simultaneously operated frequency bands,
    - availability of manufacturer-approved accessories.

There are several studies on the actual performance of the power levels of the device/equipment in real use condition. Information to determine realistic or reasonably foreseeable exposure conditions can be found in studies in Annex A. The informative Annex A provides an exemplary list of studies investigating actual EMF exposure under reasonably foreseeable use conditions.

Repair and refurbishment are reasonably foreseeable use and after repair and refurbishment the requirements for the exposure of humans to electromagnetic fields should still be fulfilled.

Use conditions not in accordance with the intended purpose of equipment as well as conditions, explicitly excluded by the manufacturer in the documentation for use but nevertheless reasonably foreseeable under the assumption that the user has not read the documentation for use, are termed in the context of this TR 'reasonably foreseeable misuse' and should not be considered for EMF exposure assessment.

The product standard committees may determine the relevance of reasonably foreseeable misuse for their standards.

Equipment which is intended exclusively for professional use by trained workers but have subsequently migrated to the consumer market have to meet the requirements for the general public at the time they are made available to the general public.

#### 6.4 Reasonably Foreseeable Use for workers

This document differentiates the case of general public and the case of workers at work who are likely to be exposed to risks from electromagnetic fields. The employer carries out a risk assessment for workers arising from EMF exposure at the workplace. The employer ensures that workers who are likely to be exposed to risks from EMF exposure at work receive any necessary documentation and training relating to the outcome of the risk assessment. It is anticipated that the employer specifies how the worker may use the equipment within the employees work instructions by relying on the manufacturer definition of intended use and any associated user training documentation. These work instructions shall include the use parameters (such as the mandated use of manufacturer-approved accessories) defined according to the equipment intended use as defined by the equipment manufacturer. The employer cannot specify how the worker could use the equipment in ways that do not conform with the manufacturer's user documentation, since employees could be subjected to EMF exposures in excess of normative limits as a result. Workers shall follow the workplace instructions so devised provided by the employer. Use conditions shall be avoided by the employer if explicitly excluded by the manufacturer in the equipment user documentation.

Use conditions, explicitly excluded by the manufacturer or employer in the documentation or training for use, are considered to be misused in this document it is expected that the worker follows the instructions provided by the employer. 973a8b94560f/sist-tp-clc-tr-50713-2021

#### 6.5 Reasonably foreseeable misuse and unreasonable use

It is noted that the Radio Equipment Directive and the Low Voltage Directive address reasonably foreseeable use defined as resulting from lawful and readily predictable human behaviour, but both directives do not cover misuse. Thus, only reasonably foreseeable use but not misuse should be considered for EMF exposure assessment under the RED or the LVD. Unreasonable misuse is also excluded from EMF exposure assessment.

#### 6.6 Realistic exposure scenarios

Reasonably foreseen conditions of use are not only relevant to the equipment user behaviour, but they are also related to the realistic function and performance of the equipment affecting users' exposure. The realistic exposure is defined as the exposure conditions representative of all readily-predictable human and system behaviour including parameters such as the duration of exposure, time variability of transmitted power, simultaneously operated frequency bands and time averaging as defined in normative limits.

Since the realistic exposure levels are reliably predictable under reasonably foreseeable conditions, the realistic power levels should be considered in compliance assessments. The assessment of realistic power levels should be based on realistic exposure scenarios.

In the case when compliance assessment standards require the equipment under test to be operated at maximum power levels, highly conservative assessment could result. As a consequence, all other exposure scenarios may be considered as covered.

Workers shall follow the workplace instructions provided by the employer. The employer can enforce equipment use instructions. Workers conduct misuse if they are likely to be exposed to risks from electromagnetic fields at work and neglect safety documentation or equipment user training.