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Electromagnetic compatibility and Radio spectrum Matters (ERM); Guidance on risk assessment for radio equipment

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Foreword

This Technical Report (TR) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

A technical Report (TR) is an ETSI deliverable, containing only informative elements, approved for publication by a Technical Body (TB), see ETSI Directives [i.18], clause A.3.

Modal verbs terminology

In the present document "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

Introduction

The conformity assessment procedure for radio equipment requires manufacturers to adequately analyse and assess the risk(s) related to the essential requirements of the Radio Equipment Directive 2014/53/EU (RED) [i.1], as set out in its article 3, even if a harmonised standard is fully applied.

Several guidance documents related to the essential requirements in general and specifically of RED already exist:

- Both Blue Guide [i.2] and the RED Guide [i.3] provide brief guidance on risk assessment.

- CENELEC has already published the CENELEC GUIDE 32 on Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment which is applicable to the risk assessment and risk reduction related to article 3(1)a (electrical safety and health) of RED [i.7]. ISO/IEC has published a similar Guide with ISO/IEC Guide 51 [i.8].

- REDCA has published in May 2022 the Technical Guidance Note 30 (TGN30) on Notified Body examination of a manufacturer's risk assessment under Annex III of Directive 2014/53/EU [i.6]. This guidance is intended for notified bodies, but may also be useful for manufacturers.

The present document is intended to assist manufacturers in the collection of relevant information for risk assessment and the subsequent performance of risk assessment and mitigation. This risk assessment should be documented and be part of the technical documentation required by article 21 of Directive 2014/53/EU [i.6].

1 Scope

The present document is to support manufacturers with a systematic and easy-to-understand guidance on how to carry out a risk assessment.

The present document covers the essential requirements of Directive 2014/53/EU (RED) [i.1], articles 3(1)b and 3(2).

NOTE: The present document provides guidance on risk assessment only for RED articles 3(1)b and 3(2), which does not mean that manufacturers need to perform risk assessment only for these two articles. The general approach to risk assessment should apply to all aspects of the essential requirements described in RED article 3.

2 References

2.1 Normative references

Normative references are not applicable in the present document.

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

NOTE: The hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long-term validity.

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (RED).

[i.2] Commission Notice: "The 'Blue Guide' on the implementation of EU product rules 2022".

[i.3] Guide to the Radio Equipment Directive 2014/53/EU ('RED Guide'), Version of 19 December 2018.

[i.4] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011.

[i.5] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

[i.6] REDCATechnical Guidance Note 30, V3.1, May 2022: "Notified Body examination of a manufacturer's risk assessment under Annex III of Directive 2014/53/EU".

[i.7] CENELEC Guide 32, Edition 1, 2014-07: "Guidelines for Safety Related Risk Assessment and Risk Reduction for Low Voltage Equipment which is applicable to the risk assessment and risk reduction related to article 3(1)a (electrical safety and health) of the RED".

[i.8] ISO/IEC Guide 51:2014: "Safety aspects -- Guidelines for their inclusion in standards".

[i.9] ETSI EG 203 367 (V1.1.1): "Guide to the application of harmonised standards covering articles 3.1b and 3.2 of the Directive 2014/53/EU (RED) to multi-radio and combined radio and non-radio equipment".

[i.10] ETSI EN 303 446-1 (V1.2.1): "ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment; Part 1: Requirements for equipment intended to be used in residential, commercial and light industry locations".

[i.11] ETSI EN 303 446-2 (V1.2.1): "ElectroMagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment; Part 2: Requirements for equipment intended to be used in industrial locations".

[i.12] ERC Recommendation 70-03 (February 2022): "Relating to the use of Short Range Devices (SRD)".

[i.13] Guide for the EMCD (Directive 2014/30/EU), Publication date: 24/01/2019.

[i.14] Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) Text with EEA relevance.

[i.15] Recommendation ITU-R SM.329-12 (09/2012): "Unwanted emissions in the spurious domain".

[i.16] ETSI EG 203 336 (V1.2.1): "Guide for the selection of technical parameters for the production of Harmonised Standards covering article 3.1(b) and article 3.2 of Directive 2014/53/EU".

[i.17] IEC TR 61000-2-5: 2017: "Electromagnetic compatibility (EMC) - Part 2-5: Environment - Description and classification of electromagnetic environment".

[i.18] ETSI Directives.

3 Definition of terms, symbols and abbreviations

3.1 Terms

For the purposes of the present document, the following terms apply:

combined equipment: equipment consisting of two or more products where at least one of which is radio communication or radio determination equipment (according to ETSI EG 203 367 [i.9], clause 3.1)

essential requirements: For the purposes of the present document, unless otherwise defined, the term refers to the essential requirements set out in articles 3.1(b) and 3.2 of the Radio Equipment Directive 2014/53/EU (RED) [i.1].

harmonised standard listed in the OJEU (hEN): European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation which is cited in the Official Journal for Directive 2014/53/EU

multi-radio equipment: combined equipment consisting of two or more radio products (according to ETSI EG 203 367 [i.9], clause 3.1)

3.2 Symbols

Void.

3.3 Abbreviations

For the purposes of the present document, the following abbreviations apply:

AFA	Adaptive Frequency Agility
CAP	Conformity Assessment Procedures
DFS	Dynamic Frequency Selection
DoC	Declaration of Conformity
EAU	Electrical Aggregation Unit
EMC	ElectroMagnetic Compatibility

EMCD	ElectroMagnetic Compatibility Directive
EN	European standard
ESOs	European Standardization Organizations
EU/EEA	European Union / European Economic Area
EUA	Equipment Under Assessment
EUT	Equipment Under Test
GPS	Global Positioning System
GSM	General System for Mobile communication
hEN	harmonised European standard (listed in the OJEU)
LBT	Listen Before Talk
LTE	3GPP Long Term Evolution (4G)
MU	Measurement Uncertainty
NB	Notified Body
OJEU	Official Journal of the European Union
OJEU-RED	Official Journal - Directive 2014/53/EU

NOTE: See https://ec.europa.eu/docsroom/documents/51934.

RED	Radio Equipment Directive (Directive 2014/53/EU)
RF	Radio Frequency
TD	Technical Documentation
TX	Transmitter
Wi-Fi®	Wireless Fidelity

4 General

4.1 Legal background

The legal references to a manufacturer's risk assessment are spread across multiple documents, some of which are not easily accessible. Therefore, some of the relevant legal documents related to the risk assessment are listed here, as information to the manufacturer. These documents may be updated at any time and therefore any manufacturer wishing to reference these documents should check for new versions.

The RED Guide [i.3]: Clause 2.6b (Conformity assessment procedures (CAP)):

> *"…Under the Modules mentioned above, an assessment needs to be performed for ensuring that radio equipment complies with the essential requirements set out in Article 3 of the RED (that includes an assessment of the risks and aspects covered by Article 3). Based on the wording of Article 21 and Annex V of the RED, this assessment (whether Module A, B+C or H has been followed) shall be included in the technical documentation…."*

Directive 2014/53/EU (RED) [i.1]: Annex III Module B paragraph 3c (Conformity assessment modules B and C):

> *"…The technical documentation shall make it possible to assess the radio equipment's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the radio equipment…"*

The RED Guide [i.3]: Clause 2.6d (Technical Documentation (TD)):

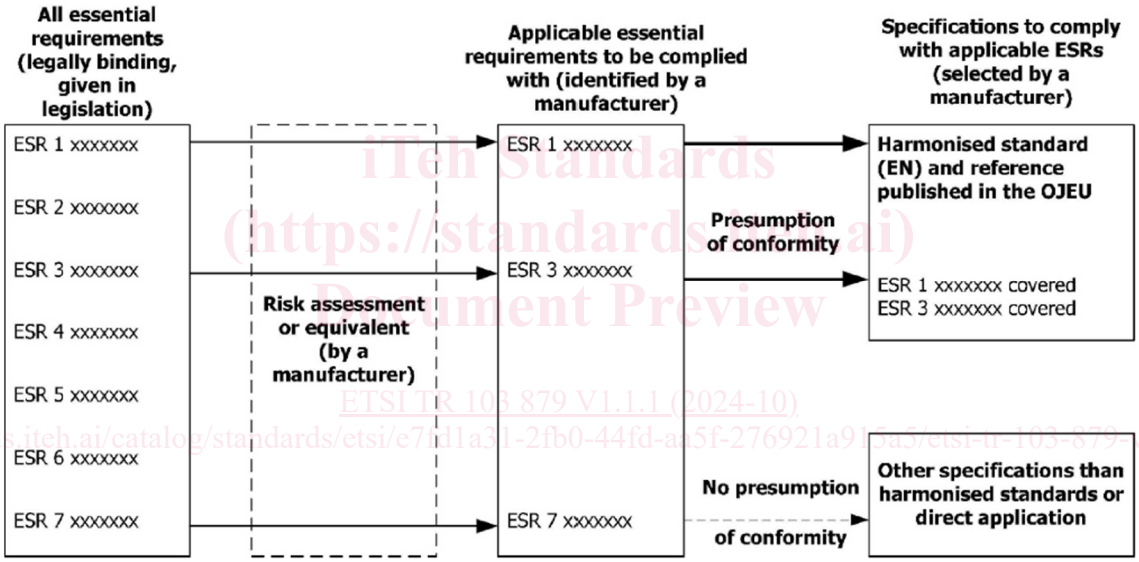
> *"…Annex III of the RED asks to include "an adequate analysis and assessment of the risk(s)" in the TD. Chapter 4.3 of the Blue Guide provides clarification on how such assessment shall be documented…"*

The Blue Guide [i.2]: Clause 4.1.1 (Definitions of essential requirements):

"Essential requirements must be applied as a function of the hazard inherent to a given product. Therefore, manufacturers have to carry out a risk analysis to ***first identify all possible risks that the product may pose*** *and* ***determine the essential requirements relevant for the product****. This analysis implies that the manufacturer should assess all the different elements of the products and* ***determine which Union harmonisation legislation applies to it****, and which specific essential requirements as set out therein.* ***This analysis has to be documented and included in the technical documentation****. In addition, the manufacturer needs to document the assessment of* ***how the risks identified are addressed to ensure that the product complies with the relevant essential requirements*** *(for example, by applying harmonised standards). If only part of the harmonised standard is applied or it does not cover all relevant essential requirements, then the way relevant essential requirements not covered by it are dealt with, should be documented (179).*

(179) Even where the manufacturer uses a harmonised standard (where its reference is published in the OJEU and which aims to cover certain risks) to satisfy essential requirements, the risk assessment has to be carried out and he must check whether the harmonised standard covers all risks of the product. This is because it cannot be assumed that the harmonised standard covers all requirements of all legislative acts applicable to a given product (or, indeed, all the requirements of the specific act under which it has been developed) or whether the product in question introduces also other risks not considered in the harmonised standard."

The Blue Guide [i.2]: Clause 4.1.2.2 (Role of harmonised standards):



The Blue Guide [i.2]: Clause 4.3 (Technical Documentation):

"…the requirement for an 'adequate analysis and assessment of the risk(s)' requires the manufacturer to first identify all possible risks of the product and determine the essential requirements applicable. This analysis has to be documented and included in the technical documentation. In addition, the manufacturer needs to document the assessment of how he is addressing the risks identified to ensure that the product complies with the applicable essential requirements (for example, by applying harmonised standards). If only part of the harmonised standard is applied or it does not cover all applicable essential requirements, then also the way applicable essential requirements not covered by it are dealt with should be documented in the technical documentation…"

Decision 768/2008/EC [i.5]: Annex II Module A Paragraph 2 (Module A)

"The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s)…"

Decision 768/2008/EC [i.5]: Annex II Module B Paragraph 3 (Module B)

"The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of the legislative instrument and shall include an adequate analysis and assessment of the risk(s)…"

4.2 What is risk?

Traditionally, 'risk' means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm, according to article 3 (18) of Regulation (EU) 2019/1020 [i.4]. The determination of the related risk requires then assumptions for the probability of an occurrence of such a harm A, and the degree of severity of the relevant harm B. In theory the related risk is then calculated as A x B. However, this is in practice mostly not a simple multiplication.

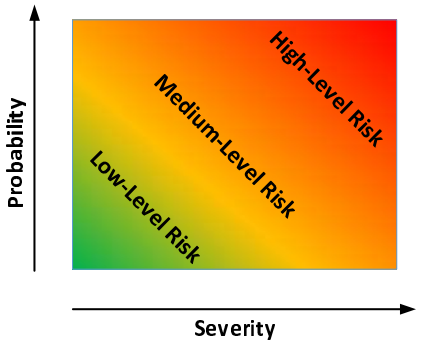


Figure 1: Risk = f (Probability, Severity) in the traditional way

The risk within the scope of the present document is interference/immunity related to the essential requirements in:

- RED article 3.1b (EMC): For example, electromagnetic interference due to the EUT's radiation into the radio spectrum (radiation) and Degradation of performance or loss of functionality of the EUT due to the electromagnetic environment in which the EUT is located (immunity).
- RED article 3.2 (Radio): For example, radio interference due to the EUT's emissions into the radio spectrum and insufficient receiver requirements (e.g. sensitivity, selectivity).

4.3 What is risk assessment?

Risk assessment is the systematic process of determining all potential risks linked with the use of the product as intended. It is followed by the phase of the risk reduction and finally the phase to determine if the residual risk could be acceptable. As a first step, the manufacturer should determine all legislation(s) applicable to his product and extract the applicable essential requirements.

Risk assessment accompanies the whole development process of a new product. Unlike the DoC, which should be established and signed at the end of the development process, the risk assessment should be considered as a 'live' document during the whole lifecycle of the product since the risks/hazards may change over time. The risk assessment should therefore be regularly updated.

A risk assessment should, at least, contain the following elements:

- Identification of applicable legislation and associated essential requirements.
- Identification of intended user.
- Identification of intended use including the environmental conditions.
- Identification of all possible risks associated with the essential requirements, taking into account the defined user and intended use.
- Assessment of the identified risks by applying standards (harmonised or non-harmonised, see Annex A) or their own technical specifications to test their radio equipment and ensure that it meets the essential requirements as specified in article 3 of the RED [i.1].
- Measures / Solutions to mitigate the risks that are non-compliant according to the test result.
- Monitor and review the (new) risks.